Greer, Leslie

From: Lazarus, Steven
Sent: Monday, July 29, 2013 2:28 PM
To: Greer, Leslie
Cc: Martone, Kim; sally.herlihy@wchn.org
Subject: FW: New Milford Hospital, Inc. CON Application
Attachments: OHCA NMH SIM CON Application 07 29 2013.pdf

Leslie,

Please add to the record.

Thank you,

Steve

Steven W. Lazarus
Associate Health Care Analyst
Office of Health Care Access
Department of Public Health
410 Capitol Avenue
Hartford, CT 06134
Phone (Direct): 860.418.7012
Fax (Main): 860.418.7053

From: Herlihy, Sally [mailto:Sally.Herlihy@wchn.org]
Sent: Monday, July 29, 2013 2:25 PM
To: Martone, Kim; Lazarus, Steven
Cc: Herlihy, Sally
Subject: New Milford Hospital, Inc. CON Application

Please find attached a PDF file for a CON submission for New Milford Hospital, Inc.
The original document, including an Affidavit and the Filing Fee are being sent Federal Express to the OHCA office.
Thank you.

____
Sally F. Herlihy, FACHE
Vice President, Planning
Western Connecticut Health Network

203-739-4903

Executive Assistant: Michelle Johnson
Voice: (203) 739-4935
Email: michelle.johnson@wchn.org

WESTERN CONNECTICUT HEALTH NETWORK
DANBURY HOSPITAL • NEW MILFORD HOSPITAL

WESTERN CONNECTICUT
HEALTH NETWORK
DANBURY HOSPITAL · NEW MILFORD HOSPITAL

24 Hospital Ave.
Danbury, CT 06810
203.739.7000

WesternConnecticutHealthNetwork.org
DanburyHospital.org
NewMilfordHospital.org

RECEIVED
JUL 29 2013
OFFICE OF
HEALTH CARE ACCESS

July 29, 2013

Kimberly R. Martone
Director of Operations
Department of Public Health
Office of Health Care Access
410 Capitol Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

Re: New Milford Hospital, Inc. CON Request

Dear Ms. Martone,

Pursuant to Section 19a-638, C.G.S., please find enclosed a Certificate of Need for New Milford Hospital, Inc. to acquire replacement simulation technology for its Diebold Family Cancer Center, located on the hospital's campus at 21 Elm Street, New Milford, CT.

If you have any questions that the attached submission does not answer, please contact me so that we may provide whatever additional information you need in your deliberations. I can be reached directly at 203-739-4903, or sally.herlihy@wchn.org.

Thank you,

Sally F. Herlihy

Sally F. Herlihy, MBA, FACHE
Vice President, Planning

(Note: Submitted via email to Kimberly.martone@ct.gov and steven.lazarus@ct.gov, with original copy and Filing Fee mailed to OHCA).

WESTERN CONNECTICUT HEALTH NETWORK

DANBURY HOSPITAL • NEW MILFORD HOSPITAL

Application Checklist

Instructions:

1. **Please check each box below, as appropriate; and**
2. **The completed checklist *must* be submitted as the first page of the CON application.**

☑ **Attached is the CON application filing fee in the form of a certified, cashier or business check made out to the "Treasurer State of Connecticut" in the amount of $500.**

For OHCA Use Only:

Docket No.: ________________ **Check No.:** __________
OHCA Verified by:____________ **Date:** ______________

☑ **Attached is evidence demonstrating that public notice has been published in a suitable newspaper that relates to the location of the proposal, 3 days in a row, at least 20 days prior to the submission of the CON application to OHCA. (*OHCA requests that the Applicant fax a courtesy copy to OHCA (860) 418-7053, at the time of the publication)***

☑ **Attached is a paginated hard copy of the CON application including a completed affidavit, signed and notarized by the appropriate individuals.**

☑ **Attached are completed Financial Attachments I and II.**

N/A **Submission includes one (1) original and four (4) hard copies with each set placed in 3-ring binders.**

Note: A CON application may be filed with OHCA electronically through email, if the total number of pages submitted is 50 pages or less. In this case, the CON Application must be emailed to ohca@ct.gov.

Important: For CON applications(less than 50 pages) filed electronically through email, the singed affidavit and the check in the amount of $500 must be delivered to OHCA in hardcopy.

N/A **The following have been submitted on a CD**

1. **A scanned copy of each submission in its entirety, including all attachments in Adobe (.pdf) format.**
2. **An electronic copy of the documents in MS Word and MS Excel as appropriate.**

WESTERN CONNECTICUT HEALTH NETWORK
DANBURY HOSPITAL • NEW MILFORD HOSPITAL

No. 828396

Check Date: 07/23/2013

TREASURER STATE OF CT, 410 CAPITOL AVE, HARTFORD, CT 06134 (12592)

Description	Date	Gross Amount	Discount Amount	Net Amount Paid
PETCTCONAPP2013	07/19/13	$500.00	$0.00	$500.00
Totals		$500.00	$0.00	$500.00

Detach at Perforation Before Depositing Check

Any questions, please contact
Accounts.Payable@Danhosp.org or call 203-739-7169

Page 1 of 1

WESTERN CONNECTICUT HEALTH NETWORK
DANBURY HOSPITAL • NEW MILFORD HOSPITAL

Wachovia Bank of Delaware, NA
62-22/311

Check No. 828396

Check Date
07/23/2013

Accounts Payable Telephone: 203-739-7169

PAY *Five Hundred AND 00/100*

Net Check Amount
$ *******500.00

TO THE ORDER OF
TREASURER STATE OF CT
410 CAPITOL AVE
HARTFORD, CT 06134

12592

⑈00828396⑈ ⑆031100225⑆ 2079960001550⑈

Order Confirmation

Ad Order Number	Customer	Payor Customer
0001871563	DANB.HOSP.WEST.CT HEALT	DANB.HOSP.WEST.CT.HEALT
Sales Rep.	**Customer Account**	**Payor Account**
dsattani	197666	197666
Order Taker	**Customer Address**	**Payor Address**
dsattani	24 HOSPITAL AVENUE DANBURY CT 06810 USA	24 HOSPITAL AVENUE DANBURY CT 06810 USA
Ordered By	**Customer Phone**	**Payor Phone**
ANDREA	203-739-7919	203-739-7919
Order Source		
E-mail		
PO Number	**Customer Fax**	**Customer EMail**
	203-739-1680	Andrea.Ryan@wchealthnetwork.org

Ad Content Proof

PUBLIC NOTICE
Statute of Reference:
Section 19a-638 of the Connecticut General Statutes
Applicant:
New Milford Hospital, Inc. (NMH), a subsidiary of We
Health Network, Inc.
Address:
NMH, 21 Elm Street, New Milford, CT 06776
Proposal:
NMH is filing a Certificate of Need with the Office of H
for the acquisition of CT Scan Simulation replacement
radiation oncology service. The capital expenditure for
mated to be $850,000.

Tear Sheets	Proofs	Affidavits	Special Pricing	Promo Type
1	0	0	None	

Order Notes: APPROVED BY ANDREA

Invoice Text:

Blind Box **Materials** **Payment Method**

Net Amount	Tax Amount	Total Amount	Payment Amt	Amount Due
$550.65	$0.00	$550.65	$0.00	$550.65

Ad Number	Ad Type	Ad Size	Pick Up Number
0001871563-01	Legal Liners	2.0 X 15 Li	

External Ad # **Ad Released** No **Ad Attributes**

Color <NONE> **Production Method** AdBooker **Production Notes**

Product / Run Dates / Sort Text / Run Schedule Invoice Text	Placement/Class	# Inserts	Cost
Danbury News-Times 4/26/2013, 4/27/2013, 4/28/2013 PUBLICNOTICESTATUTEOFREFERENCESECTION19A638OFTHECONNECTICUTGENERALST PUBLIC NOTICE Statute of Reference: Section 19a-638 of the Conne	Public Notices	3	$517.65
newstimes.com 4/26/2013, 4/27/2013, 4/28/2013 PUBLICNOTICESTATUTEOFREFERENCESECTION19A638OFTHECONNECTICUTGENERALST PUBLIC NOTICE Statute of Reference: Section 19a-638 of the Conne	Public Notices	3	$30.00

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Toll-Free: 877-542-6053 | classified@newstimes.com | H

PUBLIC NOTICES

PUBLIC NOTICE
Statute of Reference:
Section 19a-638 of the Connecticut General Statutes
Applicant:
New Milford Hospital, Inc. (NMH), a subsidiary of Western Connecticut Health Network, Inc.
Address:
NMH, 21 Elm Street, New Milford, CT 06776
Proposal:
NMH is filing a Certificate of Need with the Office of Health Care Access for the acquisition of CT Scan Simulation replacement technology for its radiation oncology service. The capital expenditure for this project is estimated to be $850,000.

PUBLIC NOTICE

GENERAL HELP WANTED

SEM OPTIMIZATION ANALYST

Hearst Media Services is seeking a SEM Optimization Analyst who will be responsible for assisting the digital operations team in the overall Search Engine Marketing strategy development and implementation for all relevant digital products.

The SEM Optimization Analyst provides a high level of customer service for a small group of specialized customers, assisting with all PPC related issues. He/she will develop and execute advanced SEM campaign management strategies in an effort to drive traffic, leads and conversions for our large custome

AFFIDAVIT

Applicant: New Milford Hospital, Inc.

Project Title: Acquisition of a Replacement Simulator Technology

I, Steven H. Rosenberg, Senior Vice President and CFO, of Western Connecticut Health Network, Inc., being duly sworn, depose and state that New Milford Hospital Inc.'s information submitted in this Certificate of Need Application is accurate and correct to the best of my knowledge.

Steven Rosenberg
Signature

7/29/13
Date

Subscribed and sworn to before me on 7/29/13

Susan M. Kania
Notary Public/Commissioner of Superior Court

My commission expires: 2/28/2015

State of Connecticut
Office of Health Care Access
Certificate of Need Application

__Instructions__: Please complete all sections of the Certificate of Need ("CON") application. If any section or question is not relevant to your project, a response of "Not Applicable" may be deemed an acceptable answer. If there is more than one applicant, identify the name and all contact information for each applicant. OHCA will assign a Docket Number to the CON application once the application is received by OHCA.

Docket Number:	TBD
Applicant:	New Milford Hospital, Inc.
Contact Person:	Sally Herlihy, MBA, FACHE
Contact Person's Title:	Vice President, Planning Western Connecticut Health Network, Inc.
Contact Person's Address:	24 Hospital Avenue, Danbury, CT 06810
Contact Person's Phone Number:	203-739-4903
Contact Person's Fax Number:	203-739-1974
Contact Person's Email Address:	sally.herlihy@wchn.org
Project Town:	New Milford, CT
Project Name:	Acquisition of Replacement Simulator Technology
Statute Reference:	Section 19a-638, C.G.S.
Estimated Total Capital Expenditure:	$1,100,000

1. Project Description: Acquisition of Equipment

a. Please provide a narrative detailing the proposal.

New Milford Hospital, Inc. ("NMH") proposes to replace its existing radiation oncology simulator with a computerized tomography simulator ("CT simulator") at a total capital expenditure of $1.1M. The Hospital's Diebold Family Cancer Center ("Center") has a reputation for excellence and a commitment to the highest standards of cancer care. It is accredited in radiology, mammography and radiation oncology services by the American College of Radiology and the National Accreditation Program for Breast Centers.

In December 2012, the Center was re-approved "with commendation" by the American College of Surgeons (ACoS), Commission on Cancer. The designation, offered by ACoS every three years, distinguishes exceptional hospital performance in ongoing improvement and public accountability for cancer treatment services. NMH exceeded standards in multiple areas of clinical care and operations and earned the highest scores possible in standards for outcomes analysis, data management timeliness and quality, patient guidelines, prevention and early detection activities, professional education and quality improvement.

This proposal requests approval to replace an outdated conventional radiotherapy simulator with new CT simulator technology. The simulator is used as part of the treatment planning process for determining a patient's course of radiation therapy. The images that are generated by the simulator assist physicians in determining the optimal treatment path. Because simulation procedures are usually the first step in patient care, it is critical that new patients feel welcome and comfortable during this process, and confident they've chosen the right place to receive treatment. The advanced technology of a CT simulator will address these needs and truly provide a higher level of care.

Outdated Technology

The existing conventional radiotherapy simulator was acquired in 1998 with approval of the radiation oncology program at NMH, and has been in operation for over 15+ years. The technology has reached end-of-life, with technical support for the equipment discontinued, and x-ray film used by the simulator difficult to obtain. NMH is one of the few remaining hospitals in Connecticut that has a conventional radiography simulator and film processor.

Operational Inefficiency and Inconvenience

Currently the patient visits the Radiation Oncology department where immobilization devices are constructed. The patient must then be escorted down the hall to the Radiology department to be scanned on the CT scanner there to obtain CT images for planning. Patients are usually dressed in gowns during these procedures and also while walking between departments, which is a concern for patient modesty and comfort, especially for breast and prostate cancer patients (a large percentage of cases treated at the Center). Since the CT bore is sized for diagnostic scans, we often have to reposition the patient and the treatment immobilization devices to fit the patient through the scanner, causing discomfort for the patient.

A CT simulator offers multiple clinical, operational and administrative advantages, all of which will greatly enhance cancer care delivery:

- Treatment Efficiencies – The CT simulator's advanced imaging capabilities will eliminate the need for patients to visit both the Radiation Oncology and Radiology departments as part of treatment planning, making the process easier and more convenient for patients and consolidating treatment planning.

- Digitalization – The CT simulator will allow the Hospital's Radiation Oncology department to become completely digitalized, eliminating the need for x-ray film, service contracts for film processors and silver reclaiming, as well as the need for fixer and developer, which are potentially hazardous chemicals. Because images play a key role in cancer diagnosis and treatment and are an important component of the medical record, the use of digital images will support the use of electronic medical records (EMR).

- Comfort and Convenience – Acquisition of new technology will enable the patient to have their entire planning procedure completed within the Radiation Oncology department. Additionally, a large-bore CT simulator (one with a large interior diameter) increases patient comfort by enabling more diversity in positioning and more easily accommodating immobilization devices. The large bore also comfortably accommodates larger-sized patients.

- Potential for Expanded Treatment Options – The CT simulator's "4D CT capability," a radiation oncology-specific software package, will allow the Cancer Center to provide expanded stereotactic body radiation therapy ("SBRT") services, a treatment in which highly accurate, precise, and focused radiation is delivered to tumors while minimizing radiation to adjacent healthy tissue. SBRT has not only shown dramatically better outcomes than conventional radiation therapy, but SBRT patients experience fewer treatment visits and side effects than with conventional radiation therapy. The Center currently offers stereotactic treatment only for brain lesions. The CT simulator will allow this treatment to be offered for other parts of the body as well.

Tentative Timing of the Project:

- September 2013 - Certificate of Need (CON) authorization
- Fall 2013 - Equipment vendor selection, simulation room preparation, and CT simulator Installation and testing
- Winter 2013 - Patients receive simulation procedures using the new technology

b. Provide letters that have been received in support of the proposal.

See Exhibit A with Letters of Support from:

- Joseph Bargellini, M.D., Medical Director, Radiation Oncology, NMH
- Sandra Lombardo, M.D., Medical Oncology, NMH
- Andrea Crowley, M.D., Chair, Diagnostic Radiology, NMH

c. Provide the Manufacturer, Model, Number of slices/tesla strength of the proposed scanner (as appropriate to each piece of equipment).

Three vendor quotations (Phillips, GE and Siemens) have been received and are currently under evaluation for acquisition of large bore CT simulator technology. They include software; workstations, CT simulator couch, and a linac couch upgrade (these couchtops must "match" for treatment reproducibility).

Exhibit B contains a summary of the initial estimates for the proposed technology.

d. List each of the Applicant's sites and the imaging modalities and other services currently offered by location.

The imaging modalities provided at NMH include the following:

- RT Simulator
- 64-slice low-dose CT scanner
- Open bore 1.5 Tesla MRI
- General Radiography
- Mammography
- Ultrasound
- Nuclear Medicine
- Bone Density

2. Clear Public Need

a. Explain why there is a clear public need for the proposed equipment. Provide evidence that demonstrates this need.

NMH's Center provides comprehensive cancer care to over 185 newly diagnosed cancer patients each year. Radiation therapy is an integral component of this care, providing approximately 2,500 radiation treatments annually.

The Hospital's current simulator, a "conventional radiotherapy simulator," reached end of life in April 2013. Technical support for the equipment has been discontinued and x-ray film used by the simulator (produced by Eastman Kodak, currently in bankruptcy) will likely become difficult to obtain. NMH is one of the few remaining hospitals in Connecticut that still uses a conventional radiography simulator and film processor.

The radiation oncology industry standard of care is no longer a conventional simulator, but CT simulator, more importantly one with a large bore to accommodate the patient and treatment immobilization devices. NMH desires to offer its patients the advanced imaging technology and efficient workflow a large bore CT simulator would provide.

In addition, the CT Simulator's a radiation-oncology-specific software package, will offer the opportunity for the Cancer Center to provide expanded stereotactic body radiation therapy (SBRT) services as the need arises, a treatment in which highly accurate, precise, and focused radiation is delivered to tumors while minimizing radiation to adjacent healthy tissue. This capability will also allow treatment plans to accurately account for areas of the body affected by motion (i.e., breathing), a significant benefit to patients treated for lung cancer. SBRT has not only shown dramatically better outcomes than conventional radiation therapy, but SBRT patients experience fewer treatment visits and side effects than with conventional radiation therapy. The Cancer Center currently offers stereotactic treatment only for brain lesions. The CT Simulator will allow this treatment to be offered for other parts of the body, as well.

b. Provide the utilization of existing health care facilities and health care services in the Applicant's service area.

The only other hospital provider in the service area is our affiliate hospital, DH, located at 24 Hospital Avenue, Danbury, CT. The DH CT Simulator volume for FY 2013 is projected to be 995 (annualized based on 9 months actual, Oct-June).

This proposal will not affect the utilization at other hospitals in the region.

c. Complete **Table 1** for each piece of equipment of the type proposed currently operated by the Applicant at each of the Applicant's sites.

Table 1: Existing Equipment Operated by the Applicant

Provider Name **Street Address** **Town, Zip Code**	**Description of Service ***	**Hours/Days of Operation ****	**Utilization ***** July 2012 - June 2013
New Milford Hospital Diebold Family Cancer Center 21 Elm Street New Milford, CT 06776	Conventional Radiotherapy Simulator	8:30 AM – 4:30 PM; Urgent addressed as needed	149

* Include equipment strength (e.g. slices, tesla strength), whether the unit is open or closed (for MRI)
** Days of the week unit is operational, and start and end time for each day; and
*** Number of scans/exams performed on each unit for the most recent 12-month period (identify period).

d. Provide the following regarding the proposal's location:

i. The rationale for locating the proposed equipment at the proposed site;

Locating the CT simulator within the Radiation Oncology area of NMH will ensure coordinated care to our cancer patients.

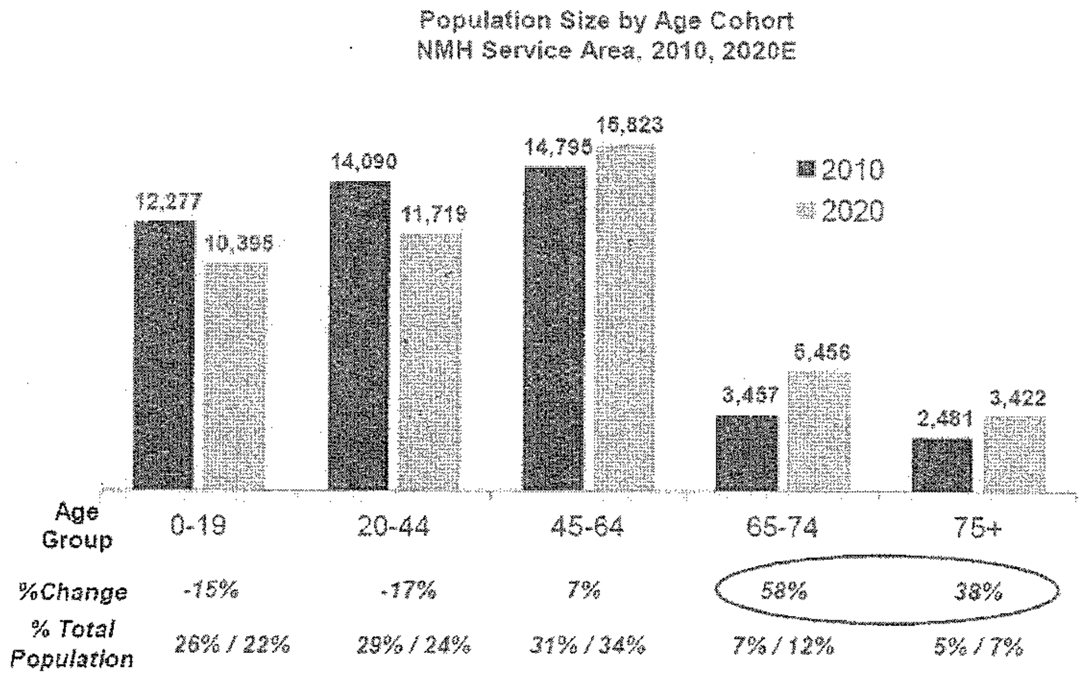
ii. The population to be served, including specific evidence such as incidence, prevalence, or other demographic data that demonstrates need;

The population to be served is residents within the primary service areas of NMH, and those from outside the area receiving cancer treatment services at NMH.

Towns Primarily Served by NMH	**2010 Population**	**2020 Population Estimate**
New Milford	28,217	28,608
Wingdale, NY	4,235	4,432
Sherman	3,853	3,450
Washington	3,630	3,511
Kent	2,984	2,980
Roxbury	2,302	2,224
Bridgewater	1,879	1,610
TOTAL	**47,100**	**46,815**

Source: 2010 Census, 2020 UCONN CT State Data Center

According to the American Cancer Society, the probability of developing cancer increases as we age. By 2020, 19% of the service area population, an additional 3,000 residents, will be age 65 and over. These demographics support the investment in CT Simulation technology at the NMH Cancer Center for comprehensive oncology treatment.



iii. How and where the proposed patient population is currently being served;

The proposed patient population is currently being served by NMH and this is not projected to change.

iv. All existing providers (name, address) of the proposed service in the towns listed above and in nearby towns;

Existing providers with CT simulators capabilities within the service area include NMH and The Danbury Hospital ("DH"), 24 Hospital Avenue, Danbury CT (our WCHN affiliate hospital).

v. The effect of the proposal on existing providers; and

This proposal for replacement simulation technology is not expected to have any effect on existing providers.

vi. If the proposal involves a new site of service, identify the service area towns and the basis for their selection.

This proposal does not involve a new site of service.

e. Explain why the proposal will not result in an unnecessary duplication of existing or approved health care services.

This proposal for a replacement s CT simulator will not result in unnecessary duplication of service. The new technology replaces out of date technology and will enhance the quality of services provided to our existing (and future) patient base.

Effectiveness and success of the CT simulator can be measured utilizing several criteria, including utilization and patient satisfaction:

- CT simulation is a standard practice in radiation therapy departments throughout the country. With rare exception, all patients being treated at the Diebold Family Cancer Center will utilize this service.
- All lung cancer cases will utilize the CT simulator's 4D capability accounting for organ and target motion. Lung cancer is one of the major diseases treated at the Center.
- Patient comfort, convenience, and satisfaction are expected to increase, as both the simulation and treatment process will be in the Center in its entirety.

3. Actual and Projected Volume

a. Complete the following tables for the past three fiscal years ("FY"), current fiscal year ("CFY"), and first three projected FYs of the proposal, for each of the Applicant's existing and proposed pieces of equipment (of the type proposed, at the proposed location only). In Table 2a, report the units of service by piece of equipment, and in Table 2b, report the units of service by type of exam (e.g. if specializing in orthopedic, neurosurgery, or if there are scans that can be performed on the proposed scanner that the Applicant is unable to perform on its existing scanners).

Table 2a: Historical, Current, and Projected Volume, by Equipment Unit

	Actual Volume (Last 3 Completed FYs)			CFY Volume*	Projected Volume (First 3 Full Operational FYs)**		
	FY10	FY11	FY12	FY13	FY14	FY15	FY16

Complex CT Sims	86	123	121	156	156	156	156
Total	86	123	121	156	156	156	156

* For periods greater than 6 months, report annualized volume, identifying the number of actual months covered and the method of annualizing. For periods less than six months, report actual volume and identify the period covered. **FY 2013 volume annualized based on October – June actual**
** If the first year of the proposal is only a partial year, provide the first partial year and then the first three full FYs. Add columns as necessary.
*** Identify each scanner separately and add lines as necessary. Also break out inpatient/outpatient/ED volumes if applicable.
**** Fill in years. In a footnote, identify the period covered by the Applicant's FY (e.g. July 1-June 30, calendar year, etc.).

Table 2b: Historical, Current, and Projected Volume, by Type of Scan/Exam

	Actual Volume (Last 3 Completed FYs)			CFY Volume*	Projected Volume (First 3 Full Operational FYs)**		
	FY10	FY11	FY12	FY13	FY14	FY15	FY16
Complex CT Sims	86	123	121	156	156	156	156
Total	86	123	121	156	156	156	156

* For periods greater than 6 months, report annualized volume, identifying the number of actual months covered and the method of annualizing. For periods less than six months, report actual volume and identify the period covered. **FY 2013 volume annualized based on October – June actual**
** If the first year of the proposal is only a partial year, provide the first partial year and then the first three full FYs. Add columns as necessary.
*** Identify each type of scan/exam (e.g. orthopedic, neurosurgery or if there are scans/exams that can be performed on the proposed piece of equipment that the Applicant is unable to perform on its existing equipment) and add lines as necessary.
**** Fill in years. In a footnote, identify the period covered by the Applicant's FY (e.g. July 1-June 30, calendar year, etc.).

b. Provide a breakdown, by town, of the volumes provided in Table 2a for the most recently completed full FY.

Zip Code	Town	State	FY12 Volume
06776	NEW MILFORD	CT	51
12522	DOVER PLAINS	NY	6
06754	WARREN	CT	5
06777	NEW PRESTON MARB	CT	5
06794	WASHINGTON DEPOT	CT	5
12594	WINGDALE	NY	5
06757	KENT	CT	4
06069	SHARON	CT	3
06488	SOUTHBURY	CT	3
06804	BROOKFIELD	CT	3

06811	DANBURY	CT	3
06470	NEWTOWN	CT	2
06752	BRIDGEWATER	CT	2
06801	BETHEL	CT	2
06810	DANBURY	CT	2
12531	HOLMES	NY	2
12545	MILLBROOK	NY	2
12546	MILLERTON	NY	2
12564	PAWLING	NY	2
06018	CANAAN	CT	1
06068	SALISBURY	CT	1
06450	MERIDEN	CT	1
06756	GOSHEN	CT	1
06759	LITCHFIELD	CT	1
06783	ROXBURY	CT	1
06784	SHERMAN	CT	1
06787	THOMASTON	CT	1
06790	TORRINGTON	CT	1
06798	WOODBURY	CT	1
06906	STAMFORD	CT	1
12501	AMENIA	NY	1
12592	WASSAIC	NY	1
Grand Total			**122**

c. Describe existing referral patterns in the area to be served by the proposal.

Physician referral patterns for the radiation oncology program (and simulation) include in descending order: Urology (166), Medical Oncology (151) and surgery (117). Otolaryngology provided 12 referrals and 10 were from Dermatology. In reviewing diagnosis codes, Breast was the most common at 91, followed by prostate at 52 and Lung at 38.

d. Explain how the existing referral patterns will be affected by the proposal.

There are not any changes anticipated in existing referral patterns.

e. Explain any increases and/or decreases in volume seen in the tables above.

Since 2010, NMH has experienced an increase in overall volume, both in terms of treatments given and number of patients treated. The increase is multifactorial, but likely due to expanded technology with the Trilogy System becoming operational in October 2010. This system enhanced the delivery of radiation oncology with image guidance, stereotactic capability, and robotic couch positioning. The affiliation with DH positively impacted patient volumes as well through increased collaboration between the two institutions.

f. Provide a detailed explanation of all assumptions used in the derivation/ calculation of the projected volume by scanner and scan type.

Volume is projected based on a general utilization that approximately one half of all new cancer patients will receive radiation therapy. Each of these patients will require one CT simulation in order to formulate their individualized treatment plan.

g. Provide a copy of any articles, studies, or reports that support the need to acquire the proposed scanner, along with a brief explanation regarding the relevance of the selected articles.

The proposed technology will substitute CT based simulation for the outdated conventional system. CT Simulator features a state of the art CT scanner with a localization package, patient marking system and a virtual simulator capable of producing real-time digitally composited radiographs (DCRs). This system offers high-resolution imaging and short examination time for the full range of procedures including volumetric localization, simulation and verification for conformal, high-precision and stereotactic radiotherapy planning.

See Exhibit C for the British Journal of Radiology (2006), "*Localization: conventional and CT simulation*", a journal article discussing the components for achieving standard of care for radiation oncology treatment planning and the role of a dedicated CT simulator.

4. Quality Measures

a. Submit a list of all key professional, administrative, clinical, and direct service personnel related to the proposal. Attach a copy of their Curriculum Vitae.

See Exhibit D for Curriculum Vitaes for the following individuals:

Joseph Bargellini, MD – Medical Director of Radiation Oncology, will prescribe simulation procedures when appropriate.

Lee Anne Zarger, MSDABR, Chief Medical Physicist, oversees acceptance testing, quality assurance, and radiation safety.

b. Explain how the proposal contributes to the quality of health care delivery in the region.

Provision of care at the Center includes radiation therapy, which is reliant on use of a simulator to help determine, before treatment begins, how to direct and combine the radiation treatment fields for maximum safety and effectiveness. This simulator uses X-rays and fluoroscopy with freeze-frame capability to pinpoint the exact treatment area. The conventional simulator at NMH no longer can provide the necessary data for the 3-D Treatment Planning System, resulting in workarounds for obtaining imaging data.

Conventional simulators are no longer used in Radiation Oncology Departments. The state of the art choice is a large bore CT simulator with localization software which enables the radiation oncologist to clearly image and delineate treatment. Additionally 4D imaging capability of the CT simulator allows departments to outline treatment volumes for areas of the body affected by breathing motion to allow more accurate imaging, treatment planning and treatment delivery to these areas and to offer treatments we are currently not offering: namely stereotactic body radiation therapy.

5. Organizational and Financial Information

a. Identify the Applicant's ownership type(s) (e.g. Corporation, PC, LLC, etc.).

b. Does the Applicant have non-profit status?
☒ Yes (Provide documentation) ☐ No

c. Provide a copy of the State of Connecticut, Department of Public Health license(s) currently held by the Applicant and indicate any additional licensure categories being sought in relation to the proposal.

A copy of the hospital license is included as Exhibit E. There are no additional licensure categories being requested.

d. Financial Statements

i. If the Applicant is a Connecticut hospital: Pursuant to Section 19a-644, C.G.S., each hospital licensed by the Department of Public Health is required to file with OHCA copies of the hospital's audited financial statements. If the hospital has filed its most recently completed fiscal year audited financial statements, the hospital may reference that filing for this proposal.

ii. If the Applicant is not a Connecticut hospital (other health care facilities): Audited financial statements for the most recently completed fiscal year. If audited financial statements do not exist, in lieu of audited financial statements, provide other financial documentation (e.g. unaudited balance sheet, statement of operations, tax return, or other set of books.)

NMH has filed its most recently completed fiscal year audited statements with OHCA.

e. Submit a final version of all capital expenditures/costs as follows:

Table 3: Proposed Capital Expenditures/Costs

Medical Equipment Purchase	$
Imaging Equipment Purchase	$900,000
Non-Medical Equipment Purchase	
Land/Building Purchase *	
Construction/Renovation **	$200,000
Other Non-Construction (Specify)	
Total Capital Expenditure (TCE)	**$1,100,000**
Medical Equipment Lease (Fair Market Value) ***	$
Imaging Equipment Lease (Fair Market Value) ***	
Non-Medical Equipment Lease (Fair Market Value) ***	
Fair Market Value of Space ***	
Total Capital Cost (TCC)	**$0**
Total Project Cost (TCE + TCC)	**$1,100,000**
Capitalized Financing Costs (Informational Purpose Only)	
Total Capital Expenditure with Cap. Fin. Costs	**$1,100,000**

* If the proposal involves a land/building purchase, attach a real estate property appraisal including the amount; the useful life of the building; and a schedule of depreciation.

** If the proposal involves construction/renovations, attach a description of the proposed building work, including the gross square feet; existing and proposed floor plans; commencement date for the construction/ renovation; completion date of the construction/renovation; and commencement of operations date.

*** If the proposal involves a capital or operating equipment lease and/or purchase, attach a vendor quote or invoice; schedule of depreciation; useful life of the equipment; and anticipated residual value at the end of the lease or loan term.

f. List all funding or financing sources for the proposal and the dollar amount of each. Provide applicable details such as interest rate; term; monthly payment; pledges and funds received to date; letter of interest or approval from a lending institution.

This proposal is financially supported by a $1 million grant received from the Diebold Foundation to fully fund acquisition of the CT Simulator.

g. Demonstrate how this proposal will affect the financial strength of the state's health care system.

The acquisition of the proposed CT simulator will not directly impact the financial strength of the state's health care system, however, due to improved operational efficiencies which will reduce operating costs associated with current processes.

6. Patient Population Mix: Current and Projected

a. Provide the current and projected patient population mix (based on the number of patients, not based on revenue) with the CON proposal for the proposed program.

Table 4: Patient Population Mix

	FY2013 FP1-9	FY2014	FY2015	FY2016
Medicare*	46.7%	46.7%	46.7%	46.7%
Medicaid*	10.1%	10.1%	10.1%	10.1%
CHAMPUS & TriCare	0.2%	0.2%	0.2%	0.2%
Total Government	**56.9%**	**56.9%**	**56.9%**	**56.9%**
Commercial Insurers*	39.9%	39.9%	39.9%	39.9%
Uninsured	1.9%	1.9%	1.9%	1.9%
Workers Compensation	1.4%	1.4%	1.4%	1.4%
Total Non-Government	**43.1%**	**43.1%**	**43.1%**	**43.1%**
Total Payer Mix	**100.0%**	**100.0%**	**100.0%**	**100.0%**

* Includes managed care activity.
** New programs may leave the "current" column blank.
*** Fill in years. Ensure the period covered by this table corresponds to the period covered in the projections provided.

b. Provide the basis for/assumptions used to project the patient population mix.

The patient population at NMH is not projected to change as result of this proposal.

7. **Financial Attachments I & II**

a. Provide a summary of revenue, expense, and volume statistics, without the CON project, incremental to the CON project, and with the CON project. **Complete Financial Attachment I.** (Note that the actual results for the fiscal year reported in the first column must agree with the Applicant's audited financial statements.) The projections must include the first three full fiscal years of the project.

See Exhibit F for Financial Attachment I.

b. Provide a three year projection of incremental revenue, expense, and volume statistics attributable to the proposal by payer. **Complete Financial Attachment II.** The projections must include the first three full fiscal years of the project.

See Exhibit F for Financial Attachment II.

c. Provide the assumptions utilized in developing **both Financial Attachments I and II** (e.g., full-time equivalents, volume statistics, other expenses, revenue and expense % increases, project commencement of operation date, etc.).

See Exhibit F for Financial Assumptions.

d. Provide documentation or the basis to support the proposed rates for each of the FYs as reported in Financial Attachment II. Provide a copy of the rate schedule for the proposed service(s).

Not applicable.

e. Provide the minimum number of units required to show an incremental gain from operations for each fiscal year.

Not applicable.

f. Explain any projected incremental losses from operations contained in the financial projections that result from the implementation and operation of the CON proposal.

The proposed incremental loss from operations is a result of the increase in depreciation and equipment maintenance contract related to the new equipment.

g. Describe how this proposal is cost effective.

This proposal involves the replacement of a 15+ year old out-dated and end-of-life conventional simulator with a new state-of-the-art CT simulator that will improve operational efficiencies, quality and convenience of this service for our patients.

EXHIBIT A
LETTERS OF SUPPORT

WESTERN CONNECTICUT HEALTH NETWORK

NEW MILFORD HOSPITAL

AFFILIATED WITH DANBURY HOSPITAL

Radiation Oncology
Diebold Family Regional Cancer Center

21 Elm Street
New Milford, CT 06776
860.210-5000

June 10, 2013

To Whom It May Concern:

New Milford Hospital is looking to replace its current conventional simulator with a CT simulator. In addition to CT simulation being a standard for modern radiation therapy, it will provide us with the ability to offer and provide more services for our patients.

Our conventional simulator will be reaching end of life shortly. Servicing it would then become problematic. Conventional simulators are not being replaced with conventional simulators as it is outdated technology. CT simulators allow for the acquisition of three dimensional data for radiation treatment planning. This is used for both external beam radiation and brachytherapy.

At the present time we are using the CT scanner is Diagnostic Radiology for this purpose. As this CT unit was not designed specifically for radiation therapy use, it has limitations in terms of bore size and patient positioning that have been problems for us in the past. In addition, organ and target motion cannot be accounted for using this CT, and this is becoming increasingly important in radiation treatment delivery and current radiation therapy treatment protocols.

I am happy to answer any questions regarding our need for this technology at New Milford Hospital. Thank you for your consideration.

Sincerely,

Joseph Bargellini, M.D.
Medical Director, Radiation Oncology

WESTERN CONNECTICUT MEDICAL GROUP
DANBURY HOSPITAL · NEW MILFORD HOSPITAL

Regional Cancer Center
Oncology & Hematology

21 Elm Street
New Milford, CT 06776
(860) 210-5300
Fax (860) 210-5030
WesternConnecticutHealthNetwork.org

Sandra Lombardo, MD

Medical Oncology
Diebold Family Regional Cancer Center

June 10, 2013

To Whom It May Concern:

New Milford Hospital is looking to replace its current conventional simulator with a CT simulator. As a Medical Oncologist working in the cancer center, I fully support this.

The Radiation Oncology unit at New Milford Hospital provides a very important service to the cancer patients in our community. It is important that the facility remain current with technology, in this highly technical service. Many of my patients in addition to receiving chemotherapy also receive radiation, and I want them to receive the best care possible.

I came to New Milford Hospital from a practice in New York City where all modern Radiation Oncology Departments had CT simulators. We should be able to provide the same level of care and service here in New Milford.

I am happy to answer any questions you might have, and thank you for your consideration.

Sincerely,

Sandra Lombardo, M.D.
Medical Oncology

WESTERN CONNECTICUT HEALTH NETWORK

NEW MILFORD HOSPITAL

AFFILIATED WITH DANBURY HOSPITAL

21 Elm Street
New Milford, CT 06775
860.210-5000

Diagnostic Imaging

June 11, 2013

To Whom It May Concern:

New Milford Hospital is looking to replace its current conventional simulator with a CT simulator. As the Chair of Diagnostic Radiology at the hospital, I fully support this.

Over the years, the CT in Diagnostic Radiology has been used by Radiation Oncology for their treatment planning purposes. As the technology has changed, the CT scanners designed for use in Radiation Oncology have evolved to better serve their purposes with wider bore sizes to better accommodate the patient positioning required for radiation therapy.

New technology is also available to help manage organ motion, which is becoming more important for Radiation Oncology, and is not available on our scanner. Being part of the medical staff at New Milford Hospital, I fully recognize the need to provide the best possible care for our patients close to home, especially when they are facing a potentially life threatening disease.

I am happy to answer any questions you might have, and thank you for your consideration.

Sincerely,

Andrea Crowley, M.D.
Chair, Diagnostic Radiology

EXHIBIT B
EQUIPMENT ESTIMATES - FINAL SYSTEM TBD

	Phillips		
	Equipment	Civco Couchtops	Total
System	712,077	74,350	786,427
Options	126,547	0	126,547
Total Equipment	**838,624**	**74,350**	**912,974**
Room Renovations			200,000
Total Capital			**1,112,974**

	Siemens		
	Equipment	Civco Couchtops	Total
System	675,000	74,350	749,350
Options	34,800	0	34,800
Total Equipment	**709,800**	**74,350**	**784,150**
Room Renovations			200,000
Total Capital			**984,150**

	GE		
	Equipment	Civco Couchtops	Total
System	732,896	74,350	807,246
Options	32,970	0	32,970
Total Equipment	**765,866**	**74,350**	**840,216**
Room Renovations			200,000
Total Capital			**1,040,216**

EXHIBIT C

JOURNAL ARTICLE

The British Journal of Radiology, 79 (2006), S36–S49

Localization: conventional and CT simulation

G R BAKER, BSc, MSc, MIPEM

Kent Oncology Centre, Maidstone Hospital, Maidstone, Kent ME16 9QQ, UK

ABSTRACT. Recent developments in imaging and computer power have led to the ability to acquire large three dimensional data sets for target localization and complex treatment planning for radiation therapy. Conventional simulation implies the use of a machine capable of the same mechanical movements as treatment units. Images obtained from these machines are essentially two dimensional with the facility to acquire a limited number of axial slices to provide patient contours and tissue density information. The recent implementation of cone beam imaging on simulators has transformed them into three dimensional imaging devices able to produce the data required for complex treatment planning. The introduction of computed axial tomography (CT) in the 1970s was a step-change in imaging and its potential use in radiotherapy was quickly realised. However, it remained a predominantly diagnostic tool until modifications were introduced to meet the needs of radiotherapy and software was developed to perform the simulation function. The comparability of conventional and virtual simulation has been the subject of a number of studies at different disease sites. The development of different cross sectional imaging modalities such as MRI and positron emission tomography has provided additional information that can be incorporated into the simulation software by image fusion and has been shown to aid in the delineation of tumours. Challenges still remain, particularly in localizing moving structures. Fast multislice scanning protocols freeze patient and organ motion in time and space, which may lead to inaccuracy in both target delineation and the choice of margins in three dimensions. Breath holding and gated respiration techniques have been demonstrated to produce four-dimensional data sets that can be used to reduce margins or to minimize dose to normal tissue or organs at risk. Image guided radiotherapy is being developed to address the interfraction movement of both target volumes and critical normal structures. Whichever method of localization and simulation is adopted, the role of quality control is important for the overall accuracy of the patient's treatment and must be adapted to reflect the networked nature of the process.

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The development of the delivery of radiation therapy is closely related to the accuracy with which the target tumour can be located with respect to surrounding anatomical structures. In recent years, the increase in computing power and the development of refined computer graphics have resulted in the ability to perform complex treatment planning in three dimensions and to manipulate images in real time. Early simulators were machines capable of the same mechanical movements as treatment units and were used to confirm treatment set up rather than for localization [1, 2]. Simulators that were developed commercially in the 1960s had the addition of fluoroscopy that was used to set the isocentre with the aid of remotely controlled movements of the couch. Field portals adequate to encompass the target volume to be treated could also be set by remote adjustments to the field defining wires. The introduction of computed axial tomography (CT) scanning in the 1970s was a step change in the ability to define tumours in relation to normal anatomy, and over the ensuing years has been widely adopted in tumour localization. Today it may be used in conjunction with complex graphics software as a virtual simulator. However, the conventional simulator still retains its place in many radiotherapy departments for localization of some tumour sites, either as a result of lack of sufficient access to a CT scanner or for relatively simple techniques not requiring the production of a dose plan. The conventional simulator is also frequently used to verify the more complex treatment plans, producing an image corresponding to a beam's eye view (BEV) from the treatment planning system (TPS) or by verifying the isocentre location from orthogonal films.

Brief history

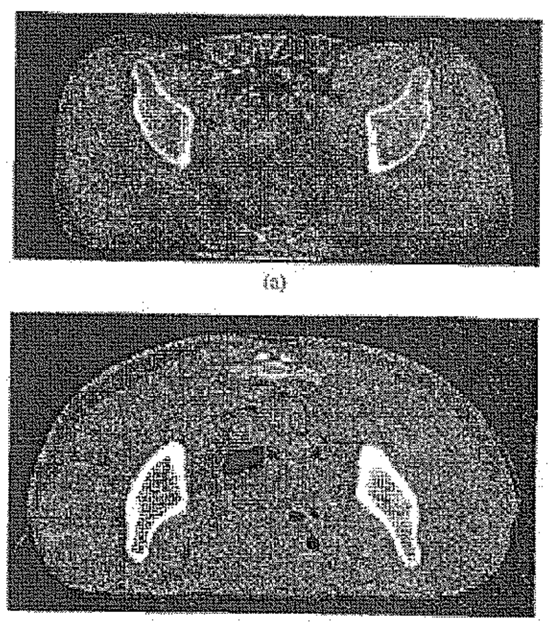
Mould [3] describes the development of simulation, from the use of diagnostic radiographs and skin marks in the 1950s to the introduction of virtual simulation in the 1980s. In 1973, Hounsfield and Ambrose [4, 5] published their work on computerized transverse axial tomography and the potential uses of CT in radiotherapy were quickly recognized [6]. However, access to a CT scanner was often very limited, and in many cases the scanner was not even in the same hospital as the treatment facilities. In addition, a CT scanner was principally a diagnostic tool with limitations for treatment planning imposed by the small aperture and the design of the couch, which frequently prevented the patient from being scanned in the treatment position. Harrison and Farmer [7] recognized the usefulness of being able to acquire a cross-sectional image of the patient in the treatment position using a simulator as a CT scanner and went on to describe the implementation of their idea using a fluorescent screen and an Isocon camera [8]. A number of other adaptations of the simulator to produce cross-sectional images were also proposed at this time [9–12]. This functionality was called Sim-CT and became standard on simulators in the 1990s, but the system had its limitations:

1. The heat capacity of the X-ray tube generally meant that only a few slices could be scanned;
2. The time taken to scan was limited to approximately one revolution per minute, which introduced motion artefacts resulting in images that were of a poorer quality than those produced on a diagnostic scanner;
3. The uncertainty in the Hounsfield units (HU), which depends on the field of view and the phantom/patient size, a result of the beam hardening in the unfiltered X-ray beam from the simulator CT. However, the uncertainty in HU is translated into dose variation not exceeding 3% for photon beams in the range 6–18 MV [13];
4. The relatively high dose to the patient which was shown to be approximately 10 times that delivered with a diagnostic scanner under similar conditions [14].

In spite of its limitations, the Sim-CT was a useful tool for planning in a department with limited access to a diagnostic scanner. It was a more accurate way of producing a patient outline than manual methods using callipers and flexicurves and enabled CT numbers to be converted to relative electron densities for tissue inhomogeneity corrections to be applied to a single CT slice in dose calculations. The dose distributions and monitor unit calculations showed good agreement with those obtained with diagnostic scan data [14].

In 1998, Cho et al [15] described the application of digital technology to a radiotherapy simulator in which the imaging system was replaced by a digital spot imager (DSI). The DSI consisted of an image intensifier, digital image processing, display and data transfer facilities. The images were stored during acquisition for later archiving or transfer to workstations. Simulator manufacturers now offer digital capabilities on their machines and conventional image intensifiers have been replaced by flat panel amorphous silicon (aSi) detectors. Their longevity in this application has to be proved and it is possible that the need for regular replacement may have significant revenue consequences. The most recent simulators include anatomical protocol selection, automatic correction for image distortion, last image hold, multileaf collimator (MLC) verification, a variety of image viewing and manipulation tools with annotation, image printing to film or paper, Digital Image Communications in Medicine (DICOM) export to TPS, electronic portal imaging device (EPID), record and verify, and patient management systems. The image manipulation tools enable adjustments to be made to field parameters and image quality on the last-held image, which reduces the screening time and hence patient dose compared with non-digital systems. A wide aperture (typically 90 cm) CT option is available. However, because of the restriction on gantry rotation speed, acquisition times are still slow and reconstruction time does not match that of a diagnostic scanner. In an attempt to overcome this, volume or cone beam CT (CBCT) has been developed. A number of authors describe cone beam reconstructions, based on Feldkamp's original back projection algorithm [16], for the acquisition of volumetric data [17–19].

When first proposed, the size of the detector was a severe limitation on the reconstruction volume and, although promising results were obtained, its use in treatment planning was not realised until aSi flat panel detectors of a reasonable size became available. Commercial systems are now available. For example, the Acuity (Varian, Palo Alto, CA) with cone beam option gives a cone of 17 cm at the isocentre but with added penumbra of 1.9 cm at either end regardless of the scan length. It is therefore not appropriate to acquire a single narrow slice. A single slice takes 45 s and 675 images are acquired per rotation. Early reports (private communications, A Vinall, K Venables, 2005) suggest that the geometric performance and image quality are adequate for radiotherapy planning purposes although the images are not of diagnostic quality. The rotation time of 45 s does, however, result in significant movement artefacts. Figure 1a shows the streaking that results from the movement of bowel gas during the acquisition of a CBCT scan compared with a CT planning scan.



(a)

(b)

Figure 1. (a) Movement artefacts on an axial slice of a CBCT scan as a result of movement of bowel gas. (b) An axial slice from a planning CT of the pelvis for comparison. (Courtesy of Varian Medical Systems, Palo Alto, CA and Memorial Sloan-Kettering Cancer Centre).

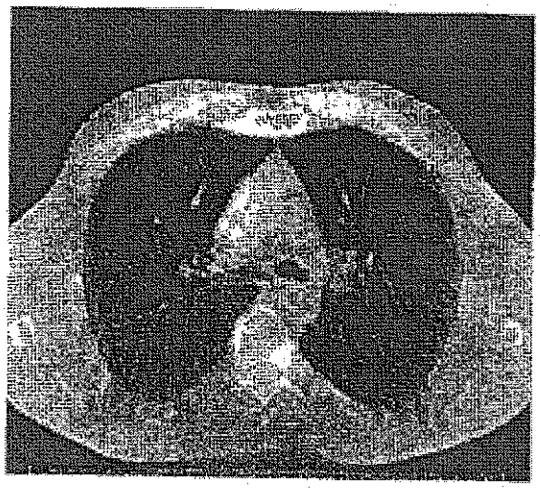


Figure 2. Movement artefacts on an axial slice from a CBCT acquired during normal breathing. (Courtesy of Varian Medical Systems and Hirslanden Klinik, Aarau).

Figure 2 shows similar streaking in the soft tissue around lungs in a CBCT taken during normal breathing. As with the single slice option on the simulator, there seem to be problems with the HU values both in accuracy compared with the calibration and reproducibility on a day-to-day basis. Slice thicknesses of 1–5 mm are available. Reconstruction times vary with the slice thickness and are in the order of 90 s. There is no standard way of quoting doses for these scans. Computed tomography dose index ($CTDI_w$) is a measure of the dose from a CT scan, weighted between the centre and the surface to give an average value across the section. A $CTDI_w$/810 mAs value of 15 mGy has been measured for a 10 cm scan length collimated to 13.8 cm (15 pulse s^{-1}, pulse length 15 ms, 80 mA, 125 kV, 45 s rotation). Setting the scan length to 1 cm in clinical mode gave 54 mGy/810 mAs with the same exposure factors. This compares with the national reference dose of 20 mGy for a multislice scanner [20].

CT simulation

The alternative to using the simulator and CBCT to acquire a volume data set of the patient in the treatment position was to modify CT scanners to meet the needs of radiotherapy and add software to perform the simulation function.

With the rapid development of computer technology, enabling fast reconstruction of images in three dimensions, the true value of the enormous quantity of data acquired by a CT scanner and its use in radiotherapy planning was recognized.

The development of the concept of the beam's eye view (BEV) into the transmission image from CT scans that would result from any beam orientation paved the way to producing images from CT data that correspond to conventional simulator films [21–23]. These digitally reconstructed radiographs (DRRs) could be overlaid with the outlines of anatomic structures, field shapes and cross wires, and hence could display images similar to simulator radiographs. However, the spatial resolution of DRRs is limited by the voxel size of the CT scans and cannot match that of a simulator radiograph taken with a small focal spot and a short exposure. Even in the early implementation of this process the reconstruction time of the DRRs was reasonable, being in the region of 10 s for a 50 slice study. However, studies were limited by the specification of the CT scanner. The acquisition of a single slice might take 2–3 s with a delay between scans required for repositioning of the scanner and tubes with low heat capacity needed cooling time during the scan [24].

Early critical analysis of the CT simulation process highlighted the areas for improvement [25]. These included the limitations imposed on both treatment technique and the size of the patient by the aperture of the scanner (normally 70 cm), the time required for CT data acquisition and transfer from the scanner to the planning system, time required for outlining and contouring target volume and critical structures and the inconsistent accuracy of portal marking on the patient's skin. Complete field ports were marked on the patient's skin in most cases and novel devices for doing this constituted an important part of the virtual simulation process reported. [26, 27]. These drawbacks have now largely been overcome.

Multislice helical scanning, with high heat capacity CT tubes, has reduced the time required to acquire a CT data set of 100 slices to a matter of seconds. Wide bore scanners have removed most of the constraints of patient size and technique. Increased computing capacity and speed allows for real time reconstruction of the slice images at the scanner and real time manipulation of images in the virtual simulation software. In addition, the DICOM protocol facilitates fast transfer of image data between systems.

Current practice

Conformal radiotherapy (CRT) is now accepted best practice for a number of treatment sites, having the advantages of sparing normal tissue and providing the opportunity for dose escalation. Intensity-modulated radiotherapy (IMRT) is the ultimate expression of this, but successful implementation of CRT and IMRT cannot be achieved without three-dimensional information on the location and extent of the target volume and the position of adjacent organs at risk (OAR). The three-dimensionality of virtual simulation is essential to visualize the coverage of the target volume and the avoidance of OARs in the highly complex treatment plans required for CRT and IMRT. For some sites, such as the lung where the relative position of the target and OARs varies with time, this fourth dimension needs to be taken into account.

Sherouse et al [28] introduced the term virtual simulation in 1987 to describe the process of using computer aided design and digitally reconstructed radiographs to replace the process of physical simulation. The process of virtual simulation has been described in detail by Aird and Conway [29] who also gave examples of its application to a number of different sites.

The specification of a CT simulator

The fundamental requirements of a CT simulator are a CT scanner with a flat couch, positioning lasers and virtual simulation software.

CT scanner

Advances in the design and capabilities of CT scanners have modified the specifications given by Aird and Conway [29]. Multislice scanners enable very fast scanning times, even for the large studies, with narrow slice thicknesses required for the production of good DRRs. High heat capacity anodes are required for the large datasets that are frequently required for treatment planning applications. One manufacturer (Siemens Medical, Erlangen, Germany) has introduced a new design of directly cooled anode that should eliminate delays due to anode heating and enable fast acquisition of scans with the large number of narrow slices required for good DRRs.

Three manufacturers now produce wide aperture (85 cm) scanners designed for radiotherapy applications. In two, the scanned field of view (SFOV) is 60 cm with an extended reconstructed FOV of 85 cm. It should be noted that in the extended reconstructed FOV the HU numbers may not be consistent with the SFOV. In reality, it is unlikely that the uncertainty in HU translates into a dose discrepancy of more that 1–2% in the target. The third manufacturer claims a true SFOV of 85 cm.

Positioning lasers

A system of three lasers for the accurate positioning and alignment of the patient is required. The lateral lasers may be wall or frame mounted, and may be either fixed or move in a vertical plane. The sagittal laser must be able to move laterally to account for lack of lateral movement on the CT couch. These lasers move under computer control to define the isocentre for the treatment plan in terms of shifts from the reference marks.

Virtual simulation software

The virtual simulation software may either be part of a treatment planning system or may be a stand-alone system. If the latter is chosen, it is essential that connectivity is easily established with the treatment planning system for dose calculation. Since the introduction of DICOM-RT this connectivity is more readily achievable, but the user must be aware that not all manufacturers interpret the standard in the same way and there are frequently hidden licensing issues associated with the connectivity. Essential features of virtual simulation software include automatic contouring of body outlines and semi-automatic contouring of other structures and critical organs such as spinal cord, kidneys and lungs. Particular attention should be paid to treatment of bifurcating structures. Contouring tools should be simple to use and interpolation between non-adjacent slices, with correction as necessary, should be provided to speed the contouring process. The ability to contour in three dimensions, *i.e.* in sagittal and coronal as well as axial sections, is particularly helpful. Figure 3 shows how three single contours in orthogonal planes produce a three dimensional structure. This functionality can considerably reduce the time taken to outline structures. The shape of the contours can be modified on any slice as necessary. Similar interpolation tools should be available for target volume delineation and true three-dimensional volume margin growth with different margin widths in different directions. Three-dimensional display systems are an essential feature of

Figure 3. A single contour in axial sagittal and coronal planes defines a three dimensional target in Prosoma. (Courtesy of Oncology Systems Limited, Shrewsbury, UK and Medcom, Darmstadt, Germany).

any virtual simulation software. It should be possible to display axial, sagittal and coronal sections on the same screen and relate each section to the others, and to visualize the DRRs in the same window. An Observer's Eye View, with the patient on the couch and the floor and gantry angles depicted, is an aid to patient setup, as is a light-field displayed on the patient's skin related to skin marks or tattoos. Anti-collision software avoids planning a treatment field which it is physically impossible to reproduce in the treatment room. There are many different ways of rendering the target volume and OARs, but they should be unambiguous and should be rendered in three-dimensions so that coverage can be checked from all aspects. Optimization of MLC leaf positions and collimator angle should be available but adjustable by the planner. For treatment planning where a full dose distribution will not be calculated, a particularly useful feature is the calculation of the equivalent square of an irregular field, the parameter required for simple dose calculations. Increasingly, oncologists are using a number of other imaging modalities such as MRI (see Khoo and Joon in this issue) and positron emission tomography (PET) (see Jarritt et al in this issue) to help in determining target volumes. Most virtual simulation packages include an image fusion function enabling registration of two datasets of the same or different modalities, CT/CT, CT/MRI, CT/PET. Image registration and fusion may be achieved in a number of different ways, both manual and automatic (see Kessler in this issue). Irrespective of the algorithm, there is a variety of display modes to assist in performing and viewing the fusion, some of which are shown in Figure 4. Figure 4a shows the two data sets (MR and CT) fused with information from both sets displayed in the same window. The image can be "faded" between the two showing 100% of the primary data set (CT in this case) through to 100% of the secondary data set (MRI in this example). Figure 4b shows a split screen, with two quadrants displaying the CT data and two showing the MRI data. The point of intersection can be moved around the image to display the intersection at any position on the image. This will assist in delineating the structures using information from both data sets. Figure 4c shows a split screen with the secondary data set fused with the primary in the centre of the image and the primary image on either side. Contours outlining the target or OARs can be drawn on either data set or on the fused images in any of these display modes. These three screens show the fused images in the top three windows and the secondary data set in the lower windows. Figure 4d shows the region of discrepancy between the two fused data sets, in this case two CT studies, as areas of enhancement on the image. Improved localization of a brain tumour when CT and MRI data sets are fused compared with localization on CT alone for treatment planning is demonstrated in Figure 5.

Comparison of conventional and virtual simulation

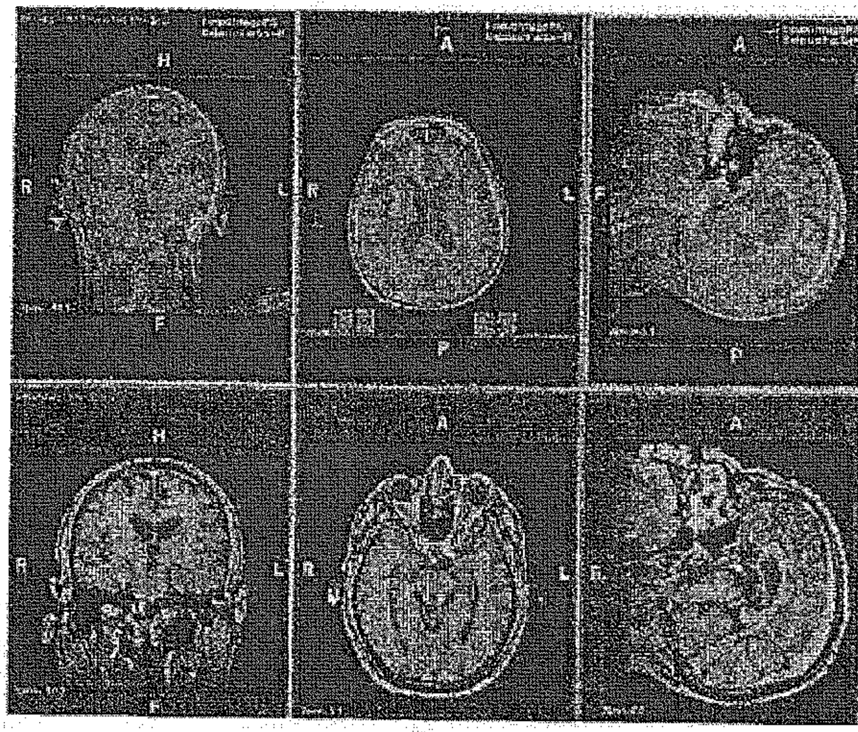
Conventional and virtual simulation approach the task of localizing the target volume for treatment planning in very different ways, which may result in significantly different treatments. Realisation of the steps performed to provide the data to a treatment planning system is compared for the two modalities in Table 1.

In comparing the two methods of simulation, the first question that arises is whether the two are comparable in terms of accuracy of the treatment set up. There are a number of studies addressing this question for different treatment sites. Bollet et al [30] showed that in a series of 20 patients who were CT scanned and had conventional simulation, the precision of set up evaluations using DRRs was similar to that using simulator films in conformal prostate treatments. They also considered whether errors were introduced at the simulation stage and found a statistically significant systematic error between DRRs and simulator, in both the craniocaudal direction and the anteroposterior direction. In another study of prostate patients Valicenti et al [31] showed that there was no statistically significant reduction in treatment setup error if patients have physical simulation following virtual simulation and concluded that physical simulation may be omitted if virtual simulation is available. In a study of 86 patients undergoing palliative radiotherapy for lung cancer using parallel opposed fields, McJury et al [32] found that setup errors were comparable between the group planned by virtual simulation and that planned using conventional simulation. Similar results are reported at different treatment sites [33–35]. In a detailed study of setup errors in 39 patients undergoing CT planned radiotherapy for lung cancer, de Boer et al [36] concluded that the setup errors introduced at simulation, which become systematic errors if the simulator film is used as the reference image, were comparable with systematic errors at the treatment unit. Hence, omission of the simulation stage would reduce systematic errors on treatment. This conclusion supported a similar result for prostate patients [37].

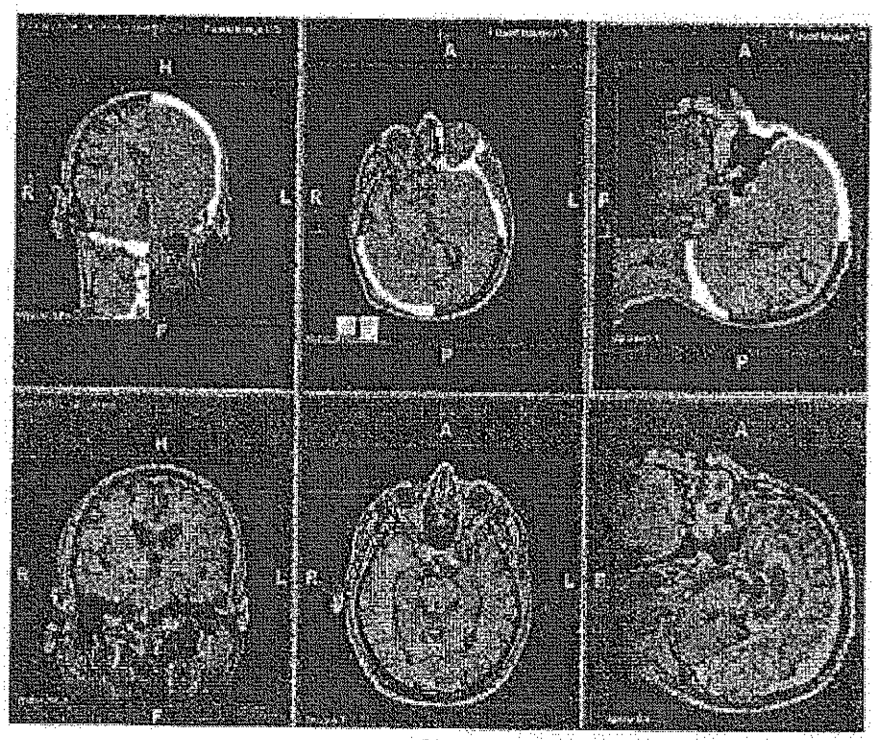
In comparing the two methods of simulation, studies have shown that the target volumes and field sizes are smaller for virtual than conventional simulation in lung cancer with the associated reduction in irradiation of normal tissue [32, 38]. Smaller field sizes have also been reported for maxillary cancer with a corresponding reduction in long-term side effects [39].

One of the perceived advantages of virtual simulation is the improved coverage of the gross tumour volume (GTV) and the avoidance of OARs as a result of better visualization of soft tissue structures on a CT scan compared with a simulator image, particularly if shielded by bone. This is aided by software functions that remove overlying structures, giving better definition of the region of interest. A study comparing conventional and virtual simulation in the treatment planning of malignant lymphoma showed incomplete coverage of the spleen and spleen hilus in 5 of 15 and 6 of 15 patients, respectively, on conventional simulation and incomplete coverage of the right and left hilus in 4 of 15 and 1 of 15 patients, respectively. In addition, the left kidney was inadequately shielded in 6 of 15 of the conventionally planned patients [40]. Similar improvements in target coverage and OAR avoidance are reported for other anatomical sites [41–44].

Improved visualization of soft tissue structures may bring to light hitherto unsuspected pathology. Mehta

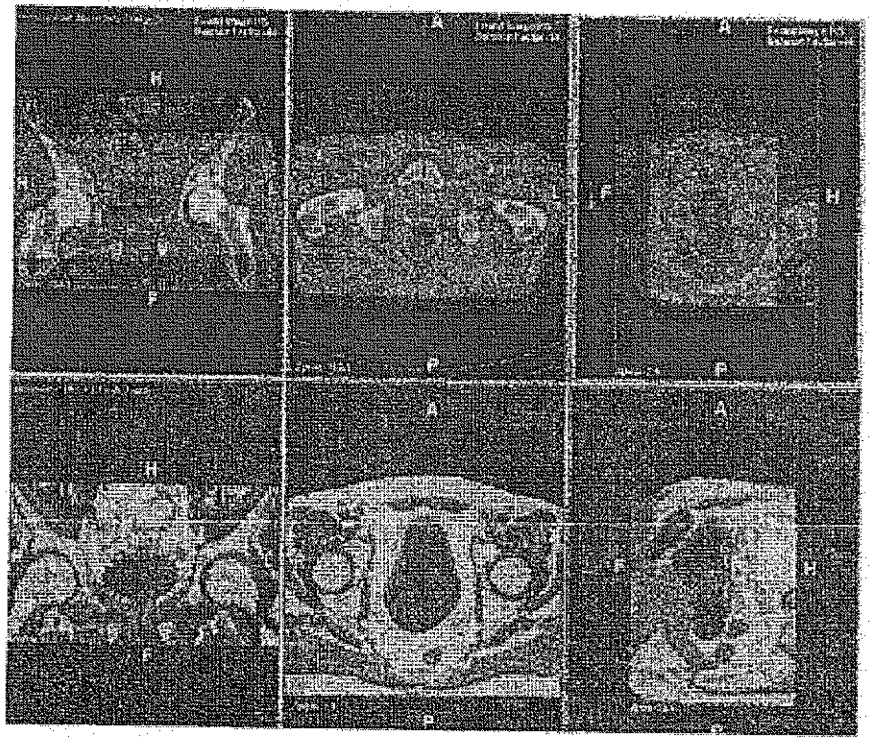


(a)

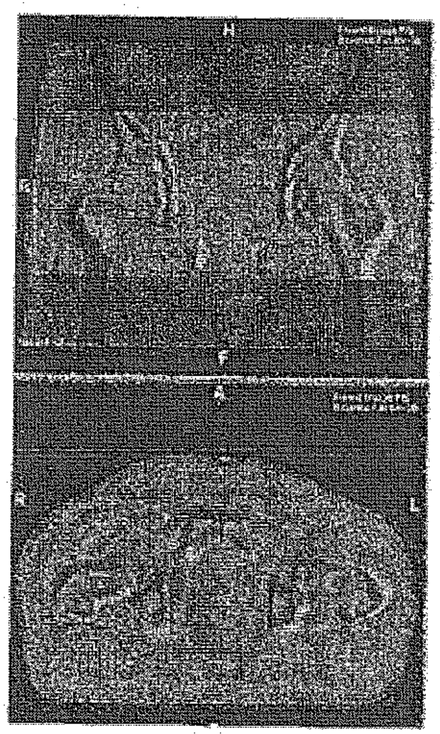


(b)

Figure 4. (a) Fusion of MRI and CT data sets, fused images in the top windows and MRI images below. (b) A split screen showing fusion between CT and MRI data sets in quadrants. (*Continued*)



(c)



(d)

Figure 4. (Cont.) (c) An alternative split screen representation of fusion between CT and MRI data sets. (d) Areas of mismatch between two CT data sets displayed as image enhancement. (Courtesy of OSL and Medcom).

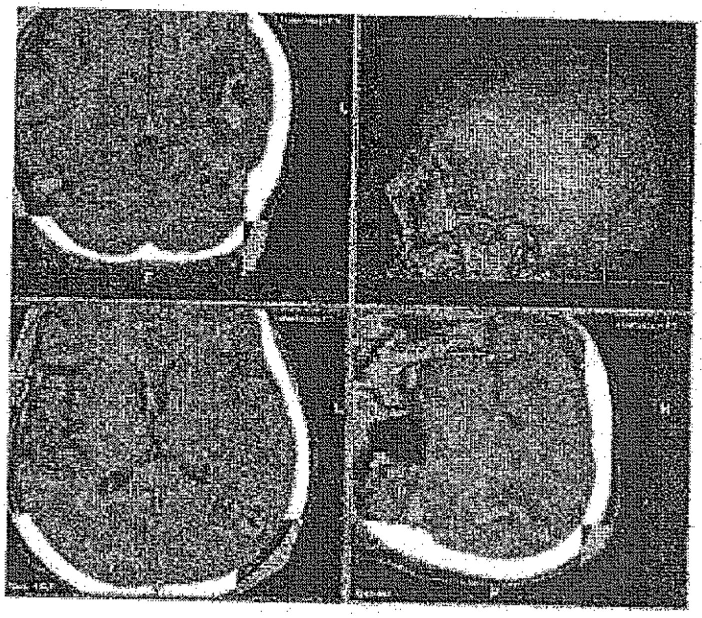


Figure 5. Improved localization of brain tumour using fused CT and MRI data sets. (Courtesy of OSL and Medcom).

and Goffinet [45] reported 17 unsuspected abnormalities in 153 scans (11%) obtained for treatment planning for patients referred for irradiation of the breast or chest wall. Of these, four represented disease that altered the treatment plan.

Working practices

The introduction of CT simulation has had a considerable impact on working practices in radiotherapy departments.

Oncologist attendance

The most notable change is that an oncologist is not required to be present during the scanning process. This releases the planning schedule from reliance on the oncologist's timetable, and the oncologists are free to undertake volume definition at a time convenient to them.

Time

A number of centres have reported on the different time allocation between conventional and virtual simulation [25, 28, 35]. Experience at the Kent Oncology Centre has shown that there is little difference in the total time needed for localization between the two modalities for the planning radiographers. With three radiographers in the scanning suite, 20 min appointments are adequate for most patients. Patients undergoing planning for breast radiotherapy are usually allocated 30 min because of the complex immobilization and positioning required with a narrow aperture scanner. These times are shorter than conventional simulation (30 min and 45 min, respectively), but more time is spent in manipulating the acquired data in the virtual simulation software. This includes the registering of reference marks and the production of DRRs for palliative patients, and outlining of target volumes and OARs for radical patients. Reduced simulation time for the patient leads to improved patient compliance, resulting in fewer problems from movement during scanning.

Table 1. Comparison of localization with CT and conventional simulation

Function	Conventional simulation	Virtual simulation
Patient alignment	Room lasers	Room lasers
Reference point definition	Skin markers	Skin markers
Localization	Fluoroscopy	CT scan
Definition of target and organs at risk	Drawing on plane films	Contouring on original or reconstructed slices
Isocentre	From simulator scales or film	DRR from CT
Field definition	From simulator scales or film	Virtual Sim
Patient outline	Manual/optical/single slice on Sim CT	Axial slice
Isocentre compared with reference point	Shifts measured on film	Calculated from Virtual Sim data
Treatment verification	Plane films	DRRs

DRR, digitally reconstructed radiograph.

Reference marks

In conventional simulation, using fluoroscopy for localization of the target volume, the isocentre can usually be established and marked at the time of simulation. In CT simulation, a reference point is chosen at the scanning session and the eventual isocentre is defined by movements of the couch from the reference point. If virtual simulation of palliative patients is undertaken with the patient remaining on the couch, the isocentre can be marked immediately from the couch movements indicated.

Verification

It has already been shown that to verify a plan on a conventional simulator after virtual simulation is not only unnecessary, but it could also be a source of systematic errors. However, treatment verification is still required and is of greater importance because of the use of reference marks. Verification takes place on the treatment unit with the electronic portal imaging system. The portal images acquired are then compared with the DRRs produced by the TPS or the virtual simulation software. For complex plans, this may require an extra treatment slot to allow time for the detailed comparison of portal images and DRRs before treatment.

Advantages and disadvantages of conventional and CT simulation

The advantages and disadvantages of conventional and CT simulation are summarized in Tables 2 and 3.

The availability of a three-dimensional dataset for all patients has some unexpected benefits. The increased information available may demonstrate previously unsuspected disease that may influence patient management. In palliative patients the extent of bone destruction from osteolytic lesions is easier to visualize on a CT scan than on a simulator film (Figure 6) and the use of software functions to remove overlying structures and display images optimized for different tissue types enables quicker localization of the disease. In breast planning, cardiac and lung volumes are more clearly demonstrated and therefore the fields can be adjusted or shielding employed accordingly.

One disadvantage of CT simulation is the increased patient dose. Doses for CT scanners are quoted as $CTDI_w$ with values in the region of 20 mGy. This dose is delivered to regions of normal healthy tissue as well as the tumour volume. Manufacturers of CT scanners provide various methods to reduce the total dose to the patient, taking account of the different dimensions of the patient at different levels and modulating the exposure in response to the detector measurements.

Some challenges still remain. Respiratory motion can affect the position of lung tumours and their relationship to OARs. Fast scanning protocols freeze patient and organ motion giving a snapshot view in time and space which may lead to inaccuracy in target delineation and choice of margins in three dimensions. Imaging techniques to overcome this drawback are an area of active investigation. The conventional method of treatment planning for lung tumours is to use fluoroscopic imaging to determine the maximum migration of the tumour during respiration and adopt large margins around the CTV to ensure that the target remains in the high dose region throughout the breathing cycle. A similar philosophy can be adopted by performing scans at deep inhale and deep exhale [46]. However, a number of other techniques have been suggested involving breath holding and respiratory gating techniques [47]. Deep inspiration breath hold (DIBH) increases the lung volume relative to normal breathing and hence the total volume of lung irradiated will be reduced using this technique [48]. In some patients, DIBH may displace the tumour away from OARs [49], which has the potential for dose escalation to the target for the same level of toxicity to OARs. Gated respiration techniques may either be active or passive. In active breathing control (ABC), the patient is prevented from breathing at a given part of the respiratory cycle during which the scan is performed and subsequent treatment takes place. By acquiring a number of scans at different parts of the breathing cycle, motion of the organ in three-dimensions can be demonstrated. Passive techniques allow the patient to breathe normally and a surrogate for the respiratory induced motion, such as the movement of the anterior chest wall, is monitored. Images obtained from CT scans are sorted according to respiratory phase to produce a 4D CT data set [50–52].

Table 2. Advantages and disadvantages of CT simulation

Advantages	Disadvantages
Three-dimensional dataset available, resulting in better visualization of tumour and nodal involvement, leads to reduction in side effects	Organ motion not visualized
Reduced simulation time leads to improved patient compliance	Repeat scan required for changes in patient set-up/shape/size during treatment
One fewer patient visit during planning	Palliative patients may spend longer in department between scanning and treatment
Oncologist not required during scanning	Transfer of verification to treatment unit may require extra treatment slot
Reduced transfer inaccuracies by omitting conventional simulator verification	Some patients/techniques may not be suitable for small aperture scanners (availability of wide aperture scanners should eliminate this problem)
Can simulate non-coplanar fields	Data storage
	Higher patient doses

Table 3. Advantages and disadvantages of conventional simulation

Advantages	Disadvantages
Fluoroscopy gives idea of organ motion	Difficult to visualize some tumours, especially if overlaid by bone (*e.g.* mediastinal lesions)
High spatial resolution	Limited three-dimensional information, even with CT option. Therefore cannot plan conformal or IMRT (cone beam may improve this)
Field visualization on patients skin	Two patient appointments required, localization and verification
	Difficult or impossible to simulate non-coplanar treatment fields

IMRT, intensity-modulated radiotherapy.

Breath hold and ABC techniques both require the co-operation of the patient and are therefore not appropriate for all patients. Some verbal or visual coaching helps to maintain regular breathing.

An alternative approach to the problem of organ motion is suggested by Murphy [53] who describes the real-time tracking of moving organs. Tracking respiratory motion is a complex procedure as it involves fast movement of organs relative to each other. For real-time tracking to be successful, the system must be able to locate the target, predict the motion to account for any time delays in repositioning the beam and adapt the treatment plan to allow for the change in relative positions of target and OARs. Although respiratory motion appears fairly regular, there are changes in amplitude and period from one cycle to the next which make prediction complicated. Murphy discusses two ways of predicting respiratory movement, by developing a mathematical model and by using an empirical algorithm that is based on measurements of previous breathing cycles. The technical challenges of fast response times to organ motion in continuous real time tracking are presented, but Murphy suggests that in the future it should be possible to treat lung tumours in some patients during free breathing, without needing to include movement margins in the treatment plan.

Respiratory correlation techniques developed to minimize motion artefacts in axial and helical scanning are not applicable to CBCT and different techniques have been developed for the CB application. Sonke et al [54] describe a method for sorting the projections into different phases of the breathing cycle to produce a 4D CBCT scan. Sillanpaa et al describe a method of acquiring megavoltage cone beam CT projection images at the same phase of breathing at all acquisition angles, giving a three-dimensional reconstruction at a single breathing phase [55]. It must be emphasised that gated respiration techniques must be employed at both the localization stage and during treatment.

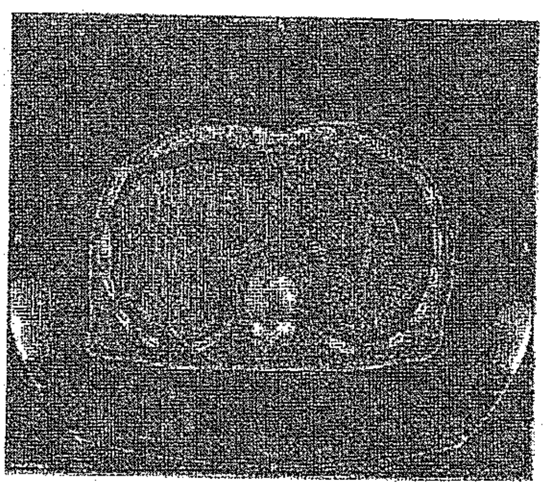


Figure 6. Osteolytic lesion of the spine.

Quality assurance

The accuracy of both conventional and CT simulation has a crucial effect on the overall accuracy of the patient's treatment. Whereas the accuracy of conventional simulation relies mainly on geometric features such as gantry and collimator angles and field defining wire positions, that of CT simulation depends on the image obtained by the scanner and the faithful transfer to the virtual simulation software. This connectivity should be part of any quality assurance (QA) programme.

A detailed description of quality control tests in conventional simulation and their recommended frequency is given by Tuohy [56].

Virtual simulation forms part of the network of the radiotherapy department, the end result of which is the treatment of the patient. The QA of this network should be seen as a process to which the various components of the hardware and software contribute. Guidance for the QA of a networked radiotherapy department is due to be published soon [57]. A QA programme should be established that reflects the importance of the contribution of each component of the system to the accuracy of the patient's treatment. Some components will be checked daily, such as the alignment of the lasers, the accuracy of positioning of any moving lasers and the HU accuracy for water. Others may be checked monthly, annually or after significant upgrades to the system. Special phantoms have been designed to assist with various aspects of QA [58, 59]. The Kent Oncology Centre has produced its own phantom that incorporates checks for a number of parameters in one scan study. These include spatial resolution, HU number, slice thickness, alignment and geometric accuracy.

Mutic et al [60] provide a comprehensive guide to the QA of CT simulators. They stress the need for audit and review of the process and flexibility in the programme as CT simulation evolves.

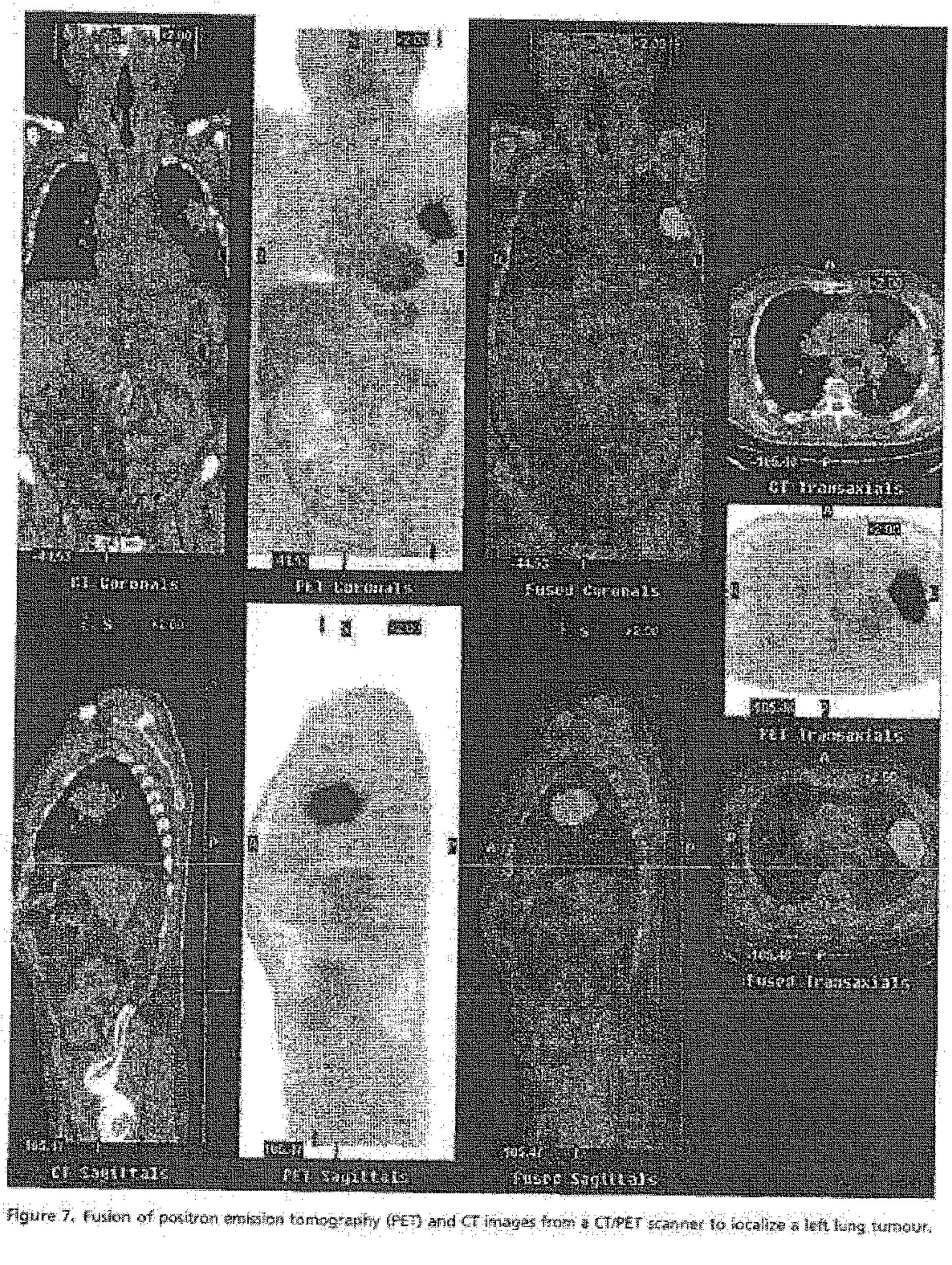


Figure 7. Fusion of positron emission tomography (PET) and CT images from a CT/PET scanner to localize a left lung tumour.

The future

The aim of radiotherapy is to deliver a tumoricidal dose of radiation to the clinical target volume (CTV) whilst sparing normal tissue and critical organs as far as possible. Localization is aimed at answering the question "where is the target?" The gross tumour volume (GTV) is neither a simple line nor an unchanging volume. It is an oncological concept and will vary according to the imaging technique or techniques used, any additional clinical data available and the judgement of the clinician. Each imaging modality displays different information about the GTV. Traditionally, delineation of the GTV has been associated with an anatomical abnormality that is imaged by plane radiography, CT or in some cases MRI. This gives structural, not functional information. However, molecular and physiological imaging techniques are now available which give an indication of the functional state of the tissues. This information can potentially be used in addition to CT and MRI to assist in defining clinically relevant targets more accurately [61]. Ling et al [62] proposed treating a biological target volume defined from anatomical, physiological and/or molecular images. For example, increased glycolysis is a function of a tumour and fluorine-18 fluorodeoxyglucose positron emission tomography (^{18}FDG-PET) studies have been used as an addition to CT for planning patients with poorly defined non-small cell lung cancer (NSCLC) [63, 64], head and neck cancers [65] and malignant gliomas [66] (see Jarritt et al in this issue). Figure 7 shows the fused images from ^{18}FDG-PET and CT acquired in a single session on a PET/CT scanner. The lesion in the left lung is clearly demonstrated in both modalities in this example. Other PET agents may be used to identify areas of hypoxia within a tumour that may benefit from higher doses of radiation such as can be delivered by IMRT. Similar inhomogeneous dose distributions may be applied to regions of the prostate demonstrating a high choline:citrate ratio, indicating a region of active tumour, as demonstrated on MR spectroscopy [67] (see Payne and Leach in this issue). Modalities such as functional MRI (fMRI) and single photon emission computed tomography (SPECT) may also be used to assist in GTV and OAR delineation. SPECT perfusion studies for NSCLC can be used in treatment planning to provide information on normal lung tissue and help to reduce the volume of normal lung irradiated [68].

Imaging techniques are continually evolving and as they are refined they will reveal more information about the disease to be treated. Collaboration between radiologists and oncologists will be essential if the information contained within these new images is to be maximized for the benefit of the patient.

No consideration of the future of radiation therapy would be complete without mention of image guided radiotherapy (IGRT). IGRT aims to address the interfraction movement of tumours and their relationship to OARs. Of the linear accelerator manufacturers, both Elekta (Crawley, Sussex, UK) and Varian (Palo Alto, CA) provide kilovoltage cone beam CT (CBCT) on the gantry and Siemens (Erlangen, Germany) have installed a CT scanner on rails in the treatment room (see Moore et al and Thieke et al, respectively, in this issue).

These imaging devices provide the ability to localize the tumour immediately prior to treatment and to reposition the patient to correct for interfraction variation in tumour position. Wong et al [69] describe the use of daily scans in the treatment room to reposition prostate patients for the final phase of their treatment. 46% required no isocentre adjustment in the anterior–posterior direction, but 44% required a shift of greater than 5 mm. In the superoinferior direction, 25% required a shift greater than 5 mm and in left-right direction 24% required a shift greater than 5 mm. The shifts were associated with significant changes in the dosimetry. Other authors describe the implementation of CBCT for IGRT [54, 70, 71].

IGRT is a rapidly evolving field and will undoubtedly have implications for treatment planning.

Conclusion

Both conventional and virtual simulation have developed in line with the changes in imaging techniques over recent years. The anticipated advantages of virtual simulation have been realised to a great extent and have changed the work flow in treatment planning. The availability of wide bore scanners enables most treatment techniques to be imaged. Fast computer graphics that have reduced image reconstruction times enable the acquisition of large data sets that can be manipulated for respiratory correlated techniques. The rapid development of biological imaging holds the prospect of multimodality localization, which is already being realised for some disease sites such as lung and prostate. The addition of cone beam CT to conventional simulators may add flexibility to departments with both a scanner and a simulator. However localization is achieved, it must be considered as part of the overall process that leads to treatment. The accuracy of the data acquisition and transfer is vital to this process and a comprehensive QA programme is essential.

I would like to thank Dr Ruth Beddows for the design of the Kent Oncology Centre phantom, Ms Alison Vinall and Ms Karen Venables for reports on cone beam CT, David Hill for assistance with image processing and colleagues for discussions during the preparation of this manuscript.

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EXHIBIT D
CURRICULUM VITAES

JOSEPH BARGELLINI, M.D.
Medical Director, Radiation Oncology
New Milford Hospital
860-210-5020 (W)

CURRICULUM VITAE

- **Medical Director, Radiation Oncology, New Milford Hospital**, New Milford, CT
- Member Western Connecticut Medical Group, July 2011 to the present
- Responsible for building a practice in a hospital based setting where radiation therapy was a new service.
- Planned and implemented replacement of hospital's original Varian Clinac 2100 linear accelerator with new Varian Trilogy linear accelerator.
- Implemented prostate brachytherapy program and high dose rate brachytherapy program.
- Implemented Intensity Modulated Radiation Therapy using Varian Eclipse Software.
- Implemented radiopharmaceutical therapy program.
- Implemented Image Guided Radiation Therapy (IGRT) program
- Implemented Stereotactic Radiation Therapy program for brain tumors
- Responsible for developing and implementing policies, procedures, and quality assurance programs for the different radiation therapy modalities offered.
- Radiation Oncology representative to hospital committees, including weekly Cancer Conference, and Multidisciplinary Cancer Committee.
- Chairman, New Milford Hospital Multidisciplinary Cancer Committee
- **Radiation Safety Officer,** New Milford Hospital, New Milford, CT.
- Member New Milford Hospital Research Committee.
- Participated in certification process of the New Milford Hospital Radiation Oncology program by the American College of Radiology (ACR).
- Participated in certification process of the New Milford Hospital Cancer program by the American College of Surgeons.

Academic Training

Yale University, New Haven, Connecticut, B.S., 1986

University of Medicine and Dentistry of New Jersey, New Jersey Medical School, Newark, New Jersey, M.D., 1993

Licensure: Connecticut State, September 1998, #037262, Expiration 8/31/2011
New York State, 209956, Expiration 12/31/2011

Indiana State, 2011 - 2012

Traineeship

Internship: The New York Hospital - Cornell Medical Center, New York, NY
Internal Medicine, 1993-1994

Residency: Mallinckrodt Institute of Radiology, St. Louis, MO
Resident in Radiation Oncology, 1994-1995

Columbia-Presbyterian Medical Center, New York, NY
Resident in Radiation Oncology, 1995-1998
Chief Resident July 1996 through February 1997

Board Certification

Diplomate, National Board of Medical Examiners, 1994

NBME Step 1 passed 7/1991, USMLE Step 2 passed 9/1992, NBME passed 3/1994

Diplomate, American Board of Radiology – Radiation Oncology, 1998, Certificate #43451

American Board of Radiology – Radiation Oncology Recertification 2008

Skills

- Three Dimensional Conformal Radiation Therapy using Varian Eclipse Software
- High Dose Rate Brachytherapy
- Low Dose Rate Brachytherapy
- Real Time Prostate Brachytherapy using Variseed software
- Stereotactic Radiosurgery using both Linac and Gamma Knife modalities
- Intensity Modulated Radiation Therapy
- Radiopharmaceutical Therapy
- Partial Breast Radiation Therapy
- Image Guided Radiation Therapy

Academic Appointments

2005 - 2009 Adjunct Professor
Department of Radiation Oncology
College of Physicians & Surgeons of Columbia University
New York, NY

1999 - 2004	Assistant Professor Department of Radiation Oncology College of Physicians & Surgeons of Columbia University New York, NY
1998 - 1999	Instructor Department of Radiation Oncology College of Physicians & Surgeons of Columbia University New York, NY
1997-1998	Resident Fellow Department of Radiation Oncology College of Physicians & Surgeons of Columbia University New York, NY

Hospital Appointments

1999-Present	Medical Director, Radiation Oncology New Milford Hospital New Milford, CT
2011-Present	Regional Hospital, Covering Radiation Oncology Terre Haute, Indiana
2011-Present	Charlotte Hungerford Hospital, Covering Radiation Oncology Torrington, CT
1998-2004	Assistant Attending Radiation Oncology Service The Presbyterian Hospital New York, NY
1997-1998	Chief Resident Radiation Oncology Service The Presbyterian Hospital New York, NY

Work Experience

1987-1989	Analyst, Domestic and International Fixed Income Securities Drexel Burnham Lambert New York, NY

Honors

Magna Cum Laude, Yale University 1986
Tuition Scholarship for Academic Excellence, New Jersey Medical School, 1989-1993

Alpha Omega Alpha National Medical Honor Society, 1993

Selected Invited Lectures:

1. Treatment Planning Issues in the Management of Breast Cancer. Physics Presentation, Mallinckrodt Institute of Radiology Washington University Medical Center, St. Louis, MO, 1994.
2. Melanoma. Grand Rounds, Mallinckrodt Institute of Radiology, Washington University Medical Center, St. Louis, MO, 1995.
3. Post-operative Radiation Therapy for Prostate Cancer, Urology Tumor Board, Department of Urology Columbia-Presbyterian Medical Center, New York, NY, January 1996.
4. Malignant Melanoma. Grand Rounds, Department of Radiation Oncology, Columbia-Presbyterian Medical Center, New York, NY, May 1996.
5. Radiation Nephropathy. Presented at Grand Rounds, Department of Radiation Oncology, Columbia-Presbyterian Medical Center, New York, NY, November 1996.
6. Bladder Cancer with Emphasis on Bladder Preservation. Presented at Urology Tumor Board, Department of Urology, Columbia-Presbyterian Medical Center, New York, NY, June 1997.
7. Bladder Cancer with Emphasis on Bladder Preservation. Presented at Grand Rounds, Department of Radiation Oncology, Columbia-Presbyterian Medical Center, New York, NY, June 1997.

Grants

1996-1997 House Staff Research Award, Columbia-Presbyterian Medical Center, NY $1500.

Teaching

1. Faculty leader of Columbia-Presbyterian Residency Journal Club.
2. Columbia-Presbyterian Resident teaching through case conferences.
3. MCAT Instructor, Stanley Kaplan Educational Centers, Location, 1990-1991.

Publications

1. Hill, H.Z., Cathcart, K.N., Bargellini, J., Trizna, Z., Hill, G.J., Schallreuter, K.U., Wood, J.M. Does Melanin affect the Low LET Radiation Response of Cloudman S91 Mouse Melanoma Cell Lines. Pigment Cell Research, 4(2):80-6, 1991.

Abstracts

1. Trichter, F., Bargellini, J., Amols, H., Schiff, P. Clinical Implementation of a Matrix Ion Chamber EPID in Obese Patients Treatment. 40th AAPM Annual Meeting, San Antonio, Texas, August 1998. Med. Phys. 25(7):A198, 1998.

LEE ANN ZARGER, MSDABR
Chief Medical Physicist
New Milford Hospital
Work: (860) 210-5022

EDUCATIONAL BACKGROUND

Albright College, Reading, Pa. B.S. 1976
Overlook Hospital School of Nuclear Medicine Technology, Summit, N.J. , certificate in Nuclear Medicine Technology, 1980
Rutgers University Graduate School, Piscataway, N.J. M.S. in Radiation Science, 1985
Board Certification by American Board of Radiology in Therapeutic Radiological Physics 1991

EXPERIENCE

1980-1984 Nuclear Medicine Technologist-worked full time as a nuclear medicine technologist at Hackensack Hospital and Morristown Memorial Hospital while attending graduate school part time.

1984-1985 Junior physicist at Memorial Sloan Kettering- worked on a research project in the Biophysics Department designing and fabricating an anthromorphic tissue equivalent phantom for use in a monoclonal antibody NCI grant project.

1985-1989 Junior physicist Valley Hospital in Ridgewood, N.J. Clinical duties including brachytherapy planning for breast, gyn and prostate, external beam treatment planning, sealed source quality assurance, linear accelerator quality assurance. Assisted chief physicist in acceptance testing and commissioning of new treatment planning system and linear accelerator, nuclear medicine quarterly quality assurance.
Taught physics and math classes to x-ray students at the hospital based school.

1989-1993 Consultant physicist for George Zacharopoulos at Dover General Hospital, Dover, N.J. Clinical duties including external beam and brachytherapy treatment planning(gyn), hdr treatment planning and associated radiation safety duties. and sealed source quality assurance duties.
Linear accelerator quality assurance, cobalt machine quality assurance and orthovoltage unit quality assurance.. Assisted in commissioning and acceptance testing of new treatment planning system,linear accelerator, and the high dose rate remote afterloader(Nucletron)..

1994-1994 Radiation Oncology Physicist Hackensack Medical Center. Prostate seed implant planning and associated radiation safety duties. Linear accelerator and cobalt machine quality assurance. Worked with other physicists on acceptance testing and commissioning of linear accelerator.

1995-1998 Solo medical physicist in Radiation Oncology Dept. of Clara Maas Medical Center, Belleville, N.J. Performed acceptance testing of 3D treatment planning system. Clinical duties included external beam and brachytherapy treatment planning(gyn, prostate) and radiation safety duties associated with brachytherapy. Trained a junior Dosimetrist. Physics aspects of beginning a prostate seed implant program. Performed quality assurance duties on 2 linear accelerators and a simulator. Sealed source quality assurance duties. Writing of license amendment for NRC for HDR program. During this time I also provided vacation coverage for Bayonne Hospital for HDR duties(Nucletron).

1998-2002 Senior physicist and radiation safety officer Danbury Hospital, Danbury, Ct. Oversight and direct involvement in the physics aspects of beginning a prostate seed implant program and CT simulator installation and implementation. Radiation safety aspects of radiation oncology, radiology and nuclear medicine, including quality assurance. Supervised work of the radiology engineers as well as physics section. Radiation safety instuction to all personnel in hospital using or dealing with radiation, including x-ray students. During this time period I also provided part time coverage for Bristol Radiation Oncology, Bristol, Ct.

5/02 to 10/03 Solo medical physicist in Radiation Oncology Dept. of Midstate Medical Center in Meriden, Ct. Brachytherapy treatment planning and associated radiation safety duties for a busy seed implant program. Acceptance testing of the new treatment planning computer and physics aspects of starting an IMRT program. Oversight of dosimetrist's work. Quality assurance of linear accelerator and simulator. Equipment: Elekta Precise linac, Pinnacle, Impac.. During this time period I also provided part time coverage for Bristol Radiation Oncology, Bristol, Ct.
I am currently per diem here(give vacation coverage).

10/03 to 9/07 Solo medical physicist in Radiation Oncology at Charlotte Hungerford Hospital in Torrington, Ct. Acceptance testing of the new treatment planning computer and physics aspects of starting IMRT program. Physics aspects of starting up an HDR program(license, acceptance testing coordinated training). External beam treatment planning(including IMRT and partial breast external beam protocol patients) and brachytherapy treatment planning(for seed implants and HDR including mammosites) and oversight of dosimetrists' work. Performed treatment planning in dosimetrist's absence. Quality assurance for linear accelerator and orthovoltage machine. Equipment: Elekta Precise linac, Pinnacle, Brachyvision, Impac, Gammamed,Variseed.
I am currently per diem here(give vacation coverage)

9/07 to present

Chief Physicist New Milford Hospital Radiation Therapy Department, New Milford, Ct. Quality assurance of linear accelerator and simulator, Physics aspects of HDR(including assisted department in beginning Mammosite treatments). IMRT quality assurance. Perform treatment planning in dosimetrist's absence. Brachytherapy treatment planning. Supervision of dosimetrist and per diem physicists and dosimetrists. Assist radiation safety officer. Radiation safety aspects of radionuclide therapies. Physics aspects of prostate seed implants. Was actively involved in planning for and ordering new linear accelerator. Equipment: Varian 2100 CD, Eclipse, Brachyvision, Aria, Varisource,Variseed. Equpment updated October 2011 to Trilogy with VMAT and IGRT and Varisource IX HDR. Performed acceptance testing of both machines and assisted physics group with linac commissioning. Performed acceptance testing of treatment planning systems after new machines. Responsible for physics aspects of developing VMAT(RapidArc) treatment program for imrt and srt.

Professional Activities

Board Certification by American Board of Radiology.
American College of Radiology Physicist Surveyor for practice accreditation
Member of American Association of Physicists in Medicine and its Local chapter. ASTRO member Served as Treasurer, President-Elect and President of New Jersey Medical Physics Society and Secretary, President-Elect and President of Connecticut Area Medical Physics Society. Served on the Clinical Practice Committee of AAPM.

EXHIBIT E
HOSPITAL LICENSE

STATE OF CONNECTICUT

Department of Public Health

LICENSE

License No. 0032

General Hospital

In accordance with the provisions of the General Statutes of Connecticut Section 19a-493:

New Milford Hospital, Inc. of New Milford, CT d/b/a New Milford Hospital is hereby licensed to maintain and operate a General Hospital.

New Milford Hospital is located at 21 Elm Street, New Milford, CT 06776.

The maximum number of beds shall not exceed at any time:

0 Bassinets
85 General Hospital Beds

This license expires **June 30, 2015** and may be revoked for cause at any time.
Dated at Hartford, Connecticut, July 1, 2013. RENEWAL.

Satellite:

New Milford Hospital Community Mental Health Services, 23 Poplar Street, New Milford, CT

Jewel Mullen, MD, MPH, MPA
Commissioner

EXHIBIT F

FINANCIAL ATTACHMENTS & ASSUMPTIONS

New Milford Hospital CT-Simulator CON Application

7.a. Financial Attachment I

(Dollars are in thousands)

Total Facility: Description	FY 2012 Actual Results	FY 2013 Projected W/out CON	FY 2013 Projected Incremental	FY 2013 Projected With CON	FY 2014 Projected W/out CON	FY 2014 Projected Incremental	FY 2014 Projected With CON	FY 2015 Projected W/out CON	FY 2015 Projected Incremental	FY 2015 Projected With CON	FY 2016 Projected W/out CON	FY 2016 Projected Incremental	FY 2016 Projected With CON
NET PATIENT REVENUE													
Non-Government	$48,136	45,592	-	$45,592	47,042	-	47,042	48,544	-	48,544	50,221	-	50,221
Medicare	24,242	19,229	-	$19,229	18,687	-	$18,687	18,842	-	$18,842	19,098	-	$19,098
Medicaid and Other Medical Assistance	5,632	5,340	-	$5,340	5,344	-	$5,344	5,349	-	$5,349	5,376	-	$5,376
Other Government	101	85	-	85	85		85	85		85	85		$85
Total Net Patient Patient Revenue	$78,111	$70,245	$0	$70,245	$71,157	$0	$71,157	$72,820	$0	$72,820	74,780	$0	$74,780
Other Operating Revenue	$1,101	$980	-	$980	$980	$0	$980	$980	$0	$980	$980	$0	$980
Revenue from Operations	$79,212	$71,225	$0	$71,225	$72,137	$0	$72,137	$73,799	$0	$73,799	$75,759	$0	$75,759
OPERATING EXPENSES													
Salaries and Fringe Benefits	$45,235	$40,419	-	$40,419	$41,329	-	$41,329	$42,259	-	$42,259	$43,209	-	$43,209
Professional / Contracted Services	12,196	8,713	-	8,713	8,887	-	8,887	9,065	-	9,065	9,246	-	9,246
Supplies and Drugs	10,418	9,589	-	9,589	9,876	-	9,876	10,173	-	10,173	10,478	-	10,478
Other Operating Expense	10,942	10,360	-	10,360	10,360	186	10,546	10,360	186	10,546	10,360	186	10,546
Subtotal	$78,792	$69,081	$0	$69,081	$70,452	$186	$70,638	$71,856	$186	$72,042	$73,294	$186	$73,480
Depreciation/Amortization	5,527	5,862	220	6,082	6,162	220	6,382	7,162	220	7,382	8,162	220	8,382
Interest Expense	419	268	-	268	268	-	268	268	-	268	268	-	268
Lease Expense	447	824	-	824	832	-	832	841	-	841	849	-	849
Total Operating Expenses	$85,184	$76,035	$220	$76,255	$77,715	$406	$78,121	$80,127	$406	$80,533	$82,573	$406	$82,979
Gain/(Loss) from Operations	($5,972)	($4,810)	($220)	($5,030)	($5,578)	($406)	($5,984)	($6,328)	($406)	($6,734)	($6,813)	($406)	($7,219)
Plus: Non-Operating Income	$772	$0		$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Income before provision for income taxes	($5,200)	($4,810)	($220)	($5,030)	($5,578)	($406)	($5,984)	($6,328)	($406)	($6,734)	($6,813)	($406)	($7,219)
Provision for income taxes			-	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Revenue Over/(Under) Expense	($5,200)	($4,810)	($220)	($5,030)	($5,578)	($406)	($5,984)	($6,328)	($406)	($6,734)	($6,813)	($406)	($7,219)
FTEs	420.0	375.0	-	375.0	375.0	-	375.0	375.0	-	375.0	375.0	-	375.0
*Volume Statistics:													
Complex Sims Performed	121	176	-	176	176	-	176	176	-	176	176	-	176
Key Ratios:													
Op Margin	-7.5%	-6.8%		-7.1%	-7.7%		-8.3%	-8.6%		-9.1%	-9.0%		-9.5%
Operating EBIDA Margin	0.0%	1.9%		1.9%	1.2%		0.9%	1.5%		1.2%	2.1%		1.9%
Excess Margin	-6.6%	-6.8%		-7.1%	-7.7%		-8.3%	-6.6%		-9.1%	-9.0%		-9.5%

New Milford Hospital CT-Simulator CON Application

7.b. Financial Attachment II

(Dollars are in thousands)

Please provide three years of projections of incremental revenue, expense and volume statistics attributable to the proposal in the following reporting format:

FY 2013 FY Projected Incremental Total Incremental Expenses: Total Facility by Payer Category:	(1) $220	(2) Rate	(3) Units	(4) Gross Revenue Col. 2 * Col. 3	(5) Allowances/ Deductions	(6) Charity Care	(7) Bad Debt	(8) Net Revenue Col.4 - Col.5 -Col.6 - Col.7	(9) Operating Expenses Col. 1 Total * Col. 4 / Col. 4 Total	(10) Gain/(Loss) from Operations Col. 8 - Col. 9
Medicare		-	-	$0	-	-	-	$0	$103	($103)
Medicaid		-	-	$0	-	-	-	-	21	(21)
CHAMPUS/TriCare		-				-	-	-	0	(0)
Total Governmental			0	$0	-	$0	$0	$0	$124	($124)
Commericial Insurers		-	-	$0	-	-	-	-	91	(91)
Uninsured		-	-	$0	-	-	-	-	4	(4)
Total NonGovernment			0	$0	-	$0	$0	$0	$96	($96)
Total All Payers		-	0	$0	$0	$0	$0	$0	$220	($220)

FY 2014 FY Projected Incremental Total Incremental Expenses: Total Facility by Payer Category:	(1) $406	(2) Rate	(3) Units	(4) Gross Revenue Col. 2 * Col. 3	(5) Allowances/ Deductions	(6) Charity Care	(7) Bad Debt	(8) Net Revenue Col.4 - Col.5 -Col.6 - Col.7	(9) Operating Expenses Col. 1 Total * Col. 4 / Col. 4 Total	(10) Gain/(Loss) from Operations Col. 8 - Col. 9
Medicare		-	-	$0	-	-	-	$0	$189	($189)
Medicaid		-	-	$0	-	-	-	-	39	(39)
CHAMPUS/TriCare		-				-	-	-	1	(1)
Total Governmental			0	$0	$0	$0	$0	$0	$229	($229)
Commericial Insurers		-	-	$0	-	-	-	-	169	(169)
Uninsured		-	-	$0	-	-	-	-	8	(8)
Total NonGovernment			0	$0	$0	$0	$0	$0	$177	($177)
Total All Payers		-	0	$0	$0	$0	$0	$0	$406	($406)

FY 2015 FY Projected Incremental Total Incremental Expenses: Total Facility by Payer Category:	(1) $406	(2) Rate	(3) Units	(4) Gross Revenue Col. 2 * Col. 3	(5) Allowances/ Deductions	(6) Charity Care	(7) Bad Debt	(8) Net Revenue Col.4 - Col.5 -Col.6 - Col.7	(9) Operating Expenses Col. 1 Total * Col. 4 / Col. 4 Total	(10) Gain/(Loss) from Operations Col. 8 - Col. 9
Medicare		-	-	$0	-	-	-	$0	$189	($189)
Medicaid		-	-	$0	-	-	-	-	39	(39)
CHAMPUS/TriCare		-				-	-	-	1	(1)
Total Governmental			0	$0	$0	$0	$0	$0	$229	($229)
Commericial Insurers		-	-	$0	-	-	-	-	169	(169)
Uninsured		-	-	$0	-	-	-	-	8	(8)
Total NonGovernment			0	$0	$0	$0	$0	$0	$177	($177)
Total All Payers		-	0	$0	$0	$0	$0	$0	$406	($406)

New Milford Hospital CT-Simulator CON Application

7.c. Financial Assumptions

Net Patient Revenue:	
Without Project:	Based on current payor mix and volume assumptions with annual increases of 0% in govt rates, 2% in nongovt rates, elimination of medicare low volume reimb in FY14.
With Project:	Same as above - no change related to project
Volume:	
Without Project:	Overall, a 1% decrease in inpatient volume, 0.4% increase in outpt volume was included in projections
With Project:	Same as above - no change related to project
Other Operating Revenue:	
Without Project:	Assumes 0% increase annually
With Project:	Same as above - no change related to project
Salaries and Fringe Benefits:	
Without Project:	Assumed 2.25% annual inflationary increase.
With Project:	Same as above - no change related to project
Professional / Contracted Srvs:	
Without Project:	Assumes 2% annual increase on current expense levels.
With Project:	Same as above - no change related to project
Supplies and Drugs:	
Without Project:	Assumes 3% annual increase on current expense levels.
With Project:	Same as above - no change related to project
Other Op Expense:	
Without Project:	Based on historic trend
With Project:	Incremental expense associated with project includes $186K in annual maintenace fees for equipment beginning in Year 2.
Depreciation:	
Without Project:	Assumption is based on historic and planned annual capital spending
With Project:	Assumes $1.1M acquisition fee depreciated straightline over 5 years
Interest:	
Without Project:	Based on current interest of existing debt rolled forward annually.
With Project:	Same as above - no change related to project
Lease Expense:	
Without Project:	Includes a 1% annual increase on expenses annually.
With Project:	Same as above - no change related to project
FTEs:	
Without Project:	FTEs increases necessary for any relative volume change will be offset with productivity improvement initiatives.
With Project:	Same as above - no change related to project

WESTERN CONNECTICUT
HEALTH NETWORK
DANBURY HOSPITAL • NEW MILFORD HOSPITAL

24 Hospital Ave.
Danbury, CT 06810
203.739.7000

WesternConnecticutHeatlhNetwork.org
DanburyHospital.org
NewMilfordHospital.org

July 29, 2013

Kimberly R. Martone
Director of Operations
Department of Public Health
Office of Health Care Access
410 Capitol Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

Re: New Milford Hospital, Inc. CON Request

Dear Ms. Martone,

Pursuant to Section 19a-638, C.G.S., please find enclosed a Certificate of Need for New Milford Hospital, Inc. to acquire replacement simulation technology for its Diebold Family Cancer Center, located on the hospital's campus at 21 Elm Street, New Milford. CT.

If you have any questions that the attached submission does not answer, please contact me so that we may provide whatever additional information you need in your deliberations. I can be reached directly at 203-739-4903, or sally.herlihy@wchn.org.

Thank you,

Sally F. Herlihy

Sally F. Herlihy, MBA, FACHE
Vice President, Planning

(Note: Submitted via email to Kimberly.martone@ct.gov and steven.lazarus@ct.gov, with original copy and Filing Fee mailed to OHCA).

RECEIVED
30 2013
OFFICE OF
HEALTH CARE ACCESS

Application Checklist

Instructions:

1. **Please check each box below, as appropriate; and**
2. **The completed checklist *must* be submitted as the first page of the CON application.**

☑ **Attached is the CON application filing fee in the form of a certified, cashier or business check made out to the "Treasurer State of Connecticut" in the amount of $500.**

For OHCA Use Only:

Docket No.: 13-31855-CON **Check No.:** 828396
OHCA Verified by: lmg **Date:** 7-30-13

☑ **Attached is evidence demonstrating that public notice has been published in a suitable newspaper that relates to the location of the proposal, 3 days in a row, at least 20 days prior to the submission of the CON application to OHCA. (*OHCA requests that the Applicant fax a courtesy copy to OHCA (860) 418-7053, at the time of the publication)***

☑ **Attached is a paginated hard copy of the CON application including a completed affidavit, signed and notarized by the appropriate individuals.**

☑ **Attached are completed Financial Attachments I and II.**

N/A **Submission includes one (1) original and four (4) hard copies with each set placed in 3-ring binders.**

Note: **A CON application may be filed with OHCA electronically through email, if the total number of pages submitted is 50 pages or less. In this case, the CON Application must be emailed to ohca@ct.gov.**

Important: **For CON applications(less than 50 pages) filed electronically through email, the singed affidavit and the check in the amount of $500 must be delivered to OHCA in hardcopy.**

N/A **The following have been submitted on a CD**

1. **A scanned copy of each submission in its entirety, including all attachments in Adobe (.pdf) format.**
2. **An electronic copy of the documents in MS Word and MS Excel as appropriate.**

WESTERN CONNECTICUT HEALTH NETWORK
DANBURY HOSPITAL • NEW MILFORD HOSPITAL

No. 828396

Check Date: 07/23/2013

TREASURER STATE OF CT, 410 CAPITOL AVE, HARTFORD, CT 06134 (12592)

Description	Date	Gross Amount	Discount Amount	Net Amount Paid
PETCTCONAPP2013	07/19/13	$500.00	$0.00	$500.00
Totals		$500.00	$0.00	$500.00

Detach at Perforation Before Depositing Check

Any questions, please contact
Accounts.Payable@Danhosp.org or call 203-739-7169

Page 1 of 1

WESTERN CONNECTICUT HEALTH NETWORK
DANBURY HOSPITAL • NEW MILFORD HOSPITAL

Wachovia Bank of Delaware, NA
62-22/311

Check No. 828396

Check Date
07/23/2013

Accounts Payable Telephone: 203-739-7169

PAY *Five Hundred AND 00/100*

Check Amount
$ *******500.00

TO THE ORDER OF
TREASURER STATE OF CT
410 CAPITOL AVE
HARTFORD, CT 06134

12592

⑈00828396⑈ ⑆031100225⑆ 2079960001550⑈

Order Confirmation

Ad Order Number	Customer	Payor Customer
0001871563	DANB.HOSP.WEST.CT.HEALT	DANB.HOSP.WEST.CT.HEALT
Sales Rep.	**Customer Account**	**Payor Account**
dsettani	197666	197666
Order Taker	**Customer Address**	**Payor Address**
dsettani	24 HOSPITAL AVENUE DANBURY CT 06810 USA	24 HOSPITAL AVENUE DANBURY CT 06810 USA
Ordered By	**Customer Phone**	**Payor Phone**
ANDREA	203-739-7919	203-739-7919
Order Source		
E-mail		
PO Number	**Customer Fax**	**Customer EMail**
	203-739-1689	Andrea.Rynn@wcthealthnetwork.org

Ad Content Proof

PUBLIC NOTICE
Statute of Reference:
Section 19a-638 of the Connecticut General Statutes
Applicant:
New Milford Hospital, Inc. (NMH), a subsidiary of We
Health Network, Inc.
Address:
NMH, 21 Elm Street, New Milford, CT 06776
Proposal:
NMH is filing a Certificate of Need with the Office of H
for the acquisition of CT Scan Simulation replacement
radiation oncology service. The capital expenditure for
mated to be $850,000.

Tear Sheets	Proofs	Affidavits	Special Pricing	Promo Type
1	0	0	None	

Order Notes: APPROVED BY ANDREA

Invoice Text:

Blind Box	Materials	Payment Method

Net Amount	Tax Amount	Total Amount	Payment Amt	Amount Due
$550.65	$0.00	$550.65	$0.00	$550.65

Ad Number	Ad Type	Ad Size	Pick Up Number
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PUBLIC NOTICES

PUBLIC NOTICE
Statute of Reference:
Section 19a-638 of the Connecticut General Statutes
Applicant:
New Milford Hospital, Inc. (NMH), a subsidiary of Western Connecticut Health Network, Inc.
Address:
NMH, 21 Elm Street, New Milford, CT 06776
Proposal:
NMH is filing a Certificate of Need with the Office of Health Care Access for the acquisition of CT Scan Simulation replacement technology for its radiation oncology service. The capital expenditure for this project is estimated to be $850,000.

PUBLIC NOTICE

AFFIDAVIT

Applicant: New Milford Hospital, Inc.

Project Title: Acquisition of a Replacement Simulator Technology

I, Steven H. Rosenberg, Senior Vice President and CFO, of Western Connecticut Health Network, Inc., being duly sworn, depose and state that New Milford Hospital Inc.'s information submitted in this Certificate of Need Application is accurate and correct to the best of my knowledge.

Steven Rosenberg
Signature

7/29/13
Date

Subscribed and sworn to before me on 7/29/13

Susan M. Kania
Notary Public/Commissioner of Superior Court

My commission expires: 2/28/2015

State of Connecticut
Office of Health Care Access
Certificate of Need Application

Instructions: Please complete all sections of the Certificate of Need ("CON") application. If any section or question is not relevant to your project, a response of "Not Applicable" may be deemed an acceptable answer. If there is more than one applicant, identify the name and all contact information for each applicant. OHCA will assign a Docket Number to the CON application once the application is received by OHCA.

Docket Number:	TBD
Applicant:	New Milford Hospital, Inc.
Contact Person:	Sally Herlihy, MBA, FACHE
Contact Person's Title:	Vice President, Planning Western Connecticut Health Network, Inc.
Contact Person's Address:	24 Hospital Avenue, Danbury, CT 06810
Contact Person's Phone Number:	203-739-4903
Contact Person's Fax Number:	203-739-1974
Contact Person's Email Address:	sally.herlihy@wchn.org
Project Town:	New Milford, CT
Project Name:	Acquisition of Replacement Simulator Technology
Statute Reference:	Section 19a-638, C.G.S.
Estimated Total Capital Expenditure:	$1,100,000

1. Project Description: Acquisition of Equipment

a. Please provide a narrative detailing the proposal.

New Milford Hospital, Inc. ("NMH") proposes to replace its existing radiation oncology simulator with a computerized tomography simulator ("CT simulator") at a total capital expenditure of $1.1M. The Hospital's Diebold Family Cancer Center ("Center") has a reputation for excellence and a commitment to the highest standards of cancer care. It is accredited in radiology, mammography and radiation oncology services by the American College of Radiology and the National Accreditation Program for Breast Centers.

In December 2012, the Center was re-approved "with commendation" by the American College of Surgeons (ACoS), Commission on Cancer. The designation, offered by ACoS every three years, distinguishes exceptional hospital performance in ongoing improvement and public accountability for cancer treatment services. NMH exceeded standards in multiple areas of clinical care and operations and earned the highest scores possible in standards for outcomes analysis, data management timeliness and quality, patient guidelines, prevention and early detection activities, professional education and quality improvement.

This proposal requests approval to replace an outdated conventional radiotherapy simulator with new CT simulator technology. The simulator is used as part of the treatment planning process for determining a patient's course of radiation therapy. The images that are generated by the simulator assist physicians in determining the optimal treatment path. Because simulation procedures are usually the first step in patient care, it is critical that new patients feel welcome and comfortable during this process, and confident they've chosen the right place to receive treatment. The advanced technology of a CT simulator will address these needs and truly provide a higher level of care.

Outdated Technology

The existing conventional radiotherapy simulator was acquired in 1998 with approval of the radiation oncology program at NMH, and has been in operation for over 15+ years. The technology has reached end-of-life, with technical support for the equipment discontinued, and x-ray film used by the simulator difficult to obtain. NMH is one of the few remaining hospitals in Connecticut that has a conventional radiography simulator and film processor.

Operational Inefficiency and Inconvenience

Currently the patient visits the Radiation Oncology department where immobilization devices are constructed. The patient must then be escorted down the hall to the Radiology department to be scanned on the CT scanner there to obtain CT images for planning. Patients are usually dressed in gowns during these procedures and also while walking between departments, which is a concern for patient modesty and comfort, especially for breast and prostate cancer patients (a large percentage of cases treated at the Center). Since the CT bore is sized for diagnostic scans, we often have to reposition the patient and the treatment immobilization devices to fit the patient through the scanner, causing discomfort for the patient.

A CT simulator offers multiple clinical, operational and administrative advantages, all of which will greatly enhance cancer care delivery:

- Treatment Efficiencies – The CT simulator's advanced imaging capabilities will eliminate the need for patients to visit both the Radiation Oncology and Radiology departments as part of treatment planning, making the process easier and more convenient for patients and consolidating treatment planning.

- Digitalization – The CT simulator will allow the Hospital's Radiation Oncology department to become completely digitalized, eliminating the need for x-ray film, service contracts for film processors and silver reclaiming, as well as the need for fixer and developer, which are potentially hazardous chemicals. Because images play a key role in cancer diagnosis and treatment and are an important component of the medical record, the use of digital images will support the use of electronic medical records (EMR).

- Comfort and Convenience – Acquisition of new technology will enable the patient to have their entire planning procedure completed within the Radiation Oncology department. Additionally, a large-bore CT simulator (one with a large interior diameter) increases patient comfort by enabling more diversity in positioning and more easily accommodating immobilization devices. The large bore also comfortably accommodates larger-sized patients.

- Potential for Expanded Treatment Options – The CT simulator's "4D CT capability," a radiation oncology-specific software package, will allow the Cancer Center to provide expanded stereotactic body radiation therapy ("SBRT") services, a treatment in which highly accurate, precise, and focused radiation is delivered to tumors while minimizing radiation to adjacent healthy tissue. SBRT has not only shown dramatically better outcomes than conventional radiation therapy, but SBRT patients experience fewer treatment visits and side effects than with conventional radiation therapy. The Center currently offers stereotactic treatment only for brain lesions. The CT simulator will allow this treatment to be offered for other parts of the body as well.

Tentative Timing of the Project:

- September 2013 - Certificate of Need (CON) authorization
- Fall 2013 - Equipment vendor selection, simulation room preparation, and CT simulator Installation and testing
- Winter 2013 - Patients receive simulation procedures using the new technology

b. Provide letters that have been received in support of the proposal.

See Exhibit A with Letters of Support from:

- Joseph Bargellini, M.D., Medical Director, Radiation Oncology, NMH
- Sandra Lombardo, M.D., Medical Oncology, NMH
- Andrea Crowley, M.D., Chair, Diagnostic Radiology, NMH

c. Provide the Manufacturer, Model, Number of slices/tesla strength of the proposed scanner (as appropriate to each piece of equipment).

Three vendor quotations (Phillips, GE and Siemens) have been received and are currently under evaluation for acquisition of large bore CT simulator technology. They include software; workstations, CT simulator couch, and a linac couch upgrade (these couchtops must "match" for treatment reproducibility).

Exhibit B contains a summary of the initial estimates for the proposed technology.

d. List each of the Applicant's sites and the imaging modalities and other services currently offered by location.

The imaging modalities provided at NMH include the following:

- RT Simulator
- 64-slice low-dose CT scanner
- Open bore 1.5 Tesla MRI
- General Radiography
- Mammography
- Ultrasound
- Nuclear Medicine
- Bone Density

2. Clear Public Need

a. Explain why there is a clear public need for the proposed equipment. Provide evidence that demonstrates this need.

NMH's Center provides comprehensive cancer care to over 185 newly diagnosed cancer patients each year. Radiation therapy is an integral component of this care, providing approximately 2,500 radiation treatments annually.

The Hospital's current simulator, a "conventional radiotherapy simulator," reached end of life in April 2013. Technical support for the equipment has been discontinued and x-ray film used by the simulator (produced by Eastman Kodak, currently in bankruptcy) will likely become difficult to obtain. NMH is one of the few remaining hospitals in Connecticut that still uses a conventional radiography simulator and film processor.

The radiation oncology industry standard of care is no longer a conventional simulator, but CT simulator, more importantly one with a large bore to accommodate the patient and treatment immobilization devices. NMH desires to offer its patients the advanced imaging technology and efficient workflow a large bore CT simulator would provide.

In addition, the CT Simulator's a radiation-oncology-specific software package, will offer the opportunity for the Cancer Center to provide expanded stereotactic body radiation therapy (SBRT) services as the need arises, a treatment in which highly accurate, precise, and focused radiation is delivered to tumors while minimizing radiation to adjacent healthy tissue. This capability will also allow treatment plans to accurately account for areas of the body affected by motion (i.e., breathing), a significant benefit to patients treated for lung cancer. SBRT has not only shown dramatically better outcomes than conventional radiation therapy, but SBRT patients experience fewer treatment visits and side effects than with conventional radiation therapy. The Cancer Center currently offers stereotactic treatment only for brain lesions. The CT Simulator will allow this treatment to be offered for other parts of the body, as well.

b. Provide the utilization of existing health care facilities and health care services in the Applicant's service area.

The only other hospital provider in the service area is our affiliate hospital, DH, located at 24 Hospital Avenue, Danbury, CT. The DH CT Simulator volume for FY 2013 is projected to be 995 (annualized based on 9 months actual, Oct-June).

This proposal will not affect the utilization at other hospitals in the region.

c. Complete **Table 1** for each piece of equipment of the type proposed currently operated by the Applicant at each of the Applicant's sites.

Table 1: Existing Equipment Operated by the Applicant

Provider Name **Street Address** **Town, Zip Code**	**Description of Service** *	**Hours/Days of Operation** **	**Utilization** *** July 2012 - June 2013
New Milford Hospital Diebold Family Cancer Center 21 Elm Street New Milford, CT 06776	Conventional Radiotherapy Simulator	8:30 AM – 4:30 PM; Urgent addressed as needed	149

* Include equipment strength (e.g. slices, tesla strength), whether the unit is open or closed (for MRI)
** Days of the week unit is operational, and start and end time for each day; and
*** Number of scans/exams performed on each unit for the most recent 12-month period (identify period).

d. Provide the following regarding the proposal's location:

i. The rationale for locating the proposed equipment at the proposed site;

Locating the CT simulator within the Radiation Oncology area of NMH will ensure coordinated care to our cancer patients.

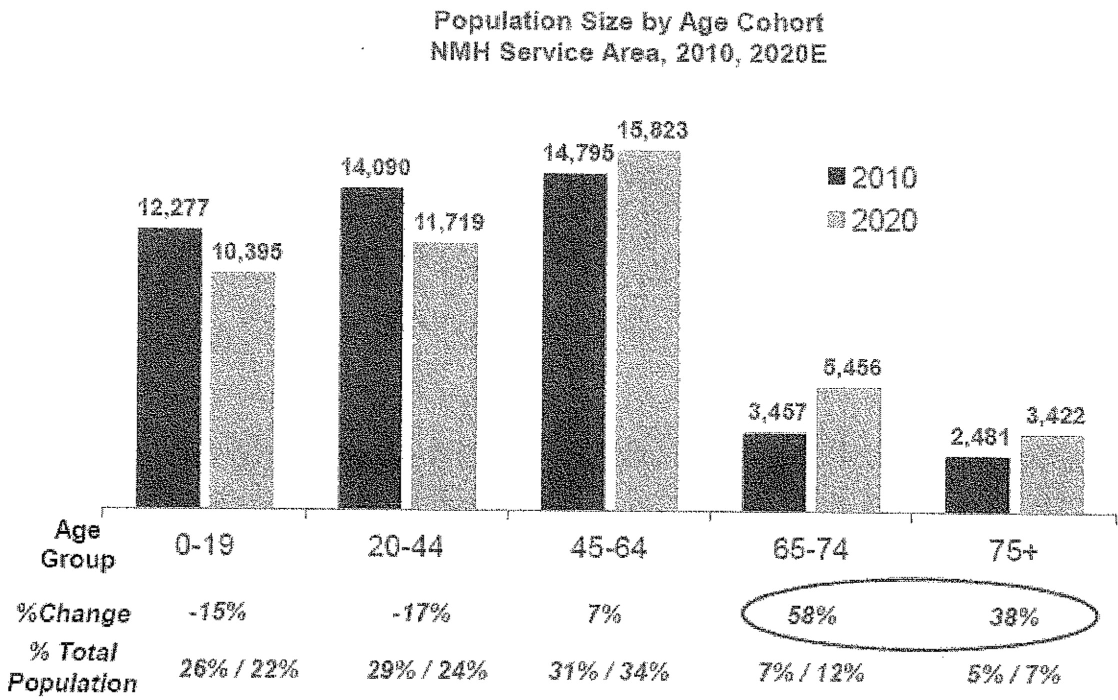
ii. The population to be served, including specific evidence such as incidence, prevalence, or other demographic data that demonstrates need;

The population to be served is residents within the primary service areas of NMH, and those from outside the area receiving cancer treatment services at NMH.

Towns Primarily Served by NMH	2010 Population	2020 Population Estimate
New Milford	28,217	28,608
Wingdale, NY	4,235	4,432
Sherman	3,853	3,450
Washington	3,630	3,511
Kent	2,984	2,980
Roxbury	2,302	2,224
Bridgewater	1,879	1,610
TOTAL	**47,100**	**46,815**

Source: 2010 Census, 2020 UCONN CT State Data Center

According to the American Cancer Society, the probability of developing cancer increases as we age. By 2020, 19% of the service area population, an additional 3,000 residents, will be age 65 and over. These demographics support the investment in CT Simulation technology at the NMH Cancer Center for comprehensive oncology treatment.



iii. How and where the proposed patient population is currently being served;

The proposed patient population is currently being served by NMH and this is not projected to change.

iv. All existing providers (name, address) of the proposed service in the towns listed above and in nearby towns;

Existing providers with CT simulators capabilities within the service area include NMH and The Danbury Hospital ("DH"), 24 Hospital Avenue, Danbury CT (our WCHN affiliate hospital).

v. The effect of the proposal on existing providers; and

This proposal for replacement simulation technology is not expected to have any effect on existing providers.

vi. If the proposal involves a new site of service, identify the service area towns and the basis for their selection.

This proposal does not involve a new site of service.

e. Explain why the proposal will not result in an unnecessary duplication of existing or approved health care services.

This proposal for a replacement s CT simulator will not result in unnecessary duplication of service. The new technology replaces out of date technology and will enhance the quality of services provided to our existing (and future) patient base.

Effectiveness and success of the CT simulator can be measured utilizing several criteria, including utilization and patient satisfaction:

- CT simulation is a standard practice in radiation therapy departments throughout the country. With rare exception, all patients being treated at the Diebold Family Cancer Center will utilize this service.
- All lung cancer cases will utilize the CT simulator's 4D capability accounting for organ and target motion. Lung cancer is one of the major diseases treated at the Center.
- Patient comfort, convenience, and satisfaction are expected to increase, as both the simulation and treatment process will be in the Center in its entirety.

3. Actual and Projected Volume

a. Complete the following tables for the past three fiscal years ("FY"), current fiscal year ("CFY"), and first three projected FYs of the proposal, for each of the Applicant's existing and proposed pieces of equipment (of the type proposed, at the proposed location only). In Table 2a, report the units of service by piece of equipment, and in Table 2b, report the units of service by type of exam (e.g. if specializing in orthopedic, neurosurgery, or if there are scans that can be performed on the proposed scanner that the Applicant is unable to perform on its existing scanners).

Table 2a: Historical, Current, and Projected Volume, by Equipment Unit

	Actual Volume (Last 3 Completed FYs)			CFY Volume*	Projected Volume (First 3 Full Operational FYs)**		
	FY10	FY11	FY12	FY13	FY14	FY15	FY16

Complex CT Sims	86	123	121	156	156	156	156
Total	86	123	121	156	156	156	156

* For periods greater than 6 months, report annualized volume, identifying the number of actual months covered and the method of annualizing. For periods less than six months, report actual volume and identify the period covered. **FY 2013 volume annualized based on October – June actual**
** If the first year of the proposal is only a partial year, provide the first partial year and then the first three full FYs. Add columns as necessary.
*** Identify each scanner separately and add lines as necessary. Also break out inpatient/outpatient/ED volumes if applicable.
**** Fill in years. In a footnote, identify the period covered by the Applicant's FY (e.g. July 1-June 30, calendar year, etc.).

Table 2b: Historical, Current, and Projected Volume, by Type of Scan/Exam

	Actual Volume (Last 3 Completed FYs)			CFY Volume*	Projected Volume (First 3 Full Operational FYs)**		
	FY10	FY11	FY12	FY13	FY14	FY15	FY16
Complex CT Sims	86	123	121	156	156	156	156
Total	86	123	121	156	156	156	156

* For periods greater than 6 months, report annualized volume, identifying the number of actual months covered and the method of annualizing. For periods less than six months, report actual volume and identify the period covered. **FY 2013 volume annualized based on October – June actual**
** If the first year of the proposal is only a partial year, provide the first partial year and then the first three full FYs. Add columns as necessary.
*** Identify each type of scan/exam (e.g. orthopedic, neurosurgery or if there are scans/exams that can be performed on the proposed piece of equipment that the Applicant is unable to perform on its existing equipment) and add lines as necessary.
**** Fill in years. In a footnote, identify the period covered by the Applicant's FY (e.g. July 1-June 30, calendar year, etc.).

b. Provide a breakdown, by town, of the volumes provided in Table 2a for the most recently completed full FY.

Zip Code	Town	State	FY12 Volume
06776	NEW MILFORD	CT	51
12522	DOVER PLAINS	NY	6
06754	WARREN	CT	5
06777	NEW PRESTON MARB	CT	5
06794	WASHINGTON DEPOT	CT	5
12594	WINGDALE	NY	5
06757	KENT	CT	4
06069	SHARON	CT	3
06488	SOUTHBURY	CT	3
06804	BROOKFIELD	CT	3

06811	DANBURY	CT	3
06470	NEWTOWN	CT	2
06752	BRIDGEWATER	CT	2
06801	BETHEL	CT	2
06810	DANBURY	CT	2
12531	HOLMES	NY	2
12545	MILLBROOK	NY	2
12546	MILLERTON	NY	2
12564	PAWLING	NY	2
06018	CANAAN	CT	1
06068	SALISBURY	CT	1
06450	MERIDEN	CT	1
06756	GOSHEN	CT	1
06759	LITCHFIELD	CT	1
06783	ROXBURY	CT	1
06784	SHERMAN	CT	1
06787	THOMASTON	CT	1
06790	TORRINGTON	CT	1
06798	WOODBURY	CT	1
06906	STAMFORD	CT	1
12501	AMENIA	NY	1
12592	WASSAIC	NY	1
Grand Total			**122**

c. Describe existing referral patterns in the area to be served by the proposal.

Physician referral patterns for the radiation oncology program (and simulation) include in descending order: Urology (166), Medical Oncology (151) and surgery (117). Otolaryngology provided 12 referrals and 10 were from Dermatology. In reviewing diagnosis codes, Breast was the most common at 91, followed by prostate at 52 and Lung at 38.

d. Explain how the existing referral patterns will be affected by the proposal.

There are not any changes anticipated in existing referral patterns.

e. Explain any increases and/or decreases in volume seen in the tables above.

Since 2010, NMH has experienced an increase in overall volume, both in terms of treatments given and number of patients treated. The increase is multifactorial, but likely due to expanded technology with the Trilogy System becoming operational in October 2010. This system enhanced the delivery of radiation oncology with image guidance, stereotactic capability, and robotic couch positioning. The affiliation with DH positively impacted patient volumes as well through increased collaboration between the two institutions.

f. Provide a detailed explanation of all assumptions used in the derivation/ calculation of the projected volume by scanner and scan type.

Volume is projected based on a general utilization that approximately one half of all new cancer patients will receive radiation therapy. Each of these patients will require one CT simulation in order to formulate their individualized treatment plan.

g. Provide a copy of any articles, studies, or reports that support the need to acquire the proposed scanner, along with a brief explanation regarding the relevance of the selected articles.

The proposed technology will substitute CT based simulation for the outdated conventional system. CT Simulator features a state of the art CT scanner with a localization package, patient marking system and a virtual simulator capable of producing real-time digitally composited radiographs (DCRs). This system offers high-resolution imaging and short examination time for the full range of procedures including volumetric localization, simulation and verification for conformal, high-precision and stereotactic radiotherapy planning.

See Exhibit C for the British Journal of Radiology (2006), "*Localization: conventional and CT simulation*", a journal article discussing the components for achieving standard of care for radiation oncology treatment planning and the role of a dedicated CT simulator.

4. Quality Measures

a. Submit a list of all key professional, administrative, clinical, and direct service personnel related to the proposal. Attach a copy of their Curriculum Vitae.

See Exhibit D for Curriculum Vitaes for the following individuals:

Joseph Bargellini, MD – Medical Director of Radiation Oncology, will prescribe simulation procedures when appropriate.

Lee Anne Zarger, MSDABR, Chief Medical Physicist, oversees acceptance testing, quality assurance, and radiation safety.

b. Explain how the proposal contributes to the quality of health care delivery in the region.

Provision of care at the Center includes radiation therapy, which is reliant on use of a simulator to help determine, before treatment begins, how to direct and combine the radiation treatment fields for maximum safety and effectiveness. This simulator uses X-rays and fluoroscopy with freeze-frame capability to pinpoint the exact treatment area. The conventional simulator at NMH no longer can provide the necessary data for the 3-D Treatment Planning System, resulting in workarounds for obtaining imaging data.

Conventional simulators are no longer used in Radiation Oncology Departments. The state of the art choice is a large bore CT simulator with localization software which enables the radiation oncologist to clearly image and delineate treatment. Additionally 4D imaging capability of the CT simulator allows departments to outline treatment volumes for areas of the body affected by breathing motion to allow more accurate imaging, treatment planning and treatment delivery to these areas and to offer treatments we are currently not offering: namely stereotactic body radiation therapy.

5. Organizational and Financial Information

a. Identify the Applicant's ownership type(s) (e.g. Corporation, PC, LLC, etc.).

b. Does the Applicant have non-profit status?
☒ Yes (Provide documentation) ☐ No

c. Provide a copy of the State of Connecticut, Department of Public Health license(s) currently held by the Applicant and indicate any additional licensure categories being sought in relation to the proposal.

A copy of the hospital license is included as Exhibit E. There are no additional licensure categories being requested.

d. Financial Statements

i. If the Applicant is a Connecticut hospital: Pursuant to Section 19a-644, C.G.S., each hospital licensed by the Department of Public Health is required to file with OHCA copies of the hospital's audited financial statements. If the hospital has filed its most recently completed fiscal year audited financial statements, the hospital may reference that filing for this proposal.

ii. If the Applicant is not a Connecticut hospital (other health care facilities): Audited financial statements for the most recently completed fiscal year. If audited financial statements do not exist, in lieu of audited financial statements, provide other financial documentation (e.g. unaudited balance sheet, statement of operations, tax return, or other set of books.)

NMH has filed its most recently completed fiscal year audited statements with OHCA.

e. Submit a final version of all capital expenditures/costs as follows:

Table 3: Proposed Capital Expenditures/Costs

Medical Equipment Purchase	$
Imaging Equipment Purchase	$900,000
Non-Medical Equipment Purchase	
Land/Building Purchase *	
Construction/Renovation **	$200,000
Other Non-Construction (Specify)	
Total Capital Expenditure (TCE)	**$1,100,000**
Medical Equipment Lease (Fair Market Value) ***	$
Imaging Equipment Lease (Fair Market Value) ***	
Non-Medical Equipment Lease (Fair Market Value) ***	
Fair Market Value of Space ***	
Total Capital Cost (TCC)	**$0**
Total Project Cost (TCE + TCC)	**$1,100,000**
Capitalized Financing Costs (Informational Purpose Only)	
Total Capital Expenditure with Cap. Fin. Costs	**$1,100,000**

* If the proposal involves a land/building purchase, attach a real estate property appraisal including the amount; the useful life of the building; and a schedule of depreciation.

** If the proposal involves construction/renovations, attach a description of the proposed building work, including the gross square feet; existing and proposed floor plans; commencement date for the construction/ renovation; completion date of the construction/renovation; and commencement of operations date.

*** If the proposal involves a capital or operating equipment lease and/or purchase, attach a vendor quote or invoice; schedule of depreciation; useful life of the equipment; and anticipated residual value at the end of the lease or loan term.

f. List all funding or financing sources for the proposal and the dollar amount of each. Provide applicable details such as interest rate; term; monthly payment; pledges and funds received to date; letter of interest or approval from a lending institution.

This proposal is financially supported by a $1 million grant received from the Diebold Foundation to fully fund acquisition of the CT Simulator.

g. Demonstrate how this proposal will affect the financial strength of the state's health care system.

The acquisition of the proposed CT simulator will not directly impact the financial strength of the state's health care system, however, due to improved operational efficiencies which will reduce operating costs associated with current processes.

6. Patient Population Mix: Current and Projected

a. Provide the current and projected patient population mix (based on the number of patients, not based on revenue) with the CON proposal for the proposed program.

Table 4: Patient Population Mix

	FY2013 FP1-9	FY2014	FY2015	FY2016
Medicare*	46.7%	46.7%	46.7%	46.7%
Medicaid*	10.1%	10.1%	10.1%	10.1%
CHAMPUS & TriCare	0.2%	0.2%	0.2%	0.2%
Total Government	**56.9%**	**56.9%**	**56.9%**	**56.9%**
Commercial Insurers*	39.9%	39.9%	39.9%	39.9%
Uninsured	1.9%	1.9%	1.9%	1.9%
Workers Compensation	1.4%	1.4%	1.4%	1.4%
Total Non-Government	**43.1%**	**43.1%**	**43.1%**	**43.1%**
Total Payer Mix	**100.0%**	**100.0%**	**100.0%**	**100.0%**

* Includes managed care activity.
** New programs may leave the "current" column blank.
*** Fill in years. Ensure the period covered by this table corresponds to the period covered in the projections provided.

b. Provide the basis for/assumptions used to project the patient population mix.

The patient population at NMH is not projected to change as result of this proposal.

7. **Financial Attachments I & II**

a. Provide a summary of revenue, expense, and volume statistics, without the CON project, incremental to the CON project, and with the CON project. **Complete Financial Attachment I.** (Note that the actual results for the fiscal year reported in the first column must agree with the Applicant's audited financial statements.) The projections must include the first three full fiscal years of the project.

See Exhibit F for Financial Attachment I.

b. Provide a three year projection of incremental revenue, expense, and volume statistics attributable to the proposal by payer. **Complete Financial Attachment II.** The projections must include the first three full fiscal years of the project.

See Exhibit F for Financial Attachment II.

c. Provide the assumptions utilized in developing **both Financial Attachments I and II** (e.g., full-time equivalents, volume statistics, other expenses, revenue and expense % increases, project commencement of operation date, etc.).

See Exhibit F for Financial Assumptions.

d. Provide documentation or the basis to support the proposed rates for each of the FYs as reported in Financial Attachment II. Provide a copy of the rate schedule for the proposed service(s).

Not applicable.

e. Provide the minimum number of units required to show an incremental gain from operations for each fiscal year.

Not applicable.

f. Explain any projected incremental losses from operations contained in the financial projections that result from the implementation and operation of the CON proposal.

The proposed incremental loss from operations is a result of the increase in depreciation and equipment maintenance contract related to the new equipment.

g. Describe how this proposal is cost effective.

This proposal involves the replacement of a 15+ year old out-dated and end-of-life conventional simulator with a new state-of-the-art CT simulator that will improve operational efficiencies, quality and convenience of this service for our patients.

EXHIBIT A
LETTERS OF SUPPORT

WESTERN CONNECTICUT HEALTH NETWORK

NEW MILFORD HOSPITAL

AFFILIATED WITH DANBURY HOSPITAL

Radiation Oncology
Diebold Family Regional Cancer Center

21 Elm Street
New Milford, CT 06776
860.210-5000

June 10, 2013

To Whom It May Concern:

New Milford Hospital is looking to replace its current conventional simulator with a CT simulator. In addition to CT simulation being a standard for modern radiation therapy, it will provide us with the ability to offer and provide more services for our patients.

Our conventional simulator will be reaching end of life shortly. Servicing it would then become problematic. Conventional simulators are not being replaced with conventional simulators as it is outdated technology. CT simulators allow for the acquisition of three dimensional data for radiation treatment planning. This is used for both external beam radiation and brachytherapy.

At the present time we are using the CT scanner is Diagnostic Radiology for this purpose. As this CT unit was not designed specifically for radiation therapy use, it has limitations in terms of bore size and patient positioning that have been problems for us in the past. In addition, organ and target motion cannot be accounted for using this CT, and this is becoming increasingly important in radiation treatment delivery and current radiation therapy treatment protocols.

I am happy to answer any questions regarding our need for this technology at New Milford Hospital. Thank you for your consideration.

Sincerely,

Joseph Bargellini, M.D.
Medical Director, Radiation Oncology

WESTERN CONNECTICUT
MEDICAL GROUP
DANBURY HOSPITAL · NEW MILFORD HOSPITAL

Regional Cancer Center
Oncology & Hematology

21 Elm Street
New Milford, CT 06776
(860) 210-5300
Fax (860) 210-5030
WesternConnecticutHealthNetwork.org

Sandra Lombardo, MD

Medical Oncology
Diebold Family Regional Cancer Center

June 10, 2013

To Whom It May Concern:

New Milford Hospital is looking to replace its current conventional simulator with a CT simulator. As a Medical Oncologist working in the cancer center, I fully support this.

The Radiation Oncology unit at New Milford Hospital provides a very important service to the cancer patients in our community. It is important that the facility remain current with technology, in this highly technical service. Many of my patients in addition to receiving chemotherapy also receive radiation, and I want them to receive the best care possible.

I came to New Milford Hospital from a practice in New York City where all modern Radiation Oncology Departments had CT simulators. We should be able to provide the same level of care and service here in New Milford.

I am happy to answer any questions you might have, and thank you for your consideration.

Sincerely,

Sandra Lombardo, M.D.
Medical Oncology

WESTERN CONNECTICUT HEALTH NETWORK

NEW MILFORD HOSPITAL

AFFILIATED WITH DANBURY HOSPITAL

21 Elm Street
New Milford, CT 06776
860.210-5000

Diagnostic Imaging

June 11, 2013

To Whom It May Concern:

New Milford Hospital is looking to replace its current conventional simulator with a CT simulator. As the Chair of Diagnostic Radiology at the hospital, I fully support this.

Over the years, the CT in Diagnostic Radiology has been used by Radiation Oncology for their treatment planning purposes. As the technology has changed, the CT scanners designed for use in Radiation Oncology have evolved to better serve their purposes with wider bore sizes to better accommodate the patient positioning required for radiation therapy.

New technology is also available to help manage organ motion, which is becoming more important for Radiation Oncology, and is not available on our scanner. Being part of the medical staff at New Milford Hospital, I fully recognize the need to provide the best possible care for our patients close to home, especially when they are facing a potentially life threatening disease.

I am happy to answer any questions you might have, and thank you for your consideration.

Sincerely,

Andrea Crowley, M.D.
Chair, Diagnostic Radiology

EXHIBIT B
EQUIPMENT ESTIMATES - FINAL SYSTEM TBD

	Phillips		
	Equipment	Civco Couchtops	Total
System	712,077	74,350	786,427
Options	126,547	0	126,547
Total Equipment	**838,624**	**74,350**	**912,974**
Room Renovations			200,000
Total Capital			**1,112,974**

	Siemens		
	Equipment	Civco Couchtops	Total
System	675,000	74,350	749,350
Options	34,800	0	34,800
Total Equipment	**709,800**	**74,350**	**784,150**
Room Renovations			200,000
Total Capital			**984,150**

	GE		
	Equipment	Civco Couchtops	Total
System	732,896	74,350	807,246
Options	32,970	0	32,970
Total Equipment	**765,866**	**74,350**	**840,216**
Room Renovations			200,000
Total Capital			**1,040,216**

EXHIBIT C

JOURNAL ARTICLE

The British Journal of Radiology, 79 (2006), S36–S49

Localization: conventional and CT simulation

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ABSTRACT. Recent developments in imaging and computer power have led to the ability to acquire large three dimensional data sets for target localization and complex treatment planning for radiation therapy. Conventional simulation implies the use of a machine capable of the same mechanical movements as treatment units. Images obtained from these machines are essentially two dimensional with the facility to acquire a limited number of axial slices to provide patient contours and tissue density information. The recent implementation of cone beam imaging on simulators has transformed them into three dimensional imaging devices able to produce the data required for complex treatment planning. The introduction of computed axial tomography (CT) in the 1970s was a step-change in imaging and its potential use in radiotherapy was quickly realised. However, it remained a predominantly diagnostic tool until modifications were introduced to meet the needs of radiotherapy and software was developed to perform the simulation function. The comparability of conventional and virtual simulation has been the subject of a number of studies at different disease sites. The development of different cross sectional imaging modalities such as MRI and positron emission tomography has provided additional information that can be incorporated into the simulation software by image fusion and has been shown to aid in the delineation of tumours. Challenges still remain, particularly in localizing moving structures. Fast multislice scanning protocols freeze patient and organ motion in time and space, which may lead to inaccuracy in both target delineation and the choice of margins in three dimensions. Breath holding and gated respiration techniques have been demonstrated to produce four-dimensional data sets that can be used to reduce margins or to minimize dose to normal tissue or organs at risk. Image guided radiotherapy is being developed to address the interfraction movement of both target volumes and critical normal structures. Whichever method of localization and simulation is adopted, the role of quality control is important for the overall accuracy of the patient's treatment and must be adapted to reflect the networked nature of the process.

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The development of the delivery of radiation therapy is closely related to the accuracy with which the target tumour can be located with respect to surrounding anatomical structures. In recent years, the increase in computing power and the development of refined computer graphics have resulted in the ability to perform complex treatment planning in three dimensions and to manipulate images in real time. Early simulators were machines capable of the same mechanical movements as treatment units and were used to confirm treatment set up rather than for localization [1, 2]. Simulators that were developed commercially in the 1960s had the addition of fluoroscopy that was used to set the isocentre with the aid of remotely controlled movements of the couch. Field portals adequate to encompass the target volume to be treated could also be set by remote adjustments to the field defining wires. The introduction of computed axial tomography (CT) scanning in the 1970s was a step change in the ability to define tumours in relation to normal anatomy, and over the ensuing years has been widely adopted in tumour localization. Today it may be used in conjunction with complex graphics software as a virtual simulator. However, the conventional simulator still retains its place in many radiotherapy departments for localization of some tumour sites, either as a result of lack of sufficient access to a CT scanner or for relatively simple techniques not requiring the production of a dose plan. The conventional simulator is also frequently used to verify the more complex treatment plans, producing an image corresponding to a beam's eye view (BEV) from the treatment planning system (TPS) or by verifying the isocentre location from orthogonal films.

Brief history

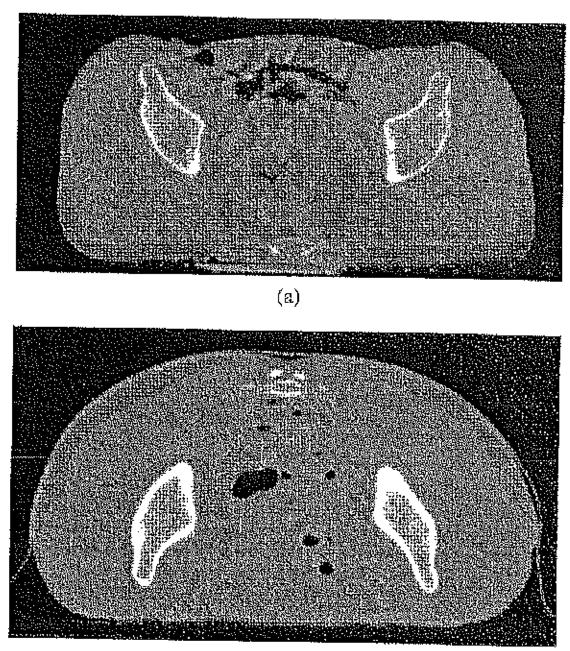
Mould [3] describes the development of simulation, from the use of diagnostic radiographs and skin marks in the 1950s to the introduction of virtual simulation in the 1980s. In 1973, Hounsfield and Ambrose [4, 5] published their work on computerized transverse axial tomography and the potential uses of CT in radiotherapy were quickly recognized [6]. However, access to a CT scanner was often very limited, and in many cases the scanner was not even in the same hospital as the treatment facilities. In addition, a CT scanner was principally a diagnostic tool with limitations for treatment planning imposed by the small aperture and the design of the couch, which frequently prevented the patient from being scanned in the treatment position. Harrison and Farmer [7] recognized the usefulness of being able to acquire a cross-sectional image of the patient in the treatment position using a simulator as a CT scanner and went on to describe the implementation of their idea using a fluorescent screen and an Isocon camera [8]. A number of other adaptations of the simulator to produce cross-sectional images were also proposed at this time [9–12]. This functionality was called Sim-CT and became standard on simulators in the 1990s, but the system had its limitations:

1. The heat capacity of the X-ray tube generally meant that only a few slices could be scanned;
2. The time taken to scan was limited to approximately one revolution per minute, which introduced motion artefacts resulting in images that were of a poorer quality than those produced on a diagnostic scanner;
3. The uncertainty in the Hounsfield units (HU), which depends on the field of view and the phantom/patient size, a result of the beam hardening in the unfiltered X-ray beam from the simulator CT. However, the uncertainty in HU is translated into dose variation not exceeding 3% for photon beams in the range 6–18 MV [13];
4. The relatively high dose to the patient which was shown to be approximately 10 times that delivered with a diagnostic scanner under similar conditions [14].

In spite of its limitations, the Sim-CT was a useful tool for planning in a department with limited access to a diagnostic scanner. It was a more accurate way of producing a patient outline than manual methods using callipers and flexicurves and enabled CT numbers to be converted to relative electron densities for tissue inhomogeneity corrections to be applied to a single CT slice in dose calculations. The dose distributions and monitor unit calculations showed good agreement with those obtained with diagnostic scan data [14].

In 1998, Cho et al [15] described the application of digital technology to a radiotherapy simulator in which the imaging system was replaced by a digital spot imager (DSI). The DSI consisted of an image intensifier, digital image processing, display and data transfer facilities. The images were stored during acquisition for later archiving or transfer to workstations. Simulator manufacturers now offer digital capabilities on their machines and conventional image intensifiers have been replaced by flat panel amorphous silicon (aSi) detectors. Their longevity in this application has to be proved and it is possible that the need for regular replacement may have significant revenue consequences. The most recent simulators include anatomical protocol selection, automatic correction for image distortion, last image hold, multileaf collimator (MLC) verification, a variety of image viewing and manipulation tools with annotation, image printing to film or paper, Digital Image Communications in Medicine (DICOM) export to TPS, electronic portal imaging device (EPID), record and verify, and patient management systems. The image manipulation tools enable adjustments to be made to field parameters and image quality on the last-held image, which reduces the screening time and hence patient dose compared with non-digital systems. A wide aperture (typically 90 cm) CT option is available. However, because of the restriction on gantry rotation speed, acquisition times are still slow and reconstruction time does not match that of a diagnostic scanner. In an attempt to overcome this, volume or cone beam CT (CBCT) has been developed. A number of authors describe cone beam reconstructions, based on Feldkamp's original back projection algorithm [16], for the acquisition of volumetric data [17–19].

When first proposed, the size of the detector was a severe limitation on the reconstruction volume and, although promising results were obtained, its use in treatment planning was not realised until aSi flat panel detectors of a reasonable size became available. Commercial systems are now available. For example, the Acuity (Varian, Palo Alto, CA) with cone beam option gives a cone of 17 cm at the isocentre but with added penumbra of 1.9 cm at either end regardless of the scan length. It is therefore not appropriate to acquire a single narrow slice. A single slice takes 45 s and 675 images are acquired per rotation. Early reports (private communications, A Vinall, K Venables, 2005) suggest that the geometric performance and image quality are adequate for radiotherapy planning purposes although the images are not of diagnostic quality. The rotation time of 45 s does, however, result in significant movement artefacts. Figure 1a shows the streaking that results from the movement of bowel gas during the acquisition of a CBCT scan compared with a CT planning scan.



(a)

(b)

Figure 1. (a) Movement artefacts on an axial slice of a CBCT scan as a result of movement of bowel gas. (b) An axial slice from a planning CT of the pelvis for comparison. (Courtesy of Varian Medical Systems, Palo Alto, CA and Memorial Sloan-Kettering Cancer Centre).

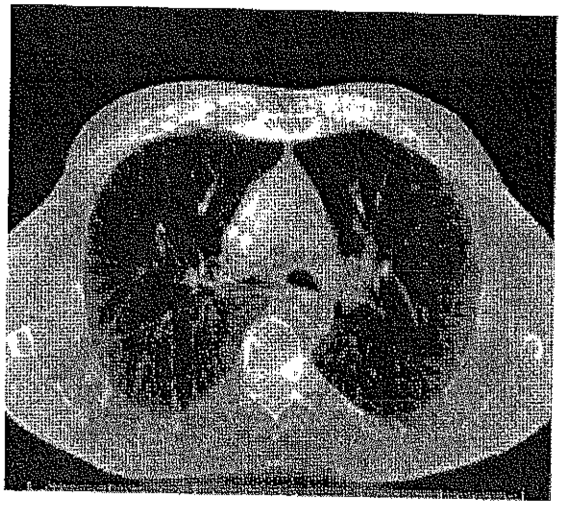


Figure 2. Movement artefacts on an axial slice from a CBCT acquired during normal breathing. (Courtesy of Varian Medical Systems and Hirslanden Klinik, Aarau).

Figure 2 shows similar streaking in the soft tissue around lungs in a CBCT taken during normal breathing. As with the single slice option on the simulator, there seem to be problems with the HU values both in accuracy compared with the calibration and reproducibility on a day-to-day basis. Slice thicknesses of 1–5 mm are available. Reconstruction times vary with the slice thickness and are in the order of 90 s. There is no standard way of quoting doses for these scans. Computed tomography dose index ($CTDI_w$) is a measure of the dose from a CT scan, weighted between the centre and the surface to give an average value across the section. A $CTDI_w$/810 mAs value of 15 mGy has been measured for a 10 cm scan length collimated to 13.8 cm (15 pulse s^{-1}, pulse length 15 ms, 80 mA, 125 kV, 45 s rotation). Setting the scan length to 1 cm in clinical mode gave 54 mGy/810 mAs with the same exposure factors. This compares with the national reference dose of 20 mGy for a multislice scanner [20].

CT simulation

The alternative to using the simulator and CBCT to acquire a volume data set of the patient in the treatment position was to modify CT scanners to meet the needs of radiotherapy and add software to perform the simulation function.

With the rapid development of computer technology, enabling fast reconstruction of images in three dimensions, the true value of the enormous quantity of data acquired by a CT scanner and its use in radiotherapy planning was recognized.

The development of the concept of the beam's eye view (BEV) into the transmission image from CT scans that would result from any beam orientation paved the way to producing images from CT data that correspond to conventional simulator films [21–23]. These digitally reconstructed radiographs (DRRs) could be overlaid with the outlines of anatomic structures, field shapes and cross wires, and hence could display images similar to simulator radiographs. However, the spatial resolution of DRRs is limited by the voxel size of the CT scans and cannot match that of a simulator radiograph taken with a small focal spot and a short exposure. Even in the early implementation of this process the reconstruction time of the DRRs was reasonable, being in the region of 10 s for a 50 slice study. However, studies were limited by the specification of the CT scanner. The acquisition of a single slice might take 2–3 s with a delay between scans required for repositioning of the scanner and tubes with low heat capacity needed cooling time during the scan [24].

Early critical analysis of the CT simulation process highlighted the areas for improvement [25]. These included the limitations imposed on both treatment technique and the size of the patient by the aperture of the scanner (normally 70 cm), the time required for CT data acquisition and transfer from the scanner to the planning system, time required for outlining and contouring target volume and critical structures and the inconsistent accuracy of portal marking on the patient's skin. Complete field ports were marked on the patient's skin in most cases and novel devices for doing this constituted an important part of the virtual simulation process reported. [26, 27]. These drawbacks have now largely been overcome.

Multislice helical scanning, with high heat capacity CT tubes, has reduced the time required to acquire a CT data set of 100 slices to a matter of seconds. Wide bore scanners have removed most of the constraints of patient size and technique. Increased computing capacity and speed allows for real time reconstruction of the slice images at the scanner and real time manipulation of images in the virtual simulation software. In addition, the DICOM protocol facilitates fast transfer of image data between systems.

Current practice

Conformal radiotherapy (CRT) is now accepted best practice for a number of treatment sites, having the advantages of sparing normal tissue and providing the opportunity for dose escalation. Intensity-modulated radiotherapy (IMRT) is the ultimate expression of this, but successful implementation of CRT and IMRT cannot be achieved without three-dimensional information on the location and extent of the target volume and the position of adjacent organs at risk (OAR). The three-dimensionality of virtual simulation is essential to visualize the coverage of the target volume and the avoidance of OARs in the highly complex treatment plans required for CRT and IMRT. For some sites, such as the lung where the relative position of the target and OARs varies with time, this fourth dimension needs to be taken into account.

Sherouse et al [28] introduced the term virtual simulation in 1987 to describe the process of using computer aided design and digitally reconstructed radiographs to replace the process of physical simulation. The process of virtual simulation has been described in detail by Aird and Conway [29] who also gave examples of its application to a number of different sites.

The specification of a CT simulator

The fundamental requirements of a CT simulator are a CT scanner with a flat couch, positioning lasers and virtual simulation software.

CT scanner

Advances in the design and capabilities of CT scanners have modified the specifications given by Aird and Conway [29]. Multislice scanners enable very fast scanning times, even for the large studies, with narrow slice thicknesses required for the production of good DRRs. High heat capacity anodes are required for the large datasets that are frequently required for treatment planning applications. One manufacturer (Siemens Medical, Erlangen, Germany) has introduced a new design of directly cooled anode that should eliminate delays due to anode heating and enable fast acquisition of scans with the large number of narrow slices required for good DRRs.

Three manufacturers now produce wide aperture (85 cm) scanners designed for radiotherapy applications. In two, the scanned field of view (SFOV) is 60 cm with an extended reconstructed FOV of 85 cm. It should be noted that in the extended reconstructed FOV the HU numbers may not be consistent with the SFOV. In reality, it is unlikely that the uncertainty in HU translates into a dose discrepancy of more that 1–2% in the target. The third manufacturer claims a true SFOV of 85 cm.

Positioning lasers

A system of three lasers for the accurate positioning and alignment of the patient is required. The lateral lasers may be wall or frame mounted, and may be either fixed or move in a vertical plane. The sagittal laser must be able to move laterally to account for lack of lateral movement on the CT couch. These lasers move under computer control to define the isocentre for the treatment plan in terms of shifts from the reference marks.

Virtual simulation software

The virtual simulation software may either be part of a treatment planning system or may be a stand-alone system. If the latter is chosen, it is essential that connectivity is easily established with the treatment planning system for dose calculation. Since the introduction of DICOM-RT this connectivity is more readily achievable, but the user must be aware that not all manufacturers interpret the standard in the same way and there are frequently hidden licensing issues associated with the connectivity. Essential features of virtual simulation software include automatic contouring of body outlines and semi-automatic contouring of other structures and critical organs such as spinal cord, kidneys and lungs. Particular attention should be paid to treatment of bifurcating structures. Contouring tools should be simple to use and interpolation between non-adjacent slices, with correction as necessary, should be provided to speed the contouring process. The ability to contour in three dimensions, *i.e.* in sagittal and coronal as well as axial sections, is particularly helpful. Figure 3 shows how three single contours in orthogonal planes produce a three dimensional structure. This functionality can considerably reduce the time taken to outline structures. The shape of the contours can be modified on any slice as necessary. Similar interpolation tools should be available for target volume delineation and true three-dimensional volume margin growth with different margin widths in different directions. Three-dimensional display systems are an essential feature of

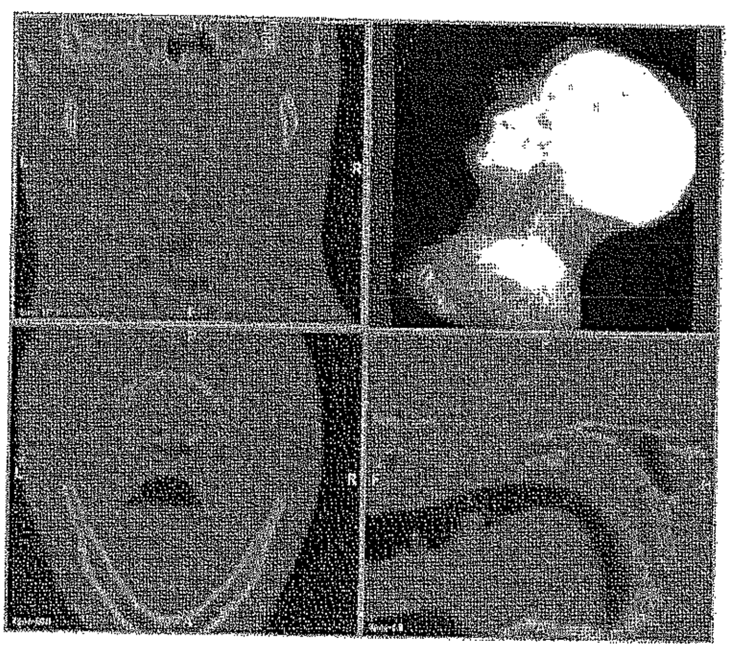


Figure 3. A single contour in axial sagittal and coronal planes defines a three dimensional target in Prosoma. (Courtesy of Oncology Systems Limited, Shrewsbury, UK and Medcom, Darmstadt, Germany).

any virtual simulation software. It should be possible to display axial, sagittal and coronal sections on the same screen and relate each section to the others, and to visualize the DRRs in the same window. An Observer's Eye View, with the patient on the couch and the floor and gantry angles depicted, is an aid to patient setup, as is a light-field displayed on the patient's skin related to skin marks or tattoos. Anti-collision software avoids planning a treatment field which it is physically impossible to reproduce in the treatment room. There are many different ways of rendering the target volume and OARs, but they should be unambiguous and should be rendered in three-dimensions so that coverage can be checked from all aspects. Optimization of MLC leaf positions and collimator angle should be available but adjustable by the planner. For treatment planning where a full dose distribution will not be calculated, a particularly useful feature is the calculation of the equivalent square of an irregular field, the parameter required for simple dose calculations. Increasingly, oncologists are using a number of other imaging modalities such as MRI (see Khoo and Joon in this issue) and positron emission tomography (PET) (see Jarritt et al in this issue) to help in determining target volumes. Most virtual simulation packages include an image fusion function enabling registration of two datasets of the same or different modalities, CT/CT, CT/MRI, CT/PET. Image registration and fusion may be achieved in a number of different ways, both manual and automatic (see Kessler in this issue). Irrespective of the algorithm, there is a variety of display modes to assist in performing and viewing the fusion, some of which are shown in Figure 4. Figure 4a shows the two data sets (MR and CT) fused with information from both sets displayed in the same window. The image can be "faded" between the two showing 100% of the primary data set (CT in this case) through to 100% of the secondary data set (MRI in this example). Figure 4b shows a split screen, with two quadrants displaying the CT data and two showing the MRI data. The point of intersection can be moved around the image to display the intersection at any position on the image. This will assist in delineating the structures using information from both data sets. Figure 4c shows a split screen with the secondary data set fused with the primary in the centre of the image and the primary image on either side. Contours outlining the target or OARs can be drawn on either data set or on the fused images in any of these display modes. These three screens show the fused images in the top three windows and the secondary data set in the lower windows. Figure 4d shows the region of discrepancy between the two fused data sets, in this case two CT studies, as areas of enhancement on the image. Improved localization of a brain tumour when CT and MRI data sets are fused compared with localization on CT alone for treatment planning is demonstrated in Figure 5.

Comparison of conventional and virtual simulation

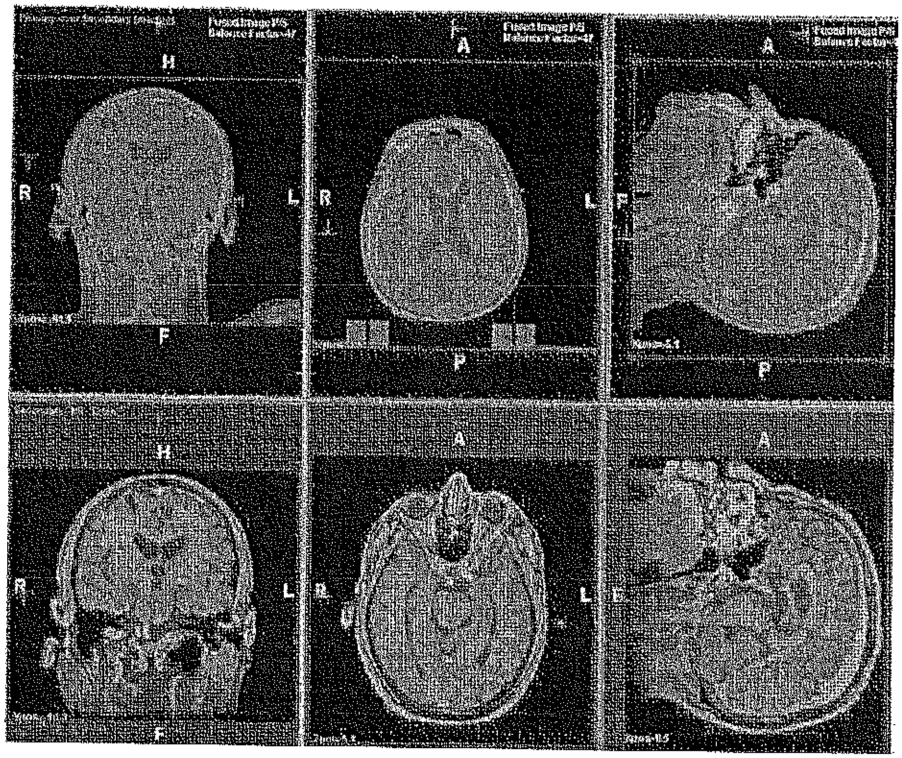
Conventional and virtual simulation approach the task of localizing the target volume for treatment planning in very different ways, which may result in significantly different treatments. Realisation of the steps performed to provide the data to a treatment planning system is compared for the two modalities in Table 1.

In comparing the two methods of simulation, the first question that arises is whether the two are comparable in terms of accuracy of the treatment set up. There are a number of studies addressing this question for different treatment sites. Bollet et al [30] showed that in a series of 20 patients who were CT scanned and had conventional simulation, the precision of set up evaluations using DRRs was similar to that using simulator films in conformal prostate treatments. They also considered whether errors were introduced at the simulation stage and found a statistically significant systematic error between DRRs and simulator, in both the craniocaudal direction and the anteroposterior direction. In another study of prostate patients Valicenti et al [31] showed that there was no statistically significant reduction in treatment setup error if patients have physical simulation following virtual simulation and concluded that physical simulation may be omitted if virtual simulation is available. In a study of 86 patients undergoing palliative radiotherapy for lung cancer using parallel opposed fields, McJury et al [32] found that setup errors were comparable between the group planned by virtual simulation and that planned using conventional simulation. Similar results are reported at different treatment sites [33–35]. In a detailed study of setup errors in 39 patients undergoing CT planned radiotherapy for lung cancer, de Boer et al [36] concluded that the setup errors introduced at simulation, which become systematic errors if the simulator film is used as the reference image, were comparable with systematic errors at the treatment unit. Hence, omission of the simulation stage would reduce systematic errors on treatment. This conclusion supported a similar result for prostate patients [37].

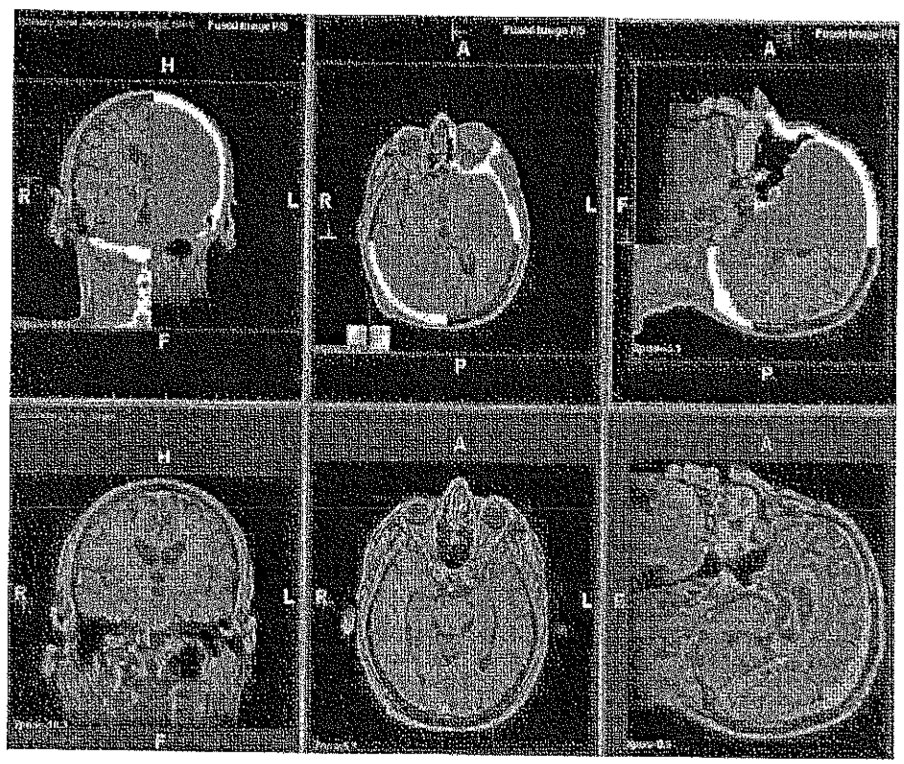
In comparing the two methods of simulation, studies have shown that the target volumes and field sizes are smaller for virtual than conventional simulation in lung cancer with the associated reduction in irradiation of normal tissue [32, 38]. Smaller field sizes have also been reported for maxillary cancer with a corresponding reduction in long-term side effects [39].

One of the perceived advantages of virtual simulation is the improved coverage of the gross tumour volume (GTV) and the avoidance of OARs as a result of better visualization of soft tissue structures on a CT scan compared with a simulator image, particularly if shielded by bone. This is aided by software functions that remove overlying structures, giving better definition of the region of interest. A study comparing conventional and virtual simulation in the treatment planning of malignant lymphoma showed incomplete coverage of the spleen and spleen hilus in 5 of 15 and 6 of 15 patients, respectively, on conventional simulation and incomplete coverage of the right and left hilus in 4 of 15 and 1 of 15 patients, respectively. In addition, the left kidney was inadequately shielded in 6 of 15 of the conventionally planned patients [40]. Similar improvements in target coverage and OAR avoidance are reported for other anatomical sites [41–44].

Improved visualization of soft tissue structures may bring to light hitherto unsuspected pathology. Mehta

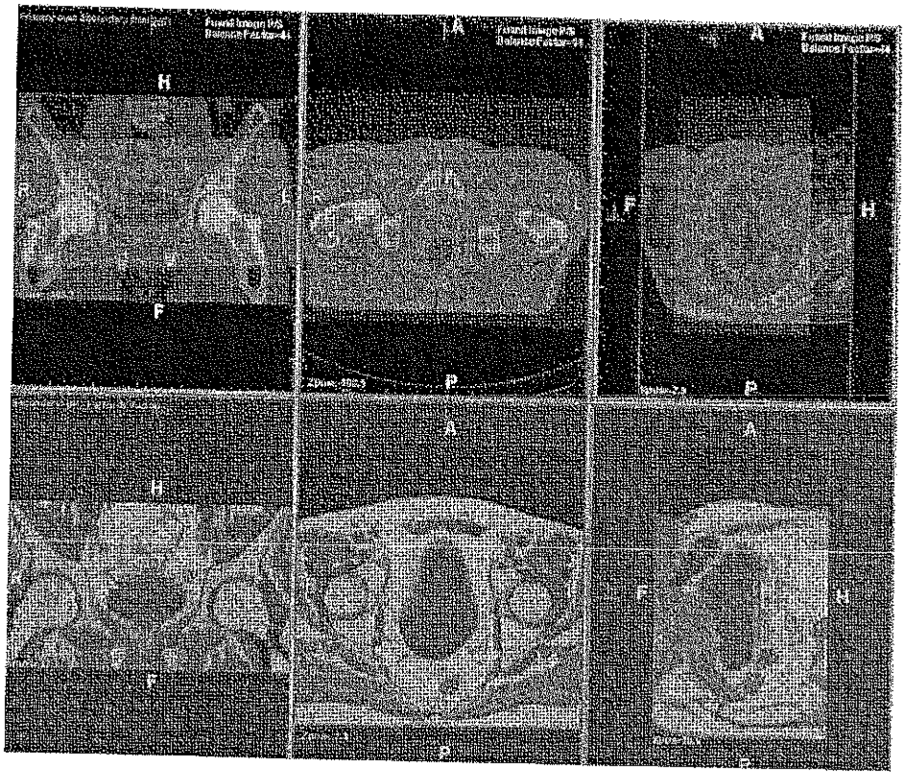


(a)

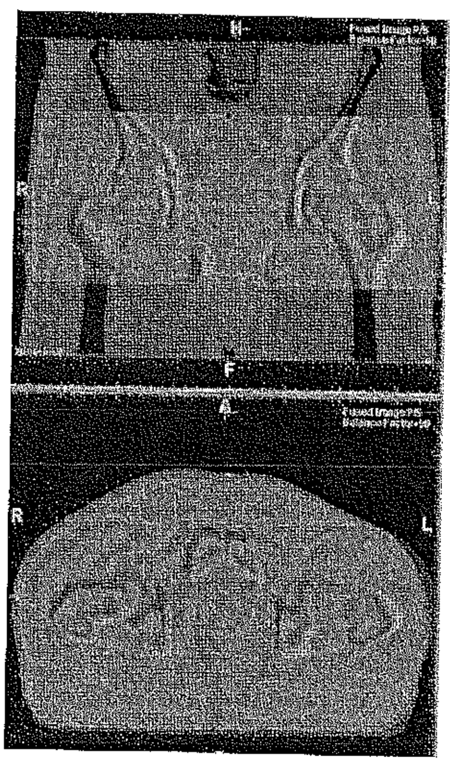


(b)

Figure 4. (a) Fusion of MRI and CT data sets, fused images in the top windows and MRI images below. (b) A split screen showing fusion between CT and MRI data sets in quadrants. *(Continued)*



(c)



(d)

Figure 4. (*Cont.*) (c) An alternative split screen representation of fusion between CT and MRI data sets. (d) Areas of mismatch between two CT data sets displayed as image enhancement. (Courtesy of OSL and Medcom).

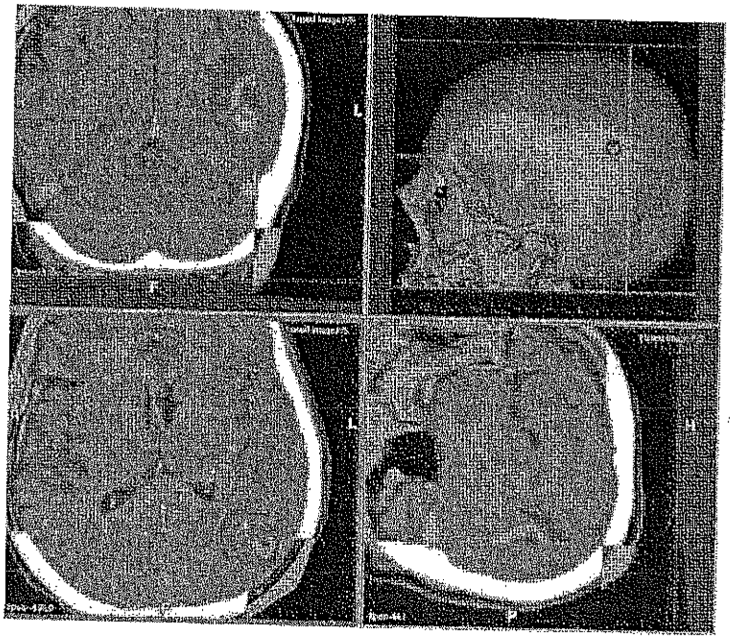


Figure 5. Improved localization of brain tumour using fused CT and MRI data sets. (Courtesy of OSL and Medcom).

and Goffinet [45] reported 17 unsuspected abnormalities in 153 scans (11%) obtained for treatment planning for patients referred for irradiation of the breast or chest wall. Of these, four represented disease that altered the treatment plan.

Working practices

The introduction of CT simulation has had a considerable impact on working practices in radiotherapy departments.

Oncologist attendance

The most notable change is that an oncologist is not required to be present during the scanning process. This releases the planning schedule from reliance on the oncologist's timetable, and the oncologists are free to undertake volume definition at a time convenient to them.

Time

A number of centres have reported on the different time allocation between conventional and virtual simulation [25, 28, 35]. Experience at the Kent Oncology Centre has shown that there is little difference in the total time needed for localization between the two modalities for the planning radiographers. With three radiographers in the scanning suite, 20 min appointments are adequate for most patients. Patients undergoing planning for breast radiotherapy are usually allocated 30 min because of the complex immobilization and positioning required with a narrow aperture scanner. These times are shorter than conventional simulation (30 min and 45 min, respectively), but more time is spent in manipulating the acquired data in the virtual simulation software. This includes the registering of reference marks and the production of DRRs for palliative patients, and outlining of target volumes and OARs for radical patients. Reduced simulation time for the patient leads to improved patient compliance, resulting in fewer problems from movement during scanning.

Table 1. Comparison of localization with CT and conventional simulation

Function	Conventional simulation	Virtual simulation
Patient alignment	Room lasers	Room lasers
Reference point definition	Skin markers	Skin markers
Localization	Fluoroscopy	CT scan
Definition of target and organs at risk	Drawing on plane films	Contouring on original or reconstructed slices
Isocentre	From simulator scales or film	DRR from CT
Field definition	From simulator scales or film	Virtual Sim
Patient outline	Manual/optical/single slice on Sim CT	Axial slice
Isocentre compared with reference point	Shifts measured on film	Calculated from Virtual Sim data
Treatment verification	Plane films	DRRs

DRR, digitally reconstructed radiograph.

Reference marks

In conventional simulation, using fluoroscopy for localization of the target volume, the isocentre can usually be established and marked at the time of simulation. In CT simulation, a reference point is chosen at the scanning session and the eventual isocentre is defined by movements of the couch from the reference point. If virtual simulation of palliative patients is undertaken with the patient remaining on the couch, the isocentre can be marked immediately from the couch movements indicated.

Verification

It has already been shown that to verify a plan on a conventional simulator after virtual simulation is not only unnecessary, but it could also be a source of systematic errors. However, treatment verification is still required and is of greater importance because of the use of reference marks. Verification takes place on the treatment unit with the electronic portal imaging system. The portal images acquired are then compared with the DRRs produced by the TPS or the virtual simulation software. For complex plans, this may require an extra treatment slot to allow time for the detailed comparison of portal images and DRRs before treatment.

Advantages and disadvantages of conventional and CT simulation

The advantages and disadvantages of conventional and CT simulation are summarized in Tables 2 and 3.

The availability of a three-dimensional dataset for all patients has some unexpected benefits. The increased information available may demonstrate previously unsuspected disease that may influence patient management. In palliative patients the extent of bone destruction from osteolytic lesions is easier to visualize on a CT scan than on a simulator film (Figure 6) and the use of software functions to remove overlying structures and display images optimized for different tissue types enables quicker localization of the disease. In breast planning, cardiac and lung volumes are more clearly demonstrated and therefore the fields can be adjusted or shielding employed accordingly.

One disadvantage of CT simulation is the increased patient dose. Doses for CT scanners are quoted as $CTDI_w$ with values in the region of 20 mGy. This dose is delivered to regions of normal healthy tissue as well as the tumour volume. Manufacturers of CT scanners provide various methods to reduce the total dose to the patient, taking account of the different dimensions of the patient at different levels and modulating the exposure in response to the detector measurements.

Some challenges still remain. Respiratory motion can affect the position of lung tumours and their relationship to OARs. Fast scanning protocols freeze patient and organ motion giving a snapshot view in time and space which may lead to inaccuracy in target delineation and choice of margins in three dimensions. Imaging techniques to overcome this drawback are an area of active investigation. The conventional method of treatment planning for lung tumours is to use fluoroscopic imaging to determine the maximum migration of the tumour during respiration and adopt large margins around the CTV to ensure that the target remains in the high dose region throughout the breathing cycle. A similar philosophy can be adopted by performing scans at deep inhale and deep exhale [46]. However, a number of other techniques have been suggested involving breath holding and respiratory gating techniques [47]. Deep inspiration breath hold (DIBH) increases the lung volume relative to normal breathing and hence the total volume of lung irradiated will be reduced using this technique [48]. In some patients, DIBH may displace the tumour away from OARs [49], which has the potential for dose escalation to the target for the same level of toxicity to OARs. Gated respiration techniques may either be active or passive. In active breathing control (ABC), the patient is prevented from breathing at a given part of the respiratory cycle during which the scan is performed and subsequent treatment takes place. By acquiring a number of scans at different parts of the breathing cycle, motion of the organ in three-dimensions can be demonstrated. Passive techniques allow the patient to breathe normally and a surrogate for the respiratory induced motion, such as the movement of the anterior chest wall, is monitored. Images obtained from CT scans are sorted according to respiratory phase to produce a 4D CT data set [50–52].

Table 2. Advantages and disadvantages of CT simulation

Advantages	Disadvantages
Three-dimensional dataset available, resulting in better visualization of tumour and nodal involvement, leads to reduction in side effects	Organ motion not visualized
Reduced simulation time leads to improved patient compliance	Repeat scan required for changes in patient set-up/shape/size during treatment
One fewer patient visit during planning	Palliative patients may spend longer in department between scanning and treatment
Oncologist not required during scanning	Transfer of verification to treatment unit may require extra treatment slot
Reduced transfer inaccuracies by omitting conventional simulator verification	Some patients/techniques may not be suitable for small aperture scanners (availability of wide aperture scanners should eliminate this problem)
Can simulate non-coplanar fields	Data storage
	Higher patient doses

Table 3. Advantages and disadvantages of conventional simulation

Advantages	Disadvantages
Fluoroscopy gives idea of organ motion	Difficult to visualize some tumours, especially if overlaid by bone (*e.g.* mediastinal lesions)
High spatial resolution	Limited three-dimensional information, even with CT option. Therefore cannot plan conformal or IMRT (cone beam may improve this)
Field visualization on patients skin	Two patient appointments required, localization and verification
	Difficult or impossible to simulate non-coplanar treatment fields

IMRT, intensity-modulated radiotherapy.

Breath hold and ABC techniques both require the co-operation of the patient and are therefore not appropriate for all patients. Some verbal or visual coaching helps to maintain regular breathing.

An alternative approach to the problem of organ motion is suggested by Murphy [53] who describes the real-time tracking of moving organs. Tracking respiratory motion is a complex procedure as it involves fast movement of organs relative to each other. For real-time tracking to be successful, the system must be able to locate the target, predict the motion to account for any time delays in repositioning the beam and adapt the treatment plan to allow for the change in relative positions of target and OARs. Although respiratory motion appears fairly regular, there are changes in amplitude and period from one cycle to the next which make prediction complicated. Murphy discusses two ways of predicting respiratory movement, by developing a mathematical model and by using an empirical algorithm that is based on measurements of previous breathing cycles. The technical challenges of fast response times to organ motion in continuous real time tracking are presented, but Murphy suggests that in the future it should be possible to treat lung tumours in some patients during free breathing, without needing to include movement margins in the treatment plan.

Respiratory correlation techniques developed to minimize motion artefacts in axial and helical scanning are not applicable to CBCT and different techniques have been developed for the CB application. Sonke et al [54] describe a method for sorting the projections into different phases of the breathing cycle to produce a 4D CBCT scan. Sillanpaa et al describe a method of acquiring megavoltage cone beam CT projection images at the same phase of breathing at all acquisition angles, giving a three-dimensional reconstruction at a single breathing phase [55]. It must be emphasised that gated respiration techniques must be employed at both the localization stage and during treatment.

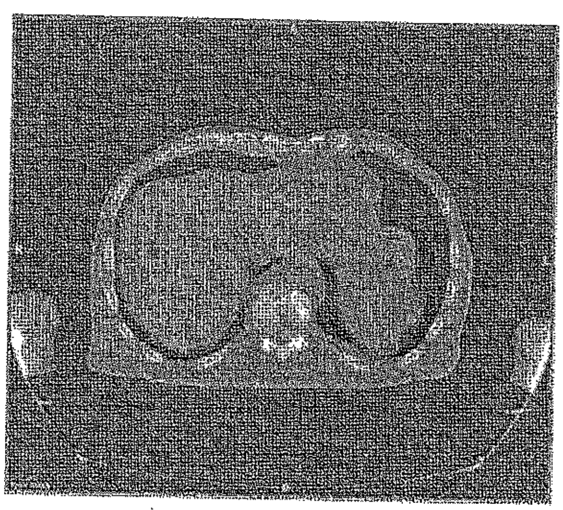


Figure 6. Osteolytic lesion of the spine.

Quality assurance

The accuracy of both conventional and CT simulation has a crucial effect on the overall accuracy of the patient's treatment. Whereas the accuracy of conventional simulation relies mainly on geometric features such as gantry and collimator angles and field defining wire positions, that of CT simulation depends on the image obtained by the scanner and the faithful transfer to the virtual simulation software. This connectivity should be part of any quality assurance (QA) programme.

A detailed description of quality control tests in conventional simulation and their recommended frequency is given by Tuohy [56].

Virtual simulation forms part of the network of the radiotherapy department, the end result of which is the treatment of the patient. The QA of this network should be seen as a process to which the various components of the hardware and software contribute. Guidance for the QA of a networked radiotherapy department is due to be published soon [57]. A QA programme should be established that reflects the importance of the contribution of each component of the system to the accuracy of the patient's treatment. Some components will be checked daily, such as the alignment of the lasers, the accuracy of positioning of any moving lasers and the HU accuracy for water. Others may be checked monthly, annually or after significant upgrades to the system. Special phantoms have been designed to assist with various aspects of QA [58, 59]. The Kent Oncology Centre has produced its own phantom that incorporates checks for a number of parameters in one scan study. These include spatial resolution, HU number, slice thickness, alignment and geometric accuracy.

Mutic et al [60] provide a comprehensive guide to the QA of CT simulators. They stress the need for audit and review of the process and flexibility in the programme as CT simulation evolves.

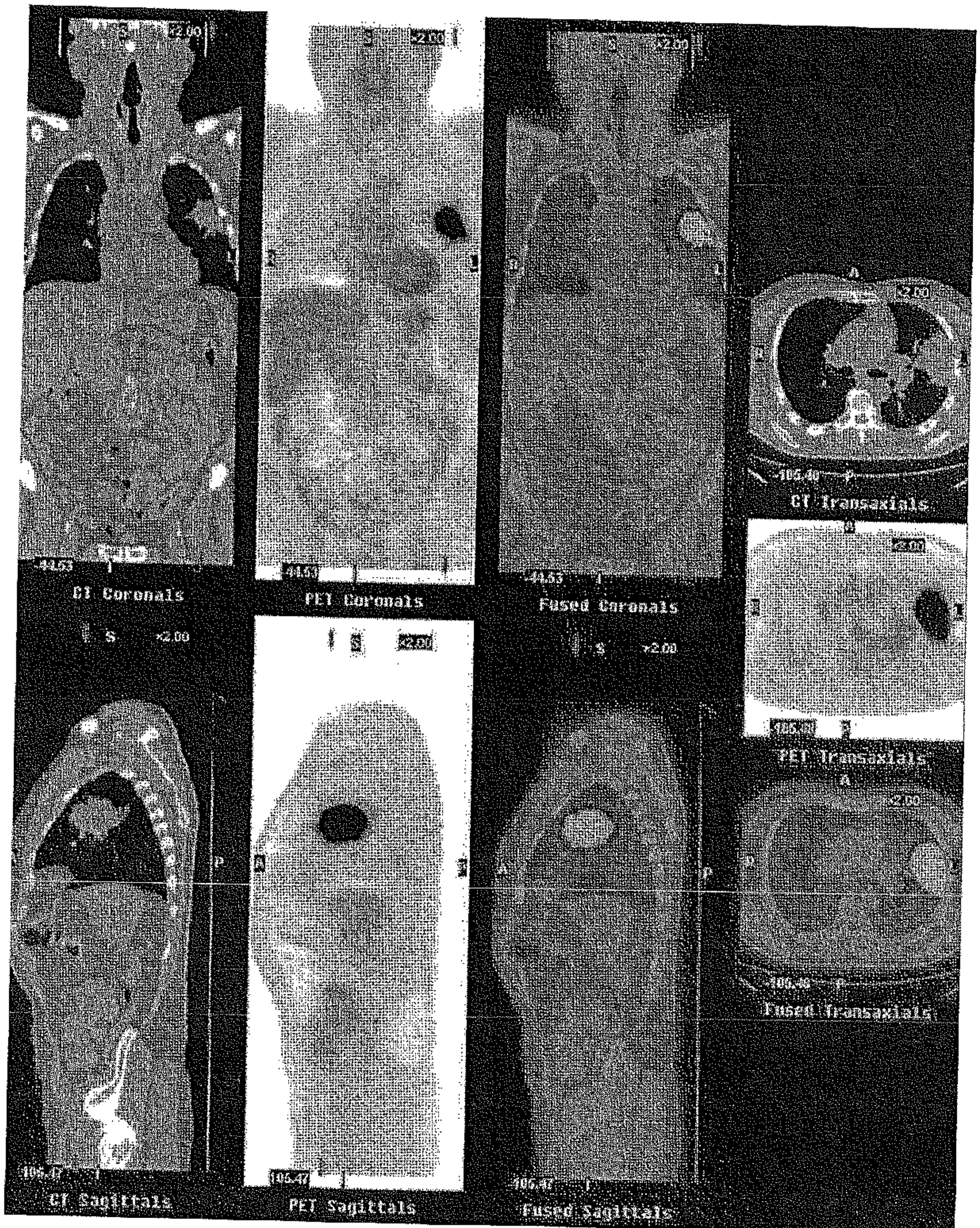


Figure 7. Fusion of positron emission tomography (PET) and CT images from a CT/PET scanner to localize a left lung tumour.

The future

The aim of radiotherapy is to deliver a tumoricidal dose of radiation to the clinical target volume (CTV) whilst sparing normal tissue and critical organs as far as possible. Localization is aimed at answering the question "where is the target?" The gross tumour volume (GTV) is neither a simple line nor an unchanging volume. It is an oncological concept and will vary according to the imaging technique or techniques used, any additional clinical data available and the judgement of the clinician. Each imaging modality displays different information about the GTV. Traditionally, delineation of the GTV has been associated with an anatomical abnormality that is imaged by plane radiography, CT or in some cases MRI. This gives structural, not functional information. However, molecular and physiological imaging techniques are now available which give an indication of the functional state of the tissues. This information can potentially be used in addition to CT and MRI to assist in defining clinically relevant targets more accurately [61]. Ling et al [62] proposed treating a biological target volume defined from anatomical, physiological and/or molecular images. For example, increased glycolysis is a function of a tumour and fluorine-18 fluorodeoxyglucose positron emission tomography (^{18}FDG-PET) studies have been used as an addition to CT for planning patients with poorly defined non-small cell lung cancer (NSCLC) [63, 64], head and neck cancers [65] and malignant gliomas [66] (see Jarritt et al in this issue). Figure 7 shows the fused images from ^{18}FDG-PET and CT acquired in a single session on a PET/CT scanner. The lesion in the left lung is clearly demonstrated in both modalities in this example. Other PET agents may be used to identify areas of hypoxia within a tumour that may benefit from higher doses of radiation such as can be delivered by IMRT. Similar inhomogeneous dose distributions may be applied to regions of the prostate demonstrating a high choline:citrate ratio, indicating a region of active tumour, as demonstrated on MR spectroscopy [67] (see Payne and Leach in this issue). Modalities such as functional MRI (fMRI) and single photon emission computed tomography (SPECT) may also be used to assist in GTV and OAR delineation. SPECT perfusion studies for NSCLC can be used in treatment planning to provide information on normal lung tissue and help to reduce the volume of normal lung irradiated [68].

Imaging techniques are continually evolving and as they are refined they will reveal more information about the disease to be treated. Collaboration between radiologists and oncologists will be essential if the information contained within these new images is to be maximized for the benefit of the patient.

No consideration of the future of radiation therapy would be complete without mention of image guided radiotherapy (IGRT). IGRT aims to address the inter-fraction movement of tumours and their relationship to OARs. Of the linear accelerator manufacturers, both Elekta (Crawley, Sussex, UK) and Varian (Palo Alto, CA) provide kilovoltage cone beam CT (CBCT) on the gantry and Siemens (Erlangen, Germany) have installed a CT scanner on rails in the treatment room (see Moore et al and Thieke et al, respectively, in this issue).

These imaging devices provide the ability to localize the tumour immediately prior to treatment and to reposition the patient to correct for interfraction variation in tumour position. Wong et al [69] describe the use of daily scans in the treatment room to reposition prostate patients for the final phase of their treatment. 46% required no isocentre adjustment in the anterior–posterior direction, but 44% required a shift of greater than 5 mm. In the superoinferior direction, 25% required a shift greater than 5 mm and in left-right direction 24% required a shift greater than 5 mm. The shifts were associated with significant changes in the dosimetry. Other authors describe the implementation of CBCT for IGRT [54, 70, 71].

IGRT is a rapidly evolving field and will undoubtedly have implications for treatment planning.

Conclusion

Both conventional and virtual simulation have developed in line with the changes in imaging techniques over recent years. The anticipated advantages of virtual simulation have been realised to a great extent and have changed the work flow in treatment planning. The availability of wide bore scanners enables most treatment techniques to be imaged. Fast computer graphics that have reduced image reconstruction times enable the acquisition of large data sets that can be manipulated for respiratory correlated techniques. The rapid development of biological imaging holds the prospect of multi-modality localization, which is already being realised for some disease sites such as lung and prostate. The addition of cone beam CT to conventional simulators may add flexibility to departments with both a scanner and a simulator. However localization is achieved, it must be considered as part of the overall process that leads to treatment. The accuracy of the data acquisition and transfer is vital to this process and a comprehensive QA programme is essential.

I would like to thank Dr Ruth Beddows for the design of the Kent Oncology Centre phantom, Ms Alison Vinall and Ms Karen Venables for reports on cone beam CT, David Hill for assistance with image processing and colleagues for discussions during the preparation of this manuscript.

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EXHIBIT D
CURRICULUM VITAES

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CURRICULUM VITAE

- **Medical Director, Radiation Oncology, New Milford Hospital**, New Milford, CT
- Member Western Connecticut Medical Group, July 2011 to the present
- Responsible for building a practice in a hospital based setting where radiation therapy was a new service.
- Planned and implemented replacement of hospital's original Varian Clinac 2100 linear accelerator with new Varian Trilogy linear accelerator.
- Implemented prostate brachytherapy program and high dose rate brachytherapy program.
- Implemented Intensity Modulated Radiation Therapy using Varian Eclipse Software.
- Implemented radiopharmaceutical therapy program.
- Implemented Image Guided Radiation Therapy (IGRT) program
- Implemented Stereotactic Radiation Therapy program for brain tumors
- Responsible for developing and implementing policies, procedures, and quality assurance programs for the different radiation therapy modalities offered.
- Radiation Oncology representative to hospital committees, including weekly Cancer Conference, and Multidisciplinary Cancer Committee.
- Chairman, New Milford Hospital Multidisciplinary Cancer Committee
- **Radiation Safety Officer**, New Milford Hospital, New Milford, CT.
- Member New Milford Hospital Research Committee.
- Participated in certification process of the New Milford Hospital Radiation Oncology program by the American College of Radiology (ACR).
- Participated in certification process of the New Milford Hospital Cancer program by the American College of Surgeons.

Academic Training

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Traineeship

Internship: The New York Hospital - Cornell Medical Center, New York, NY
Internal Medicine, 1993-1994

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Board Certification

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Skills

- Three Dimensional Conformal Radiation Therapy using Varian Eclipse Software
- High Dose Rate Brachytherapy
- Low Dose Rate Brachytherapy
- Real Time Prostate Brachytherapy using Variseed software
- Stereotactic Radiosurgery using both Linac and Gamma Knife modalities
- Intensity Modulated Radiation Therapy
- Radiopharmaceutical Therapy
- Partial Breast Radiation Therapy
- Image Guided Radiation Therapy

Academic Appointments

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1998-2004	Assistant Attending Radiation Oncology Service The Presbyterian Hospital New York, NY
1997-1998	Chief Resident Radiation Oncology Service The Presbyterian Hospital New York, NY

Work Experience

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Honors

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3. Post-operative Radiation Therapy for Prostate Cancer, Urology Tumor Board, Department of Urology Columbia-Presbyterian Medical Center, New York, NY, January 1996.
4. Malignant Melanoma. Grand Rounds, Department of Radiation Oncology, Columbia-Presbyterian Medical Center, New York, NY, May 1996.
5. Radiation Nephropathy. Presented at Grand Rounds, Department of Radiation Oncology, Columbia-Presbyterian Medical Center, New York, NY, November 1996.
6. Bladder Cancer with Emphasis on Bladder Preservation. Presented at Urology Tumor Board, Department of Urology, Columbia-Presbyterian Medical Center, New York, NY, June 1997.
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Teaching

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Publications

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Abstracts

1. Trichter, F., Bargellini, J., Amols, H., Schiff, P. Clinical Implementation of a Matrix Ion Chamber EPID in Obese Patients Treatment. 40th AAPM Annual Meeting, San Antonio, Texas, August 1998. Med. Phys. 25(7):A198, 1998.

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EDUCATIONAL BACKGROUND

Albright College, Reading, Pa. B.S. 1976
Overlook Hospital School of Nuclear Medicine Technology, Summit, N.J. , certificate in Nuclear Medicine Technology, 1980
Rutgers University Graduate School, Piscataway, N.J. M.S. in Radiation Science, 1985
Board Certification by American Board of Radiology in Therapeutic Radiological Physics 1991

EXPERIENCE

1980-1984 Nuclear Medicine Technologist-worked full time as a nuclear medicine technologist at Hackensack Hospital and Morristown Memorial Hospital while attending graduate school part time.

1984-1985 Junior physicist at Memorial Sloan Kettering- worked on a research project in the Biophysics Department designing and fabricating an anthromorphic tissue equivalent phantom for use in a monoclonal antibody NCI grant project.

1985-1989 Junior physicist Valley Hospital in Ridgewood, N.J. Clinical duties including brachytherapy planning for breast, gyn and prostate, external beam treatment planning, sealed source quality assurance, linear accelerator quality assurance. Assisted chief physicist in acceptance testing and commissioning of new treatment planning system and linear accelerator, nuclear medicine quarterly quality assurance.
Taught physics and math classes to x-ray students at the hospital based school.

1989-1993 Consultant physicist for George Zacharopoulos at Dover General Hospital, Dover, N.J. Clinical duties including external beam and brachytherapy treatment planning(gyn), hdr treatment planning and associated radiation safety duties. and sealed source quality assurance duties.
Linear accelerator quality assurance, cobalt machine quality assurance and orthovoltage unit quality assurance.. Assisted in commissioning and acceptance testing of new treatment planning system,linear accelerator, and the high dose rate remote afterloader(Nucletron)..

1994-1994 Radiation Oncology Physicist Hackensack Medical Center. Prostate seed implant planning and associated radiation safety duties. Linear accelerator and cobalt machine quality assurance. Worked with other physicists on acceptance testing and commissioning of linear accelerator.

1995-1998 Solo medical physicist in Radiation Oncology Dept. of Clara Maas Medical Center, Belleville, N.J. Performed acceptance testing of 3D treatment planning system. Clinical duties included external beam and brachytherapy treatment planning(gyn, prostate) and radiation safety duties associated with brachytherapy. Trained a junior Dosimetrist. Physics aspects of beginning a prostate seed implant program. Performed quality assurance duties on 2 linear accelerators and a simulator. Sealed source quality assurance duties. Writing of license amendment for NRC for HDR program. During this time I also provided vacation coverage for Bayonne Hospital for HDR duties(Nucletron).

1998-2002 Senior physicist and radiation safety officer Danbury Hospital, Danbury, Ct. Oversight and direct involvement in the physics aspects of beginning a prostate seed implant program and CT simulator installation and implementation. Radiation safety aspects of radiation oncology, radiology and nuclear medicine, including quality assurance. Supervised work of the radiology engineers as well as physics section. Radiation safety instuction to all personnel in hospital using or dealing with radiation, including x-ray students. During this time period I also provided part time coverage for Bristol Radiation Oncology, Bristol, Ct.

5/02 to 10/03 Solo medical physicist in Radiation Oncology Dept. of Midstate Medical Center in Meriden, Ct. Brachytherapy treatment planning and associated radiation safety duties for a busy seed implant program. Acceptance testing of the new treatment planning computer and physics aspects of starting an IMRT program. Oversight of dosimetrist's work. Quality assurance of linear accelerator and simulator. Equipment: Elekta Precise linac, Pinnacle, Impac.. During this time period I also provided part time coverage for Bristol Radiation Oncology, Bristol, Ct.
I am currently per diem here(give vacation coverage).

10/03 to 9/07 Solo medical physicist in Radiation Oncology at Charlotte Hungerford Hospital in Torrington, Ct. Acceptance testing of the new treatment planning computer and physics aspects of starting IMRT program. Physics aspects of starting up an HDR program(license, acceptance testing coordinated training). External beam treatment planning(including IMRT and partial breast external beam protocol patients) and brachytherapy treatment planning(for seed implants and HDR including mammosites) and oversight of dosimetrists' work. Performed treatment planning in dosimetrist's absence. Quality assurance for linear accelerator and orthovoltage machine. Equipment: Elekta Precise linac, Pinnacle, Brachyvision, Impac, Gammamed,Variseed.
I am currently per diem here(give vacation coverage)

9/07 to present

Chief Physicist New Milford Hospital Radiation Therapy Department, New Milford, Ct. Quality assurance of linear accelerator and simulator, Physics aspects of HDR(including assisted department in beginning Mammosite treatments). IMRT quality assurance. Perform treatment planning in dosimetrist's absence. Brachytherapy treatment planning. Supervision of dosimetrist and per diem physicists and dosimetrists. Assist radiation safety officer. Radiation safety aspects of radionuclide therapies. Physics aspects of prostate seed implants. Was actively involved in planning for and ordering new linear accelerator. Equipment: Varian 2100 CD, Eclipse, Brachyvision, Aria, Varisource,Variseed. Equpment updated October 2011 to Trilogy with VMAT and IGRT and Varisource IX HDR. Performed acceptance testing of both machines and assisted physics group with linac commissioning. Performed acceptance testing of treatment planning systems after new machines. Responsible for physics aspects of developing VMAT(RapidArc) treatment program for imrt and srt.

Professional Activities

Board Certification by American Board of Radiology.
American College of Radiology Physicist Surveyor for practice accreditation
Member of American Association of Physicists in Medicine and its Local chapter. ASTRO member Served as Treasurer, President-Elect and President of New Jersey Medical Physics Society and Secretary, President-Elect and President of Connecticut Area Medical Physics Society. Served on the Clinical Practice Committee of AAPM.

EXHIBIT E
HOSPITAL LICENSE

STATE OF CONNECTICUT

Department of Public Health

LICENSE

License No. 0032

General Hospital

In accordance with the provisions of the General Statutes of Connecticut Section 19a-493:

New Milford Hospital, Inc. of New Milford, CT d/b/a New Milford Hospital is hereby licensed to maintain and operate a General Hospital.

New Milford Hospital is located at 21 Elm Street, New Milford, CT 06776.

The maximum number of beds shall not exceed at any time:

0 Bassinets
85 General Hospital Beds

This license expires **June 30, 2015** and may be revoked for cause at any time.
Dated at Hartford, Connecticut, July 1, 2013. RENEWAL.

Satellite:
New Milford Hospital Community Mental Health Services, 23 Poplar Street, New Milford, CT

Jewel Mullen, MD, MPH, MPA
Commissioner

EXHIBIT F

FINANCIAL ATTACHMENTS & ASSUMPTIONS

New Milford Hospital CT-Simulator CON Application

7.a. Financial Attachment I

(Dollars are in thousands)
Total Facility:

Description	FY 2012 Actual Results	FY 2013 Projected W/out CON	FY 2013 Projected Incremental	FY 2013 Projected With CON	FY 2014 Projected W/out CON	FY 2014 Projected Incremental	FY 2014 Projected With CON	FY 2015 Projected W/out CON	FY 2015 Projected Incremental	FY 2015 Projected With CON	FY 2016 Projected W/out CON	FY 2016 Projected Incremental	FY 2016 Projected With CON
NET PATIENT REVENUE													
Non-Government	$48,136	45,592	-	$45,592	47,042	-	47,042	48,544	-	48,544	50,221	-	50,221
Medicare	24,242	19,229	-	$19,229	18,687	-	$18,687	18,842	-	$18,842	19,098	-	$19,098
Medicaid and Other Medical Assistance	5,632	5,340	-	$5,340	5,344	-	$5,344	5,349	-	$5,349	5,376	-	$5,376
Other Government	101	85	-	85	85		85	85		85	85		$85
Total Net Patient Patient Revenue	$78,111	$70,245	$0	$70,245	$71,157	$0	$71,157	$72,820	$0	$72,820	74,780	$0	$74,780
Other Operating Revenue	$1,101	$980	-	$980	$980	$0	$980	$980	$0	$980	$980	$0	$980
Revenue from Operations	$79,212	$71,225	$0	$71,225	$72,137	$0	$72,137	$73,799	$0	$73,799	$75,759	$0	$75,759
OPERATING EXPENSES													
Salaries and Fringe Benefits	$45,235	$40,419	-	$40,419	$41,329	-	$41,329	$42,259	-	$42,259	$43,209	-	$43,209
Professional / Contracted Services	12,196	8,713	-	8,713	8,887	-	8,887	9,065	-	9,065	9,246	-	9,246
Supplies and Drugs	10,418	9,589	-	9,589	9,876	-	9,876	10,173	-	10,173	10,478	-	10,478
Other Operating Expense	10,942	10,360	-	10,360	10,360	186	10,546	10,360	186	10,546	10,360	186	10,546
Subtotal	$78,792	$69,081	$0	$69,081	$70,452	$186	$70,638	$71,856	$186	$72,042	$73,294	$186	$73,480
Depreciation/Amortization	5,527	5,862	220	6,082	6,162	220	6,382	7,162	220	7,382	8,162	220	8,382
Interest Expense	419	268	-	268	268	-	268	268	-	268	268	-	268
Lease Expense	447	824	-	824	832	-	832	841	-	841	849	-	849
Total Operating Expenses	$85,184	$76,035	$220	$76,255	$77,715	$406	$78,121	$80,127	$406	$80,533	$82,573	$406	$82,979
Gain/(Loss) from Operations	($5,972)	($4,810)	($220)	($5,030)	($5,578)	($406)	($5,984)	($6,328)	($406)	($6,734)	($6,813)	($406)	($7,219)
Plus: Non-Operating Income	$772	$0		$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Income before provision for income taxes	($5,200)	($4,810)	($220)	($5,030)	($5,578)	($406)	($5,984)	($6,328)	($406)	($6,734)	($6,813)	($406)	($7,219)
Provision for income taxes			-	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Revenue Over/(Under) Expense	($5,200)	($4,810)	($220)	($5,030)	($5,578)	($406)	($5,984)	($6,328)	($406)	($6,734)	($6,813)	($406)	($7,219)
FTEs	420.0	375.0	-	375.0	375.0	-	375.0	375.0	-	375.0	375.0	-	375.0
*Volume Statistics:													
Complex Sims Performed	121	176	-	176	176	-	176	176	-	176	176	-	176
			-	-	-	-	-	-	-	-	-	-	-
Key Ratios:													
Op Margin	-7.5%	-6.8%		-7.1%	-7.7%		-8.3%	-8.6%		-9.1%	-9.0%		-9.5%
Operating EBIDA Margin	0.0%	1.9%		1.9%	1.2%		0.9%	1.5%		1.2%	2.1%		1.9%
Excess Margin	-6.6%	-6.8%		-7.1%	-7.7%		-8.3%	-8.6%		-9.1%	-9.0%		-9.5%

New Milford Hospital CT-Simulator CON Application

7.b. Financial Attachment II

(Dollars are in thousands)

Please provide **three** years of projections of <u>incremental</u> revenue, expense and volume statistics **attributable to the proposal** in the following reporting format:

FY 2013	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
FY Projected Incremental		Rate	Units	Gross Revenue Col. 2 * Col. 3	Allowances/ Deductions	Charity Care	Bad Debt	Net Revenue Col.4 - Col.5 -Col.6 - Col.7	Operating Expenses Col. 1 Total * Col. 4 / Col. 4 Total	Gain/(Loss) from Operations Col. 8 - Col. 9
Total Incremental Expenses:	$220									
Total Facility by Payer Category:										
Medicare		-	-	$0	-	-	-	$0	$103	($103)
Medicaid		-	-	$0	-	-	-	-	21	(21)
CHAMPUS/TriCare		-				-	-	-	0	(0)
Total Governmental			0	$0	-	$0	$0	$0	$124	($124)
Commercial Insurers		-	-	$0	-	-	-	-	91	(91)
Uninsured		-	-	$0	-	-	-	-	4	(4)
Total NonGovernment			0	$0	-	$0	$0	$0	$96	($96)
Total All Payers		-	0	$0	$0	$0	$0	$0	$220	($220)

FY 2014	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
FY Projected Incremental		Rate	Units	Gross Revenue Col. 2 * Col. 3	Allowances/ Deductions	Charity Care	Bad Debt	Net Revenue Col.4 - Col.5 -Col.6 - Col.7	Operating Expenses Col. 1 Total * Col. 4 / Col. 4 Total	Gain/(Loss) from Operations Col. 8 - Col. 9
Total Incremental Expenses:	$406									
Total Facility by Payer Category:										
Medicare		-	-	$0	-	-	-	$0	$189	($189)
Medicaid		-	-	$0	-	-	-	-	39	(39)
CHAMPUS/TriCare		-				-	-	-	1	(1)
Total Governmental			0	$0	$0	$0	$0	$0	$229	($229)
Commericial Insurers		-	-	$0	-	-	-	-	169	(169)
Uninsured		-	-	$0	-	-	-	-	8	(8)
Total NonGovernment			0	$0	$0	$0	$0	$0	$177	($177)
Total All Payers		-	0	$0	$0	$0	$0	$0	$406	($406)

FY 2015	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
FY Projected Incremental		Rate	Units	Gross Revenue Col. 2 * Col. 3	Allowances/ Deductions	Charity Care	Bad Debt	Net Revenue Col.4 - Col.5 -Col.6 - Col.7	Operating Expenses Col. 1 Total * Col. 4 / Col. 4 Total	Gain/(Loss) from Operations Col. 8 - Col. 9
Total Incremental Expenses:	$406									
Total Facility by Payer Category:										
Medicare		-	-	$0	-	-	-	$0	$189	($189)
Medicaid		-	-	$0	-	-	-	-	39	(39)
CHAMPUS/TriCare		-				-	-	-	1	(1)
Total Governmental			0	$0	$0	$0	$0	$0	$229	($229)
Commericial Insurers		-	-	$0	-	-	-	-	169	(169)
Uninsured		-	-	$0	-	-	-	-	8	(8)
Total NonGovernment			0	$0	$0	$0	$0	$0	$177	($177)
Total All Payers		-	0	$0	$0	$0	$0	$0	$406	($406)

New Milford Hospital CT-Simulator CON Application

7.c. Financial Assumptions

Net Patient Revenue:	
Without Project:	Based on current payor mix and volume assumptions with annual increases of 0% in govt rates, 2% in nongovt rates, elimination of medicare low volume reimb in FY14.
With Project:	Same as above - no change related to project
Volume:	
Without Project:	Overall, a 1% decrease in inpatient volume, 0.4% increase in outpt volume was included in projections
With Project:	Same as above - no change related to project
Other Operating Revenue:	
Without Project:	Assumes 0% increase annually
With Project:	Same as above - no change related to project
Salaries and Fringe Benefits:	
Without Project:	Assumed 2.25% annual inflationary increase.
With Project:	Same as above - no change related to project
Professional / Contracted Srvs:	
Without Project:	Assumes 2% annual increase on current expense levels.
With Project:	Same as above - no change related to project
Supplies and Drugs:	
Without Project:	Assumes 3% annual increase on current expense levels.
With Project:	Same as above - no change related to project
Other Op Expense:	
Without Project:	Based on historic trend
With Project:	Incremental expense associated with project includes $186K in annual maintenace fees for equipment beginning in Year 2.
Depreciation:	
Without Project:	Assumption is based on historic and planned annual capital spending
With Project:	Assumes $1.1M acquisition fee depreciated straightline over 5 years
Interest:	
Without Project:	Based on current interest of existing debt rolled forward annually.
With Project:	Same as above - no change related to project
Lease Expense:	
Without Project:	Includes a 1% annual increase on expenses annually.
With Project:	Same as above - no change related to project
FTEs:	
Without Project:	FTEs increases necessary for any relative volume change will be offset with productivity improvement initiatives.
With Project:	Same as above - no change related to project

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Office of Health Care Access

August 28, 2013 VIA FAX ONLY

Sally F. Herlihy, MBA, FACHE
Vice President, Planning
Western Connecticut Heatlh Network
24 Hospital Avenue
Danbury, CT 06810

RE: Certificate of Need Application, Docket Number 13-31855-CON
New Milford Hospital, Inc.
Acquisition of a Computed Tomography-Simulator at New Milford Hospital

Dear Ms. Herlihy:

On July 30, 2013, the Office of Health Care Access ("OHCA") received your Certificate of Need ("CON") application filing on behalf of New Milford Hospital ("Hospital") proposing to acquire a Computed Tomography-Simulation ("CT-Simulator"), with an associated cost of $1,100,000.

OHCA has reviewed the responses and requests the following additional information pursuant to General Statutes §19a-639a(c).

1. On page 10 of the CON application, the Hospital lists the towns of New Milford, Sherman, Washington, Kent, Roxbury, Bridgewater and Wingdale (NY) as its primary service area towns. Please provide the rationale for choosing these towns and provide evidence.

2. On page 17 of the CON application, the Hospital states that it plans to pay for the $1,100,000 acquisition with a $1,000,000 grant received from the Diebold Foundation. Please address the following:

    a) Provide the specific purpose of the Diebold Foundation Grant being utilized to fund this acquisition. Provide evidence that the funds from this grant may be used for the purpose of acquiring the proposed CT-Simulator and that thse funds are available.
    b) Will there be any difference in the amount of the grant and the proposed capital expenditure that will need to be funded by the Hospital?

3. Please provide the minimum number of CT simulations required annually for this proposal to show an incremental gain from operations for each of the three projected fiscal years.

4. Please provide a thorough discussion on the continuum of cancer care/services at New Milford Hospital and within the Western Connecticut Health Network ("WCHN"), including access to CT simulations for cancer patients within WCHN. Specifically, please explain how the proposed acquisition is in line with the need of both Hospital and WCHN patients.

5. As there is an application filed with OHCA to merge the Hospital under Danbury Hospital's license (all under the WCHN), please explain in detail the need for New Milford Hospital to acquire the proposed CT-Simulator in light of the relatively small annual volume and the proposed service being available at Danbury Hospital.

In responding to the questions contained in this letter, please repeat each question before providing your response. Paginate and date your response, i.e., each page in its entirety. Information filed after the initial CON application submission (i.e. completeness response letter, prefile testimony, late file submissions and the like) must be numbered sequentially from the Applicant's document preceding it. Please begin your submission using Page 51 and reference "Docket Number: 13-31855-CON." Submit one (1) original and two (2) hard copies of your response. In addition, please submit a scanned copy of your response, in an Adobe format (.pdf) including all attachments on CD. If available, a copy of the response in MS Word should also be copied to the CD.

Pursuant to Section 19a-639a(c) of the Connecticut General Statutes, you must submit your response to this request for additional information not later than sixty days after the date that this request was transmitted. Therefore, please provide your written responses to OHCA no later than October 26, 2013, otherwise your application will be automatically considered withdrawn. If you have any questions concerning this letter, please feel free to contact me by email or at (860) 418-7012.

Sincerely,

Steven W. Lazarus
Associate Health Care Analyst

****
*** TX REPORT ***
****

TRANSMISSION OK

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RECIPIENT ADDRESS	912037391974
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RESULT	OK

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS

FAX SHEET

TO: Sally Herlihy

FAX: (203) 739-1974

AGENCY:

FROM: Steven Lazarus

DATE: 8/28/13 **TIME:**

NUMBER OF PAGES: 3
(including transmittal sheet)

Comments: CL for DN: 13-31855 Enclosed

PLEASE PHONE IF THERE ARE ANY TRANSMISSION PROBLEMS.

Phone: (860) 418-7001 *Fax: (860) 418-7053*

WESTERN CONNECTICUT HEALTH NETWORK

DANBURY HOSPITAL

24 Hospital Ave
Danbury, CT 06810
203.739.4903
DanburyHospital.org

From:	Sally Herlihy Vice President, Planning		
To:	Steven Lazarus		
Fax:	860-418-7053	No. of Pages:	14 (including fax cover sheet)
Phone:	860-418-7012	Date:	October 25, 2013
RE:	Docket No. 13-31855-CON	CC:	

☐ Urgent ☒ For Review ☐ Please Comment ☐ Please Reply ☐ Please Recycle

Fax

The original document along with two hard copies and a CD will be mailed to your office via FedEx.

Thank you

WESTERN CONNECTICUT HEALTH NETWORK

DANBURY HOSPITAL • NEW MILFORD HOSPITAL

24 Hospital Ave.
Danbury, CT 06810
203.739.4903

WesternConnecticutHealthNetwork.org
DanburyHospital.org
NewMilfordHospital.org

October 25, 2013

Mr. Steven W. Lazarus
Associate Health Care Analyst
Department of Public Health
Office of Health Care Access
410 Capitol Avenue: MS# 13HCA
P.O. Box 340308
Hartford, CT 06134-0308

Re: Certificate of Need Application, Docket No. 13-31855- CON
Responses to OHCA CON Completeness Questions

Dear Mr. Lazarus,

Enclosed please find Responses on behalf of New Milford Hospital, Inc. and Western Connecticut Health Network, Inc. to the Completeness Questions asked by OHCA in a letter dated August 28, 2013 in the above-captioned docket. We have included the original and two hard copies of the Responses, as well as a CD with an Adobe format of the Responses.

Please contact me if you have any questions regarding this submission.

Sincerely,

Sally F. Herlihy

Sally F. Herlihy, MBA, FACHE
Vice President, Planning

Enclosures

Completeness Questions & Responses

1. **On Page 10 of the CON application, the Hospital lists the towns of New Milford, Sherman, Washington, Kent, Roxbury, Bridgewater, and Wingdale (NY) as its primary service area towns. Please provide the rationale for choosing these towns and provide evidence.**

Response:

Western Connecticut Health Network, Inc. (WCHN) includes two affiliated hospitals – New Milford Hospital, Inc. (NMH) and The Danbury Hospital (DH). WCHN's service area includes municipalities in both Connecticut and New York, and its PSA identified as the towns of Bethel, Bridgewater, Brookfield, Danbury, Kent, New Fairfield, New Milford, Newtown, Redding, Ridgefield, Roxbury, Sherman, and Washington, CT, and Brewster, Dover Plains, Patterson, Pawling, and Wingdale, NY.

The towns noted in Q.1. were identified specific to NMH based on their collective volumes representing 75% of the hospital's total volume and 78% of the inpatient volume, and are in close proximity to the town of New Milford with historical utilization of the facility. A chart representing NMH's patient volume for FY 2012 is included as Exhibit A.

2. **On page 17 of the CON application, the Hospital states that it plans to pay for the $1,100,000 acquisition with a $1,000,000 gift received from the Diebold Foundation. Please address the following:**
   a. **Provide the specific purpose of the Diebold Foundation grant being utilized to fund this acquisition. Provide evidence that the funds from this grant may be used for the purpose of acquiring the proposed CT Simulator and that these funds are available.**
   b. **Will there be any difference in the amount of the grant and the proposed capital expenditure that will need to be funded by the Hospital?**

Response:

The Diebold Foundation grant received is specific to the acquisition of CT simulation technology for NMH's Diebold Family Cancer Center. The commitment letter from the Diebold Foundation is included as Exhibit A.

The proposed capital expenditure is $1,100,000. The difference between the donated amount and capital expenditure is $100,000 which will be funded by the hospital.

3. **Please provide the minimum number of CT simulations required annually for this proposal to show an incremental gain from operations for each of the three projected fiscal years.**

Response:

An incremental gain from operations would require an additional 99 cases in year one and an additional 182 cases in year two and thereafter. We understand the acquisition of replacement simulation technology does not produce a positive return on investment, but recognize this investment is a critical element to preserving a community service, maintaining local access, and enhancing the quality of comprehensive cancer care and treatment.

4. Please provide a thorough discussion on the continuum of cancer services at New Milford Hospital and within the Western Connecticut Health Network ("WCHN"), including access to CT simulation for cancer patients within WCHN. Specifically, please explain how the proposed acquisition is in line with the need of both Hospital and WCHN patients.

Response:

With a highly experienced and committed multidisciplinary team of over 100 professionals, the continuum of cancer care offered by WCHN includes risk assessment, prevention, screening, detection, diagnosis, treatment, supportive services, research, survivorship, and end-of-life care. An outline of the continuum of cancer care services provided across WCHN is included as Exhibit C.

The acquisition of a CT simulation at NMH is in concert with WCHN delivery of quality care to all patients in the regions we serve. CT Simulation is an "imitation" of radiation treatment without the actual radiation beam and is the first critical step in the treatment planning process for radiation therapy. The information gathered by the CT scan will be used to create a treatment plan, which outlines the parameters for the radiation therapy treatment.

The NMH conventional simulator is no longer manufactured, has reached end of useful life in April of 2013, and is not supported by the vendor. In 2010, NMH installed a new highly sophisticated linear accelerator. Without this new and complimentary CT simulation NMH is limited in its ability to use that existing installed equipment to its maximum capacity and potential for all its patients. The implementation of next generation improvements in radiation treatments requires a CT Simulator specific to radiation oncology.

Oncology patients require a CT image for comparison to deliver the same standards of care at both our sites. In the interim we have been using the 64-slice CT at the NMH site for simulations. The 64-slice CT is not designed for radiation therapy but is designed as a diagnostic unit. A CT simulation designed for radiation therapy has some important capabilities that are lacking on the diagnostic CT unit. For example:

- A larger bore (central opening in the CT ring) gives more room to allow for proper positioning for cancer care patients. NMH has experienced frequent issues where patients do not optimally fit in the CT simulator due to both the location of cancers and the size of the patient with their radiation oncology immobilization devices.
- Motion management cannot be done on the existing CT and is important in lung cancers which can move with breathing.
- Having the CT simulator located within the Diebold Family Cancer Center at NMH improves patient care by reducing wait time for the main hospital 64-slice CT; cancer patients can be delayed due to emergency cases that must be a priority.
- Radiation Oncology LAP lasers, patient alignment laser systems, are the more precise positioning required and enable the oversight of the quality assurance process.
- 4D imaging capability will enable NMH to treat patients that they currently have to refer elsewhere. New capabilities due to the technology will enhance patient treatment services such as stereotactic body radiation that will provide that same standard of care required throughout our network. This new imaging capability is required in treating lung or abdominal areas as it features a very small field accommodating the knowledge to the physician that the tumor is moving so margins are large enough and any geographic miss is avoided.

- Operationally, it is critical to note that the CT simulator couchtop and linear accelerator couchtop are required to match and the NMH linear accelerator couchtop is different than those offered at our Danbury location.
- Also operationally, it is essential that the managing physician be present for CT simulation treatment as it is the basis for future care, and accounts for differences in immobilization practices, devices, and the treatment machines themselves, the NMH linear accelerator has distinct differences than the ones at DH.

In order to provide radiation oncology services, a CT simulator designed specific to a linear accelerator is necessary.

5. **As there is an application filed with OHCA to merge the Hospital under Danbury Hospital's license (all under the WCHN), please explain in detail the need for New Milford Hospital to acquire the proposed CT-Simulator in light of the relatively small annual volume and the proposed service being available at Danbury Hospital.**

Response:

WCHN is committed to providing comprehensive cancer services at NMH, and has been working on a thoughtful plan for NMH within the WCHN integrated delivery system. This plan will ensure continued delivery of high quality services across the entire network and provide access to those services to meet patient needs. As explained in response to Q.4. above, CT simulation is necessary for treatment planning for patients receiving radiation therapy. Maintaining simulation technology at NMH will accommodate and facilitate the provision of cancer care to NMH's primary market area, which includes towns located to the north of New Milford, including but not limited to Kent, Sherman, and Washington, CT and NY border towns, as well as access for patients from other surrounding communities. Maintaining a comprehensive cancer center at NMH also aligns with the anticipated increase in cancer cases associated with an aging population, where the volumes and complexity of those cases are expected to increase. This request is also consistent with the referenced CON application for a single license between NMH and DH which is part of WCHN's overall plan for maximizing NMH's role within the WCHN integrated delivery system. Specifically, the acquisition of the CT simulator allows WCHN, through NMH, to provide high quality cancer care that is convenient for patients in our communities.

Exhibit A

New Milford Hospital Patient Volume – FY 2012

New Milford Hospital, Inc. Patient Volume in Descending Order

	FY 2012		
	TOTAL Volume	IP Only Volume	
New Milford - CT	31,983	1,219	*
Danbury- CT	3,230	65	
Washington Depot- CT	2,608	65	**
Sherman- CT	2,386	96	
Kent- CT	2,377	128	***
Brookfield Center- CT	2,063	77	
Marbledale- CT	1,867	61	** part of Washington
Roxbury- CT	1,573	50	
Bridgewater- CT	1,494	55	
Wingdale- NY	1,368	46	
Gaylordsville- CT	1,307		* included in New Milford
Cornwall Bridge- CT	999	37	
Pawling- NY	809	38	
Dover Plains- NY	707	25	
Southbury- CT	644	32	
South Kent- CT	593		*** included in Kent
Woodbury- CT	585	25	
Torrington- CT	478		
Bantam- CT	473	30	
Litchfield- CT	401		
Bethel- CT	352	16	
Newtown- CT	313	18	
All Other Towns	4,925	107	
Total	**63,535**	**2,190**	
Identified Towns	47,556	1,720	
Percentage of Total	**74.9%**	**78.5%**	

Exhibit B

Diebold Foundation Commitment Letter and Pledge

The Diebold Foundation, Inc.

102 Painter Hill Road
Roxbury, Connecticut 06783
860-354-1964 FAX 860-354-1096

June 12, 2013

Dr. John M. Murphy, MD, Pres. & CEO WCHN
New Milford Hospital Inc.
21 Elm Street
New Milford, CT 06776

Dear Dr. Murphy,

The Diebold Foundation, Inc. is pleased to provide New Milford Hospital, Inc. with a grant in the amount of Two Hundred Fifty Thousand Dollars ($250,000.00). This grant is to be used specifically to purchase a new large-bore CT Simulator for the Diebold Family Cancer Center.

As a condition of this grant, we request a full report be submitted to The Diebold Foundation, Inc. at the end of the 2013 calendar year (no later than 2/28/2014). A grant evaluation report form is enclosed for this purpose.

It is our understanding that New Milford Hospital, Inc. has been recognized by the Internal Revenue Service as a tax-exempt organization, as described in Section 501(c)(3) of the Internal Revenue Code, and not as a private foundation. If there is any change in this status and/or classification, please notify us at once. In the event that your tax-exempt status is revoked, expenditure of grant funds should cease, and all unspent funds must be returned to The Diebold Foundation, Inc.

As acceptance of this grant, please send a letter of acknowledgement for this donation on your letterhead, including your federal tax identification number, and return it to us at the address listed above as soon as possible. Please be sure to include this statement in your letter:

> *New Milford Hospital, Inc., a 501(c)(3) tax-exempt organization, acknowledges the receipt of a grant from The Diebold Foundation, Inc. in the amount of Two Hundred Fifty Thousand Dollars ($250,000.00) to be used specifically to purchase a new large-bore CT Simulator for the Diebold Family Cancer Center. We note that no goods or services were given to Diebold Foundation, Inc. or its directors in return for this grant.*

On behalf of the board and staff of The Diebold Foundation, Inc., please know that we are delighted to support the important work that you are doing. We wish you much success in your efforts as you undertake the responsibilities of this grant.

Yours truly,

Dudley G. Diebold

Dudley G. Diebold, President

The Diebold Foundation, Inc.

102 Painter Hill Road
Roxbury, Connecticut 06783
860-354-1964 FAX 860-354-1096

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New Milford Hospital, Inc.
21 Elm Street
New Milford, CT 06776

Dear Dr. Murphy:

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$250,000.00	November 2014
$250,000.00	November 2015
$250,000.00	November 2016
$750,000.00	TOTAL PLEDGED

Please feel free to contact Debbie Donahue at 860-354-1964 (Weds.) or dieboldfound@aol.com if you have any questions.

Yours truly,

Dudley G. Diebold

Dudley G. Diebold
President

Exhibit C

WCHN Cancer Continuum

Western Connecticut Health Network Continuum of Cancer Services

Service	Does this service exist? Yes or No	Praxair Cancer Center Danbury Hospital	Diebold Family Cancer Center New Milford
Inpatient Services			
Dedicated Oncology Inpatient Unit	Yes	X	
ONS Oncology Certified Nursing	Yes	X	X
Clinical Nurse Specialist	Yes	X	
Surgery	Yes	X	X
Palliative Care	Yes	X	
Chemotherapy Administration	Yes	X	X
Radiation Therapy	Yes	X	X
Palliative Care/Pain Management	Yes	X	
Stem Cell	No		
Integrative/Complementary Medicine	Yes	X	X
Brachytherapy	Yes	X	X
Breast Center	Virtual	X	X
Medical and Radiation Oncology integrated physician group	Yes	X	X
Outpatient Services			
Psychosocial Counseling	Yes	X	X
Patient Care Navigator/Coordinator	Yes	X	X
Pastoral Services	Yes	X	
American Cancer Society	Yes	X	X
Nutritional Services	Yes	X	X
Bereavement Counseling	Yes	X	X
Financial Counseling/navigation	Yes	X	
Genetics Counseling Program	Yes	X	
Survivorship Program	Yes	X	X
Prevention/Screening/Detection Programs	Yes	X	X
Community Education/Information	Yes	X	X
Rehabilitation Programs	Yes	X	X
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Home Health	Yes	X	X
Transportation Services	ACS	X	X
Support Groups	Yes	X	X
Volunteer Services	Yes	X	X
Boutique	No	X	

Service	Does this service exist? Yes or No	Praxair Cancer Center Danbury Hospital	Diebold Family Cancer Center New Milford
Lymphedema Program	Yes	X	
Physician Resources			
Multidisciplinary Consultation	Yes	X	X
Subspecialties			
- Gynecological	Yes	X	X
- Urologic	Yes	X	X
- Surgical	Yes	X	X
- Surgical Oncology	Yes	X	
- GYN Oncology	Yes	X	
- Breast Oncology	Yes	X	
- Thoracic Oncology	Yes	X	
- Neuro Oncology	Limited	X	
- ENT	Yes	X	
-Plastic/reconstruction	Yes	X	
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Radiation Oncology	Yes	X	X
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Clinical Lab	Yes	X	X
Molecular Profiling	Yes	X	
Radiology	Yes	X	X
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Dedicated Oncology Pharmacy	Yes	X	
Interventional Radiology	Yes	X	
GI specialty procedures	Yes	X	
Pulmonary specialty procedures	Yes	X	
American College of Surgeons			
Cancer Committee	Yes	X	X
Tumor Board	Yes	X	X
Tumor Registry	Yes	X	X
Patient Care Evaluation Studies	Yes	X	X
Other Accreditations	Yes	X	X
Administrative Director	Yes	X	
Medical Director/Physician Director for WCHN	Search in progress		
Other Program Components			
Clinical Research Programs	Yes	X	X
Basic Science/Tumor Biology Lab	Yes	X	

Service	Does this service exist? Yes or No	Praxair Cancer Center Danbury Hospital	Diebold Family Cancer Center New Milford
Academic Affiliation	Yes	X	
Electronic Medical Record	In process		
Performance and Outcomes Measurements	Yes	X	X
Teaching Hospital- multiple residency programs	Yes	X	

WESTERN CONNECTICUT HEALTH NETWORK
DANBURY HOSPITAL • NEW MILFORD HOSPITAL

24 Hospital Ave.
Danbury, CT 06810
203.739.4903

WesternConnecticutHeatlhNetwork.org
DanburyHospital.org
NewMilfordHospital.org

October 25, 2013

Mr. Steven W. Lazarus
Associate Health Care Analyst
Department of Public Health
Office of Health Care Access
410 Capitol Avenue: MS# 13HCA
P.O. Box 340308
Hartford, CT 06134-0308

Re: Certificate of Need Application, Docket No. 13-31855- CON
Responses to OHCA CON Completeness Questions

Dear Mr. Lazarus,

Enclosed please find Responses on behalf of New Milford Hospital, Inc. and Western Connecticut Health Network, Inc. to the Completeness Questions asked by OHCA in a letter dated August 28, 2013 in the above-captioned docket. We have included the original and two hard copies of the Responses, as well as a CD with an Adobe format of the Responses.

Please contact me if you have any questions regarding this submission.

Sincerely,

Sally F. Herlihy

Sally F. Herlihy, MBA, FACHE
Vice President, Planning

Enclosures

Completeness Questions & Responses

1. **On Page 10 of the CON application, the Hospital lists the towns of New Milford, Sherman, Washington, Kent, Roxbury, Bridgewater, and Wingdale (NY) as its primary service area towns. Please provide the rationale for choosing these towns and provide evidence.**

Response:

Western Connecticut Health Network, Inc. (WCHN) includes two affiliated hospitals – New Milford Hospital, Inc. (NMH) and The Danbury Hospital (DH). WCHN's service area includes municipalities in both Connecticut and New York, and its PSA identified as the towns of Bethel, Bridgewater, Brookfield, Danbury, Kent, New Fairfield, New Milford, Newtown, Redding, Ridgefield, Roxbury, Sherman, and Washington, CT, and Brewster, Dover Plains, Patterson, Pawling, and Wingdale, NY.

The towns noted in Q.1. were identified specific to NMH based on their collective volumes representing 75% of the hospital's total volume and 78% of the inpatient volume, and are in close proximity to the town of New Milford with historical utilization of the facility. A chart representing NMH's patient volume for FY 2012 is included as Exhibit A.

2. **On page 17 of the CON application, the Hospital states that it plans to pay for the $1,100,000 acquisition with a $1,000,000 gift received from the Diebold Foundation. Please address the following:**
   a. **Provide the specific purpose of the Diebold Foundation grant being utilized to fund this acquisition. Provide evidence that the funds from this grant may be used for the purpose of acquiring the proposed CT Simulator and that these funds are available.**
   b. **Will there be any difference in the amount of the grant and the proposed capital expenditure that will need to be funded by the Hospital?**

Response:

The Diebold Foundation grant received is specific to the acquisition of CT simulation technology for NMH's Diebold Family Cancer Center. The commitment letter from the Diebold Foundation is included as Exhibit A.

The proposed capital expenditure is $1,100,000. The difference between the donated amount and capital expenditure is $100,000 which will be funded by the hospital.

3. **Please provide the minimum number of CT simulations required annually for this proposal to show an incremental gain from operations for each of the three projected fiscal years.**

Response:

An incremental gain from operations would require an additional 99 cases in year one and an additional 182 cases in year two and thereafter. We understand the acquisition of replacement simulation technology does not produce a positive return on investment, but recognize this investment is a critical element to preserving a community service, maintaining local access, and enhancing the quality of comprehensive cancer care and treatment.

4. **Please provide a thorough discussion on the continuum of cancer services at New Milford Hospital and within the Western Connecticut Health Network ("WCHN"), including access to CT simulation for cancer patients within WCHN. Specifically, please explain how the proposed acquisition is in line with the need of both Hospital and WCHN patients.**

Response:

With a highly experienced and committed multidisciplinary team of over 100 professionals, the continuum of cancer care offered by WCHN includes risk assessment, prevention, screening, detection, diagnosis, treatment, supportive services, research, survivorship, and end-of-life care. An outline of the continuum of cancer care services provided across WCHN is included as Exhibit C.

The acquisition of a CT simulation at NMH is in concert with WCHN delivery of quality care to all patients in the regions we serve. CT Simulation is an "imitation" of radiation treatment without the actual radiation beam and is the first critical step in the treatment planning process for radiation therapy. The information gathered by the CT scan will be used to create a treatment plan, which outlines the parameters for the radiation therapy treatment.

The NMH conventional simulator is no longer manufactured, has reached end of useful life in April of 2013, and is not supported by the vendor. In 2010, NMH installed a new highly sophisticated linear accelerator. Without this new and complimentary CT simulation NMH is limited in its ability to use that existing installed equipment to its maximum capacity and potential for all its patients. The implementation of next generation improvements in radiation treatments requires a CT Simulator specific to radiation oncology.

Oncology patients require a CT image for comparison to deliver the same standards of care at both our sites. In the interim we have been using the 64-slice CT at the NMH site for simulations. The 64-slice CT is not designed for radiation therapy but is designed as a diagnostic unit. A CT simulation designed for radiation therapy has some important capabilities that are lacking on the diagnostic CT unit. For example:

- A larger bore (central opening in the CT ring) gives more room to allow for proper positioning for cancer care patients. NMH has experienced frequent issues where patients do not optimally fit in the CT simulator due to both the location of cancers and the size of the patient with their radiation oncology immobilization devices.
- Motion management cannot be done on the existing CT and is important in lung cancers which can move with breathing.
- Having the CT simulator located within the Diebold Family Cancer Center at NMH improves patient care by reducing wait time for the main hospital 64-slice CT; cancer patients can be delayed due to emergency cases that must be a priority.
- Radiation Oncology LAP lasers, patient alignment laser systems, are the more precise positioning required and enable the oversight of the quality assurance process.
- 4D imaging capability will enable NMH to treat patients that they currently have to refer elsewhere. New capabilities due to the technology will enhance patient treatment services such as stereotactic body radiation that will provide that same standard of care required throughout our network. This new imaging capability is required in treating lung or abdominal areas as it features a very small field accommodating the knowledge to the physician that the tumor is moving so margins are large enough and any geographic miss is avoided.

- Operationally, it is critical to note that the CT simulator couchtop and linear accelerator couchtop are required to match and the NMH linear accelerator couchtop is different than those offered at our Danbury location.
- Also operationally, it is essential that the managing physician be present for CT simulation treatment as it is the basis for future care, and accounts for differences in immobilization practices, devices, and the treatment machines themselves, the NMH linear accelerator has distinct differences than the ones at DH.

In order to provide radiation oncology services, a CT simulator designed specific to a linear accelerator is necessary.

5. **As there is an application filed with OHCA to merge the Hospital under Danbury Hospital's license (all under the WCHN), please explain in detail the need for New Milford Hospital to acquire the proposed CT-Simulator in light of the relatively small annual volume and the proposed service being available at Danbury Hospital.**

Response:

WCHN is committed to providing comprehensive cancer services at NMH, and has been working on a thoughtful plan for NMH within the WCHN integrated delivery system. This plan will ensure continued delivery of high quality services across the entire network and provide access to those services to meet patient needs. As explained in response to Q.4. above, CT simulation is necessary for treatment planning for patients receiving radiation therapy. Maintaining simulation technology at NMH will accommodate and facilitate the provision of cancer care to NMH's primary market area, which includes towns located to the north of New Milford, including but not limited to Kent, Sherman, and Washington, CT and NY border towns, as well as access for patients from other surrounding communities. Maintaining a comprehensive cancer center at NMH also aligns with the anticipated increase in cancer cases associated with an aging population, where the volumes and complexity of those cases are expected to increase. This request is also consistent with the referenced CON application for a single license between NMH and DH which is part of WCHN's overall plan for maximizing NMH's role within the WCHN integrated delivery system. Specifically, the acquisition of the CT simulator allows WCHN, through NMH, to provide high quality cancer care that is convenient for patients in our communities.

Exhibit A

New Milford Hospital Patient Volume – FY 2012

New Milford Hospital, Inc. Patient Volume in Descending Order

	FY 2012		
	TOTAL Volume	IP Only Volume	
New Milford - CT	31,983	1,219	*
Danbury- CT	3,230	65	
Washington Depot- CT	2,608	65	**
Sherman- CT	2,386	96	
Kent- CT	2,377	128	***
Brookfield Center- CT	2,063	77	
Marbledale- CT	1,867	61	** part of Washington
Roxbury- CT	1,573	50	
Bridgewater- CT	1,494	55	
Wingdale- NY	1,368	46	
Gaylordsville- CT	1,307		* included in New Milford
Cornwall Bridge- CT	999	37	
Pawling- NY	809	38	
Dover Plains- NY	707	25	
Southbury- CT	644	32	
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Identified Towns	47,556	1,720	
Percentage of Total	**74.9%**	**78.5%**	

Exhibit B

Diebold Foundation Commitment Letter and Pledge

The Diebold Foundation, Inc.

102 Painter Hill Road
Roxbury, Connecticut 06783
860-354-1964 FAX 860-354-1096

June 12, 2013

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21 Elm Street
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As a condition of this grant, we request a full report be submitted to The Diebold Foundation, Inc. at the end of the 2013 calendar year (no later than 2/28/2014). A grant evaluation report form is enclosed for this purpose.

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As acceptance of this grant, please send a letter of acknowledgement for this donation on your letterhead, including your federal tax identification number, and return it to us at the address listed above as soon as possible. Please be sure to include this statement in your letter:

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On behalf of the board and staff of The Diebold Foundation, Inc., please know that we are delighted to support the important work that you are doing. We wish you much success in your efforts as you undertake the responsibilities of this grant.

Yours truly,

Dudley G. Diebold

Dudley G. Diebold, President

The Diebold Foundation, Inc.

102 Painter Hill Road
Roxbury, Connecticut 06783
860-354-1964 FAX 860-354-1096

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New Milford Hospital, Inc.
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$250,000.00	November 2016
$750,000.00	TOTAL PLEDGED

Please feel free to contact Debbie Donahue at 860-354-1964 (Weds.) or dieboldfound@aol.com if you have any questions.

Yours truly,

Dudley G. Diebold
President

Exhibit C

WCHN Cancer Continuum

Western Connecticut Health Network Continuum of Cancer Services

Service	Does this service exist? Yes or No	Praxair Cancer Center Danbury Hospital	Diebold Family Cancer Center New Milford
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American Cancer Society	Yes	X	X
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Medical Director/Physician Director for WCHN	Search in progress		
Other Program Components			
Clinical Research Programs	Yes	X	X
Basic Science/Tumor Biology Lab	Yes	X	

Service	**Does this service exist? Yes or No**	**Praxair Cancer Center Danbury Hospital**	**Diebold Family Cancer Center New Milford**
Academic Affiliation	Yes	X	
Electronic Medical Record	In process		
Performance and Outcomes Measurements	Yes	X	X
Teaching Hospital- multiple residency programs	Yes	X	

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
Office of Health Care Access

December 11, 2013

VIA FACISIMILE ONLY

Sally F. Herlihy, MBA, FACHE
Vice President, Planning
Western Connecticut Heatlh Network
24 Hospital Avenue
Danbury, CT 06810

RE: Certificate of Need Application, Docket Number 13-31855-CON
New Milford Hospital, Inc.
Acquisition of a Computed Tomography-Simulator at New Milford Hospital

Dear Ms. Herlihy,

This letter is to inform you that, pursuant to Section 19a-639a (d) of the Connecticut General Statutes, the Office of Health Care Access has deemed the above-referenced application complete as of November 29, 2013.

If you have any questions regarding this matter, please feel free to contact me at (860) 418-7012.

Sincerely,

Steven W. Lazarus
Associate Health Care Analyst

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*********************
***   TX REPORT   ***
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STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS

FAX SHEET

TO: SALLY HERLIHY

FAX: (203)739-1974

AGENCY:

FROM: STEVEN LAZARUS

DATE: 12/12/13 Time:

NUMBER OF PAGES: 2
(including transmittal sheet)

Comments:

Please see the enclosed letter deeming the CON Application under DN 13-31855-CON, Complete on 11/29/13.

PLEASE PHONE IF THERE ARE ANY TRANSMISSION PROBLEMS

Greer, Leslie

From: Lazarus, Steven
Sent: Tuesday, February 25, 2014 7:14 AM
To: Greer, Leslie
Cc: Riggott, Kaila
Subject: FW: Docket No. 13-31855-CON

Leslie,

Please put in the record.

Steven

Steven W. Lazarus
Associate Health Care Analyst
Division of Office of Health Care Access
Connecticut Department of Public Health
410 Capitol Avenue
Hartford, CT 06134
Phone: 860-418-7012
Fax: 860-418-7053

From: Herlihy, Sally [mailto:Sally.Herlihy@wchn.org]
Sent: Monday, February 24, 2014 4:47 PM
To: Lazarus, Steven
Subject: Docket No. 13-31855-CON

Hi Steven,
Per your phone call this afternoon regarding the 12-month actual FY13 volume for the simulation program at NMH, please note the chart below:

	Actual Volume (Last 4 Completed FYs)				Projected Volume (First 3 Full Operational FYs)		
	FY10	**FY11**	**FY12**	**FY13**	**FY14**	**FY15**	**FY16**
Inpatient	8	6	6	3	3	3	3
Outpatient	78	117	115	149	149	149	149
Total Complex CT Sims	**86**	**123**	**121**	**152**	**152**	**152**	**152**

The FY13 year-end actual volume was very close to the projected volume (152 vs. 156) and the FY14, FY15, FY16 projected volumes would be adjusted to 152 as well.
If you have any questions please give me a call.

Regards,
Sally

____
Sally F. Herlihy, FACHE
Vice President, Planning
Western Connecticut Health Network

203-739-4903

Executive Assistant: Michelle Johnson
Voice: (203) 739-4935
Email: michelle.johnson@wchn.org

WESTERN CONNECTICUT HEALTH NETWORK
DANBURY HOSPITAL • NEW MILFORD HOSPITAL

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Office of Health Care Access

February 28, 2014

IN THE MATTER OF:

An Application for a Certificate of Need filed Pursuant to Section 19a-638, C.G.S. by:

Notice of Final Decision
Office of Health Care Access
Docket Number: 13-31855-CON

New Milford Hospital

Acquisition of a Computed Tomography-Simulator at New Milford Hospital

To:

Sally F. Herlihy, MBA, FACHE
Vice President, Planning
Western Connecticut Heatlh Network
24 Hospital Avenue
Danbury, CT 06810

Dear Ms. Herlihy:

This letter will serve as notice of the Final Decision of the Office of Health Care Access in the above matter, as provided by Section 19a-638, C.G.S. On February 28, 2014, the Final Decision was rendered as the finding and order of the Office of Health Care Access. A copy of the Final Decision is attached hereto for your information.

Kimberly R. Martone
Director of Operations

Enclosure
KRM:swl

Department of Public Health
Office of Health Care Access
Certificate of Need Application

Final Decision

Applicant: **New Milford Hospital, Inc.**
21 Elm Street, New Milford, Connecticut

Docket Number: **13-31855-CON**

Project Title: **Acquisition of a Computed-Tomography Simulator**

Project Description: New Milford Hospital, Inc. ("Hospital" or "Applicant"), proposes to acquire a Computed-Tomography ("CT") Simulator to be located at New Milford Hospital, 21 Elm Street, New Milford, Connecticut. The total capital expenditure associated with this proposal is $1,100,000.

Procedural History: On July 29, 2013, the Office of Health Care Access ("OHCA") received the initial Certificate of Need ("CON") application from the Hospital for the above-referenced project. The Hospital published notice of its intent to file the CON Application in the *News Times* (Danbury) on April 26, 27 and 28, 2013. The application was deemed complete on November 29, 2013. OHCA received no responses from the public concerning the Hospital's proposal and no hearing requests were received from the public per Connecticut General Statutes § 19a-639a(e). In rendering her decision, Deputy Commissioner Davis considered the entire record in this matter.

To the extent the findings of fact actually represent conclusions of law, they should be so considered, and vice versa. *SAS Inst., Inc., v. S & H Computer Systems, Inc.*, 605 F.Supp. 816 (Md. Tenn. 1985).

Findings of Fact and Conclusions of Law

1. The Hospital is an acute care hospital located at 21 Elm Street, New Milford, Connecticut. Ex. A, p. 3.

2. The Hospital is proposing to acquire a new CT Simulator to replace its existing conventional Radiation Oncology Simulator. Ex. A, p. 6.

3. Western Connecticut Health Network, Inc. ("WCHN") is the parent corporation of New Milford Hospital and Danbury Hospital. Office of Health Care Access, Fiscal Year 2012 Annual Reporting.

4. The Hospital's primary service area consists of the following Connecticut towns: New Milford, Sherman, Washington, Kent, Roxbury, and Bridgewater. Ex. A, p. 10.

5. WCHN offers a full continuum of cancer care services, including risk assessment, prevention, screening, detection, diagnosis, treatment, support services, research, survivorship, and end-of-life care. Exhibit C, p. 53.

6. The Hospital's Diebold Family Cancer Center ("Center") is accredited in radiology, mammography and radiation oncology services by the American College of Radiology and the National Accreditation Program for Breast Centers. Ex. A, p. 6.

7. In December 2012, the Center was re-approved "with commendation" by the American College of Surgeons ("ACoS"), Commission on Cancer. The designation, offered by ACoS every three years, distinguishes exceptional hospital performance in ongoing improvement and public accountability for cancer treatment services. Ex. A, p. 6.

8. A Simulator is used as part of the treatment planning process for determining a patient's course of radiation therapy. The images generated by a Simulator assist physicians in determining the optimal treatment path. Ex. A, p. 6.

9. Currently, the Hospital's patients first visit the Radiation Oncology Department where immobilization devices are constructed. A patient, usually dressed in a hospital gown, must then be escorted down the hall to the Radiology Department to obtain CT imaging for planning. Since the CT bore is sized for diagnostic scans, the patient often has to be repositioned along with the treatment immobilization devices to fit the patient through the scanner, causing discomfort for the patient. Ex. A, pp. 6-7.

10. The Hospital's existing Simulator was acquired in 1998 and has been in operation for more than 15 years. The Simulator reached end-of-life in April 2013, with

technical support for the equipment discontinued and x-ray film used by the Simulator difficult to obtain. Ex. A, pp. 6, 9.

11. The proposed CT Simulator offers multiple clinical, operational and administrative advantages, all of which lead to enhanced cancer care delivery:

    a) Treatment efficiencies;
    b) Digitalization;
    c) Comfort and convenience; and
    d) Potential for expanded treatment options.
    Ex. A, p. 7.

12. The proposed CT Simulator will offer advanced imaging capabilities that will eliminate the need for patients to visit both the Radiation Oncology and Radiology Departments, thus consolidating treatment planning. Ex. A, p. 7.

13. The proposed CT Simulator will allow the Hospital's Radiation Oncology Department to become completely digitalized, eliminating the need for x-ray film, service contracts for film processors and silver reclaiming, as well as the need for fixer and developer. Additionally, the use of digital images will support the use of electronic medical records. Ex. A, p. 7.

14. With the proposed CT Simulator, patients will be able to have their entire planning procedure completed within the Radiation Oncology Department. The large bore CT Simulator provides for enhanced diversity in positioning and better accommodates immobilization devices and larger-sized patients. Ex. A, p. 7.

15. Additionally, "4-D CT capability," a radiation oncology-specific software package, will allow the Hospital to provide expanded stereotactic body radiation therapy ("SBRT"). SBRT treatment provides highly accurate, precise and focused radiation delivery to tumors while minimizing radiation to adjacent healthy tissue. SBRT patients experience fewer treatment visits and side effects than with conventional radiation therapy. Ex. A, p. 7.

16. The Center currently offers SBRT treatment only for brain lesions. The proposed CT Simulator will allow this treatment to be offered for other parts of the body as well. Ex. A, p. 7.

17. There is also the potential for expanded treatment options with 4D CT capability which will allow the Radiation Oncology Department to outline treatment volumes for areas of the body affected by breathing motion, in order to allow for more accurate imaging, treatment planning and delivery to these areas. Ex. A, p.16.

18. The proposed CT Simulator features a state-of-the-art CT scanner with a localization package, patient marking system and a virtual simulator capable of producing real-time digitally composited radiographs, thus offering high-

resolution imaging and short examination time for a full range of procedures including volumetric localizations, simulation and verification for conformal, high-precision and stereotactic radiotherapy planning. Ex. A, p.15.

19. The Hospital has experienced overall growth in CT Simulation volume since 2010:

Table 1: Historical CT Simulations

	2010	2011	2012	2013
CT Simulations*	86	123	121	152

*Conventional Simulator and CT Scan
Ex. A, p. 13 & Ex. E.

20. The volume increase is multifactorial, including the expanded technology available with the Hospital's Trilogy System, a linear accelerator system becoming operational in October 2010. The system enhanced the delivery of radiation oncology with image guidance, stereotactic capability and robotic couch positioning. The Hospital's affiliation with Danbury Hospital positively impacted patient volumes as well, through increased collaboration between the two institutions. Ex. A, pp. 14-15.

21. The Hospital is projecting stable utilization for FYs 2014-2016 based on historical volume:

Table 2: Projected CT Simulations

	FY 2014	FY 2015	FY 2016
CT Simulations	152	152	152

Ex. E.

22. The projected volume is also based partly on the assumption that approximately one half of all new cancer patients will receive radiation therapy. Each of those patients will require one CT simulation in order to formulate their individualized treatment plan. Ex. A, p. 15.

23. The proposed CT Simulator will not result in unnecessary duplication of service as it is replacing an existing piece of equipment. The only other provider in the service area is the Hospital's affiliate, Danbury Hospital. Ex. A, pp. 9, 12.

24. The proposed total capital expenditure associated with this proposal is as follows:

Table 3: Total Capital Expenditure

CT Simulator	$900,000
Other Non-Construction	$200,000
Total Capital Expenditure	**$1,100,000**

Ex. A, p. 17.

25. This proposal is financially supported by a $1,000,000 grant received from the Diebold Foundation. Ex. A, p. 17.

26. The Hospital will provide funding for the $100,000 difference between Diebold Foundation funding and the actual total capital expenditure required for the purchase of the equipment. Ex. C, p. 52.

27. Although the Hospital is projecting annual losses for the next three years, only $406,000 is attributed to this proposal, due to depreciation and a maintenance contract:

Table 4: Hospital Revenues with the Proposal

	FY 2014	FY 2015	FY 2016
Revenue from Operations	$72,137,000	$73,799,000	$75,759,000
Total Operating Expenses*	$(78,121,000)	$(80,533,000)	$(82,797,000)
Gain/(Loss) from Operations	**$(5,984,000)**	**$(6,734,000)**	**$(7,272,000)**

Note: Projected incremental losses attributed to depreciation and maintenance contract are $406,000 annually.
*Operating expenses include salaries/fringe benefits, professional/contracted services, supplies/drugs, bad debts, other operating expenses, depreciation/amortization, interest expense and lease expense.
Exhibit A, pp. 19, 48.

28. WCHN reported an actual Gain from Operations of $42,512,453 for FY 2012. Office of Health Care Access, Fiscal Year 2012 Annual Reporting.

29. The acquisition of the proposed CT Simulator will reduce the Hospital's operating costs due to operational efficiencies. Ex. A, p. 17.

30. The Hospital's patient population mix will remain unchanged as a result of this proposal:

Table 5: Applicant's Projected Payer Mix

Payer	Actual FY2013	Year 1 FY 2014	Year 2 FY 2015	Year 3 FY 2016
Medicare	46.7%	46.7%	46.7%	46.7%
Medicaid	10.1%	10.1%	10.1%	10.1%
CHAMPUS & TriCare	0.2%	0.2%	0.2%	0.2%
Total Government	**56.9%**	**56.9%**	**56.9%**	**56.9%**
Commercial Insurers	39.9%	39.9%	39.9%	39.9%
Uninsured	1.9%	1.9%	1.9%	1.9%
Workers Compensation	1.4%	1.4%	1.4%	1.4%
Total Non-Government	**43.1%**	**43.1%**	**43.1%**	**43.1%**
Total Payer Mix	**100.0%**	**100.0%**	**100.0%**	**100.0%**

Ex. A, p. 18.

31. This proposal is cost effective as it replaces an outdated and end-of-life conventional simulator with a new state-of-the-art CT Simulator that will improve operational efficiencies. Ex. A, p. 19.

32. OHCA is currently in the process of establishing its policies and standards as regulations. Therefore, OHCA has not made any findings as to this proposal's relationship to any regulations adopted by OHCA. (Conn. Gen. Stat. § 19a-639(a)(1))

33. The application is consistent with the overall goals of the State Health Care Facilities and Services Plan. (Conn. Gen. Stat. § 19a-639(a)(2))

34. The Applicant has established that there is a clear public need for its proposal. (Conn. Gen. Stat. § 19a-639(a)(3))

35. The Applicant has satisfactorily demonstrated that its proposal is financially feasible. (Conn. Gen. Stat. § 19a-639(a)(4))

36. The Applicant has satisfactorily demonstrated that its proposal will maintain access and improve the quality of health care delivery in the region and it has satisfactorily demonstrated an improvement in cost effectiveness. (Conn. Gen. Stat. § 19a-639(a)(5))

37. The Applicant has shown that there will be an improvement in the provision of health care services to the relevant populations and payer mix. (Conn. Gen. Stat. § 19a-639(a)(6))

38. The Applicant has satisfactorily identified the population to be served and has satisfactorily demonstrated that this population has a need as proposed. (Conn. Gen. Stat. § 19a-639(a)(7))

39. The Applicant's historical provision of treatment in the service area supports this proposal. (Conn. Gen. Stat. § 19a-639(a)(8))

40. The Applicant has satisfactorily demonstrated that the proposal will not result in an unnecessary duplication of existing services in the area. (Conn. Gen. Stat. § 19a-639(a)(9))

Discussion

CON applications are decided on a case by case basis and do not lend themselves to general applicability due to the uniqueness of the facts in each case. In rendering its decision, OHCA considers the factors set forth in General Statutes § 19a-639(a). The Applicant bears the burden of proof in this matter by a preponderance of the evidence. *Jones v. Connecticut Medical Examining Board, 309 Conn. 727 (2013).*

The Hospital, a subsidiary of WCHN, is seeking authorization to acquire a CT Simulator to replace its conventional Radiation Oncology Simulator. *FF1-3.* The existing Simulator, acquired in 1998, is past its useful life and the vendor no longer provides technical support. Additionally, x-ray film utilized by the current Simulator is difficult to obtain. *FF10.*

The Hospital operates the comprehensive, nationally accredited and certified Diebold Family Cancer Center, which utilizes a conventional Simulator as part of patients' treatment planning process for determining the course of radiation therapy. *FF6-8.* Currently, patients must undergo portions of their simulation planning in two different locations within the Hospital. Patients first visit the Radiation Oncology Department where immobilization devices are constructed. Patients then must be escorted to the Radiology Department to be scanned on a traditional CT scanner to obtain imaging for planning. Since the Radiation Department CT scanner is sized for diagnostic scanning, the patient has to be repositioned and treatment immobilization devices have to be fitted, causing discomfort for the patient. *FF9.*

The CT Simulator will consolidate treatment planning and eliminate the need for transferring/transporting patients between departments, as it allows for enhanced diversity in positioning and better accommodates immobilization devices and larger-sized patients. *FF12,14.* In addition to the aforementioned treatment efficiencies, the proposed CT Simulator offers operational, administrative and clinical advantages. *FF11.* It will allow the Hospital's Radiation Oncology Department to become completely digitalized, resulting in operational efficiencies and enhancing support for electronic medical records. *FF13.* Additionally, the acquisition of a CT Simulator and its radiation oncology-specific software will allow the Hospital to expand its Stereotactic Body Radiation Therapy beyond the brain, the only area of the body for which it is currently offered. This treatment provides highly accurate, precise and focused radiation delivery to tumors, resulting in the minimization of radiation to adjacent healthy tissue. As an added benefit, this treatment results in fewer treatment visits and side effects for patients. *FF15&16.* It will also allow the Hospital to more accurately plan treatment and delivery to areas of the body affected by breathing motion. *FF17.* It is clear that the advancement in technology provided by the proposed CT Simulator will provide a higher quality treatment option for the patient. Therefore, the Applicant has demonstrated that its proposal will maintain access while improving the quality of health care delivery in its service area.

Danbury Hospital, also owned by WCHN, is the only other provider with a CT Simulator in the Hospital's service area. Since the CT Simulator is replacing existing out-of-date equipment, there will be no impact on area providers, no duplication of service in the service area and no change in the patient payer mix. *FF3,23,31.* Therefore, the Applicant has satisfactorily demonstrated that its proposal will not result in an unnecessary duplication of existing CT Simulation services in its service area.

The Hospital has seen growth in simulations since FY2010 and is projecting stable utilization for the first three years of the proposal. *FF19,21.* Based on the actual historical utilization, the projections appear to be reasonable and achievable.

Although the capital expenditure associated with the acquisition of the CT Simulator is $1,100,000, the proposal is financially supported by a $1,000,000 grant from the Diebold Foundation. *FF24&25.* The Hospital will only be responsible for contributing $100,000 toward the cost of the CT Simulator. *FF26.*Due to the equipment depreciation and cost of the annual maintenance contract, the Hospital is projecting incremental losses. *FF27.* However, considering WCHN reported an actual gain from operations of $42,512,453 for FY 2012; the Applicant has demonstrated that its proposal is financially feasible. *FF28.*

The Applicant has demonstrated clear public need for the acquisition of the CT Simulator due to the overall superior care it delivers. Replacing the conventional Simulator with a CT Simulator will improve the quality of care provided to cancer patients at the Hospital and in the service area by providing the standard of care associated with modern treatment planning and delivery. The Applicant has satisfactorily shown that access to care will be maintained, quality of care will be improved and a potential improvement in cost effectiveness may be achieved through operational efficiencies.

Order

Based upon the foregoing Findings of Fact and Discussion, the Certificate of Need application of The New Milford Hospital, Inc. for the acquisition of a Computed Tomography Simulator to be located at 21 Elm Street, New Milford, Connecticut is hereby **APPROVED**.

All of the foregoing constitutes the final order of the Office of Health Care Access in this matter.

By Order of the
Office of Health Care Access

2/28/14
Date

Lisa A. Davis, MBA, BSN, RN
Deputy Commissioner, OHCA

* * * COMMUNICATION RESULT REPORT (MAR. 3. 2014 11:05AM) * * *

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Comments:

Final decision regarding DN: 13-31855, enclosed.

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