#### **Application Checklist**

#### Instructions:

1. Please check each box below, as appropriate; and

OFFICE OF 2. The completed checklist must be submitted as the first page of the ARE ACCESS CON application.

 $\boxtimes$ 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.: **OHCA** Verified by Check No.: 04-40214110

 $\boxtimes$ 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)

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

- $\boxtimes$ Attached are completed Financial Attachments I and II.
- $\boxtimes$ 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 the following email addresses: steven.lazarus@ct.gov and leslie.greer@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.

- $\boxtimes$ 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.

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Figath Center 263 Farmington Avenue Farmington, Connecticut 06030-5332	Chack Date	_

Check Date

04-40214110

Check Amount 09/05/12 \$\*\*\*\*\*\*\*500.00

\*\*Pive Hundred & 00/100 Dollars\*\*\*\*\*

TOTHE State of Connecticut
ORDER Office of the State Treasurer
OR 55 Elm St

OF HART FOR GF 06106

IN 11 of States of America

THE BACK OF THIS CHECK CONTAINS A SECURITY MARK - DO NOT ACCEPT WITHOUT HOLDING AT AN ANGLE TO VERIFY SECURITY MARK

#40214110# #011900445# 0000405346#

SEE REVERSE SIDE FOR OPENING INSTRUCTIONS



University of Connecticut Health Center 263 Farmington Avenue Farmington, CT 06030-5332

IMPORTANT DATED DOCUMENT ENCLOSED

State of Connecticut Office of the State Treasurer 55 Elm St Hartford CT 06106 United States of America

#### **HARTFORD COURANT PROOF**

∩ustomer:

ST OF CT UCONN HLTH CTR/MARKET&COMM

ontact:

**QB-MONTE GIANNINI** 

Phone:

8606792984

Ad Number: **2511091** 

Insert Dates: 08/01/2012 08/02/2012 08/03/2012

Price:

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Section:

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Class:

2174; CONNECTICUT

Date:

Size:

 $1 \times 0.75$ 

Printed By:

**JSMIETAN** 

Date:

07/27/2012

Signature of Approval:\_

Statute Reference: 19a-639
Applicant: John Dempsey Hospital
Town: Farmington
Street Address: 263 Farmington Aveneue
Description: The applicant is seeking
approval from the Office of Health Care
Access for the acquisition of a CT Simulator

Amont Active Addum 62+ Practimes Villege & Whitspering Pines II, 1 & 2 BM carbin and a chie units, private sentance, fully applianced kitchen, washer/ draw, put friendly Call Sandy 869-974-8639

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Check it out today

courant.com 5

Centers Active Adute 55- Boulder Ridge, 1 & 2 BR ranch tryle units, private trachor, Culy applianced litcher, worker/dyn, pet thendy Cell Sensy 860-674-8838

EAST CRANBY -1 & 2 BR opartments available Call 677-1391.

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copy of the statement to the Connecticut Insurance Department. P. G. Box 1816, 115 Market Street, National Formal Solid. Alternion: National Solid. All such witten statements must be received by the Department on or before August 15, 3012.

Dated at Harfford, Commedicut, this 10th day of July, 2012.

Edward J. Samorakzyk, Jr., Incorporator

#CITCE

Statute Reference: 198-639
Applicant, John Dempsey Hospital
Town: Farmington
Street Address: 263 Farmington AveBeach Committed to the Street Address: 263 Farmington AveBeach Committed The Applicant is seeking Approval from the Office of Health Care
Access for the acquisition of a CT Simu-

courant com THE HARTFORD COURANT WEDNESDAY, AUGUST 1, 2012 | C9

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OPEN MONDAY-FADAY 9:30 2:30 OPEN SUNDAY 12:30-4:30 Call 860-674-6635

August 1, 2012

Sealed bids for the project name by by the project of the office the Director of Finance until 11:00. Thursday, August 30, 2012, There the blook, will be opened in public age in about.

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Section 8 Welcome, EHC, Cast
880-880-7774 or 860-304-6173

therdord Deep South End offic. & 18R

TSIOU, IRENA, Plaintiff

Ys. TSIOL, George, Defendant

Return Date: 8/21/2012 NOTICE TO: TSIOU, GEORGE

The Court has reviewd the Motion for Order of Notice and the Complany Application/Mexiton which asks for divorce (dissolution of marriage)

The notice should appear beafore Aupust 2, 2012 and proof of service shall be filed with this Court.

The notice shall appear once a week for two successive weeks commencing on or before August 2, 2012, and proof of service shall be filed with this Court.

NewDord Formington Ave. Westend 18R Starting at \$750 inc. H/HW. \$61-8774 HARTFORD Southwest. 1st ft., 5 ms. \$750, \$86.249-1386 sz; 859-9178

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Hardroot Houses
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1845 Washington 8t

\* MANCHENTER \* SEBG-61360/ Inchica Bit condos or multi-family. Some w/hest & hot wo.

Water, \$275/5405 BED-704-0102 ANNE MILLER REAL ESTATE

BOLTON NOTCH Office - Retail. High traf fic. Owner/agent. Cell 860-649-53? 1;

TOUR HELL WEDNESDAY THURSDAY.

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#### PUBLIC NOTICES

#### Hartford

#### STATE OF COMMECTICUT SUPERIOR COURT

Notice to Militon Torres Sr, father of child born to Carolyn Hernandez on 7/21/12 of parts unknown.

A petition has been filed seeking: Commitment of minor child(ren) of the above named or vesting custody and care of said child(ren) of the above named in a lawful, private or public agency or a suitable and worthy per-son.

The petition, whereby the court's decision can affect your parental rights, if any, regarding manor children; will be heard on: 76/12 at 11:00 AM at 920 Broad St., Hartford, CT 06106

Hearing on an Order of Temporary Cus-tody will be heard on: 2/3/12 at 10:15 AM at 920 Broad St., Hartford, CT 05106

Therefore, ORDERED, that notice of the hearing of this petition be given by publishing this order of Notice once, immediately upon receipt, in the Hantlord Courant, a newspaper having circulation in the town/city of: Hereford, CT

Hon. Christine Keller, Judge Debra A. Rubert, Clerk 7/27/12

Right to Counsel: Upon proof of inability to pay for a lawyer, the court will make sure that an attorney is provided to you by the Chef Public Defender. Request for an attorney should be made imme-diately in person, by mail, or by fax at the court office where your hearing is to be held.

## STATE OF CONNECTICUT SUPERIOR COLREY JUVENILL MATTERS

Notice to Joseph Rivera, father of child born to Carolyn Hernandez on 7/21/12 of parts unknown.

A petition has been filed seeking: Commitment of mirror child(ren) of the above pamed or vesting custody and care of said child(ren) of the above named in a lawful, private or public agency or a suitable and worthy per-son.

The petition, whereby the court's decision can affect your parental rights. If any, regarding minor child(ren) will be heard on: 9/6/12 at 11:00 AM at 920 Broad St., Hartford, CT 06106

Hearing on an Order of Temporary Cus-tody will be heard on: 8/3/12 at 10:15 AM at 920 Broad St., Hartford, CT 06106

Therefore, ORDERED, that notice of the hearing of this petition be given by publishing this Order of Notice once, immediately upon receipt. In the Harriord Courant, a newspaper having circulation in the town/city of: Harriord, CT

Hon, Christine Keller, Judge Debra A. Rubert, Clerk 7/27/12

Right to Counsel: Upon proof of inability to pay for a lawyer, the court will make sure that an attorney is provided to you by the Chief Public Befender. Request for an attorney should be made immediately in person, by mail, or by fax at the court office where your hearing is to be held.

#### STATE OF COMMECTICAL

RETURN DATE: SEPTEMBER 4, 2012 SUPERIOR OF JUDICIAL DISTRICT OF HART

WENDOVER FINANCIAL SERVICES CORPORATION

MICHAEL D. SROKOWSKI, ET AL

MICHAEL IL SHINDHESING ET IN.
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SCHIEGE IN THIS COLUM LAINT, ADVE
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OR CONTINGENT.

The Plaintiff has named as a Defendant, THE WIDOWER, HERS AND/OR CREDITORS TO THE ESTATE OF SUSIE E. SROKOWSKI, AND ALL UNKNOWN DETSONS, Claiming or ROWSKI A/K/A SUSIE EVA SROKOWSKI, and all unknown persons, claiming arwine may claim, any rights, title, interest or estate in or lien or encumbrance upon the property described in this Complaint, adverse to the Plaintiff, whether such claim or possible claim can be vested or contingent, if not living, as a party defendant(s) in the complaint which it is bringing to the abovenamed Court seeking a forcelosure of its mortgage upon premises known as 682 PALISADO AVENUE, WINDSOR, CT 06005.

The Plaintiff has represented to the said Court, by means of an affidavit annexed to the Convolaint, that, despite all resonable efforts to ascertain such information, it has been unable to determine the identity and/or whereabouls of the WIDOWER, HERS AND/OR CREDITORS TO THE ESTATE OF SUSIE E. SROMOWSKI AVIVA SUSIE EVA. SROKOWSKI, and all unknown persons, claiming or who may claim, any rights, title, infarest or estate in or lien or encumbrance upon the property described in this Complaint, adverse to the Plaintiff, whether such claim or possible claim can be vested or contingent, if not living.

If not living.

Now, Therefore, it is hereby ORDERED that notice of the institution of this action be given to said THE WIDOWER, HERS AND/OR CREDITORS TO THE ESTATE OF SUSIE E SPOKOWSKI ANA SUSIE EVA SRCROWSKI and all unknown persons, claiming or who may claim, any rights, title, interest or estate in or lish or encumbrance upon the property described in this Complaint, adverse to the Plaintiff, whether such claim or possible claim can be vested or contingent. by some proper officer causing a true and attested copy of this Order of Notice to be published in THE HARTFORD COURANT, once a week for 2 successive weeks, commencing on or before August 2, 2012, and that return of such service be made to this Court.

BY THE COURT

By: Adam Bulewhich, Assistant Clerk

A TRUE COPY
ATTEST:
JOHN T. FIORALO
CONNECTICUT STATE MARSHALL
HARTFORD COUNTY

#### **Heithein**

All bid notices for the Town of West Hartford are available at http://www.west-hartford.com/. Bid notices may also be obtained through public accessors as any Town librar accessors may be to the control of the contro

#### Own at 850-561-7470

Statute Reference: 19a-539 Applicant: John Dempsey Hospital Town: Farmington Street Address: 263 Farmington Ave-

preet Audress: 263 Farmington Ave-neue Description: The applicant is seeking approval from the Office of Neatin Care Access for the acquisition of a CT Simulator

#### STANSA A PARAMENTAL

Notice is now that seek farmington Bank, 32 Main Street, Farmington, CT. 05032, has submitted an application to the Federal Deposit Insurance Corporation for consent to establish a branch office located at 1095 & 1099 Main St. Newington, CT 05111

Newington, G 193111

Any person wishing to comment on this application may file his or her comments in writing with the regional director of the Federal Deposis Insurance Corporation at its regional office, 15 Braintree Hill Office Park, Braintree, M.A. 02184-8701, no later than August 17, 2012. The nonconfidential portions of the application are on file in the regional office and are available for public inspection during regular business hours. Photocopies of the nonconfidential portion of the application will be made available upon request.

John J. Patrick, Jr. Chairman, President and CEO Farmington Bank

#### LIGHT HOTHER

Community Health Services inc. a federality qualified health center, will Issue a Required the proposale (RPP) for Design Build Services. The successful proposes of this RPP will complete the Design Build Services. The successful proposes of this RPP will complete the Design Build or a 3,700 st Medical Office space in Windsor, CT. The estimated length of the project is from September 1, 2012 through January 31, 2013. The Requires for Proposals will be issued on or about August 3, 2012, Proposals are due by 5:00 pm est on August 13, 2012.

Community Health Service, Inc. is an equal apportunity employer. Minority and momentumed businesses are encouraged to reply.

For further information and to obtain a copy of the Request for Proposals, confact:

Andrea Montgomery Chief Operating Offic 500 Albany Average Hartford, CT, 06120

Telephone: 860-808-9794 Email: andrea.montgomery@chshartford.org

> FOME Every Thursday.

Constitut

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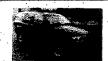
HONDA CIVIC S 2009 AT, A/C, pwr, 20kml excoond, \$12,995, 860-643-0506

HORDA ELEMENT EX 2004 AWD, 401, 5 spd. Fully loaded, sund. Ext. cond. \$10,995, BR Motors 203-753-2277



MYUNDAI ELANTRA BLUE 2010

INFINITE G35 X 2008 130,000K excellent cond. premium package. \$10.500,802-535-2917



SEEP GRAND CHEROKEE LAREDO 400 2001 DK Blue fully loaded ext cond. Lthr int.Htd seath Sunroot, CD & more. 114K mi. \$4800 860-829-0260

MA OPTIMA 2005 Auto, A/C, 4dr, runs good, 4cyl, \$2950 obo, 860-880-0670



Ditts E8336 2004 Only 77,000 mt, Blue w gray interior, VERY Clean Car, Non-Smoker, Orig Owner \$ 13K 080 \$80-480-3833.



LEXUS RX 200 2003 AWO Silver/ Bik 121K hwy mi \$11900 860-992-9645

MAZDA 6 2004 LTD 4ct auto libr snd 1 70K hwy mi \$3950 860-868-3308

## NAZDA MAZDASPEED PROTEGE

Ong Owner, 101k miles, Sept turbo, Bias, Good condition, reliable car, new-retrainment of the church 3.5yrs ago, clean, nonsmolest, Add set of low profile rims included. Must see \$8.000 - Call GR at \$80.693.8011 or small at mago 74@comcest.net

MAZDA WHATA 2006 Touring Slir, ten top. Dec. cond., 64kml, garage kept 6 speed. AC, per windws, \$15,000 Call 860-653-1976

courant.com **NEWS UPDATES 247** 



MERCEDES 2400 1963. "This is Actually a 30007" "Dispet, ritier, gold. 198K, \$5800 C/T 800-300-4510

JERCEDES BEAR E-CLASS 300E 1982 For additional information con-tact freidy at 321 063-7487

MERCURY GRAND MARQUIS GS, 2001, 47kml, 1 Owner, fully loader 57495, Call 203-753-2277

Marcury Smand Manusle LS 1993, gold. 230kmi, new rebuilt trans & cooling system, etc. \$1495 OBO. 860-649-6586, Call after 11 am.

missam saxuma ove 1866 4cr., uto 10 diec od changer, new trez, ali pwr. 148k milez, 1 owner, \$2200 Cell: 860-529-7681

NISSAN ALTIMA '97 ALZO, AC, Part, 90k ml, Excellent Condition, \$7999. 860-847-9583

#### PUBLIC NOTICES

CITY OF HARTYCES
PLANSING AND ZONERS COMMISSION
The Planning and Zoning Commission
held a Public Hearing on Tuesday, July
24, 2012 and took the following action:
I) Approved with conditions: 1093 Albany Averus-Special Permit application for the continuation of a cafe use
with a new liquor license in the 8-4 zoning district.
II) Denied: Text Amendment to Section
1001(77)(ii) in the City of Hartford Zoning Requisitions to allow the conversion
of existing static outdoor advertising
signs to chargeable electronic outdoor
advertising signs at a distance of no
less than 500 feet from other static or
chargeable electronic outdoor advertising signs when the current permitted
minimum distance or 500 feet.
III) Tabled: aLand on north side of Ely
Street at the corner of Main Street Abuting the train tracks to the contin and
property of Sacred Heart Church to the
east known at 1-400 Main Street & 1 6
Ely Street. Application to change the
Ric City, One Plan POCD land use man
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putse Administration, Health Care to
CORMI-Agent II.

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CORMI-Agent II. caretary Roger J. O.s

Statute Reference: 19a-639 Applicant: John Demosey Inspital Applicant: John Dampsey (respital Town: Farmington Street Address: 263 Farmington Ave-

neue Description: The applicant is seeking approved from the Office of Health Care Access for the acquisition of a CT Simp-

ublic sale of the contents of af Cube-af Cube-Flanders Rd. Mystic, CT 05355, phone (850) 536-2424 on August 17th, 2012 at 200 PM. Each space will be sold as one lot. All Items in storage units contain nuusehold items unless otherwise mentioned.

Cube 4702 Judy A Slocum Plus 2 misc cubes, one w LPst

#### invitation to Hid

Bloomfield Public Schools invites pro-posals from qualified architect/engi-neering firms licensed in the State of Connecticut for the following:

Inspection and Certification of Ou Metal Bleachers at Bioomfield School

#### 

Community Health Services Inc., a federally qualified health center, will issue a Buguest for Proposals. Clery for Design Build Services. The successful proposer of this RFP will complete the Design Build of a 3,700 st Medical Office space in Windsor, CT. The estimated length of the project is from September 1, 2012 through January 31, 2013. The Request fee Proposals will be issued on or about August 3, 2012. Proposals are due by 5:00 pm est on August 13, 2012.

Community Health Service, Inc. is an equal opportunity employer, Minority and women-owned businesses are encouraged to reply.

For further information and to obtain a copy of the Request for Proposals, contact:

Andrea Montgomery Chief Operating Officer 500 Albany Avenue Hartford, CT, 06120

Telephone: 950-808-8794 Email: unitres.montgomery@chshartford.org

#### LEGAL MOTICE

The Public Utilities Regulatory Authority vill conduct an administrative proceeding, pursuant to its Decision rendered in Docket No. 07-09-19, OPIC.
Reg w and investigation of the New Andrews of the New Andrews

The State of Connecticut Eudiclai Branch is requesting proposals from qualified organizations or individuals to perform an evaluation that will provide a comprehensive report that ascertains the efficiency and effectiveness of the Foreclosure Mediation program in meeting its stated goals and objectives.

Sealed proposals must be received be-fore 2:30 p.m. on August 24, 2012. Im-mediately thereafter, all proposals will be publicly opened and prices read aloud. Late proposals will NOT be ac-

RESPONDENTS CURRENTLY REGISTERED UNDER THE STATE'S SMALL BUSHNESS SET-ASIDE PROGRAM ARE ENCOURAGED TO APPLY.

Proposal package may be obtained at Judicial Materials Management Lint. Purchasing Services at 30 Washington Street. 487 Floor. Hartford. CT of CMI (080) 705-500 to request by mail, or access the web site below.

PLEASE CHECK THE JUDICIAL WEB SITE www.kud.ct.gov/external/news/bu

MATERIALS MANAGEMENT UNIT PURILLS MANAGEMENT UNIT PURILS SERVICES:
90 WASHINGTON STREET HANTERIAL COLOR AND COLOR AN

DEPARTMENT OF AGRICULTURE
The Harriord Regional Market
Notice of Intest to Lisea - Invitation (
Submit Proposals
For Stalls at the
Harriord Regional Market

The Connecticut Marketing Authority will accept hotices of intent to lease proposals from interested agricultural cooperatives, wholesalers of farm produce or other commodilies for the general benefit of the Regional Market, located at 101 Reserve Road in Hartford.

cated at 107 Reserve Road in hartford.

Stall space will be available for a period beginning this fail, Eleven stalls, many of which have refrisperation units, the maintenance of which will be the tenant's sole responsibility, measuring approximately 25 x 80° each will be available. Proposals may be submitted on a per stall basis, or for multiple stalls, Proposals will, be reviewed by the Connecticut Marketing Authority, Leases may be for a term of two years, with the option to renew, at the discretion of the Marketing Authority; for an additional two years.

# LEAL NOTICE PUBLIC SCORMS ASSETTING FOR PUBLIC NALE CAN ADMINISTRATION MEC PUTTING PROSPER MORTHEAST CONSISTON, MA DC TO ROSTON, MA

The Federal Raliroad Administration (FRA) initiated NEC FUTURE, a comprehensive planning effort to address congestion and future demand for rail passenger travel and freight movement along the Northeast Cornidor (NEC) between Washington, DC and Boston, Massachusetta, NEC FUTURE is being conducted in compliance with the National Future and Boston, Massachusetta, NEC FUTURE is being conducted in compliance with the National Future and Statement (See 1968 and FRA's Frocedures for Considering Environmental Impacts. A Tier I Environmental Impact (See 1969) and See 1969 and Se

The Connecticut Meeting will be held: Tuesday. August 14 at the Shube Theatre 247 College Street, New Haven, CT 4:30 to 7:30 p.m.

Comments on the scope of the study may be provided to a stenographer in writing at the meetings, or addressed to Rebecca Reyes-Alices, USDOT Federal Railroad Administration, Office of Railroad Policy & Development, Mail Stop 20, 1200 New Jersey Avenue, St. Washington, D.C. 2059d. Comments may also be submitted online at www.nactuture.com. All comments must be submitted online and www.nactuture.com. All comments must be submitted on the Scoping Summary Report.
All meeting locations are accessible to persons with disabilities, Persons requiring special assistance should contact the project team by email at info@nectuture.com at least five days proof to the meeting.



# University of Connecticut Health Center John Dempsey Hospital

October 2, 2012

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

Dear Mr. Lazarus:

Enclosed please find for your review and original and four copies of John Dempsey Hospitals's Certificate of Need Application for the Acquisition of a CT Simulator.

If you should have any questions, or would like additional information, I can be reached at 860-679-8780. Thank you for your consideration.

Sincerely,

Jim Thibeault

Director, Strategy and Planning

Attachment

## **CON Application**

John Dempsey Hospital's Certificate of Need Application for the Acquisition of a CT Simulator

#### **AFFIDAVIT**

Applicant: John Dempsey Hospital
Project Title: <i>Acquisition of a CT Simulator</i>
I, <u>Dr. Mike Summerer</u> , <u>CEO – Hospital Director</u> (Individual's Name) (Position Title – CEO or CFO)
of <u>John Dempsey Hospital</u> being duly sworn, depose and state that (Hospital or Facility Name)
John Dempsey Hospital's information submitted in this Certificate of (Hospital or Facility Name)
Need Application is accurate and correct to the best of my knowledge.
My Mu Mo 9-5-Zorz Signature Date
Subscribed and sworn to before me on 9/5/2012
Sennife L. Lidgust
Notary Public/Commissioner of Superior Court  Jennifer L. Lindquist
My commission expires:  My commission expires:  My Commission Expires  November 30, 2016



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

<u>Instructions</u>: 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:** 

**Applicant:** 

John Dempsey Hospital

**Contact Person:** 

Jim Thibeault

**Contact Person's** 

Title:

Director, Strategy and Planning

**Contact Person's** 

Address:

University of Connecticut Health Center

263 Farmington Ave.

Farmington, CT 06030-3804

Contact Person's Phone Number:

860-679-8780

Contact Person's

Fax Number:

860-679-1135

**Contact Person's** 

**Email Address:** 

jthibeault@uchc.edu

**Project Town:** 

Farmington, CT

**Project Name:** 

Acquisition of a CT Simulator

Statute Reference:

Section 19a-638, C.G.S.

**Estimated Total** 

Capital Expenditure:

\$1,600,000

- 1. Project Description: Acquisition of Equipment:
  - a. Please provide a narrative detailing the proposal.

John Dempsey Hospital proposes to replace its existing Radiation Oncology simulator with a Philips Brilliance CT Big Bore Oncology Systems at a total capital expenditure of \$1,600,000. The existing simulator, a Varian Ximatron, was acquired in 1991 and has been in operation for over twenty years. A certificate of need was not required for the purchase of this simulator because it cost less than the CON threshold in place at the time.

The simulator is used as part of the radiation therapy treatment planning process provided in the hospital's Radiation Oncology Department. Physicians are able to determine the optimal treatment course for cancer patients utilizing the images generated by the simulator.

The industry standard for radiation treatment involves the use of CT technology to design treatment plans. The simulator enables the physicist and dosimetrists to create three-dimensional images of body sites. The radiation oncologist uses these images to identify tumors, surrounding areas and ultimately choose treatment areas and targets for radiation therapy doses. The radiation oncologist, physicist and dosimetrists are then able to accurately design radiation beams to treat those targeted areas while avoiding as much of the healthy tissue as possible.

The CT simulator will benefit cancer patients by reducing the amount of time required for their direct participation in the treatment planning process. Currently, patients must undergo portions of their simulation planning in two different locations within the hospital. They initially see the radiation oncologist and simulator technologists to be assessed and fitted for immobilization devices, and set up in a position that is suitable for the anatomical area. The patient must disrobe for this assessment. When this stage is completed, the patient must re-dress and be escorted to the Radiology Department where they will be set up again in the correct position. Once the patient is correctly set up, CT imaging takes place. The imaging is sent to the planning area where it is assessed for appropriateness. The current time for positioning, stabilizing, imaging and evaluating takes up to two hours, with wait times between.

In contrast, with a CT simulator, patients will be positioned, stabilized with devices, imaged and evaluated all on one machine and in considerably less time. This results in greater comfort for the patient since they are expected to hold their treatment position for less time. Patients also only need to disrobe once with this process versus many with the existing configuration. With the proposed CT simulator this process would take less than one hour, and with no wait time.

The CT simulator has different physical characteristics than the typical CT scanner in a Radiology Department. A CT simulator allows patients to be positioned in more comfortable positions with the added support of immobilization devices that cannot fit through the existing CT scanner in the Radiology Department. The proposed CT simulator also has a tabletop that matches the treatment machines for radiation therapy. Furthermore, it has specialized localization and planning software that is not available on diagnostic CT equipment.

An on-site CT simulator is considered the standard of care for Radiation Oncology departments. This ensures the radiation oncologist and all other planning staff are available on site for consultation, particularly to assess for 3d and 4d imaging accuracy. The use of CT imaging along with simulation software is the accepted standard of best practice care for Radiation Oncology, supported by ACR guidelines. Acquisition of this technology will conform to the current standards of practice and will provide on-site seamless service for our patients.

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

Please refer to Attachment A for the letters of support we have been received for this proposal:

- Dr. Douglas W. Fellows, MD, Chair, Department of Diagnostic Imaging and Therapeutics
- Dr. Robert J. Dowsett, Division Chief, Department of Diagnostic Imaging and Therapeutics
- Dr. Pramod K. Srivastava, Director, Carole and Ray Neag Comprehensive Cancer Center
- c. Provide the Manufacturer, Model, Number of slices/tesla strength of the proposed scanner (as appropriate to each piece of equipment).

The proposed scanner is the Philips Brilliance CT Big Bore Oncology Systems. The unit offers 16 slices per revolution, 85 cm bore size with an expandable 70 cm scan field of view, which makes this configuration ideal for oncology cases where patient positioning and accuracy are critical.

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

The imaging modalities provided on the campus of John Dempsey Hospital are shown below:

	John Dempsey Hospital	John Dempsey Medical Arts Building
General Radiography	Х	X
Ultrasound	x	
CT	x	X
Nuclear Medicine	X	
Mammography	x	
MRI	X	X
PET CT	x	
Bone Density		Х
Angiography	X	
Linear Accelerator	X	
RTT Simulator	x	

#### 2. Clear Public Need

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

The University of Connecticut Health Center's Neag Cancer Center provides comprehensive cancer care to over 1,200 newly diagnosed cancer patients each year. Radiation Therapy is an integral component of this care, providing over 8,000 radiation treatments annually. Treatment planning is an important function within the Radiation Oncology Service.

The industry standard of care is to replace conventional simulators with CT Simulators. The unit at John Dempsey is over 20 years old. Maintenance agreements are no longer available for this unit and service parts are difficult to acquire. The proposed CT Simulator is not for general CT diagnostic scans. It will be used by the Radiation Oncology staff for treatment planning purposes. The combination of the CT Scanner and simulator as one piece of equipment, located in one location within the Radiation Oncology Department, enhances the ability of the Radiation Oncology Team to produce the most effective treatment plans for our cancer patients. And as mentioned previously, this proposal will improve patient convenience and comfort because it takes less time, and the patient will not have to travel to another location within the hospital, and will not have to disrobe more than once.

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

Utilization data on other facilities is not available. The Cancer Centers located at the other hospitals in the service area have been replacing their conventional simulators with CT Simulators over the years. This proposal will not affect the utilization at other hospitals in the service area.

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 **	FY 12 Simulations (Jul 2011 – Jun 2012)
Varian Ximatron Simulator	kV simulator	M-F 7:30-5:00	686

<sup>\*</sup> Include equipment strength (e.g. slices, tesla strength), whether the unit is open or closed (for MRI)

- d. Provide the following regarding the proposal's location:
  - i. The rationale for locating the proposed equipment at the proposed site;

The rational for locating the CT simulator equipment within the Radiation Oncology Department of John Dempsey Hospital is to ensure comprehensive, coordinated care to our cancer patients. The industry standard is for cancer patients to receive their CT planning on a CT simulator in the same location and by the same staff who will provide the treatment simulation, planning and radiation therapy treatment.

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 the John Dempsey Hospital primary and secondary service area. The population in the service area grew 4.5% between 2000 and 2010. The table below shows the 2010 census population by gender and by service area, and the expected incidence of cancer. The source for the projected incidence rates of cancer for males and females in Connecticut is the American Cancer Society (Please refer to Attachment B, "Cancer Facts and Figures 2012" by the American Cancer Society). For males, the incidence rate for cancer is 590.0 per 100,000 population; for females, the rate is 458.5 per 100,000 population. These figures indicate that approximately 4900 new cancer cases are expected to develop annually in the JDH service area.

<sup>\*\*</sup> Days of the week unit is operational, and start and end time for each day; and

<sup>\*\*\*</sup> Number of scans/exams performed on each unit for the most recent 12-month period (identify period).

In addition, according to the American Cancer Society, the probability of developing cancer increases as we age. For males 70 years old and above, the probability of developing an invasive cancer is 1 in 3. For females, the probability is 1 in 4.

The demographics in our service area are important considerations for this proposal. Several towns in the Farmington Valley, for example, have experienced rapid population growth between 2000 and 2010. The rate of growth in the towns of Avon, Burlington, and Canton was 14.3%, 13.6%, and 16.4% respectively. The population in Farmington increased 7.2% during this period. The population grew even more rapidly among the elderly — residents who are 65 years and above. Population growth in this age group was 26.5% in Avon; 60.0% in Burlington, 48.7% in Canton; and 18.0% in Farmington.

We believe the demographics in our service area – particularly the growth in the elderly population – clearly demonstrate the need for this proposal.

	2	2010 Census	Population		ence Rate per : pulation *	1000
JDH Service Area	Males	Female	Total	Males	Female	Total
Primary Service Area	220,872	240,501	461,373	1,303	1,103	2,406
Secondary Service Area	232,418	248,861	481,279	1,371	1,141	2,512
Total Service Area	453,290	489,362	942,652	2,674	2,244	4,918

<sup>\*</sup>Cancer Facts & Figures 2012, American Cancer Society (Attachment B)

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

The proposed patient population is currently being served by John Dempsey Hospital. This is not expected to change.

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

Existing providers in the service area with CT simulators are:

- Hartford Hospital, 85 Seymour Street, Hartford
- Hartford Hospital, 80 Fisher Drive, Avon
- St Francis Hospital and Medical Center, 114 Woodland St, Hartford
- Hospital of Central Connecticut, 100 Grand St, New Britain
- Manchester Memorial Hospital, 71 Haynes St, Manchester

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

This proposal is not expected to have any effect on existing providers. The project is intended to enhance the quality of services we provide to our existing population.

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.

The proposed CT Simulator is not an unnecessary duplication of existing services. This project is to replace an outdated 20 year old simulator.

#### 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 Total Number of Simulations by Type

	Actua	l Last 3 Fiscal	l Years	Current Year	Projec	ted Year 1, 2	and 3
	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016
Total	648	614	686	693	700	707	714

<sup>\*</sup> 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.

<sup>\*\*</sup> 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.

<sup>\*\*\*</sup> Identify each scanner separately and add lines as necessary. Also break out inpatient/eD volumes if applicable.

<sup>\*\*\*\*</sup> 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

	Actua	l Last 3 Fisca	l Years	Current Year	Projec	ted Year 1,	2 and 3
Scan Type	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016
Simple	223	208	285	288	291	294	297
Complex	357	326	309	312	315	318	321
3D Recons	68	80	92	93	94	95	96
Total	648	614	686	693	700	707	714

<sup>\*</sup> 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.

<sup>\*\*</sup> 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.

<sup>\*\*\*</sup> 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.

<sup>\*\*\*\*</sup> 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.

#### Total Number of Simulations by Town for FY 12, last completed full year:

Service Area	Service Area Town	FY 2012
Farmington Valley	Avon	22
,	Burlington	10
	Canton	17
	Farmington	67
	Simsbury	11
	West Hartford	46
	Subtotal Farmington Valley	173
Other Primary Service Area	Bloomfield	17
Other Filliary Service Area	East Hartford	36
	Granby	9
	Hartford	28
	New Britain	31
	Newington	23
	Subtotal Other Primary	144
Canandam Camilas Avas	Davida averate d	0
Secondary Service Area	Barkhamsted Berlin	0 13
	Bristol	65
	Cromwell	3 2
	East Granby	_
	East Windsor	11 5
	Glastonbury	_
	Hartland Harwinton	0 4
	Litchfield	11
	Manchester	17
	New Hartford	4
		•
	Plainville	18 19
	Plymouth	19
	Rocky Hill South Windsor	2
		19
	Southington	13
	Torrington Vernon	13 8
	Wethersfield	3
	Winchester Windsor	0 4
	Subtotal Secondary	230
		255
All Other Connecticut	Subtotal Other CT	135
Out of State	Subtotal Out of State	4
Grand Total	Total	686

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

Approximately 80% of our patients and referrals come from the Farmington Valley, and our other primary and secondary service area towns as shown in the table above.

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

No change is expected in the existing referral patterns.

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

Volume decreased in FY 2011 due to the loss of two very productive physician faculty members. New replacement faculty physicians were brought on in FY 2012 and volume subsequently grew from 614 to 686, an increase of about 12%. We expect the number of simulations we performed in FY 12 to have stabilized and the projected increase will be due to demographic factors in the service area – population growth and the aging of the population, and our full complement of oncology physicians.

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

Using the volume of simulations we performed in FY 12 as the baseline, we anticipate a marginal increase in simulations of about 1 percent per year over the next few years. The growth we are projecting is independent of the scope of this project. We anticipate an increase in simulations even if we do not replace the existing unit. The projected increase in simulations is based primarily on the modest population growth in our service area, the aging of the population, and our faculty physicians. Further, we are also recruiting for an additional breast surgeon in FY 13. Once this physician is on board, and his or her practice has been established, we can expect additional referrals. For these reasons, we believe a modest increase of about 7 simulations per year will occur even if we do not replace our current unit.

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.

Below is a brief description regarding the relevance of the articles, studies and reports that are presented in Attachment C.

The proposed CT Simulator to replace the existing Ximatron simulator will substitute CT based simulation for the outdated conventional system. The British Journal of Radiology article "Localization: conventional and CT simulation" by GR Baker is a comparison of the two methods. The enhanced requirements for 3-Dimensional data in implementing Intensity Modulated Radiation Therapy (IMRT) and Image Guided Radiation Therapy (IGRT)

which are now the accepted standard of practice in treatment delivery are explained in the article "From New Frontiers to New Standards of Practice: Advances in Radiotherapy Planning and Delivery" by James A. Purdy. The addition of 4-Dimensional information (including patient structure motion in Time) and the added requirements for dedicated CT simulation motion capture software in planning of thoracic treatments is addressed in "Stereotactic body radiation therapy: The report of AAPM Task Group 101", Benedict et al. Finally, the two sets of ACR practice guidelines for Radiation Oncology and Intensity-Modulated Radiation Therapy (IMRT) lend support to the assertion that CT Simulation has become the expected standard of practice in modern treatment planning and delivery.

#### 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.

A listing of all key professional, administrative, and clinical personnel is listed below. A copy of their Curriculum Vitae, is shown in Attachment D.

- Administrative Staff:
  - o Mike Summerer, MD, FACPE, Hospital Director
  - o John Biancamano, CPA, MBA, Chief Financial Officer
- Professional and Clinical Staff:
  - o Robert J. Dowsett, MD, Division Chief
  - o Christopher James, MS, Medical Physicist
  - o Karen Stook, Chief Dosimetrist
- b. Explain how the proposal contributes to the quality of health care delivery in the region.

The industry standard of care is to replace conventional simulators with CT Simulators. The unit at John Dempsey is over 20 years old. Replacing this unit with a state of the art simulator will contribute to the quality of care provided to cancer patients at John Dempsey Hospital and, therefore, the region, by providing the standard of care associated with modern treatment planning and delivery.

#### 5. Organizational and Financial Information

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

John Dempsey Hospital is the university hospital of the University of Connecticut Health Center, part of the University of Connecticut system. The Health Center comprises the School of Medicine, School of Dental Medicine, John Dempsey Hospital, UConn Medical Group, UConn Health Partners, and University Dentists.

Does the Applicant have non-profit status?  ☐ Yes (Provide documentation)  ☐ No	
John Dampson does not have non profit status	It is an antity of

John Dempsey does not have non-profit status. It is an entity of the State of Connecticut.

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.

Please refer to Attachment E.

#### 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.

The most recently completed fiscal year audited financial statements for John Dempsey Hospital are on file with OHCA.

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

Table 3: Proposed Capital Expenditures/Costs

Medical Equipment Purchase:	
Imaging Equipment Purchase: See response below	\$675,332
Non-Medical Equipment Purchase	
Land/Building Purchase *	
Construction/Renovation **	\$924,668
Other Non-Construction (Specify)	
Total Capital Expenditure (TCE)	\$1,600,000
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)	\$1,600,000
Total Project Cost (TCE + TCC)	
Capitalized Financing Costs (Informational Purpose Only)	
Total Capital Expenditure with Cap. Fin. Costs	\$1,600,000

#### Response: the vendor quote is presented in Attachment F.

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 project will be funded by applicant's equity

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

The CT simulator will improve the overall comfort, convenience and quality of the care we provide to cancer patients at John Dempsey Hospital, as well as improving the Hospital's operational efficiencies of treating these patients. This project is not expected to affect the financial strength of the State's health care system.

#### 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

	Last				
	Full	Current			
	Year	Year	Projec	ted Year 1,	2 and 3
Payer	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016
Medicare	44.8%	44.8%	44.8%	44.8%	44.8%
Medicaid	11.7%	11.7%	11.7%	11.7%	11.7%
CHAMPUS	0.0%	0.0%	0.0%	0.0%	0.0%
Total Government	56.4%	56.4%	56.4%	56.4%	56.4%
Commercial	43.3%	43.3%	43.3%	43.3%	43.3%
Uninsured	0.3%	0.3%	0.3%	0.3%	0.3%
Workers Comp	0.0%	0.0%	0.0%	0.0%	0.0%
Total Non Govt	43.6%	43.6%	43.6%	43.6%	43.6%
Total Payer Mix	100.0%	100.0%	100.0%	100.0%	100.0%

<sup>\*</sup> 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.

<sup>\*\*</sup> 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

<sup>\*\*\*</sup> 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.

\* Includes managed care activity.

\*\* New programs may leave the "current" column blank.

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

We anticipate this proposal will have no impact on the existing patient population mix over the next few years.

#### 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.

Financial Attachment I is presented on page 18.

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 <u>full</u> fiscal years of the project.

Financial Attachment II is not applicable because there is no anticipated volume or revenue increase associated with this project.

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.).

The projected commencement of operations is April 2013. We do not anticipate a revenue impact because the increase in volume is projected to occur even if the project is not implemented. Also, there are no additional FTEs.

The only expenses associated with this project are depreciation and a maintenance contract. The maintenance contract begins 18 months after the commencement of operations. The capital expenses of this proposal, CT Simulator and associated room renovations, are depreciated over 7 years. Consistent with Hospital policy, 50% of the annual depreciation will be applied in the first year. Since the equipment is expected to be installed in April 2013, a half year of depreciation expense was calculated for FY 2013.

<sup>\*\*\*</sup> Fill in years. Ensure the period covered by this table corresponds to the period covered in the projections provided.

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).

A copy of the rate schedule is presented in Attachment G. We do not anticipate a change to the existing rates.

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

There is no anticipated volume or revenue increase associated with this project. Accordingly, there is no incremental gain from operations.

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 projected incremental losses from operations are due to depreciation and a maintenance contract.

g. Describe how this proposal is cost effective.

John Dempsey Hospital is proposing to replace its existing simulator, which has been in operation for over 20 years, with a modern, state of the art CT Simulator. There is no anticipated cost reductions associated with this project, but we believe it will improve the overall comfort and convenience of our cancer patients.

Financial Attachment 1: John Dempsey Hospital

Please provide one year of actual results and three years of projections of Total Facility revenue, expense and volume statistics without, incremental to and with the CON proposal in the following reporting format: 12. C (i).

Total Facility: Description	` 1 Actual <u>Results</u>	FY 13 Projected Wout CON	FY 13 F Projected P <u>Incremental</u> <u>V</u>	FY 13 Projected With CON	FY 14 Projected <u>W/out CON</u>	Projected <u>Incremental</u>	FY 14 Projected <u>With CON</u>	FY 15 Projected Wout CON	FY 15 Projected <u>Incremental</u>	FY 15 Projected <u>With CON</u>
NET PATIENT REVENUE Non-Government Medicare Medicaid and Other Medical Assistance Other Government	\$107,558,795 \$93,934,206 \$55,380,437 \$7,459,396	\$112,844,996 \$101,560,496 \$59,243,623 \$8,463,375	<del>07                                    </del>	\$112,844,996 \$101,560,496 \$59,243,623 \$8,463,375	\$118,360,340 \$106,524,306 \$62,139,178 \$8,877,025		\$118,360,340 \$106,524,306 \$62,139,178 \$8,877,025	\$125,554,045 \$112,998,640 \$65,915,874 \$9,416,553		\$125,554,045 \$112,998,640 \$65,915,874 \$9,416,553
Total Net Patient Patient Revenue Other Operating Revenue	\$264,332,834 \$1,954,663	\$282,112,489	80	\$282,112,489 \$20,496,854	\$295,900,849	0\$	\$295,900,849	\$313,885,112	O <del>\$</del>	\$313,885,112
Revenue from Operations	\$266,287,497	\$302,609,344	\$ 0\$	\$302,609,344	\$317,035,046	\$0	\$317,035,046	\$335,676,727	\$0	\$335,676,727
OPERATING EXPENSES Salaries and Fringe Benefits Professional / Contracted Services Maintenance Contract ***	\$153,975,650 \$22,267,346	\$171,612,071 \$24,303,779	67	\$171,612,071 \$24,303,779	\$178,093,764 \$25,120,315		\$178,093,764 \$25,120,315	\$189,922,281 \$25,968,488	\$60,117	\$189,922,281 \$25,968,488 \$60,117
Supplies and Drugs Bad Debts	\$51,662,400 \$0	\$53,508,300 \$0		\$53,508,300 \$0	\$55,482,427 \$0		\$55,482,427 \$0	\$57,534,367 \$0		\$57,534,367 \$0
Other Operating Expense Subtotal Denteciation/Amortization	\$45,514,815 \$273,420,211 \$9.498,680	\$51,213,970 \$300,638,120 \$10,230,702	\$ 0\$	\$51,213,970 \$300,638,120 \$10,239,792	\$52,758,089 \$311,454,595 \$10,444,588	0\$	\$52,758,089 \$311,454,595 \$10,444,588	\$56,554,483 \$329,979,619 \$10,653,480	\$60,117	\$56,554,483 \$330,039,736 \$10,653,480
Depreciation ** Interest Expense Lease Expense	\$149,794	\$140,000	\$144,285	\$144,285 \$140,000 \$140,000	\$136,500	\$228,571	\$228,571 \$228,571 \$136,500 \$0	\$132,000	\$228,571	\$228,571 \$228,571 \$132,000 \$0
Total Operating Expense	\$283,068,685	\$311,017,912	\$144,285	\$311,162,197	\$322,035,683	\$228,571	\$322,264,254	\$340,765,099	\$288,688	\$341,053,787
Gain/(Loss) from Operations	(\$16,781,188)	(\$8,408,569)	(\$144,285)	(\$8,552,854)	(\$5,000,636)	(\$228,571)	(\$5,229,207)	(\$5,088,371)	(\$288,688)	(\$5,377,059)
Plus: Non-Operating Revenue Revenue Over/(Under) Expense	\$19,409,872 \$2,628,684	8,450,000.00 \$41,431	(\$144,285)	\$8,450,000 (\$102,854)	5,050,000.00 \$49,364	(\$228,571)	\$5,050,000 (\$179,207)	5,100,000.00 \$11,629	(\$288,688)	\$5,100,000 (\$277,059)
FTEs	1476.56	1585.39		1585.39	1585.39		1585.39	1585.39		1585.39
"Volume Statistics: Simulations	614	693		693	700		200	707		707

<sup>\*\*</sup> CT Sim Capital Cost = \$1.60 million including construction - 7 year amortization starting in FY 2013 - one half year depreciation taken the first year FY 2013

<sup>\*\*\*</sup> Maintenance Expense for the new CT Sim is \$20,039 per quarter - Maintenance expense to Start Sept 2014 - we will have three quarters of maintanence expense in FY 2015 (Sept 2014 to June 30, 2015

#### List of Attachments

- A. Letters of Support
- B. Cancer Facts and Figures
- C. Articles Supporting the Need for the Proposed CT Simulator
- D. Curriculum Vitae of Key Personnel
- E. John Dempsey Hospital license
- F. Vendor quote
- G. Current Rate Schedule

#### Attachment A: Letters of Support



## University of Connecticut Health Center School of Medicine

Douglas W. Fellows, MD, FACR Professor and Chain Department of Diagnostic Inviging and Therapeutics (86th 679-3626 Eacsunik) (860) 679-3145

September 7, 2012

Dr. Jewel Mullen, Commissioner Department of Public Health Office of Health Care Access 410 Capitol Ave. MS #13HCA Hartford, CT 06134-0308

Dear Commissioner Mullen:

I am writing in support of making Computed Tomography (CT) Simulation available at John Dempsey Hospital. As a practicing physician, I witness first-hand the vital role radiation therapy plays in the struggle against cancer. CT simulation is the community standard that referring clinicians expect, when sending their patients for radiation therapy, in order to provide them with a comprehensive and all-encompassing treatment plan. In order to ensure that these patients are receiving the best level of care and not being made vulnerable to delays in obtaining the necessary treatment, a CT-Simulator should be purchased for the Radiology Department.

CT Simulation has been proven to be the most successful approach in planning for radiation therapy treatment. It allows adequate coverage of target areas while simultaneously avoiding extensive damage to normal tissue. There is a clear and established need for this technology at the John Dempsey Hospital. Patients should be able to have all of the necessary procedures carried out in the Radiology unit. It should not be necessary for the patient to have to travel to different areas of the hospital in order to receive proper treatment.

I urge you to carefully review the compelling facts presented in the John Dempsey Hospital Certificate of Need application. In it you will find all of the evidence supporting the request for the CT Simulator.

Thank you for your efforts in reviewing this application.

Douglas W. Fellows, MD, FACR

Chair and Professor

Sincerely

An Family Oppositions I mplaces



# University of Connecticut Health Center John Dempsey Hospital

Department of Diagnostic Imaging and Therapeutics

September 4, 2012

Division of Radiation Oncology

Office of the Commissioner State of Connecticut Office of Health Care Access 410 Capitol Avenue P.O. Box 340308 Hartford, CT 06134

Dear Commissioner Mullen,

I am writing to support the purchase and installation of a Radiation Oncology CT Simulator in the John Dempsey Hospital at the University of Connecticut Health Center. State of the art radiation treatment planning in 2012 involves the use of CT technology to produce the 3D data set used to produce treatment plans. Radiation can be delivered with high precision to a complex target volume, while minimizing damaging radiation dose to critical adjacent normal structures, with the use of the spatial information produced by the CT. The CT simulator product was specifically designed for radiation oncology applications and is superior to the use of diagnostic CT scans for the purpose of radiation treatment planning. The advantages of the CT simulator are numerous. A CT simulator is designed with a large bore size to accommodate a wide array of patient positions. Unconventional patient positions are often extremely advantageous for optimal radiation delivery. In addition, there is sophisticated radiation planning software contained on the CT simulator to optimize and streamline the planning process. Lastly the CT simulator has sophisticated software to track a tumor's position in time. This is particularly advantageous for treating lung and liver tumors where there is a change in target position with respiration. Finally, the CT simulator technology will allow us to optimally use the capabilities of our Tomotherapy machine. Tomotherapy delivers state of the art Intensity Modulated Radiation Therapy (IMRT) and Image Guidance Radiation Therapy (IGRT). The John Dempsey Hospital is the only institution in the state offering Tomotherapy to the citizens of the State of Connecticut. Our current technology for radiation planning is suboptimal consisting of an outdated conventional simulator (installed in 1991) and diagnostic CT technology with the limitations noted previously.

In addition, a dedicated CT simulator has other advantages for our patients above and beyond the important technical factors noted above. We will have greater access to the CT technology needed for treatment planning making the planning process more convenient and timely for the patient. Since we will be able to treat with an optimal body position, I anticipate the treatment procedure will often be a more comfortable experience for the patients.

I thank you for considering our request which will allow us to continue to deliver excellent radiation oncology treatment to the men and women of the region as well as the entire state.

Sincerely,

Robert J. Dowsett, MD

Division Chief

Department of Diagnostic Imaging and Therapeutics

John Dempsey Hospital

University of Connecticut Health Center.

In Equal Opportunity Employee

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Telephone (800) v 8/3/2/3 Facsimile: (800) (C) 1/369



Pramod K. Srivastava, PhD, MD

Northeast Utilities Chair in Experimental Oncology Director, Carole and Ray Neag Comprehensive Cancer Center

#### University of Connecticut Health Center Carole and Ray Neag Comprehensive Cancer Center

August 30, 2012

Office of the Commissioner State of Connecticut Office of Health Care Access 410 Capitol Ave. P.O. Box 340308 Hartford, CT 06134

Dear Commissioner Mullen.

I am writing in support of acquiring a Computed Tomography Simulator for John Dempsey Hospital. As the director of the Carole and Ray Neag Comprehensive Cancer Center, I am delighted to ensuring our patients are provided with the best comprehensive care in the area. This means having the latest and most effective technology available for the treatment of cancer.

The current machinery has been in service since 1991 and has an estimated expected life of seven years. It has since then fully depreciated and is at the end of its useful life. Replacing the current technology with a CT Simulator will allow us to perform on-site 3D imaging and radiation planning for patients and enhance the quality of care provided. Research shows that Simulator-CT based radiation is one of the best methods of radiation treatment planning. Making this change is one way of preserving the Neag's lasting goal that Connecticut residents will never have to travel far for world class cancer care.

I thank you for your attention to this important matter, and I appreciate your consideration and time.

Sincerely,

Pramod K. Srivastava, PhD, MD

Northeast Utilities Chair in Experimental Oncology

Professor of Immunology and Professor of Medicine

Director, Center for Immunotherapy of Cancer & Infectious Diseases

Director, Carole and Ray Neag Comprehensive Cancer Center

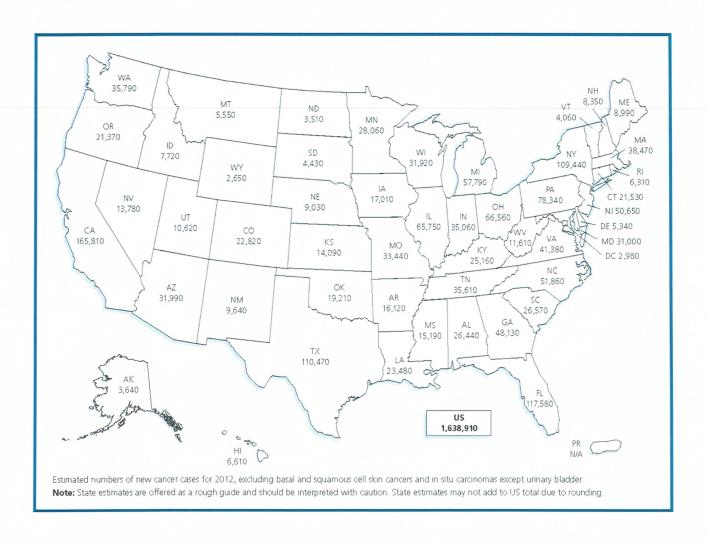
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#### Attachment B: Cancer Facts and Figures

# Cancer Facts 2012 & Figures



Special Section: Cancers with Increasing Incidence Trends see page 25



#### **Contents**

Basic Cancer Facts	1
Age-adjusted Cancer Death Rates, Males by Site, US, 1930-2008*	2
Age-adjusted Cancer Death Rates, Females by Site, US, 1930-2008*	
Estimated New Cancer Cases and Deaths by Sex, US, 2012*	4
Estimated Numbers of New Cases for Selected Cancers by State, US, 2012*	5
Estimated Numbers of Deaths for Selected Cancers by State, US, 2012*	6
Incidence Rates for Selected Cancers by State, US, 2004-2008*	7
Death Rates for Selected Cancers by State, US, 2004-2008*	8
Selected Cancers	9
Leading New Cancer Cases and Deaths – 2012 Estimates*	
Probability (%) of Developing Invasive Cancers over Selected Age Intervals by Sex, US, 2006-2008*	
Five-year Relative Survival Rates (%) by Stage at Diagnosis, 2001-2007*	
Trends in 5-year Relative Survival Rates (%) by Race, US, 1975-2007*	18
Special Section: Cancers with Increasing Incidence Trends in the US: 1999-2008	25
Tobacco Use	36
<b>Tobacco Use</b> Annual Number of Cancer Deaths Attributable to Smoking by Sex and Site, US, 2000-2004*	36
Annual Number of Cancer Deaths Attributable to Smoking by Sex and Site, US, 2000-2004*  Cancer Disparities	37
Annual Number of Cancer Deaths Attributable to Smoking by Sex and Site, US, 2000-2004*	37
Annual Number of Cancer Deaths Attributable to Smoking by Sex and Site, US, 2000-2004*  Cancer Disparities	37 43
Annual Number of Cancer Deaths Attributable to Smoking by Sex and Site, US, 2000-2004*  Cancer Disparities  Cancer Incidence and Death Rates by Site, Race, and Ethnicity, US, 2004-2008*	37 43 44 45
Annual Number of Cancer Deaths Attributable to Smoking by Sex and Site, US, 2000-2004*  Cancer Disparities  Cancer Incidence and Death Rates by Site, Race, and Ethnicity, US, 2004-2008*  Geographic Patterns in Lung Cancer Death Rates by State, US, 2004-2008*	37434445
Annual Number of Cancer Deaths Attributable to Smoking by Sex and Site, US, 2000-2004*  Cancer Disparities  Cancer Incidence and Death Rates by Site, Race, and Ethnicity, US, 2004-2008*  Geographic Patterns in Lung Cancer Death Rates by State, US, 2004-2008*  Nutrition and Physical Activity	37434548
Annual Number of Cancer Deaths Attributable to Smoking by Sex and Site, US, 2000-2004*  Cancer Disparities  Cancer Incidence and Death Rates by Site, Race, and Ethnicity, US, 2004-2008*  Geographic Patterns in Lung Cancer Death Rates by State, US, 2004-2008*  Nutrition and Physical Activity  Environmental Cancer Risks	3743454551
Annual Number of Cancer Deaths Attributable to Smoking by Sex and Site, US, 2000-2004*  Cancer Disparities  Cancer Incidence and Death Rates by Site, Race, and Ethnicity, US, 2004-2008*  Geographic Patterns in Lung Cancer Death Rates by State, US, 2004-2008*  Nutrition and Physical Activity  Environmental Cancer Risks  The Global Fight against Cancer	374345455153
Annual Number of Cancer Deaths Attributable to Smoking by Sex and Site, US, 2000-2004*  Cancer Disparities  Cancer Incidence and Death Rates by Site, Race, and Ethnicity, US, 2004-2008*  Geographic Patterns in Lung Cancer Death Rates by State, US, 2004-2008*  Nutrition and Physical Activity  Environmental Cancer Risks  The Global Fight against Cancer  The American Cancer Society	37434545515354



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This publication attempts to summarize current scientific information about cancer. Except when specified, it does not represent the official policy of the American Cancer Society.

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#### **Basic Cancer Facts**

#### What Is Cancer?

Cancer is a group of diseases characterized by uncontrolled growth and spread of abnormal cells. If the spread is not controlled, it can result in death. Cancer is caused by both external factors (tobacco, infectious organisms, chemicals, and radiation) and internal factors (inherited mutations, hormones, immune conditions, and mutations that occur from metabolism). These causal factors may act together or in sequence to initiate or promote the development of cancer. Ten or more years often pass between exposure to external factors and detectable cancer. Cancer is treated with surgery, radiation, chemotherapy, hormone therapy, biological therapy, and targeted therapy.

#### Can Cancer Be Prevented?

All cancers caused by cigarette smoking and heavy use of alcohol could be prevented completely. The American Cancer Society estimates that in 2012 about 173,200 cancer deaths will be caused by tobacco use. Scientific evidence suggests that about one-third of the 577,190 cancer deaths expected to occur in 2012 will be related to overweight or obesity, physical inactivity, and poor nutrition and thus could also be prevented. Certain cancers are related to infectious agents, such as hepatitis B virus (HBV), human papillomavirus (HPV), human immunodeficiency virus (HIV), Helicobacter pylori (H. pylori), and others, and could be prevented through behavioral changes, vaccines, or antibiotics. In addition, many of the more than 2 million skin cancers that are diagnosed annually could be prevented by protecting skin from intense sun exposure and avoiding indoor tanning.

Regular screening examinations by a health care professional can result in the detection and removal of precancerous growths, as well as the diagnosis of cancers at an early stage, when they are most treatable. Cancers of the cervix, colon, and rectum can be prevented by removal of precancerous tissue. Cancers that can be diagnosed early through screening include cancers of the breast, colon, rectum, cervix, prostate, oral cavity, and skin. However, screening is known to reduce mortality only for cancers of the breast, colon, rectum, and cervix. A heightened awareness of changes in the breast or skin may also result in detection of these tumors at earlier stages. Cancers that can be prevented or detected earlier by screening account for at least half of all new cancer cases.

#### Who Is at Risk of Developing Cancer?

Anyone can develop cancer. Since the risk of being diagnosed with cancer increases with age, most cases occur in adults who are middle aged or older. About 77% of all cancers are diagnosed in persons 55 years of age and older. Cancer researchers use the word "risk" in different ways, most commonly expressing risk as lifetime risk or relative risk.

Lifetime risk refers to the probability that an individual will develop or die from cancer over the course of a lifetime. In the US, men have slightly less than a 1 in 2 lifetime risk of developing cancer; for women, the risk is a little more than 1 in 3.

Relative risk is a measure of the strength of the relationship between risk factors and a particular cancer. It compares the risk of developing cancer in persons with a certain exposure or trait to the risk in persons who do not have this characteristic. For example, male smokers are about 23 times more likely to develop lung cancer than nonsmokers, so their relative risk is 23. Most relative risks are not this large. For example, women who have a first-degree relative (mother, sister, or daughter) with a history of breast cancer have about twice the risk of developing breast cancer, compared to women who do not have this family history.

All cancers involve the malfunction of genes that control cell growth and division. About 5% of all cancers are strongly hereditary, in that an inherited genetic alteration confers a very high risk of developing one or more specific types of cancer. However, most cancers do not result from inherited genes but from damage to genes occurring during one's lifetime. Genetic damage may result from internal factors, such as hormones or the metabolism of nutrients within cells, or external factors, such as tobacco, chemicals, and excessive exposure to sunlight.

### How Many People Alive Today Have Ever Had Cancer?

The National Cancer Institute estimates that nearly 12 million Americans with a history of cancer were alive in January 2008. Some of these individuals were cancer free, while others still had evidence of cancer and may have been undergoing treatment.

## How Many New Cases Are Expected to Occur This Year?

About 1,638,910 new cancer cases are expected to be diagnosed in 2012. This estimate does not include carcinoma in situ (noninvasive cancer) of any site except urinary bladder, and does not include basal and squamous cell skin cancers, which are not required to be reported to cancer registries.

### How Many People Are Expected to Die of Cancer This Year?

In 2012, about 577,190 Americans are expected to die of cancer, more than 1,500 people a day. Cancer is the second most common cause of death in the US, exceeded only by heart disease, accounting for nearly 1 of every 4 deaths.

#### What Percentage of People Survive Cancer?

The 5-year relative survival rate for all cancers diagnosed between 2001 and 2007 is 67%, up from 49% in 1975-1977 (see page 18). The improvement in survival reflects both progress in diagnosing certain cancers at an earlier stage and improvements

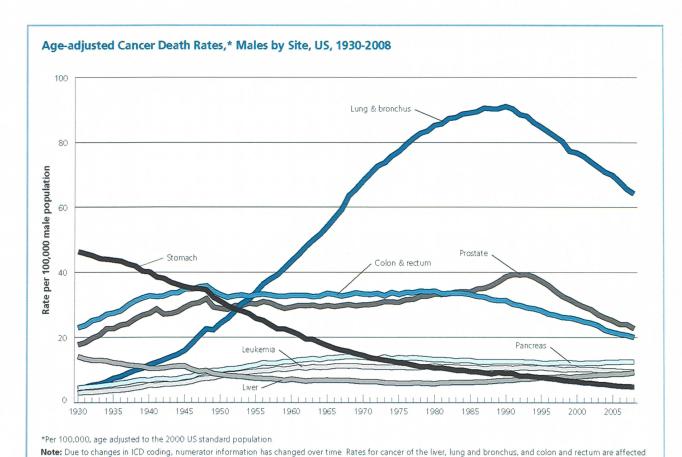
in treatment. Survival statistics vary greatly by cancer type and stage at diagnosis. Relative survival compares survival among cancer patients to that of people not diagnosed with cancer who are of the same age, race, and sex. It represents the percentage of cancer patients who are alive after some designated time period (usually 5 years) relative to persons without cancer. It does not distinguish between patients who have been cured and those who have relapsed or are still in treatment. While 5-year relative survival is useful in monitoring progress in the early detection and treatment of cancer, it does not represent the proportion of people who are cured permanently, since cancer deaths can occur beyond 5 years after diagnosis.

Although relative survival for specific cancer types provides some indication about the average survival experience of cancer patients in a given population, it may or may not predict individual prognosis and should be interpreted with caution. First, 5-year relative survival rates for the most recent time period are based on patients who were diagnosed from 2001 to 2007 and thus, do not reflect recent advances in detection and treatment.

Second, factors that influence survival, such as treatment protocols, other illnesses, and biological or behavioral differences of each individual, cannot be taken into account in the estimation of relative survival rates. For more information about survival rates, see Sources of Statistics on page 62.

#### **How Is Cancer Staged?**

Staging describes the extent or spread of the disease at the time of diagnosis. Proper staging is essential in determining the choice of therapy and in assessing prognosis. A cancer's stage is based on the primary tumor's size and whether it has spread to other areas of the body. A number of different staging systems are used to classify tumors. The TNM staging system assesses tumors in three ways: extent of the primary tumor (T), absence or presence of regional lymph node involvement (N), and absence or presence of distant metastases (M). Once the T, N, and M are determined, a stage of I, II, III, or IV is assigned, with stage I being early and stage IV being advanced disease. A different system of summary staging (in situ, local, regional, and distant) is used for descriptive and statistical



Source: US Mortality Volumes 1930 to 1959, US Mortality Data 1960 to 2008, National Center for Health Statistics, Centers for Disease Control and Prevention

by these coding changes

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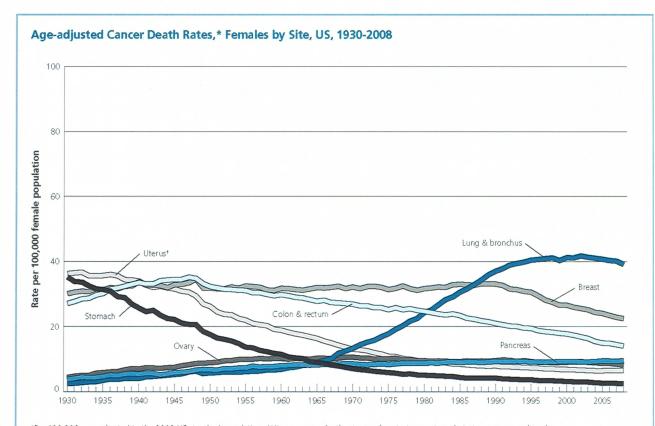
analysis of tumor registry data. If cancer cells are present only in the layer of cells where they developed and have not spread, the stage is in situ. If cancer cells have penetrated the original layer of tissue, the cancer is invasive and categorized as local, regional, or distant stage. (For a description of the summary stage categories, see the footnotes in the table on page 17, Five-year Relative Survival Rates (%) by Stage at Diagnosis, 2001-2007.) As the molecular properties of cancer have become better understood, prognostic models and treatment plans for some cancer sites (e.g., breast) have incorporated the tumor's biological markers and genetic features in addition to stage.

#### What Are the Costs of Cancer?

The National Institutes of Health (NIH) estimates that the overall costs of cancer in 2007 were \$226.8 billion: \$103.8 billion for direct medical costs (total of all health expenditures) and \$123.0 billion for indirect mortality costs (cost of lost productivity due to premature death). PLEASE NOTE: These estimates are not comparable to those published in previous years because as of

2011, the NIH is using a different data source: the Medical Expenditure Panel Survey (MEPS) of the Agency for Healthcare Research and Quality. The MEPS estimates are based on more current, nationally representative data and are used extensively in scientific publications. As a result, direct and indirect costs will no longer be projected to the current year, and estimates of indirect morbidity costs have been discontinued. For more information, please visit nhlbi.nih.gov/about/factpdf.htm.

Lack of health insurance and other barriers prevents many Americans from receiving optimal health care. According to the US Census Bureau, almost 51 million Americans were uninsured in 2009; almost one-third of Hispanics (32%) and one in 10 children (17 years of age and younger) had no health insurance coverage. Uninsured patients and those from ethnic minorities are substantially more likely to be diagnosed with cancer at a later stage, when treatment can be more extensive and more costly. For more information on the relationship between health insurance and cancer, see *Cancer Facts & Figures 2008*, Special Section, available online at cancer.org/statistics.



\*Per 100,000, age adjusted to the 2000 US standard population. †Uterus cancer death rates are for uterine cervix and uterine corpus combined.

Note: Due to changes in ICD coding, numerator information has changed over time. Rates for cancer of the lung and bronchus, colon and rectum, and ovary are affected by these coding changes.

Source: US Mortality Volumes 1930 to 1959, US Mortality Data 1960 to 2008, National Center for Health Statistics, Centers for Disease Control and Prevention.

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	Es	stimated New Cas	es	E	stimated Deaths	
	<b>Both Sexes</b>	Male	Female	Both Sexes	Male	Female
All Sites	1,638,910	848,170	790,740	577,190	301,820	275,370
Oral cavity & pharynx Tongue Mouth Pharynx	40,250 12,770 11,620 13,510	28,540 9,040 7,030 10,790	11,710 3,730 4,590 2,720	7,850 2,050 1,790 2,330	5,440 1,360 1,070 1,730	2,410 690 720 600
Other oral cavity	2,350	1,680	670	1,680	1,280	400
Digestive system Esophagus Stomach Small intestine Colon† Rectum Anus, anal canal, & anorectum Liver & intrahepatic bile duct	284,680 17,460 21,320 8,070 103,170 40,290 6,230 28,720	156,760 13,950 13,020 4,380 49,920 23,500 2,250 21,370	127,920 3,510 8,300 3,690 53,250 16,790 3,980 7,350	142,510 15,070 10,540 1,150 51,690 780 20,550	80,560 12,040 6,190 610 26,470 300 13,980	61,95( 3,03( 4,35( 54( 25,22( 48( 6,57(
Gallbladder & other biliary Pancreas Other digestive organs	9,810 43,920 5,690	4,480 22,090 1,800	5,330 21,830 3,890	3,200 37,390 2,140	1,240 18,850 880	1,960 18,540 1,260
Respiratory system Larynx Lung & bronchus Other respiratory organs	244,180 12,360 226,160 5,660	130,270 9,840 116,470 3,960	113,910 2,520 109,690 1,700	164,770 3,650 160,340 780	91,110 2,880 87,750 480	73,660 770 72,590 300
Bones & joints	2,890	1,600	1,290	1,410	790	62
Soft tissue (including heart)	11,280	6,110	5,170	3,900	2,050	1,85
Skin (excluding basal & squamous) Melanoma-skin Other nonepithelial skin	81,240 76,250 4,990	46,890 44,250 2,640	34,350 32,000 2,350	12,190 9,180 3,010	8,210 6,060 2,150	3,98 3,12 86
Breast.	229,060	2,190	226,870	39,920	410	39,51
Genital system Uterine cervix Uterine corpus Ovary Vulva Vagina & other genital, female Prostate Testis Penis & other genital, male	340,650 12,170 47,130 22,280 4,490 2,680 241,740 8,590 1,570	251,900 241,740 8,590 1,570	88,750 12,170 47,130 22,280 4,490 2,680	58,360 4,220 8,010 15,500 950 840 28,170 360 310	28,840 28,170 360 310	29,52( 4,22( 8,01( 15,50( 95( 84(
Urinary system Urinary bladder Kidney & renal pelvis Ureter & other urinary organs	141,140 73,510 64,770 2,860	97,610 55,600 40,250 1,760	43,530 17,910 24,520 1,100	29,330 14,880 13,570 880	19,670 10,510 8,650 510	9,660 4,370 4,920 370
Eye & orbit	2,610	1,310	1,300	270	120	150
Brain & other nervous system	22,910	12,630	10,280	13,700	7,720	5,980
ndocrine system Thyroid Other endocrine	58,980 56,460 2,520	14,600 13,250 1,350	44,380 43,210 1,170	2,700 1,780 920	1,240 780 460	1,46 1,00 46
ymphoma Hodgkin lymphoma Non-Hodgkin lymphoma	79,190 9,060 70,130	43,120 4,960 38,160	36,070 4,100 31,970	20,130 1,190 18,940	10,990 670 10,320	9,14 52 8,62
Vyeloma	21,700	12,190	9.510	10,710	6,020	4.69

26,830

3,450

9,490

7,350

3,210 3,330

15,620

20,320

2,600 6,570

6,430 2,220 2,500

15,380

47,150 6,050

16,060

13,780

5,430 5,830

31,000

Source: Estimated new cases are based on 1995-2008 incidence rates from 47 states and the District of Columbia as reported by the North American Association of Central Cancer Registries (NAACCR), representing about 95% of the US population. Estimated deaths are based on US Mortality Data, 1994 to 2008, National Center for Health Statistics, Centers for Disease Control and Prevention.

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13,500

820 2,730 5,790 370

3,790

25,150

23,540

1,440

4,580 10,200 610 6,710

45,900

Leukemia

Acute lymphocytic leukemia Chronic lymphocytic leukemia Acute myeloid leukemia

Chronic myeloid leukemia

Other & unspecified primary sites\*

Other leukemia\*

10,040

620 1,850 4,410 240 2,920

20,750

<sup>\*</sup>Rounded to the nearest 10; estimated new cases exclude basal and squamous cell skin cancers and in situ carcinomas except urinary bladder. About 63,300 carcinoma in situ of the female breast and 55,560 melanoma in situ will be newly diagnosed in 2012. †Estimated deaths for colon and rectal cancers are combined. ‡More deaths than cases may reflect lack of specificity in recording underlying cause of death on death certificates or an undercount in the case estimate.

## Estimated Numbers of New Cases for Selected Cancers by State, US, 2012\*

State	All Sites	Female Breast	Uterine Cervix	Colon & Rectum	Uterine Corpus	Leukemia	Lung & Bronchus	Melanom of the Skin	a Non- Hodgkin Lymphoma	Prostate	Urinary Bladder
Alabama	26,440	3,450	220	2,540	590	630	4,440	1,090	1,000	3,860	1,050
Alaska	3,640	470	+	290	100	120	490	70	160	490	160
Arizona	31,990	4,470	250	2,700	820	960	3,970	1,650	1,390	4,390	1,520
Arkansas	16,120	2,150	130	1,590	370	460	2,760	570	680	2,400	690
California	165,810	25,040	1,450	14,370	4,960	5,070	18,060	9,250	7,460	23,410	6,880
Colorado	22,820	3,420	140	1,750	600	730	2,400	1,470	1,000	3,830	1,070
Connecticut	21,530	3,140	110	1,730	680	550	2,720	1,290	890	3,340	1,170
Delaware	5,340	740	†	410	170	140	800	280	220	850	230
Dist. of Columbia	2,980	460	†	260	80	70	370	80	100	540	90
Florida	117,580	15,540	910	10,200	2,910	3,310	17,860	5,450	4,970	17,160	5,460
Georgia	48,130	6,970	410	4,090	1,170	1,230	6,570	2,150	1,840	7,900	1,680
Hawaii	6,610	1,120	50	680	220	180	860	280	230	740	220
Idaho	7,720	1,000	50	640	210	230	920	400	320	1,320	380
Illinois	65,750	9,090	510	6,030	1,900	1,980	9,190	2,460	2,870	8,950	3,030
Indiana	35,060	4,490	250	3,200	1,070	1,020	5,460	1,450	1,500	4,320	1,690
lowa	17,010	2,350	90	1,680	540	560	2,330	850	800	2,640	850
Kansas	14,090	1,990	90	1,330	420	440	1,910	610	630	1,890	630
Kentucky	25,160	3,160	180	2,280	630	670	4,430	1,370	1,070	3,200	1,080
Louisiana	23,480	3,320	200	2,350	520	660	3,660	810	930	4,040	930
Maine	8,990	1,170	50	750	300	240	1,340	480	390	1,320	520
Maryland	31,000	4,700	210	2,420	920	780	4,250	1,420	1,280	5,190	1,200
Massachusetts	38,470	5,480	190	2,990	1,250	930	4,920	2,190	1,590	6,180	2,000
Michigan	57,790	7,710	350	5,080	1,770	1,700	8,210	2,700	2,550	9,450	2,830
Minnesota	28,060	4,110	150	2,370	910	900	3,750	1,130	1,290	4,520	1,320
Mississippi	15,190	1,990	140	1,580	330	360	2,550	510	540	2,330	550
Missouri	33,440	4,440	230	3,250	1,060	1,010	5,370	1,280	1,460	4,110	1,510
Montana	5,550	740	+	470	150	170	700	320	250	1,000	270
Nebraska	9,030	1,270	60	910	280	300	1,230	380	440	1,240	430
Nevada	13,780	1,770	120	1,260	330	390	1,930	510	530	1,850	610
New Hampshire	8,350	1,160	†	680	280	240	1,130	470	350	1,260	460
New Jersey	50,650	6,970	390	4,630	1,670	1,460	5,990	2,340	2,160	7,550	2,480
New Mexico	9,640	1,310	70	840	260	310	1,090	560	420	1,430	380
New York	109,440	14,730	850	9,390	3,730	2,970	13,620	4,700	4,680	17,090	5,460
North Carolina	51,860	7,090	390	4,140	1,390	1,410	7,950	2,360	2,050	8,010	2,100
North Dakota	3,510	490	†	350	110	120	460	130	160	530	170
Ohio	66,560	8,990	400	6,020	2,110	1,810	10,270	3,030	2,920	8,560	3,160
Oklahoma	19,210	2,630	170	1,780	470	600	3,370	750	850	2,560	820
Oregon	21,370	3,200	130	1,670	620	610	2,920	1,290	950	3,460	1,020
Pennsylvania	78,340	10,290 870	460 †	7,330 540	2,570	2,340 170	10,890 860	3,470 290	3,510 240	11,890 810	4,150
Rhode Island	6,310										
South Carolina	26,570	3,570	220	2,350	670	700	4,270	1,150	1,040	4,140	1,060
South Dakota	4,430	600	770	420	140	130	620	170	200	700	220
Tennessee	35,610	4,680	270	3,240	850	920	6,140	1,640	1,440	4,900	1,490
Texas Utah	110,470 10,620	15,050 1,480	1,080 70	9,700 780	2,600 290	3,530 370	14,810 880	4,020 780	4,750 480	15,730 1,850	3,940 420
							550				
Vermont	4,060	560	700	330	130	110		220	160	580	210
Virginia	41,380	6,190	290	3,250 2,770	1,220 1,080	1,020 1,050	5,550	2,150 2,140	1,700	6,860	1,620 1,670
Washington West Virginia	35,790 11,610	5,240 1,430	220 80	1,080	330	330	4,700 2,070	520	1,600 490	5,060 1,540	510
West Virginia Wisconsin	31,920	4,270	190	2,730	1,040	1,110	4,220	1,370	1,460	4,310	1,600
Wyoming	2,650	360	190	2,730	70	80	330	1,370	1,460	4,310	130
		226,870		143,460	47,130	47,150	226,160	76,250		241,740	73,510
United States	1,638,910	220,070	12,170	143,400	47,130	47,150	220,100	70,250	70,130	241,740	13,510

<sup>\*</sup>Rounded to nearest 10. Excludes basal and squamous cell skin cancers and in situ carcinomas except urinary bladder. †Estimate is fewer than 50 cases.

**Note:** These estimates are offered as a rough guide and should be interpreted with caution. State estimates may not sum to US total due to rounding and exclusion of state estimates fewer than 50 cases.

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State	All Sites	Brain/ Nervous System	Female Breast	Colon & Rectum	Leukemia	Liver	Lung & Bronchus	Non- Hodgkin Lymphoma	Ovary	Pancreas	Prostate
Alabama	10,290	230	710	980	390	320	3,240	320	300	600	560
Alaska	930	†	70	80	7	†	260	†	†	60	†
Arizona	11,090	300	780	1,010	460	440	2,850	400	330	720	570
Arkansas	6,570	150	420	610	260	180	2,160	170	150	370	290
California	56,620	1,540	4,110	5,140	2,430	2,880	12,830	2,000	1,680	3,860	3,110
Colorado	7,190	230	510	680	300	270	1,690	250	250	490	380
Connecticut	6.940	160	480	560	270	230	1,780	230	210	510	380
Delaware	1,930	50	120	170	70	70	580	60	50	120	90
Dist. of Columbia	1,010	†	80	100	†	†	250	†	†	80	60
Florida	42,170	850	2,600	3,660	1,760	1,460	12,200	1,400	1,040	2,670	2,160
Georgia	15,790	350	1,140	1,470	600	480	4,650	470	450	970	860
Hawaii	2,380	†	140	240	80	120	580	80	60	200	100
Idaho	2,640	90	170	220	130	80	660	100	70	190	160
Illinois	23,970	500	1,650	2,300	990	730	6,590	760	620	1,580	1,140
Indiana	13,240	320	850	1,160	560	350	4,140	450	340	790	560
lowa	6,410	180	400	590	290	180	1,790	230	190	390	330
Kansas	5,400	150	370	510	250	160	1,790	200	140	340	230
Kentucky	9,890	190	570	890	350	250	3,530	310	220	530	360
Louisiana	9,150	210	660	900	330	380	2,730	270	220	570	390
Maine	3,230	80	180	260	120	90	970	110	70	200	130
Maryland	10,440	230	810	940	420	350	2,850	320	280	720	510
Massachusetts	12,930	300	800	1,060	500	480	3,570	420	370	910	600
	20,430	530	1,350	1,730	890	660	5,910	720	550	1,370	840
Michigan Minnesota	9,490	240	600	800	440	320	2,500	330	260	600	480
Mississippi	6,330	140	440	640	240	220	1,960	170	140	370	310
		300	900		550	390	3,970	390	280		580
Missouri	12,710	60	110	1,120 170	90	50	580	70	60	800 130	
Montana Nebraska	2,010 3,450	100	210	360	150	80	900	130	90	210	110 190
Nevada	4,590	140	350	510	170	210	1,490	140	120	340	260
New Hampshire	2,700	70	180	220	100	80	750	80	60	200	120
New Jersey	16,650	340	1,340	1,600	650	540	4,200	550	490	1,130	720
New Mexico	3,530	90	240	350	140	170	780	110 1,080	100	240	200
New York	34,140	740 390	2,420 1,290	3,090	1,430	1,350 580	8,880		1,010	2,420	1,610
North Carolina North Dakota	18,440 1,300	7	90	1,530 130	690 60	500	5,600 320	560 50	460	1,130 90	1,020 70
Ohio	25,030	570	1,750	2,250	970	720	7,350	800	600	1,710	1,210
Oklahoma	7,800	200	500	720	310	240	2,440	260	180	420	430
Oregon	7,790	220	510 1,950	670	310	270 880	2,120	280	240	520	410
Pennsylvania	28,790	570 50	1,950	2,460 170	1,190 100	80	7,750 620	1,030 70	810 60	1,940 130	1,330 90
Rhode Island	2,190										
South Carolina	9,670	220	660	830	350	300	2,970	280	220	570	440
South Dakota	1,630	Ť	110	160	70	†	450	60	50	100	80
Tennessee	13,880	340	890	1,230	510	410	4,570	430	330	790	580
Texas	36,820	900	2,650	3,400	1,490	1,830	9,780	1,180	930	2,240	1,630
Utah	2,780	110	250	240	160	90	460	110	90	210	270
Vermont	1,300	†	80	110	50	†	370	†	†	90	60
Virginia	14,610	320	1,110	1,290	570	440	4,150	450	420	990	660
Washington	12,170	400	800	990	510	500	3,270	390	390	810	670
West Virginia	4,600	100	280	440	160	110	1,460	160	120	220	160
Wisconsin	11,240	300	690	920	510	350	3,000	400	320	760	570
Wyoming	940	†	60	90	+	+	250	†	†	70	†
United States	577,190	13,700	39,510	51,690	23,540	20,550	160,340	18,940	15,500	37,390	28,170

\*Rounded to nearest 10. †Estimate is fewer than 50 deaths.

Note: State estimates may not add to US total due to rounding and exclusion of state estimates fewer than 50 deaths.

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## Incidence Rates\* for Selected Cancers by State, US, 2004-2008

	All	Sites	Breast		on & ctum		ng & nchus		lodgkin ohoma	Prostate		nary dder
State	Male	Female	Female	Male	Female	Male	Female	Male	Female	Male	Male	Female
Alabama†	579.9	391.1	117.2	61.3	42.0	106 8	54.1	19.8	13.8	160.8	32.8	7.6
Alaska	531.4	441.0	130.4	55.1	45.5	85 3	64.8	22.3	18.2	141.5	39.4	8.6
Arizona	447.5	360.6	106.7	43.4	32.5	63 9	48.2	18.0	13.3	122.9	32.5	8.6
Arkansas	556.4	385.6	109.0	56.2	41.4	109 2	61.0	21.7	15.4	156.4	32.8	8.4
California	512.8	396.9	122.4	51.2	38.6	63 3	45.7	22.8	15.6	146.5	34.3	8.1
Colorado	498.2	393.5	122.3	48.4	37.0	57 6	45.0	22.0	15 8	156.3	32.1	8 3
Connecticut	590.0	458.5	136.2	57.4	42.9	80 2	60.0	26.3	17.9	162.1	47.6	12 3
Delaware	614.3	446.9	126.6	59.6	42.6	94 4	69.5	24.3	17.0	181.7	44.4	11 9
Dist. of Columbia <sup>‡</sup>	573.2	398.3	126.7	54.1	43.7	80 3	45.3	22.7	12.8	187.9	24.4	7 7
Florida	531.2	402.6	113.6	51.9	39.3	85 1	59.0	21.7	15.3	137.3	35.9	9 1
Georgia	571.9	395.7	119.2	55.7	40.0	97.3	54.5	21.7	14.5	167.4	33.1	8.0
Hawaii	503.7	393.3	122.4	59.7	39.8	70.5	40.7	20.3	12.4	132.1	26.2	6.4
Idaho	532.0	408.7	116.5	46.5	37.8	66.8	49.0	22.5	17.1	162.5	36.6	9.2
Illinois	577.0	433.8	123.9	63.9	46.5	89.9	59.8	24.2	16.3	157.7	40.1	10.2
Indiana	544.0	418.6	115.1	59.5	44.2	99.8	63.6	23.0	17.0	132.7	36.7	9.2
lowa	563.7	431.4	122.5	61.3	47.1	88.0	55.3	26.4	18.4	141.7	42.1	8.9
Kansas	556.4	420.6	124.4	57.9	41.7	85.0	53.6	23.9	17.6	158.1	37.0	9.3
Kentucky	612.1	456.4	120.5	66.7	47.4	130.1	79.5	24.7	17.3	139.8	40.1	10.1
Louisiana†	618.1	409.9	118.2	66.0	44.7	105.8	58.6	24.0	17.1	172.0	35.0	8.4
Maine	612.7	468.1	128.9	58.3	46.0	97.2	66.6	26.0	18.6	163.3	48.2	13.5
Maryland†	533.1	411.6	123.4	52.4	39.3	80 0	57.4	20.5	14 2	157.0	33.0	9 7
Massachusetts	588.6	459.2	133.4	56.8	42.0	82 4	64.1	24.6	16.6	160.8	45.6	12.7
Michigan	582.8	432.7	120.3	54.6	41.6	89 1	61.8	25.1	18 3	169.4	41.7	10.7
Minnesota	573.1	421.1	126.4	53.7	41.1	67.6	49.6	26.9	18.1	184.2	40.7	9.7
Mississippi†	608.1	392.1	112.8	64.7	45.7	117.2	56.0	21.6	14.2	174.1	31.3	7.3
Missouri	547.1	418.8	120.6	59.7	43.1	101.3	63.8	22.1	16.0	131.8	35.8	8.4
Montana	518.7	410.9	120.0	51.2	39.3	72.8	58.2	22.2	15.5	160.7	36.3	9.7
Nebraska	559.7	425.4	125.0	65.2	46.9	82.3	52.0	24.4	17.5	157.2	37.2	9.1
Nevada‡	507.6	404.1	111.7	51.2	41.1	79.0	66.8	20.4	15.7	135.5	37.6	10.6
New Hampshire	576.3	455.7	132.2	54.3	41.4	82.2	62.2	23.1	17.3	154.8	46.0	13.2
New Jersey New Mexico New York North Carolina North Dakota	595.1 467.4 580.9 576.6 559.3	453.8 369.5 438.4 412.5 417.1	129.7 110.5 124.3 123.3 124.2	60.6 46.2 56.7 55.8 66.4	44.4 35.5 43.0 39.9 44.5	76.7 54.5 77.3 101.6 72.5	56.7 39.4 54.8 57.8 46.2	25.6 18.5 25.5 22.7 23.1	17.7 14.4 17.5 15.6 17.4	171.0 137.6 166.9 158.8 169.5	46.7 25.9 42.5 37.1 40.8	12.2 7.0 11.0 9.1
Ohio Oklahoma Oregon Pennsylvania Rhode Island	551.1 566.3 531.6 586.6 603.1	421.2 428.0 431.5 449.4 464.5	119.8 125.6 130.3 124.8 132.5	58.5 56.8 50.0 61.4 59.0	43.6 42.7 38.7 46.0 44.8	94.9 103.2 76.0 88.4 90.8	60.0 65.6 59.8 57.6 63.2	23.2 23.0 24.2 24.9 24.4	16.2 17.7 16.3 17.6 17.5	146.0 151.8 149.2 155.8 155.1	39.0 35.8 38.7 45.1 53.1	9.6 8.7 10.0 11.0
South Carolina	569.1	396.9	119 9	55.6	41.0	97.9	53.4	20.5	14 1	165.5	30.9	7.8
South Dakota	515.1	386.8	117 4	55.8	40.9	76.3	46.6	20.3	16 7	158.5	34.0	7.9
Tennessee	558.0	404.6	117 2	57.4	42.2	108.7	60.7	22.1	16 1	142.2	34.4	8.3
Texas <sup>†</sup>	529.9	388.5	113 7	54.4	37.8	82.3	49.9	22.3	15 8	143.3	29.4	7.0
Utah	476.2	344.7	109.5	42.2	31.2	34.1	22.3	23.4	16 0	173.7	28.7	5.8
Vermont	552.6	453.2	130.1	46.7	41.5	81.9	62.1	23.7	17.4	152.1	43.8	13.1
Virginia	542.1	396.9	124.2	52.3	39.5	88.0	54.3	21.2	14.2	159.4	34.0	8.4
Washington	552.5	434.8	129.8	49.5	37.4	73.4	58.3	26.5	17.7	157.9	39.7	9.5
West Virginia	581.9	441.2	112.6	64.7	47.4	115.0	73.2	23.9	17.3	140.4	40.0	11.1
Wisconsin	555.8	430.9	123.4	53.2	41.0	78.1	54.3	28.3	20.1	150.9	38.7	10.0
Wyoming United States	517.6 553.0	391.2 416.5	114.6	51.2 55.7	39.6 41.4	59.5 84.4	48.1	22.4	14.8 16.3	166.2 152.9	41.4 37.6	10.1

<sup>\*</sup>Per 100,000, age adjusted to the 2000 US standard population. †Data for 2005 are limited to cases diagnosed from January-June due to the effect of large migrations of populations on this state as a result of Hurricane Katrina in September 2005. ‡This state's data are not included in the rates for the US overall because its cancer registry did not achieve high-quality data standards for one or more years during 2004-2008 according to the North American Association of Central Cancer Registry (NAACCR) data quality indicators.

Source: NAACCR, 2011. Data are collected by cancer registries participating in the National Cancer Institute's SEER program and the Centers for Disease Control and Prevention's National Program of Cancer Registries.

American Cancer Society, Surveillance Research, 2012

	All	Sites	Breast		lon & ctum				Hodgkin phoma	Pai	Prostate	
State	Male	Female	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male
Alabama	262.0	158.7	24.5	23.6	15.2	90.3	41.0	8.5	5.5	12.9	9.4	29.9
Alaska	212.4	157.2	21.7	21.5	13.5	62.3	46.3	7.7	5.1	11.9	10.4	22.5
Arizona	186.7	132.4	21.0	17.5	11.9	52.1	33.9	7.7	4.9	11.4	7.8	20.6
Arkansas	254.9	164.1	24.0	23.2	15.6	93.2	47.4	8.6	5.2	12.7	9.5	26.2
California	197.4	143.4	22.5	18.4	13.3	50.3	33.9	8.2	5.1	11.8	9.3	23.6
Colorado	187.3	135.7	20.5	18.3	13.3	46.1	32.3	8.2	4.7	11.2	8.8	24.3
Connecticut	216.4	152.5	23.2	18.1	13.8	58.5	39.1	8.2	5.4	14.4	10.1	25.7
Delaware	238.5	167.5	24.3	20.8	15.0	73.7	50.3	9.0	5.1	12.1	9.8	26.7
Dist. of Columbia	260.4	161.1	27.6	23.0	18.1	68.6	35.1	8.8	3.2	16.1	10.1	41.7
Florida	209.4	143.9	21.9	18.7	13.3	65.1	40.1	8.0	5.0	11.9	8.6	20.3
Georgia	237.1	149.5	23.2	20.7	14.3	78.9	38.9	8 0	4.8	12.8	8.8	28.6
Hawaii	186.2	120.7	17.8	18.8	10.7	51.8	27.4	7 2	4.4	12.9	9.4	16.8
Idaho	197.9	145.7	21.2	15.9	13.8	52.0	34.9	8 2	5.8	11.6	10.2	27.3
Illinois	233.3	162.0	24.7	23.2	16.2	69.9	42.0	9 1	5.6	13.2	10.1	26.1
Indiana	247.3	164.8	24.0	23.1	15.6	82.8	47.2	9 9	5.8	12.9	9.5	25.2
lowa	224.7	151.7	22.1	21.3	15.5	70.0	39.3	9.2	5.6	12.1	8.8	25.1
Kansas	224.7	151.3	23.1	21.8	14.5	71.8	40.9	9.7	5.5	12.7	9.4	22.2
Kentucky	271.2	175.1	23.5	24.4	17.0	103.0	56.1	9.3	6.0	12.3	9.3	25.6
Louisiana	268.1	168.6	26.8	25.8	16.3	87.8	45.0	9.3	5.5	14.0	10.9	28.6
Maine	243.4	164.7	21.5	20.9	15.4	75.6	47.3	9.3	6.0	12.7	10.0	25.0
Maryland	229.7	159.7	25.6	22.6	15.0	67.4	42.2	8.1	5.0	12.8	10.5	27.5
Massachusetts	227.3	156.0	22.3	20.1	14.4	64.0	42.7	8.7	5.4	13.2	10.3	24.1
Michigan	231.1	162.1	24.4	20.6	15.1	71.5	43.9	9.2	6.2	13.6	9.9	23.6
Minnesota	208.8	147.6	21.6	18.2	13.0	57.0	37.3	9.5	5.4	11.8	9.3	25.1
Mississippi	276.1	161.4	25.5	25.2	16.6	98.9	43.3	8.5	4.6	13.6	9.6	31.7
Missouri	242.0	162.7	25.4	22.1	15.0	83.1	46.4	8 5	5.5	12.9	9.5	23.1
Montana	208.1	153.0	20.7	17.5	13.9	59.5	42.4	8 5	5.6	12.3	9.3	28.0
Nebraska	217.1	147.2	22.0	22.9	15.6	64.1	35.9	9 0	5.9	12.2	8.7	24.9
Nevada	214.7	163.0	23.5	21.3	16.4	62.7	50.0	6 8	4.9	12.1	10.0	24.5
New Hampshire	223.4	159.1	22.8	20.5	13.9	63.4	43.7	8 3	5.1	12.8	11.0	25.1
New Jersey New Mexico New York North Carolina North Dakota	218.5 193.0 204.6 241.4 212.8	160.6 136.8 148.0 155.5 146.0	26.5 21.5 23.1 24.4 22.3	22.6 19.6 20.2 20.4 22.2	16.0 13.4 14.5 14.2 14.3	59.7 45.5 56.6 81.1 59.3	39.1 29.5 36.4 41.9 35.4	8.5 6.6 8.0 8.0	5.7 4.8 5.1 5.3 5.1	13.3 11.5 12.6 12.5 12.4	9.9 9.3 9.8 9.7 9.5	23 4 24 6 23 0 27 0 25 9
Ohio	246.5	165.5	25.9	23.3	16.0	78.5	45.0	95	5.6	13.1	9.7	26.3
Oklahoma	245.4	161.5	24.1	23.3	14.9	84.0	46.8	92	5.7	11.8	8.7	23.9
Oregon	217.7	158.7	22.5	19.0	14.1	62.9	44.3	91	5.9	12.3	10.3	26.0
Pennsylvania	235.6	161.1	24.8	22.7	15.8	69.9	40.3	94	5.9	13.5	9.8	24.5
Rhode Island	234.4	155.0	22.2	20.6	13.5	69.0	43.4	91	4.8	12.3	8.7	23.8
South Carolina	245.7	153.9	24.3	20.9	14.6	81.7	39 9	7.8	5.1	12.6	9.5	28.5
South Dakota	214.2	142.7	21.8	20.5	14.3	65.4	36 3	8.7	5.3	11.2	9.2	24.4
Tennessee	261.1	164.0	24.5	22.7	15.6	93.9	47 2	9.3	5.5	12.8	9.4	26.3
Texas	217.8	145.1	22.6	20.7	13.4	65.7	36 9	8.2	5.2	11.8	8.6	22.6
Utah	158.3	112.4	22.1	14.6	10.2	29.5	16 9	7.8	5.0	9.7	7.9	25.6
Vermont Virginia Washington West Virginia Wisconsin Wyoming	214.2 232.7 211.9 257.1 222.8 199.4	155.5 155.5 155.7 174.0 154.3 150.7	21.7 25.1 22.4 23.9 22.1 22.1	20.2 21.0 18.2 24.4 19.4 19.9	15.0 14.4 13.1 16.9 13.6 14.6	62.5 73.0 59.7 89.1 61.4 52.5	43 2 41.3 43.2 50.8 39.2 38.2	7.7 8.3 8.9 9.6 9.5 8.1	5.1 5.7 6.5 5.9 6.3	11.5 13.1 12.1 11.7 12.8 12.4	9.6 9.9 9.8 7.6 9.7 10.4	24.3 26.3 25.2 21.6 26.7 22.7
United States	223.0	153.2	23.5	20.7	14.5	67.4	40.1	8.6	5.4	12.4	9.4	24.4

\*Per 100,000, age adjusted to the 2000 US standard population. **Source:** US Mortality Data, National Center for Health Statistics, Centers for Disease Control and Prevention.

American Cancer Society, Surveillance Research, 2012

## **Selected Cancers**

#### **Breast**

New Cases: An estimated 226,870 new cases of invasive breast cancer are expected to occur among women in the US during 2012; about 2,190 new cases are expected in men. Excluding cancers of the skin, breast cancer is the most frequently diagnosed cancer in women. The breast cancer incidence rate began to decline in 2000 after peaking at 142 per 100,000 women in 1999. The dramatic decrease of almost 7% from 2002 to 2003 has been attributed to reductions in the use of menopausal hormone therapy (MHT), previously known as hormone replacement therapy, following the publication of results from the Women's Health Initiative in 2002; this study found that the use of combined estrogen plus progestin MHT was associated with an increased risk of breast cancer, as well as coronary heart disease. From 2004-2008, the most recent five years for which data are available, breast cancer incidence rates were stable.

In addition to invasive breast cancer, 63,300 new cases of in situ breast cancer are expected to occur among women in 2012. Of these, approximately 85% will be ductal carcinoma in situ (DCIS). Since 2004, in situ breast cancer incidence rates have been stable in white women and increasing in African American women by 2.0% per year.

**Deaths:** An estimated 39,920 breast cancer deaths (39,510 women, 410 men) are expected in 2012. Breast cancer ranks second as a cause of cancer death in women (after lung cancer). Death rates for breast cancer have steadily decreased in women since 1990, with larger decreases in younger women; from 2004 to 2008, rates decreased 3.1% per year in women younger than 50 and 2.1% per year in women 50 and older. The decrease in breast cancer death rates represents progress in earlier detection, improved treatment, and possibly decreased incidence.

Signs and symptoms: Breast cancer typically produces no symptoms when the tumor is small and most treatable. Therefore, it is important for women to follow recommended screening guidelines for detecting breast cancer at an early stage, before symptoms develop. Larger tumors may become evident as a painless mass. Less common symptoms include persistent changes to the breast, such as thickening, swelling, distortion, tenderness, skin irritation, redness, scaliness, or nipple abnormalities, such as ulceration, retraction, or spontaneous discharge. Typically, breast pain results from benign conditions and is not an early symptom of breast cancer.

**Risk factors:** Besides being female, increasing age is the most important risk factor for breast cancer. Potentially modifiable risk factors include weight gain after age 18, being overweight or obese (for postmenopausal breast cancer), use of MHT (combined

estrogen and progestin hormone therapy), physical inactivity, and alcohol consumption. Medical findings that predict higher risk include high breast tissue density (a mammographic measure of the amount of glandular tissue relative to fatty tissue in the breast), high bone mineral density (women with low density are at increased risk for osteoporosis), and biopsy-confirmed hyperplasia (overgrowth of cells), especially atypical hyperplasia (overgrowth of cells that do not appear normal). High-dose radiation to the chest for cancer treatment also increases risk. Reproductive factors that increase risk include a long menstrual history (menstrual periods that start early and/or end later in life), recent use of oral contraceptives, never having children, and having one's first child after age 30.

Risk is also increased by a family history of one or more firstdegree relatives with breast cancer (though most women with breast cancer do not have a family history of the disease). Inherited mutations (alterations) in breast cancer susceptibility genes account for approximately 5%-10% of all female and male breast cancer cases, but are very rare in the general population (much less than 1%). Most of these mutations are located in BRCA1 and BRCA2 genes, although mutations in other known genes have also been identified. Individuals with a strong family history of breast cancer and cancer at other sites, such as ovarian and colon cancer, should consider counseling to determine if genetic testing is appropriate. Prevention measures may be possible for individuals with breast cancer susceptibility mutations. In BRCA1 and BRCA2 mutation carriers, studies suggest that prophylactic removal of the ovaries and/or breasts decreases the risk of breast cancer considerably, although not all women who choose this surgery would have developed breast cancer. Women who consider prophylactic surgery should undergo counseling before reaching a decision.

The International Agency for Research on Cancer has concluded that there is limited evidence that tobacco smoking and shift work, particularly at night, are associated with an increased risk of breast cancer.

Modifiable factors that are associated with a lower risk of breast cancer include breastfeeding, moderate or vigorous physical activity, and maintaining a healthy body weight. Two medications, tamoxifen and raloxifene, have been approved to reduce breast cancer risk in women at high risk. Raloxifene appears to have a lower risk of certain side effects, such as uterine cancer and blood clots.

Early detection: Mammography can often detect breast cancer at an early stage, when treatment is more effective and a cure is more likely. Numerous studies have shown that early detection with mammography saves lives and increases treatment options. Steady declines in breast cancer mortality among women since 1990 have been attributed to a combination of early detection and improvements in treatment. Mammography is a very accurate screening tool, both for women at average and increased risk;

#### Leading New Cancer Cases and Deaths - 2012 Estimates

Estimated	New Cases*	Estimated Deaths					
Male	Female	Male	Female				
Prostate	Breast	Lung & bronchus	Lung & bronchus				
241,740 (29%)	226,870 (29%)	87,750 (29%)	72,590 (26%)				
Lung & bronchus	Lung & bronchus	Prostate	Breast				
116,470 (14%)	109,690 (14%)	28,170 (9%)	39,510 (14%)				
Colon & rectum	Colon & rectum	Colon & rectum	Colon & rectum				
73,420 (9%)	70,040 (9%)	26,470 (9%)	25,220 (9%)				
Urinary bladder	Uterine corpus	Pancreas	Pancreas				
55,600 (7%)	47,130 (6%)	18,850 (6%)	18,540 (7%)				
Melanoma of the skin	Thyroid	Liver & intrahepatic bile duct	Ovary				
44,250 (5%)	43,210 (5%)	13,980 (5%)	15,500 (6%)				
Kidney & renal pelvis	Melanoma of the skin	Leukemia	Leukemia				
40,250 (5%)	32,000 (4%)	13,500 (4%)	10,040 (4%)				
Non-Hodgkin lymphoma	Non-Hodgkin lymphoma	Esophagus	Non-Hodgkin lymphoma				
38,160 (4%)	31,970 (4%)	12,040 (4%)	8,620 (3%)				
Oral cavity & pharynx	Kidney & renal pelvis	Urinary bladder	Uterine corpus				
28,540 (3%)	24,520 (3%)	10,510 (3%)	8,010 (3%)				
Leukemia	Ovary	Non-Hodgkin lymphoma	Liver & intrahepatic bile duct				
26,830 (3%)	22,280 (3%)	10.320 (3 %)	6,570 (2%)				
Pancreas	Pancreas	Kidney & renal pelvis	Brain & other nervous system 5,980 (2%)				
22,090 (3%)	21,830 (3%)	8,650 (3%)					
All sites	All sites	All sites	All sites				
848,170 (100%)	790,740 (100%)	301,820 (100%)	275,370 (100%)				

\*Excludes basal and squamous cell skin cancers and in situ carcinoma except urinary bladder.

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however, like most medical tests, it is not perfect. On average, mammography will detect about 80%-90% of breast cancers in women without symptoms. Although the majority of women with an abnormal mammogram do not have cancer, all suspicious lesions should be biopsied for a definitive diagnosis. Annual screening using magnetic resonance imaging (MRI) in addition to mammography is recommended for women at high lifetime risk of breast cancer starting at age 30. (For more information, see Breast Cancer Facts & Figures 2011-2012 at cancer.org/statistics.) Concerted efforts should be made to improve access to health care and to encourage all women 40 and older to receive regular mammograms. For more information on the American Cancer Society's recommendations for breast cancer screening, see page 64.

Treatment: Taking into account tumor size, extent of spread, and other characteristics, as well as patient preference, treatment usually involves lumpectomy (surgical removal of the tumor and surrounding tissue) or mastectomy (surgical removal of the breast). Numerous studies have shown that for women whose cancer has not spread to the skin, chest wall, or distant organs, long-term survival for lumpectomy plus radiation therapy is similar to that for mastectomy. For women undergoing mastectomy, significant advances in reconstruction techniques provide several options for breast reconstruction, including the timing

of the procedure (i.e., during mastectomy or in the time period following the procedure).

Removal of some of the underarm lymph nodes during surgery is usually recommended to determine whether the tumor has spread beyond the breast. In women with early stage disease, sentinel lymph node biopsy, a procedure in which only the first lymph nodes to which cancer is likely to spread are removed, is as effective as and less damaging than full axillary node dissection, in which many underarm nodes are removed.

Treatment may also involve radiation therapy, chemotherapy (before or after surgery), hormone therapy (tamoxifen, aromatase inhibitors), or targeted therapy. Postmenopausal women with breast cancer that tests positive for hormone receptors benefit from treatment with an aromatase inhibitor (e.g., letrozole, anastrozole, or exemestane), either after, or instead of, tamoxifen. For women whose cancer tests positive for HER2/neu, approved targeted therapies include trastuzumab (Herceptin) and, for advanced disease, lapatinib (Tykerb). The US Food and Drug Administration (FDA) revoked approval of bevacizumab (Avastin) for the treatment of metastatic breast cancer in 2011 because subsequent studies have shown minimal benefit and some potentially dangerous side effects.

It is recommended that all patients with ductal carcinoma in situ (DCIS) be treated to avoid potential progression to invasive cancer. Treatment options for DCIS include lumpectomy with radiation therapy or mastectomy; either of these options may be followed by treatment with tamoxifen if the tumor is hormone receptor-positive. Removal of axillary lymph nodes is not generally needed. A report by a panel of experts convened by the National Institutes of Health concluded that in light of the noninvasive nature and favorable prognosis of DCIS, the primary goal for future research is the ability to accurately group patients into risk categories that will allow the most successful outcomes with the minimum necessary treatment.

Survival: The 5-year relative survival rate for female breast cancer patients has improved from 63% in the early 1960s to 90% today. The 5-year relative survival for women diagnosed with localized breast cancer (cancer that has not spread to lymph nodes or other locations outside the breast) is 99%; if the cancer has spread to nearby lymph nodes (regional stage) or distant lymph nodes or organs (distant stage), the survival rate falls to 84% or 23%, respectively. For all stages combined, relative survival rates at 10 and 15 years after diagnosis are 82% and 77%, respectively. Caution should be used when interpreting long-term survival rates because they represent patients who were diagnosed many years ago and do not reflect recent advances in detection and treatment. For example, 15-year relative survival is based on patients diagnosed as early as 1990.

Many studies have shown that being overweight adversely affects survival for postmenopausal women with breast cancer. In addition, women who are more physically active are less likely to die from the disease than those who are inactive.

For more information about breast cancer, see the American Cancer Society's *Breast Cancer Facts & Figures 2011-2012*, available online at cancer.org/statistics.

### **Childhood Cancer**

**New cases:** An estimated 12,060 new cases are expected to occur among children 0 to 14 years of age in 2012. Childhood cancers are rare, representing less than 1% of all new cancer diagnoses. Overall, childhood cancer incidence rates increased slightly by 0.5% per year from 2004 to 2008, a consistent trend since 1975.

Deaths: An estimated 1,340 cancer deaths are expected to occur among children 0 to 14 years of age in 2012, about one-third of these from leukemia. Although uncommon, cancer is the second leading cause of death in children, exceeded only by accidents. Mortality rates for childhood cancer have declined by 66% over the past four decades, from 6.5 (per 100,000) in 1969 to 2.2 in 2008. The substantial progress in reducing childhood cancer mortality is largely attributable to improvements in treatment and high rates of participation in clinical trials.

Signs and symptoms: Early symptoms are usually nonspecific. Parents should ensure that children have regular medical checkups and be alert to any unusual, persistent symptoms. Signs of childhood cancer include an unusual mass or swelling; unexplained paleness or loss of energy; sudden tendency to bruise; a persistent, localized pain; prolonged, unexplained fever or illness; frequent headaches, often with vomiting; sudden eye or vision changes; and excessive, rapid weight loss. Major categories of pediatric cancer and specific symptoms include:

- Leukemia (34% of all childhood cancers), which may be recognized by bone and joint pain, weakness, pale skin, bleeding, and fever
- Brain and other nervous system (27%), which may cause headaches, nausea, vomiting, blurred or double vision, dizziness, and difficulty walking or handling objects
- Neuroblastoma (7%), a cancer of the nervous system that is most common in children younger than 5 years of age and usually appears as a swelling in the abdomen
- Wilms tumor (5%), a kidney cancer that may be recognized by a swelling or lump in the abdomen
- Non-Hodgkin lymphoma (4%) and Hodgkin lymphoma (4%), which affect lymph nodes but may spread to bone marrow and other organs, and may cause swelling of lymph nodes in the neck, armpit, or groin, as well as weakness and fever
- Rhabdomyosarcoma (3%), a soft tissue sarcoma that can occur in the head and neck, genitourinary area, trunk, and extremities, and may cause pain and/or a mass or swelling
- Retinoblastoma (3%), an eye cancer that is typically recognized because of discoloration of the eye pupil and usually occurs in children younger than 5 years of age
- Osteosarcoma (3%), a bone cancer that most often occurs in adolescents and commonly appears as sporadic pain in the affected bone that may worsen at night or with activity, with eventual progression to local swelling
- Ewing sarcoma (1%), another type of cancer that usually arises in bone, is most common in adolescents, and typically appears as pain at the tumor site.

(Proportions are provided for all races combined and may vary according to race/ethnicity.)

Treatment: Childhood cancers can be treated by a combination of therapies (surgery, radiation, and chemotherapy) chosen based on the type and stage of the cancer. Treatment is coordinated by a team of experts, including pediatric oncologists, pediatric nurses, social workers, psychologists, and others who assist children and their families. Because these cancers are uncommon, outcomes are more successful when treatment is managed by a children's cancer center. If the child is eligible, placement in a clinical trial, which compares a new treatment to the best current treatment, should also be considered.

Survival: For all childhood cancers combined, the 5-year relative survival rate has improved markedly over the past 30 years, from 58% in the mid-1970s to 83% today, due to new and improved treatments. However, rates vary considerably depending on cancer type, patient age, and other characteristics. For the most recent time period (2001-2007), the 5-year survival among children 0-14 years of age for Hodgkin lymphoma is 95%; Wilms tumor, 88%; non-Hodgkin lymphoma, 86%; leukemia, 83%; neuroblastoma, 74%; brain and other nervous system tumors, 71%; osteosarcoma, 70%; and rhabdomyosarcoma, 68%.

Pediatric cancer patients may experience treatment-related side effects not only during treatment, but many years after diagnosis as well. Late treatment effects include impairment in the function of specific organs, secondary cancers, and cognitive impairments. The Children's Oncology Group (COG) has developed long-term follow-up guidelines for screening and management of late effects in survivors of childhood cancer. For more information on childhood cancer management, see the COG Web site at survivorship guidelines.org. The Childhood Cancer Survivor Study, which has followed more than 14,000 long-term childhood cancer survivors, has also provided important and valuable information about the late effects of cancer treatment; for more information, visit ccss. stjude.org.

#### **Colon and Rectum**

New cases: An estimated 103,170 cases of colon and 40,290 cases of rectal cancer are expected to occur in 2012. Colorectal cancer is the third most common cancer in both men and women. Colorectal cancer incidence rates have been decreasing for most of the past two decades, which has largely been attributed to increases in the use of colorectal cancer screening tests that allow the detection and removal of colorectal polyps before they progress to cancer. From 2004 to 2008, annual declines in white men were much larger than those in African American men, 2.9% versus 0.8%, respectively; whereas, among women, declines among whites (2.2% per year) and African Americans (1.7% per year) were similar. In contrast to the overall declines, colorectal cancer incidence rates have been increasing by 1.7% per year since 1992 among adults younger than 50 years of age, for whom screening is not recommended for those at average risk.

Deaths: An estimated 51,690 deaths from colorectal cancer are expected to occur in 2012, accounting for 9% of all cancer deaths. Mortality rates for colorectal cancer have declined in both men and women over the past two decades; from 2004 to 2008, the rate declined by 2.7% per year in men and by 2.5% per year in women. This decrease reflects declining incidence rates and improvements in early detection and treatment.

**Signs and symptoms:** Early stage colorectal cancer does not typically have symptoms; therefore, screening is usually necessary to detect colorectal cancer in its early stages. Advanced disease may cause rectal bleeding, blood in the stool, a change in

bowel habits, and cramping pain in the lower abdomen. In some cases, blood loss from the cancer leads to anemia (low red blood cells), causing symptoms such as weakness and excessive fatigue. Due to an increase in colorectal cancer incidence in younger adults in recent years, timely evaluation of symptoms consistent with colorectal cancer in adults under age 50 is especially important.

Risk factors: The risk of colorectal cancer increases with age; 91% of cases are diagnosed in individuals 50 years of age and older. Modifiable factors associated with increased risk include obesity, physical inactivity, a diet high in red or processed meat, alcohol consumption, long-term smoking, and possibly very low intake of fruits and vegetables. Hereditary and medical factors that increase risk include a personal or family history of colorectal cancer and/or polyps, a personal history of chronic inflammatory bowel disease, and certain inherited genetic conditions (e.g., Lynch syndrome, also known as hereditary nonpolyposis colorectal cancer, and familial adenomatous polyposis [FAP]). Studies have also found that individuals with type 2 diabetes are at higher risk of colorectal cancer.

Consumption of milk and calcium and higher blood levels of vitamin D appear to decrease colorectal cancer risk. Studies suggest that regular use of nonsteroidal anti-inflammatory drugs, such as aspirin, and menopausal hormone therapy also reduce risk. However, these drugs are not recommended for the prevention of colorectal cancer among individuals at average risk because they can have serious adverse health effects.

Early detection: Beginning at age 50, men and women who are at average risk for developing colorectal cancer should begin screening. Screening can result in the detection and removal of colorectal polyps that might have become cancerous, as well as the detection of cancer at an early stage, when treatment is usually less extensive and more successful. In 2008, the American Cancer Society collaborated with several other organizations to release updated colorectal cancer screening guidelines. These joint guidelines emphasize cancer prevention and draw a distinction between colorectal screening tests that primarily detect cancer and those that can detect both cancer and precancerous polyps. There are a number of recommended screening options that vary by the extent of bowel preparation, as well as test performance, limitations, time interval, and cost. For detailed information on colorectal cancer screening options, see Colorectal Cancer Facts & Figures 2011-2013 at cancer.org/statistics; see page 64 for the American Cancer Society's screening guidelines for colorectal cancer

**Treatment:** Surgery is the most common treatment for colorectal cancer. For cancers that have not spread, surgical removal may be curative. A permanent colostomy (creation of an abdominal opening for elimination of body waste) is rarely needed for colon cancer and is infrequently required for rectal cancer. Chemotherapy alone, or in combination with radiation, is given before

or after surgery to most patients whose cancer has penetrated the bowel wall deeply or spread to lymph nodes. Adjuvant chemotherapy (anticancer drugs in addition to surgery or radiation) for colon cancer in otherwise healthy patients 70 years of age and older is equally effective as in younger patients; toxicity in older patients can be limited if certain drugs (e.g., oxaliplatin) are avoided. Patients who have chemotherapy soon after surgery have better survival than those who begin later. Three targeted monoclonal antibody therapies are approved by the FDA to treat metastatic colorectal cancer: bevacizumab (Avastin) blocks the growth of blood vessels to the tumor, and cetuximab (Erbitux) and panitumumab (Vectibix) block the effects of hormone-like factors that promote cancer growth.

Survival: The 1- and 5-year relative survival rates for persons with colorectal cancer are 83% and 64%, respectively. Survival continues to decline to 58% at 10 years after diagnosis. When colorectal cancers are detected at an early, localized stage, the 5-year survival is 90%; however, only 39% of colorectal cancers are diagnosed at this stage, in part due to the underuse of screening. After the cancer has spread regionally to involve adjacent organs or lymph nodes, the 5-year survival drops to 69%. When the disease has spread to distant organs, the 5-year survival is 12%.

## Kidney

New cases: An estimated 64,770 new cases of kidney (renal) cancer are expected to be diagnosed in 2012. Kidney cancer includes renal cell carcinoma (92%), renal pelvis carcinoma (7%), and Wilms tumor (1%), a childhood cancer that usually develops before age 5 (see Childhood Cancer, page 11). From 2004 to 2008, kidney cancer incidence rates increased by 4.1% per year in men and 3.3% per year in women, primarily due to an increase in early stage disease. Early stage kidney cancer does not typically produce symptoms, and some of the increase in kidney cancer rates over the past two decades may be due to incidental diagnosis during abdominal imaging performed for other reasons.

Deaths: An estimated 13,570 deaths from kidney cancer are expected to occur in 2012. Death rates for kidney cancer decreased by 0.6% per year in women and by 0.4% per year in men from 2004 to 2008.

Signs and symptoms: Early stage kidney cancer usually has no symptoms. Symptoms that may develop as the tumor progresses include blood in the urine, a pain or lump in the lower back or abdomen, fatigue, weight loss, fever, or swelling in the legs and ankles.

Risk factors: Tobacco use is a strong risk factor for kidney cancer, with the largest increased risk for cancer of the renal pelvis, particularly for heavy smokers. Additional risk factors for renal cell carcinoma include obesity, to which an estimated 30% of cases can be attributed; hypertension (high blood pressure); chronic renal failure; and occupational exposure to certain chemicals, such as trichloroethylene, an industrial agent used as

a metal degreaser and chemical additive. Radiation exposure (e.g., in medical procedures) slightly increases risk. A small proportion of renal cell cancers are the result of rare hereditary conditions, such as von Hippel-Lindau disease.

Early detection: There are no reliable screening tests for people at average risk.

Treatment: Surgery (traditional or laparoscopic, i.e., minimally invasive, performed through very small incisions) is the primary treatment for most kidney cancers. Patients who are not surgical candidates may be offered ablation therapy, a procedure that uses heat or cold to destroy the tumor. Kidney cancer tends to be resistant to both traditional chemotherapy and radiation therapy. Improved understanding of the biology of kidney cancer has led to the development of new targeted therapies that control cancer growth by blocking the tumor's blood supply or through other mechanisms. Since 2005, six of these agents have been approved by the FDA for the treatment of metastatic disease: sorafenib (Nexavar), sunitinib (Sutent), temsirolimus (Torisel), everolimus (Afinitor), bevacizumab (Avastin), and pazopanib (Votrient).

Survival: The 1- and 5-year relative survival rates for cancers of the kidney are 84% and 70%, respectively. More than half of cases are diagnosed at the local stage, for which the 5-year relative survival rate is 91%. Five-year survival is lower for renal pelvis (50%) than for renal cell (71%) carcinoma.

### Leukemia

New cases: An estimated 47,150 new cases of leukemia are expected in 2012. Leukemia is a cancer of the bone marrow and blood and is classified into four main groups according to cell type and rate of growth: acute lymphocytic (ALL), chronic lymphocytic (CLL), acute myeloid (AML), and chronic myeloid (CML). Almost 90% of leukemia cases are diagnosed in adults 20 years of age and older, in whom the most common types are AML and CLL. Among children and teens, ALL is most common, accounting for three-fourths of leukemia cases (see Childhood Cancer, page 11). From 2004 to 2008, overall leukemia incidence rates increased slightly by 0.5% per year, a consistent trend since 1992.

Deaths: An estimated 23,540 deaths are expected to occur in 2012. Death rates for leukemia have been declining for the past several decades; from 2004 to 2008, rates decreased by 0.8% per year among males and by 1.4% per year among females.

Signs and symptoms: Symptoms may include fatigue, paleness, weight loss, repeated infections, fever, bruising easily, and nosebleeds or other hemorrhages. In acute leukemia, these signs can appear suddenly. Chronic leukemia typically progresses slowly with few symptoms and is often diagnosed during routine blood tests.

Risk factors: Exposure to ionizing radiation increases risk of several types of leukemia. Medical radiation, such as that used

Probability (%) of Developing Invasive Cancers over Selected Age Intervals by Sex, US, 2006-2008\*

		Birth to 39	40 to 59	60 to 69	70 and Older	Birth to Death
All sites†	Male	1.45 (1 in 69)	8.68 (1 in 12)	16.00 (1 in 6)	38 27 (1 in 3)	44.85 (1 in 2)
	Female	2.15 (1 in 46)	9.10 (1 in 11)	10.34 (1 in 10)	26.68 (1 in 4)	38.08 (1 in 3)
Urinary	Male	0.02 (1 in 5,035)	0.38 (1 in 266)	0.92 (1 in 109)	3.71 (1 in 27)	3.84 (1 in 26)
bladder*	Female	0.01 (1 in 12,682)	0.12 (1 in 851)	0.25 (1 in 400)	0.98 (1 in 102)	1.15 (1 in 87)
Breast	Female	0.49 (1 in 203)	3.76 (1 in 27)	3.53 (1 in 28)	6.58 (1 in 15)	12.29 (1 in 8)
Colon & rectum	Male	0.08 (1 in 1,236)	0.92 (1 in 109)	1.44 (1 in 70)	4.32 (1 in 23)	5.27 (1 in 19)
	Female	0.08 (1 in 1,258)	0.73 (1 in 137)	1.01 (1 in 99)	3.95 (1 in 25)	4.91 (1 in 20)
Leukemia	Male	0.16 (1 in 614)	0.22 (1 in 445)	0.34 (1 in 291)	1.24 (1 in 81)	1.57 (1 in 64)
	Female	0.14 (1 in 737)	0.15 (1 in 665)	0.21 (1 in 482)	0.81 (1 in 123)	1.14 (1 in 88)
Lung &	Male	0.03 (1 in 3,631)	0.91 (1 in 109)	2.26 (1 in 44)	6.69 (1 in 15)	7.66 (1 in 13)
bronchus	Female	0.03 (1 in 3,285)	0.76 (1 in 132)	1.72 (1 in 58)	4.91 (1 in 20)	6.33 (1 in 16)
Melanoma	Male	0.15 (1 in 677)	0.63 (1 in 158)	0.75 (1 in 133)	1.94 (1 in 52)	2.80 (1 in 36)
of the skins	Female	0.27 (1 in 377)	0.56 (1 in 180)	0.39 (1 in 256)	0.82 (1 in 123)	1.83 (1 in 55)
Non-Hodgkin	Male	0.13 (1 in 775)	0.45 (1 in 223)	0.60 (1 in 167)	1.77 (1 in 57)	2.34 (1 in 43)
lymphoma	Female	0.09 (1 in 1,152)	0.32 (1 in 313)	0.44 (1 in 228)	1.41 (1 in 71)	1.94 (1 in 51)
Prostate	Male	0.01 (1 in 8,499)	2.63 (1 in 38)	6.84 (1 in 15)	12.54 (1 in 8)	16.48 (1 in 6)
Uterine cervix	Female	0.15 (1 in 650)	0.27 (1 in 373)	0.13 (1 in 771)	0.18 (1 in 549)	0.68 (1 in 147)
Uterine corpus	Female	0 07 (1 in 1,373)	0.77 (1 in 130)	0.87 (1 in 114)	1.24 (1 in 81)	2.61 (1 in 38)

<sup>\*</sup>For people free of cancer at beginning of age interval. †All sites excludes basal and squamous cell skin cancers and in situ cancers except urinary bladder. ‡Includes invasive and in situ cancer cases. §Statistic is for whites only.

Source: DevCan: Probability of Developing or Dying of Cancer Software, Version 6.6.0. Statistical Research and Applications Branch, National Cancer Institute, 2011, www.srab.cancer.gov/devcan.

American Cancer Society, Surveillance Research, 2012

in cancer treatment, is a substantial source of radiation exposure. Leukemia may also occur as a side effect of chemotherapy. Children with Down syndrome and certain other genetic abnormalities have higher incidence rates of leukemia. Some recent studies suggest that obesity may also be associated with an increased risk of leukemia. Family history is one of the strongest risk factors for CLL. Cigarette smoking and exposure to certain chemicals such as benzene, a component in gasoline and cigarette smoke, are risk factors for AML. There is limited evidence that parental smoking and maternal exposure to paint increases the risk of childhood leukemia. Infection with human T-cell leukemia virus type I (HTLV-I) can cause a rare type of CLL called adult T-cell leukemia/lymphoma. The prevalence of HTLV-I infection is geographically localized and is most common in southern Japan and the Caribbean; infected individuals in the US tend to be descendants or immigrants from endemic regions.

**Early detection:** Leukemia can be difficult to diagnose early because symptoms often resemble those of other, less serious conditions. When a physician does suspect leukemia, diagnosis can be made using blood tests and a bone marrow biopsy.

**Treatment:** Chemotherapy is the most effective method of treating leukemia. Various anticancer drugs are used, either in combination or as single agents. Imatinib (Gleevec), nilotinib (Tasigna), and dasatinib (Sprycel) are very effective targeted drugs for the treatment of CML. These drugs are also sometimes

used to treat a certain type of ALL. Some people with CLL may not need treatment right away, unless the leukemia is progressing or causing symptoms. Recent clinical trials have shown that adults with AML who are treated with twice the conventional dose of daunorubicin experience higher and more rapid rates of remission. Antibiotics and transfusions of blood components are used as supportive treatments. Under appropriate conditions, stem cell transplantation may be useful in treating certain types of leukemia.

**Survival:** Survival rates vary substantially by leukemia type, ranging from a 5-year relative survival of 24% for patients diagnosed with AML to 81% for those with CLL. Advances in treatment have resulted in a dramatic improvement in survival over the past three decades for most types of leukemia. For example, from 1975-1977 to 2001-2007, the 5-year relative survival rate for ALL increased from 41% to 67% overall, and from 58% to 91% among children. In large part due to the discovery of the targeted cancer drug imatinib (Gleevec), the 5-year survival rate for CML increased from 31% for cases diagnosed during 1990-1992 to 55% for those diagnosed during 2001-2007.

#### Liver

**New Cases:** An estimated 28,720 new cases of liver cancer (including intrahepatic bile duct cancers) are expected to occur in the US during 2012. More than 80% of these cases are hepato-

cellular carcinoma (HCC), originating from hepatocytes, the predominant liver cell type. Liver cancer incidence rates increased by 3.6% per year in men and by 3.0% per year in women from 2004 to 2008, trends that have persisted since 1992.

Deaths: An estimated 20,550 liver cancer deaths (6,570 women, 13,980 men) are expected in 2012. From 2004 to 2008, death rates for liver cancer increased by 2.2% per year in men and were stable in women. Incidence and mortality rates are more than twice as high in men as in women.

Signs and symptoms: Common symptoms include abdominal pain and/or swelling, weight loss, weakness, loss of appetite, jaundice (a yellowish discoloration of the skin and eyes), and fever. Enlargement of the liver is the most common physical sign, occurring in 50%-90% of patients.

Risk factors: In the US and other western countries, alcoholrelated cirrhosis, and possibly non-alcoholic fatty liver disease associated with obesity, account for the majority of liver cancer cases. Chronic infections with hepatitis B virus (HBV) and hepatitis C virus (HCV) are associated with less than half of liver cancer cases in the US, although they are the major risk factors for the disease worldwide. In the US, rates of HCC are higher in immigrants from areas where HBV is endemic, such as China, Southeast Asia, and sub-Saharan Africa. A vaccine that protects against HBV has been available since 1982. The HBV vaccination is recommended for all infants at birth; for all children under 18 years of age who were not vaccinated at birth; and for adults in high-risk groups, including health care workers. It is also recommended that all pregnant women be tested for HBV. There is no vaccine available against HCV. The Centers for Disease Control and Prevention (CDC) recommends routine HCV testing for individuals at high risk (e.g., injection drug users) so that infected individuals can receive counseling in order to reduce the risk of HCV transmission to others. Other preventive measures for HCV infection include screening of donated blood, organs, and tissues; instituting infection control practices during all medical, surgical, and dental procedures; and needle-exchange programs for injecting drug users. Treatment of chronic HCV infection with interferon and other drugs may reduce the risk of liver cancer and is the subject of ongoing research. For more information on hepatitis infections, including who is at risk, visit the CDC Web site at cdc.gov/hepatitis/.

Other risk factors for liver cancer, particularly in economically developing countries, include parasitic infections (schistosomiasis and liver flukes) and consumption of food contaminated with aflatoxin, a toxin produced by mold during the storage of agricultural products in a warm, humid environment.

Early detection: Screening for liver cancer has not been proven to improve survival. Nonetheless, many doctors in the US screen high-risk persons (e.g., HCV-infected persons with cirrhosis) with ultrasound or blood tests.

Treatment: Early stage liver cancer can sometimes be successfully treated with surgery in patients with sufficient healthy liver tissue; liver transplantation may also be an option. Fewer surgical options exist for patients diagnosed at an advanced stage of the disease, often because the portion of the liver not affected by cancer is also damaged. Patients whose tumors cannot be surgically removed may choose ablation (tumor destruction) or embolization, a procedure that cuts off blood flow to the tumor. Sorafenib (Nexavar) is a targeted drug approved for the treatment of HCC in patients who are not candidates for surgery.

Survival: The overall 5-year relative survival rate for patients with liver cancer is 14%. Thirty-nine percent of patients are diagnosed at an early stage, for which five-year survival is 27%. Survival decreases to 9% and 4% for patients who are diagnosed at regional and distant stages of disease, respectively.

## **Lung and Bronchus**

New cases: An estimated 226,160 new cases of lung cancer are expected in 2012, accounting for about 14% of cancer diagnoses. The incidence rate has been declining in men over the past two decades, from a high of 102 (cases per 100,000 men) in 1984 to 72 in 2008. In women, the rate has just begun to decrease after a long period of increase. From 2004 to 2008, lung cancer incidence rates decreased by 1.9% per year in men and by 0.3% per year in

Deaths: Lung cancer accounts for more deaths than any other cancer in both men and women. An estimated 160,340 deaths, accounting for about 28% of all cancer deaths, are expected to occur in 2012. Death rates began declining in men in 1991; from 2004 to 2008, rates decreased 2.6% per year. Lung cancer death rates did not begin declining in women until 2003; from 2004 to 2008, rates decreased by 0.9% per year. Gender differences in lung cancer mortality patterns reflect historical differences between men and women in the uptake and reduction of cigarette smoking over the past 50 years.

Signs and symptoms: Symptoms may include persistent cough, sputum streaked with blood, chest pain, voice change, and recurrent pneumonia or bronchitis.

Risk factors: Cigarette smoking is by far the most important risk factor for lung cancer; risk increases with both quantity and duration of smoking. Cigar and pipe smoking also increase risk. Exposure to radon gas released from soil and building materials is estimated to be the second leading cause of lung cancer in Europe and North America. Other risk factors include occupational or environmental exposure to second hand smoke, as bestos(particularly among smokers), certain metals (chromium, cadmium, arsenic), some organic chemicals, radiation, air pollution, and paint (occupational). Risk is also probably increased among people with a medical history of tuberculosis. Genetic susceptibility plays a contributing role in the development of lung cancer, especially in those who develop the disease at a younger age.

Early detection: Recently published results from a large clinical trial showed that annual screening with chest x-ray does not reduce lung cancer mortality. Newer tests, such as low-dose spiral computed tomography (CT) scans and molecular markers in sputum, have produced promising results in detecting lung cancers at earlier, more operable stages in high-risk patients. Results from the National Lung Screening Trial, a clinical trial designed to determine the effectiveness of lung cancer screening in high-risk individuals, showed 20% fewer lung cancer deaths among current and former heavy smokers who were screened with spiral CT compared to standard chest x-ray. However, it is not known how relevant these results are to individuals with a lesser smoking history compared with the study participants, who had a history of very heavy smoking - the equivalent of at least a pack of cigarettes per day for 30 years. In addition, the potential risks associated with screening, including cumulative radiation exposure from multiple CT scans, and unnecessary lung biopsy and surgery, have not yet been evaluated. It will take some time to develop formal guidelines based on a careful evaluation of the benefits, limitations, and harms associated with screening an asymptomatic population at high risk for lung cancer. In the interim, the Society has issued lung cancer screening guidance for adults who would have met the criteria for participation in the screening trial. For more information, visit cancer.org/healthy/ findcancerearly.

Treatment: Lung cancer is classified as small cell (14%) or nonsmall cell (85%) for the purposes of treatment. Based on type and stage of cancer, treatments include surgery, radiation therapy, chemotherapy, and targeted therapies such as bevacizumab (Avastin), erlotinib (Tarceva), and crizotinib (Xalkori). For localized non-small cell lung cancers, surgery is usually the treatment of choice, and survival for most of these patients is improved by giving chemotherapy after surgery. Because the disease has usually spread by the time it is discovered, radiation therapy and chemotherapy are often used, sometimes in combination with surgery. Advanced-stage non-small cell lung cancer patients are usually treated with chemotherapy, targeted drugs, or some combination of the two. Chemotherapy alone or combined with radiation is the usual treatment of choice for small cell lung cancer; on this regimen, a large percentage of patients experience remission, though the cancer often returns.

Survival: The 1-year relative survival for lung cancer increased from 37% in 1975-1979 to 43% in 2003-2006, largely due to improvements in surgical techniques and combined therapies. However, the 5-year survival rate for all stages combined is only 16%. The 5-year survival rate is 52% for cases detected when the disease is still localized, but only 15% of lung cancers are diagnosed at this early stage. The 5-year survival for small cell lung cancer (6%) is lower than that for non-small cell (17%).

## Lymphoma

New cases: An estimated 70,130 new cases of lymphoma will occur in 2012. Lymphoma is cancer of the lymphocytes, a type of white blood cell, and is classified as Hodgkin (9,060 cases in 2012) or non-Hodgkin (70,130 cases in 2012). Incidence rates were stable in men and women for both non-Hodgkin and Hodgkin lymphoma from 2004 to 2008. However, non-Hodgkin lymphoma (NHL) encompasses a wide variety of disease subtypes for which incidence patterns vary.

Deaths: An estimated 20,130 deaths from lymphoma will occur in 2012 (Hodgkin lymphoma, 1,190; non-Hodgkin lymphoma, 18,940). Death rates for NHL began decreasing in 1998 in both men and women; from 2004 to 2008, rates decreased 2.8% per year in men and 3.4% per year in women. Death rates for Hodgkin lymphoma have been decreasing in both men and women for the past four decades. Declines in lymphoma death rates reflect improvements in treatment over time.

Signs and symptoms: Symptoms may include swollen lymph nodes, itching, night sweats, fatigue, unexplained weight loss, and intermittent fever.

Risk factors: Like most cancers, the risk of developing NHL increases with age. In contrast, the risk of Hodgkin lymphoma is highest during adolescence and early adulthood. In most cases of lymphoma the cause is unknown, although various risk factors associated with altered immune function have been identified. Non-Hodgkin lymphoma risk is elevated in persons who receive immune suppressants to prevent organ transplant rejection, in people with severe autoimmune conditions, and in people infected with human immunodeficiency virus (HIV) and human T-cell leukemia virus type I. Epstein Barr virus causes Burkitt lymphoma (an aggressive type of NHL that occurs most often in children and young adults) and is associated with a number of autoimmune-related NHLs and some types of Hodgkin lymphoma. H. pylori infection increases the risk of gastric lymphoma. A family history of lymphoma and a growing number of common genetic variations are associated with modestly increased risk. Occupational and environmental exposures to certain chemicals may also be associated with moderately increased risk.

Treatment: Non-Hodgkin lymphoma patients are usually treated with chemotherapy; radiation, alone or in combination with chemotherapy, is used less often. Highly specific monoclonal antibodies directed at lymphoma cells, such as rituximab (Rituxan) and alemtuzumab (Campath), are used for initial treatment and recurrence of some types of NHL, as are antibodies linked to a radioactive atom, such as ibritumomab tiuxetan (Zevalin) and tositumomab (Bexxar). High-dose chemotherapy with stem cell transplantation and low-dose chemotherapy with stem cell transplantation (called nonmyeloablative) may be options if NHL persists or recurs after standard treatment.

#### Five-year Relative Survival Rates\* (%) by Stage at Diagnosis, 2001-2007

	All Stages	Local	Regional	Distant		All Stages	Local	Regional	Distant
Breast (female)	89	99	84	23	Ovary	44	92	72	27
Colon & rectum	64	90	69	12	Pancreas	6	22	9	2
Esophagus	17	37	18	3	Prostate	99	100	100	29
Kidney <sup>†</sup>	70	91	63	11	Stomach	26	62	28	4
Larynx	61	77	42	33	Testis	95	99	96	73
Liver*	14	27	9	4	Thyroid	97	100	97	56
Lung & bronchus	16	52	24	4	Urinary bladder§	78	71	35	5
Melanoma of the skin	91	98	61	15	Uterine cervix	69	91	57	19
Oral cavity & pharynx	61	82	56	34	Uterine corpus	82	96	67	16

<sup>\*</sup>Rates are adjusted for normal life expectancy and are based on cases diagnosed in the SEER 17 areas from 2001-2007, followed through 2008. †Includes renal pelvis. ‡Includes intrahepatic bile duct. § Rate for in situ cases is 97%.

**Local:** an invasive malignant cancer confined entirely to the organ of origin. **Regional:** a malignant cancer that 1) has extended beyond the limits of the organ of origin directly into surrounding organs or tissues; 2) involves regional lymph nodes by way of lymphatic system; or 3) has both regional extension and involvement of regional lymph nodes. **Distant:** a malignant cancer that has spread to parts of the body remote from the primary tumor either by direct extension or by discontinuous metastasis to distant organs, tissues, or via the lymphatic system to distant lymph nodes.

Source: Howlader N, Krapcho M, Neyman N, et al. (eds). SEER Cancer Statistics Review, 1975-2008, National Cancer Institute, Bethesda, MD, www.seer.cancer.gov/cst/1975\_2008/, 2011.

American Cancer Society, Surveillance Research 2012

Hodgkin lymphoma is usually treated with chemotherapy, radiation therapy, or a combination of the two, depending on stage and cell type of the disease. Bone marrow or stem cell transplantation may be an option if these are not effective. The FDA recently approved the targeted drug brentuximab vedotin (Adcetris) to treat Hodgkin lymphoma (as well as a rare form of NHL) in patients whose disease has failed to respond to other treatment.

**Survival:** Survival varies widely by cell type and stage of disease. For NHL, the overall 1- and 5-year relative survival is 81% and 67%, respectively; survival declines to 55% at 10 years after diagnosis. For Hodgkin lymphoma, the 1-, 5-, and 10-year relative survival rates are 92%, 84%, and 79%, respectively.

#### **Oral Cavity and Pharynx**

New cases: An estimated 40,250 new cases of cancer of the oral cavity and pharynx (throat) are expected in 2012. Incidence rates are more than twice as high in men as in women. From 2004 to 2008, incidence rates declined by 1.0% per year in women and were stable in men. However, recent studies have shown that incidence is increasing for cancers of the oropharynx that are associated with human papillomavirus (HPV) infection among white men and women.

**Deaths:** An estimated 7,850 deaths from oral cavity and pharynx cancer are expected in 2012. Death rates have been decreasing over the past three decades; from 2004 to 2008, rates decreased by 1.2% per year in men and by 2.2% per year in women.

Signs and symptoms: Symptoms may include a sore in the throat or mouth that bleeds easily and does not heal, a red or white patch that persists, a lump or thickening, ear pain, a neck mass, or coughing up blood. Difficulties in chewing, swallowing, or moving the tongue or jaws are often late symptoms.

Risk factors: Known risk factors include all forms of smoked and smokeless tobacco products and excessive consumption of alcohol. Many studies have reported a synergism between smoking and alcohol use, resulting in a more than 30-fold increased risk for individuals who both smoke and drink heavily. HPV infection is associated with cancers of the tonsil, base of tongue, and some other sites within the oropharynx and is believed to be transmitted through sexual contact.

Early detection: Cancer can affect any part of the oral cavity, including the lip, tongue, mouth, and throat. Through visual inspection, dentists and primary care physicians can often detect premalignant abnormalities and cancer at an early stage, when treatment is both less extensive and more successful.

**Treatment:** Radiation therapy and surgery, separately or in combination, are standard treatments; chemotherapy is added for advanced disease. Targeted therapy with cetuximab (Erbitux) may be combined with radiation in initial treatment or used alone to treat recurrent cancer.

**Survival:** For all stages combined, about 84% of persons with oral cavity and pharynx cancer survive 1 year after diagnosis. The 5-year and 10-year relative survival rates are 61% and 50%, respectively.

#### Ovary

**New cases:** An estimated 22,280 new cases of ovarian cancer are expected in the US in 2012. Ovarian cancer accounts for about 3% of all cancers among women. Incidence rates have been relatively stable since 1992.

**Deaths:** An estimated 15,500 deaths are expected in 2012. Ovarian cancer causes more deaths than any other cancer of the female reproductive system. The death rate for ovarian cancer decreased by 1.9% per year from 2004 to 2008.

		All races			White		Af	rican Americ	an
	1975-77	1987-89	2001-2007	1975-77	1987-89	2001-2007	1975-77	1987-89	2001-2007
All sites	49	56	67 <sup>†</sup>	50	57	69†	39	43	59 <sup>†</sup>
Brain	22	29	35 <sup>t</sup>	22	28	34 <sup>†</sup>	25	31	40 <sup>†</sup>
Breast (female)	75	84	90†	76	85	91†	62	71	77†
Colon	51	60	65 <sup>†</sup>	51	61	67 <sup>†</sup>	45	53	55 <sup>†</sup>
Esophagus	5	10	191	6	11	20 <sup>†</sup>	3	7	13†
Hodgkin lymphoma	72	79	86†	72	80	88†	70	72	81†
Kidney & renal pelvis	50	57	71†	50	57	71†	49	55	68 <sup>†</sup>
Larynx	66	66	63†	67	67	65	59	56	52
Leukemia	34	43	57 <sup>†</sup>	35	44	57 <sup>†</sup>	33	36	50 <sup>†</sup>
Liver & intrahepatic bile du	ct 3	5	15†	3	6	15†	2	3	10 <sup>†</sup>
Lung & bronchus	12	13	16†	12	13	17†	11	11	13 <sup>†</sup>
Melanoma of the skin	82	88	93†	82	88	931	58 <sup>‡</sup>	79 <sup>‡</sup>	73 <sup>‡</sup>
Myeloma	25	28	41†	25	27	42†	30	30	41†
Non-Hodgkin lymphoma	47	51	70 <sup>†</sup>	47	52	71†	48	46	62 <sup>†</sup>
Oral cavity & pharynx	53	54	63 <sup>†</sup>	54	56	65 <sup>†</sup>	36	34	45 <sup>†</sup>
Ovary	36	38	44*	35	38	43†	42	34	36
Pancreas	2	4	67	3	3	61	2	6	4 <sup>†</sup>
Prostate	68	83	100*	69	85	100 <sup>†</sup>	61	72	98†
Rectum	48	58	68†	48	59	69 <sup>†</sup>	45	52	61†
Stomach	15	20	27*	14	19	261	16	19	27
Testis	83	95	96†	83	95	97†	73**	88‡	86
Thyroid	92	95	97 <sup>†</sup>	92	94	98†	90	92	95
Urinary bladder	73	79	80 <sup>†</sup>	74	80	81†	50	63	64†
Uterine cervix	69	70	69	70	73	70	65	57	61
Uterine corpus	87	83	83†	88	84	85†	60	57	61

<sup>\*</sup>Survival rates are adjusted for normal life expectancy and are based on cases diagnosed in the SEER 9 areas from 1975-77, 1987-89, and 2001 to 2007, and followed through 2008. †The difference in rates between 1975-1977 and 2001-2007 is statistically significant (p <0.05). ‡The standard error is between 5 and 10 percentage points. #Survival rate is for cases diagnosed in 1978-1980.

Source: Howlader N, Krapcho M, Neyman N, et al. (eds). SEER Cancer Statistics Review, 1975-2008, National Cancer Institute, Bethesda, MD. seer cancer gov/csr/1975, 2008/, 2011.

American Cancer Society, Surveillance Research, 2012

Signs and symptoms: Early ovarian cancer usually has no obvious symptoms. Studies have indicated, however, that some women may experience persistent, nonspecific symptoms, such as bloating, pelvic or abdominal pain, difficulty eating or feeling full quickly, or urinary urgency or frequency. Women who experience such symptoms daily for more than a few weeks should seek prompt medical evaluation. The most common sign is enlargement of the abdomen, which is caused by the accumulation of fluid. Abnormal vaginal bleeding is rarely a symptom of ovarian cancer, though it is a symptom of cervical and uterine cancers.

Risk factors: The most important risk factor is a strong family history of breast or ovarian cancer. Women who have had breast cancer or who have tested positive for inherited mutations in BRCA1 or BRCA2 genes are at increased risk. Studies indicate that preventive surgery to remove the ovaries and fallopian tubes in these women can decrease the risk of ovarian cancer. Other medical conditions associated with increased risk include pelvic inflammatory disease and a genetic condition called Lynch

syndrome. The use of estrogen alone as postmenopausal hormone therapy has been shown to increase risk in several large studies. Tobacco smoking increases risk of mucinous ovarian cancer. Heavier body weight may be associated with increased risk of ovarian cancer. Pregnancy, long-term use of oral contraceptives, and tubal ligation reduce the risk of developing ovarian cancer; hysterectomy also appears to decrease risk.

Early detection: There is currently no sufficiently accurate screening test proven to be effective in the early detection of ovarian cancer. Pelvic examination only occasionally detects ovarian cancer, generally when the disease is advanced. However, for women who are at high risk of ovarian cancer and women who have persistent, unexplained symptoms, the combination of a thorough pelvic exam, transvaginal ultrasound, and a blood test for the tumor marker CA125 may be offered. Although one clinical trial in the US showed that these tests had no effect on ovarian cancer mortality when used as a screening tool, another large screening trial using these methods is under way in the United Kingdom, with results expected in 2015.

Treatment: Treatment includes surgery and usually chemotherapy. Surgery usually involves removal of one or both ovaries and fallopian tubes (salpingo-oophorectomy) and the uterus (hysterectomy). In younger women with very early stage tumors who wish to have children, only the involved ovary and fallopian tube may be removed. Among patients with early ovarian cancer, more complete surgical staging has been associated with better outcomes. For women with advanced disease, surgically removing all abdominal metastases enhances the effect of chemotherapy and helps improve survival. For women with stage III ovarian cancer that has been optimally debulked (removal of as much of the cancerous tissue as possible), studies have shown that chemotherapy administered both intravenously and directly into the abdomen improves survival. Studies have also found that ovarian cancer patients whose surgery is performed by a gynecologic oncologist have more successful outcomes. Clinical trials are currently under way to test targeted drugs such as bevacizumab and cediranib in the treatment of ovarian cancer.

**Survival:** Relative survival varies by age; women younger than 65 are twice as likely to survive 5 years (57%) following diagnosis as women 65 and older (27%). Overall, the 1-, 5-, and 10-year relative survival of ovarian cancer patients is 75%, 44%, and 35%, respectively. If diagnosed at the localized stage, the 5-year survival rate is 93%; however, only 15% of all cases are detected at this stage, usually incidentally during another medical procedure. The majority of cases (63%) are diagnosed at distant stage. For women with regional and distant disease, 5-year survival rates are 72% and 27%, respectively.

#### **Pancreas**

**New cases:** An estimated 43,920 new cases of pancreatic cancer are expected to occur in the US in 2012. Since 2004, incidence rates of pancreatic cancer have been increasing by 1.5% per year.

**Deaths:** An estimated 37,390 deaths are expected to occur in 2012, about the same number in women (18,540) as in men (18,850). During 2004 to 2008, the death rate for pancreatic cancer increased by 0.4% per year.

Signs and symptoms: Cancer of the pancreas often develops without early symptoms. Symptoms may include weight loss, pain in the upper abdomen that may radiate to the back, and occasionally glucose intolerance (high blood glucose levels). Tumors that develop near the common bile duct may cause a blockage that leads to jaundice (yellowing of the skin and eyes), which can sometimes allow the tumor to be diagnosed at an early stage.

Risk factors: Tobacco smoking and smokeless tobacco use increase the risk of pancreatic cancer; incidence rates are about twice as high for cigarette smokers as for nonsmokers. Risk also increases with a family history of pancreatic cancer and a personal history of pancreatitis, diabetes, obesity, and possibly high

levels of alcohol consumption. Individuals with Lynch syndrome and certain other genetic syndromes are also at increased risk. Though evidence is still accumulating, consumption of red meat may increase risk.

**Early detection:** At present, there is no widely used method for the early detection of pancreatic cancer, though research is under way in this area.

Treatment: Surgery, radiation therapy, and chemotherapy are treatment options that may extend survival and/or relieve symptoms in many patients, but seldom produce a cure. Less than 20% of patients are candidates for surgery because pancreatic cancer is usually detected after it has spread beyond the pancreas; even when surgery is performed, it often cannot remove all of the cancer. For patients who do undergo surgery, adjuvant treatment with the chemotherapy drug gemcitabine lengthens survival. The targeted anticancer drug erlotinib (Tarceva) has demonstrated a small improvement in advanced pancreatic cancer survival when used in combination with gemcitabine. Clinical trials with several new agents, combined with radiation and surgery, may offer improved survival and should be considered as a treatment option.

**Survival:** For all stages combined, the 1-and 5-year relative survival rates are 26% and 6%, respectively. Even for those people diagnosed with local disease, the 5-year survival is only 22%. More than half of patients are diagnosed at a distant stage, for which 5-year survival is 2%.

#### **Prostate**

New cases: An estimated 241,740 new cases of prostate cancer will occur in the US during 2012. Prostate cancer is the most frequently diagnosed cancer in men aside from skin cancer. For reasons that remain unclear, incidence rates are significantly higher in African Americans than in whites, 241 (per 100,000 men) versus 149, respectively, in 2008. Incidence rates for prostate cancer changed substantially between the mid-1980s and mid-1990s and have since fluctuated widely from year to year, in large part reflecting changes in prostate cancer screening with the prostate-specific antigen (PSA) blood test. Since 2004, incidence rates have decreased by 2.7% per year among men 65 years of age and older and have remained stable among men younger than 65 years.

Deaths: With an estimated 28,170 deaths in 2012, prostate cancer is the second-leading cause of cancer death in men. Prostate cancer death rates have been decreasing since the early 1990s in both African Americans and whites. Although death rates have decreased more rapidly among African American than white men, rates in African Americans remain more than twice as high as those in whites. Prostate cancer death rates decreased 3.0% per year in white men and 3.5% per year in African American men from 2004 to 2008.

Signs and symptoms: Early prostate cancer usually has no symptoms. With more advanced disease, men may experience weak or interrupted urine flow; inability to urinate or difficulty starting or stopping the urine flow; the need to urinate frequently, especially at night; blood in the urine; or pain or burning with urination. Advanced prostate cancer commonly spreads to the bones, which can cause pain in the hips, spine, ribs, or other areas.

Risk factors: The only well-established risk factors for prostate cancer are increasing age, African ancestry, and a family history of the disease. About 60% of all prostate cancer cases are diagnosed in men 65 years of age and older, and 97% occur in men 50 and older. African American men and Jamaican men of African descent have the highest documented prostate cancer incidence rates in the world. The disease is common in North America and northwestern Europe, but less common in Asia and South America. Genetic studies suggest that strong familial predisposition may be responsible for 5%-10% of prostate cancers. Recent studies suggest that a diet high in processed meat or dairy foods may be a risk factor, and obesity appears to increase risk of aggressive prostate cancer. There is some evidence that risk is elevated in firefighters.

Prevention: The chemoprevention of prostate cancer is an active area of research. Two drugs of interest, finasteride and dutasteride, reduce the amount of certain male hormones in the body and are already used to treat the symptoms of benign prostate enlargement. Both drugs have been found to lower the risk of prostate cancer by about 25% in large clinical trials with similar potential side effects, including reduced libido and risk of erectile dysfunction. However, it is not entirely clear which men are most likely to gain benefit from prophylactic treatment with these agents, and in December 2010, an advisory committee to the FDA recommended against approval for both finasteride and dutasteride for the prevention of prostate cancer based on riskbenefit analyses.

Early detection: At this time, there are insufficient data to recommend for or against routine testing for early prostate cancer detection with the PSA test. The American Cancer Society recommends that beginning at age 50, men who are at average risk of prostate cancer and have a life expectancy of at least 10 years receive information about the potential benefits and known limitations associated with testing for early prostate cancer detection and have an opportunity to make an informed decision about testing. Men at high risk of developing prostate cancer (African Americans or men with a close relative diagnosed with prostate cancer before age 65) should have this discussion with their health care provider beginning at age 45. Men at even higher risk (because they have several close relatives diagnosed with prostate cancer at an early age) should have this discussion with their provider at age 40. All men should be given sufficient information about the benefits and limitations of testing and early detection to allow them to make a decision based on their personal values and preferences.

Results from clinical trials designed to determine the efficacy of PSA testing for reducing prostate cancer deaths have been mixed; two European studies found a lower risk of death from prostate cancer among men receiving PSA screening while a study in the US found no reduction. Current research is exploring new biologic markers for prostate cancer, as well as alternative ages of screening initiation and timing of testing, with the goal of identifying and treating men at highest risk for aggressive disease while minimizing unnecessary testing and over-treatment of men at low risk for prostate cancer death. See page 64 for the American Cancer Society's screening guidelines for the early detection of prostate cancer.

Treatment: Treatment options vary depending on age, stage, and grade of cancer, as well as other medical conditions. The grade assigned to the tumor, typically called the Gleason score, indicates the likely aggressiveness of the cancer and ranges from 2 (nonaggressive) to 10 (very aggressive). Surgery (open, laparo $scopic, or robotic-assisted), external \, beam \, radiation, or \, radioactive$ seed implants (brachytherapy) may be used to treat early stage disease. Data show similar survival rates for patients with early stage disease treated with any of these methods, and there is no current evidence supporting a "best" treatment for prostate cancer. Adjuvant hormonal therapy may be indicated in some cases. All of these treatments may impact a man's quality of life through side effects or complications that include urinary and erectile difficulties. Accumulating evidence suggests that careful observation ("active surveillance"), rather than immediate treatment, can be an appropriate option for men with less aggressive tumors and for older men.

Hormonal therapy, chemotherapy, radiation, or a combination of these treatments is used to treat more advanced disease. Hormone treatment may control advanced prostate cancer for long periods by shrinking the size or limiting the growth of the cancer, thus helping to relieve pain and other symptoms. An option for some men with advanced prostate cancer that is no longer responding to hormones is a cancervaccine known as sipuleucel-T (Provenge). For this treatment, special immune cells are removed from a man's body, exposed to prostate proteins in a lab, and then reinfused back into the body, where they attack prostate cancer cells. Another option for these men is Abiraterone (Zytiga), which was recently approved for the treatment of metastatic disease that is resistant to hormone and chemotherapy.

Survival: More than 90% of all prostate cancers are discovered in the local or regional stages, for which the 5-year relative survival rate approaches 100%. Over the past 25 years, the 5-year relative survival rate for all stages combined has increased from 68% to almost 100%. According to the most recent data, 10- and 15-year relative survival rates are 98% and 91%, respectively. Obesity and smoking are associated with an increased risk of dying from prostate cancer.

#### Skin

New cases: The number of basal cell and squamous cell skin cancers (i.e., nonmelanoma skin cancers, or NMSC) is difficult to estimate because these cases are not required to be reported to cancer registries. One report on NMSC occurrence in the US estimated that 3.5 million cases were diagnosed and 2.2 million people were treated for the disease in 2006, with some patients having multiple diagnoses. Most, but not all, of these forms of skin cancer are highly curable. Melanoma is expected to be diagnosed in about 76,250 persons in 2012, accounting for less than 5% of all skin cancer cases but the vast majority of skin cancer deaths. Melanoma is 10 times more common in whites than in African Americans. Although before age 40, incidence rates are higher in women than in men, after 40, rates are almost twice as high in men as in women. Melanoma incidence rates have been increasing for at least 30 years. Since 2004, incidence rates among whites have been increasing by almost 3% per year in both men and women.

**Deaths:** An estimated 12,190 deaths (9,180 from melanoma and 3,010 from other nonepithelial skin cancers) will occur in 2012. The death rate for melanoma has been declining rapidly in whites younger than 50 years of age; from 2004 to 2008, rates decreased by 2.9% per year in men and by 2.3% per year in women. In contrast, among whites 50 years of age and older, death rates increased by 1.0% per year in men and have been stable in women during this same time period.

Signs and symptoms: Important warning signs of melanoma include changes in size, shape, or color of a mole or other skin lesion or the appearance of a new growth on the skin. Changes that occur over a few days are usually not cancer, but changes that progress over a month or more should be evaluated by a doctor. Basal cell carcinomas may appear as growths that are flat, or as small, raised, pink or red, translucent, shiny areas that may bleed following minor injury. Squamous cell cancer may appear as growing lumps, often with a rough surface, or as flat, reddish patches that grow slowly. Another sign of basal and squamous cell skin cancers is a sore that doesn't heal.

Risk factors: Risk factors vary for different types of skin cancer. For melanoma, major risk factors include a personal or family history of melanoma and the presence of atypical or numerous moles (more than 50). Other risk factors for all types of skin cancer include sun sensitivity (sunburning easily, difficulty tanning, natural blond or red hair color); a history of excessive sun exposure, including sunburns; use of tanning booths; diseases that suppress the immune system; and a past history of basal cell or squamous cell skin cancers.

**Prevention:** Skin should be protected from intense sun exposure by covering with tightly woven clothing and a wide-brimmed hat, applying sunscreen that has a sun protection factor (SPF) of 15 or higher to unprotected skin, seeking shade (especially at

midday, when the sun's rays are strongest), and avoiding sunbathing and indoor tanning. Sunglasses should be worn to protect the skin around the eyes. Children in particular should be protected from the sun because severe sunburns in childhood may greatly increase risk of melanoma in later life. Tanning beds and sun lamps, which provide an additional source of UV radiation, are associated with cancer risk and should be avoided. In 2009, the International Agency for Research on Cancer upgraded their classification of indoor tanning devices from "probably" to "definitively" carcinogenic to humans after a reassessment of the scientific evidence.

Early detection: At this time, the best way to detect skin cancer early is to recognize changes in skin growths, including the appearance of new growths. Adults should periodically examine their skin so that they develop an awareness of any changes. New or unusual lesions or a progressive change in a lesion's appearance (size, shape, or color, etc.) should be evaluated promptly by a physician. Melanomas often start as small, mole-like growths that increase in size and may change color. A simple ABCD rule outlines the warning signals of the most common type of melanoma: A is for asymmetry (one half of the mole does not match the other half); B is for border irregularity (the edges are ragged, notched, or blurred); C is for color (the pigmentation is not uniform, with variable degrees of tan, brown, or black); D is for diameter greater than 6 millimeters (about the size of a pencil eraser). Other types of melanoma may not have these signs, so be alert for any new or changing skin growths.

Treatment: Removal and microscopic examination of all suspicious skin lesions are essential. Early stage basal and squamous cell cancers can be removed in most cases by one of several methods: surgical excision, electrodesiccation and curettage (tissue destruction by electric current and removal by scraping with a curette), or cryosurgery (tissue destruction by freezing). Radiation therapy and certain topical medications may be used in some cases. For malignant melanoma, the primary growth and surrounding normal tissue are removed and sometimes a sentinel lymph node is biopsied to determine stage. More extensive lymph node surgery may be needed if the lymph nodes contain cancer. Melanomas with deep invasion or that have spread to lymph nodes may be treated with surgery, immunotherapy, chemotherapy, and/or radiation therapy. Advanced cases of melanoma are treated with palliative surgery, immunotherapy, and/or chemotherapy, and sometimes radiation therapy. Two newer targeted drugs, ipilimumab (Yervoy) and vemurafenib (Zelboraf), have recently been approved by the FDA and may extend survival in people with advanced melanoma.

**Survival:** Most basal and squamous cell cancers can be cured, especially if the cancer is detected and treated early. Melanoma is also highly curable if detected in its earliest stages and treated properly. However, melanoma is more likely than other skin tumors to spread to other parts of the body. The 5-and 10-year

relative survival rates for persons with melanoma are 91% and 89%, respectively. For localized melanoma (84% of cases), the 5-year survival rate is 98%; survival declines to 62% and 15% for regional and distant stage disease, respectively.

## **Thyroid**

New cases: An estimated 56,460 new cases of thyroid cancer are expected to be diagnosed in 2012 in the US, with 3 in 4 cases occurring in women. The incidence rate of thyroid cancer has been increasing sharply since the mid-1990s, and it is the fastest-increasing cancer in both men and women. Since 2004, incidence rates have been increasing by 5.5% per year in men and 6.6% per year in women.

**Deaths:** An estimated 1,780 deaths from thyroid cancer are expected in 2012 in the US. From 2004 to 2008, the death rate for thyroid cancer increased slightly from 0.47 (per 100,000) to 0.50 in men, and from 0.47 to 0.52 in women.

Signs and symptoms: The most common symptom of thyroid cancer is a lump in the neck that is noticed by a patient or felt by a health care provider in a clinical exam. Other symptoms include a tight or full feeling in the neck, difficulty breathing or swallowing, hoarseness or swollen lymph nodes, and pain in the throat or neck that does not go away. Although most lumps in the thyroid gland are not cancerous, individuals who detect an abnormality should seek timely medical attention.

Risk factors: Risk factors for thyroid cancer include being female, having a history of goiter (enlarged thyroid) or thyroid nodules, a family history of thyroid cancer, and radiation exposure related to medical treatment during childhood. Radiation exposure as a result of radioactive fallout from atomic weapons testing and nuclear power plant accidents, such as Chernobyl, has also been linked to increased risk of thyroid cancer, especially in children. Certain rare genetic syndromes also increase risk. People who test positive for an abnormal gene that causes a hereditary form of thyroid cancer can decrease the chance of developing the disease by surgical removal of the thyroid gland. Unlike other adult cancers, for which older age increases risk, 80% of newly diagnosed thyroid cancer patients are under 65 years of age.

Early detection: At present, there is no screening test recommended for the early detection of thyroid cancer in people without symptoms. However, because symptoms usually develop early, most thyroid cancers (68%) are diagnosed at an early stage. Tests used in the evaluation of thyroid nodules include: blood tests to determine levels of hormones related to normal functions of the thyroid gland; medical imaging techniques to determine the size and characteristics of the nodule and nearby lymph nodes; and biopsy to determine if the cells in the nodule are benign or malignant.

Treatment: Most thyroid cancers are highly curable, though about 5% of cases (medullary and anaplastic) are more aggressive and tend to spread to other organs. Treatment depends on the cell type, tumor size, and extent of the disease. The first choice of treatment is surgery in nearly all cases. Total removal of the thyroid gland (thyroidectomy), with or without lymph node removal, is recommended for most patients. Treatment with radioactive iodine (I-131) after surgery to destroy any remaining thyroid tissue may be recommended for more advanced disease. Hormone therapy is given to replace hormones normally produced by the thyroid gland after thyroidectomy and to prevent the body from making thyroid-stimulating hormone, decreasing the likelihood of recurrence.

Survival: The 5-year relative survival rate for all thyroid cancer patients is 97%. However, survival varies by stage, age at diagnosis, and disease subtype. The 5-year survival rate approaches 100% for localized disease, is 97% for regional stage disease, and 56% for distant stage disease. For all stages combined, survival is highest for patients under 45 years of age (almost 100%), and progressively decreases to 82% for those 75 or older.

## **Urinary Bladder**

New cases: An estimated 73,510 new cases of bladder cancer are expected to occur in 2012. Since 2004, bladder cancer incidence rates have been stable in men and decreasing slightly (by 0.3% per year) in women, trends that have persisted since 1992. Bladder cancer incidence is about four times higher in men than in women, and is almost twice as high in white men as in African American men.

**Deaths:** An estimated 14,880 deaths will occur in 2012. From 2004 to 2008, death rates were stable in men and decreasing slowly in women (by 0.5% per year).

**Signs and symptoms:** The most common symptom is blood in the urine. Other symptoms may include increased frequency or urgency of urination and irritation during urination.

Risk factors: Smoking is the most well-established risk factor for bladder cancer. Smokers' risk of bladder cancer is approximately four-fold that of nonsmokers', and smoking is estimated to cause about half of all bladder cancer cases in both men and women. Workers in the dye, rubber, or leather industries, painters, and people who live in communities with high levels of arsenic in the drinking water also have increased risk.

Early detection: There is currently no screening method recommended for people at average risk. Bladder cancer is diagnosed by microscopic examination of cells from urine or bladder tissue and examination of the bladder wall with a cystoscope, a slender tube fitted with a lens and light that can be inserted through the urethra. These tests may be used to screen people at increased risk due to occupational exposure or certain bladder birth

defects, or for follow up after bladder cancer treatment to detect recurrent or new tumors.

**Treatment:** Surgery, alone or in combination with other treatments, is used in more than 90% of cases. Localized cancers may be treated by administering immunotherapy or chemotherapy directly into the bladder after surgery. More advanced cancers may require removal of the entire bladder (cystectomy). Chemotherapy, alone or with radiation before cystectomy, has improved treatment results. Timely follow-up care is extremely important because of the high rate of bladder cancer recurrence.

Survival: For all stages combined, the 5-year relative survival rate is 78%. Survival declines to 71% at 10 years and 65% at 15 years after diagnosis. Half of all bladder cancer patients are diagnosed while the tumor is in situ (noninvasive, present only in the layer of cells in which the cancer developed), for which the 5-year survival is 97%. Patients with invasive tumors diagnosed at a localized stage have a 5-year survival rate of 71%; 35% of cancers are detected at this early stage. For regional and distant staged disease, 5-year survival is 35% and 5%, respectively.

#### **Uterine Cervix**

**New cases:** An estimated 12,170 cases of invasive cervical cancer are expected to be diagnosed in 2012. Incidence rates have declined over most of the past several decades in both white and African American women. Since 2004, rates have decreased by 2.1% per year in women younger than 50 years of age and by 3.1% per year in women 50 and older.

**Deaths:** An estimated 4,220 deaths from cervical cancer are expected in 2012. Mortality rates declined rapidly in past decades, due to prevention and early detection as a result of screening with the Pap test, but have slowed in recent years. From 2004 to 2008, rates decreased by 2.6% per year in African American women and were stable in white women.

Signs and symptoms: Symptoms usually do not appear until abnormal cervical cells become cancerous and invade nearby tissue. When this happens, the most common symptom is abnormal vaginal bleeding. Bleeding may start and stop between regular menstrual periods, or it may occur after sexual intercourse, douching, or a pelvic exam. Menstrual bleeding may last longer and be heavier than usual. Bleeding after menopause or increased vaginal discharge may also be symptoms.

Risk factors: The primary cause of cervical cancer is infection with certain types of human papillomavirus (HPV). While women who begin having sex at an early age or who have had many sexual partners are at increased risk for HPV infection and cervical cancer, a woman may be infected with HPV even if she has had only one sexual partner. In fact, it is important to understand that HPV infections are common in healthy women and are typically cleared successfully by the immune system; only

rarely does the infection persist and result in cervical cancer. Persistence of HPV infection and progression to cancer may be influenced by many factors, including immunosuppression, high parity (number of childbirths), and cigarette smoking. Long-term use of oral contraceptives (birth control pills) is also associated with increased risk of cervical cancer.

**Prevention:** There are two vaccines approved for the prevention of the most common types of HPV infection that cause cervical cancer; Gardasil is recommended for use in females 9 to 26 years of age, and Cervarix in females 9 to 25 years of age. Gardasil is also approved for use in males 9 to 26 years of age to prevent anal cancer and associated precancerous lesions; approximately 90% of anal cancers have been linked to HPV infection. These vaccines cannot protect against established infections, nor do they protect against all HPV types.

Screening can prevent cervical cancer by detecting precancerous lesions. As screening has become more common, precancerous lesions of the cervix are detected far more frequently than invasive cancer. The Pap test is the most widely used cervical cancer screening method. It is a simple procedure in which a small sample of cells is collected from the cervix and examined under a microscope. Pap tests are effective, but not perfect. Sometimes results are reported as normal when abnormal cells are present (false negative), and likewise, sometimes test results are abnormal when no abnormal cells are present (false positive). DNA tests that detect HPV strains associated with cervical cancer may be used in conjunction with the Pap test, either as an additional screening test or when Pap test results are uncertain. Fortunately, most cervical precancers develop slowly, so nearly all cancers can be prevented if a woman is screened regularly. It is important for all women, even those who have received the HPV vaccine, to follow cervical cancer screening guidelines.

Early detection: In addition to preventing cancer, cervical cancer screening can detect cancer early, when treatment is most successful. Today, liquid-based Pap tests are used by most clinicians as an alternative to conventional Pap tests. See page 64 for the American Cancer Society's screening guidelines for the early detection of cervical cancer.

**Treatment:** Preinvasive lesions may be treated by electrocoagulation (the destruction of tissue through intense heat by electric current), cryotherapy (the destruction of cells by extreme cold), laser ablation, or local surgery. Invasive cervical cancers are generally treated with surgery, radiation, or both, and with chemotherapy in selected cases.

**Survival:** One- and 5-year relative survival rates for cervical cancer patients are 87% and 69%, respectively. The 5-year survival rate for patients diagnosed with localized disease is 91%. Cervical cancer is diagnosed at an early stage more often in whites (49%) than in African Americans (42%) and more often in women younger than 50 years of age (60%) than in women 50 and older (34%).

## **Uterine Corpus (Endometrium)**

**New cases:** An estimated 47,130 cases of cancer of the uterine corpus (body of the uterus) are expected to be diagnosed in 2012. These usually occur in the endometrium (lining of the uterus). Since 2004, incidence rates of endometrial cancer have been stable in white women, but increasing in African American women by 1.9% per year.

**Deaths:** An estimated 8,010 deaths are expected in 2012. Death rates for cancer of the uterine corpus are stable in both white and African American women.

**Signs and symptoms:** Abnormal uterine bleeding or spotting (especially in postmenopausal women) is a frequent early sign. Pain during urination, intercourse, or in the pelvic area is also a symptom.

Risk factors: Obesity and greater abdominal fatness increase the risk of endometrial cancer, most likely by increasing the amount of estrogen in the body. Estrogen exposure is a strong risk factor for endometrial cancer. Other factors that increase estrogen exposure include menopausal estrogen therapy (without use of progestin), late menopause, never having children, and a history of polycystic ovary syndrome. (Estrogen plus progestin menopausal hormone therapy does not appear to increase risk.)

Tamoxifen, a drug used to reduce breast cancer risk, increases risk slightly because it has estrogen-like effects on the uterus. Medical conditions that increase risk include Lynch syndrome, also known as hereditary nonpolyposis colon cancer (HNPCC), and diabetes. Pregnancy, use of oral contraceptives, and physical activity provide protection against endometrial cancer.

Early detection: There is no standard or routine screening test for endometrial cancer. Most endometrial cancer (68%) is diagnosed at an early stage because of postmenopausal bleeding. Women are encouraged to report any unexpected bleeding or spotting to their physicians. The American Cancer Society recommends that women with known or suspected Lynch syndrome be offered annual screening with endometrial biopsy and/or transvaginal ultrasound beginning at 35 years of age.

**Treatment:** Uterine corpus cancers are usually treated with surgery, radiation, hormones, and/or chemotherapy, depending on the stage of disease.

**Survival:** The 1- and 5-year relative survival rates for uterine corpus cancer are 92% and 82%, respectively. The 5-year survival rate is 96%, 67%, or 16%, if the cancer is diagnosed at a local, regional, or distant stage, respectively. Relative survival in whites exceeds that for African Americans by more than 7 percentage points at every stage of diagnosis.

## Special Section:

# **Cancers with Increasing Incidence Trends** in the US: 1999-2008

#### Introduction

The incidence rates of many cancers have declined in recent years due to numerous factors. Decreases in smoking have manifested as declines in lung cancer incidence rates among men, and more recently among women.1 Colorectal and cervical cancer incidence rates have declined due in part to early detection and removal of precancerous lesions.2 The incidence of stomach cancer has declined due to a decreasing prevalence of Helicobacter pylori infection associated with improved hygiene and overall improvements in diet and food storage practices.3 More recently, declines in prostate cancer incidence may be associated with a plateau in prostate-specific antigen (PSA) screening among men. Female breast cancer incidence rates have remained stable after declining 7% from 2002 to 2003, largely due to reductions in the use of hormone replacement therapy, an important risk factor for breast cancer.4

Despite these improvements in incidence trends for the major cancer sites, incidence rates for several cancers are increasing, including: human papillomavirus (HPV)-related oropharyngeal cancer; esophageal adenocarcinoma; melanoma of the skin; and cancers of the pancreas, liver and intrahepatic bile duct, thyroid, and kidney and renal pelvis. The causes of these increasing incidence trends are unclear, but may reflect the combined effects of changes in cancer risk factors and detection practices. Notably, as the US population continues to shift to older age groups where

### **Data and Methods**

Cancer incidence rates are based on surveillance data from the North American Association of Central Cancer Registries (NAACCR),6 a compilation of population-based incidence data from the National Cancer Institute's Surveillance, Epidemiology and End Result program and the Centers for Disease Control and Prevention's National Program of Cancer Registries. Average incidence rates per 100,000 population are reported by gender and race/ethnicity for the most recent five-year period combined (2004-2008). Trends in rates were assessed for the most recent 10-year period (1999-2008) and expressed as the average annual percentage change (AAPC). Average five-year incidence rates during 2004-2008 are also reported by state and gender to inform local cancer control programs. Average annual incidence rates by stage at cancer diagnosis and five-year relative survival rates are also presented to assess trends over time.7

cancer risk is highest, if rates of other more common cancers remain unchanged or decline, cancers with increasing trends will account for a greater proportion of all cancer cases over time.5

The purpose of this special section is to highlight cancers with increasing incidence rates among people 15 years of age or older and to describe trends by age, race/ethnicity, and stage at diagnosis. This information is intended to inform communities, policy makers, researchers, and private and governmental health agencies charged with cancer prevention and control. Additional information for most of these cancers, including estimated numbers of new cases and deaths, signs and symptoms, and treatment, can be found in Selected Cancers, beginning on page 9 of this report.

## **HPV-related Oropharynx**

The oropharynx is the part of the throat just behind the mouth. It includes the back one-third of the tongue, the soft palate (back of the roof of mouth), the tonsils, and the side and back walls of the throat. Most oropharyngeal cancers are called squamous cell carcinomas because they begin in squamous cells - the cells that line the mouth and throat. Oropharyngeal cancers can be categorized as human papillomavirus (HPV) related or unrelated, based on whether the tumor tests positive for HPV. Most oropharyngeal cancers that are not caused by HPV infection are due to tobacco and alcohol use.8

Risk factors: Although there are many different types of HPV, most (90%) HPV-related oropharyngeal cancers are due to infection with the HPV 16 subtype. 9,10 Prior infection with HPV 16 is associated with a nine-fold increased risk of oropharyngeal cancer, specifically for squamous cell carcinomas of the base of the tongue, tonsil, and epiglottis. 11 Sexual behaviors as well as openmouth kissing are important routes of exposure to oral HPV infection.12 Risk of oral HPV infection is also increased among smokers. Persistent HPV infection of the oral cavity may lead to genetic damage and altered immune function, promoting progression to cancer.

Rates and trends: During 1999-2008, incidence rates of HPVrelated or opharyngeal cancers increased by 4.4% per year among white men and by 1.9% per year among white women; however, there were no significant changes among men and women of other racial and ethnic groups (Table 1). Incidence rates increased among men in all age groups and among women for those 15-64 years of age (Figure 1, A). By stage, rates increased for regional-

Table 1. Rates (2004-2008) and Trends (1999-2008) for Cancers with Increasing Incidence by Race/Ethnicity and Sex, Ages 15 Years and Older, US

	Ove	Overall		Overall				Overall		Overall White		nite	African American		Asian or Pacific Islander		American Indian or Alaska Native		Hispanic/ Latino†	
	Rate	AAPC	Rate	AAPC	Rate	AAPC	Rate	AAPC	Rate	AAPC	Rate	AAPC								
Male																				
HPV-related oropharynx	7.8	3.9*	8.0	4.4*	8.0	-0.1	2.1	0.7	4.1	-0.1	4.4	0.3								
Esophageal adenocarcinoma	7.2	1.7*	8.0	1.8*	1.8	0.9	1.3	4.0	3.6	-0.1	3.7	2.8*								
Pancreas	17.1	0.8*	16.8	0.9*	21.3	0.5	12.3	0.3	11.8	-0.2	14.6	0.3								
Liver & intrahepatic bile duct	12.3	3.9*	10.9	3.8*	17.9	5.4*	27.6	-0.2	17.4	3.4	21.5	2.4*								
Thyroid	7.0	6.2*	7.4	6.3*	3.8	5.6*	6.3	5.0*	3.1	0.6	5.4	4.5*								
Kidney & renal pelvis	26.2	2.4*	26.3	2.3*	28.5	3.1*	12.5	3.5*	29.4	1.9	24.5	2.0*								
Melanoma of the skin	30.3	2.1*	33.4	2.1*	1.4	-0.1	2.0	0.0	4.6	0.3	5.9	-0.3								
Female																				
HPV-related oropharynx	1.7	1.6*	1.8	1.9*	1.7	-0.6	0.5	-2.2	0.8	NA	0.9	-0.7								
Esophageal adenocarcinoma	1.0	1.9*	1.1	2.1*	0.5	1.0	0.3	6.4	0.9	3 2	0.6	-1.1								
Pancreas	13.2	0.9*	12.8	1.0*	17.6	0.4	10.3	-0.4	11.5	-0.4	12.6	0.2								
Liver & intrahepatic bile duct	4.1	1.9*	3.7	1.5	5.1	2.7*	10.4	0.2	8.5	4.4	8.1	1.0								
Thyroid	21.0	7.3*	21.6	7.3*	12.6	6.8*	21.5	6.4*	10.0	3.1*	20.4	6.7*								
Kidney & renal pelvis	13.6	2.9*	13.7	2.8*	14.6	3.8*	6.1	3.7*	17.0	3.4*	14.0	2.7*								
Melanoma of the skin	19.5	2.3*	22.1	2.4*	1.3	1.0	1.6	-1.9	4.0	1.9	5.4	0.2								

AAPC = average annual percent change from 1999 to 2008. HPV = human papillomavirus. NA = trend could not be calculated due to sparse data. Incidence rates are per 100,000 population and were age-adjusted to the 2000 US standard population. \*AAPC is significantly different from zero (p <0.05). †Persons of Hispanic origin may be of any race.

Source: North American Association of Central Cancer Registries (NAACCR) 2011 Data are collected by cancer registries participating in NCI's SEER program and CDC's National Program of Cancer Registries.

American Cancer Society, Surveillance Research, 2012

and distant-staged tumors, but not for localized disease (Figure 2). The increasing incidence rates for HPV-related or opharyngeal cancers are in stark contrast to steady declines in rates for HPVunrelated oropharyngeal cancers, which are largely due to decreases in smoking prevalence. 13 Reasons for these increasing rates are unclear, but may be related to changing sexual practices among men (such as an increase in the prevalence of oral sex).12,14 The most dramatic increase in rates was among men 55-64 years of age, consistent with changes in sexual behaviors that increase risk of HPV-exposure in this population.10 The rapid increase in whites may reflect trends in risk factors such as oral-genital sexual behavior. However, existing data do not provide a clear explanation for the observed differences by race. Additional research is needed to clarify the routes of oral HPV transmission and to develop appropriate, targeted prevention strategies.

Survival: Despite the concerning trends in increasing incidence rates, survival rates for HPV-related oropharyngeal cancer are generally higher than those for HPV-unrelated oropharyngeal cancers.10 Five-year survival rates for HPV-related or opharyngeal cancer have increased over time for each stage of diagnosis, with the largest improvement (20%) for regional disease (Table 3).

Prevention and early detection: The continued increases in incidence rates among white men and women and sustained high burden of disease among African American men suggests the need for interventions specific to these groups. Education to promote safer sexual practices (particularly oral sex), as well as continued reductions in tobacco use, may be important prevention strategies to consider. Additional research is also needed to determine if the HPV vaccine (currently recommended to prevent cervical cancer in women) might also prevent HPV-related oropharyngeal cancer among men and women. 15 The observation that incidence of regionally advanced oropharyngeal cancer was greater than less-advanced stages points to the need for improved early detection methods. Although survival was generally optimistic among those with localized tumors, poorer survival among those with advanced tumors also underscores the need for improvements in treatment.

## Esophageal adenocarcinoma

Overall, esophageal cancer incidence rates have declined rapidly in African American men and women, remained unchanged in white women, and increased slightly among white men. Rates were historically higher among African Americans compared to whites, but more recently, the highest incidence is observed among non-Hispanic white men. 16,17 Although both major subtypes of

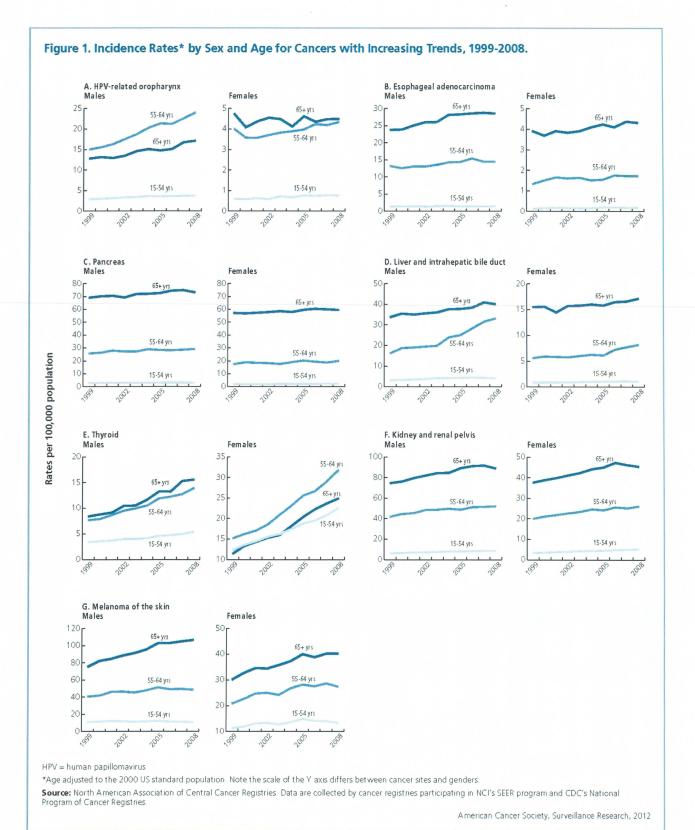


Table 2. Incidence Rates\* for Cancers with Increasing Trends by State and Sex, Ages 15 Years and Older, 2004-2008

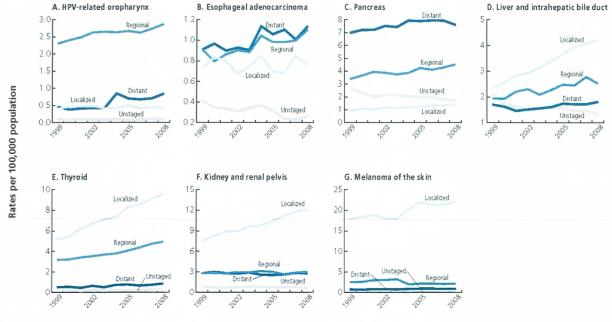
		related harynx		hageal arcinoma	Par	icreas	intra	Liver & intrahepatic bile duct Thyroid				ney & I pelvis	Melanoma of the skin	
	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female
Alabamat	8.6	2.2	6.5	0.6	17.6	12.4	10.2	3.6	5.3	14.2	25.9	13.3	31.5	18.0
Alaska	7.6	1.2	7.3	1.7	17.2	14.3	14.0	6.0	7.2	22.0	26.4	15.6	14:4	12.9
Arizona	6.2	1.7	5.9	0.7	14.5	11.2	11.5	3.9	7.6	23.6	23.3	13.2	24.7	14.5
Arkansas	8.6	2.1	5.6	0.7	16.4	11.8	9.9	3.1	5.1	12.8	27.2	14.3	22.7	13.8
California	7.0	1.5	5.4	0.7	16.3	13.3	16.2	5.7	6.1	18.2	23.2	11.2	34.3	20.0
Colorado	6.5	1.3	7.4	0.9	15.0	12.8	10.5	3.8	7.4	21.4	22.5	11.5	32.3	23.5
Connecticut	7.8	1.5	7.9	1.1	20.6	14.9	13.2	3.6	9.8	29.2	26.4	13.7	37.9	25.8
Delaware	9.6	1.9	7.6	1.2	18.1	13.8	12.0	3.0	6.9	20.7	25.8	14.8	42.0	22.8
District of Columbia	8.9	3.3	4.3	0.6	19.7	12.9	17.3	4.7	7.4	15.9	21.9	10.5	15.7	7.2
Florida	9.7	2.2	6.4	0.8	16.7	12.5	12.3	3.8	6.4	18.9	24.0	12.3	30.3	17.9
Georgia	8.5	1.8	5.5	0.6	17.2	12.7	11.4	3.5	5.7	17.1	24.7	12.5	35.5	20.5
Hawaii	7.3	1.3	3.4	0.3	18.0	14.3	19.1	7.2	7.9	24.7	21.8	10.6	34.5	19.1
Idaho	7.6	1.5	8.1	1.0	16.4	13.5	8.1	2.9	7.9	28.9	22.9	12.8	38.1	23.6
Illinois	8.0	1.9	8.1	1.1	18.9	14.2	11.6	4.1	7.1	21.0	28.8	15.1	25.0	16.6
Indiana	8.1	1.8	9.3	1.1	17.0	12.7	9.5	3.4	6.0	18.1	28.3	15.9	26.6	18.1
lowa	7.1	1.5	9.8	1.2	17.0	12.4	8.6	3.2	7.5	19.8	29.0	14.6	29.7	22.1
Kansas	6.9	1.2	7.0	0.8	15.9	12.2	8.2	2.9	8.2	24.5	25.4	13.7	31.7	22.7
Kentucky	8.8	2.1	8.4	1.0	16.6	13.1	9.8	3.7	7.1	21.4	30.6	16.3	35.2	23.8
Louisianat	9.3	1.6	6.0	0.7	18.7	15.4	15.1	4.2	5.8	16.1	32.4	17.0	23.4	12.8
Maine	8.7	2.2	12.0	1.2	17.7	14.4	9.2	3.4	6.3	21.4	25.8	15.3	32.6	24.6
Maryland‡	_	_	-	-	-	-	-	_	-	_	-	-	_	-
Massachusetts	8.0	1.8	10.7	1.5	17.8	14.0	14.2	3.8	10.6	31.1	28.4	13.7	35.5	23.9
Michigan	7.5	1.8	8.1	1.3	18.5	14.0	10.8	4.1	6.5	18.5	25.8	14.1	27.8	20.0
Minnesota	6.9	1.7	8.5	1.1	14.9	11.3	8.1	2.9	7.0	19.2	26.4	13.6	32.5	24.5
Mississippi†	8.9	2.0	5.3	0.6	17.8	12.6	11.6	3.8	5.6	14.6	30.1	15.5	25.4	15.2
Missouri	8.8	1.8	7.8	1.0	17.3	13.2	11.5	3.6	6.8	19.7	29.5	15 0	28.4	17.3
Montana	6.8	1.5	8.4	1.1	16.2	12.2	6.7	3.3	6.5	22.9	21.2	11.0	26 0	21.0
Nebraska	6.4	1.2	8.4	1.0	17.7	12.3	8.5	2.9	6.9	22.9	25.9	15.0	27.6	19.2
Nevada	6.3	2.1	6.9	0.8	16.3	13.5	11.3	4.8	7.7	23.0	22.6	11.5	26.5	14.4
New Hampshire	7.7	2.2	12.3	1.8	16.9	14.7	8.3	2.4	8.0	24.7	24.4	12.3	43.2	30.3
New Jersey	6.9	1.6	7.0	1.1	18.8	14.3	12.7	4.2	9.1	27.2	27.4	13.4	34.5	22.6
New Mexico	5.1	1.2	5.8	0.6	15.0	12.0	15.3	5.5	7.3	23.9	21.1	11.7	28.9	17.8
New York	6.9	1.5	6.7	1.2	18.7	14.7	15.5	4.7	8.7	25.1	27.4	13.0	25.9	16.2
North Carolina	9.3	2.0	6.7	0.9	16.5	13.4	10.8	3.4	6.7	19.4	29.8	13.6	32.6	20.5
North Dakota	5.8	1.1	7.3	1.5	18.0	11.9	6.3	2.9	7.0	22.9	25.6	13.4	22.4	21.6
Ohio	7.7	1.9	9.1	1.3	17.2	12.9	9.3	3.1	6.1	18.8	25.8	14.8	28.7	21.5
Oklahoma	8.0	1.9	7.4	0.8	16.1	12.0	11.3	4.5	5.0	15.6	27.2	15.1	30.5	19.2
Oregon	8.6	1.7	9.1	1.1	15.7	13.4	11.0	3.9	6.5	19.0	24.4	12.7	38.2	30.3
Pennsylvania	7.5	1.7	9.0	1.3	18.4	14.1	12.5	3.6	9.3	30.2	28.4	14.7	27.5	19.3
Rhode Island	8.0	2.2	10.3	1.5	16.4	12.1	14.3	4.4	10.0	28.7	29.5	15.3	33.8	23.8
South Carolina	9.0	2.1	5.6	0.7	16.9	13.1	10.0	2.8	4.9	15.4	24.4	13.5	34.7	22.2
South Dakota	4.5	1.1	8.5	1.1	14.2	11.2	5.8	2.2	5.4	18.5	23.3	13.9	20.9	16.2
Tennessee	8.2	2.0	6.2	0.9	16.0	12.0	10.0	3.2	6.9	19.4	26.6	14.0	32.0	19.9
Texast	7.6	1.6	6.1	0.7	16.4	12.5	16.7	5.6	6.7	19.4	28.3	15.6	23.2	12.9
Utah	5.0	0.6	6.3	0.5	13.6	10.9	6.6	2.4	8.4	26.8	17.2	10.5	46.5	26.7
Vermont	9.6	1.7	8.7	1.5	17.2	14.7	9.3	2.8	7.1	24.6	24.8	13.5	41.9	34.2
Virginia	8.0	1.6	6.5	0.8	16.9	13.2	11.1	3.6	6.2	17.3	24.0	12.4	33.8	20.3
Washington	7.9	1.5	7.9	1.3	16.8	13.8	12.3	4.7	7.2	20.6	25.4	13.4	37.1	28.2
_	8.6	2.4	8.8	1.2	16.0	11.3	8.6	3.6	7.1	20.6	27.5	15.5	29.1	20.0
West Virginia	7.1	1.9	8.7	1.4	17.7	13.1	10.3	4.0	6.1	18.2	26.5		26.7	18.9
Wisconsin												14.0		
Wyoming	6.7	1.7	9.2	1.2	14.3	11.4	7.5	3.3	7.4	27.1	24.2	11.6	29.6	23.8

HPV = human papillomavirus. \*Per 100,000, age adjusted to the 2000 US standard population. †Data for 2005 are limited to cases diagnosed from January-June due to the effect of large migrations of populations on this state as a result of Hurricane Katrina in September 2005. ‡Data from this state are not available.

**Source:** North American Association of Central Cancer Registries. Data are collected by cancer registries participating in NCI's SEER program and CDC's National Program of Cancer Registries

American Cancer Society, Surveillance Research, 2012





HPV = human papillomavirus

\*Age adjusted to the 2000 US standard population. Note the scale of the Y axis differs between cancer sites and genders. Trends in incidence rates by stage at diagnosis should be interpreted with caution because of the introduction of Collaborative Staging criteria in 2004, which may have impacted the stage distribution for some cancers.

Source: Surveillance, Epidemiology, and End Results (SEER) Program, SEER 13 database 1992-2008. National Cancer Institute

American Cancer Society, Surveillance Research, 2012

esophageal cancer (squamous cell carcinoma and adenocarcinoma) are related to smoking, decreases in smoking prevalence have only manifested declines in squamous cell carcinoma of the esophagus.

Risk factors: Obesity is associated with a 16-fold increased risk of esophageal adenocarcinoma. <sup>18</sup> Gastroesophageal reflux also increases risk through the establishment of Barrett's esophagus, a premalignant condition that can progress to esophageal adenocarcinoma. <sup>19,20</sup> Abdominal obesity is associated with both gastroesophageal reflux and Barrett's esophagus, possibly by increasing intra-abdominal pressure promoting acid reflux, which can initiate the malignant transformation of esophageal cells. <sup>21</sup> Current and former smoking is also associated with a two-fold increased risk of esophageal adenocarcinoma. <sup>21</sup>

Rates and trends: Incidence rates for esophageal adenocarcinoma increased significantly among white men (1.8% per year), white women (2.1% per year), and Hispanic men (2.8% per year) during 1999-2008, while there were no significant changes for men or women of other racial/ethnic groups (Table 1). Overall rates increased in men and women 55 years of age or older

(Figure 1, B) and for distant- and regional-staged disease (Figure 2, B). These increasing trends coincide with rises in obesity and gastroesophageal reflux disease. <sup>22</sup> However, the extent to which increasing obesity rates contribute to the increasing trends and higher burden in whites is unclear because obesity prevalence has increased in men and women of all racial/ethnic groups and because obesity prevalence is highest among African Americans. <sup>23</sup> Rather, these patterns may reflect the higher prevalence of abdominal obesity among whites. <sup>24</sup>

**Survival:** Five-year survival rates for esophageal adenocarcinoma increased from 33.5% in 1992-1995 to 49.3% in 2001-2007 for local-staged tumors, and from 9.4% to 20.6% for regional-staged tumors. Survival was poor for distant-staged tumors, with a five-year relative survival rate of 2.8% during 2001-2007 (Table 3).

Prevention and early detection: Maintaining a healthy body weight may reduce the risk for esophageal adenocarcinoma. Treatment of gastroesophageal reflux disease with proton-pump inhibitors, which reduces gastric acid, thereby slowing or preventing the development of Barrett's esophagus, may also lower risk, although the most effective regimen to reduce cancer

Table 3. Trends in Five-year Relative Survival Rates (%) for Cancers with Increasing Incidence by Stage at Diagnosis, Ages 15 Years and Older, 1992-2007

	Loca	alized	Reg	ional	Distant		
	1992-1995	2001-2007	1992-1995	2001-2007	1992-1995	2001-2007	
HPV-related oropharynx	63.3	78.3	47.3	66.7	21.7	37.2	
Esophageal adenocarcinoma	33.5	49.3	9.4	20.6	1.9	2.8	
Pancreas	15.4	21.9	6.3	9.1	1.6	1.8	
Liver & intrahepatic bile duct	12.5	27.4	5.8	8.8	1.6	2.5	
Thyroid	99.4	99.7	94.5	97.0	60.5	57.3	
Kidney & renal pelvis	88.4	91.1	60.0	62.7	7.3	10.1	
Melanoma of the skin	96.1	99.5	58.9	66.1	11.9	14.8	

HPV = human papillomavirus

Source: Surveillance, Epidemiology, and End Results (SEER) Program, SEER 13 database 1992-2008. National Cancer Institute.

American Cancer Society, Surveillance Research, 2012

risk in these patients is not known.21 In addition, medical surveillance for people diagnosed with Barrett's esophagus to monitor for the development of esophageal adenocarcinoma may also be beneficial; however, the timing and frequency of such screening is unclear.25

#### **Pancreas**

Pancreatic cancer is one of the most deadly forms of cancer and the fourth leading cause of cancer death among men and women.

Risk factors: Cigarette smoking accounts for 25%-30% of pancreatic cancer cases and confers about a two-fold increased pancreatic cancer risk relative to nonsmokers.26 Cigar and pipe smoking, as well as use of smokeless tobacco, are also associated with elevated risks. Obesity is another important modifiable risk factor for pancreatic cancer, and obese individuals have a 20% increased risk relative to normal-weight individuals.27 Additional risk factors include inherited genetic disorders, preexisting diabetes, and a history of pancreatitis.

Rates and trends: Increases in pancreatic cancer incidence rates were limited to white men (0.9% per year) and white women (1.0% per year) during 1999-2008 (Table 1). Incidence rates increased for men 55 years of age or older and for women of all ages, as well as for local-, regional-, and distant-staged tumors, though these increase were likely limited to whites (Figures 1, C and 2, C). Increases in obesity prevalence are thought to contribute to the rising incidence rates. 26,27 However, the prevalence of obesity has increased among all racial/ethnic groups, suggesting the presence of other factors resulting in increasing pancreatic cancer rates among white men and women only.23

During 2004-2008, pancreatic cancer incidence rates (per 100,000) were highest among African American men (21.3) and women (17.6), and second highest among white men (16.8) and women (12.8) (Table 1). The racial disparity in the burden of pancreatic cancer has been explained in part by higher rates of cigarette smoking and diabetes mellitus among African American men versus white men and elevated body mass index among African American women versus white women.28

Survival: Five-year survival for pancreatic cancer was poor regardless of stage and improved little over time. During the most recent time period (2001-2007), the five-year survival rate was 21.9% for local-staged cancer, 9.1% for regional-staged cancer, and 1.8% for distant-staged cancer. The overall poor survival for pancreatic cancer underscores the lack of effective treatments for this malignancy (Table 3).

Prevention and early detection: Avoiding tobacco use is important in the prevention of pancreatic cancer.26 Risk can also be reduced by maintaining a healthy weight throughout life.26 There is no recommended screening procedure for pancreatic cancer, and symptoms do not usually appear until the disease has spread to distant organs, creating a challenge for early detection.

## Liver and intrahepatic bile duct

Surveillance reporting for liver cancer includes hepatocellular carcinoma (HCC), the major subtype of liver cancer accounting for approximately 80% of all cases, and tumors of the intrahepatic bile duct (cholangiocarcinomas).29

Risk factors: Chronic infection with hepatitis B virus (HBV) or hepatitis C virus (HCV) can lead to fibrosis and cirrhosis (scarring) of the liver, which dramatically increases risk of HCC. Among people with chronic HBV infection, the lifetime risk of liver cancer is 10%-25%, and these cases account for approximately 16% of all liver cancers in the US. 29,30 Among people with chronic HCV infection, there is an estimated 17-fold increased risk of HCC, and these cases account for approximately 48% of liver cancers occurring in the US. 30,31 In other parts of the world where these infections are more common, they account for a greater proportion of liver cancers. Other important risk factors for liver cancer include alcohol-induced liver disease, smoking, obesity, and diabetes. 29,32,33 A recent study found an increased risk associated with metabolic syndrome, which reflects the interaction between obesity, diabetes, and hypertension and underscores the complex nature of multiple shared risk factors for these cancers. <sup>34</sup> The following sections refer to the combined group of liver and intrahepatic bile duct malignancies as "liver cancer."

Rates and trends: Significant increases in liver cancer incidence rates were observed among white (3.8% per year), African American (5.4% per year), and Hispanic men (2.4% per year) and among African American women (2.7% per year) during 1999-2008 (Table 1). Incidence rates increased for all age groups, most notably for men 55-64 years of age (Figure 1, D). Liver cancer incidence rates increased for all stages at diagnosis, although most notably for localized disease, from 2.3 (per 100,000) in 1999 to 4.2 in 2008 (Figure 2). The increasing burden of liver cancer among African American men and women, and white men, is consistent with an aging cohort of people infected with HCV through injection drug use in the past who are now reaching ages at which liver cancer risk is highest. 35

Incidence rates continue to be highest among Asian or Pacific Islander men (27.6 per 100,000 population) and women (10.4 per 100,000 population), consistent with the substantial burden of endemic HBV infection among Asian and Pacific Islanders born elsewhere who emigrated to the US (Table 1). 36,37 The increasing incidence trends and high burden of disease in some population subgroups warrant continued monitoring as rates may continue to rise.

**Survival:** Five-year survival for localized liver cancer increased from 12.5% during 1992-1995 to 27.4% during 2001-2007 (Table 3). There was little improvement in five-year survival for regional-(5.8% during 1992-1995 to 8.8% during 2001-2007) or distant-(1.6% during 1992-1995 to 2.5% during 2001-2007) staged liver cancers.

Prevention and early detection: Hepatitis B vaccination, which prevents chronic HBV infection and thus HBV-related liver cancer, is recommended for all newborn children, with catch-up vaccination recommended for adolescents.<sup>38</sup> Hepatitis B vaccination is also recommended for high-risk adults (such as health care workers and people who inject drugs).39 Both HBV and HCV are transmitted through injection drug use, so safe injection practices (using a sterile needle, not sharing injection drug equipment) may reduce transmission. Risk of sexual transmission of HBV and HCV may also be reduced by proper and consistent condom use. Antiviral treatment for those with chronic HBV or HCV infections also reduces liver cancer risk. 40 Risk can also be decreased by limiting alcohol intake and not smoking. Finally, maintaining a healthy body weight also decreases risk of liver cancer. Persons at high risk for liver cancer (for example, those with HBV- or HCV-related cirrhosis) may be screened every six months via ultrasound, although the effectiveness of such screening is unclear.41

## **Thyroid**

Risk factors: Childhood exposure to ionizing radiation is a strong risk factor for thyroid cancer, with risk increasing with greater levels of exposure. 42 Goiter and benign thyroid nodules, as well as certain genetic characteristics, are also risk factors. 43 Thyroid cancer is more common among women than men, and various female hormonal and reproductive factors have been investigated, including miscarriage as a first pregnancy and later age at first birth. 44 These risk factors are weakly associated with thyroid cancer risk, with the associations stronger for younger versus older women, suggesting an additional role of age-specific sex hormone changes. Certain genetic factors also increase the risk of thyroid cancer.

Rates and trends: Thyroid cancer incidence rates significantly increased among men and women of every racial/ethnic background except American Indian or Alaska Native men during 1999-2008 (Table 1). Rates increased for men and women of all ages, most notably for women 55-64 years of age (Figure 1). Incidence rates (per 100,000 population) increased for tumors of all stages, although the greatest increase was for localized disease (from 5.2 in 1999 to 9.6 in 2008) (Figure 2). Reasons for these increases are not known. Some studies suggested the increasing rates are due to detection of small tumors (through ultrasound and confirmation via fine needle aspiration), 45,46 while other, more recent studies argue that the increase is in part real, and involves both small and large tumors. 47.49

**Survival:** During 2001-2007, five-year survival rates were 99.7% for localized tumors, 97.0% for regional-staged tumors, and 57.3% for distant-staged tumors (Table 3).

**Prevention and early detection:** People with genetic risk factors for thyroid cancer may have their thyroid removed to prevent cancer. <sup>42</sup> There are no clear recommendations to prevent thyroid cancer or established early detection methods.

## Kidney and renal pelvis

Risk factors for kidney and renal pelvis cancers are somewhat different, although the two cancers are typically combined for surveillance purposes, as they are for the incidence and survival statistics presented herein.

Risk factors: Cigarette smoking is a risk factor for kidney and renal pelvis cancers, though smoking is most strongly associated with renal pelvis cancer. Risk increases with both quantity and duration of smoking. For kidney cancer, smoking accounts for approximately 20%-30% of cases among men (conferring a 54% increased risk) and approximately 10%-20% of cases among women (conferring a 22% increased risk). <sup>50</sup> For cancer of the renal pelvis, smoking accounts for approximately 70%-82% of cases among men and approximately 37%-61% of cases among women. <sup>51</sup> Obesity also increases risk of kidney cancer, and accounts for 30%-40% of cases. <sup>50,51</sup> Hypertension (high blood pressure) also

risk associated with metabolic syndrome, which reflects the interaction between obesity, diabetes, and hypertension and underscores the complex nature of multiple shared risk factors for these cancers. <sup>54</sup> The following sections refer to the combined group of liver and intrahepatic bile duct malignancies as "liver cancer."

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increases risk of kidney cancer. There are also inherited forms of kidney cancer, which account for a small fraction of cases.

Rates and trends: During 1999-2008, kidney cancer incidence rates significantly increased for men and women of every race/ethnicity except American Indian or Alaska native men, for every age group, and most dramatically for localized tumors from 7.6 (per 100,000) in 1999 to 12.2 in 2008 (Table 1, Figures 1, F and 2, F). Previous studies analyzing data through 1995 or 1998 found increases in local- and regional-staged kidney cancer. <sup>52, 53</sup> However, in the current analysis from 1999 through 2008, only incidence of localized disease increased, suggesting that these trends may be due to greater uptake of imaging procedures (ultrasound, computed tomography, and magnetic resonance imaging), which detect asymptomatic early stage cancers that may have otherwise gone undiagnosed.

Rates (per 100,000) during 2004-2008 rates were two-fold higher among men (26.2) than among women (13.6), and highest for African American and American Indian or Alaska Native men (28.5 and 29.4, respectively), perhaps reflecting the higher prevalence of obesity in these populations (Table 1).

**Survival:** The five-year survival rate for kidney cancer increased slightly over time for localized disease, from 88.4% during 1992-1995 to 91.1% during 2001-2007 (Table 3). Survival for regional-staged kidney cancer also increased slightly from 60.0% (1992-1995) to 62.7% (2001-2007) and for distant-staged disease from 7.3% (1992-1995) to 10.1% (2001-2007).

Prevention and early detection: Avoiding smoking and maintaining a healthy weight throughout life are likely important preventive steps for kidney cancer. In addition, avoiding hypertension (through diet and exercise) and treatment of existing hypertension are also likely preventive measures.

#### Melanoma of the skin

Melanoma is the deadliest form of skin cancer, and is more common among whites of European descent than other racial and ethnic groups.

Risk factors: The major risk factor for melanoma of the skin is exposure to ultraviolet light. Immunosuppression, which is common among organ transplant recipients and those with HIV infection and autoimmune diseases, is also a risk factor. Exposure to ionizing radiation and some chemicals may also increase risk. People with fair skin, freckles, and/or moles and those with a family history of skin cancer and certain genetic markers may also be at increased risk for melanoma. <sup>54</sup> In the following section melanoma of the skin is referred to as "melanoma."

Rates and trends: Melanoma incidence rates continued to increase among white men (2.1% per year) and white women (2.4% per year) during 1999-2008 (Table 1). Rates increased for

men over 55 years of age and for women of all ages (Figure 1). By stage at diagnosis, only rates of localized disease increased (from 18.0 per 100,000 in 1999 to 22.2 per 100,000 in 2008) (Figure 2). Other studies have shown that rates have increased for both thin and thick lesions. <sup>55</sup> Overall, the continued increases in melanoma incidence rates may reflect changing sun exposure patterns and the use of indoor tanning booths by young women, as well as increased awareness and detection practices. <sup>55,56</sup>

Melanoma incidence rates in whites are 5 times higher than in Hispanics and 20 times higher than in African Americans. During the most recent period (2004-2008), rates (per 100,000) were higher among men (30.3) than among women (19.5) (Table 1), reflecting differences in sun exposure.

**Survival:** Five-year survival rates for melanoma increased slightly for localized disease from 96.1% (1992-1995) to 99.5% (2001-2007), for regional-staged disease from 58.9% (1992-1995) to 66.1% (2001-2007), and for distant-staged disease from 11.9% (1992-1995) to 14.8% (2001-2007) (Table 3).

Prevention and early detection: Strategies to reduce risk of certain types of melanoma include proper and consistent use of sunscreen, wearing sun-protective clothing, seeking shade, and avoiding tanning beds. <sup>54</sup> In addition to individual-level policies, community-level policies that restrict access to tanning beds for minors and facilitate sun-safe behaviors among children are also likely to be important. Finally, increased melanoma awareness among both individuals and health care providers may also increase early detection of cancerous lesions, leading to successful treatment.

## **Future challenges**

In 2012, cancers with increasing incidence rates are expected to account for approximately 135,000 new cancer cases among men and 110,000 cases among women. Increasing incidence of esophageal adenocarcinoma and cancers of the pancreas and liver is particularly concerning because of their poor survival, highlighting the need for early detection and treatment options for these highly fatal cancers. Additional studies are needed to determine the underlying causes of the observed increases in incidence rates for the seven cancers discussed and to address the determinants of gender and racial/ethnic differences in incidence rates and trends. While temporal trends in risk factors (in particular, the recent rise in obesity in the US) can be plausibly linked to a number of these cancers, other factors, such as increased diagnostic imaging may also be important, although the precise nature and relative contribution of these and other factors remains unclear.

Research into cancer biology utilizing genome-wide association studies may yield important etiologic findings for some cancers with strong genetic risks.<sup>57</sup> In addition, identification of biomarkers of tumor aggressiveness may enable more individualized treatment options. The extensive efforts to develop personalized and/or targeted therapies hold some promise as they take into account the complex molecular composition and gene expression profiles of individual tumors. <sup>58-60</sup> Additionally, the development of improved early detection techniques and screening guidelines for specific high-risk populations are also important future considerations. However, the most prudent cancer prevention activities include avoiding tobacco use and obesity and increasing physical activity.

Due to population growth and aging, the number of new cancer patients is expected to double to 2.6 million people by 2050.5 This number could further increase if the trends for cancers that are increasing are not reversed. Further, as survival from some of the cancers highlighted in this special section was generally good (in particular, thyroid cancer and melanoma of the skin), this will add to the growing population of cancer survivors with complex health care and societal needs, including reduced income and productivity due to a prolonged illness, economic stress, and limited or diminishing social support. 61 In addition, as cancer survivors age, some will be at increased risk for second cancers, requiring additional medical surveillance. The need will also grow for access to comprehensive cancer centers, for trained medical professionals (oncologists, specialized nursing staff, and others), and for health officials to develop appropriate plans to meet these needs.62

In summary, cancers with increasing incidence rates in the US represent an area of focus for cancer prevention and control programs and the public at-large. A number of these cancers are preventable through smoking cessation and avoidance of obesity. However, additional research is needed to determine the role of other factors and to develop appropriate screening, early detection, and treatment programs to reduce pain and suffering from these cancers.

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## **Tobacco Use**

Smoking-related diseases remain the world's most preventable cause of death. Since the first US Surgeon General's report on smoking and health in 1964, there have been more than 15 million premature deaths attributable to smoking in the US alone. Leglibrate Globally, the World Health Organization (WHO) estimates that there are 6 million smoking-related premature deaths each year. Section 1988.

## **Health Consequences of Smoking**

Half of all those who continue to smoke will die from smoking-related diseases. In the US, tobacco use is responsible for nearly 1 in 5 deaths, or about 443,000 premature deaths each year. In addition, an estimated 8.6 million people suffer from chronic conditions related to smoking, such as chronic bronchitis, emphysema, and cardiovascular diseases.

- Smoking accounts for at least 30% of all cancer deaths and 80% of lung cancer deaths.<sup>6,8,9</sup>
- The risk of developing lung cancer is about 23 times higher in male smokers and 13 times higher in female smokers, compared to lifelong nonsmokers.<sup>1</sup>
- Smoking increases the risk of the following types of cancer: nasopharynx, nasal cavity and paranasal sinuses, lip, oral cavity, pharynx, larynx, lung, esophagus, pancreas, uterine cervix, ovary (mucinous), kidney, bladder, stomach, colorectum, and acute myeloid leukemia. 1,10
- The International Agency for Research on Cancer recently concluded that there is limited evidence that tobacco smoking causes female breast cancer.<sup>10</sup>
- Smoking is a major cause of heart disease, cerebrovascular disease, chronic bronchitis, and emphysema, and is associated with gastric ulcers.<sup>19</sup>
- The risk of lung cancer is just as high in smokers of "light" or "low-tar" yield cigarettes as in those who smoke "regular" or "full-flavored" products.<sup>11</sup>

#### Reducing Tobacco Use and Exposure

In 2000, the US Surgeon General outlined the goals and components of comprehensive statewide tobacco control programs. <sup>12</sup> These programs seek to prevent the initiation of tobacco use among youth; promote quitting at all ages; eliminate nonsmokers' exposure to secondhand smoke; and identify and eliminate the disparities related to tobacco use and its effects among different population groups. <sup>13</sup> The Centers for Disease Control and Prevention (CDC) recommends funding levels for comprehensive tobacco use prevention and cessation programs for all 50 states and the District of Columbia. In fiscal year 2012, 6 states allocated 50% or more of CDC-recommended funding levels for tobacco control programs. <sup>14</sup> States that have invested in comprehensive

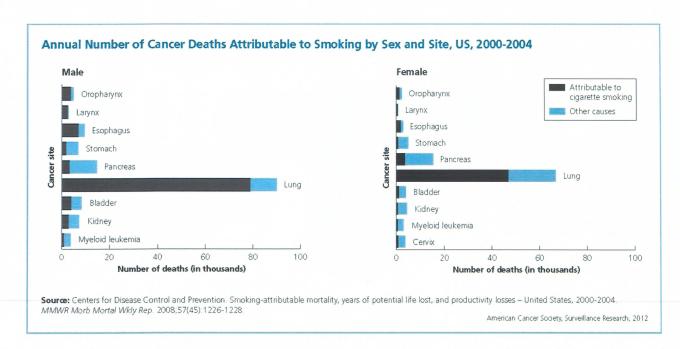
tobacco control programs, such as California, Massachusetts, and Florida, have reduced smoking rates and saved millions of dollars in tobacco-related health care costs. 12,15 Recent federal initiatives in tobacco control, including national legislation ensuring coverage of clinical cessation services, regulation of tobacco products, tax increases, and increased tobacco control funding, hold promise for reducing tobacco use. Provisions in the Affordable Care Act signed into law on March 23, 2010, ensure at least minimum coverage of evidence-based cessation treatments, including pharmacotherapy and cessation counseling, to previously uninsured tobacco users, pregnant Medicaid recipients, and eligible Medicare recipients. The Centers for Medicare and Medicaid subsequently issued a decision memo changing the eligibility requirement for Medicare recipients so that they no longer have to be diagnosed with a smoking-related disease in order to access cessation treatments. Starting in 2014, state Medicaid programs can no longer exempt cessation pharmacotherapy from prescription drug coverage. Several provisions of the Family Smoking Prevention and Tobacco Control Act, which for the first time grants the US Food and Drug Administration the authority to regulate the manufacturing, selling, and marketing of tobacco products, have already gone into effect.

For more information about tobacco control, see the American Cancer Society's *Cancer Prevention & Early Detection Facts & Figures 2011*, available online at cancer.org/statistics.

## **Trends in Smoking**

- Between 1965 and 2004, cigarette smoking among adults 18 years of age and older declined by half from 42% to 21%. Between 2005 (20.9%) and 2010 (19.3%), there was a modest, but statistically significant, decline in smoking prevalence. However, declines were not consistent from year-to-year and were not observed in all population subgroups. In 2010, approximately 45.3 million adults were current smokers, about 3 million fewer than there were in 2005. 16,17
- Importantly, the proportion of daily smokers reporting light or intermittent smoking (less than 10 cigarettes a day) increased significantly between 2005 (16%) and 2010 (22%), whereas heavy smoking declined from 13% to 8%.<sup>17</sup>
- Although cigarette smoking became prevalent among men before women, the gender gap narrowed in the mid-1980s and has remained constant since. 

  18 As of 2010, there was a 3% absolute difference in smoking prevalence between white men (23%) and women (20%), an 8% difference between African American men (25%) and women (17%), a 7% difference between Hispanic men (16%) and women (9%), and a 10% difference between Asian men (15%) and women (4%).
- Smoking is most common among the least educated. While
  the percentage of smokers has decreased at every level of
  educational attainment since 1983, college graduates had the



greatest decline, from 21% to 8% in 2010. In contrast, among those with a high school diploma, prevalence decreased modestly from 34% to 27% during the same time period. <sup>19</sup> Adults with a GED certificate (high school equivalency diploma) had the highest smoking rate (45%) in 2010. <sup>17</sup> Groups with a high school degree or less quit smoking at lower rates than higher educated groups between 1998 and 2008. <sup>20</sup>

- The decrease in smoking prevalence among high school students between the late 1970s and early 1990s was more rapid among African Americans than whites; consequently, lung cancer rates among adults younger than 40 years of age, which historically has been substantially higher in African Americans, have converged in these two groups. <sup>21</sup>
- Although cigarette smoking among US high school students increased significantly from 28% in 1991 to 36% in 1997, the rate had declined to 21% (male: 22%, female: 22%) by 2003.<sup>22,23</sup>
   Between 2003 and 2009, there was no significant change in the smoking rate among high school males (20%) and females (19%).<sup>24</sup>

### **Smokeless Tobacco Products**

Smokeless tobacco products include moist snuff, chewing tobacco, snus (a "spitless," moist powder tobacco pouch), dissolvable nicotine products (Orbs, Strips, and Sticks), and a variety of other tobacco-containing products that are not smoked. Recently, the smokeless market in high-income countries, including the US, has been increasingly consolidated from smaller tobacco companies into the control of the multinational cigarette corporations. <sup>25</sup> As part of their marketing strategy, the

industry is actively promoting smokeless tobacco products both for use in settings where smoking is prohibited and as a way to quit smoking; however, there is no evidence that these products are as effective as proven cessation therapies. When smokeless tobacco was aggressively marketed in the US in the 1970s, use of these products increased among adolescent males, not among older smokers trying to quit. <sup>26,27</sup> Use of any smokeless tobacco product is not considered a safe substitute for quitting. These products cause oral, esophageal, and pancreatic cancers, precancerous lesions of the mouth, gum recession, bone loss around the teeth, and tooth staining; they can also lead to nicotine addiction. <sup>28</sup>

- Smokers who use smokeless products as a supplemental source of nicotine to postpone or avoid quitting will increase rather than decrease their risk of lung cancer.<sup>29</sup>
- Long-term use of snuff substantially increases the risk of cancers of the oral cavity, particularly cancers of the cheek and gum.<sup>28</sup>
- According to the US Department of Agriculture, manufactured output of moist snuff has increased more than 83% in the past two decades, from 48 million pounds in 1991 to an estimated 88 million pounds in 2007, <sup>30,31</sup>
- Sales of smokeless tobacco products are growing at a more rapid pace than cigarettes. Between 1990 and 2006, per capita sales of smokeless products in the US increased by nearly 100%, while sales of cigarettes declined by 42%.<sup>32,33</sup>
- According to the 2010 National Health Interview Survey, 2.7% of adults 18 years of age and older 5% of men and 0.2% of women were current users of smokeless products.<sup>34</sup>

- According to the 2010 National Survey on Drug Use and Health (NSDUH), whites were more likely to use smokeless tobacco than African Americans, Hispanics/Latinos, or Asians.<sup>35</sup>
- Adult smokeless tobacco use (including snus use) varied from 0.9% to 8.2% across states in 2010, with higher rates observed in the South and North-Central states.<sup>36</sup>
- Nationwide, 9% of high school students 15% of males and 2% of females – used chewing tobacco, snuff, or dip in 2009.<sup>24</sup> Data from the NSDUH indicate that initiation of smokeless tobacco products and past month use among youth 12-17 years of age increased between 2000 and 2009, primarily among boys.<sup>37</sup>

## Cigars

Cigar smoking has health consequences similar to those of cigarette smoking and smokeless tobacco.<sup>38</sup>

- Regular cigar smoking is associated with an increased risk
  of cancers of the lung, oral cavity, larynx, esophagus, and
  probably pancreas. Cigar smokers have 4 to 10 times the risk
  of dying from laryngeal, oral, or esophageal cancer compared
  to nonsmokers.<sup>38</sup>
- In 2010, 2.5% of adults 18 years of age and older 4.7% of men and 0.5% of women – were current users of cigars (had smoked at least 50 cigars in their lifetime and now smoked some days or every day).<sup>34</sup>
- According to the 2010 NSDUH, African Americans and American Indians/Alaska Natives had the highest prevalence of past month cigar use, followed by, whites, Hispanics, and Asians,<sup>35</sup>
- Among states, cigar smoking prevalence among adults ranges from between 2.2% to 5.4%.  $^{36}$
- In 2009, 14% of US high school students had smoked cigars, cigarillos, or little cigars at least once in the past 30 days.<sup>24</sup>
- Between 1997 and 2007, while sales of little cigars increased by 240%, large cigar sales decreased by 6%.<sup>39</sup> Small cigars are similar in shape and size to cigarettes, but are not regulated or taxed like cigarettes, making them more affordable to youth.

#### **Smoking Cessation**

A US Surgeon General's Report outlined the benefits of smoking cessation:  $^{\rm 40}$ 

- People who quit, regardless of age, live longer than people who continue to smoke.
- Smokers who quit before 50 years of age cut their risk of dying in the next 15 years in half, compared to those who continue to smoke.
- Quitting smoking substantially decreases the risk of lung, laryngeal, esophageal, oral, pancreatic, bladder, and cervical cancers.

 Quitting lowers the risk for other major diseases, including heart disease, chronic lung disease, and stroke.

While the majority of ever-smokers in the US have quit smoking, rates of a dult smoking cessation remained stable between 1998 and 2008.  $^{20}$ 

- In 2010, an estimated 49.5 million adults were former smokers, representing 53% of living persons who ever smoked.<sup>34</sup>
- Smokers with an undergraduate or graduate degree are more likely to quit than less educated smokers.<sup>20</sup> Among those who smoked in 2010, an estimated 20.6 million (or 47%) had stopped smoking at least one day during the preceding 12 months because they were trying to quit.<sup>34</sup>
- In 47 states and the District of Columbia, the majority of adults (50% or more) who ever smoked have quit smoking.<sup>41</sup>
- In 2009, among high school students who were current cigarette smokers, national data showed that one-half (51%) had tried to quit smoking cigarettes during the 12 months preceding the survey; female students (54%) were more likely to have made a quit attempt than male students (48%).<sup>24</sup>

Tobacco dependence is a chronic disease and should be treated with effective treatments that may double or triple smokers' chances of long-term abstinence.<sup>42</sup> Certain racial and ethnic groups (Hispanics and non-Hispanic African Americans) and those with low socioeconomic status are significantly less likely to receive cessation services.<sup>36</sup> Improving access to these services by promoting coverage for these treatments through government health programs, including Medicaid and Medicare, and private health insurance mandates can help reduce these disparities.

#### Secondhand Smoke

Secondhand smoke (SHS), or environmental tobacco smoke, contains numerous human carcinogens for which there is no safe level of exposure. It is estimated that more than 88 million nonsmoking Americans 3 years of age and older were exposed to SHS in 2007-2008.<sup>48</sup> Numerous scientific consensus groups have reviewed data on the health effects of SHS.<sup>44-49</sup> In 2006, the US Surgeon General published a comprehensive report titled *The Health Consequences of Involuntary Exposure to Tobacco Smoke.*<sup>44</sup> Public policies to protect people from SHS are based on the following detrimental effects:

- SHS contains more than 7,000 chemicals, at least 69 of which cause cancer.<sup>2</sup>
- Each year, about 3,400 nonsmoking adults die of lung cancer as a result of breathing SHS.<sup>6</sup>
- SHS causes an estimated 46,000 deaths from heart disease in people who are not current smokers.  $^{\rm 6}$
- SHS may cause coughing, wheezing, chest tightness, and reduced lung function in adult nonsmokers.<sup>44</sup>

Some studies have reported an association between SHS
exposure and breast cancer. The US Surgeon General has
designated this evidence suggestive rather than conclusive.<sup>44</sup>
In any case, women should be aware that there are many
health reasons to avoid exposure to tobacco smoke.

Laws that prohibit smoking in public places and create smoke-free environments are an extremely effective approach to prevent exposure to and harm from SHS. <sup>50</sup> In addition to providing protection against harmful exposure to secondhand smoke, there is strong evidence that smoke-free policies decrease the prevalence of both adult and youth smoking. <sup>51</sup> Momentum to regulate public smoking began to increase in 1990, and these laws have become increasingly common and comprehensive. <sup>52</sup>

- In the past decade, the largest decline in SHS exposure among nonsmokers occurred between 1999-2000 (52.5%) and 2001-2002 (41.7%); current exposure estimates (2007-2008) remain stable at 40.1%.<sup>43</sup>
- In the US, as of October 2011, 3,397 municipalities have passed smoke-free legislation, and 35 states, along with the District of Columbia, the Northern Mariana islands, Puerto Rico, American Samoa, and the US Virgin Islands, have either implemented or enacted statewide smoking bans that prohibit smoking in workplaces and/or restaurants and/or bars. 53
- Currently, approximately 80% of the US population is covered by a smoke-free policy or provision in workplaces and/or restaurants and/or bars.<sup>53</sup>
- Nationally, coverage of all indoor workers by smoke-free policies increased substantially from 1992-1993 (46%) to 2006-2007 (75%).<sup>54</sup>

Workplace smoking restrictions vary by geographic area; 72% of Southern residents reported working under a smoke-free policy, compared to 81% of workers in the Northeast.  $^{55}$ 

#### **Costs of Tobacco**

The number of people who die prematurely or suffer illness from tobacco use imposes substantial health-related economic costs to society. It is estimated that in the US, between 2000 and 2004, smoking accounted for 3.1 million years of potential life lost in men and 2.0 million years of potential life lost in women. Smoking, on average, reduces life expectancy by approximately 14 years. <sup>6</sup>

#### In addition:

- Between 2000 and 2004, smoking, on average, resulted in more than \$193 billion in annual health-related economic costs, including medical costs and productivity losses.<sup>6</sup>
- Smoking-attributable health care expenditures totaled an estimated \$99.5 billion annually between 2000 and 2004, up \$24 billion from \$75.5 billion during 1997-2001.<sup>6</sup>

 Smoking-attributable productivity losses in the US amounted to \$96.8 billion annually during 2000-2004, up about \$4.3 billion from the \$92 billion annually during 1997-2001.<sup>6,56</sup>

#### Worldwide Tobacco Use

During the past 25 years, while the prevalence of smoking has been slowly declining in the US and many other high-income countries, smoking rates have been increasing in many low- and middle-income nations, where about 85% of the world population resides.

- In 2011, tobacco use killed almost 6 million people, with 80% of these deaths occurring in low- and middle-income countries.<sup>25</sup> If current trends continue, by 2030 tobacco will kill more than 8 million people worldwide each year and, without further intervention, could kill 1 billion people over the course of the 21st century.<sup>8,25</sup>
- Between 2002 and 2030, tobacco-attributable deaths are projected to decline by 9% in high-income countries, but are expected to double from 3.4 million to 6.8 million in low-and middle-income countries.<sup>57</sup> For example, tobacco use is currently the number one killer in China, responsible for 1.2 million deaths annually. This number is expected to rise to 3.5 million deaths annually by the year 2030.<sup>58</sup>
- Approximately 18% of the world's population more than 1 billion men and 250 million women – smoke. In 32 countries male smoking prevalence is greater than or equal to 45%: all but 5 of these are low- and middle-income countries.<sup>3,25</sup>
- In many low- and middle-income countries, smoking prevalence is increasing among females, while rates in most high-income countries have peaked or are decreasing.<sup>25</sup>
- Data from the Global Youth Tobacco Survey conducted during 2000-2007 found that among youth 13 to 15 years of age, 12% of boys and 7% of girls reported smoking cigarettes, and 12% of boys and 8% of girls reported using other tobacco products.<sup>59</sup> In every region of the world, the ratio of male-to-female smoking among youth was smaller than the ratio reported among adults, reflecting a global trend of increased smoking among female youth.<sup>50</sup>
- It has been estimated that in 2004, more than 600,000 nonsmokers worldwide died as a result of exposure to secondhand smoke, and 40% of children were exposed to secondhand smoke.<sup>61</sup>
- The use of smokeless tobacco accounts for a significant and growing portion of tobacco use throughout the world. The majority of smokeless tobacco is consumed in South Asia.<sup>25</sup> However, consistent with trends in the US, the sales of smokeless tobacco products are growing at a rapid pace in high-income countries, even as smoking rates decline.<sup>25</sup>

- As emerging and developing economies come to prominence and their health systems develop further, the medical costs of tobacco-related disease will continue to grow. In China, for example, the direct costs of smoking were \$6.2 billion in 2008 (an increase of 154% compared to 2000), while the indirect costs of smoking were \$22.7 billion in 2008 (an increase of 376% compared to 2000).<sup>62</sup>
- Spending on tobacco products diverts resources from essential goods and services. For example, in India tobacco consumption impoverishes roughly 15 million people, and in Cambodia, the amount of money spent on one pack of premium cigarettes can buy as much as 3,500 food calories comprising a typical daily diet in that country.<sup>63,64</sup>
- About 55% of the world's population was covered by one or more evidence-based tobacco control measure in 2010, up from less than 10% in 2008.³ The WHO estimates that 11% of the world's population lives in smoke-free environments 14% is covered by cessation programs, 15% is exposed to health warnings on tobacco products, 28% to mass media campaigns, 6% to tobacco advertising bans, and 8% is subject to the recommended tobacco tax level.³

The first global public health treaty, the Framework Convention on Tobacco Control (FCTC), was unanimously adopted by the World Health Assembly on May 21, 2003, and subsequently entered into force as a legally binding accord for all ratifying states on February 27, 2005.65 The FCTC features specific provisions to control both the global supply and demand for tobacco, including regulation of tobacco product contents, packaging, labeling, advertising, promotion, sponsorship, taxation, smuggling, youth access, exposure to secondhand tobacco smoke, and environmental and agricultural impacts. 65 Parties to the treaty are expected to strengthen national legislation, enact effective tobacco control policies, and cooperate internationally to reduce global tobacco consumption. 66,67 As of September 2011. out of 195 eligible countries, 174 have ratified or acceded to the treaty representing approximately 87% of the world's population.65 A number of major tobacco-producing nations, including Argentina, Indonesia, Malawi, the US, and Zimbabwe, have either not signed or have signed but not ratified the treaty.65

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## **Cancer Disparities**

An overarching objective of the American Cancer Society's 2015 challenge goals is to eliminate disparities in the cancer burden among different segments of the US population defined in terms of socioeconomic status (income, education, insurance status, etc.), race/ethnicity, residence, sex, and sexual orientation. The causes of health disparities within each of these groups are complex and include interrelated social, economic, cultural, and health system factors. However, disparities predominantly arise from inequities in work, wealth, income, education, housing, and overall standard of living, as well as social barriers to high-quality cancer prevention, early detection, and treatment services.

#### Socioeconomic Status

Persons with lower socioeconomic status (SES) have disproportionately higher cancer death rates than those with higher SES, regardless of demographic factors such as race/ethnicity. For example, cancer mortality rates among both African American and non-Hispanic white men with 12 or fewer years of education are almost 3 times higher than those of college graduates for all cancers combined, and 4-5 times higher for lung cancer. Furthermore, progress in reducing cancer death rates has been slower in persons with lower SES. These disparities occur largely because persons with lower SES are at higher risk for cancer and have less favorable outcomes after diagnosis. People with lower SES are more likely to engage in behaviors that increase cancer risk, such as tobacco use, physical inactivity, and poor diet, in part because of marketing strategies that target these populations and in part because of environmental or community factors that provide fewer opportunities for physical activity and less access to fresh fruits and vegetables. Lower SES is also associated with financial, structural, and personal barriers to health care, including inadequate health insurance, reduced access to recommended preventive care and treatment services, and lower literacy rates. Individuals with no health insurance are more likely to be diagnosed with advanced cancer and less likely to receive standard treatment and survive their disease. For more information about the relationship between SES and cancer, see Cancer Facts & Figures 2011, Special Section and Cancer Facts & Figures 2008, Special Section, available online at cancer.org.

#### **Racial and Ethnic Minorities**

Disparities in the cancer burden among racial and ethnic minorities largely reflect obstacles to receiving health care services related to cancer prevention, early detection, and high-quality treatment, with poverty (low SES) as the overriding factor.

According to the US Census Bureau, in 2010, more than 1 in 4 African Americans and Hispanics/Latinos lived below the poverty line, compared to 1 in 10 non-Hispanic whites. Moreover, 1 in 5 African Americans and 1 in 3 Hispanics/Latinos were uninsured, while only 1 in 10 non-Hispanic whites lacked health insurance.

Discrimination is another factor that contributes to racial/ethnic disparities in cancer mortality. Racial and ethnic minorities tend to receive lower quality health care than whites even when insurance status, age, severity of disease, and health status are comparable. Social inequalities, including discrimination, communication barriers, and provider assumptions, can affect interactions between patient and physician and contribute to miscommunication or delivery of substandard care.

In addition to poverty and social discrimination, cancer occurrence in a population may also be influenced by cultural and/or inherited factors that decrease or increase risk. For example, Hispanic women have a lower risk of breast cancer probably in part because they tend to begin having children at a younger age, which decreases breast cancer risk. Individuals who maintain a primarily plant-based diet or do not use tobacco because of cultural or religious beliefs have a lower risk of many cancers. Higher rates of cancers related to infectious agents (e.g., stomach, liver, uterine cervix) in populations that include a large number of recent immigrants, such as Hispanics and Asians, may reflect a higher prevalence of infection in the country of origin. Genetic factors may also explain some differences in cancer incidence. For example, women from population groups with an increased frequency of mutations in the breast cancer susceptibility genes (BRCA1 and BRCA2), such as women of Ashkenazi Jewish descent, have an increased risk of breast and ovarian cancer. Genetic factors may also play a role in the elevated risk of prostate cancer among African American men and the incidence of more aggressive forms of breast cancer in African American women. However, genetic differences associated with race are thought to make a minor contribution to the disparate cancer burden between populations. Following is a brief overview of the cancer burden for each of the four major nonwhite racial/ethnic groups.

African Americans: African Americans are more likely to develop and die from cancer than any other racial or ethnic group. The death rate for cancer among African American males is 33% higher than among white males; for African American females, it is 16% higher than among white females. African American men have higher incidence and mortality rates than whites for each of the cancer sites listed on page 44 with the exception of kidney cancer, for which rates are the same. For more information on cancer in African Americans, see Cancer Facts & Figures for African Americans 2011-2012, available online at cancer.org/statistics.

Incidence	White	African American	Asian American or Pacific Islander	American Indian or Alaska Native <sup>‡</sup>	Hispanic/ Latino
All sites Male	545.0	626.2	332.4	427.8	423.4
Female	420.8	394.2	284.0	362.1	333.5
Breast (female)	122.3	116.1	84.9	89.2	92.3
Colon & rectum					
Male	54.6	66.9	42.4	51.5	48.6
Female	40.3	49.7	32.7	41.5	34.2
Kidney & renal pelvis					
Male	20.8	22.6	9.9	27.4	19.4
Female	10.9	11.7	4.9	16.8	11.2
Liver & intrahepatic bile duct					
Male	8.6	14.1	21.7	15.8	17.0
Female	2.9	4.0	8.2	7.6	6.4
Lung & bronchus					
Male	83.7	102.7	49.8	71.0	46.8
Female	57.2	51.4	28.1	51.7	27.0
Prostate	142.8	230.8	79.7	101.2	126.7
Stomach					
Male	8.5	16.4	16.8	13.9	13.8
Female	4.0	8.2	9.4	6.8	8.4
Uterine cervix	7.7	10.6	7.4	9.8	12.2
		African	A-1 A	A	
Mortality	White	American	Asian American and Pacific Islander	American Indian and Alaska Native <sup>‡</sup>	Hispanic Latino
	Willie	runcheun	and racine loanact	and maska matte	Lucino
All sites	2220	205.2	13.4.7	100.0	1404
Male	222.0	295.3	134.7 94.1	190.0	149.1
Female	152.8	177,7		138.4	101.5
Breast (female)	22.8	32.0	12.2	17.2	15.1
Colon & rectum					
Male	20.1	30.5	13.3	19.8	15.5
Female	14.0	20.4	9.9	14.0	10.3
Cidney & renal pelvis					
Male	6.0	6.0	2.6	8.9	5.2
Female	2.7	2.6	1.2	4.1	2.3
iver & intrahepatic bile duct					
Male	7.2	11.5	14.7	11.9	11.6
Female	3.0	3.9	6.3	6.7	5.2
ung & bronchus					
Male	66.9	85.4	36.7	50.5	31.9
Female	41.2	38.8	18.5	33.9	14.3
rostate	22.4	54.9	10.5	20.7	18.5
itomach					
Male	4.5	10.7	9.2	8.5	7.7
Female	2.3	5.0	5.4	3.9	4.5

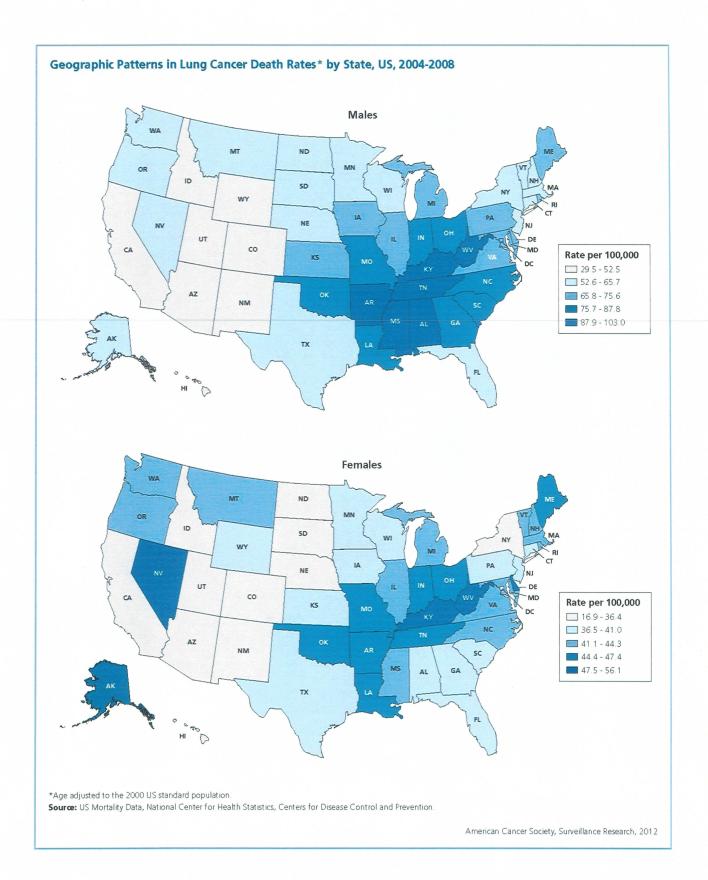
<sup>\*</sup>Per 100,000, age adjusted to the 2000 US standard population.

American Cancer Society, Surveillance Research, 2012

<sup>†</sup>Race and ethnicity categories are not mutually exclusive, persons of Hispanic origin may be of any race.

Data based on Contract Health Service Delivery Areas, comprising about 55% of the US American Indian/Alaska Native population; for more information, please see: Espey DK, Wu XC, Swan J, et al. Annual report to the nation on the status of cancer, 1975-2004, featuring cancer in American Indians and Alaska Natives.

**Source:** Incidence: NAACCR, 2011. Data are collected by cancer registries participating in the National Cancer Institute's SEER program and the Centers for Disease Control and Prevention's National Program of Cancer Registries. Mortality: National Center for Health Statistics 2011.



Hispanics: Hispanics have lower incidence rates for all cancers combined and for most common types of cancer compared to whites, but have higher rates of cancers associated with infection, such as liver, stomach, and uterine cervix. For example, Hispanic women have the highest incidence rate for cervical cancer, and rates of liver cancer are about twice as high in Hispanics as in whites. For more information on cancer in Hispanics, see Cancer Facts & Figures for Hispanics/Latinos 2009-2011, available online at cancer.org/statistics.

Asian Americans and Pacific Islanders: Compared to other racial/ethnic groups, Asian Americans and Pacific Islanders have the lowest overall cancer incidence rates, as well as the lowest rates for most common cancer types. However, similar to Hispanics, this population has higher rates for many of the cancers related to infection. As shown in the table on page 44, they have the highest incidence rates for liver and stomach cancers of all racial and ethnic groups in both men and women, and among the highest death rates for these cancer sites. Liver cancer incidence among Asian American and Pacific Islander men and women is almost 30% higher than that among Hispanics, who have the second-highest rates. (For more information on cancers related to infection, see Cancer Facts & Figures 2005, Special Section, available online at cancer.org.)

American Indians and Alaska Natives: Mortality rates for kidney cancer in American Indian and Alaska Native men and women are higher than in any other racial or ethnic population. Cancer information for American Indians and Alaska Natives is known to be incomplete because the racial/ethnic status of many of these individuals is not correctly identified in medical and death records. Although efforts have been made to collect more accurate information through linkage with the Indian Health Service records, available statistics probably do not represent the true cancer burden in this population.

Note: It is important to recognize that although cancer data in the US are primarily reported for broad racial and ethnic minority groups, these populations are not homogenous. There are significant variations in the cancer burden within each racial/ ethnic group. For example, among Asian Americans, incidence rates for cervical cancer are almost three times as high in Vietnamese women as in Chinese and Japanese women, partly because the Vietnamese, in general, immigrated more recently, are poorer, and have less access to cervical cancer screening.

#### **Geographic Variability**

Cancer rates in the US vary widely by geographic area. The figure on page 45 depicts geographic variability in lung cancer mortality by state and sex in the US. Among both men and women, lung cancer death rates are more than 3-fold higher in Kentucky (103 and 56 per 100,000 in men and women, respectively), the state

with the highest rates, than in Utah (30 and 17 per 100,000 in men and women, respectively), which has the lowest rates. These differences reflect the large and continuing differences in smoking prevalence among states, which is influenced to some extent by state tobacco control legislative policies. Geographic variations also reflect differences in environmental exposures and socioeconomic factors in population demographics. For more information about cancer disparities, see Cancer Facts & Figures 2011, Special Section, available online at cancer.org.

#### **Public Policy**

The American Cancer Society and the American Cancer Society Cancer Action Network<sup>SM</sup> (ACS CAN), the Society's nonprofit, nonpartisan advocacy affiliate, are dedicated to reducing cancer incidence and mortality rates among minority and medically underserved populations. This goal can be achieved by instituting effective policies and public health programs that promote overall wellness and help save lives. Listed below are some of the efforts at both the state and federal levels that the Society and ACS CAN have been involved with in the past few years:

- · Patient Protection and Affordable Care Act. The Society and ACS CAN are working to ensure that key provisions of the Affordable Care Act (ACA) that benefit cancer patients and survivors are implemented as strongly as possible and are adequately funded. Some of the law's provisions that will directly help address disparities include:
  - · Improving the affordability of coverage by increasing insurance subsidies and eliminating arbitrary annual and lifetime caps on coverage for all insurance plans so that families affected by cancer will face fewer financial barriers
  - · Focusing on prevention and early detection by requiring all new insurance plans to provide coverage for essential, evidence-based preventive measures with no additional copays. As of January 2011, preventive services like colonoscopies were exempt from copayments and deductibles under the Medicare program.
  - · Eliminating discrimination based on health status and preexisting conditions, which has been so detrimental to cancer patients over the years
  - · Increasing funding for community health centers, which provide comprehensive health care for everyone, regardless of the ability to pay
  - · Requiring qualified health plans to provide materials in appropriate languages

ACS CAN will continue to look for ways to strengthen the legislation throughout the implementation process both at the federal and state level.

- · National Breast and Cervical Cancer Early Detection Program. A high priority for the Society and ACS CAN at both the state and federal level is fighting to increase funding for the National Breast and Cervical Cancer Early Detection Program (NBCCEDP). This successful program, which began in 1991, provides community-based breast and cervical cancer screening to low-income, uninsured, and underinsured women, more than 50% of whom are from racial/ethnic minority groups. Due to a large cut in funding, screening rates within the program greatly declined in 2007; rates have been increasing slowly since, but still have not fully recovered. ACS CAN is asking Congress to increase funding to \$275 million for fiscal year 2013 to support continued growth and to give women access to lifesaving screening services. While the Affordable Care Act will greatly improve access to screening, the NBCCEDP will remain an essential program for improving breast and cervical cancer screening and treatment in our nation's most vulnerable populations. It will be critical to use the program's infrastructure and communityoutreach specialists to help women receive the lifesaving services they need.
- Colorectal Cancer Prevention, Early Detection, and Treatment Act. The Society and ACS CAN are advocating for the Colorectal Cancer Prevention, Early Detection, and Treatment Act, a national screening, treatment, and outreach program focused on increasing colorectal cancer screening rates in low-income, medically underserved populations.
- Patient Navigation. Patient navigation demonstration
  programs have shown navigation to be an important aspect
  of improving satisfaction and care among cancer patients,
  especially those in medically underserved and minority
  populations. In order to increase patient navigation services,
  ACS CAN is looking to expand the reach of patient navigators
  through the implementation of the Affordable Care Act.

The Society and ACS CAN also are leading efforts to increase federal investment in cutting-edge biomedical and cancer research and treatments, and ways to expand access to them.

To learn more, to get involved, and to make a difference in the fight against cancer, visit cancer.org/involved/advocate.

## Nutrition and Physical Activity

It's been estimated that approximately one-third of the cancer deaths that occur in the US each year are due to poor nutrition, physical inactivity, and excess weight. Maintaining a healthy body weight, being physically active on a regular basis, and eating a healthy diet are as important as not using tobacco products in reducing cancer risk. The American Cancer Society's nutrition and physical activity guidelines emphasize the importance of weight control, physical activity, dietary patterns, and limited, if any, alcohol consumption in reducing cancer risk and helping people stay well; unfortunately, the majority of Americans are not meeting these recommendations. Increasing trends in unhealthy eating and physical inactivity - and resultant increases in overweight and obesity - have largely been influenced by the environments in which people live, learn, work, and play. As a result, the guidelines include an explicit Recommendation for Community Action to promote the availability of healthy food choices and opportunities for physical activity in communities, schools, and workplaces.

The following recommendations reflect the best nutrition and physical activity evidence available to help Americans reduce their risk of cancer, as well as lower their risk of heart disease and diabetes.

#### Recommendations for Individual Choices

#### 1. Achieve and maintain a healthy weight throughout life.

- Be as lean as possible throughout life without being underweight.
- Avoid excess weight gain at all ages. For those who are currently overweight or obese, losing even a small amount of weight has health benefits and is a good place to start.
- Engage in regular physical activity and limit consumption of high-calorie foods and beverages as key strategies for maintaining a healthy weight.

In the United States, it has been estimated that overweight and obesity contribute to 14% to 20% of all cancer-related mortality. Overweight and obesity are clearly associated with increased risk for developing many cancers, including cancers of the breast in postmenopausal women, colon and rectum, endometrium, adenocarcinoma of the esophagus, kidney, and pancreas. Overweight and obesity may also be associated with increased risk of cancers of the liver, non-Hodgkin lymphoma, multiple myeloma, cervix, ovary, and aggressive prostate cancer, and obesity also likely increases the risk of cancer of the gallbladder. In addition, abdominal fatness is convincingly associated with colorectal cancer, and probably related to higher risk of pancreatic, endometrial, and postmenopausal breast cancers.

Increasing evidence also suggests that being overweight increases the risk for cancer recurrence and decreases the likelihood of survival for many cancers. Some studies have shown that surgery to treat morbid obesity reduces mortality from major chronic diseases, including cancer. Although knowledge about the relationship between weight loss and cancer risk is incomplete, individuals who are overweight should be encouraged and supported in their efforts to reduce weight.

At the same time that evidence connecting excess weight to increased cancer risk has been accumulating, trends in overweight and obesity have been increasing dramatically. The prevalence of obesity in the US more than doubled between 1976-1980 and 2003-2006. Although rates appear to have stabilized in the most recent time period (2007-2008), more than one-third of adults – more than 72 million people – are currently obese. More than likely, these trends are already impacting cancer trends: in the midpoint assessment of its 2015 Challenge Goals, American Cancer Society researchers reported that while the incidence of both colorectal cancer and postmenopausal breast cancer had been declining, it is likely that the declines in both would have started earlier and would have been steeper had it not been for the increasing prevalence of obesity.

Similar to adults, obesity among adolescents has tripled over the past several decades. Increases occurred across race, ethnicity, and gender. As in adults, obesity prevalence stabilized between 2003-2006 and 2007-2008. Because overweight in youth tends to continue throughout life, efforts to establish healthy body weight patterns should begin in childhood. The increasing prevalence of overweight and obesity in preadolescents and adolescents may increase incidence of cancer in the future.

#### 2. Adopt a physically active lifestyle.

- Adults should engage in at least 150 minutes of moderateintensity or 75 minutes of vigorous-intensity activity each week, or an equivalent combination, preferably spread throughout the week.
- Children and adolescents should engage in at least 1 hour of moderate- or vigorous- intensity activity each day, with vigorous-intensity activity at least three days each week.
- Limit sedentary behavior such as sitting, lying down, and watching television and other forms of screen-based entertainment.
- Doing any intentional physical activity above usual activities, even if currently inactive, can have many health benefits.

Living a physically active lifestyle is important to reduce the risk of a variety of types of cancer, as well as heart disease and diabetes. Scientific evidence indicates that physical activity may reduce the risk of several types of cancer, including cancers of the breast, colon, and endometrium, as well as advanced prostate cancer. Physical activity also indirectly reduces the risk of

developing the many types of obesity-related cancers because of its role in helping to maintain a healthy weight. Being active is thought to reduce cancer risk largely by improving energy metabolism and reducing circulating concentrations of estrogen, insulin, and insulin-like growth factors. Physical activity also improves the quality of life of cancer patients and is associated with a reduction in the risk of cancer recurrences and improved overall mortality in multiple cancer survivor groups, including breast, colorectal, prostate, and ovarian cancer.

Despite the wide variety of health benefits from being active, 25% of adults report no leisure-time activity, and only 49% meet minimum recommendations for moderate activity. Similarly, only 37% of youth meet recommendations.

#### 3. Consume a healthy diet, with an emphasis on plant foods.

- · Choose foods and beverages in amounts that help achieve and maintain a healthy weight.
- Limit consumption of processed meat and red meat.
- · Eat at least two and a half or more cups of vegetables and fruits each day.
- · Choose whole grains instead of refined grain products.

There is strong scientific evidence that healthy dietary patterns, in combination with regular physical activity, are needed to maintain a healthy body weight and to reduce cancer risk. Studies have shown that individuals who eat more processed and red meat, potatoes, refined grains, and sugar-sweetened beverages and foods are at a higher risk of developing or dying from a variety of cancers, and that consuming a diet that contains a variety of fruits and vegetables, whole grains, and fish or poultry and fewer red and processed meats is associated with lower risk. A recent study found that greater adherence to the American Cancer Society nutrition and physical activity guidelines was associated with lower mortality rates for all causes of death combined, and for cancer and cardiovascular diseases, specifically. Despite the known benefits of a healthy diet, Americans are not following those recommendations. According to the US Department of Agriculture, the majority of Americans would need to substantially lower their intake of added sugars, added fats, refined grains, and sodium, and increase their consumption of fruits, vegetables, whole grains, and low-fat dairy products in order to meet the 2010 Dietary Guidelines for Americans.

Currrently, the overall evidence related to dietary supplements does not support their use in cancer prevention. The results of recently completed randomized clinical trials of antioxidant supplements and selenium showed no reduction in risk for cancer, at least in generally well-nourished populations.

The scientific study of nutrition and cancer is highly complex, and many important questions remain unanswered. It is not presently clear how single nutrients, combinations of nutrients, over-nutrition, and energy imbalance, or the amount and distribution of body fat at particular stages of life affect a person's risk of specific cancers. Until more is known about the specific components of diet that influence cancer risk, the best advice is to consume a mostly plant-based diet that limits red and processed meats and emphasizes a variety of vegetables, fruits, and whole grains. A special emphasis should be placed on controlling total caloric intake to help achieve and maintain a healthy weight.

#### 4. If you drink alcoholic beverages, limit consumption.

People who drink alcohol should limit their intake to no more than two drinks per day for men and one drink per day for women. Alcohol consumption is an established cause of cancers of the mouth, pharynx, larynx, esophagus, liver, colorectum, and breast. For each of these cancers, risk increases substantially with the intake of more than two drinks per day. Even a few drinks per week may be associated with a slightly increased risk of breast cancer in women. The mechanism for how alcohol can affect breast cancer is not known with certainty, but it may be due to alcohol-induced increases in circulating estrogen or other hormones in the blood, reduction of folic acid levels, or a direct effect of alcohol or its metabolites on breast tissue. Alcohol consumption combined with tobacco use increases the risk of cancers of the mouth, larynx, and esophagus far more than either drinking or smoking alone.

#### The American Cancer Society's Recommendation for Community Action

While many Americans would like to adopt a healthy lifestyle, many encounter substantial barriers to consuming healthy food and engaging in physical activity. Increased portion sizes, especially of restaurant meals; marketing and advertising of foods and beverages high in calories, fat, and added sugar, particularly to kids; schools and worksites that are not conducive to good health; community design that hinders physical activity; economic and time constraints, as well as other influences, have collectively contributed to increasing trends in obesity.

The Society's nutrition and physical activity guidelines include a Recommendation for Community Action because of the tremendous influence that the surrounding environment has on individual food and activity choices. Acknowledging that turning obesity trends around will require extensive policy and environmental changes, the Society calls for public, private, and community organizations to create social and physical environments that support the adoption and maintenance of healthy nutrition and physical activity behaviors to help people stay well. This includes implementing strategies that increase access to affordable, healthy foods in communities, worksites, and schools; that decrease access to and marketing of foods and beverages of low nutritional value, particularly to youth; and that provide safe, enjoyable, and accessible environments for physical activity in worksites and schools, and for transportation and recreation in communities.

Achieving this Recommendation for Community Action will require multiple strategies and bold action, ranging from the implementation of community and workplace health promotion programs to policies that affect community planning, transportation, school-based physical education, and food services. The Centers for Disease Control and Prevention (CDC), the Institute of Medicine, the World Health Organization (WHO), and others have outlined a variety of evidenced-based approaches in communities, worksites, and schools to halt and ultimately turn around the obesity trends. Following are some specific approaches that are currently under way:

- · Limit the availability, advertising, and marketing of foods and beverages of low nutritional value, particularly in schools.
- · Strengthen nutrition standards in schools for foods and beverages served as part of the school meals program and for competitive foods and beverages served outside of the program.
- Increase and enforce physical education requirements in grades K-12.
- · Ensure that worksites have healthy food and beverage options and that physical environments are designed or adapted and maintained to facilitate physical activity and weight control.
- · Provide calorie information on chain restaurant menus.
- · Invest in community design that supports development of sidewalks, bike lanes, and access to parks and green space.

The tobacco control experience has shown that policy and environmental changes at the national, state, and local levels are critical to achieving changes in individual behavior. Measures such as clean indoor air laws and increases in cigarette excise taxes are highly effective in deterring tobacco use. To avert an epidemic of obesity-related disease, similar purposeful changes in public policy and in the community environment will be required to help individuals maintain a healthy body weight and remain physically active.

## **Environmental Cancer Risks**

Two major classes of factors influence the incidence of cancer: hereditary factors and acquired (environmental) factors. Hereditary factors come from our parents and cannot be modified. Environmental factors, which include behavioral choices, are potentially modifiable. These include tobacco use, poor nutrition, physical inactivity, obesity, certain infectious agents, certain medical treatments, excessive sun exposure, and exposures to carcinogens (cancer-causing agents) that exist as pollutants in our air, food, water, and soil. Some carcinogens occur naturally, and some are created or concentrated by human activity. For example, radon is a naturally occurring carcinogen present in soil and rock; however, occupational radon exposure occurs in underground mines, and substantial exposures also occur in poorly ventilated basements in regions where radon soil emissions are high.

Environmental factors (as opposed to hereditary factors) account for an estimated 75%-80% of cancer cases and deaths in the US. Exposure to carcinogenic agents in occupational, community, and other settings is thought to account for a relatively small percentage of cancer deaths - about 4% from occupational exposures and 2% from environmental pollutants (man-made and naturally occurring). Although the estimated percentage of cancers related to occupational and environmental carcinogens is small compared to the cancer burden from tobacco smoking (30%) and the combination of poor nutrition, physical inactivity, and obesity (35%), the relationship between such agents and cancer is important for several reasons. First, even a small percentage of cancers can represent many deaths: 6% of cancer deaths in the US in 2011 correspond to approximately 34,320 deaths. Second, the burden of exposure to occupational and environmental carcinogens is borne disproportionately by lowerincome workers and communities, contributing to disparities in the cancer burden across the US population. Third, although much is known about the relationship between occupational and environmental exposure and cancer, some important research questions remain. These include the role of exposures to certain classes of chemicals (such as hormonally active agents) during critical periods of human development and the potential for pollutants to interact with each other, as well as with genetic and acquired factors.

#### **How Environmental Carcinogens Are Identified**

The term carcinogen refers to exposures that can increase the incidence of malignant tumors (cancer). The term can apply to a single chemical such as benzene; fibrous minerals such as asbestos; metals and physical agents such as x-rays or ultraviolet light;

or exposures linked to specific occupations or industries (e.g., nickel refining). Carcinogens are usually identified on the basis of epidemiological studies or by testing in animals. Studies of occupational groups (cohorts) have played an important role in understanding many chemical carcinogens - as well as radiation - because exposures are often higher among workers, who can be followed for long periods of time. Some information has also come from studies of persons exposed to carcinogens during medical treatments (such as radiation and estrogen), as well as from studies conducted among individuals who experienced high levels of short-term exposure to a chemical or physical agent due to an accidental or intentional release (such as survivors of the atomic bomb explosions of Hiroshima and Nagasaki). It is more difficult to study the relationship between exposure to potentially carcinogenic substances and cancer risk in the general population because of uncertainties about exposure and the challenge of long-term follow up. Moreover, relying upon epidemiological information to determine cancer risk does not fulfill the public health goal of prevention since by the time the increased risk is detected, a large number of people may have been exposed.

Thus, for the past 40 years, the US and many other countries have developed methods for identifying carcinogens through animal testing using the "gold standard" of a 2-year or lifetime bioassay in rodents. This test is expensive and time-consuming, but it can provide information about potential carcinogens so that human exposure can be reduced or eliminated. Many substances that are carcinogenic in rodent bioassays have not been adequately studied in humans, usually because an acceptable study population has not been identified. Among the substances that have proven carcinogenic in humans, all have shown positive results in animals when tested in well-conducted 2-year bioassays.1 Between 25%-30% of established human carcinogens were first identified through animal bioassays. Since animal tests necessarily use high-dose exposures, human risk assessment usually requires extrapolation of the exposure-response relationship observed in rodent bioassays to predict effects in humans at lower doses. Typically, regulatory agencies in the US and abroad have adopted the default assumption that no threshold level (level below which there is no increase in risk) of exposure exists for carcinogenesis.

#### **Evaluation of Carcinogens**

The National Toxicology Program (NTP) plays an important role in the identification and evaluation of carcinogens in the US, and the International Agency for Research on Cancer (IARC) plays a similar role internationally. The NTP was established in 1978 to coordinate toxicology testing programs within the federal government, including tests for carcinogenicity. The NTP is also responsible for producing the Report on Carcinogens, an informational scientific and public health document that identifies agents, substances, mixtures, or exposure circumstances that may increase the risk of developing cancer.2 There are currently 107 agents classified by IARC as Group 1, i.e., carcinogenic to humans. For a list of substances included in the 11th Report on Carcinogens as known or reasonably anticipated to be human carcinogens, see ntp.niehs.nih.gov/ntp/roc/tocl1.html. The IARC is a branch of the World Health Organization that regularly convenes scientific consensus groups to evaluate potential carcinogens. After reviewing published data from laboratory, animal, and human research, these committees reach consensus about whether the evidence should be designated "sufficient," "limited," or "inadequate" to conclude that the substance is a carcinogen. For a list of substances that have been reviewed by the IARC monograph program, visit monographs.iarc.fr/ENG/ Classification/index.pdf. The American Cancer Society does not have a formal program to systematically review and evaluate carcinogens. However, information on selected topics can be found at cancer.org.

Although the relatively small risks associated with low-level exposure to carcinogens in air, food, or water are difficult to detect in epidemiological studies, scientific and regulatory bodies worldwide have accepted the principle that it is reasonable and prudent to reduce human exposure to substances shown to be carcinogenic at higher levels of exposure. Although much public concern about the influence of manmade pesticides and industrial chemicals has focused on cancer, pollution may adversely affect the health of humans and ecosystems in many other ways. Research to understand the short- and long-term impact of environmental pollutants on a broad range of outcomes, as well as regulatory actions to reduce exposure to recognized hazards, has contributed to the protection of the public and the preservation of the environment for future generations. It is important that this progress be recognized and sustained. For more information on environmental cancer risks, see the article published by Fontham et al. in CA: A Cancer Journal for Clinicians.3

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# The Global Fight against Cancer

The ultimate mission of the American Cancer Society is to eliminate cancer as a major health problem. Because cancer knows no boundaries, this mission extends around the world.

Cancer is an enormous global health burden, touching every region and socioeconomic level. Today, cancer accounts for one in every eight deaths worldwide - more than HIV/AIDS, tuberculosis, and malaria combined. In 2008, there were an estimated 12.7 million cases of cancer diagnosed and 7.6 million deaths from cancer around the world. More than 60 percent of all cancer deaths occur in low- and middle-income countries, many of which lack the medical resources and health systems to support the disease burden. Moreover, the global cancer burden is growing at an alarming pace; in 2030 alone, about 21.4 million new cancer cases and 13.2 million cancer deaths are expected to occur, simply due to the growth and aging of the population. The future burden may be further increased by the adoption of behaviors and lifestyles associated with economic development and urbanization (e.g., smoking, poor diet, physical inactivity, and reproductive patterns) in low- and middle-income countries.

Tobacco use is the most preventable cause of death worldwide, and is responsible for the deaths of approximately half of long-term users. Tobacco use killed 100 million people in the 20th century and will kill 1 billion people in the 21st century if current trends continue. Each year, tobacco use is responsible for approximately 5 million premature deaths, and by 2030 this number is expected to increase to 8 million, 70% of whom will reside in low- and middle-income countries.

With nearly a century of experience in cancer control, the American Cancer Society is uniquely positioned to help in leading the global fight against cancer and tobacco, assisting and empowering the world's cancer societies and anti-tobacco advocates. The Society's Global Health and Intramural Research departments are raising awareness about the growing global cancer burden and promoting evidence-based cancer and tobacco control programs.

The American Cancer Society has established three integrated goals to reduce the global burden of cancer:

• Make cancer control a political and public health priority. According to the World Health Organization, noncommunicable diseases (NCDs) – such as cancer, heart disease and diabetes – claim more lives each year and account for about 60% of the world's deaths. About 28 million (80%) of the people who die live in low- and middle-income countries, yet less than 1% of private and public funding for health is allocated to preventing and controlling cancer in these areas. The Society has become actively involved in working with

- global partners, including the Union for International Cancer Control (UICC), the International Diabetes Federation, the World Heart Federation, Livestrong Foundation, and others to prioritize cancer and NCDs on the global health agenda.
- Saharan Africa. Through a \$7 million (US) grant received from the Bill & Melinda Gates Foundation in 2010, the Society and its partners, including the Africa Tobacco Control Regional Initiative, the Africa Tobacco Control Alliance, the Framework Convention Alliance, the Campaign for Tobacco-Free Kids, and the International Union Against Tuberculosis and Lung Disease, support and assist national governments and civil societies in Africa to implement tobacco control policies such as advertising bans, tobacco tax increases, graphic warning labels, and the promotion of smoke-free environments. The partners on this project actively advocate for further tobacco control resources in sub-Saharan Africa and help establish mechanisms to protect existing laws from tobacco industry efforts to overturn them.
- Increase awareness about the burden of cancer and its leading risk factor, tobacco use. The Society continues to work with global partners to increase awareness about the growing global cancer and tobacco burdens and their impact on low- and middle-income countries. In addition to print publications, the American Cancer Society provides cancer information to millions of individuals throughout the world on its Web site, cancer.org. More than 20% of the visitors to the Web site come from outside the US. Information is currently available in English, Spanish, Mandarin, and several other Asian languages, with plans to include more languages in the near future. For more information on the global cancer burden, visit the Society's Global Health program Web site at cancer.org/international and see the following intramural research program publications available on cancer.org:
  - · Global Cancer Facts & Figures 2nd Edition
  - · The Tobacco Atlas, Third Edition
  - · The Cancer Atlas

# The American Cancer Society

In 1913, 10 physicians and five laypeople founded the American Society for the Control of Cancer. Its purpose was to raise awareness about cancer symptoms, treatment, and prevention; to investigate what causes cancer; and to compile cancer statistics. Later renamed the American Cancer Society, Inc., the organization now works with its more than 3 million volunteers to save lives and create a world with less cancer and more birthdays by helping people stay well, helping people get well, by working to find cures, and by fighting back against the disease. By working relentlessly to bring cancer under control, the Society is making remarkable progress in cancer prevention, early detection, treatment, and patient quality of life. The overall cancer death rate has steadily declined since the early 1990s, and the 5-year survival rate is now 67%, up from 49% in the 1970s. Thanks to this progress, nearly 12 million cancer survivors in the US will celebrate another birthday this year.

#### How the American Cancer Society Is Organized

The American Cancer Society consists of a National Home Office with 12 chartered Divisions and a local presence in nearly every community nationwide.

#### The National American Cancer Society

A National Assembly of volunteer representatives from each of the American Cancer Society's 12 Divisions elects a national volunteer Board of Directors and the nominating committee. In addition, the Assembly approves corporate bylaw changes and the organization's division of funds policy. The Board of Directors sets and approves strategic goals for the Society, ensures management accountability, approves Division charters and charter requirements, and provides stewardship of donated funds. The National Home Office is responsible for overall planning and coordination of the Society's programs, provides technical support and materials to Divisions and local offices, and administers the Society's research program.

#### American Cancer Society Divisions

The Society's 12 Divisions are responsible for program delivery and fundraising in their regions. They are governed by Division Boards of Directors composed of both medical and lay volunteers in their regions.

#### Local Offices

The Society has a presence in nearly every community nationwide, with local offices responsible for raising funds at the community level and delivering programs that help people stay well and get

well from cancer, as well as rally communities to fight back against the disease.

#### Volunteers

More than 3 million volunteers carry out the Society's work in communities across the country. These dedicated people donate their time and talents in many ways to help bring cancer under control as early as possible. Some volunteers choose to educate people about things they can do to prevent cancer or find it early to stay well. Some choose to offer direct support to patients, like driving them to treatment or providing guidance and emotional support. Others work to make cancer a top priority for lawmakers and participate in local community events to raise funds and awareness to fight cancer. No matter how volunteers choose to fight back, they are all saving lives while fulfilling their own.

#### **How the American Cancer Society Saves Lives**

The American Cancer Society is working relentlessly to saves lives from cancer by helping people stay well and get well, by finding cures, and by fighting back against the disease.

#### Helping People Stay Well

The American Cancer Society provides information that empowers people to take steps that help them prevent cancer or find it early, when it is most treatable.

#### Prevention

The Society helps people quit tobacco through the American Cancer Society Quit For Life\* Program, managed and operated by Alere Wellbeing. The two organizations have 35 years of combined experience in tobacco cessation coaching and have helped more than 1 million tobacco users.

The American Cancer Society Choose You\* movement encourages women nationwide to put their own health first in the fight against cancer. The movement challenges women to make healthier choices and supports them in their commitment to eat right, get active, quit smoking, and get regular health checks.

The Society offers many programs to companies to help their employees stay well and reduce their cancer risk, too. These include FreshStart\*, a group-based tobacco cessation counseling program designed to help employees plan a successful quit attempt by providing essential information, skills for coping with cravings, and group support; content subscription service, a free electronic tool kit subscription offered by the Society to employers that support the health and wellness needs of employees with information about cancer prevention and early detection, and support services and resources for those facing cancer; Healthy Living, a monthly electronic newsletter produced by the American Cancer Society that teaches the importance of making healthy lifestyle choices; the American Cancer Society Workplace Solutions Assessment, which surveys a company's health and

wellness policies and practices and recommends evidence-based strategies that help improve employee health behaviors, control health care costs, and increase productivity; and Active For Life<sup>SM</sup>, a 10-week online program that uses individual and group strategies to help employees become more physically active.

Across the nation, the Society works with its nonprofit, nonpartisan advocacy affiliate, the American Cancer Society Cancer Action Network<sup>SM</sup> (ACS CAN), to create healthier communities by protecting people from the dangers of secondhand smoke so they can stay well. As of July 1, 2011, 48% of the US population was covered by comprehensive smoke-free workplace, restaurant, and bar laws, and 80% was covered by a smoke-free law in one or more or these categories. In 2009, the Family Smoking Prevention and Tobacco Control Act was signed into law. A decade in the making, the law, grants the US Food and Drug Administration the authority to regulate the manufacturing, selling, and marketing of tobacco products. Strong implementation of the law is vital to reducing death and disease from tobacco products.

For the majority of Americans who do not smoke, the most important ways to reduce cancer risk are to maintain a healthy weight, be physically active on a regular basis, and eat a mostly plant-based diet, consisting of a variety of vegetables and fruit, whole grains, and limited amounts of red and processed meats. The Society publishes guidelines on nutrition and physical activity for cancer prevention in order to review the accumulating scientific evidence on diet and cancer; to synthesize this evidence into clear, informative recommendations for the general public; to promote healthy individual behaviors, as well as environments that support healthy eating and physical activity habits; and, ultimately, to reduce cancer risk. These guidelines form the foundation for the Society's communication, worksite, school, and community strategies designed to encourage and support people in making healthy lifestyle behavior changes.

#### **Early Detection**

Finding cancer at its earliest, most treatable stage gives patients the greatest chance of survival. To help the public and health care providers make informed decisions about cancer screening, the American Cancer Society publishes a variety of early detection guidelines. These guidelines are assessed regularly to ensure that recommendations are based on the most current scientific evidence.

The Society currently provides screening guidelines for cancers of the breast, cervix, colorectum, prostate, and endometrium, and general recommendations for a cancer-related component of a periodic checkup to examine the thyroid, mouth, skin, lymph nodes, testicles, and ovaries.

Throughout its history, the American Cancer Society has implemented a number of aggressive awareness campaigns targeting the public and health care professionals. Campaigns to increase usage of Pap testing and mammography have contributed to a

70% decrease in cervical cancer incidence rates since the introduction of the Pap test in the 1950s and a steady decline in breast cancer mortality rates since 1990. More recently, the Society launched ambitious multimedia campaigns to encourage adults 50 years of age and older to get tested for colorectal cancer. The Society also continues to encourage the early detection of breast cancer through public awareness and other efforts targeting poor and underserved communities.

#### Helping People Get Well

For the 1.6 million cancer patients diagnosed this year and nearly 12 million US cancer survivors, the American Cancer Society is available anytime, day and night, to offer free information, programs, services, and community referrals to patients, survivors, and caregivers to help them make decisions through every step of a cancer experience. These resources are designed to help people facing cancer on their journey to getting well.

#### Information, 24 Hours a Day, Seven Days a Week

The American Cancer Society is available 24 hours a day, seven days a week online at cancer.org and by calling 1-800-227-2345. Callers are connected with a Cancer Information Specialist who can help them locate a hospital, understand cancer and treatment options, learn what to expect and how to plan, help address insurance concerns, find financial resources, find a local support group, and more. The Society can also help people who speak languages other than English or Spanish find the assistance they need, offering services in 170 languages in total.

Information on every aspect of the cancer experience, from prevention to survivorship, is also available through the Society's Web site, cancer.org. The site includes an interactive cancer resource center containing in-depth information on every major cancer type.

The Society also publishes a wide variety of pamphlets and books that cover a multitude of topics, from patient education, qualityof-life, and caregiving issues to healthy living. A complete list of Society books is available for order at cancer.org/bookstore.

The Society publishes a variety of information sources for health care providers, including three clinical journals: Cancer, Cancer Cytopathology, and CA: A Cancer Journal for Clinicians. More information about free subscriptions and online access to CA and Cancer Cytopathology articles is available at cancer.org/ journals. The American Cancer Society also collaborates with numerous community groups, nationwide health organizations, and large employers to deliver health information and encourage Americans to adopt healthy lifestyle habits through the Society's science-based worksite programs.

#### Day-to-day Help and Emotional Support

The American Cancer Society can help cancer patients and their families find the resources they need to make decisions about the

day-to-day challenges that can come from a cancer diagnosis, such as transportation to and from treatment, financial and insurance needs, and lodging when having to travel away from home for treatment. The Society also connects people with others who have been through similar experiences to offer emotional support.

Help with the health care system: Learning how to navigate the cancer journey and the health care system can be overwhelming for anyone, but it is particularly difficult for those who are medically underserved, those who experience language or health literacy barriers, or those with limited resources. The American Cancer Society Patient Navigator Program was designed to reach those most in need. As the largest oncologyfocused patient navigator program in the country, the Society has specially trained patient navigators at 135 cancer treatment facilities across the nation. Patient navigators work in cooperation with patients, family members, caregivers, and these facilities' staff to connect patients with information, resources, and support to decrease barriers and ultimately to improve health outcomes. In 2010, more than 83,000 people relied on the Patient Navigator Program to help them through their diagnosis and treatment. The Society collaborates with a variety of organizations, including the National Cancer Institute's Center to Reduce Cancer Health Disparities, the Center for Medicare and Medicaid Services, numerous cancer treatment centers, and others to implement and evaluate this program.

Transportation to treatment: Cancer patients cite transportation to and from treatment as a critical need, second only to direct financial assistance. The American Cancer Society Road To Recovery program matches these patients with specially trained volunteer drivers. This program offers patients an additional key benefit of companionship and moral support during the drive to medical appointments. The Society's transportation grants program allows hospitals and community organizations to apply for resources to administer their own transportation programs. In some areas, primarily where transportation assistance programs are difficult to sustain, the Society helps patients or their drivers via prepaid gas cards to help defray costs associated with transportation to treatment. In 2010, the American Cancer Society provided more than 1.3 million transportation services to more than 63,000 cancer patients. Our service requests for transportation assistance increased by 11% in 2010 over the previous year, and the number of rides that we provided in 2010 increased by 35%.

Lodging during treatment: When someone diagnosed with cancer must travel away from home for the best treatment, where to stay and how to afford accommodations are immediate concerns and can sometimes affect treatment decisions. American Cancer Society Hope Lodge® facilities provide free, homelike, temporary lodging for patients and their caregivers close to treatment centers, thereby easing the emotional and financial burden of finding affordable lodging. In 2010, the 31 Hope Lodge locations provided 240,000 nights of free lodging to more than 32,000 patients and caregivers - saving them \$23 million in lodging expenses.

Breast cancer support: Breast cancer survivors provide one-onone support, information, and inspiration to help people facing the disease cope with breast cancer through the American Cancer Society Reach To Recovery® program. Volunteer survivors are trained to respond in person or by telephone to people facing breast cancer diagnosis, treatment, recurrence, or recovery.

Prostate cancer support: Men facing prostate cancer can find one-on-one or group support through the American Cancer Society Man To Man\* program. The program also offers men the opportunity to educate their communities about prostate cancer and to advocate with lawmakers for stronger research and treatment policies.

Cancer education classes: People with cancer and their caregivers need help coping with the challenges of living with the disease. Doctors, nurses, social workers, and other health care professionals provide them with that help by conducting the American Cancer Society I Can Cope® educational classes to guide patients and their families through their cancer journey.

Hair-loss and mastectomy products: Some women wear wigs, hats, breast forms, and bras to help cope with the effects of mastectomy and hair loss. The American Cancer Society "tlc" Tender Loving Care\*, which is a magazine and catalog in one, offers helpful articles and a line of products to help women battling cancer restore their appearance and dignity at a difficult time. All proceeds from product sales go back into the Society's programs and services for patients and survivors.

Help with appearance-related side effects of treatment: When women are in active cancer treatment, they want to look their best, and Look Good...Feel Better\* helps them do just that. The free program, which is a collaboration of the American Cancer Society, the Personal Care Products Council Foundation, and the Professional Beauty Association | National Cosmetology Association, helps women learn beauty techniques to restore their self-image and cope with appearance-related side effects of cancer treatment. Certified beauty professionals, trained as Look Good...Feel Better volunteers, provide tips on makeup, skin care, nail care, and head coverings. Additional information and materials are available for men and teens.

Finding hope and inspiration: People with cancer and their loved ones do not have to face their cancer experience alone. They can connect with others who have "been there" through the American Cancer Society Cancer Survivors Network®. The online community is a welcoming and safe place that was created by and for cancer survivors and their families.

#### **Finding Cures**

Research is at the heart of the American Cancer Society's mission. For more than 60 years, the Society has been finding answers that save lives – from changes in lifestyle to new approaches in therapies to improving cancer patients' quality-of-life. No single nongovernmental, not-for-profit organization in the US has invested more to find the causes and cures of cancer than the American Cancer Society. We relentlessly pursue the answers that help us understand how to prevent, detect, and treat all cancer types. We combine the world's best and brightest researchers with the world's largest, oldest, and most effective community-based anti-cancer organization to put answers into action.

The Society's comprehensive research program consists of extramural grants, as well as intramural programs in epidemiology, surveillance and health policy research, behavioral research, international tobacco control research, and statistics and evaluation. Intramural research programs are led by the Society's own staff scientists.

#### **Extramural Grants**

The American Cancer Society's extramural grants program supports research in a wide range of cancer-related disciplines at more than 200 US medical schools and universities. Grant applications are solicited through a nationwide competition and are subjected to a rigorous external peer-review process, ensuring that only the most promising research is funded. The Society primarily funds investigators early in their research careers, a time when they are less likely to receive funding from the federal government, thus giving the best and the brightest a chance to explore cutting-edge ideas at a time when they might not find funding elsewhere. In addition to funding research across the continuum of cancer research, from basic science to clinical and quality-of-life research, the Society also focuses on needs that are unmet by other funding organizations. For instance, for 10 years, the Society supported a targeted research program to address the causes of the higher cancer mortality in the poor and medically underserved and has recently become a priority area for funding.

To date, 46 Nobel Prize winners have received grant support from the Society early in their careers, a number unmatched in the nonprofit sector, and proof that the organization's approach to funding young researchers truly helps launch high-quality scientific careers.

#### **Intramural Research**

For more than 60 years, the Society's intramural research program has conducted and published high-quality epidemiologic research to advance understanding of the causes and prevention of cancer and monitored and disseminated surveillance information on cancer occurrence, risk factors, and screening.

#### **Epidemiology**

As a leader in cancer research, the Society's Epidemiology Research program has been conducting studies to identify factors that cause or prevent cancer since 1951. The first of these, the Hammond-Horn Study, helped to establish cigarette smoking as a cause of death from lung cancer and coronary heart disease, and also demonstrated the Society's ability to conduct very large prospective cohort studies. The Cancer Prevention Study I (CPS-I) was launched in 1959 and included more than 1 million men and women recruited by 68,000 volunteers. Results from CPS-I clearly demonstrated that the sharp increase in lung cancer death rates among US women between 1959-1972 occurred only in smokers, and was the first to show a relationship between obesity and risk of mortality.

In 1982, Cancer Prevention Study II (CPS-II) was established through the recruitment of 1.2 million men and women by 77,000 volunteers. The more than 480,000 lifelong nonsmokers in CPS-II provide the most stable estimates of lung cancer risk in the absence of active smoking. CPS-II data are used extensively by the Centers for Disease Control and Prevention (CDC) to estimate deaths attributable to smoking. The CPS-II study also made important contributions in establishing the link between obesity and cancer. A subgroup of CPS-II participants, the CPS-II Nutrition Cohort has been particularly valuable for clarifying associations between cancer risk and obesity, physical activity, diet, aspirin use, and hormone use. Blood samples from this group allow Society investigators and their collaborators at other institutions to study how genetic, hormonal, nutritional, and other blood markers are related to cancer risk and/or progression.

The Cancer Prevention Studies have resulted in more than 400 scientific publications and have provided unique contributions both within the Society and the global scientific community. In addition to key contributions to the effects of the tobacco epidemic over the past half-century, other important findings from these studies include:

- The association of obesity with increased death rates for at least 10 cancer sites, including colon and postmenopausal breast cancer
- The link between aspirin use and lower risk of colon cancer, opening the door to research on chronic inflammation and cancer
- The relationships between other potentially modifiable factors, such as physical inactivity, prolonged hormone use, and certain dietary factors, with cancer risk
- The association between air pollution, especially small particulates and ozone, with increased death rates from heart and lung conditions, which helped to motivate the Environmental Protection Agency to propose more stringent limits on air pollution

While landmark findings from the CPS-II Nutrition Cohort have informed multiple areas of public health policy and clinical practice, the cohort is aging. A new cohort is needed to explore the effects of changing exposures and to provide greater opportunity to integrate biological measurements into studies of genetic and environmental risk factors. In 2006, Society epidemiologists began the enrollment of a new cohort, CPS-3, with the goal of recruiting and following approximately 300,000 men and women. All participants are providing blood samples at the time of enrollment. Following on the long history of partnering with Society volunteers and supporters for establishing a cohort, the Society's community-based Relay For Life" events are the primary venues for recruiting and enrolling participants. Although similar large cohorts are being established in some European and Asian countries, there are currently no nationwide studies of this magnitude; therefore, the data collected from CPS-3 participants will provide unique opportunities for research in the US.

#### Surveillance Research

Through the Surveillance Research program, the Society disseminates the most current cancer statistics in CA: A Cancer Journal for Clinicians (caonline.amcancersoc.org), as well as a variety of Cancer Facts & Figures publications. These publications are the most widely cited sources for cancer statistics and are available in hard copy from Division offices and online through the Society's Web site at cancer.org/statistics. Society scientists also monitor trends in cancer risk factors and screening and publish these results annually – along with Society recommendations, policy initiatives, and evidence-based programs – in Cancer Prevention & Early Detection Facts & Figures. Surveillance Research also collaborates with the International Agency for Research on Cancer (IARC) to publish Global Cancer Facts & Figures, an international companion to Cancer Facts & Figures.

Since 1998, the Society has collaborated with the National Cancer Institute, the Centers for Disease Control and Prevention, the National Center for Health Statistics, and the North American Association of Central Cancer Registries to produce the Annual Report to the Nation on the Status of Cancer, a peer-reviewed journal article that reports current information related to cancer rates and trends in the US.

Epidemiologists in Surveillance Research also conduct and publish high-quality epidemiologic research in order to advance the understanding of the disease. Research topics include exploring differences in the burden of cancer by socioeconomic status in the US, describing global cancer trends, and demonstrating the association between public health interventions, such as tobacco control, and cancer incidence and mortality. Recent studies have focused on state differences in colorectal cancer mortality, temporal trends in breast cancer incidence rates, and use of sunless tanning products by adolescents in the US.

#### **Health Services Research**

Interest in developing a Health Services Research (HSR) program within the American Cancer Society National Home Office began in the late 1990s, motivated by several factors, including increasing disparities in the quality and outcomes of cancer care. These factors indicated the need to develop methods and systems to monitor quality of cancer care, as well as interventions to improve cancer care and patient outcomes, issues of great importance to Society stakeholders. The HSR program was founded in 2006, and since that time the group has developed into a highly productive multidisciplinary research team consisting of five full-time and one part-time staff members, including both clinician and non-clinician staff.

The primary objective of the HSR program is to perform high-quality, high-impact research that supports the Society's mission and program initiatives. Additional, related objectives include identifying critical gaps in evaluating and improving quality of cancer patient care, and taking leadership in policy and technical initiatives to address these gaps. The HSR program is uniquely positioned to respond rapidly to critical information needs by Society personnel, as well as national and international policy makers. The HSR program analyzes cancer treatment patterns and outcomes and has examined the role of health insurance in explaining disparities in access to care, quality of care among patients with access, and outcomes such as morbidity and mortality.

To accomplish its objectives, HSR's work has primarily involved the use of secondary data sources. The National Cancer Data Base (NCDB), jointly sponsored by the American Cancer Society and the American College of Surgeons, has been key to HSR's research on the impact of insurance on cancer status, treatments, and outcomes, as well as for broader surveillance of cancer incidence/prevalence and treatment patterns. Other databases used to support HSR's objectives include linked SEER-Medicare data, linked state registry and Medicaid enrollment data, and Medical Expenditure Panel Survey Data linked with National Health Interview Survey Data.

#### **International Tobacco Control Research**

The predecessor of the International Tobacco Control Research Program (ITCRP), the International Tobacco Surveillance unit, was created in 1998 to support collaborative international tobacco surveillance efforts involving the Society, the WHO Tobacco Free Initiative, the World Bank, and the Centers for Disease Control and Prevention's (CDC) Office of Smoking and Health. Its special publications, the *Tobacco Control Country Profiles*, 1st and 2nd editions, were distributed during the 11th and 12th World Conference on Tobacco or Health in 2000 and in 2003, respectively.

Since 2006, ITCRP has begun to focus on economic research in tobacco control, taking advantage of established partnerships with numerous academic and nonprofit organizations. In addition to original research, the program helps build capacity for the collection and analysis of economic data to provide the evidence base for tobacco control in low- and middle- income countries. To that end, ITCRP received funding from the Bloomberg Global Initiative to Reduce Tobacco Use, the Bill & Melinda Gates Foundation, and a grant from the National Institutes of Health Fogarty International Center.

The most important service publication of the ITCRP is *The Tobacco Atlas*, which is produced in collaboration with the Society's Global Health department, Georgia State University, and the World Lung Foundation. *The Tobacco Atlas, Fourth Edition* will be released at the 15th World Conference on Tobacco or Health in 2012 in Singapore.

#### **Behavioral Research Center**

The American Cancer Society was one of the first organizations to recognize the importance of behavioral and psychosocial factors in the prevention and control of cancer and to fund extramural research in this area. In 1995, the Society established the Behavioral Research Center (BRC) as an intramural department. The BRC's work currently focuses on cancer survivorship, quality of life, and tobacco research. It also addresses the issues of special populations, including minorities, the poor, rural populations, and other underserved groups. The BRC's ongoing projects include:

- Studies of the quality of life of cancer survivors, which include a nationwide longitudinal study and a cross-sectional study, that explore the physical and psychosocial adjustment to cancer and identify factors affecting quality of life
- Studies to identify and prioritize gaps in information and resources for cancer survivors as they transition from active treatment back to the community care setting
- Contributions to the development of a National Cancer Survivorship Resource Center meant to advance survivorship as a distinct phase of cancer care, promote healthy behaviors to reduce late and long-term effects of cancer and its treatment, and improve surveillance and screening practices to detect the return of cancer
- Studies of family caregivers that explore the impact of the family's involvement in cancer care on the quality of life of the cancer survivor and the caregiver
- Efforts to establish and implement a process to measure the effective control of pain, other symptoms, and side effects for those who have been affected by cancer
- Studies of African American-white disparities in cancerrelated behaviors among Georgians, focusing on the role of sociocultural factors and neighborhood barriers in disparities

- in smoking, poor diet, lack of exercise, and cancer screening among a statewide sample of more than 1,000 African Americans
- Studies investigating how social, psychological, and other
  factors impact smokers' motivation and ability to quit in order
  to improve existing Society programs for smoking cessation
  (e.g., FreshStart, Great American Smokeout\*) or to develop
  new technology-based interventions for smokers who seek
  cessation assistance.

#### **Statistics and Evaluation Center**

The Statistics & Evaluation Center (SEC) provides expert statistical, survey, study design, and evaluative consultation services to the American Cancer Society National Home Office and its Divisions. The SEC has two groups – Statistics and Survey Research – that work independently or in tandem depending upon the nature of the project, the service to be rendered, or the problem to be solved. The SEC's mission is to improve the Society's programs and processes based on good science. The center always seeks to capture data systematically, and objectively deliver valid, reliable, accurate, and timely information to its stakeholders for evidence-based decision making.

SEC staff designs and conducts process and outcome evaluations of Society programs, projects, and initiatives, and conducts focus groups, structured/semi-structured interviews, and needs assessments. All evaluations are logic model driven. The SEC continues to be engaged in evaluations of the Society's national survivorship, quality-of-life, early detection, prevention, global health, and extramural grants funding programs. The center's professional staff is involved in multiple projects across the Society, where their extensive statistical, study design, survey research skills, and experience are applied to evaluation and quantitative problem solving. The results of these studies improve Society mission and income delivery.

In the past year, the SEC has worked with staff in the Society's National Home Office and Divisions on strategic planning for the next generation of the Society's services to cancer patients and caregivers. Findings from recent program evaluations play a large role in these discussions. The SEC has supported the evaluation of the Society's patient service (call) centers by the Integrated Evaluation Team and has worked with the extramural grants program to evaluate grant programs in palliative care and health services research. The SEC staff is designing and implementing projects that will facilitate evaluation of internally and externally funded programs using community health advisors and focused media events to increase cancer screening in communities that have high cancer mortality rates and screening rates that lag national averages. Statisticians in the SEC continue to work with staff in the surveillance research program and the National Cancer Institute on improving cancer mortality and incidence projection models.

#### Fighting Back

Conquering cancer is as much a matter of public policy as scientific discovery. Whether it's advocating for quality, affordable health care for all Americans, increasing funding for cancer research and programs, or enacting laws and policies that help decrease tobacco use, government action is constantly required. The American Cancer Society and its nonprofit, nonpartisan advocacy affiliate, the American Cancer Society Cancer Action Network (ACS CAN), use applied policy analysis, direct lobbying, grassroots action, and media outreach to ensure elected officials nationwide pass laws furthering the organizations' shared mission to create a world with less cancer.

Created in 2001, ACS CAN is the force behind a new movement uniting and empowering cancer patients, survivors, caregivers, and their families. ACS CAN is a community-based grassroots movement that unites cancer survivors and caregivers, volunteers and staff, health care professionals, researchers, public health organizations, and other partners. ACS CAN gives ordinary people extraordinary power to fight back against cancer. In recent years, the Society and ACS CAN have successfully partnered to pass a number of laws at the federal, state, and local levels focused on preventing cancer and detecting it early, increasing research on ways to prevent and treat cancer, improving access to lifesaving screenings and treatment, and improving quality of life for cancer patients. Some of our recent advocacy accomplishments impacting cancer patients include:

- Passage and implementation of the Affordable Care Act (ACA) of 2010, comprehensive legislation that:
  - Prohibits insurance companies from denying insurance coverage based on a preexisting conditions (children starting in 2010, adults in 2014)
- · Prohibits insurance coverage from being rescinded when a patient gets sick
- · Removes lifetime limits from all insurance plans
- · Allows children and young adults to be covered under their parents' insurance plans until they turn 26
- $\cdot\,$  Makes coverage for routine care costs available to patients who take part in clinical trials
- Establishes a National Institutes of Health Interagency
  Pain Research Advisory Committee to coordinate pain
  management research initiatives and an Institute of
  Medicine Pain Conference series that will be important
  to relieving cancer-related pain and other chronic pain
  conditions
- Establishes a National Prevention and Health Promotion Strategy; a National Prevention, Health Promotion and Public Health Council; and a Prevention and Public Health Fund with mandatory funding to prioritize, coordinate, oversee, and fund prevention-related activities nationwide

- Requires all new health insurance plans and Medicare to cover preventive services rated "A" or "B" by the US Preventive Services Task Force (USPTF) at no cost to patients (including breast, cervical, and colorectal cancer screening and smoking cessation treatment)
- Requires state Medicaid programs to provide pregnant women with tobacco cessation treatment at no cost
- Protects children and families against states rules that limit program eligibility or increase premiums or enrollment fees in Medicaid
- Provides new funding to states to make expansions or improvements to Medicaid
- · Saves states money in uncompensated care by replacing local dollars with new federal subsidies
- · Expands coverage to all low-income adults below 133% of the federal poverty level eligible for Medicaid beginning in 2014
- Prioritizes health disparities at the National Institutes of Health, establishes a network of federal-specific offices of minority health, and creates an Office of Women's Health
- Enhances data collection and reporting to ensure racial and ethnic minorities are receiving appropriate, timely, and quality health care
- Authorizes grants to help states and local jurisdictions address health workforce needs
- Secures coverage for a new annual wellness visit with a personalized prevention plan and gradually reduces out-of-pocket costs for prescription drugs for Medicare beneficiaries
- Creates incentives for health care providers to deliver more coordinated and integrated care to beneficiaries enrolled in Medicare and Medicaid
- Requires chain restaurants to provide calorie information on menus and have other nutrition information available to consumers upon request and requires chain vending machine owners or operators to display calorie information for all products available for sale

Please refer to *The Affordable Care Act How It Helps People with Cancer and their Families* for more information (http://action.acscan.org/site/DocServer/Affordable\_Care\_Act\_Through\_the\_Cancer\_Lens\_Final.pdf?docID=18421).

- Supporting legislation that focuses on preventing cancer by reducing tobacco use, obesity, and sun exposure, improving nutrition, and increasing physical activity. By successfully working with partners, the Society and ACS CAN have:
  - Empowered the FDA with authority over tobacco products, including support for new graphic warning labels to be on cigarette packs by September 2012

- · Passed comprehensive smoke-free laws in 23 states and the District of Columbia that require all workplaces, restaurants, and bars to be smoke free, covering nearly half of the US population, and defended these laws in court
- · Increased taxes on tobacco products to an average state cigarette tax of \$1.46 per pack and defended against tax rollbacks
- Continued our role as interveners in the US government's lawsuit against the tobacco industry, in which manufacturers have been convicted as racketeers for decades of fraud associated with marketing of tobacco products
- Began implementing the Healthy, Hunger-Free Kids Act of 2010, strong legislation to reauthorize the federal child nutrition programs and strengthen school nutrition. The law improves nutrition standards and increases funding for school meals, establishes nutrition standards for foods sold in schools outside of meal programs, and strengthens local wellness policies by providing resources and technical assistance for their implementation and requiring them to be publicly available and periodically reviewed.
- · Advocated for state requirements for increased, quality physical education in all schools
- · Supported the federal government's development of voluntary nutrition standards for foods marketed to children
- · Worked with state governments to implement laws prohibiting tanning bed use for everyone under the age of 18
- $\cdot$  Worked to improve access to essential cancer screening services, especially among low-income, uninsured, and underinsured populations
- · Advocated for full funding for the National Breast and Cervical Cancer Early Detection Program (NBCCEDP), which provides free breast and cervical cancer screenings and treatment to low-income, uninsured, and medically underserved women
- Advocated for legislation to create a new nationwide colorectal screening and treatment program modeled after NBCCEDP
- · Improving quality of life for cancer patients by ensuring that patients and survivors receive the best cancer care that matches treatments to patient and family goals across their life course. The Society and ACS CAN have:
  - · Advocated for balanced pain policies in multiple states and at the federal level to ensure patients and survivors have continued access to the treatments that promote better pain management and improved quality of life
  - · Passed federal legislation to promote patient- and familycentered quality cancer care, survivorship care planning, pain and symptom management, and care coordination to improve quality of life for patients, survivors, and their families

- · Advanced a new quality-of-life legislative platform to include and implement palliative care as a patient-centered and quality-of-life improvement for people facing serious illnesses such as cancer
- · Increased public awareness of the increasingly urgent cancer drug shortage problem and advocated for solutions to the complex, multiple causes of cancer drug shortages

Some efforts in the fight against cancer are more visible than others, but each successful battle is an important contribution to what will ultimately be victory over the disease. The Society, working together with ACS CAN and its grassroots movement, is making sure the voice of the cancer community is heard in the halls of government and is empowering communities everywhere to fight back.

The Society is also rallying people to fight back against the disease through our Relay For Life, Making Strides Against Breast Cancer®, DetermiNation®, and Choose You programs. The American Cancer Society Relay For Life is a life-changing event that gives everyone in communities across the globe a chance to celebrate the lives of people who have battled cancer, remember loved ones lost, and fight back against the disease, making it the world's largest movement to end cancer. At Relay events, teams of people camp out at a local high school, park, or fairground and take turns walking or running around track or path for up to 24 hours. Making Strides Against Breast Cancer events are powerful and inspiring walks that unite communities to celebrate people who have battled breast cancer, to raise awareness about the steps people can take to help prevent the disease, and to raise money to help find cures and support programs and services for people facing the disease. The DetermiNation program offers people an opportunity to do the unthinkable, achieve what seems impossible, and change the course of cancer forever. Every step participants take and every mile they conquer in a half-marathon, marathon, or triathlon is a triumph over cancer. The Choose You movement encourages women to put their own health first in the fight against cancer by challenging them to make healthier choices and supporting them in their commitment to take the necessary steps to stay well.

### **Sources of Statistics**

New cancer cases. The numbers of new US cancer cases in 2012 are projected using a two-step process. First, the total number of cases in each state is estimated using a spatiotemporal model based on incidence data from 47 states and the District of Columbia for the years 1995-2008 that met the North American Association of Central Cancer Registries' (NAACCR) high-quality data standard for incidence, which covers about 95% of the US population. This method considers geographic variations in sociodemographic and lifestyle factors, medical settings, and cancer screening behaviors as predictors of incidence, as well as accounting for expected delays in case reporting. Then, the number of new cases nationally and in each state is projected four years ahead using a temporal projection method. (For more information on the estimation of new cases, see "A" in Additional Information on page 63.)

Incidence rates. Incidence rates are defined as the number of people per 100,000 who are diagnosed with cancer during a given time period. Incidence rates in this publication are age adjusted to the 2000 US standard population to allow comparisons across populations with different age distributions. State incidence rates were published in NAACCR's publication Cancer Incidence in North America, 2004-2008. (See "B" in Additional Information, page 63, for full reference.) Trends in cancer incidence provided for selected cancer sites are based on incidence rates that have been adjusted for delays in reporting and were originally published in the Surveillance, Epidemiology, and End Results (SEER) Cancer Statistics Review (CSR) 1975-2008. (See "C" in Additional Information, page 63, for full reference). Incidence rates that are not adjusted for delays in reporting may underestimate the number of cancer cases in the most recent time period. Cancer rates most affected by reporting delays are melanoma of the skin, leukemia, and prostate because these cancers are frequently diagnosed in nonhospital settings. Cancer incidence rates by race/ethnicity were obtained from NAACCR.

Cancer deaths. The estimated numbers of US cancer deaths are calculated by fitting the numbers of cancer deaths for 1994-2008 to a statistical model that forecasts the numbers of deaths expected to occur in 2012. The estimated numbers of cancer deaths for each state are calculated similarly, using state-level data. For both US and state estimates, data on the numbers of deaths are obtained from the National Center for Health Statistics (NCHS) at the Centers for Disease Control and Prevention. (For more information on this method, see "D" in Additional Information on page 63.)

Mortality rates. Mortality rates, or death rates, are defined as the number of people per 100,000 dying of a disease during a

given year. In this publication, mortality rates are based on counts of cancer deaths compiled by NCHS and population data from the US Census Bureau. Death rates in this publication are age adjusted to the 2000 US standard population to allow comparisons across populations with different age distributions. These rates should be compared only to other statistics that are age adjusted to the US 2000 standard population. Trends in cancer mortality rates provided for selected cancer sites were first published in the CSR 1975-2008. (See "C" in Additional Information, page 63, for full reference.)

Important note about estimated cancer cases and deaths for the current year. The estimated numbers of new cancer cases and deaths in the current year are model-based and may produce numbers that vary considerably from year to year for reasons other than changes in cancer occurrence. For this reason, the use of our estimates to track year-to-year changes in cancer occurrence or deaths is strongly discouraged. Incidence and mortality rates reported by the SEER program and NCHS are more informative statistics to use when tracking cancer incidence and mortality trends for the US. Rates from state cancer registries are useful for tracking local trends.

Survival. This report presents relative survival rates to describe cancer survival. Relative survival adjusts for normal life expectancy (and events such as death from heart disease, accidents, and diseases of old age) by comparing survival among cancer patients to that of people not diagnosed with cancer who are of the same age, race, and sex. Five-year survival statistics presented in this publication were originally published in CSR 1975-2008 and are for diagnosis years 2001 to 2007, with all patients followed through 2008. In addition to 5-year relative survival rates, 1-, 10-, and 15-year survival rates are presented for selected cancer sites. These survival statistics are generated using the National Cancer Institute's SEER 17 database and SEER\*Stat software version 7.0.4. (See "E" in Additional Information, page 63, for full references.) One-year survival rates are based on cancer patients diagnosed from 2004 and 2007, 10-year survival rates are based on diagnoses from 1995 and 2007, and 15-year survival rates are based on diagnoses from 1990 and 2007; all patients were followed through 2008.

Probability of developing cancer. Probabilities of developing cancer are calculated using DevCan (Probability of Developing Cancer) software version 6.6.0, developed by the National Cancer Institute. (See "F" in Additional Information, page 63, for full reference.) These probabilities reflect the average experience of people in the US and do not take into account individual behaviors and risk factors. For example, the estimate of 1 man in 13 developing lung cancer in a lifetime underestimates the risk for smokers and overestimates the risk for nonsmokers.

**Additional information.** More information on the methods used to generate the statistics for this report can be found in the following publications:

A. Zhu L, Pickle LW, Naishadham D, et al. Predicting US and state-level cancer counts for the current calendar year: part II – evaluation of spatio-temporal projection methods for incidence.  $\it Cancer. 2011$ ; in press.

B. Copeland G, Lake A, Firth R, et al. (eds). Cancer in North America: 2004-2008. Volume Two: Registry-specific Cancer Incidence in the United States and Canada. Springfield, IL: North American Association of Central Cancer Registries, Inc. May 2011. Available at naaccr.org/Dataand-Publications/CINAPubs.aspx.

C. Howlader N, Noone AM, Krapcho M, et al. (eds). SEER Cancer Statistics Review, 1975-2008. National Cancer Institute. Bethesda, MD, 2011. Available at seer.cancer.gov.

D. Chen HS, Portier K, Ghosh K, et al. Predicting US and State-level counts for the current calendar year: part I – evaluation of temporal projection methods for mortality. *Cancer*. 2011; in press.

E. SEER 17 database: Surveillance, Epidemiology, and End Results (SEER) Program (www.seer.cancer.gov) SEER\*Stat Database: Incidence - SEER 17 Regs Research Data + Hurricane Katrina Impacted Louisiana Cases, Nov 2010 Sub (1973-2008 varying) - Linked To County Attributes - Total U.S., 1969-2009 Counties, National Cancer Institute, DCCPS, Surveillance Research Program, Cancer Statistics Branch, released April 2011, based on the November 2010 submission.

SEER\*Stat software: Surveillance Research Program, National Cancer Institute SEER\*Stat software (www.seer.cancer.gov/seerstat) version 7.0.4.

F. DevCan: Probability of Developing or Dying of Cancer Software, Version 6.6.0; Statistical Research and Applications Branch, National Cancer Institute, 2005. http://srab.cancer.gov/devcan

## Screening Guidelines for the Early Detection of Cancer in Average-risk Asymptomatic People

Cancer Site	Population	Test or Procedure	Frequency
Breast	Women, age 20+	Breast self-examination (BSE)	It is acceptable for women to choose not to do BSE or to do BSE regularly (monthly) or irregularly. Beginning in their early 20s, women should be told about the benefits and limitations of breast self-examination (BSE). Whether a woman ever performs BSE, the importance of prompt reporting of any new breast symptoms to a health professional should be emphasized. Women who choose to do BSE should receive instruction and have their technique reviewed on the occasion of a periodic health examination.
		Clinical breast examination (CBE)	For women in their 20s and 30s, it is recommended that clinical breast examination (CBE) be part of a periodic health examination, preferably at least every three years. Asymptomatic women age 40 and older should continue to receive a clinical breast examination as part of a periodic health examination, preferably annually.
		Mammography	Begin annual mammography at age 40.*
Cervixt	Women, age 21+	Pap test Pap test HPV DNA test	Cervical cancer screening should begin approximately three years after a woman begins having vaginal intercourse, but no later than 21 years of age. Screening should be done every year with conventional Pap tests or every two years using liquid-based Pap tests. At or after age 30, women who have had three normal test results in a row may undergo screening every two to three years with cervical cytology (either conventional or liquid-based Pap test) alone, or every three years with an HPV DNA test plus cervical cytology. Women 70 years of age and older who have had three or more normal Pap tests and no abnormal Pap tests in the past 10 years and women who have had a total hysterectomy may choose to stop cervical cancer screening.
Colorectal Men and women, age 50+		Fecal occult blood test (FOBT) with at least 50% test sensitivity for cancer, or fecal immunochemical test (FIT) with at least 50% test sensitivity for cancer, <b>or</b>	Annual, starting at age 50. Testing at home with adherence to manufacturer's recommendation for collection techniques and number of samples is recommended. FOBT with the single stool sample collected on the clinician's a fingertip during a digital rectal examination in the health care setting is not recommended. Guaiac based toilet bowl FOBT tests also are not recommended. In comparison with guaiac-based tests for the detection of occult blood, immunochemical tests are more patient-friendly, and are likely to be equal or better in sensitivity and specificity. There is no justification for repeating FOBT in response to an initial positive finding.
		Stool DNA test, or	Interval uncertain, starting at age 50
		Flexible sigmoidoscopy (FSIG), <b>or</b>	Every 5 years, starting at age 50. FSIG can be performed alone, or consideration can be given to combining FSIG performed every 5 years with a highly sensitive gFOBT or FIT performed annually
		Double contrast barium enema (DCBE), <b>or</b>	Every 5 years, starting at age 50
		Colonoscopy	Every 10 years, starting at age 50
		CT Colonography	Every 5 years, starting at age 50
Endometrial	Women, at menopause	At the time of menopause, women at average risk should be informed about risks and symptoms of endometrial car and strongly encouraged to report any unexpected bleeding or spotting to their physicians	
Prostate	Men, ages 50+	Digital rectal examination (DRE) and prostate-specific antigen test (PSA)	Men who have at least a 10-year life expectancy should have an opportunity to make an informed decision with their health care provider about whether to be screened for prostate cancer, after receiving information about the potential benefits, risks, and uncertainties associated with prostate cancer screening. Prostate cancer screening should not occur without an informed decision- making process.
Cancer- related checkup	Men and women, age 20+	On the occasion of a periodic health examination, the cancer-related checkup should include examination for cancers of the thyroid, testicles, ovaries, lymph nodes, oral cavity, and skin, as well as health counseling about tobacco, sun exposure, diet and nutrition, risk factors, sexual practices, and environmental and occupational exposures	

<sup>\*</sup>Beginning at age 40, annual clinical breast examination should be performed prior to mammography.

Note: Screening recommendations for lung cancer will be released in 2012, please refer to cancer.org for the most current information.

<sup>†</sup>New recommendations will be released in early 2012; please refer to cancer.org for the most current guidelines.

## Screening Guidelines for the Early Detection of Cancer in Average-risk Asymptomatic People

Cancer Site	Population	Test or Procedure	Frequency	
Breast	Women, age 20+	Breast self-examination (BSE)	It is acceptable for women to choose not to do BSE or to do BSE regularly (monthly) or irregularly. Beginning in their early 20s, women should be told about the benefits and limitations of breast self-examination (BSE). Whether a woman ever performs BSE, the importance of prompt reporting of any new breast symptoms to a health professional should be emphasized. Women who choose to do BSE should receive instruction and have their technique reviewed on the occasion of a periodic health examination.	
		Clinical breast examination (CBE)	For women in their 20s and 30s, it is recommended that clinical breast examination (CBE) be part of a periodic health examination, preferably at least every three years. Asymptomatic women age 40 and older should continue to receive a clinical breast examination as part of a periodic health examination, preferably annually.	
		Mammography	Begin annual mammography at age 40.*	
Cervix†	Women, age 21+	Pap test Pap test HPV DNA test	Cervical cancer screening should begin approximately three years after a woman begins having vaginal intercourse, but no later than 21 years of age. Screening should be done every year with conventional Pap tests or every two years using liquid-based Pap tests. At or after age 30, women who have had three normal test results in a row may undergo screening every two to three years with cervical cytology (either conventional or liquid-based Pap test) alone, or every three years with an HPV DNA test plus cervical cytology. Women 70 years of age and older who have had three or more normal Pap tests and no abnormal Pap tests in the past 10 years and women who have had a total hysterectomy may choose to stop cervical cancer screening.	
Colorectal Men and women, age 50+		fecal immunochemical test	Annual, starting at age 50. Testing at home with adherence to manufacturer's recommendation for collection techniques and number of samples is recommended. FOBT with the single stool sample collected on the clinician's a fingertip during a digital rectal examination in the health care setting is not recommended. Guaiac based toilet bowl FOBT tests also are not recommended. In comparison with guaiac-based tests for the detection of occult blood, immunochemical tests are more patient-friendly, and are likely to be equal or better in sensitivity and specificity. There is no justification for repeating FOBT in response to an initial positive finding.	
		Stool DNA test, or	Interval uncertain, starting at age 50	
		Flexible sigmoidoscopy (FSIG), <b>or</b>	Every 5 years, starting at age 50. FSIG can be performed alone, or consideration can be given to combining FSIG performed every 5 years with a highly sensitive gFOBT or FIT performed annually.	
		Double contrast barium enema (DCBE), <b>or</b>	Every 5 years, starting at age 50	
		Colonoscopy	Every 10 years, starting at age 50	
		CT Colonography	Every 5 years, starting at age 50	
Endometrial	Women, at menopause		e time of menopause, women at average risk should be informed about risks and symptoms of endometrial cancer trongly encouraged to report any unexpected bleeding or spotting to their physicians	
Prostate	Men, ages 50+	Digital rectal examination (DRE) and prostate-specific antigen test (PSA)		
Cancer- related checkup	Men and women, age 20+	On the occasion of a periodic health examination, the cancer-related checkup should include examination for cancers of the thyroid, testicles, ovaries, lymph nodes, oral cavity, and skin, as well as health counseling about tobacco, sun exposure, diet and nutrition, risk factors, sexual practices, and environmental and occupational exposures.		

<sup>\*</sup>Beginning at age 40, annual clinical breast examination should be performed prior to mammography.

Note: Screening recommendations for lung cancer will be released in 2012, please refer to cancer.org for the most current information.

<sup>†</sup>New recommendations will be released in early 2012; please refer to cancer.org for the most current guidelines.

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## Attachment C: Articles Supporting Need for Proposal

#### Stereotactic body radiation therapy: The report of AAPM Task Group 101

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Task Group 101 of the AAPM has prepared this report for medical physicists, clinicians, and therapists in order to outline the best practice guidelines for the external-beam radiation therapy technique referred to as stereotactic body radiation therapy (SBRT). The task group report includes a review of the literature to identify reported clinical findings and expected outcomes for this treatment modality. Information is provided for establishing a SBRT program, including protocols, equipment, resources, and QA procedures. Additionally, suggestions for developing consistent documentation for prescribing, reporting, and recording SBRT treatment delivery is provided. © 2010 American Association of Physicists in Medicine. [DOI: 10.1118/1.3438081]

Key words: stereotactic body radiation therapy, SBRT, BED, patient safety, 4DCT, immobilization, IGRT; hypofractionation

#### **TABLE OF CONTENTS**

I. INTRODUCTION AND SCOPE	4079
II. HISTORY AND RATIONALE FOR SBRT	4079
III. CURRENT STATUS OF SBRT-PATIENT	
SELECTION CRITERIA	4080
IV. SIMULATION IMAGING AND TREATMENT	
PLANNING	4081
IV.A. Simulation imaging	4081
IV.B. Data acquisition for mobile tumors,	
patient-specific tumor-motion determination,	
and respiratory motion management	4081
IV.C. Imaging artifacts	4082
IV.D. Treatment planning	4082
IV.D.1. Dose heterogeneity, gradient and fall-off,	
and beam geometry	4083
IV.D.2. Beam selection and beam geometry	4083
IV.D.3. Calculation grid size	4083
IV.D.4. Bioeffect-based treatment planning and	
SBRT	4084
IV.D.5. Normal tissue dose tolerance	4084
IV.E. Treatment plan reporting	4085
V. PATIENT POSITIONING, IMMOBILIZATION,	
TARGET LOCALIZATION, AND DELIVERY	4085
V.A. Immobilization	4088
V.B. Image-guided localization	4088
V.C. Localization, tumor-tracking, and gating	
techniques for respiratory motion	
management	4089
V.C.1. Image-guided techniques	4089
V.C.2. Optical tracking techniques	4089
V.C.3. Respiratory gating techniques	4089
V.D. Delivery data reporting	4090
VI. SPECIAL DOSIMETRY CONSIDERATIONS	4090
VI.A. Problems associated with dosimetry of	
small/narrow field geometry	4090
VI.B. Problems associated with small-field	
heterogeneity calculations	4090
VII. CLINICAL IMPLEMENTATION OF SBRT	4091
VII.A. Establishing the scope and clinical goals of	
the SBRT program	4091
VII.A.1. Equipment considerations	4091
VII.A.2. Time and personnel considerations	4092

VII.B. Acceptance, commissioning, and quality	
assurance	4092
VII.C. Patient safety and the medical physicist	
VII.D. Quality process improvement: Vigilance in	
the error reduction process in the treatment	
planning and delivery process	4094
VIII. FUTURE DIRECTIONS	4094

#### I. INTRODUCTION AND SCOPE

Stereotactic body radiation therapy (SBRT) refers to an emerging radiotherapy procedure that is highly effective in controlling early stage primary and oligometastatic cancers at locations throughout the abdominopelvic and thoracic cavities, and at spinal and paraspinal sites. The major feature that separates SBRT from conventional radiation treatment is the delivery of large doses in a few fractions, which results in a high biological effective dose (BED). In order to minimize the normal tissue toxicity, conformation of high doses to the target and rapid fall-off doses away from the target is critical. The practice of SBRT therefore requires a high level of confidence in the accuracy of the entire treatment delivery process. In SBRT, confidence in this accuracy is accomplished by the integration of modern imaging, simulation, treatment planning, and delivery technologies into all phases of the treatment process; from treatment simulation and planning, and continuing throughout beam delivery.

In addition to these major features, there are other characteristics that distinguish SBRT from conventional radiation therapy (Table I). These include a general increase in the number of beams used for treatment, the frequent use of noncoplanar beam arrangements, small or no beam margins for penumbra, and the use of inhomogeneous dose distributions and dose-painting techniques (including IMRT). All of these technology improvements result in the highly conformal dose distribution that characterizes the SBRT technique.

#### **II. HISTORY AND RATIONALE FOR SBRT**

Over 4000 publications spanning several decades have affirmed the clinical usefulness of stereotactic radiosurgery (SRS) in the treatment of benign and malignant lesions, <sup>1-5</sup> as well as functional disorders. <sup>6,7</sup> The radiobiological rationale for SBRT is similar to that for SRS; delivering a few fractions of large dose in relatively short overall treatment time results in a more potent biological effect. <sup>8</sup> The clinical out-

TABLE I. Comparison of typical characteristics of 3D/IMRT radiotherapy and SBRT.

Characteristic	3D/IMRT	SBRT
Dose/fraction	1.8~3 Gy	6-30 Gy
No. of fractions	10-30	1-5
	CTV/PTV (gross disease+clinical extension):	GTV/CTV/ITV/PTV
Target definition	Tumor may not have a sharp boundary.	(well-defined tumors: GTV=CTV)
Margin	Centimeters	Millimeters
Physics/dosimetry monitoring	Indirect	Direct
Required setup accuracy	TG40, TG142	TG40, TG142
Primary imaging modalities used for treatment planning	(T	Multimodality: CT/MR/PET-CT
Redundancy in geometric verification	No	Yes
· ·		Strictly enforced (sufficient immobilization
Maintenance of high spatial targeting accuracy	Moderately enforced	and high frequency position monitoring
for the entire treatment	(moderate patient position control and monitoring)	through integrated image guidance)
Need for respiratory motion management	Moderate Must be at least considered	Highest
Staff training	Highest	Highest+special SBRT training
Technology implementation	Highest	Highest
Radiobiological understanding	Moderately well understood	Poorly understood
Interaction with systemic therapies	Yes	Yes

comes of SBRT for both primary and metastatic diseases compare favorably to surgery with minimal adverse effects. 9.10 In addition, the limited number of treatment fractions makes SBRT more convenient for the patient, and a potentially more cost-effective treatment modality than traditional radiation therapy.

The specific argument for the application of SBRT to grossly evident sites of metastatic disease can be constructed in accordance with several conceptual theories.

- The "patterns of failure" concept combines systemic treatment with localized radiation therapy because of the expectation that sites of gross disease contain the highest number of clonogenic cells and are thus least likely to be eliminated by chemotherapy.<sup>1,11-13</sup>
- The theory of oligometastases proposes a stage of disease that is at an intermediate point in its natural history, between completely absent and widely metastatic, and which might be cured if the limited numbers of metastatic sites are eradicated.<sup>14–20</sup>
- The Norton-Simon hypothesis suggests that the systemic burden of cancer cells increases from an initially low, undetectable level, through a phase of exponential growth, to a lethal plateau level. A local intervention such as SBRT might aid in reducing the systemic burden of the disease in a manner that could help prevent or delay as long as possible the condition of lethal tumor burden that is fatal to the patient.
- SBRT is now being explored within the broader concept of immunomodulation, whereby an effort is made to exploit the systemic antitumoral immune response generated in certain conditions of radiation-induced tumor cell death.<sup>22-25</sup>
- SBRT can offer a means of providing palliative treatment in certain settings, especially when there is a need to be particularly careful in the administration of treatment. For example, the added precision with SBRT

might be advantageous when a tumor abuts or overlaps a previously irradiated region.

Because such dose intensification can also increase the risk of normal tissue toxicities, careful dose delivery and patient selection are of paramount importance. SBRT attempts to provide a clinical advantage relative to conventional radiation therapy by reducing dose to normal tissues and critical structures, and maximizing tumor coverage through the use of accurate tumor localization, patient immobilization, specialized planning, and image guidance techniques.

Clinical patient outcomes for SBRT were first published in 1995. <sup>26</sup> In Germany, investigators initially focused on the treatment of liver and lung lesions. <sup>27–31</sup> In the United States, the first publications described the treatment of lung tumors. <sup>32,33</sup> Retrospective studies first described the safety and efficacy of SBRT for the treatment of lung and liver lesions. <sup>28,31,34–39</sup> Prospective Phase I and/or II trials were published in 2001 for the treatment of lung and, in 2003, for liver. <sup>28,30,32,33</sup> The RTOG has completed enrollment of a Phase II study of SBRT for medically inoperable primary non-small-cell lung cancer (NSCLC). Outcomes of retrospective series treating spinal lesions were first published in 2003. <sup>40–44</sup>

## III. CURRENT STATUS OF SBRT-PATIENT SELECTION CRITERIA

The majority of patients treated with SBRT are those with lung, liver, and spinal tumors. Most investigators limit eligibility to well-circumscribed tumors with a maximum cross-sectional diameter of up to 5 cm, although some centers have reported results for tumors as large as 7 cm. <sup>32</sup> <sup>34</sup> 45 <sup>47</sup> The use of SBRT as a boost in addition to regional nodal irradiation has been proposed. Even with the expectation that small volumes of adjacent organs at risk (OARs) will be irradiated during SBRT, an assessment of patient eligibility should in-

clude a careful evaluation of normal tissue function and dose distribution. Typically, pulmonary function and the volume of normal liver that is irradiated are the most immediate considerations. <sup>32,48-51</sup> Tumors proximal to mainstem bronchi, trachea, esophagus, gastric wall, bowel, blood vessels, or spinal cord should be approached with great caution, or not at all, if the lack of spatial separation places them within the high-dose gradient region of treatment, which can lead to potentially devastating clinical outcomes. <sup>18,28,32,49,52-54</sup>

Recommendation: Since SBRT is still developing, the most effective way to further the radiation oncology community's SBRT knowledge base is through participation in formal group trials; whether single-institutional or multiinstitutional trials sponsored by the NCI or other sources, or through NCI-sponsored cooperative group trials such as those of the RTOG. Treating patients under such protocols guarantees that strict guidelines developed by experts are followed and is an effective way to further the radiation oncology community's SBRT knowledge base. When appropriate protocols are not available, clinicians wishing to develop a SBRT program must decide whether they will treat patients in accordance with published guidelines or develop new SBRT guidelines. At a minimum, an institutional treatment protocol or set of guidelines should be developed by radiation oncologists and physicists. If a decision is made to routinely employ SBRT regimens that depart substantially from published experiences or to apply SBRT for indications not previously reported, it is best to structure the work as a formal prospective clinical trial to be reviewed, approved, and monitored by an institutional review board.

## IV. SIMULATION IMAGING AND TREATMENT PLANNING

The goal of imaging during SBRT simulation is to provide visualization of patient anatomy as it will appear during patient setup and throughout treatment. Treatment planning is concerned with the designation of target(s) and critical structure(s), as well as determining an optimal treatment delivery approach. The objective of reporting is to clearly communicate to the treatment team (physicists, radiation oncologists, dosimetrists, therapists, nurses, etc.) the vital specifics of the treatment, enable congruent and subsequent quality assurance, and evaluate treatment outcomes.

#### IV.A. Simulation imaging

SBRT requires precise delineation of patient anatomy, targets for planning, and clear visualization for localization during treatment delivery. Three-dimensional data sets assembled from CT or 4DCT for visualizations and dose calculation and/or MRI and positron emission tomography (PET) images assist in target and visualization for SBRT.

The most appropriate imaging modality for a given clinical situation is driven by the characteristics of the tissues being imaged. In general, CT is the primary imaging modality for SBRT and forms the basis for many treatment planning calculations. CT is helpful in identifying pulmonary nodules, parenchymal diseases, and chest-wall involvement

for superior sulcus tumors and lung disease. 55.56 Dynamic contrast-enhanced CT is the most sensitive study for the hepatic system. 57.58

MR is the gold standard for visualization of brain neoplasms and is increasingly used in SBRT applications including prostate, spinal tumors, chest, and solid abdominal tumors. 59-66

<sup>18</sup>F-fluorodeocyglucose (<sup>18</sup>FDG) PET greatly enhances the specificity and sensitivity in diagnosis and staging compared to CT. <sup>67,68</sup> Combined PET-CT systems can reduce image registration/fusion uncertainties to less than 2 mm due to inherent coregistration, achieved by acquiring both PET and CT images in a single acquisition session. <sup>69</sup> The CT image of the combined system is also used to correct the PET image for photon attenuation effects. However, the inherent limitations of spatial resolution in PET make that part of the system more useful for identification of sites of active disease rather than a source of imagery to be used for precise tumor delineation. Currently, PET/CT is widely used for lung cancer, head-and-neck tumors, colon cancer, liver cancer, melanoma, lymphoma, and ovarian cancer. <sup>70,71</sup>

Recommendation: Regardless of imaging modality, simulation of the patient should take place with the patient in the treatment position. The simulation study should cover the target and all organs at risk to obtain geometric and dosimetric information for the treatment setup. A typical scan length should extend at least 5-10 cm superior and inferior beyond the treatment field borders. For noncoplanar treatment techniques, the scan length may further be extended by ±15 cm inferior/superior beyond the target borders to adequately model the patient. Along with the target, all organs at risk should be included and covered by the selected scan length so they can be considered by the treatment planning system (TPS) and evaluated with dose-volume histograms. Scan parameters such as the slice thickness, interslice gap, and scan time per revolution, as well as the timescale of any underlying motion directly affect the size and appearance of tumor volumes in diagnostic and simulation studies. For SBRT applications, tomographic slice thickness of 1-3 mm though the tumor site is recommended for most clinical cases. 73-75

#### IV.B. Data acquisition for mobile tumors, patientspecific tumor-motion determination, and respiratory motion management

Primary sources of organ/tumor motion during simulation imaging are respiration, cardiac function, peristaltic activity, and organ filling and emptying. For instance, it has been found that respiratory motion of lung tumors ranges up to 50 mm. <sup>76</sup> This motion can cause problems in traditional imaging techniques. For example, a study using real-time fluoroscopy of implanted fiducial markers in lung tumors showed that 3D tumor motion is complex, hysteretic, and difficult to visualize from the orthogonal views obtained with planar imaging. <sup>77</sup> Planning target volumes (PTVs) deduced from radiographs at the extreme respiratory phases have been found to overestimate the actual volume. <sup>78</sup> Likewise, free-

breathing fast spiral CT studies may not accurately represent the mean target position since each slice localizes the target positions at a different respiratory phase away from the actual mean position. Multislice scanners could take a snapshot of the entire tumor at a position that may not represent the mean, and in fact could be at an extreme position away from the mean. Thus, population-based margins to account for tumor motion may be incorrectly applied to a random position of the target [gross tumor volume/clinical target volume (GTV/CTV)] instead of its "true" mean position, potentially resulting in undertreatment of the target and irradiation of unnecessary normal tissue.

The report of AAPM Task Group 76 describes the various tumor-motion strategies in detail. Techniques to image moving targets include slow CT, 50.81-83 breath-hold techniques, 34.84-94 gated approaches, 4DCT used in conjunction with maximum-intensity projection. 97 and respiration-correlated PET-CT. 9

#### IV.C. Imaging artifacts

One note of caution is that the same imaging characteristics that allow slower acquisitions to characterize the movement of the target can also lead to motion artifacts. 98 It is also possible to create artifacts due to high atomic number (Z) objects such as metal implants, prosthetics, and dental fillings. Motion-related artifacts may be improved by immobilization and patient cooperation. Barish and Jara have described some general clinical guidelines for motion control in body MR imaging. Specific MR algorithms dealing with motion may be used to improve the quality of MR images. 100 In MR, practical imaging techniques, such as selection of the appropriate imaging plane and of the proper frequency encoding gradient axes, can effectively reduce some of these artifacts. 101-103 The motion degradation of PET images can largely be minimized by respiratory-correlated gated or 4D PET techniques, as shown by Nehmeh  $et\ al.^{104-107}$  A necessary step to minimize the effect of metal artifacts in CTbased treatment planning is to update the electron density conversion table to reflect the relative electron density values of the metals implanted in patients (for addressing the issues with metal implants, the report of AAPM Task Group 65 on tissue inhomogeneity corrections for megavoltage photon beams can be used as a reference). One should verify that the treatment planning algorithm can account for these higher density materials in its calculation.

Recommendation: If target and radiosensitive critical structures cannot be localized on a sectional imaging modality with sufficient accuracy because of motion and/or metal artifacts, SBRT should not be pursued as a treatment option.

#### IV.D. Treatment planning

Unlike conventional radiotherapy which is based on the delivery of a uniform prescription dose to the target volume, a paradigm of prescribing dose for SBRT is based on the following set of conditions:<sup>26,32,49,108-110</sup>

- (1) A limited volume of tissue, containing the gross tumor and its close vicinity, is targeted for treatment through exposure to a very high dose per fraction, and hotspots within the target are often deemed to be acceptable.<sup>111</sup>
- (2) The volume of normal tissue receiving high doses outside the target should be minimized to limit the risk of treatment toxicity. Thus, the gradient describing the dose fall-off outside the target should be sharp.

The following sections describe how these conditions affect target definitions and treatment planning strategies.

SBRT, just as conventional radiation therapy, also makes use of the ICRU 50 and 62 definitions for GTV, CTV, PTV, and OAR. 112.113 The need to keep the volume of normal tissues receiving high doses kept to a minimum requires that only well-defined targets can be considered for SBRT. In SBRT (especially for metastatic lung, liver, and paraspinal cases), the GTV and CTV are often considered to be identical. 28.31,32.41,82 While there can be small volume microscopic extension of tumor around the GTV in some settings, 114 the typically very high reported local control rates after SBRT suggest that this component of tumor, if present, seems not to be a major source of recurrence, perhaps because it is still likely covered within a fairly high-dose region as dose falls off around the PTV.

The variation in CTV size and position due to respiratory motion or organ filling is generally accounted for by an internal margin added to the CTV, resulting in the internal target volume (ITV). 113 The magnitude of this margin depends on whether motion compensation is employed during delivery. The PTV addresses all the possible geometrical variations by adding a variable margin for setup uncertainties, machine tolerances, and intratreatment variations to the CTV. Typical SBRT margins for defining the minimal distance separating the CTV and PTV surfaces are 0.5 cm in the axial planes and 1.0 cm in the inferior/superior directions 32,109,115 for treatments that were performed in conditions that suppressed respiratory motion. Some centers are moving toward an isotropic expansion of the CTV when 4D imaging is used. In addition, some clinicians may include a 2-3 mm tissue margin surrounding the enhancing tumor for primary disease. 116-118

Recommendation: At the current time, it remains difficult to base target margins directly on clinical results. However the adequacy of the definitions of target margins (i.e., GTV, CTV, ITV, etc.) in SBRT should be based on an understanding of how the steep dose gradients and high fractional doses of SBRT affect the accuracy of traditional margin recipies, <sup>119</sup> as well as the natural history of the tumor, the limitations of in-house localization capabilities to reduce random and systematic treatment uncertainty, and from information in the current literature. Simultaneously, centers should make systematic efforts to gather and analyze clinical results to improve margin design in the future.

## IV.D.1. Dose heterogeneity, gradient and fall-off, and beam geometry

4083

Dose prescriptions in SBRT are often specified at low isodoses (e.g., 80% isoodse) and with small or no margins for beam penumbra at the target edge, as compared to traditional radiation therapy. The rationale is to improve dose fall-off outside of the targeted volume and help spare nearby organs at risk. This practice increases dose heterogeneity within the target. <sup>27,109</sup> However, in contrast to conventionally fractionated radiotherapy, dose heterogeneities within the target for SBRT are acceptable for targets not involving functional normal tissue. Hot spots within the target volumes are generally viewed to be clinically desirable, as long as there is no spillage into normal tissue. It has been hypothesized that hotspots within the central region of a tumor might offer a special advantage in eradicating radioresistant hypoxic cells that might be more likely located there. 120 While the locations of hypoxic subregions in solid tumors might not be stable, 121 regardless, the observed dose response for tumor control after SBRT supports an effort to administer the highest safely achievable dose. 122

The use of multiple nonoverlapping beams is the primary means of achieving a sharp dose fall-off in SBRT, similar to that in intracranial radiosurgery. This optimally requires that radiation should converge on the target as concentrically as possible from many directions. Provided that OARs (serially functioning organs such as spinal cord or sensitive mucosa) are sufficiently spaced from the target, the gradient of dose distribution outside the target should be ideally isotropic, with dose falling off uniformly away from the surface of the target. 123

Other parameters that affect the dose fall-off are beam energy and the resolution of beam shaping [e.g., multileaf collimator (MLC) leaf width]. For small beams such as those commonly used in SBRT, the higher the beam energy, the larger the beam penumbra due to lateral electron transport in medium. In a low-density medium, such as lung tissue, this effect becomes more significant. A 6 MV photon beam, available on most modern treatment machines, provides a reasonable compromise between the beam penetration and penumbra characteristics for SBRT lung applications. Additionally, most SBRT applications use MLC collimation. While the finer MLC collimation resolution improves the conformity of target dose distribution, this improvement is limited by characteristic blurring caused by the finite source size and lateral range of secondary electrons. The commonly available 5 mm MLC leaf width has been found to be adequate for most applications, with negligible improvements using the 3 mm leaf width MLC for all but the smallest lesions (<3 cm in diameter). 124-127

#### IV.D.2. Beam selection and beam geometry

In determining beam direction in SBRT, the avoidance of sensitive organs, mechanical constraints imposed by the equipment. <sup>123,128</sup> and short beam paths for most beams must all be considered. In general, a greater number of beams yields better target dose conformity and dose fall-off away

from the target, and when the number of beams is sufficiently high, the choice of beam direction becomes less significant. However, for practical reasons, it may be preferable to limit the number of beams or arcs. Restricting the entrance dose of individual beams to less than 30% of the cumulative dose and avoiding beam overlaps are desirable. This will help to prevent acute skin reactions and maintain the isotropic fall-off of dose gradients. Use of beam arrangements employing five to eight coplanar or noncoplanar static conformal beams shaped by 5-10 mm MLCs for targets in the thorax and abdomen have been reported. 29-31,116-118,129 Mechanisms for optimizing SBRT beam angles to minimize normal tissue dose have been also reported. 123,128 Recent developments in volumetric modulated arc techniques have the potential to create conformal dose distributions, achieve the required level of normal tissue sparing, and reduce treatment times, as compared to their static field counterparts. 130 In most cases, an isotopic dose gradient is desirable, though in cases where critical structures are in close proximity to the target volume, it may be preferable to increase the dose gradient between the target and the critical structure. For example, SBRT of paraspinal tumors usually require the irradiation of a vertebral bone and/or an attached soft tissue tumor growth, with a special consideration to the spinal cord a few millimeters away. An isotropically sharp dose fall-off all around the tumor may result in an unacceptable dose to the spinal cord for such a case. Nine to 11 posterior and posterior-oblique beams equally spaced 18°-20° apart have been shown to generate a sharp dose gradient of up to 12%/mm between the target and cord, adequately sparing the cord while delivering better than 90% of the prescription dose to the target volume. 131 Specific IMRT planning strategies for paraspinal cases involve the delineation and manipulation of anatomical and optimization volumes and constraints. 132

#### IV.D.3. Calculation grid size

The calculation grid resolution used in the TPS affects the accuracy of the dose distribution calculated. It has been reported in the literature that a 2.5 mm isotropic grid produces an accuracy of about 1% in the high-dose region of an IMRT plan consisting of multiple fields. Another report indicated an accuracy of ±5% for an isotropic grid resolution of 4 mm. Had Chung et al. Sound a dose difference of 2.3% of the prescribed dose for 2 mm calculation grids as compared to 1.5 mm grids, rising to 5.6% for 4 mm grids. Their conclusion is that 2 mm grids are required for IMRT procedures, especially in high-dose gradient areas.

Recommendation: SBRT commonly includes extremely high-dose gradients near the boundary of the target and often makes use of IMRT techniques. This report recommends the use of an isotropic grid size of 2 mm or finer. The use of grid sizes greater than 3 mm is discouraged for SBRT.

TABLE II. Summary of normalized tissue doses estimated using an  $\alpha/\beta$ -ratio of 10 (late complications) and 3 Gy (early complications) for various SBRT fractionation schemes used in NSCLC.

Total physical dose (Gy)	Reference	NTD <sub>10</sub> (Gv)	النط الممادية	Estimated 20 mg level research feet was ited	NTD <sub>3</sub>
(Oy)	Reference	(Oy)	Log <sub>10</sub> cen km	Estimated 30-mo. local progression-free survival <sup>a</sup>	(Gy)
$30 \times 2 = 60^{6}$ in 6 weeks	Estimated from Martel, 1999; Fowler 2004	65	9.9	17.7% with repopulation	60
$35 \times 2 = 70^{\circ}$ in 7 weeks	Estimated from Martel, 1999; Fowler 2004	72	10.9	28.4% with repopulation	70
4×12=48	Nagata, 2002 <sup>e</sup>	83	12.6	78.9% no repopulation	144
3×15=45	Nyman, 2006 <sup>t</sup>	94	14.2	90.8% no repopulation	162
5×12=60	Hodge, 2006 <sup>g</sup>	110	16.7	97.1% no repopulation	180
$3 \times 20 = 60$	McGarry, 2005; h Timmerman 2003	150	22.7	>99% no repopulation	276
$3 \times 22 = 66$	McGarry, 2005; Timmerman 2003	176	26.7	>99% no repopulation	330

<sup>a</sup>Progression-free survival at 30 months has been estimated using the following dose response model: LPF<sub>30 m</sub>=1/1+(NTD<sub>10</sub><sup>50</sup>/NTD<sub>10</sub>)<sup>4 γ<sub>50</sub></sup> using the following parameter values: NTD<sub>10</sub><sup>50</sup>=84 Gy;  $\gamma_{50}$ =1.5 (cf. Ref. 143) when repopulation is included and NTD<sub>10</sub><sup>50</sup>=70 Gy;  $\gamma_{50}$ =1.94 (cf. Ref. 120) when repopulation is not included.

<sup>b</sup>The progression-free survival of patients with NSCLC at 30 months was estimated from Martel et al. (Ref. 143) for the schedules marked with "b" and from Fowler et al. (Ref. 120) when rapid reproliferation can be neglected.

## IV.D.4. Bioeffect-based treatment planning and SBRT

SBRT involves the application of high fractional doses in a range not studied in prior decades. It is unlikely that normal tissue tolerance doses derived from the study of conventionally fractionated radiation therapy will apply in the context of SBRT. One way to evaluate the possible biological effect of a SBRT treatment plan in terms of its potential local tumor control and its potential normal tissue effects is to convert its associated physical dose distribution to a biologically normalized dose distribution. Using the biologically normalized dose distribution, bioeffect measures can then be calculated to rank and compare the SBRT treatment plan with others. Examples of such bioeffect measures are the BED concept, the normalized total dose (NTD) concept, and the equivalent uniform dose (EUD) concept. <sup>136-141</sup>

These bioeffect measures can be used in the evaluation of the effectiveness and safety of a SBRT dose distribution. In particular, the EUD concept can be used to rank competing treatment plans in terms of their expected tumor effect, while the BED and NTD concepts can be used to evaluate the biological effectiveness of different dose fraction schemes. It must be understood that a physical dose distribution, giving a total dose of 60 Gy, has different biological effects both in terms of expected normal tissue complications and tumor effects, depending on which fractionation schedule is employed (cf. Refs. 120 and 142 and Ref. 51 for a detailed discussion).

For example, NTD is defined as the total dose given in 2 Gy fractions that has the same biological effect as the actual dose-fractionation schedule under consideration. Essentially, the NTD concept simply converts BED values back to biologically equieffective doses delivered at the standard dose per fraction of 2 Gy, generating numbers that can be more

easily compared to the dose levels of standard treatment schedules. Table II summarizes the NTD for several dose-fractionation schemes. Note the biological dose equivalents are very high due to the large dose per fraction. The progression-free survival of patients with NSCLC at 30 months was estimated from Martel *et al.* <sup>143</sup> for the schedules marked with "b" and from Fowler *et al.* <sup>120</sup> when rapid reproliferation can be neglected.

The comparisons in Table II are offered only as an example of how one particular model can be applied to SBRT and they should be viewed with certain caveats in mind. First, they compare only nominal prescription dose and do not take into account differences in prescription isodose line covering the PTV or dose-calculation algorithm used. Second, clinical outcome reports of local control after a given dose-fractionation regimen are always the definitive measure of a treatment regimen's potency, not a model-based prediction. Finally, while there are reports showing higher control rates above certain BED cutoff levels, 144-146 it should be appreciated that BED, NTD, and EUD are all ultimately derived starting from the linear-quadratic model, which may not describe tissue effects in hypofractionated dose regimens. 147 As more clinical data become available, these models will have to be refined and updated. In addition, alternative approaches to radiation effect modeling have been developed and require further investigation before their validity and predictability can be fully evaluated. 148-150

#### IV.D.5. Normal tissue dose tolerance

Normal tissue dose limits for SBRT are considerably different from conventional radiotherapy due to extreme dosefractionation schemes and are still quite immature. Thus, normal tissue dose limits for SBRT should not be directly extrapolated from conventional radiotherapy data. Likewise,

<sup>&</sup>lt;sup>c</sup>Reference 143.

dReference 120.

Reference 37.

Reference 255.

Reference 256.

hReference 49.

<sup>&#</sup>x27;Reference 32.

data on intermediate-level doses, especially in organs that show partial-volume effects (lung, kidneys, etc.), are currently immature and should be treated with care.

4085

Particular attention should be paid to fraction size, total dose, time between fractions, and overall treatment time, which are important radiobiological factors that need to be maintained within clinically established parameters where available in the SBRT literature. This becomes increasingly important for new hypofractionated schedules and trials for which there is no reliable mechanism to estimate their radiobiological effects. Therefore, in a clinical trial situation, not only the fraction size but also the frequency and overall treatment time should be maintained throughout the entire trial for all patients to obtain reliable outcome data.

Scenarios in which retreatment is under consideration can be quite complicated, with (currently) sparse literature to guide treatment decisions. In retreatment situations, composite dose distributions across all treatments should be assessed when deciding if additional treatment is possible.

Table III summarizes tolerance doses from the University of Texas Southwestern<sup>8</sup> and the University of Virginia. <sup>151</sup> The doses are mostly unvalidated, and while most are based on toxicity observation and theory, there is a measure of educated guessing involved as well. <sup>266</sup> Additional information may be found in several published reports, including Indiana University's lung SBRT experience, Karolinska Hospital's SBRT experience, and a recent report from Stanford University. <sup>18,152–154</sup> Because of the sparseness of long-term follow-up for SBRT, it should be recognized that the data in both Table III and the published reports represent, at best, a first approximation of normal tissue tolerance. When proceeding in areas where there is a lack of published literature for toxicity and complications, this report recommends that formal institutional guidelines and prospective trials be implemented.

Recommendation: Normal tissue dose tolerances in the context of SBRT are still evolving and only a limited experience exists from which to draw recommendations. Except in the setting of IRB approved Phase I protocols, critical organ tolerance doses based on the SBRT experience in the evolving peer-reviewed literature must be respected.

#### IV.E. Treatment plan reporting

SBRT treatment plans often use a large numbers of beams, unconventional dose fractionations and delivery frequencies, and more comprehensive image guidance data and information. It is critical to accurately communicate the details of the treatment plan and its execution to the treatment team.

The quality of planned dose distributions for SBRT can be evaluated from parameters characterizing target coverage, dose homogeneity, dose outside of the target definition, and volumes of normal tissue exposed to lower doses. Simple methods of articulating these parameters may rely on combinations of DVHs for different organs and tables representing dose allocation in different subvolumes of these organs. Metrics that have been reported at some centers include

- · Prescription dose,
- Prescription ICRU reference point or dose/volume (e.g., isodose covering PTV to a particular percentage),
- · Number of treatment fractions,
- · Total treatment delivery period,
- · Target coverage,
- Plan conformity (example: Ratio of prescription isodose volume to PTV or a conformity index such as proposed by Hazard et al. 155),
- Dose falloff outside the target (example: Ratio of the volume of the 50% of prescription isodose curve to PTV).
- Heterogeneity index (e.g., the ratio of highest dose received by 5% of PTV to lowest dose received by 95% of PTV),
- Notable areas of high or low dose outside of the PTV, and
- Dose to organs at risk (dose to 1% and 5% volumes and mean doses).

## V. PATIENT POSITIONING, IMMOBILIZATION, TARGET LOCALIZATION, AND DELIVERY

Ideally, the delivered dose would exactly match the planned dose distribution. This is seldom achieved in practice. However, in practice, there are a number of considerations that can result in the dose delivered to the patient differing from the planned distribution (e.g., limits to beam modeling precision, treatment machine limitations, etc.). One of the most important potential sources of variation is positional changes in the target or surrounding tissue. For example, the patient's position in the immobilization system at treatment will likely not be exactly what it was at the time of CT simulation, and their soft tissue anatomy may have altered in shape and position. This may be especially true during the long treatment times associated with SBRT that result from hypofractionated doses delivered through small treatment fields.

Historically, in order to minimize many of these potential variations, the developers of SBRT (Ref. 109) scanned the patient in a body frame with an integral coordinate system that could be visualized in the CT image. Fortunately, the current availability of IGRT has made this older body frame/ fiducial based system obsolete. The setup error of a stationary target can now be corrected to within the imaging and positioning accuracy of the system for each treatment. Residual translations of less than 2 mm are achievable for bony targets. 156 Robotic couches, when used in conjunction with stereotactic x-ray or volumetric imaging, have made it possible to also correct (up to 3°-4° for roll and pitch and 10° for yaw) for the small rotational errors that can occur. 157,158 However, soft tissue targets require volumetric imaging such as CBCT or CT on rail to achieve the necessary setup precision required. 159

Recommendation: For SBRT, image-guided localization techniques shall be used to guarantee the spatial accuracy of the delivered dose distribution with a high confidence level. Body frames and associated fiducial systems may be used for

TABLE III. Summary of suggested dose constraints for various critical organs. Note that for serial tissues, the volume-dose constraints are given in terms of the critical maximum tissue volume that should receive a dose equal or greater than the indicated threshold dose for the given number of fractions used. For parallel tissue, the volume-dose constraints are based on a critical minimulm volume of tissue that should receive

4086

Serial tissue Optic pathway		allo	One fraction	Three f	Three fractions	Five fractions	actions	
Optic pathway	Max critical volume above threshold	Threshold dose (Gy)	Max point dose (Gy)*	Threshold dose (Gy)	Max point dose (Gy)*	Threshold dose (Gy)	Max point dose (Gy)*	End point (≥Grade3)
	<0.2 cc	æ	01	15.3 (5.1 Gy/fx)	17.4 (5.8 Gy/fx)	23 (4.6 Gy/fx)	25 (5 Gy/fx)	Neuritis
Cochles			ŧ					Hearing
Brainstem			<b>5</b>		17.1 (5.7 Gy/fx)		25 (5 Gy/fx)	loss
(not medulla)	20.5 cc	01	51	18 (6 (3,/62)	32.1 (7.7 Calle)	23,44,6		Cranial
Spinal cord	<0.35 cc	2 2	2 =	18 (0 Gy/fx)	25.1 (7.7 Gy/IX)	23 (4.6 Gy/fx)	51 (6.2 Gy/lx)	neuropathy
and medulla	8 17	2 ~	<u>.</u>	13 (1 1 C-1/6)	21.9 (7.5 Gy/IX)	23 (4.6 Gy/fx)	30 (6 Gy/fx)	Myelitis
Spinal cord	3	•		12.5 (4.1 Gy/fx)		14.5 (2.9 Gy/fx)		
subvolume							. * ***********************************	
(5-6 mm above	£01>						#000000000	
and below level	of						many states	
treated per Ryu)	subvolume	10	7	18 (6 Gv/fx)	21.9 (7.3 Gv/fx)	23 (4 6 Gv/fv)	30 (6 Gw/fv)	Muslitis
Cauda equina	<\$ cc	2	91	21.9 (7.3 Gw/fx)	24 (8 Gv/fx)	30 (6 Gv/fx)	12 (6.4 Gv/fv)	Vennitie
Sacral plexus	>> cc	14.4	92	22.5 (7.5 Gy/fx)	24 (8 Gy/fx)	30 (6 Gv/fx)	32 (6.4 Gv/fx)	Vencounty
Esophagus <sup>†</sup>	oo \$>	11.9	15.4	17.7 (5.9 Gy/fx)	25.2 (8.4 Gy/fx)	19.5 (3.9 Gv/fx)	35 (7 Gv/fx)	Stenosis/fistula
Brachial plexus	<3 €	<u></u>	17.5	20.4 (6.8 Gy/fx)	24 (8 Gy/fx)	27 (5.4 Gv/fx)	30.5 (6.1 Gv/fx)	Neuronathy
Heart/pericardium	<15 cc	91	22	24 (8 Gy/fx)	30 (10 Gy/fx)	32 (6.4 Gy/fx)	38 (7.6 Gv/fx)	Pericarditis
Great vessels	< 10 cc	31	37	39 (13 Gy/fx)	45 (15 Gy/fx)	47 (9.4 Gy/fx)	\$3 (10.6 Gy/fx)	Ancurysm
Trachea and large					•	•		•
bronchus"	33 <b>†</b> >	10.5	20.2	15 (5 Gy/fx)	30 (10 Gy/fx)	16.5 (3.3 Gy/fx)	40 (8 Gy/fx)	Stenosis/fistula
Bronchus-smaller	,							Stenosis
airways	20.5 cc	12.4	13.3	18.9 (6.3 Gy/fx)	23.1 (7.7 Gy/fx)	21 (4.2 Gy/fx)	33 (6.6 Gy/fx)	with atelectasis
Rit	S  >	22	30	28.8 (9.6 Gy/fx)	36.9 (12.3 Gy/fx)	35 (7 Gy/fx)	43 (8.6 Gy/fx)	Pain or fracture
	<30 cc			30.0 (10.0 Gy/fx)				
Skin	<10 cc	23	36	30 (10 Gy/fx)	33 (11 Gy/fx)	36.5 (7.3 Gy/fx)	39.5 (7.9 Gy/fx)	Ulceration
Stomach	<10 cc	1.2	12.4	16.5 (S.5 Gy/fx)	22.2 (7.4 Gy/fx)	18 (3.6 Gy/fx)	32 (6.4 Gy/fx)	Ulceration/fistula
Duodenum <sup>h</sup>	8 %	<u>:</u> :	12.4	16.5 (5.5 Gy/fx)	22.2 (7.4 Gy/fx)	18 (3.6 Gy/fx)	32 (6.4 Gy/fx)	Ulceration
	<10 cc	o		11.4 (3.8 Gy/fx)		12.5 (2.5 Gy/fx)		Linguistica
Jejunum/ileum <sup>h</sup>	ა \$>	6.11	15.4	17.7 (5.9 Gy/fx)	25.2 (8.4 Gy/fx)	19.5 (3.9 Gy/fx)	35 (7 Gy/fx)	obstruction
Colon	< 20 cc	14.3	18.4	24 (8 Gy/fx)	28.2 (9.4 Gy/fx)	25 (5 Gy/fx)	38 (7.6 Gy/fx)	Colitis/fistula
Rectum	< 20 cc	14.3	18.4	24 (8 Gy/fx)	28.2 (9.4 Gy/fx)	25 (5 Gy/fx)	38 (7.6 Gy/fx)	Proctitis/fistula
Bladder wall	<15 cc	11.4	18.4	16.8 (5.6 Gy/fx)	28.2 (9.4 Gy/fx)	18.3 (3.65 Gy/fx)	38 (7.6 Gy/fx)	Cystitis/fistula
Penilc bulb	3 €>	<u> </u>	₹.	21.9 (7.3 Gy/fx)	42 (14 Gy/fx)	30 (6 Gy/fx)	50 (10 Gy/fx)	Impotence
Femoral heads							o. o 10000 10	
(right and left)	<10 cc	<u> </u>		21.9 (7.3 Gy/fx)		30 (6 Gy/fx)		Necrosis
Renal Librarianis	6.67						entendra Visco	Malianan
munity description	5/7/	701	19 6 /6 3 (5.1/6.)			72 (16 Culle)		doi:detagned

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4087

		One f	One fraction	Three fi	Three fractions	Five fractions	ctions	
Serial tissue	Max critical volume above threshold	Threshold dose (Gy)	Threshold dose Max point dose (Gy) (Gy)	Threshold dose (Gy)	Max point dose (Gy) <sup>2</sup>	Threshold dose (Gy)	Max point dose (Gy)*	End point (≥Grade3)
		One f	One fraction	Three fi	Three fractions	Five fractions	ctions	
Parallel tissue Lung (right and left) Lung (right and left) Liver Renal cortex (right and left)	threshold threshold 1500 cc 1000 cc 700 cc 200 cc	Threshold dose (Gy) 7 7.4 9.1	Max point dose(Gy) <sup>2</sup> NA-Parallel tissue NA-Parallel tissue NA-Parallel tissue	Threshold dose(Gy) 11.6 (2.9 Gy/fx) 12.4 (3.1 Gy/fx) 19.2 (4.8 Gy/fx) 16 (4 Gy/fx)	Max point dose(Gy) <sup>2</sup> NA-Parallel tissue NA-Parallel tissue NA-Parallel tissue	Threshold dose(Gy) 12.5 (2.5 Gy/fx) 13.5 (2.7 Gy/fx) 21 (4.2 Gy/fx) 17.5 (3.5 Gy/fx)	Max point dose(Gy) <sup>2</sup> NA-Parallel tissue NA-Parallel tissue NA-Parallel tissue NA-Parallel tissue	End point (ZGrade 3)  Basic lung function Pneumonitis Basic liver function Basic renal function

\*\*Point" defined as 0.035 cc or less. \*Avoid circumferential irradiation.

TABLE IV. Achievable accuracies reported in the literature categorized by body site and immobilization/repositioning device.

Author, year	Site	Immobilization/repositioning	Reported accuracy
		Wood frame/stereotactic coordinates	
Lax, 1994 <sup>a</sup>	Abdomen	on box to skin marks	3.7 mm Lat, 5.7 mm Long
Hamilton, 1995 <sup>b</sup>	Spine	Screw fixation of spinous processes to box	2 mm
		Frameless/implanted fiducial markers with real-time	
Murphy. 1997	Spine	imaging and tracking	1.6 mm radial
Lohr, 1999 <sup>d</sup>	Spine	Body cast with stereotactic coordinates	≤3.6 mm mean vector
Yenice, 2003°	Spine	Custom stereotactic frame and in-room CT guidance	1.5 mm system accuracy, 2-3 mm positioning accuracy
		MITM BodyFix with stereotactic frame/linac/CT on rails	
Chang, 2004	Spine	with 6D robotic couch	1 mm system accuracy
Tokuuye, 1997	Liver	Prone position jaw and arm straps	5 mm
Nakagawa, 2000 <sup>g</sup>	Thoracic	MVCT on linac	Not reported
Wulf, 2000 <sup>h</sup>	Lung, liver	Elekta™ body frame	3.3mm lat,4.4 mm long
			Bony anatomy translation 0.4, 0.1, 1.6 mm (mean
			X, Y, Z; tumor translation before image guidance 2.9,
Fuss, 2004 <sup>i</sup>	Lung, liver	MI™ BodyFix	2.5, 3.2 mm (mean $X, Y, Z$ )
Herfarth, 2001	Liver	Leibinger body frame	1.8-4.4 mm
Nagata, 2002 <sup>k</sup>	Lung	Elekta™ body frame	2 mm
Fukumoto, 2002 <sup>l</sup>	Lung	Elekta™ body frame	Not reported
		Custom bed transferred to treatment unit after	
Hara, 2002 <sup>m</sup>	Lung	confirmatory scan	2 mm
Hof, 2003 <sup>n</sup>	Lung	Leibinger body frame	1.8~4 mm
Firnmerman, 2003°	Lung	Elekta™ body frame	Approx. 5 mm
		Medical Intelligence body frame stereotactic	
Wang, 2006 <sup>p</sup>	Lung	coordinates/CT on rails	$0.3 \pm 1.8 \text{ mm AP}$ , $-1.8 \pm 3.2 \text{ mm Lat}$ , $1.5 \pm 3.7 \text{ mm SI}$
Reference 109.		'Reference 160.	
Reference 257.		<sup>1</sup> Reference 28.	
Reference 258.		Reference 37.	
Reference 252.		Reference 34.	
Reference 131.		<sup>m</sup> Reference 35.	
Reference 42.		*Reference 31.	
Reference 259.		"Reference 117.	
Reference 260.		PReference 88.	

immobilization and coarse localization; however, they shall not be used as a sole localization technique. In addition, it is crucial to maintain the spatial accuracy throughout the treatment delivery through either integrated image-based monitoring systems or through aggressive immobilization of appropriate targets, such as the spine.

#### V.A. immobilization

The degree of required immobilization for SBRT is largely influenced by the ability of the dose delivery system to both detect and correct for the changes in patient position that may occur during treatment. Even current image-guided positioning systems reduce but do not eliminate the need for proper immobilization.

Table IV summarizes historical immobilization strategies and their associated localization errors. Stereotactic body frames (e.g., Elekta, Medical Intelligence Body Fix, Leibinger, Yenice, Lech Papiez, etc.) serve both to immobilize the patient physically and provide an initial approximate target localization, which is subsequently refined by in-room image-guided techniques. Body frames typically make use of vacuum cushions for immobilization. Stereotactic localization and targeting can be facilitated by a localizer arch which can be affixed to the body frame or to the linac couch top,

and define the reference coordinate system of body frame fiducials. Some body frame systems also include equipment for abdominal compression which can be used to minimize respiratory motion. <sup>88,160,161</sup>

#### V.B. Image-guided localization

Image guidance provides the finest level of localization and is used to reduce the spatial uncertainty in the positioning of targets and possibly critical structures prior to radiation delivery. In its more advanced implementations, image guidance is also used to monitor the position of the target or a surrogate during radiation delivery.

The traditional approach has been the use of 2D MV electronic portal imaging (EPID). This approach, used in conjunction with implanted fiducial hardware, has been used to deliver SBRT treatments to spinal sites while keeping the target within 2 mm of its planned position. <sup>162</sup>

Volumetric image guidance allows for the precise localization of bone and soft tissue targets. <sup>131,163</sup> This is achieved using MV (Ref. 164) or kV (Refs. 165–167) cone beam scanning, n MV fan beam using a tomographic acquisition, <sup>168</sup> and in-the-vault CT systems. <sup>131,163</sup> Dual <sup>169,170</sup> or multiple <sup>171</sup> room mounted kV imaging systems are used to provide rapid 3D localization of targets or implanted markers using pairs

of 2D radiographs for both patient setup and intrafractional monitoring. Treatment machines with gantry mounted kV units capable of fluoroscopy, radiographic localization, and cone beam imaging (especially for soft tissue targets) are being widely adopted. This has had a profound effect on SBRT. On board imaging, when integrated with an image registration software, makes accurate target positioning and verification for SBRT readily available. Ideally, IGRT systems would be capable of visualizing the actual target volume directly. In practice, the imaging system available may not be able to image the target, especially if it is soft tissue. A well established approach is to implant radiopaque markers in the vicinity of the tumor and use them as surrogates in localizing targets such as prostate, 172-174 liver, 175 and lung, 33,176-179 and spine. 180,181 Implanting fiducials percutaneously in to the lung poses a high risk of pneumothorax. 182,183 Ultrasound (U.S.) is effective for imaging soft tissue structures and tumors in the pelvis and abdomen. The probe is tracked in 3D using a stereoscopic infrared camera system installed in the treatment room, allowing the reconstructed volumetric images to be referenced to the machine isocenter. The use of U.S. in SBRT for a variety of sites has been described by Meeks et al., 184 Fuss, 185 and reviewed by Kuban and co-workers. 186

Finally, a technique that relies on radiofrequency tracking rather than imaging is that used by the Calypso system (Calypso Medical Technologies, Seattle, WA), which can continuously (at 10 Hz) report the 3D position of a target throughout a procedure, even during radiation delivery.<sup>187</sup>

With any localization methodology, a careful assessment of the random and systematic errors of the imaging system and a quality assurance program are necessary for a successful SBRT program.

## V.C. Localization, tumor-tracking, and gating techniques for respiratory motion management

The respiratory motion assessment of targets in the thorax and abdomen and its management strategies are described in detail in the Report of AAPM Task Group 76: "The Management of Respiratory Motion in Radiation Oncology." They are mentioned here briefly for the sake of completeness.

#### V.C.1. Image-guided techniques

Image-guided techniques such as fluoroscopy, gated radiographs, and cone beam imaging of soft tissue can be used to localize targets moving during treatment due to respiratory motion. <sup>189,190</sup> A few problems remain, however. For example, during the respiratory cycle, the target may move with respect to nearby critical structures which themselves may not be tracked. Therefore, though a delivery may reduce dose to a volume of critical structures, it may not lessen the uncertainty in the doses to them.

Cone beam imaging is increasingly being used for localization of lung tumors. 192-194 Cone beam scans can have an acquisition time 60 s or more, and therefore have the advantage of capturing the average tumor position over 15 or more breathing cycles, which may correspond well to the planning

ITV (Ref. 113) as obtained from 4DCT. <sup>195,196</sup> In contrast, the use of fast CT either during simulation or during image guidance at the time of treatment is less ideal because the tumor and/or critical structure position captured could be random due to motion.

Cone beam scans can be used to resolve the respiratory motion in lung tumors using a respiration-correlated approach. A large number of projections are acquired during a slow (on the order of 4 min) scan. The projections are sorted into phase bins, then each phase bin is reconstructed, thus the tumor position at each phase bin can be determined. The technique can be used to verify that the target motion amplitude is within the planned limits, and can be acquired just before treatment delivery, reducing the chance of a systematic error due to patient setup changes between imaging and treatment delivery. While not yet available commercially at the time of this report, the ability to record tumor position at each respiratory phase may be advantageous for respiratory motion management as compared to the average of a 4DCT scan.

#### V.C.2. Optical tracking techniques

After localization, some kind of monitoring is desirable to track patient breathing and monitor patient positioning during the treatment. Two optical technologies, stereoscopic infrared cameras and video photogrammetry, are used to track the 3D coordinates of points on the patient's skin in real time.

Infrared tracking systems use either active infrared light emitting diodes (IRLEDs) or passive markers that reflect the infrared light emitted from an external source. These are temporarily attached to the patient's skin. In a stereoscopic system, two infrared cameras are used to track the IRLEDs or reflectors in 3D during treatment. Several optical tracking systems have been developed for stereotactic radiation therapy. Video photogrammetry systems use several video cameras and speckle-textured light projectors to acquire a 3D surface without the need to attach any markers to the patient's skin. Finally, some systems combine in-room optical systems with kV imaging to detect changes in the correspondence between the external markers and the tumor over the course of treatment. These report RMS positioning errors as low as 2 mm in certain situations.

A critical assumption of these monitoring techniques is that the external marker motion correlates with the internal tumor/organ motion. In certain instances, this assumption has been called into question, especially for lung tumors. <sup>209</sup> Careful consideration should be given to the clinical situation when a decision is taken to use optical tracking technologies in order to ensure an appropriate level of confidence in the correlation.

#### V.C.3. Respiratory gating techniques

The localization and tracking techniques described above are often used in conjunction with respiratory gating, where dose is delivered only in particular phases of the respiratory cycle with the goal of reducing the probability of delivering dose to normal tissue and underdosing the target. <sup>210-212</sup> The efficacy of respiratory gating is affected by the reproducibility of a patient's breathing patterns from cycle-to-cycle and day-to-day. Respiratory gating increases treatment time as compared to nongated treatments; published duty cycles (ratio of beam on to total beam delivery time) range from 30% to 50%. <sup>213-215</sup> Increasing the dose rate, if possible, would counteract the increase in treatment time. Another consideration is the amplitude of the respiratory motion. Several reports have shown that the benefit of gated beam delivery is minimal and does not outweigh the increase in treatment time and complexity for patients with motion amplitudes smaller than 2 cm. <sup>119,210,216</sup>

4090

Recommendation: For all SBRT patients with targets in the thorax or abdomen, a patient-specific tumor-motion assessment is recommended. This serves to quantify the motion expected during the respiratory cycle. This data may then be used to

- (a) Determine if the patient's treatment would likely benefit from techniques such as respiratory gating;
- (b) To quantify the residual motion expected during the respiratory gated delivery if such delivery is used;
- (c) To design margins for treatment planning; and
- (d) To quantify and account for any phase shift between the tumor motion and the respiratory signal.

If external markers are used for motion tracking, it is recommended that their suitability as a surrogate for tumor motion be verified.

Repeat motion assessment for each SBRT treatment is recommended in order to verify and, if necessary, correct the treatment if changes in the motion patterns, magnitude, or correlation with the respiratory signal are observed.

#### V.D. Delivery data reporting

It is important that a SBRT program has an established quality assurance process and proper documentation for accurate treatment delivery. The treatment delivery report should indicate that a quality assurance process is in use and adherence to quality assurance is documented. Quantitative information regarding daily image registration and calculated shifts and verification of treatment ports with respect to bony anatomy and the target should be recorded.

Action levels should be defined for residual target positions and patient rotations which, if exceeded, should trigger repositioning of the patient. Action levels should also be defined for internal anatomic variation. These action levels are likely to be less than the various treatment margins defined for the treatment, and may vary according to institution, equipment, technique, and treatment site. Any significant internal organ variations or changes in the target volume that cannot be accommodated by treatment margins should be noted, and their consequences, such as resimulation and replanning, should be indicated.

The patient position should be monitored during the entire treatment and any deviations in treatment/target position as assessed from available visual, optical, and radiographic tools (such as repeat imaging) should be recorded for the entire treatment duration. Tolerance values for such deviations consistent with the applied treatment margins should be indicated. In addition, any treatment interruptions or deviations from the fractionation time interval should be recorded.

#### VI. SPECIAL DOSIMETRY CONSIDERATIONS

#### VI.A. Problems associated with dosimetry of small/ narrow field geometry

SBRT and IMRT routinely use small fields and beamlets of less than 10 mm in diameter in order to achieve the desired, highly focused and precisely modulated dose distribution. Measurement of small photon beams is complicated by the loss of lateral electronic equilibrium, 217 volume averaging, 217-220 detector-interface artifacts, collimator effects, 221-224 and detector position-orientation effects.

Recommendation: Due to the small dimensions and steep dose gradients of photon beams used in SRS/SRT and IMRT, an appropriate dosimeter with a spatial resolution of approximately 1 mm or better (stereotactic detectors) is required to measure the basic dosimetry data, e.g., the total scatter factor (or relative output factor), tissue-maximum ratio, and offaxis ratios. Even with stereotactic detectors, careful detectorphantom setup, and detailed dose corrections, one might still find more than 10% discrepancies among the measurements of very small fields (<10 mm in diameter). 218,226-228 MLCshaped fields have more geometry and dosimetry uncertainties than those of the circular cones. Li et al. 229 demonstrate that large errors are often caused by a small setup error or measuring point displacement from the central ray of the beam. For small MLC fields, the collimator leaf-edge effect is almost independent of the depth but is closely related to the field size and type of MLC. The volume effect becomes significant when the detector diameter is comparable to the half size of the small fields.

For the profile (off-axis ratio) measurement of the small photon beams, Higgins *et al.*<sup>230</sup> demonstrated a simple approach to unfolding the chamber size artifact from measured small-beam profiles using typical cylindrical chambers by deconvolving the detector-response artifact from each point in the profiles.

Recommendation: The maximum inner diameter of a detector should be less than half the FWHM of the smallest beam measured in order for the deconvolution of the detector-size effect to work properly.

### VI.B. Problems associated with small-field heterogeneity calculations

Head-and-neck and lung tumors are often situated at airtissue interfaces. The effects of transient electronic disequilibrium and increased lateral electron range in air will result in an important reduction in the central axis dose beyond the cavity and potentially an underdosage of the tumor. <sup>231-233</sup> Heterogeneity correction becomes extremely important in situations where the target is surrounded by low-density tis-

sue such as the lungs. Some dose-calculation algorithms which do not account for lateral electron scattering can yield incorrect results.

4091

Most treatment planning systems used for SBRT make use of one of a variety of advanced photon dose-calculation methods based on Monte Carlo precalculated dose-spread kernels and employing convolution/superposition techniques. Unlike conventional, approximation-based treatment planning methods which consider only photon transport, these newer algorithms consider recoil electron transport; however, the inhomogeneity corrections are still approximate. For example, dose calculation using pencil-beam superposition will not account for increased electron scattering in lower-density material. For methods using point dose-spread kernels, density scaling is performed for the distance between the interaction point and the calculation point, thereby assuming that electrons travel in a straight line along this direction.

Several studies have described the validity of inhomogeneity corrections in small-field situations. 232,234 The Radiological Physics Center conducted a study comparing various dose-calculation regimes used by institutions participating in the RTOG 0236 protocol for lung tumors using an anthropomorphic thorax phantom. Convolution/superposition and Clarkson/pencil-beam algorithms matched well at the center of the target PTV (embedded in the phantom); however, there were significant differences in the target periphery. 235

AAPM Task Group 65 on tissue inhomogeneity corrections for megavoltage photon beams reviewed the literature extensively and recommended that inhomogeneity corrections be used for patient dose calculations, while they cautioned the user of potential pitfalls for various clinical conditions with several commercially available heterogeneity correction algorithms. Task Group 65 also reported that while the dose-calculation estimations are not accurate in certain situations, they are often closer to the actual values than calculations with no inhomogeneity corrections at all. It should be noted that Task Group 65 (Ref. 236) specifically disallows the use of pencil-beam algorithms for the situation of a target surrounded by low-density tissue as this class of algorithms does not account for lateral scattering in the small field sizes used in SBRT.

Recommendation: Algorithms that account for 3D scatter integration such as convolution/superposition have been found (including by the RPC study) to perform adequately in most clinical situations, including (in many cases) circumstances where there is a loss of electronic equilibrium such as the lung tissue interface or tumor margin in low-density medium. Calculation algorithms accounting for better photon and electron transport such as Monte Carlo would be ideal for the most demanding circumstances, such as a small lesion entirely surrounded by a low-density medium. However, at the time of this publication, Monte Carlo calculations are not yet widely available in the clinic. Pencil-beam algorithms accounting for only 1D scatter corrections are not recommended for accurate estimate of the dose in such tumors and in general for any lung tumors.<sup>237</sup> For site-specific recommendations, the clinical user should refer to Report 85 of Task Group 65.236

#### VII. CLINICAL IMPLEMENTATION OF SBRT

The high dose delivery and precision targeting requirements of SBRT demands stringent procedures and tools in order to guarantee that the accuracy of the system is achieved for each treatment and each fraction. The critical steps for initiating a clinical SBRT program involve

- Establish the scope of the SBRT program including a selection of treatment sites and the clinical goal(s) for each site.
- (2) Determine a treatment modality, dose-fractionationscheme, and treatment planning goals (target definition, target coverage, conformity index, etc.) that support the clinical goals for each treatment site.
- (3) For each treatment modality and treatment scheme, determine the equipment requirements for patient positioning, treatment delivery, and verification.
- (4) Determine personnel needs for SBRT implementation and maintenance.
- (5) Establish and perform acceptance and commissioning test procedures for the SBRT equipment.
- (6) Establishing SBRT simulation, treatment planning, delivery and verification guidelines, reporting methodology and routine QA procedures, and action levels
- (7) Conducting personnel training.

#### VII.A. Establishing the scope and clinical goals of the SBRT program

The clinical rationale and historical perspective for the use of SBRT in primary and metastatic disease have been outlined previously. The clinical physics team plays an essential role in determining the limitations of available technology for patient immobilization, localization, treatment planning, and treatment delivery for a given treatment site. Strategies for addressing these issues must be thoroughly discussed with the clinical team. Outside of a formal prospective clinical trial approved by an institutional review board, clinical guidelines from national protocols and/or published literature should be used to determine the parameters for best individualized patient treatment. Also critical is the role the physics team plays in evaluating the adequacy of space and personnel resources for SBRT. A thorough feasibility analysis of existing resources to achieve the clinical and technical goals of the proposed SBRT must be performed and discussed with the medical center administration. The role and responsibility of each individual team member should be clearly laid out along the recommendations of ASTRO/ACR Practice Guidelines for SBRT.<sup>23</sup>

#### VII.A.1. Equipment considerations

The primary technical issues for SBRT equipment selection are the adequacy of physical space and the ability to integrate the new equipment with the existing technology including the treatment planning and record and verify systems. In most facilities, existing linear accelerators with image guidance capability may be adequate to perform SBRT

procedures. It is also important to make sure that the TPS has the capability of accurately calculating the sophisticated plans needed for SBRT and handling multimodality imaging (registration and fusion) and image guidance technology. However, as noted earlier and in Task Group Report 85, 236 the use of pencil-beam algorithms is not recommended for lung SBRT applications.

#### VII.A.2. Time and personnel considerations

The complexity of SBRT requires an increased level of physicist involvement in every aspect of the process, including the initial commissioning of immobilization and stereotactic localization system, small-field measurements and verifications, and continued quality assurance. Additional physics resources will be needed to implement and maintain an SBRT program for most centers. Physics staffing requirements can be derived by referencing the 2008 ABT study<sup>239,240</sup> (Medical Physicist Work Values for Radiation Oncology Physics Services). The study defines work as a product of time and intensity (Work=Time\*Intensity), where intensity is a measure of mental effort, emotional stress, and the complexity of the technique. The study reports a median work estimate for a special medical physics consultation (CPT code 77370) relative to a continuing physics consultation (the defined baseline CPT code of 77336) of 13.94. For procedures within CPT 77370, SBRT, singlefraction SRS, IMRT, and IGRT have time estimates of 4.0, 6.0, 4.0, and 1.0 h, respectively, vs 2.0 h for a routine 77370 procedure. Likewise, median intensity estimates are reported as 4.0, 5.0, 4.5, and 4.5 vs 2.0 for the routine 33730 proce-

Recommendation: The 2008 ABT report suggests that an SBRT procedure requires a total effort, which is approximately equal to that required for IMRT and significantly greater than that required for a standard 3D conformal procedure. The guidelines published by ASTRO/ACR (Ref. 238) includes provisions for SBRT personnel and clearly specifies that qualified radiation oncology staff, therapists, dosimetrists, physicists, and physicians, are required to maintain a high quality SBRT program. In this report, we underscore the commitment by everyone involved in an SBRT program to continually update the training of staff and physicians with regard to any new developments.

### VII.B. Acceptance, commissioning, and quality assurance

Acceptance test procedures provided by the vendor are typically designed to verify contractual system specifications for performance characteristics of the system. Commissioning tests should be developed by the institution's physics team to explore in detail every aspect of the system with the goal of developing a comprehensive baseline characterization of the performance of the system. A rigorous, continuing process of periodic and treatment-specific quality assurance is vital for minimizing systematic errors that can result in less than optimal treatments. Specific tests should be developed to look at all aspects of the system both individually

and in an integrated fashion. These tests should be including but not limited to integrity of the simulation imaging data, dose-calculation algorithms, MLC leaf sequencing, MU calculation algorithms, leaf speed, machine dose rates used for SBRT and accuracy of calibration at these dose rates, delivery precision at small MUs, patient positioning and localization, motion tracking and gating, etc. While in many cases the specific tests used are similar for acceptance, commissioning, and quality assurance, it is important to remember that the intent of each activity is different.

A variety of task groups and reports are available which provide guidance on best practices for performing commissioning and quality assurance of delivery devices (including TG-40 and TG-45), 243,244 imaging equipment, 243,245,246 treatment planning systems (TG-53), and IMRT. TG-142 provides an update to TG-40 and includes specific recommendations for SBRT. In addition, a recent QA supplement published in the International Journal of Radiation Oncology Biology Physics 249 suggests a set of annual, monthly, and daily QA activities and tolerances which allow verification of the overall accuracy of various aspects of the IGRT/SBRT treatment process (summarized in Table V).

For SBRT, the imperative need for accuracy requires special consideration when designing acceptance, commissioning, and quality assurance tests. For instance, it is paramount to verify that the radiation isocenter coincides with the mechanical isocenter, including couch rotation, and that the lasers are aligned to the radiation isocenter. An elaborate method of system accuracy determination has been published for intracranial applications using the BRW head frame by Lutz et al.<sup>250</sup> The integral use of on-board imaging in SBRT makes it critical to also verify the coincidence of the imaging isocenter.<sup>251</sup> Nonisocentric modalities such as the Cyberknife have tests similar to the Winston–Lutz test, which can verify overall geometric accuracy.

Redundancy tests should be introduced to check the integrity of the process of localization in CT and treatment rooms. If a technique for motion management is used, treatment delivery must be evaluated in a manner consistent with clinical use.

The individual components of the SBRT process (imaging, localization, treatment delivery, etc.) each have associated error. However, even if each of these individual errors are small by themselves, cumulative system accuracy for the procedure can be significant and needs to be characterized through an end-to-end test using phantoms with measurement detectors and imaging. The best way to accomplish this is to employ a test that uses the image guidance system to position a phantom with internal fiducial markers at isocenter then and image those markers with the treatment beam. This test demonstrates the agreement between the image-guidance system's positioning and beam delivery at isocenter. 252,253 The phantom should be positioned with known error and then the IGRT system is used to correct them. A simulation CT scan of the phantom is used to position the fields that irradiate the targets in the phantom. In situations where it is not easy to take an image with a detector behind the phantom, an alternative such as radiochromic film within the

Source	Purpose	Proposed test	Reported achievable tolerance	Proposed frequency
Ryu <i>et al.</i> . 2001² Ryu <i>et al.</i> . 2001³	End-to-end localization accuracy Intrafraction targeting variability	Sterco x ray/DRR fusion Sterco x ray/DRR fusion	1.0 to 1.2 mm root mean square 0.2 mm average, 1.5 mm maximem	Initial commissioning and annually thereafter Daily (during treatment)
Verellen et al., 2003 <sup>h</sup>	End-to-end localization accuracy	Hidden target (using stereo x ray/DRR fusion)	0.41 ± 0.92 mm	Initial commissioning and annually thereafter
Verellen et al., 2003 <sup>5</sup>	End-to-end localization accuracy	Hidden target (using implanted fiducials)	0.28 ± 0.36 mm	Initial commissioning and annually thereafter
Yu et al., 2004	End-to-end localization accuracy	Dosimetric assessment of hidden target (using implanted fiducials)	0.68 ± 0.29 mm	Initial commissioning and annually thereafter
Sharpe et al., 2006 <sup>3</sup>	CBCT mechanical stability Overall positioning accounted	Constancy comparison to MV imaging isocenter (using hidden targets)	0.50±0.5 mm	Baseline at commissioning and monthly thereafter
Galvin <i>et al.</i> , 2008° Palta <i>et al.</i> , 2008'	including image registration (frame-based systems) MLC accuracy	Winston-Lutz test modified to make use of the in-room imaging systems Light field. radiographic film, or EPID	<2 mm for multiple couch angles<0.5 mm (especially for IMRT delivery)	Initial commissioning and monthly thereafter Annually
Solberg et al., 2008*	End-to-end localization accuracy	Hidden target in anthropomorphic phantom	1.10 ± 0.42 mm	Initial commissioning and annually thereafter
Jiang et al., 2008 <sup>h</sup> Bissonnette et al., 2008 <sup>l</sup>	CBCT geometric accuracy	Phantoms with cyclical motion Portal image vs CBCT image isocenter coincidence	N/A ±2 mm	N/A daily

\*Reference 159.

\*Reference 170.

\*Reference 263.

\*Reference 262.

\*Reference 241.

\*Reference 264.

\*Reference 264.

\*Reference 264.

\*Reference 264.

phantom may be used. Moving phantoms can be employed to simulate respiratory motion effects. Multiple fiducial markers placed in the test phantoms can be used to evaluate rotational errors when investigating six degree-of-freedom tables.

Finally, it should be recognized that system accuracies determined from well-defined targets in idealized phantom geometries represent only the upper limit of targeting accuracy for ideal conditions. The actual patient targeting accuracy will likely suffer from pervasive dynamic conditions at patient setup as well as decreased image quality with the patient anatomy. Therefore, treatment-specific and patientspecific QA procedures should be established to govern both the treatment planning and delivery process as a whole as well as to provide sanity checks of the setup for individual patient fractions. The former would include institutional protocols for imaging, segmentation, normal tissue dose constraints, dose coverage criteria, motion suppression and tracking strategies, treatment verification, and treatment documentation. Patient-specific quality control would include procedures for validation of treatment plans, data integrity, beam configuration, patient setup and target localization (including specific action levels that would trigger a review of patient setup), and patient safety.

#### VII.C. Patient safety and the medical physicist

There are several patient safety issues that must be addressed on an ongoing basis in a SBRT program. These include verification of correct patient; correct patient plan; corisocenter; correct and properly configured immobilization devices; collision with patient or patient accessories; interference of patient arm, elbow, chin or accessories with the beam; redundancy check with MV orthogonal port films in addition to more sophisticated image guidance; treatment plan verification with second MU calculation or measurements; pretreatment verification of appropriate treatment machine parameters and accessories including lasers; monitoring for patient movement during treatment, etc. The large intrafractional doses delivered in SBRT mean that a mistake in any of these steps could easily lead to patient harm, and would be difficult to compensate for in subsequent fractions.

Recommendation: For these reasons, it is recommended that at least one qualified physicist be present from the beginning to end of the first treatment fraction. For subsequent fractions, it is recommended that a qualified physicist be available (e.g., in his office or available by pager and within minutes of the machine), particularly for patient setup in order to verify immobilization, imaging, registration, gating, and setup correction. It is important that the radiation therapist be well-trained in SBRT procedures. It is also recommended that a radiation oncologist approve the result of the image guidance and verify the port films before every fraction of the SBRT treatment.

## VII.D. Quality process improvement: Vigilance in the error reduction process in the treatment planning and delivery process

The complexity, variation in individual practice patterns, and continued evolution of SBRT-related technology can render a static, prescriptive QA paradigm insufficient over time.

Recommendation: A vital component of any comprehensive QA strategy should be to regularly review existing QA procedures with the objective to assess and critique the current QA practice in the context of current and proposed equipment. For some institutions, it may be useful to introduce tools which have proved effective in systems engineering, such as formalized process mapping and fault analysis. 254

#### **VIII. FUTURE DIRECTIONS**

While the development of SBRT has made great strides, many issues remain investigational, and there is clearly room for future research and development. This Task Group recommends in particular the following areas for future investigation:

- Incorporation of strategies for the adaptive conformation of treatment fields. These may include deformable image segmentation and registration strategies, probabilitybased dose distribution optimization that can predict tissue response over time.
- Incorporation of bioeffect knowledge into the treatment process.
- (3) Incorporation of improvements in small-field dosimetry performance in clinical treatment planning systems.
- (4) Incorporation of strategies for adjuvant chemotherapies in patients undergoing SBRT and timing radiation therapy and chemotherapy in a way that can enhance the tumoricidal effect.
- (5) Incorporation of molecular imaging and its applications for enhanced tumor identification, predictive oncology, and as a metric for treatment effectiveness.
- (6) Incorporation of (residual) tumor-motion effects into the treatment planning and the methods of evaluation for the delivered SBRT dose to a dynamic target.
- (7) Volumetric modulated are therapy to deliver conformal SBRT doses while substantially shortening delivery times.
- (8) Proton and heavy ion therapies which can take advantage of minimal or no exit dose and a potentially lower integral dose.

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### Original Contribution

## CT SIMULATOR: A NEW 3-D PLANNING AND SIMULATING SYSTEM FOR RADIOTHERAPY: PART 1. DESCRIPTION OF SYSTEM

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A real time CT-linked 3-D treatment planning system, called a CT simulator, has been developed. The basic system consists of a CT scanner, a multi-image display component, a treatment planning device with real time visual optimization, and a laser beam projecting component. All the components are connected on line. The system can be conveniently used for 3-D planning and simulation for radiation therapy within a reasonably short period of time.

CT simulator, 3-D treatment planning system.

#### INTRODUCTION

For many years the x-ray simulator has provided diagnostic images that aid in the choice of beam parameters and in the design of irregularly shaped fields in radiotherapy treatment planning. Although the images of the x-ray simulator are extremely useful, they lack sufficient density discrimination to distinguish soft tissue structures. With computed tomography (CT), accurate reproduction of cross-sectional anatomy is possible at multiple levels (6). Moreover, CT scanning coupled with computerized treatment planning (a) improves the outcome of radiation treatment through accurate localization of the tumor and normal structures and (b) increases the accuracy of dose calculations by utilizing the tissue density and attenuation coefficients (1, 11). Several systems that incorporate CT directly into 3-dimensional (3-D) simulation have been developed (1, 2, 3, 4, 9, 13, 14). The promise of CT-based radiotherapy treatment design, however, remains unfulfilled mainly because of the failure of the community to integrate the CT scanner into the treatment design process as mentioned by Sherouse et al. (14). We have recently developed a real time CT-linked 3-D treatment planning system called a CT simulator, in which all components are on-line and controlled from one work station. This

paper describes the hardware and the software of the CT simulator.

#### METHODS AND RESULTS

Hardware configuration and functions of the CT simulator

The basic functions of the CT simulator are CT scanning, dose calculation, simulation, and optimization for treatment planning. The configuration of the CT simulator is divided into five parts:

- 1. CT gantry/Couch/x-ray control;
- 2. CT operator console;
- Multi-image display console with data recording devices;
- 4. Treatment planning console with CT image processor:
- 5. Laser beam projecting device.

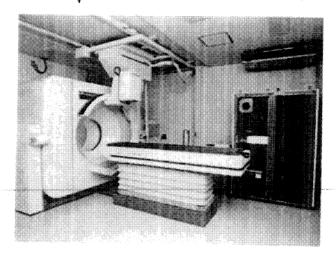
Figures 1a and 1b show the overview of the CT simulator, and Figures 2a and 2b show the block diagrams of the multi-image display console and the treatment planning console.

CT component

The basic hardware of the CT component was developed from a diagnostic CT device\*. The aperture is 60

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Reprint requests to: Takehiro Nishidai. Accepted for publication 9 August 1989. \* Shimadzu 2500T.



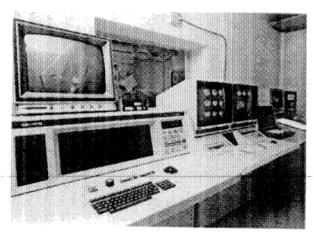


Fig. 1. (a) The CT and Laser beam projecting components in our scanning room (left). (b) The overview of our control room with a CT operator console, a multi-image display console, and the treatment planning console (right).

cm and the maximum reconstructed diameter is set at 40 cm. The x-ray tube has a 1500 kHU for obtaining multiple scanning images within a short period of time. A-P, lateral scannograms (scoutviews) and multiple CT section imagings of up to 30 slices are obtained for the 3-D treatment planning within less than 15 minutes. The patient couch is flat as is the treatment machine.

#### Multi-image display component

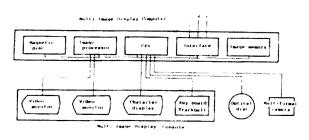
The multi-image display (MID) console has two 20-inch monitors for displaying multiple CT images and scannograms. The MID console is also equipped with controllers of a multi-format camera and of an optical disc for recording images and storing planning data. Two scannograms and multiple CT images of up to 12 slices are displayed immediately after each scanning on the monitors. The results of treatment planning also can be observed and confirmed on multiple images, which are scrolled on the screens for observation (Figs. 3a + b). The reconstructed outlines of beams with dose distribution

curves of the selected transverse section images, that is, 2-D multiple images are mentally integrated into the 3-D planning by an operator.

#### Treatment planning component

The treatment planning component<sup>†</sup> with a CT image processor (CTIP)<sup>‡</sup> is the main part of the planning system. The treatment planning console has a character monitor, a 14-inch color monitor, a graphic pen, and an optimization unit with a potentiometer (12). The CTIP operates as part of the treatment planning component and as an interface of the MID and treatment planning computers (Figs. 2a + b). The scanning data are sent to the MID computer and, at same time, to the treatment planning computer with CTIP's interface. Each pixel of the CT slice is replaced by electron density for the dose calculation, and the patient's outline is drawn by the CTIP computer before the image indication on the color monitor.

The treatment planning component has many new functions: (a) fast visual optimization of treatment plan-



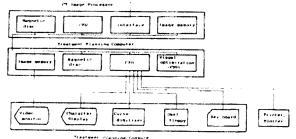
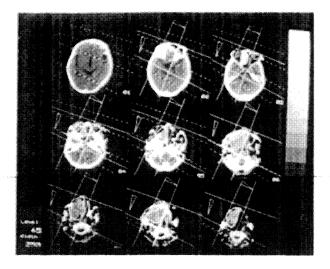


Fig. 2. (a) The block diagram of the multi-image display console with data recording devices: c and d indicate where to connect to the CT console, and to the laser beam projector (left). (b) The block diagram of the treatment planning console with CT image processor (right).

<sup>1</sup> NEC THERAC-2300.

<sup>\*</sup> NEC EWS-4800.



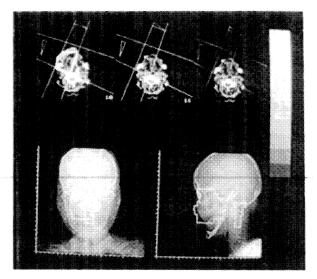


Fig. 3. (a) Dose distributions and the field indication on multi CT images. The radiation field and iso-dose curves are indicated by solid lines, the block localization is indicated by broken lines, and the wedge filters are indicated by triangles (left). (b) Dose distribution and the field indication on multi CT images and two scannograms (right).

ning (12); (b) fast reconstruction of beam's eye view of outlines of target and important organs; (c) fast reconstruction of 3-D dose calculation; (d) reconstruction of images of oblique slice; (e) reconstruction of beam's eye views, simulation images.

On the color monitor, the contours of target and important organs, which must be excluded from the radiation fields, are marked on CT slices by the graphic pen immediately after each scanning. The outlines of target and important organs are then shown on multiple CT images and scannograms on the large monitors of the MID console. The 3-D indication of the target and important organs thus can be finished at the end of CT scanning.

Using the 3-D information of the target and tissues, treatment beam localization for any type of irradiation can be quickly searched. With the fast visual optimization unit of the treatment planning component, three processes—(a) setting of beam parameters (portal number, gantry angle, field size, etc), (b) calculation of 2-D dose distributions on the slice of beam center and (c) display dose distribution curves—are automatically repeated every 0.8 second by operating the potentiometer on the color monitor as described elsewhere (12). The outlines of the target and important organs can also be reconstructed in a 3-D beam's eye view (Fig. 4). Using this view, beam parameters are re-checked, and the block localization can be set. They can be immediately confirmed over the multiple CT images (Fig. 3a), and modified using the graphic pen. These parameter sets are repeated to obtain suitable beams.

Moreover, the treatment planning device calculates the 3-D dose distribution with heterogeneity correction by a modified equivalent tissue maximum ratio (TMR) method on any slice of interest within about 10 seconds (Fig. 5). The method is modified from the equivalent tissue

air ratio (TAR) method of Sontag and Cunningham (15, 16). The method of 3-D heterogeneous compensation together with irregular field shape calculation also uses the "ring" method (7); it takes advantage of the concept of quasirandom number for speed-up of the 3-D calculation (8).

The planning results are confirmed on reconstructed oblique slice images. The oblique slice images of any direction, such as the edge of the beam, are reconstructed from data of multiple CT images in a few seconds by the treatment planning device. The planning results with the dose distribution are thus confirmed on these reconstructed images for 3-D treatment planning (Fig. 6). The reconstructed simulation image, beam's eye view, with the same geometry as that of the treatment machine is

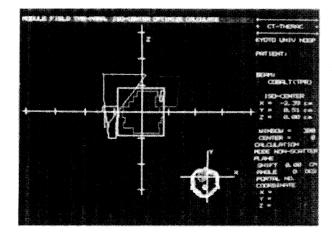
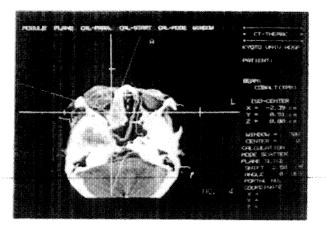


Fig. 4. Real-time visual search and optimization of radiation field. The reconstructed beam's eye view, outline of the target, the spinal cord and the lens, the radiation field, and the block for normal lens are indicated by colored lines.



1. J. Radiation Oncology 

Biology 

Physics

Fig. 5. Dose distribution. The blocked normal lens can be confirmed.

also obtained from multi-slice CT images within a few minutes (Fig. 7). The simulation image can be used to confirm the accuracy of the treatment by comparing it with the portal check film.

#### Laser beam projection

Goitein et al. (5) were the first to use an optical scanner in simulating treatment with CT data. The present projecting component is also an optical device that accurately irradiates and scans a laser beam and draws any figure on the patient's skin surface in accordance with the planning results. The laser beam projector is moved on a C-shaped arm attached to the ceiling of the CT scanning room (Fig. 8). The laser beam projector locates the beam center, field size, block localization, and treatment positioning on the patient's skin surface in accordance with the planning result (Fig. 9). The accuracy of beam positioning using the laser beam projector is less than 3 mm.

#### The treatment planning sequence

Treatment planning with the CT simulator, called CT simulation, starts after pre-planning which is designed us-

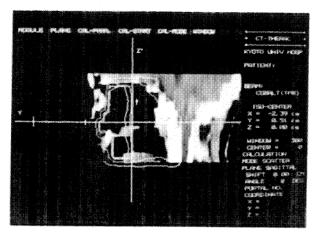


Fig. 6. Dose distribution on the reconstructed sagittal slice image. The spinal cord is recognized to be out of the field.

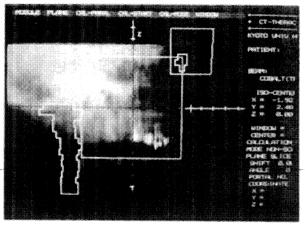


Fig. 7. The simulation image (beam's eye view) of lateral portal from 290°. It was reconstructed with a 1.0 cm interval slice.

ing information from clinical examinations, operating findings, and results of other investigations such as radiographs with or without contrast, scintigrams, ultrasound, MRI, and CT scans. The time sequence is divided into the following four steps.

1. Initial preparations. As the first step of CT simulation, the initial preparation is done at the CT operator console. The optimal conditions for CT scanning are selected here. After the patient is accurately positioned, the CT examination center is marked on the patient's skin surface using laser beams from three directions, the walls,

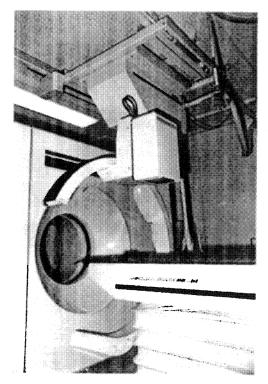


Fig. 8. The laser beam projector.



Fig. 9. The laser beam projection.

and the ceiling. Suitable immobilization devices are used, if necessary.

- 2. CT scanning and target indication. Next, anterioposterior and lateral scannograms and multiple CT slices over the tumor-bearing region are taken at 0.5-1.0 cm intervals. During CT scanning, the contours of the target and important organs are drawn with the graphic pen on each CT image on the color monitor of the treatment planning part, and they are immediately superimposed and observed on scannograms and multi-CT images of two large monitors of the MID console. The 3-D indication of the target and important organs can be finished at the end of the CT scanning.
- 3. Dose calculation and optimization. While viewing this 3-D target information on the two large monitors, preliminary beam fields and parameters can be quickly searched with the fast visual optimization unit (12) and they can be modified with a 3-D reconstructed field. The field and blocked localization can be confirmed on multi-images of MID monitors.

After the preliminary optimization, more accurate calculation of the 3-D dose distribution is performed on some slices with 3-D heterogeneity correction by the modified TMR method. These results are also confirmed in real-time on multi images on two large monitors. After the preliminary optimization and the 3-D dose calculation, the oblique slice images with dose distribution curves and simulation images can be reconstructed.

4. Marking the planning results. The last step consists of marking the beam center, field size, block localization,

and patient positioning using a computer-controlled laser beam projector. Tracing the lines with a pen, the planning results can be marked on the patient's skin surface.

5. Duration of the CT simulation. On the design of the software, the initial preparation needs about 5 minutes, and the second step of the planning by CT scanning and 3-D target indication takes about 10 to 15 minutes for 30 CT slices. The dose calculation and optimization takes about 10 to 15 minutes, and the laser beam projection needs 5 minutes. Thus, this CT simulator has the ability to complete 3-D planning and simulation within about 30 to 40 minutes.

#### DISCUSSION

The CT simulator was developed to be conveniently operated by a radiotherapist, not a medical physicist or technician, because the operations involve determining the outlines of target and important organs, and optimizing the planning results.

CT simulation should be started after the pre-planning to attain the short period of planning time. In more than half of the CT simulations in our hospital, planning was finished within 30-40 minutes. However, some CT simulation needed more time especially for setting suitable beams. If necessary, patients can leave the CT couch after scanning, provided that the coordinates of the planning have been marked on their skin.

The CT simulator uses up to 30 slices, but Lichter et al. (10) reported that the optimal number of CT scans is 40 to 60 without pause. The present limitation of the CT simulator mainly depends upon the abilities of the CT scanner and computers of the treatment planning component. An optical CT scanner and computers for CT simulation will be needed in the future.

It is easy to keep the coordinate during CT simulation by combination of each part. However, more care is needed for the reproduction accuracy of the coordinate from the CT simulator to the treatment machine the same as conventional x-ray simulators.

#### SUMMARY

A real-time CT-linked treatment planning system, called the CT simulator, has been developed. This new CT simulator is useful for 3-D planning and simulation for radiation therapy within a reasonably short period of time. The CT simulator is a useful and practical system for 3-dimensional treatment planning in routine clinical use.

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- Sherouse, G. W.: Mosher, C. E.; Novins, K.: Roseman, J.: Chaney, E. W. Virtual simulation: concept and implementation. In: Bruinvis, I. A. D., van der Giessen, P. H., van Kleffens, H. J., Wittkamper, F. H., eds. The use of computers in radiation therapy. The Netherlands: Elsevier Science Publishers B.V.; 1987:433-436.
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- Sontag, M. C.: Cunningham, J. R. Clinical application of a CT based treatment planning system. Comp. Tomog. 2: 117-130; 1978.

## Attachment D: Curriculum Vitae of Key Personnel

# CURRICULUM VITAE MIKE HAROLD SUMMERER, MD, MS, CPE, FACPE December, 2010

#### Address:

169 Bradford Walk New Britain, CT 06053 Phone: 860 505 0789

Specialties:

Cardiovascular Disease

Administrative Medicine

#### **Employment History:**

Hospital Director John Dempsey Hospital Assistant Dean for Education University of Connecticut Health Center Farmington, CT

System Vice President, Chief Medical Officer Hallmark Health Systems

Melrose, MA

Corp. Senior Vice President, Chief Medical Officer

Saint Vincent's Medical Center

Bridgeport, CT

Senior Vice President, Chief Medical Officer Bronson Healthcare Group Kalamazoo, MI

Chief Medical Officer, Senior Vice President, Health Services Delivery

Bronson Healthcare Group

Kalamazoo, MI

Vice President for Medical Affairs Bronson Methodist Hospital

Kalamazoo, MI

Cardiologist

Cardiology Associates of

West Michigan Kalamazoo, MI January 2009 - present

December 2004 - October 2007

November 2000 - November 2004

March 1998 - October 2000

May 1995 - March 1998

April 1993 - April 1995

July 1982 - March 1993

#### **Education:**

University of Connecticut B.A. with Honors in Physics	1969 - 1973
University of Connecticut, School of Medicine M.D.	1973 - 1977
Akron General Medical Center, Akron, Ohio Residency in Internal Medicine	1977 - 1980
Indiana University Medical Center Fellowship in Cardiovascular Disease	1980 - 1982
University of Wisconsin, Madison Masters Degree in Administrative Medicine	1993 - 1995

#### Academic Honors:

B.A. with Honors in Physics University of Connecticut	1973
Named to Phi Beta Kappa, Sigma Pi Sigma	
Chief Medical Resident Akron General Medical Center, Akron, Ohio	1979 - 1980
Fellow, American College of Cardiology	1984
Fellow, American College of Physicians	1988

2005

#### **Credentials:**

Licensed to practice medicine in Connecticut

Fellow, American College of Physician Executives

Board Certified, Internal Medicine, 1980

Board Certified, Cardiovascular Diseases, 1983

Certification as Physician Executive, 1999

#### **Academic Appointments:**

#### Administrative Appointments:

Assistant Clinical Professor Department of Medicine College of Human Medicine Michigan State University 1982-1993 Medical Director Cardiovascular Service Line Bronson Methodist Hospital January - December 1990

#### Offices Held:

Chief of Medicine Elect, Medicine Section, Bronson Methodist Hospital, 1988 - 1990

Chief of Medicine, Medicine Section, Bronson Methodist Hospital, 1990 - 1992

President, Kalamazoo Chapter, American Heart Association of Michigan, 1990 - 1991

Board Member, Kalamazoo Chapter, American Heart Association of Michigan, 1997 - 2000

Board Member, MSU/Kalamazoo Center for Medical Studies, 1993 - 2000

Board Chair, MSU/Kalamazoo Center for Medical Studies, 1997 - 1998, 1999-2000

Board Member, VNS of Connecticut, 2001 - 2004

#### Memberships:

American College of Physicians
American College of Physician Executives
Healthcare Roundtable for Chief Medical Officers, 1996 – 2000, 2005-2007
Chief Medical Officer Forum, Wharton School, University of Pennsylvania 1999

## PUBLICATIONS --- MIKE H. SUMMERER, M.D. Articles:

- 1. Hee-Myung Park, M.D., Mike H. Summerer, M.D., Kevin Preuss, M.D., William F. Armstrong, M.D., FACC, Yousuf Mahomed, M.D., David J. Hamilton, M.D., Anomalous Drainage of the Right Superior Vena Cava Into the Left Atrium. JACC Vol. 2, No. 2, August 1983, pgs. 358-362.
- 2. Hee-Myung Park, M.D., Mike H. Summerer, M.D., Kevin Preuss, M.D., William F. Armstrong, M.D., FACC, Yousuf Mahomed, M.D., David J. Hamilton, M.D., Reply letter. JACC Vol. 3, No. 2, February 1984, pg. 467.
- 3. Charles P. Taliercio, M.D., Jae K. Oh, M.D., Mike H. Summerer, M.D., Charles F. Butler, M.D., PhD, and Gordon K. Danielson, M.D. "Traumatic Left Ventricular False Aneurysm with Significant Regurgitation from Left Ventricular Outflow Tract to Left Atrium: Delineation by Two-Dimensional and Color Flow Doppler Echocardiography." Journal of the American Society of Echocardiography, 1988; 1:354-8.
- 4. Paul P. Antonecchia, MD, MBA, Teresa Kryspin, MD, MBA, FACP, Mike Summerer, MD, MS, FACC, CPE. "Turning Data into Information: The Cost of Making Diamonds from Coal." The Physician Executive, September-October 2003.

#### Abstracts:

- 1. The Response of Human Platelets to Hypotonic Stress: Direct Measurement of Volume Change.

  Authors: Summerer, M. H., Genco, P. V., Katz, A. J., Source: Ann Clin Lab Sci 1978 Nov-Dec; 8(6): 447-52.
- Dissecting Aortic Hematoma (aneurysm) Arising from the Coronary Cusp (Sinus of Valsalva)
   Authors: Summerer, M.H., Wunderly, D.J., Proceedings of the Research Day Activities of SMAHEC, June 1987.

### John M. Biancamano, CPA, MBA

39 Hayrake Drive Wethersfield, CT 06109

860-529-5318

jbiancamano@uchc.edu

#### **EXPERIENCE**

## UNIVERSITY OF CONNECTICUT HEALTH CENTER JOHN DEMPSEY HOSPITAL, FARMINGTON, CT

2008 - Present

**CHIEF FINANCIAL OFFICER** 

Responsible for all financial areas of the Health Center, School of Dental Medicine, School of Medicine,
 John Dempsey Hospital and UConn Medical Group.

## HARTFORD HEALTH CARE CORPORATION, HARTFORD, CT HARTFORD HOSPITAL, HARTFORD, CT

1990 - 2008

VICE PRESIDENT, FINANCE AND ADMINISTRATION, TREASURER And CHIEF FINANCIAL OFFICER

- Managed a balance sheet that has \$1.3 billion is assets with only \$200,000 in liabilities.
- Directed the investment program for \$500 million of endowment funds and \$600 million of pension assets, achieving long term results in the top quartile.
- Implemented synthetic refinancing of \$68 million of debt, saving interest cost of \$2 million.
- Developed the program for compliance with applicable portions of Sarbanes-Oxley.
- Collaborate with Human Resources to create a self insured health plan for the corporation. The annual savings on health care costs are \$3 million.
- Achieved an increase of 50% (\$11 million) in hospital based physicians collections and profitability, through education, information sharing and goal setting.
- Restructured the management team of an outpatient laboratory subsidiary resulting in a \$5 million turnaround in profitability.
- Operationalized a captive insurance company, insuring wholly owned hospitals and private attending physicians.

#### **MOUNT SINAI HOSPITAL, HARTFORD CT**

1984 - 1990

VICE PRESIDENT AND CHIEF FINANCIAL OFFICE AND TREASURER, 1988 VICE PRESIDENT AND CHIEF FINANCIAL OFFICER, 1984-1988

#### **ERNST & YOUNG, HARTFORD CT**

1970 - 1984

SENIOR HEALTHCARE AUDIT MANAGER

#### **EDUCATION**

UNIVERSITY OF CONNECTICUT – MASTERS OF BUSINESS ADMINISTRATION – 1988 UNIVERSITY OF CONNECTICUT – BACHELOR OF SCIENCE –BUSINESS ADMINISTRATION, ACCOUNTING 1970

#### **OTHER**

- CONNECTICUT HEALTH AND EDUCATIONAL FACILITIES AUTHORITY BOARD MEMBER FINANCE & AUDIT COMMITTEE, HUMAN RESOURCES COMMITTEE
- CONNECTICUT HOSPITAL ASSOCIATION COMMITTEE ON FINANCE
- HEALTHCARE FINANCIAL MANAGEMENT ASSOCIATION
- AMERICAN INSTITUTE OF CPA's
- CONNECTICUT SOCIETY OF CPA's
- CERTIFIED PUBLIC ACCOUNTANT, STATE OF CONNECTICUT 1974

#### **CURRICULUM VITAE**

Robert J. Dowsett, M.D.

Date of Birth: 5/17/58

**Home Address:** 4 Langley Park

Farmington, CT 06032

860-676-8284

Office Address: Department of Radiation Oncology

University of Connecticut Health Center

263 Farmington Ave.

Farmington, CT 06030-2930

860-679-3225 FAX: 860-679-1309

Department of Radiation Oncology

Hartford Hospital 80 Seymour Street Hartford, CT 06102

860-545-2803 FAX: 860-545-1500

Education:

1976-80 B.S. - University of Connecticut

Chemical Engineering/Materials Engineering

Summa Cum Laude

1980-84 M.D. - University of Connecticut

#### Postgraduate Training:

1984-85	Intern in Medicine, University of Connecticut Health Center
1985-87	Resident in Medicine, University of Connecticut Health Center
1987-88	Chief Resident in Medicine, University of Connecticut Health Center
1988-90	Resident in Radiation Oncology, University of Pennsylvania
1990-91	Chief Resident in Radiation Oncology, University of Pennsylvania

#### Faculty Appointments:

1987-88 Instructor of Medicine, Department of Medicine, University of

Connecticut School of Medicine

1991-Present Clinical Assistant Professor, Department of Diagnostic Imaging and

Therapeutics, University of Connecticut School of Medicine

1998-Present Division Chief, Radiation Oncology, Department of Diagnostic Imaging

and Therapeutics, University of Connecticut Health Center

#### **Specialty Certification:**

1987 American Board of Internal Medicine

1992 American College of Radiology, Radiation Oncology

<u>Licensure</u>: Connecticut

#### Awards:

1979	University of Connecticut, Alumni Scholar
1979	University of Connecticut, University Scholar
1987	University of Connecticut Health Center
	John Boylan Award for Excellence in Ambulatory Care Delivery
1990	American Cancer Society Clinical Oncology Fellowship

#### Membership in Professional and Scientific Societies:

American College of Radiology
American Society for Therapeutic Radiology and Oncology
American Society of Clinical Oncology
American Brachytherapy Society
Connecticut State Medical Society
Hartford County Medical Association

#### Committee and Administrative Services:

Radiation Safety Committee, University of Connecticut Health Center, 1991-Present Quality Assurance Committee, Division of Radiation Oncology, University of Connecticut Health Center, 1991-Present

Tumor Board Committee, University of Connecticut Health Center, 1991-Present Cancer Care Committee, University of Connecticut Health Center, 1997-Present Institutional Safety and Environmental Health Committee, University of Connecticut Health Center, 1992-2002

School of Medicine Council, University of Connecticut Health Center, 1997-2000 Capital Area Program for Clinical Oncology Research, 1992-1998 Clinical Cancer Committee, University of Connecticut Health Center, 1991-1994 Medical Affairs Committee, Greater Hartford Unit, American Cancer Society, 1994 Medical Board Committee, University of Connecticut Health Center, 1995-1996 Breast Cancer Coordinating Committee, Greater Hartford Unit, American Cancer Society, 1994-1995

Oncology Curriculum Development Committee, University of Connecticut School of Medicine, 1994-1997

#### **Invited Lectures**:

- "Radiotherapeutic Effects on the Mandible", Third Annual Head and Neck Cancer Symposium, University of Connecticut Health Center 11/91
- "Radiation Therapy in Gynecologic Malignancies", Obstetrics and Gynecology Grand Rounds, University of Connecticut Health Center 11/91
- "Radiotherapy as Definitive Treatment of Prostate Cancer", Prostate Public Forum, University of Connecticut Health Center 4/92
- "Radiation Therapy in Early Stage Breast Cancer", Medical Grand Rounds, Hartford Hospital (Hartford, CT) 8/92
- "Organ Preservation in Head and Neck Cancer", Contemporary Issues in Head and Neck Cancer, University of Connecticut Health Center 11/92
- "Management of the Clinically Negative Neck", Contemporary Issues in Head and Neck Cancer, University of Connecticut Health Center 12/92
- "Issues in Oncology/Radiotherapeutic Management", Controversies in Surgery Postgraduate Course, University of Connecticut Health Center 2/93
- "Oral Cavity and Oropharynx Tumors: Radiotherapeutic Results and Complications", Department of Oral Surgery, University of Connecticut Health Center 6/94
- "Radiotherapeutic Management of Clinically Negative Nodal Areas in Breast and Head and Neck Cancers", Controversies in Surgery Postgraduate Course, University of Connecticut Health Center 3/95
- "Radiotherapeutic Management of Locally Recurrent Rectal Cancer", Controversies in Surgery Postgraduate Course, University of Connecticut Health Center 2/96
- "Radiotherapeutic Management of Head and Neck Tumors: Techniques, Results and Complications", Department of Oral Surgery, University of Connecticut Health Center 3/96
- "Radiotherapy: Radiobiologic, Physical and Clinical Principles", University of Connecticut School of Medicine Oncology Course 2/97
- "Radiotherapy: Radiobiologic, Physical and Clinical Principles", University of Connecticut School of Medicine Oncology Course 2/98
- "Stereotactic Radiosurgery and Radiotherapy", University of Connecticut Health Center Cancer Symposium 5/98
- "Radiotherapeutic Management of Cervix Cancer", Department of Gynecology Combined Rounds, Hartford Hospital/University of Connecticut Health Center - 1/99
- "Radiotherapeutic Management of Head and Neck Tumors: Techniques, Results and Complications", Department of Oral Surgery, University of Connecticut Health Center 1/99
- "Radiotherapy: Radiobiologic, Physical and Clinical Principles", University of Connecticut School of Medicine Oncology Course 2/99
- "Prostate Cancer: Radiotherapy Treatment Alternatives", University of Connecticut Health Center Discovery Series 6/99.
- "Stereotactic Radiosurgery and Radiotherapy Techniques, Indications and Results", Middlesex Memorial Hospital Tumor Conference (Middletown, CT) 9/99.

#### <u>Invited Lectures</u> (continued):

"Radiotherapy: Radiobiologic, Physical and Clinical Principles", University of Connecticut School of Medicine Oncology Course - 2/00.

-4-

"Advances in the Radiotherapeutic Management of Brain Tumors", Management of Brain Tumors in 2000 and Beyond (Farmington, CT) - 4/00.

"Focused Radiaton Techniques", American Cancer Society Symposium (West Hartford, CT) – 10/00

"Radiotherapeutic Management of Cervix Cancer", Department of Gynecology Combined Rounds, Hartford Hospital/University of Connecticut Health Center - 12/00

"Radiotherapy: Radiobiologic, Physical and Clinical Principles", University of Connecticut School of Medicine Oncology Course - 2/01

"Radiotherapy: Radiobiologic, Physical and Clinical Principles", University of Connecticut School of Medicine Oncology Course - 2/02

"Radiotherapy: Radiobiologic, Physical and Clinical Principles", University of Connecticut School of Medicine Oncology Course - 2/03

"Innovative Systems: Multidisciplinary Approaches" (Moderator), University of Connecticut Health Center Cancer Symposium - 10/03

"Radiotherapy: Radiobiologic, Physical and Clinical Principles", University of Connecticut School of Medicine Oncology Course - 2/04

"Radiotherapy: Radiobiologic, Physical and Clinical Principles", University of Connecticut School of Medicine Oncology Course - 2/05

"Radiotherapy: Radiobiologic, Physical and Clinical Principles", University of Connecticut School of Medicine Oncology Course - 2/06

"Radiotherapy: Radiobiologic, Physical and Clinical Principles", University of Connecticut School of Medicine Oncology Course - 2/07

"Advances in External Beam Radiotherapy: Prostate Cancer", University of Connecticut Health Center Discovery Series – 11/07.

"Radiotherapy: Radiobiologic, Physical and Clinical Principles", University of Connecticut School of Medicine Oncology Course - 2/08

"IMRT/IGRT: The Evolution of External Beam Techniques in Prostate Cancer",

Urology Grand Rounds, University of Connecticut Health Center - 5/08

"Radiotherapy in the Treatment of Prostate Cancer", University of Connecticut Health Center Discovery Series -9/08

"Focal Radiation Techniques in the Treatment of Pituitary Adenomas", Endocrine Grand Rounds, University of Connecticut Health Center  $-\,11/08$ 

"Radiotherapy: Radiobiologic, Physical and Clinical Principles", University of Connecticut School of Medicine Oncology Course - 2/09

"Radiotherapy in the Treatment of Breast Cancer", Medical Grand Rounds, University of Connecticut Health Center – 5/09

"Accelerated Partial Breast Irradiation (APBI)", University of Connecticut Health Center Discovery Series – 10/09

"Radiotherapy: Radiobiologic, Physical and Clinical Principles", University of Connecticut School of Medicine Oncology Course - 2/10

Curriculum Vitae

-5-

Robert J. Dowsett, M.D.

#### Invited Lectures (continued):

"Head and Neck Cancer Radiation Induced Mucositis", University of Connecticut Cancer Center Transitional Research Forum – 11/10

"Radiotherapy: Radiobiologic, Physical and Clinical Principles", University of Connecticut School of Medicine Oncology Course - 2/11

"Radiotherapy Options for the Treatment of Prostate Cancer", University of Connecticut Health Center Discovery Series – 5/11

"Radiotherapy: Radiobiologic, Physical and Clinical Principles", University of Connecticut School of Medicine Oncology Course - 2/12

#### Bibliography:

#### Original Papers:

Dowsett, R.J., Wong, R.L., Robert, N.J., Abeles, M.: Dermatomyositis and Hodgkin's Disease: Case Report and Review of the Literature. Am. J. Medicine 80:719-723;1986.

Dowsett, R.J., Fowble, B., Sergott, R.C., Savino, P.J., Bosley, T.M., Snyder, P.J., Gennarelli, T.A.: Results of Radiotherapy in the Treatment of Acromegaly: Lack of Ophthalmologic Complications. Int. J. Radiat. Oncol. Biol. Phys. 19:453-459;1990.

Dowsett, R.J., Fowble, B.: Radiotherapy in Acromegaly: Low risk of CNS Complications. (Correspondence). New England Journal of Medicine 323(9):612;1990.

Dowsett, R.J., Galvin, J.M., Cheng, E., et al.: Contouring Structures for 3-Dimensional Treatment Planning. Int. J. Radiat. Oncol. Biol. Phys. 22:1083-1088;1992.

Kahn, A.M., Spiro, J., Dowsett, R.J., Greenberg, B.R.: Sequential Chemotherapy and Radiotherapy for Organ Preservation in Advanced Resectable Non-Laryngeal Head and Neck Cancer. Am. J. Clinical Oncology 22(4):403-407;1999.

Voynov, G., Kaufman, S., Hong, T., Pinkerton, A., Simon, R., Dowsett, R.: Treatment of Recurrent Gliomas with Stereotactic Intensity Modulated Radiation Therapy. American J. Clinical Oncology. Am. J. Clinical Oncology 25(6):606-611;2002.

Dowsett, R., Kurtzman, S.: Commentary - Partial Breast Irradiation (PBI) following conservative surgery for breast carcinoma. Journal of Surgical Oncology 80(3):129;2002.

Taxel, P., Fall, P., Albertsen, P., Dowsett, R., Trahiotis, M., Zimmerman, J., Ohannessian, C., Raisz, L.: The Effect of Micronized Estradiol on Bone Turnover and Calciotrophic Hormones in Older Men Receiving Hormonal Suppression Therapy for Prostate Cancer. Journal of Clinical Endrocrinology and Metabolism 87(11):4907-4913;2002.

Curriculum Vitae

-6-

Robert J. Dowsett, M.D.

#### Original Papers (continued):

Boxer, R., Kenney, A., Dowsett, R., Taxel, P.: The Effect of 6 Months of Androgen Deprivation Therapy on Muscle and Fat Mass in Older Men with Localized Prostate Cancer. The Aging Male 8(3/4):207-212:2005.

Rowe, B., Weiner, R., Foster, J., Dowsett, R.: Yttrium Microspheres for Nonresectable Liver Cancer: The University of Connecticut Health Center Experience. Connecticut Medicine 71(9):523-528:2007.

#### Abstracts:

Dowsett,R.J., Fowble, B., Sergott, R.C., Savino, P.J., Bosley, T.M., Snyder, P.J., Gennarelli, T.A.: Results of Radiotherapy in the Treatment of Acromegaly: Recurrence Rates and Ophthalmologic Complications. Oral Presentation at the 31<sup>st</sup> Annual ASTRO Meeting, San Francisco, CA (10/1989). Int. J. Radiat. Oncol. Biol. Phys. 17(S):134;1989.

Dowsett, R.J., Galvin, J.M., Cheng, E., et al.: Contouring Structures for 3-Dimensional Treatment Planning. Oral Presentation at the 32<sup>nd</sup> Annual ASTRO Meeting, Miami, FL (10/1990). Int. J. Radiat. Oncol. Biol. Phys. 19(S):207;1990

Taxel, P., Albertsen, P., Dowsett, R., Fall, P., Trahiotis, M., Zimmerman, J., Raisz, L.: LHRH Analog Therapy Causes Early Bone Loss in Men Receiving Treatment for Prostate Cancer. Poster Presentation at the 23<sup>rd</sup> Annual Meeting of the American Society of Bone and Mineral Research, Phoenix, AZ (10/2001). JBMR 16:S217;2001.

Kaufman, S., Voynov, G., Hong, T., Pinkerton, A., Simon, R., Dowsett, R.: Intensity Modulation Radiation Therapy as an Adjunct to Surgery and External Beam Radiotherapy in the Treatment of Patients with Malignant Gliomas. Poster Presentation at the 43<sup>rd</sup> Annual ASTRO Meeting, San Francisco, CA (11/2001). Int. J. Radiat. Oncol. Biol. Phys. 51(3S):254;2001.

Vatner, R.E., Stook, K., Willard, M., Dowsett, R.: Dosimetric Comparison of Tomotherapy and Traditional Two-field Plans for Whole Abdominal Radiation Therapy. Poster Presentation at the 51<sup>st</sup> Annual ASTRO Meeting, Chicago, IL (11/2009). Int. J. Radiat. Oncol. Biol. Phys. 75(3S):379;2009.

#### Christopher D. James M.S., D.A.B.R. Home: 32 Cumberland Rd. / West Hartford, CT 06119

Work Phone: (860)679-3289 / FAX: (860)679-1309
Home Phone: (860)231-1961 / E-mail: JustCDJ@aol.com

Cell: (860)573-9614 / Work E-mail: cjames@uchc.edu

#### **Credentials**

#### American Board of Radiology,

Therapeutic Radiological Physics - 1986

#### Career Summary

Medical Physicist with substantial experience in all aspects of Therapeutic Radiological Physics, including facility and shielding design, licensing and registration; equipment selection, commissioning, maintenance and calibration; quality assurance procedures; external beam and brachytherapy dosimetry; low and high doserate remote afterloading techniques; prostate seed implants; radiation safety; teaching and staff supervision.

#### **Education**

B.S. Marquette University Physics Department, 1972
M.S. Marquette University Physics Department, 1977
Milwaukee, Wisconsin

#### Professional Experience

University of Connecticut Health Center Physicist – Radiation Oncology Dec, 2006 to Present

MidState Medical Center, Meriden CT Physicist – Radiation Oncology March, 2004 to December, 2006

Danbury Hospital, Danbury CT Chief Physicist April, 2003 to March, 2004

New Britain General Hospital, New Britain, CT Physicist – Radiation Oncology September, 1998 to April, 2003

University of Texas Southwestern Medical Center, Dallas, TX Faculty Associate, Clinical Support – Radiation Oncology July, 1997 to September, 1998

#### Professional Experience (cont.)

Harris Methodist Fort Worth/Klabzuba Cancer Center, Fort Worth, TX Director of Physics
March, 1995 to August, 1996

Texas Oncology P.A./Charles A. Sammons Cancer Center at Baylor University Medical Center, Dallas, TX Chief Physicist August, 1994 to March 1995

Baylor Medical Center, Dallas: Chief Physicist - Radiation Safety Officer August, 1988 to August, 1994 Staff Physicist - Radiation Therapy November, 1986 to August, 1988

St. Joseph's Hospital, Milwaukee, WI Assistant Clinical Radiation Physicist January, 1981 to October, 1986

Milwaukee County Medical Complex, Milwaukee, WI Health Physics Technician January, 1978 to January, 1981

#### Teaching Experience

Baylor Medical Center School of Radiation Therapy Technology Classes in mathematics, radiation dosimetry, radionuclides. Laboratory on practical aspects of quality assurance.

St. Joseph's Hospital School of Radiation Therapy Classes in mathematics, radiobiology and radiation protection. Tutoring in physics and related subjects. General inservice lectures for hospital staff as required.

Milwaukee County Medical Complex Radiation safety classes for authorized users, hospital staff, and students in radiation therapy and nuclear medicine technology.

Marquette University Graduate School - Teaching Assistant General physics instruction in laboratory and quiz sections and individualized tutoring.

#### Societies and Honors

American Association of Physicists in Medicine Connecticut Area Medical Physics Society (Secretary 2003-2005, President 2006) National Science Foundation Traineeship, 1973-1974 Marquette University Competitive Scholarship, 1968-1970 Sigma Pi Sigma

#### **Publications**

- Benefits of a Fifty-Inch Focal Film Distance: Kebart, R.C., James, C.D. Conference of the Americas, American Society of Radiologic Technologists, Albuquerque, June, 1991. Quantitative Computed Tomography: Wilson, C.R., James, C., Voltz, D.J.
  - Proc. Fourth International Conference on Bone Measurement (Abstract: Am. J. Roentgenol, 131:548, Sept. 1978).
- <u>Ouantitative Computed Tomographic Bone Mineral Measurement:</u> Wilson, C.R., Voltz, D.J., James, C. Fifth International Conf on Medical Physics, Jerusalem, Aug.1979
- Bioassay Procedures for Radioiodine in a Large Medical Complex: James, C., Wilson, C.R. Health Physics Society Annual Meeting, Philadelphia, July, 1979.
- <u>Clearance of Calcium Pyrophosphate Dihydrate (CPPD):</u> McCarty, D.J., Palmer, D.W., James, C.D.
- Galvanomagnetic Effects in II-VI Semiconductors Hall Effect: James, C.D. Masters Thesis, May, 1977.

#### **Presentations**

- <u>Implementing Tomotherapy in the Clinical Setting:</u> Conneticut Area Medical Physics Society Meeting, Fall, 2009
- Shielding Design / Simulator QA / Linac Design and Operation: Texas Department of Health, Department of Radiation Control 1995-1996
- <u>Radioactive Iodine 131 Therapy Treatments:</u> North Texas Society of Nuclear Medicine Technologists, Annual Meeting, Dallas, Winter, 1993.
- Physics and Dosimetry Requirements for Protocol Participation: American Society of Radiological Technologists, Annual Meeting, Washington D.C., November 6, 1991 (50min.)
- <u>Benefits of a Fifty-Inch Focal Film Distance:</u> Kebart, R.C., James, C.D. Conference of the Americas, American Society of Radiologic Technologists, Albuquerque, June, 1991.
- <u>Just Compensation:</u> Texas Society of Radiologic Technologists, Annual Meeting, Dallas, April, 1990. (90min.)
- <u>Total Skin Electron Treatments:</u> North Texas Society of Radiologic Technologists, Mid-Year Meeting, Dallas, November, 1989.
- <u>Ouality Assurance/Quality Control in Radiation Therapy:</u> Texas Society of Radiologic Technologists, Annual Meeting, Dallas, April, 1988. (90min.)
- <u>Treatment Preparation: The Measurement Process:</u> North Texas Society of Radiologic Technologists, Local Chapter, Dallas, April, 1986. (30min.)

Tel: (860) 523-1988 home Tel: (860) 679-4360 work E-mail: <u>britinga@comcast.net</u>

# **Karen Stook**

### **Experience**

2004-present

**UCONN Health Center** 

Farmington, CT

#### **Chief Dosimetrist**

- Skilled in computerized treatment planning ( ADAC Pinnacle and Tomotherapy Hi-Art)
- Senior member of stereotactic R.T. program.
- · Senior member of IMRT program.
- Wrote in-house program for image guided radiation therapy using fiducial markers.
- · Administrates record/verify system (Multi-Access).
- Manages department clinical operations.
- Participates in computer network interfacing for billing/ scheduling.
- Responsible for charge code standardization
- · Participates in cost-accounting procedures.
- · Responsible for budgetary planning within the department
- Responsible for annual evaluations of all staff in department.
- Responsible for co-ordination of site design, implementation and installation of Tomotherapy Hi-Art System.
- Participates in strategic planning for department
- Responsible for co-ordination of site design, implementation and installation of Nucletron HDR System.

N.B. Work experience at UCONN dates back to 2000, functioning as an outsourced employee from Hartford Hospital.

1999-2004

Hartford Hospital Group

Hartford, CT.

#### **Medical Dosimetrist**

- Skilled in computerized treatment planning (ROCS and Theraplan).
- Assisted with charge code standardization.
- Took interim responsibilities for prostate brachytherapy program.
- Converted brachytherapy source data to NIST standards for MMS system.
- Taught dosimetry staff prostate brachytherapy planning.
- · Active member of stereotactic R.T. program.
- · Active member of IMRT initiation program.

1997-1999 University Community Hospital Tampa, FL.

#### **Medical Dosimetrist**

- Assisted in beam data entry for CMS FOCUS treatment planning system.
   Duties included beam scanning import and beam modeling.
- Implemented 3D-treatment planning.
- Active member of prostate brachytherapy program (MMS).
- Responsible for HDR brachytherapy program (Nucletron).
- Responsible for charge structure charges captured increased by 65% since participation.

1990-1997 Florida Oncology Group Eustis, FL.

### Senior Medical Dosimetrist/Physics Associate

- Skilled in computerized treatment planning (ROCS, GE Target, ADAC)
- Supervised dosimetry services for 5 centers.
- Implemented HDR brachytherapy programs (Nucletron).
- Devised QA programs.
- Responsible for interpretation and implementation of physics charges.
- Assisted with brachytherapy and external beam calibration procedures (Varian Linacs, Nucletron HDR systems).
- Assisted with commissioning of Varian Linac.
- Assisted with beam scanning and data modeling (Varian Linac).
- · Composed policies/procedures, job descriptions and evaluation forms.
- Wrote in-house programs for calculation verification. (External beam and HDR brachytherapy)
- Responsible for prostate brachytherapy programs.

1980-1990 Florida Hospitals Orlando, FL.

### **Medical Dosimetrist/Protocol Dosimetrist**

- · Skilled in computerized treatment planning.
- Supervised all dosimetry participation in national research protocols (RTOG).
- Implemented prostate brachytherapy program.

1979-1980 Orlando Regional Med. Ctr. Orlando, FL.

**Radiation Therapist** 

1977-1979 Radiology Associates P.C. Macon, GA.

**Medical Dosimetrist** 

1976-1977 Cancer Therapy/Research Ctr. San Antonio, TX.

**Radiation Therapist** 

#### **Education**

2010- Pursuing MSHSA from New England College. Anticipated graduation May, 2012.

1973-1976 Sheffield College of Radiography, Sheffield, U.K.

D.C.R.T. Therapeutic Radiography. BS equivalence

verified by ECE.

1989 Medical Dosimetrists. Certification Board U.S.A.

C.M.D

#### **Professional Affiliations**

· Active member of AAMD.

Annual Meeting Co-Chair 2007-2009
Recording Secretary, AAMD. 1998-2000

• President, AAMD. 1990-1991

Past-president board member AAMD 1992-1994

 AAMD Liaison to ACR and ASTRO committees in Radiation Therapy 1994-1997

· Served on various committees and task groups.

• AAMD Liaison to NRC 2003-2004

 Clinical and Technical Instructor for Radiation Therapy Technology Program, University of Central Florida 1980's

· Previous Author for Distance Learning Project, Stanford, CA.

Interests Golf, Scuba Diving, Snow-skiing, Reading and Gardening.

# Attachment E: Hospital License

### STATE OF CONNECTICUT

# **Department of Public Health**

#### LICENSE

#### License No. 0065

# **General Hospital**

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

University of Connecticut Health Center-John Dempsey Hospital of Farmington, CT, d/b/a John Dempsey Hospital of the University of Connecticut Health Center is hereby licensed to maintain and operate a General Hospital.

John Dempsey Hospital of the University of Connecticut Health Center is located at 263 Farmington Avenue, Farmington, CT 06032

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

20 Bassinets

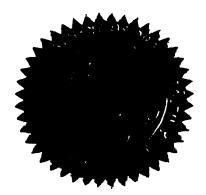
204 General Hospital beds

This license expires December 31, 2012 and may be revoked for cause at any time.

Dated at Hartford, Connecticut, January 1, 2011. RENEWAL.

Satellites

10 Talcott Notch, 10 Talcott Notch, Parmington, CT



J Robert Holin MD, MAN, MBA

J. Robert Galvin, MD, MPH, MBA, Commissioner

# Attachment F: Vendor Quote

# PHILIPS HEALTHCARE A division of Philips Electronics North America Corporation 22100 Bothell Everett Highway P.O. Box 3003 Bothell, Washington 98041-3003



Quotation #: 1-TY6NSD **Rev: 10** Effective From: 08-Aug-12 To: 22-Sep-12 Presented To: Presented By: Tel: (800) 833-3316 Fax: (845) 429-1138 UNIV OF CONNECTICUT HEALTH CENTER JOHN Stephen lametti Account Manager DEMSEY HOSP 263 FARMINGTON AVE Randal Herring Tel: (800) 833-3316 **FARMINGTON, CT 06030-1948** Regional Manager Fax: Tel: Alternate Address: Date Printed: 08-Aug-12 Submit Orders To: 22100 BOTHELL EVERETT HWY **BOTHELL WA 98021** Fax:(425) 458-0390

The Service information contained in this Quote is subject to a separate service proposal.

This quotation contains confidential and proprietary information of Philips Healthcare, a division of Philips Electronics North America Corporation ("Philips") and is intended for use only by the customer whose name appears on this quotation. It may not be disclosed to third parties without the prior written consent of Philips.

IMPORTANT NOTICE: Health care providers are reminded that if the transactions herein include or involve a loan or discount (including a rebate or other price reduction), they must fully and accurately report such loan or discount on cost reports or other applicable reports or claims for payment submitted under any federal or state health care program, including but not limited to Medicare and Medicaid, such as may be required by state or federal law, including but not limited to 42 CFR 1001.952(h).

Quotation #: 1-TY6NSD

Rev.: 10

	Quote Solution	Summary	
Line #	Product	Qty	<u>Price</u>
	100017 Brilliance CT Big Bore Oncology Systems	1	\$675,332.16
		Equipment Total:	\$675,332,16

Solution S	Summary	y Detail		
Product	<u>Qty</u>	<u>Each</u>	Monthly	Price
100017 Brilliance CT Big Bore Oncology Systems	1	\$675,332.16		\$675,332.16

SVC0931 Support \$6,679.75

The Service information contained in this Quote is subject to a separate service proposal.

Buying Group: NO CONTRACT Con

Contract #: NONE

Addt'l Terms:

Each Quotation solution will reference a specific Buying Group/Contract Number representing an agreement containing discounts, fees and any specific terms and conditions which will apply to that single quoted solution. If no Buying Group/Contract Number is shown, Philips' Terms and Conditions of Sale will apply to the quoted solution.

Each equipment system listed on purchase order/orders represents a separate and distinct financial transaction. We understand and agree that each transaction is to be individually billed and paid.

**Payment** 

10% With Signed Acceptance of the Quotation, 70% Upon Delivery of Major Components, 20% Due When the Product is Available for First Patient Use, Net due 10 days from receipt of invoice

Quotation #: 1-TY6NSD Rev.: 10 Page 2 of 43

System Type:

New

Freight Terms:

erms: FOB Destination

Warranty Terms:

Part numbers beginning with two (2) asterisks (\*\*) are covered by a System 12 Months Warranty. All other part numbers

are third (3rd) party items.

**Special Notations:** 

Contingencies must be removed 120 days before scheduled shipment to assure delivery on specified date.

Any rigging costs are the responsibility of the Purchaser.

Additional Terms:

Line # Part # Description Qty Each Price

1 \*\*NNAC612 Brilliance CT, Big Bore 1 \$537,741.20 \$537,741.20 Oncology

Brilliance CT systems are powered not only by intelligent technologies inside, but also by stunning advances in how people can interact with the systems from the outside. Both are critical in handling the large amounts of data provided by multi-slice imaging - and in helping achieve a sustainable competitive advantage.

The Brilliance CT Big Bore Oncology configuration incorporates the 85 cm large bore and 60 cm true scan field of view as well as the heavy-duty technologies throughout, making this configuration ideal for oncology where patient positioning and accuracy are especially critical. This configuration is also ideal for dual use environments.

#### **Highlights**

- · 85 cm bore size and 60 cm scan field of view
- 16-slices per revolution for large volumes and thin slices -- exam, after exam.
- Philips MRC X-ray tube with legendary reliability and nearly instantaneous cooling.
- RapidView The fast reconstruction system keeps pace with acquisition for true real-time imaging.
- DoseWise design delivers optimal dose efficiency, without compromising image quality.
- Brilliance Workspace user environment improves productivity by working the way the user does
- Logical Guided Flow prompts the user through the scanning and visualization processes.
- · ScanTools and ScanTools Pro to optimize productivity, workflow, and diagnostic confidence.

The flexibility of this high performance scanner includes features designed to automate clinical exams, ease through reconstruction and post-processing, and aid in accuracy of diagnoses. Above all, the speed and usability of the Brilliance CT Big Bore oncology configuration positively impacts everyday workflow and increases patient throughput throughout the entire workflow process.

- · Patient handling and setup
- · Scan and image acquisition
- Dose management
- Reconstruction and display
- Post-processing and communication

Philips has created a comprehensive package of Brilliance CT ScanTools containing advanced components and productivity features that make workflow smooth and easy. From start to finish, they provide everything necessary to streamline routine imaging studies.

Scan Tools Pro is a supplemental set of tools that improve productivity, workflow, and diagnostic confidence even further. Scan Tools Pro includes features like DICOM Modality Worklist, Split

Quotation #: 1-TY6NSD

**Rev.:** 10

Line # Part #

Description

Qtv

Each

Price

Study, Prefetch Study, Automatic Procedure Selection, Bolus Tracking, Spiral Auto Start, Organ ID, CD Writer, and Dual Monitor Configurations.

#### **CT User Environment**

Brilliance Workspace

The Brilliance Workspace user environment is flexible and available wherever it is needed. Designed in collaboration between Philips and its customers, it is a powerful set of CT applications that improves productivity by working the way a user does. Users can do all of their planning, scanning, visualization and archiving in a simple, easy-to-use graphical user interface (GUI) that is harmonized across Philips Healthcare.

#### **Guided Flow**

Logical Guided Flow graphical user interface increases productivity through ease-of-use features:

- Features and functions are visible, not hidden.
- Most common operations are shown most prominently.

A top-level workflow bar directs the user along important tasks and provides non-linear movement between functions without losing any current work. This provides the user with maximum flexibility for viewing, performing applications, filming or reporting.

#### Patient handling and setup

Philips' "Design for Life" approach provides high levels of flexibility for users and comfort for patients. Philips helps improve productivity during patient handling and setup through a variety of features, making patients more comfortable and making technologists' jobs easier.

#### Gantry

Scan Control Panel

Controls and displays for gantry tilt, patient couch elevation and stroke are located on both sides of the gantry.

#### Scan Control Box (ScanTools)

Gantry and patient couch controls and displays are located conveniently at the operator's console. Additional functions include emergency stop, intercom, and scan enable/pause buttons.

Gantry Aperture: 850 mm diameter

Gantry Tilt:

-30° to +30°; 0.5° increments.

#### AutoVoice (ScanTools)

A standard set of commands for patient communication: before, during and after scanning.

#### Multi-lingual AutoVoice (ScanTools)

Commands for patient communication in multiple languages including: English, French, Spanish, Italian, Japanese, Hebrew, Arabic, Russian and Georgian. Also provides the ability to record customized messages - up to 25 seconds per message.

Intercom System: Two-way intercom allows patient monitoring and communication.

#### **Table (Bariatric Patient Support)**

The Brilliance Bariatric Patient Support is designed to meet the CT imaging needs of the growing bariatric (morbidly obese) population. Allowing for patient loads of up to 295kg (650 lbs.), the

Quotation #: 1-TY6NSD

**Rev.:** 10

Page 4 of 43

Line # Part #

Description

Qty

Each

Price

Bariatric Patient Support provides CT imaging access to a larger patient population than current offerings.

#### Patient Support Specifications:

Longitudinal motion:

Stroke:

1907 mm

Maximum surview length:

1800 mm

Maximum axial scan length:

1860 mm

Maximum helical scan length:

1730 mm

Speed:

0.5 to 100 mm/sec

Position accuracy:

±0.25 mm

Vertical motion:

Range:

579 to 1012 mm (+/-3mm); 1.0 mm inc.

Table load capacity:

295 kg (650 lbs)

Floating tabletop:

Carbon-fiber table top with foot pedal and handrail control for easy

positioning and quick release.

#### Brilliance Therapy Tabletop Kit:

A comprehensive patient positioning system, the Brilliance Therapy Tabletop Kit is designed to enhance treatment effectiveness and ensure maximum clinical efficiency. Featuring Indexed Immobilization tm (trademark of Varian Medical Systems Inc), patient setup time is reduced and positioning for subsequent scans and treatment is easily duplicated. The Therapy Tabletop supports immobilization accessories that deliver the precision required for conformal and stereotactic procedures. These accessories significantly enhance positioning accuracy and patient comfort. The indexed surface allows the positioning system to be locked into place according to the treatment plan's specifications.

The kit includes the Therapy Tabletop, Phantom Holder, water level phantom, and laser calibration bar phantom with two Lok bars necessary for proper use of the laser calibration phantom. The Phantom Holder fits over the Therapy Tabletop, allowing the user to run calibrations with the QA phantom while the Therapy Tabletop is still attached.

#### Scan Planning

The Brilliance Workspace provides intuitive registration and easy entry of patient information and clinical procedure selection, using anatomic graphical display and sample images.

Expert Protocol Planning (ScanTools)

Tailor protocols to meet specific needs via a selection of parameters optimized for certain studies.

Quotation #: 1-TY6NSD

**Rev.:** 10

Page 5 of 43

Line # Part #

Description

Otv

Each

Price

Preset Post-processing (ScanTools)

User-defined presets improve workflow, by automatically opening the relevant post-processing applications for a specific type of exam. For example, automatically launching CTA studies in MIP or spine studies in MPR.

#### Surview Plan

Planning via interactive mouse control of multiple, independent acquisition series of any type on Surview image

Scan length: up to 1800mm Scan width: 600 mm

Dual Surview Planning (ScanTools)

Planning patient scans with two surviews provides flexibility in exam planning and execution, and also avoids repeat scans.

#### Multi Surview Planning (ScanTools)

Requested by radiation oncology users where patient positioning and alignment is critical, Multi Surview allows user to repeat the AP and LAT surviews until satisfied that their patient is properly aligned on the table top.

#### Manual Scan

Places slice-by-slice scans under operator control with on-line or off-line reconstruction, background image archiving to local or remote storage devices. At any time, the operator is able to switch from automatic to manual scan and back.

#### Automatic Scan

Enables automatic execution of pre-planned studies, with concurrent, on-line or off-line reconstruction, background image archiving to local or remote storage devices, without operator intervention.

#### **Productivity Tools**

QuickSetup (ScanTools)

System utilities such as quality assurance tools and service functions are readily available with a single mouse click.

#### DICOM® Modality Worklist (ScanTools Pro)

Provides HIS/RIS interface through DICOM Modality Worklist service class; enhances clinical workflow by importing patient demographics and study information from an information management system.

#### **DICOM® MPPS**

Provides performed exam information (start/end/info) to HIS/RIS using DICOM MPPS (Modality Performed Procedure Step) service.

#### Split Study (ScanTools Pro)

Many times multiple orders or accession numbers are generated for a patient's CT scan that require only a single scan acquisition. In these instances Philips' Split Study feature allows the user to virtually split the acquisition so that proper accession numbers are assigned to specific areas of the scan acquisition (i.e. chest slices to the chest accession number, etc.) and billing and tracking is completed accurately and appropriately. By assigning the accession numbers quickly and easily during scan setup, scan information is matched accurately in all subsequent steps (matching, reporting, archiving, billing, etc.). Philips' Split Study reduces error and improves workflow efficiency.

Quotation #: 1-TY6NSD

**Rev.:** 10

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Quotation #: 1-TY6NSD

**Rev.:** 10

Page 5 of 43

# Line # Part # Description

Each

Price

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Quotation #: 1-TY6NSD

**Rev.:** 10

Line # Part #

Description

Qty

Each

Price

Prefetch Study (ScanTools Pro)

This feature searches the database (PACS) for previous patient studies (CT, MR, CR, RF). After location and selection, these studies are then sent to the background of the configurable destination (e.g., Extended Brilliance Workspace).

Automatic Procedure Selection (ScanTools Pro)

Maps the procedure selection from the HIS-RIS with individual scan protocol(s) from the Brilliance CT scanners, simplifying the

cess. Only the most relevant scan protocol(s) for any requested procedure are shown to the user, ensuring that only the desired scanning procedures are performed. This is especially useful for infrequent users of the CT scanner.

#### Scan and image acquisition

Reliable, maximized system performance allows clinicians to remain focused on patient care. Brilliance CT is perfectly balanced, combining power and flexibility that maximizes image quality, speed and throughput while lowering patient dose.

System: Rotate-rotate architecture with optimized geometry for low dose imaging.

#### Generator

The Brilliance generator uses modern, low-voltage slip ring technology to provide a constant high voltage to the CT x-ray tube assembly.

Output capacity: 60 kW

kV selections: 90, 120, 140 kVp mA selections: 20 to 500 mA

#### MRC X-ray Tube

The exceptional heat management demands of multislice imaging calls for an exceptional tube. With its patented spiral groove bearing design, Philips' MRC tube dissipates heat as rapidly as it is collected, with an effective heat storage capacity far superior to a conventional ball bearing design.

- Virtually motion-free focal spot guarantees optimized image quality.
- · Noiseless design calms patients.
- 2nd generation of MRC tube technology built on proven record of performance and reliability

Equivalent Heat Storage Capacity: 26 MHU

Anode storage capacity:

8.0 MHU

Maximum cooling rate:

1608 kHU/min

Focal spot (IEC):

0.5 mm x 1.0 mm (small) 1.0 mm x 1.0 mm (large)

#### Dynamic Focal Spot (ScanTools)

Dynamic Focal Spot (DFS) doubles the data sampling density from the detectors in axial and spiral scanning.

#### Detector

Detector design is fundamental to the objective of acquiring high quality images while minimizing patient dose. Unlike single matrix detectors that simply sum elements, Philips designs configuration-specific detectors that minimize the separation between elements to always provide

Quotation #: 1-TY6NSD

**Rev.:** 10

Page 7 of 43

Line # Part #

Description

Qtv

Each

Price

the highest geometric detector efficiency. Direct-to-digital signal conversion with TACH technology reduces dose and improves image quality.

Material:

Solid State - GOS

Slip Ring:

Optical - 2.5Gbps transfer rate

Slice Collimation: 16 x 0.75mm, 16 x 1.5mm, 8 x 3.0mm, 4 x 4.56mm, 2 x 0.612mm

Image Quality **Spatial Resolution** 

High mode:

16 lp/cm @ cut-off

Standard mode:

13 lp/cm @ cut-off

Noise:

0.27% measured on Philips system phantom (21.6 cm water equivalent)

Low Contrast Resolution: 4.0 mm @ 0.3% as measured on the 32cm CATPHAN phantom

Absorption Range:

-1024 to +3071 Hounsfield units

Scanning Modes Spiral Scanning

- Multiple contiguous slices acquired simultaneously with continuous table movement during
- Multiple, bi-directional acquisitions

Spiral exposure: Up to 120 sec. of uninterrupted spiral scanning

Spiral pitch: 0.0413 to 1.7 (user selectable)

#### **Axial Scanning**

- Multiple-slice scan with up to 16 contiguous slices acquired simultaneously with incremental table movement between scans
- Fused modes for reconstructing partial volume artifacts free thick slices from thin slice acquisition

Scan Times

0.44, 0.5, 0.75, 1, 1.5, 2 seconds for full 360° scans

0.29, 0.33 seconds for partial angle 240° scans

Test Injection Bolus Timing (ScanTools)

This feature establishes the optimum delay time for contrast injection. By using a test injection, a real-time graph of the enhancement in the selected region of interest is displayed. The delay time is then selected to provide optimal peak contrast enhancement and reduced contrast usage - ideal for CTA.

Bolus Tracking (ScanTools Pro)

This automated injection planning technique permits the user to monitor actual contrast enhancement and initiate scanning at a pre-determined enhancement level. Combine with SAS for full automation and efficacy.

Spiral Auto Start (ScanTools Pro)

Spiral Auto Start integrates the injector with the scanner, allowing the technologist to monitor the contrast injection to check for extravasation, and to initiate and stop the scan (with the predetermined delay) while in the scan room.

Quotation #: 1-TY6NSD

**Rev.:** 10

Line # Part # Description Qty Each Price

NOTE: Costs to upgrade an approved injector and any cabling is the responsibility of the user. Compatible with following Injectors

Medrad Envision/Stellant, Medrad Vistron, Liebel-Flarsheim, Tyco CT 9000, Medtron CT 2, Nemoto Dual Shot, Tyco OptiVantage DH, E-Z-EM Empower, Swiss Medicare, Ulrich Injectors

#### **Dose Management**

Philips' DoseWise philosophy is a set of principles and practices that ensures the best possible outcomes with minimal risk to patients and staff. Brilliance CT systems employ a number of features that help provide extremely high dose efficiency.

DoseRight ACS (Automatic Current Selection) (ScanTools)- Optimizes the dose for each patient based on the planned scan by suggesting the lowest possible mAs settings to maintain constant image quality at low dose throughout the exam.

DoseRight D-DOM (Dynamic Dose Modulation) (ScanTools)- Automatically controls the tube current rotationally, increasing the signal over areas of higher attenuation (lateral) and decreasing signal over area of less attenuation (AP).

DoseRight Z-DOM (Longitudinal Dose Modulation) (ScanTools)- Automatically controls the tube current, adjusting the signal along the length of the scan, increasing the signal over regions of higher attenuation (shoulders, pelvis) and decreasing the signal over regions of less attenuation (neck, legs).

#### Dose Displays

- Volume CTDI (CTDIvol) (ScanTools)
- Dose Length Product (DLP) (ScanTools)

#### Dedicated Pediatric Protocols (ScanTools)

Developed in collaboration with top children's hospitals, Brilliance age and weight-based infant and pediatric protocols ensure the best clinical results with minimal dose.

#### Dedicated Oncology Protocols (ScanTools)

Developed in collaboration with top cancer centers, dedicated oncology protocols provide simplicity for the CT sim therapist and ensure optimal clinical results.

#### **Reconstruction and Display**

RapidView 4D Reconstruction

RapidView 4D reconstruction is the result of years of advanced research, and was designed to remove the bottleneck between CT scan acquisition and image visualization. RapidView 4D provides dramatic improvements in multiphase Pulmonary Retrospective 4D imaging workflow by displaying reconstructed retrospective images in under 4 minutes. This performance will allow clinicians to evaluate tumor motion within the patient's allotted simulation time slot. The RapidView 4D system employs true cone beam reconstruction algorithms and Philips-patented back projection hardware to provide this impressive performance.

Cone Beam Reconstruction Algorithm- COBRA (ScanTools)

Philips patented Cone Beam Reconstruction Algorithm (COBRA) enables true three-dimensional data acquisition and reconstruction in spiral scanning. This avoids and/or corrects artifacts present in reconstruction by reducing pixel to noise ratio, resulting in superior multislice image quality.

Quotation #: 1-TY6NSD

**Rev.:** 10

Line # Part #

Description

Qty

Each

Price

#### Reconstruction Modes

Concurrent: Axial and spiral modes - image reconstruction concurrent with acquisition Off-Line (batch): Background image reconstruction of user-defined groups of raw data files with automatic image storage.

#### Evolving Reconstruction (ScanTools)

Provides real-time 256 x 256 matrix image reconstruction and display in step with spiral acquisition. Images can be modified for window width and level, zoom and pan prior to reconstruction. At the end of the acquisition, all images are updated with the desired viewing settings.

#### Add Reconstruction (ScanTools)

Enables quick and easy unplanned or modified reconstructions of part or all of the images prospectively or retrospectively planned.

#### Extended Display Field of View (pending clinical validation)

Enables extrapolated reconstruction for visualization of anatomy out to 70cm. Useful in radiation oncology for avoidance in treatment planning. Also may be useful for evaluating out of field artifacts, contouring skin, and bariatric or off-center scanning. Data outside of 60cm shall not be considered to be of diagnostic quality; CT numbers may not be accurate and image quality may be degraded in this region.

#### Reconstruction parameters

Any study can be set up to automatically reconstruct using various reconstruction parameters. Exams can be tailored online while planning the scan, or during off-line recon. Up to six different reconstruction assignments are possible for each study. Image reconstruction parameters include image matrix, filters, enhancements, zoom and pan, and archive.

#### Ultralmage (ScanTools)

Ultralmage includes proprietary pre- and post-processing hardware and software for enhanced visualization of soft tissue structures. Ultralmage significantly improves image quality for the most accurate representation of even the most difficult to image anatomic areas, such as the bone-brain-air interface in neurological exams. The full clinical impact of Ultralmage is best appreciated in the brain, long bones, spine, pelvis or shoulder, where subtle, soft tissue structures can be obscured by adjacent high contrast bone.

#### Adaptive Filtering

Adaptive filters reduce pattern noise (streaks) in non-homogenous bodies, improving overall image quality.

#### Post-processing and communication

#### Image Processing (ScanTools)

The interactive image viewer is designed for fast, efficient and simple image review and filming purposes. Images can be handled individually or in user-selected groups.

- Image viewer window: Displays a single image or a selection of images.
- Zoom & Pan: Magnification from 0.8 to 10 times
- · Scroll Bar, Leaf and Cine, Invert Image, Image Parameters Display

#### Organ ID (ScanTools Pro)

Automatically isolates lung images for better viewing, including lung limit detection, zoom and pan setting, lung windowing, image enhancement, and image filming.

Quotation #: 1-TY6NSD Rev.: 10 Page 10 of 43

Line # Part # Description Qty Each

#### Image Graphics (ScanTools)

To help interpret clinical images, a variety of text and graphic aids can be individually positioned and manipulated with the mouse:

- · Text annotation
- Cursors for pixel value measurements.
- Regions of Interest (ROI) elliptical, rectangular, curved or freehand, with instantaneous calculation and display of area, average pixel value and standard deviation. Values of several ROIs may be added or subtracted.
- Lines, grid and scales for distance measurements, curved and freehand lines for measuring any shape.
- Arrows for pointing to features.
- · Angle measurements.
- · Histogram of pixel values in a user-defined region of interest.
- · Profile of the pixel values along any line.
- · Grid with adjustable spacing for distance assessment

#### Window Control (ScanTools)

- Eight user-defined preset windows provide fast and convenient window setting. Mousedriven fine adjustments of the window center and width enable optimal image viewing
- Highlight Window: paints user-defined range of CT densities in color.
- Double Window: Simultaneous displays two independent CT density ranges on the same image, i.e. thorax slice with lung and mediastinum windows
- Invert Window: Ability to toggle between negative and positive image.

### **Host Computer**

Computer Architecture: Windows XP Dell Precision host computer Main Memory: 4.0 GB RAM

#### Display Monitor

Dual Monitor Configuration (ScanTools Pro)

Expands the Brilliance workspace by utilizing two flat panel monitors side-by-side. The left monitor is utilized for scanning operations while the right is used for post-processing activities. These high-resolution, flat panel LCD, color monitors save space and weight when compared to conventional CRT-based monitors.

#### Post-Processing Analysis Tools

SlabViewer (ScanTools)

MPR- Multiplanar Reformation (ScanTools)

Maximum or Minimum Intensity Projection (MIP) (ScanTools)

3-D SSD Reconstruction (ScanTools)

#### MasterCut (ScanTools)

With the MasterCut feature, MPR (Multiplanar Reformatting) curved cuts along vascular structures can be defined on Maximum Intensity Projection (MIP) or volume rendered images to display panoramic and cross-sectional views that accurately visualize the vasculature.

#### RelateSlice (ScanTools)

RelateSlice is a Philips-exclusive tool provided in Volume Rendering, 3-D SSD, MIP, and MPR, that correlates the axial image to a user-selected location on multiplanar views and renderings.

Quotation #: 1-TY6NSD Rev.: 10 Page 11 of 43

Price

#### Line # Part #

Description

Otv

Each

Price

RelateSlice makes it easy for a user to compare the axial image to its post-processed presentation, improving the user's productivity and diagnostic confidence.

#### Masterlook (ScanTools)

An automated real-time image enhancement, or smoothing, that can be defined for up to three independent density ranges, such as lung, soft tissue and bone.

#### 3-D Small Volume Analysis (ScanTools)

3-D Small Volume Analysis permits tumor or nodule characterization with respect to growth rates within the 3-D application. This tool uses automatic segmentation for help in identifying a solitary nodule or tumor (early staging of lung cancer), and measures volumetric parameters such as nodule volume, long axis, and short axis for follow-up purposes.

#### Q-CTA - Quantitative CT Measurement Tool Package (ScanTools)

Q-CTA is a tool kit for quantitative measurements of anatomic structures, such as vasculature pathology from 2-D, 3-D or volume-rendered images.

#### Volume Rendering (ScanTools)

Philips advanced volume rendering 3-D visualization software provides unique simultaneous visualization of vasculature, soft tissue and bone. Unlike conventional 3-D or MIP, volume-rendering visualization offers real time interactive control over opacity and transparency values. This permits viewing through and beyond surrounding structures, such as metallic stents and arterial calcifications, and virtually eliminates the need for organ segmentation.

#### Image Management and Archiving

Image archiving is organized according to the DICOM 3.0 hierarchical model, in a DICOM 3.0 compliant image format. Loss less image compression/decompression algorithm is used during image storage/retrieval to/from all local archives. Images can be auto-archived to selected archive media.

292 GB Hard Disk: Image Storage Capacity: 512 X 512 Image Matrix = 500,000 typical number of uncompressed images

#### **DVD-RAM**

DVD-RAM is an archive solution for storing CT and other modality datasets. It provides an inexpensive, reliable method for high-speed random access recording. DVD-RAM is intended as a storage replacement to the EOD and supports multi-session writing in order to store multiple patients added to the disk at different times. DVD-RAM disks are written with proprietary Philips format and are only readable on Philips EBW (v3.0.1 or higher) and CT scanner units (v2.3 or higher) with DVD-RAM.

4.7 GB DVD: Image Storage Capacity: 512 X 512 Image Matrix = 15,000 typical number of uncompressed images

#### CD Writer (ScanTools Pro)

A Compact Disk (CD) drive stores DICOM images plus DICOM image viewing software, on very low cost CD media. The CD Writer permits a standard PC with a built-in CD drive to view and perform basic manipulations (zoom, pan, and window level) on the DICOM images stored on the CD. This Brilliance enhancement provides a low cost and flexible alternative for archiving and retrieving images, copies for referring physicians, and to use in presentations and teaching.

 Minimum PC hardware Requirements are a Pentium III 450 MHz with 128 MB RAM main memory and a 20 GB Hard Drive running Microsoft Windows operating systems

Quotation #: 1-TY6NSD Rev.: 10 Page 12 of 43

Line # Part # Description Qty Each Price

 Supported Web Browsers which must be installed in Compact or Full mode include Microsoft Internet Explorer or Netscape installed with ActiveX Plug-in. Macintosh viewing support via the "Virtual PC" application.

CD: Image Storage Capacity: 512 X 512 Image Matrix = 1,200 typical number of uncompressed images

#### **Filming**

The Brilliance filming function allows the user to set up and store desired filming parameters. Prestored protocols can also include auto-filming. The operator can film immediately after each image, at the end of a series, or film after the end of a study and review images prior to print. The operator can also automatically film the study at three different windows and incorporate Combine Images functionality to manage large datasets. Basic monochrome and color DICOM Print capability are supported.

#### Networking/Connectivity

#### Network Requirements

Network connections should be located within 10 feet of the console. The Brilliance CT supports 10/100/1000Mbps (10/100/1000BaseT) network speeds. For optimal performance, Philips recommends a minimum of 100Mbps network speed (1Gbps preferred)and for the CT network to be segmented from the rest of the hospital network.

#### **DICOM Connectivity**

Brilliance Workspace's full implementation of the DICOM 3.0 communications protocol allows connectivity to DICOM 3.0 compliant scanners, workstations, and printers; supports IHE requirements for DICOM Connectivity.

#### Brilliance Tumor LOC

This Brilliance CT Tumor Localization package meets the clinical requirements of oncology departments where segmentationand localization can be completed directly on the CT display console. The package provides tools to assist in Isocenter localization and CT Simulation. In addition to standard studies, these tools are available for respiratory correlated studies, including all phase information. Visualization capabilities within the Tumor LOC package include the generation of Digitally Reconstructed Radiographs (DRR), Digitally Composited Radiographs (DCR), and Multiplanar reformatted images (MPR). Additionally, the package provides the ability to manage different window/level settings to aid in generating the best images possible. Special visualization tools for respiratory correlated scans are also included.

- Segmentation and localization.
- Efficient advanced contouring of external and critical structures in preparation for the radiotherapy treatment planning process.
- Visualization and analysis tools can be utilized to evaluate the treatment volume(s)
- Tools for visualizing and analyzing respiratory correlated datasets (4D)

This Brilliance CT Tumor Localization Package has been specially configured to:

 Provide additional Brilliance Big Bore Scanner display console functionality that allows for increased productivity and improved workflow by minimizing CT simulation time, and enhancing the patient marking process.

Brilliance CT Tumor LOC Basic Software License:

Features and capabilities provided by the Brilliance CT Tumor LOC software include:

Quotation #: 1-TY6NSD Rev.: 10 Page 13 of 43

Line # Part # Description Qty Each Price

Contour-Based Segmentation Package: Consists of drawing and editing tools for drawing contours and maintaining groups of contours used in hand segmenting image data. Tools also exist for interpolation functions for automatic and semi-automatic segmentation. Automated generation of an external contour can be preselected as a user defined preset.

Virtual Fluoroscopy using orthogonal beam divergent DRR's for isocenter and beam border placement.

Interpolate algorithm provides interactive, shape based interpolation. A Smart algorithm fills in any number of irregularly contoured slices, Interpolated contours may be edited, accepted or rejected.

#### Isocenter Management:

Isocenter menu to support and manage multiple isocenters. Supports the generation of separate isocenters for multiple target volumes or general regions. Marked and final Isocenters are reported and displayed in the Localization package for easy confirmation of a physical simulation session. A record of the simulation session may be printed on a standard printer. If configured, RT Plan can easily be exported to the laser system for a more streamlined marking procedure.

Isocenters and structure sets can be transmitted to a compatible RTP System capable of receiving DICOM RT structure set, plan, and RT Image.

2D Image Analysis: Enables viewing of the data exactly as it was acquired, prior to any interpolation and with no preprocessing.

Markers: Permits the display of a fixed marker (cross hairs, axis or grid) on the screen as an aid in isocenter marking, or image positioning.

Screen Annotation: Allows the operator to toggle selected screen annotations on and off. Archive: Allows the user to archive a patient study from disk onto selected archive media. Information: Displays the study's original scan information, including the number of slices in the study, slice thickness, etc. Can be displayed at any time during an analysis.

Control of Window/Level: Allows adjustment to achieve optimal viewing parameters.

Measurement Package: Provides the density value (in Hounsfield units if CT) of a particular point on an image. Computes distances along straight lines.

Pan: Permits the repositioning of any image within a viewport.

Tools to allow visualization of organ motion and to assist physician in determining best treatment are the following:

Import of multiple phase datasets as well as a routine CT

Contour on any phase and apply it to a chosen primary phase

Dynamic DRR/DCR Dynamic MPR & Axial

Maximum, minimum, and average intensity projection dataset generation

#### Pulmonary Toolkit for Oncology

The Pulmonary Toolkit for Oncology includes three different modes of operation and supports two respiratory sensor devices. Pulmonary Viewer is also included.

Prospective Axial enables the user to trigger an axial scan at a particular breath level (threshold). The clinical usefulness in diagnostic radiology is that it minimizes artifacts due to respiratory motion for those patients who are not able to hold their breath during the scan. In radiation oncology, the prospective axial dataset may be used for planning gated treatments. By matching the scan phase with the treatment phase the clinician can be assured of providing the CT simulation plan that delivers the highest tumorcidal dose while maximizing the amount of healthy tissue that is spared.

Quotation #: 1-TY6NSD Rev.: 10 Page 14 of 43

Line # Part # Description Qty Each Price

Prospective Spiral enables the user to visualize the breathing waveform and begin a spiral scan at a desired breath level. This mode is used in conjunction with breath-hold imaging (typically followed by breath-hold gated treatments).

Retrospective Spiral (4D CT) results in the ability to generate multiple phases allowing for visualization of motion during the respiratory cycle. This mode entails acquiring an over-sampled ultra low pitch spiral scan of the thorax or desired area, and correlating it in reconstruction with the patient's breathing. The resulting images can be used to assess motion of the tumor and critical organs, make decisions about gating the radiotherapy delivery, and delineate a target volume that encompasses the entire range of tumor motion.

In addition to conventional phase-based binning, the 4D CT mode also features TrueImage 4D Amplitude Binning. Amplitude Binning for 4D correlated imaging uses a proprietary algorithm that utilizes the amplitude of the respiratory signal in addition to phase information when creating retrospective 4D-CT volumes. This approach can help reduce artifacts and enhance image quality for 4D studies for patients with uneven breathing patterns. Amplitude Binning is compatible with the Philips Bellows and Varian RPM respiratory gating devices.

The Philips Bellows device is a pneumatic mechanism placed around the patient's chest for dynamically observing changes in pressure caused by respiratory motion via a transducer linked to the Brilliance CT scanner.

Another supported respiratory sensor is the Varian RPMTM, for which an interface cable is provided. The Varian RPMTM device itself is not included. The customer should contact their Varian Medical Systems representative to ensure their RPM configuration is correct for the Philips Brilliance CT. RPM 1.6 and 1.7 are compatible.

Pulmonary Viewer is a dedicated software package to aid the clinician in making radiation therapy treatment planning decisions. Pulmonary Viewer provides the ability to visualize one or multiple respiratory phases, analyze and determine extent of motion, and review the patient's respiratory waveform. The comprehensive set of user tools includes cine mode with adjustable speed for visualizing motion over time and interactive slab-MIP tools.

#### **CT Reporting**

Provides reporting capabilities for paper print of clinical results from the Philips Brilliance Workspace including display of key images and results frames. The report is available for paper or electronic distribution to referring physicians, patients, or for medical records. Each report is editable and new default templates can be easily created and included in the system configuration. The report can be saved as a PDF file for digital transfer or printed as a paper report.

The CT Reporting package includes all applications-specific reports when the application itself is purchased seperately

#### Siting information

Power Requirements

- 200/208/240/380/400/416/480/500 VAC at 100 kVA and 50/60Hz
- · Three-phase distribution source

Computer cabinet is included. Computer table and operator's chair are optional.

Clinical Education Program for Brilliance CT Big Bore Oncology Systems:

Quotation #: 1-TY6NSD Rev.: 10 Page 15 of 43

# 100017 Brilliance CT Big Bore Oncology Systems Line # Part # Description Qty Each Price

Essentials Off-Site Education: Philips will provide up to two (2) lead simulation therapists, as selected by customer, with in-depth lectures covering basic clinical applications, Philips-specific imaging techniques, protocol optimization and scan parameters. A Brilliance CT "system emulator" is used during the lab sessions to simulate all basic scanning operations without x-ray exposure. Students will graduate from this class with an 80% understanding of the base system functionality. The remaining 20% is covered during the Handover On-Site experience. This twenty-eight (28) hour class is located in Cleveland, Ohio, and is scheduled based on your equipment configuration, geography, and availability. Due to program updates, the number of class hours is subject to change without notice. Customer will be notified of current, total class hours at the time of registration. This class is a prerequisite to your equipment handover On-Site Education, and should be attended no earlier than two weeks prior to system installation. ASRT CEU credits may be available for each participant that meets the Guidelines provided by Philips during the scheduling process. Travel and lodging are not included, but may be purchased through Philips. It is highly recommended that 989801292078 (CT Full Travel Pkg. Off-Site) is purchased with all Off-Site courses.

Handover On-Site Education: Clinical Education Specialists will provide twenty-four (24) hours of education for up to three (3) dedicated Therapy staff members. This training will encompass all aspects of data acquisition for CT Simulation. Day 1 is reserved for acceptance testing and commissioning if required. ASRT CEU credits may be available if the participant meets the Philips Guidelines. Note: Site must be patient-ready. Philips personnel are not responsible for actual patient contact or operation of equipment during education sessions except to demonstrate proper equipment operation.

**Follow-Up On-Site Education:** Clinical Education Specialists will provide twenty-four (24) hours of education for up to three (3) dedicated Therapy staff members, selected by customer. This course covers Tumor LOC and Respiratory Correlated Imaging. Schedule patients based on Training Guidelines. CEU(s) are not available at this time. Note: Philips personnel are not responsible for actual patient contact or operation of equipment during education sessions except to demonstrate proper equipment operation.

#### It is highly recommended that 989801292077 (CT Cross Trainer) is purchased.

The above education entitlements expire one (1) year from System installation date (or purchase date if sold separately). Ref#: 234194080-100614

2	**NCTA485	Keyboard Language - English	1	\$0.00	\$0.00
3	**NCTA020 Operator's Ma • English		1	\$0.00	\$0.00
4	**NCTA170 Primary Use o Oncolo		1	\$0.00	\$0.00
5	**NCTD296	CT Simulation on Console	1	\$14,500.00	\$14,500.00

Quotation #: 1-TY6NSD Rev.: 10 Page 16 of 43

Line # Part # Description Qty Each Price

This application adds the capabilities to Tumor LOC to enable CT simulation on the scanner console. This can provide workflow flexibility and productivity in situations such as emergency simulations, "Sim and Treat", and simple simulation cases.

Simulation capabilities include:

- · Multiple radiotherapy machine characterizations
- · Visualization and analysis of multiple treatment beams
- · Beam modifiers such as blocking and MLC capabilities

Note: Tumor LOC is a prerequisite.

6 \*\*NCTD293 O-MAR 1

Metal Artifact Reduction for Orthopedic implants reduces artifacts in image data caused by high density metal objects such as prosthetic hip replacements. This artifact reduction may aid diagnosis and help treatment planning accuracy by enhancing visualization of critical structures and target volumes

\$0.00

\$0.00

Prerequisite: For installed base upgrades on Brilliance 64-Channel, Brilliance 64-Channel w/ Essence technology, iCT SP, and iCT, O-MAR requires iDose4 installed

7 \*\*NCTD372 LAP CARINAsim 3 red(Floor) 1 \$59,212.20 \$59,212.20

LAP DORADO 3 CT Simulation Laser System with three red movable lasers for identifying the isocenter location: One Ceiling-mounted Sagittal Laser, and two (Side) Lasers mounted on floor posts on each side of the patient support. The LAP laser system along with the CARINAsim software and control console completes the integration of Tumor L.O.C. CARINAsim software imports patient's surface, isocenter, MLC and field information, along with patient orientation and patient data to enable automatic movement of lasers to patient marking position. Includes installation and one year warranty from LAP.

Note: Transfer of isocenter position from Tumor LOC to CARINAsim for automatic movement of laser to patient marking position is only applicable if system has Tumor LOC and an absolute marking couch (ie. Brilliance Big Bore).

8 \*\*NCTA140 Ethernet Switch 1 \$342.82 \$342.82

10/100/1000Mbps switch delivers power, performance and reliability in a space-saving package for ultrafast image transfer from the Brilliance Workspace.

9 \*\*NCTB850 Load and Unload Foot Pedals 1 \$4,158.00 \$4,158.00

Load and Unload foot pedals allow the operator to move the patient couch to the load or unload position using a foot pedal thus improving patient handling efficiency by the freeing the operator's hands to prepare, restrain, or release the patient.

Prerequisite: Rear Gantry Panel for Field Upgrades

10 \*\*FCT0003 Additional Operator's Manual 1 \$319.20 \$319.20

One Complete set of Operator's Manuals. One set is included with the base system.

11 \*\*NCTA082 30-min Console UPS 1 \$2,788.34 \$2,788.34

Quotation #: 1-TY6NSD Rev.: 10 Page 17 of 43

		100017 Brilliance CT Big Bo	re Oncolog	y Systems	
Line	# Part#	Description	Qty	Each	Price
	Uninterruptible F computer/recons	Power Supply (UPS) provides up to 3 struction system.	0 minutes of b	attery backup for	
12	**989605200561	Teal 100kVA Isotran LM	1	\$6,234.62	\$6,234.62
13	**989801292070	24 Hours of Additional OnSite	1	\$6,119.61	\$6,119.61

Clinical Education Specialist will provide twenty-four (24) hours of tailored CT OnSite Education for up to four (4) students, selected by customer, including technologists from night/weekend shifts if necessary. CEUs are not available in all cases. Please read Guidelines for more information, which will be provided to you during the scheduling process. Note: Philips personnel are not responsible for actual patient contact or operation of equipment during education sessions except to demonstrate proper equipment operation. Education expires one (1) year from the earlier of equipment delivery date or purchase date.

# 14 \*\*989801292078 Full Travel Package for OffSite 2 \$2,109.38 \$4,218.75 Training

Includes one (1) participant's airfare from North American customer location to Cleveland, Ohio, with modest lodging, ground transportation, and meal expenses. Breakfast/dinner provided by the hotel, and lunch/breaks are catered by Philips. All other expenses will be the responsibility of the attendee. Details are provided during the scheduling process.

Note: Cancellation/rescheduling policy strictly enforced.

Expires one (1) year from the earlier of equipment delivery date or purchase date.

#### 15 \*\*989801292279 CT ONC Motion Mgt Rad 2 \$2,030.63 \$4,061.25 Therapy

This 2-day course is held at Washington University School of Medicine, St Louis MO, and is intended for radiation oncologists, medical physicists, dosimetrists, therapists, and others who want to gain exposure to Respiratory Correlated Imaging and understand the benefits of how it can be implemented in their clinical environment to improve patient care. The course is taught by physicians, medical physicists, and other professionals from an institution leading the way in this area. The course consists of lectures, discussions, and hands-on learning lab exercises. Topics include clinical indications, scanning process, review and analysis of 4D CT studies, treatment planning, commissioning and QA, and treatment delivery. The goal is to facilitate easier implementation of respiration motion management using Philips equipment in the attendee's clinic.

Accreditation will be offered for CAMPEP, ASRT and MDCB. Philips Oncology Schedule Coordinators manage course dates and scheduling. Program updates, course dates/times, and topics are subject to change without notice. Attendees receive updated information regarding schedule changes. This quote covers tuition costs for one (1) person. Travel, lodging and transportation are the responsibility of the attendee.

Cancellation Policy For MMRT Course:

Cancellations made in writing 60 days prior to the first day of the course will be refunded less a \$300 administrative fee. Cancellations made in writing between 30 and 60 days prior to the first day of the course will be subject to a 50% cancellation fee. No refunds will be given less than 30 days prior to the first day of the course. No telephone cancellations will be accepted. In the unlikely event that the course is cancelled by the training site, Washington University will refund the registration fee, but is not responsible for any travel costs. Attendee is responsible for any cancellation fee incurred.

16 \*\*989801292492 ONC Resp Correlated Img 1 \$423.75 \$423.75 Remote Educ 2h

Quotation #: 1-TY6NSD Rev.: 10 Page 18 of 43

#### Line # Part # Description Qty Each Price

One Philips Clinical Education Specialist will provide two (2.0) hours of remote clinical education, on Respiratory Correlated Imaging-4DCT for Oncology. Please read Philips guidelines for more information, which will be provided to you during the scheduling process. This coaching session will require access to the internet from a PC at the user location. Delivery method will be through prepared presentations and software broadcasted via a WEB conference. If applicable, the training may include a session where the Philips Clinical Education Specialist will remote login to the CT Simulator to conduct a portion of the training. ASRT and MDCB CEUs are available in most cases. This training is available for Brilliance Big Bore Oncology CT software version 2.3.5 and GEMINI TF Big Bore software version 3.6.

Requirements: Customer must be able to receive an Adobe Connect Pro or Microsoft Live Meeting web conference and have a land line speaker phone. The scanner must have Philips Remote Service capability if the remote login session is desired.

Education expires one (1) year from equipment installation date (or purchase date if sold separately).

# 17 \*\*989801299678 Airfare to Cleveland for 2 \$783.00 \$1,566.00 Biomed Training

Includes one (1) participant's airfare from North American customer location to the Cleveland Training Center (CTC) in Cleveland, Ohio. All other expenses will be the responsibility of the attendee. Details are provided during the scheduling process. Note: Cancellation/rescheduling policy strictly enforced. Expires one (1) year from the earlier of equipment delivery date or purchase date.

# 18 \*\*989801299679 Food Transpt Lodging for 28 \$208.80 \$5,846.40 Cleveland Biomed Training

Includes one (1) day of modest lodging, ground transportation, and meal expenses in Cleveland, Ohio for one (1) attendee. All other expenses will be the responsibility of the attendee. Details are provided during the scheduling process. Note: Cancellation/rescheduling policy strictly enforced. Although this part is only for one day, it is sold in multiple quantities to account for entire length of course. Expires one (1) year from the earlier of equipment delivery date or purchase date.

# 19 \*\*989801299989 CT3819 Bio BRILL AIR FAMILY 2 \$11,600.00 \$23,200.00 CTC 14+

Course Number:

CT3819

Course Title:

**Brilliance Air Family** 

Course Length:

14 days (excludes Saturdays, Sundays, and Philips holidays)

Delivery Method(s):

Blended

Modality:

CT

Location:

eLearning and Instructor-led

#### **DESCRIPTION:**

This course provides the engineer with comprehensive knowledge and the skills required for installing, calibrating and repairing the Philips Healthcare Brilliance CT (air) family of scanners. This course is a blended learning course, with prerequisites of topics in eLearning which do not require the physical presence of the learner in the Training Academy. This reduces the amount of time required to be at the Academy and enhances the engineer's work/life balance.

#### PREREQUISITES:

Engineers with no prior CT experience are required to attend and complete the CT Basics blended learning sessions:

- · CT1020 CT Basics Virtual Classroom
- · CT1021 CT Basics Skills Labs

Quotation #: 1-TY6NSD Rev.: 10 Page 19 of 43

Line # Part # Description Qty Each

OR

CT9107 CT Fundamentals and CS9111Networking Fundamentals

Prior to arrival at the Training Academy, the engineer will need to successfully complete the following prerequisite modules and their associated certification tests (where appropriate) which are available on the Philips On-line Learning center. The following prereqs are part of this course and there will not be any extra cost to obtain this class.

- CT05: CT Image Quality
  JS035\_A: Laser Safety
  PSS –XXXX: Installation
- XXXX System Introduction
   Xxxx Electrostatic Discharge (ESD)
- \* PHILIPS PROPRIETARY MATERIALS SUCH AS DIAGNOSTIC SOFTWARE AND SERVICE DOCUMENTATION ARE NOT INCLUDED IN THE TRAINING AND WILL NOT BE AVAILABLE FOR USE OUTSIDE OF THE TRAINING ENVIRONMENT. THE TRAININE MUST RETURN ALL PROPRIETARY MATERIALS RECEIVED DURING THE TRAINING AT THE END OF THE TRAINING. CUSTOMER ACKNOWLEDGES AND AGREES THAT NEITHER CUSTOMER NOR TRAINEE WILL RECEIVE A LICENSE TO SUCH PROPRIETARY MATERIALS AND THAT THE TRAINEE MAY NOT BE ABLE TO FULLY UTILIZE THE TRAINING WITHOUT THE USE OF SUCH PROPRIETARY MATERIALS. (CERTAIN LICENSES MAY BE OBTAINED THROUGH PURCHASE OF A PHILIPS RIGHTFIT SERVICE AGREEMENT.) Course dates and location to be finalized by Philips. Philips shall attempt to accommodate Customer requested dates and training location. The price quoted includes course tuition. Travel and living expenses are not included, but

IMPORTANT Notes Regarding Admission to Philips Customer Engineer Training Courses:

1. Trainee must meet all prerequisites

may be purchased separately through Philips.

- Course expires one (1) year from equipment installation date (or purchase date if sold separately)
- 3. Customer must sign Philips Nondisclosure statement
- 4. Trainee must sign Philips Nondisclosure statement
- 5. Customer must sign Philips terms and conditions of training

20 SP059A Room Moves 1 \$4,600.00 \$4,600.00

Philips removal of Ximitron unit # 257

Quotation #: 1-TY6NSD Rev.: 10 Page 20 of 43

Price

#### **NET PRICE**

\$675,332.16

Buying Group:	NO CONTRACT	C	ontract#:	NONE	
Addt'l Terms:					
and any specific	solution will reference a specific B c terms and conditions which will a and Conditions of Sale will apply to	ply to that single quoted	mber repres solution. If r	enting an agreement co o Buying Group/Contra	ontaining discounts, fees ct Number is shown,
	it system listed on purchase order/o n is to be individually billed and pai		ate and dist	nct financial transaction	n. We understand and agree tha
Price above	does not include any applica	able sales taxes.			
The prelimin	ary delivery request date for	this equipment is:			
If you do not	issue formal purchase orde	rs indicate by initialir	ng here	·	
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Quotation #: 1-TY6NSD

**Rev.:** 10

### Philips Standard Terms and Conditions of Sale

The products and services listed in the quotation are offered by Philips Healthcare, a division of Philips Electronics North America Corporation ("Philips") only under the terms and conditions described below.

- 1. Price: Taxes. The purchase price stated in the quotation does not include applicable sales, excise, use, or other taxes in effect or later levied. Unless Customer provides Philips with an appropriate exemption certificate reasonably in advance of the date the product is available for delivery, Philips shall invoice Customer for those taxes, and Customer shall pay those taxes in accordance with the terms of the invoice
- 2. Cancellation, Philips' cancellation policies are set forth in the applicable schedule attached to these Terms and Conditions of Sale.

#### 3. Payment Terms.

- 3.1 Unless otherwise specified in the quotation, Philips will invoice Customer, and Customer will immediately pay such invoice on receipt for each product in accordance with the payment terms set forth in the applicable schedule attached to these Terms and
- 3.2 Orders are subject to Philips' on-going credit review and approval.
- 3,3 Customer shall pay interest on any amount not paid when due at the maximum rate permitted by applicable law. If Customer fails to pay any amount when due, in addition to any other rights or remedies available to Philips at law or in equity, Philips may discontinue the performance of services, discontinue the delivery of the product, or deduct the unpaid amount from any amounts otherwise owed to Customer by Philips under any agreement with Customer. In any action initiated to enforce the terms of the quotation following a Customer default or product cancellation under an order arising from the quotation, Philips shall be entitled to recover as part of its damages all costs and expenses, including reasonable attorneys' fees, in connection with such action.
- 3.4 Credit Card. Philips, at its discretion, will accept a credit card for payment on orders with a net value of \$50,000 or less,
- 4. Trade In. If Customer will be trading-in any equipment ("Trade-In"), then:
- 4.1 Customer represents and warrants that Customer has good and marketable title to such Trade-In;
- 4.2 Title to the Trade-in shall pass from Customer to Philips upon Philips making the new equipment available for first patient use. Removal of the Trade-in from Customer's site shall occur no later than the date Philips makes the new product available for first patient use, unless otherwise agreed in writing between Philips and the Customer; and
- 4.3 Notwithstanding anything to the contrary in any Business Associate Addendum ("BAA"), Customer represents and warrants that Customer has removed or de-identified all Protected Health Information ("PHI") from the Trade-in equipment as of the date the equipment is removed. To the extent Customer has not done so, Customer agrees to reimburse Phillips for any out-of-pocket costs Phillips incurs to remove or de-identify PHI from the Trade-In.
- 4.4 If (a) the condition of the Trade-In is not substantially the same when Philips removes the Trade-In (ordinary wear and tear excepted) as it was when Philips quoted the Trade-In value; or (b) Customer delays the removal of the Trade-In, then Philips may reduce the price quoted for such Trade-In or cancel the Trade-In and Customer will pay the adjustment amount within thirty (30) days of receipt of invoice.
- 4.5 If Philips does not receive possession of the Trade-In, Philips will charge Customer, and Customer will pay within thirty (30) days of receipt of invoice, the amount of the Trade-In allowance.
- 4.6 Evidence that Customer intends to trade in an asset as part of the purchase or lease of any product(s) shall be in the form of, but not limited to: (a) receiving a trade in quote and/or authorization from Philips on the value of the asset to be traded in; (b) providing Philips with serial numbers of assets to be traded in; and/or, (c) providing Philips with a de-installation date to remove an existing asset in order to install Philips quoted equipment.
- 5. Leases. If Customer desires to convert the purchase of any product to a lease, Customer will arrange for the lease agreement and all other related documentation to be reviewed and approved by Philips not later than ninety (90) days prior to the date of the availability for delivery of major components of the product. The Customer is responsible for converting the transaction to a lease, and is required to secure the leasing company's approval of all of these Terms and Conditions of Sale. No product will be delivered to the Customer until Phillips has received copies of the fully executed lease documents and has approved the same.
- 6. Security Interest. Customer hereby grants to Philips a purchase money security interest in the products until all payments have been made. Customer shall sign any financing statements or other documents necessary to perfect Phillips' security interests in the products. Where permitted by applicable law, Customer's signature on the quotation or on a purchase order issued as a result of the quotation gives Philips the right to sign on Customer's behalf and file any financing statement or other documents to perfect Philips' security interest in the product.

- 7. Shipment and Risk of Loss.7.1 The applicable schedule attached to these Terms and Conditions of Sale shall apply for delivery.
- 7.2 Title to any product (excluding software), and the risk of loss or damage to any product shall pass to the Customer F.O.B. destination. Customer shall obtain and pay for insurance covering such risks at destination.

8. <u>Installation. Site Preparation. Remote Services.</u>
8.1 <u>Installation.</u> Customer shall provide Philips full and free access to the installation site and suitable and safe space for the storage of the products before installation. Customer shall advise Philips of conditions at or near the site, including any hazardous materials, that could adversely affect the installation or pose a health or safety risk to Phillips' personnel, and shall ensure that those conditions are corrected and hazardous materials removed, and that the site is fully prepared and available to Philips before installation work begins. Customer shall ensure, at no charge to Philips, that there are no obstacles preventing Philips from moving the product from the entrance of the Customer's premises to the installation site. Customer shall be responsible, at its expense, for rigging, the removal of partitions or other obstacles, and restoration work. The products will be installed during normal working hours. Philips will unpack the product, construct applicable pads (if required for certain products), connect the product to a safety switch or breaker to be installed by the Customer, and calibrate and test the product. If local labor conditions, including but not limited to a requirement to utilize union labor, require the use of non-Philips employees to participate in the installation of the product, then such participation of non-Philips employees shall be at Customer's expense. In such case, Philips will provide engineering supervision during the installation.

Quotation #: 1-TY6NSD Rev.: 10 Page 22 of 43

- 8.2 Site Preparation. Except where Philips has agreed in writing to provide construction services for a fee pursuant to a construction agreement and scope of work signed by Customer, Customer shall be responsible, at its expense, for the preparation of the installation site where the product will be installed including any required structural alterations. Customer shall provide any and all plumbing, carpentry work, conduit, wiring including communications and/or computer wiring, network equipment, power supply, surge suppression and power conditioning (except to the extent they are expressly included in the quotation), fire protection and environmental controls, ground fault and isolation system, and other fixtures and utilities required to properly attach, install, and use the product. Site preparation shall be in compliance with all safety, electrical, and building codes relevant to the product and its installation and use. The sufficiency of any installation site plans shall be the responsibility of Customer. Customer, at its expense, shall obtain all permits and licenses required by federal, state, or local authorities in connection with the installation and operation of the product, including any certificate of need and zoning variances. PHILIPS MAKES NO WARRANTY AND ASSUMES NO LIABILITY FOR THE FITNESS OR ADEQUACY OF THE SITE IN WHICH THE PRODUCT IS TO BE INSTALLED OR USED, CUSTOMER INDEMNIFIES PHILIPS AGAINST ANY CLAIMS, INCLUDING SUBROGATION CLAIMS, ARISING FROM CUSTOMER'S SITE PREPARATION RESPONSIBILITIES.
- 8.3 Remote Services Network ("RSN"). Customer will (a) provide Philips with a secure location at Customer's premises to store one Philips RSN router (or a Customer-owned router acceptable to Philips at Customer's option) for connection to the equipment and to Customer's network; and (b) at all times during the warranty period provide Philips with full and free access to the router and a dedicated broadband Internet access node, including but not limited to public and private interface access, suitable to establish a successful connection to the products through the Philips RSN and Customer's network for Philips' use in remote servicing of the product, remote assistance to personnel that operate the products, updating the products software, transmitting automated status notifications from the product and regular uploading of products data files (such as but not limited to error logs and utilization data for improvement of Philips products and services and aggregation into services). Customer's failure to provide such access at the scheduled time will constitute Customer's waiver of the scheduled planned maintenance service and will void support or warranty coverage of product malfunctions until such time as planned maintenance service is completed or RSN access is provided. Customer agrees to pay Philips at the prevailing demand service rates for all time spent by Philips service personnel waiting for access to the products.

#### 9. Product Warranty

- 9.1 (a) If a separate product warranty prints as part of this quotation, that product warranty applies to your purchase and is incorporated herein; otherwise Section 9.2-9.7 shall apply unless the product is identified under 9.1 (b). (b) For Patient Monitoring and Cardiac Resuscitation and InnerCool products, the product warranty document can be found at: www.healthcare.philips.com/main/terms\_conditions/, or can be provided upon request.
- 9.2 **Hardware/Systems.** Philips warrants to Customer that the Philips equipment (including its operating software) will perform in substantial compliance with its performance specifications in the documentation accompanying the products, for a period of 12 months beginning upon availability for first patient use.
- 9.3 Stand-alone Licensed Software. For a period of ninety (90) days from the date Philips makes Stand-alone Licensed Software available for first patient use, such Stand-alone Licensed Software shall substantially conform to the technical user manual that ships with the Stand-alone Licensed Software. "Stand-alone Licensed Software" means sales of Licensed Software without a contemporaneous purchase of a server for the Licensed Software. If Philips is not the installer of the Stand-alone Licensed Software, the foregoing warranty period shall commence upon shipment.
- 9.4 If the start of the installation is delayed for any reason beyond the control of Philips for more than thirty (30) days following the date that Philips notifies Customer that the major components of the product are available for delivery, the warranty period begins on the thirty-first (31st) day following that date.
- 9.5 Philips' sole obligations and Customer's exclusive remedy under any product warranty are limited, at Philips' option, to the repair or the replacement of the product or a portion thereof within thirty (30) days after receipt of written notice of such material breach from Customer ("Product Warranty Cure Period") or, upon expiration of the Product Warranty Cure Period, to a refund of a portion of the purchase price paid by the Customer, upon Customer's request. Any refund will be paid to the Customer when the product is returned to Philips. Warranty service outside of normal working hours (i.e, 8:00 A.M. to 5:00 P.M., Monday through Friday, excluding Philips' observed holidays), will be subject to payment by Customer at Philips' standard service rates.
- 9.6 This warranty is subject to the following conditions: the product (a) is to be installed by authorized Philips representatives (or is to be installed in accordance with all Philips installation instructions by personnel trained by Philips); (b) is to be operated exclusively by duly qualified personnel in a safe and reasonable manner in accordance with Philips' written instructions and for the purpose for which the products were intended; and (c) is to be maintained and in strict compliance with all recommended and scheduled maintenance instructions provided with the product; and Customer is to notify Philips immediately if the product at any time fails to meet its printed performance specifications. Philips' obligations under any product warranty do not apply to any product defects resulting from improper or inadequate maintenance or calibration by the Customer or its agents; Customer or third party supplied interfaces, supplies, or software including without limitation loading of operating system patches to the Licensed Software and/or upgrades to anti-virus software (except DAT file changes) running in connection with the Licensed Software without prior validation approval by Philips; use or operation of the product other than in accordance with Philips' applicable product specifications and written instructions; abuse, negligence, accident, loss, or damage in transit; improper site preparation; unauthorized maintenance or modifications to the product; or viruses or similar software interference resulting from connection of the product to a network. Philips does not provide a warranty for any third party products furnished to Customer by Philips under the quotation; however, Philips shall use reasonable efforts to extend to Customer the third party warranty for the product. The obligations of Philips described herein and in the applicable product-specific warranty document are Philips' only obligations and Customer's sole and exclusive remedy for a breach of a product warranty.
- 9.7 THE WARRANTIES SET FORTH HEREIN AND IN PHILIPS' WARRANTY DOCUMENT WITH RESPECT TO A PRODUCT (INCLUDING THE SOFTWARE PROVIDED WITH THE PRODUCT) ARE THE ONLY WARRANTIES MADE BY PHILIPS IN CONNECTION WITH THE PRODUCT, THE SOFTWARE, AND THE TRANSACTIONS CONTEMPLATED BY THE QUOTATION, AND ARE EXPRESSLY IN LIEU OF ANY OTHER WARRANTIES, WHETHER WRITTEN, ORAL, STATUTORY, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF NON-INFRINGEMENT, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. Philips may use refurbished parts in the manufacture of the products, which are subject to the same quality control procedures and warranties as for new products.
- 10. Philips Proprietary Service Materials. Any Philips maintenance or service software and documentation provided with the product and/or located at Customer's premises is intended solely to assist Philips and its authorized agents to install and to test the products or to assist Philips and its authorized agents to maintain and to service the products under warranty or a separate support agreement with Customer. Customer agrees to restrict access to such software and documentation to Philips' employees and those of Philips' authorized agents only and to permit Philips to remove its Proprietary Service Materials upon request.

Quotation #: 1-TY6NSD Rev.: 10 Page 23 of 43

- 11. <u>Patent Infringement Claims.</u>
  11.1 Philips shall indemnify, defend, and hold harmless Customer against any new claim that a Philips Product provided in the quotation infringes, misappropriates, or violates any third party intellectual property right, whether patent, copyright, trademark, or trade secret, provided that Customer:
- (a) provides Philips prompt written notice of the claim;
- (b) grants Philips full and complete information and assistance necessary for Philips to defend, settle, or avoid the claim; and (c) gives Philips sole control of the defense or settlement of the claim.
- 11.2 The provisions of this section shall not apply if the product is sold or transferred.
- 11.3 If (a) a Philips Product is found or believed by Philips to infringe such a claim; or, (b) Customer has been enjoined from using the Philips Product pursuant to an injunction issued by a court of competent jurisdiction, Philips may, at its option, (i) procure the right for Customer to use the product, (ii) replace or modify the product to avoid infringement, or (iii) refund to Customer a portion of the product purchase price upon the return of the original product. Philips shall have no obligation for any claim of infringement arising from: Philips' compliance with Customer's designs, specifications, or instructions; Philips' use of technical information or technology supplied by Customer; modifications to the product by Customer or its agents; use of the product other than in accordance with the product specifications or applicable written product instructions; use of the product with any other product; if infringement would have been avoided by the use of a current unaltered release of the products; or use of the Philips Product after Philips has advised Customer, in writing, to stop use of the Philips Product in view of the claimed infringement. Philips will not be liable for any claim where the damages sought are based directly or indirectly upon the quantity or value of products manufactured by means of the products purchased under this quotation, or based upon the amount of use of the product regardless of whether such claim alleges the product or its use infringes or contributes to the infringement of such claim. The terms in this section state Philips' entire obligation and liability for claims of infringement, and Customer's sole remedy in the event of a claim of infringement.
- 12. <u>Limitation of Liability.</u> THE TOTAL LIABILITY, IF ANY, OF PHILIPS AND ITS AFFILIATES FOR ALL DAMAGES AND BASED ON ALL CLAIMS, WHETHER ARISING FROM BREACH OF CONTRACT, BREACH OF WARRANTY, NEGLIGENCE, INDEMNITY, STRICT LIABILITY OR OTHER TORT, OR OTHERWISE, ARISING FROM A PRODUCT, LICENSED SOFTWARE, AND/OR SERVICE IS LIMITED TO THE PRICE PAID HEREUNDER FOR THE PRODUCT, LICENSED SOFTWARE, OR SERVICE. THIS LIMITATION SHALL NOT APPLY TO:
- (a) THIRD PARTY CLAIMS FOR BODILY INJURY OR DEATH CAUSED BY PHILIPS' NEGLIGENCE OR PROVEN PRODUCT DÉFECT!
- (b) CLAIMS OF TANGIBLE PROPERTY DAMAGE REPRESENTING THE ACTUAL COST TO REPAIR OR REPLACE PHYSICAL PROPERTY DAMAGE;
- (c) OUT OF POCKET COSTS INCURRED BY CUSTOMER TO PROVIDE PATIENT NOTIFICATIONS, REQUIRED BY LAW, TO THE EXENT SUCH NOTICES ARE CAUSED BY PHILIPS UNAUTHORIZED DISCLOSURE OF PHI; and,
- (d) FINES/PENALTIES LEVIED AGAINST CUSTOMER BY GOVERNMENT AGENCIES CITING PHILIPS UNATHORIZED DISCLOSURE OF PHI AS THE BASIS OF THE FINE/PENALTY SUCH FINES OR PENALTIES SHALL CONSTITUTE DIRECT DAMAGES.
- 13. DISCLAIMER. IN NO EVENT SHALL PHILIPS OR ITS AFFILIATES BE LIABLE FOR ANY INDIRECT, PUNITIVE, INCIDENTAL, CONSEQUENTIAL, OR SPECIAL DAMAGES, INCLUDING WITHOUT LIMITATION, LOST REVENUES OR PROFITS, BUSINESS INTERRUPTION, LOSS OF DATA, OR THE COST OF SUBSTITUTE PRODUCTS OR SERVICES WHETHER ARISING FROM BREACH OF CONTRACT, BREACH OF WARRANTY, NEGLIGENCE, INDEMNITY, STRICT LIABILITY OR OTHER TORT.
- 14. <u>Confidentiality.</u> Each party shall maintain as confidential any information furnished or disclosed to one party by the other party, whether disclosed in writing or disclosed orally, relating to the business of the disclosing party, its customers and/or its patients, and the quotation and its terms, including the pricing terms under which Customer has agreed to purchase the products. Each party shall use the same degree of care to protect the confidentiality of the disclosed information as that party uses to protect the confidentiality of its own information, but in no event less than a reasonable amount of care. Each party shall disclose such confidential information only to its employees having a need to know such information to perform the transactions contemplated by the quotation. The obligation to maintain the confidentiality of such information shall that (a) is or becomes generally available to the public without violation of this Agreement or any other obligation of confidentiality or (b) is lawfully obtained by the receiving Party from a third party without any breach of confidentiality or violation of law.

#### 15. Compliance with Laws & Privacy.

- 15.1 Each party shall comply with all laws, rules, and regulations applicable to the party in connection with the performance of its obligations in connection with the transactions contemplated by the quotation, including, but not limited to, those relating to affirmative action, fair employment practices, FDA, Medicare fraud and abuse, and the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). Health care providers are reminded that if the purchase includes a discount or loan, they must fully and accurately report such discount or loan on cost reports or other applicable claims for payment submitted under any federal or state health care program, including but not limited to Medicare and Medicaid, as required by federal law (see 42 CFR 1001.952[h]).
- 15.2 In the course of providing project implementation related services and/or warranty services to Customer, hereunder, it may be necessary for Philips to have access to, view and/or download computer files from the products that might contain Personal Data. "Personal Data" means information relating to an individual, from which that individual can be directly or indirectly identified. Personal Data can include both personal health information (i.e. images, heart monitor data, and medical record number) and non-health information (i.e. date of birth, gender). Philips will process Personal Data only to the extent necessary to perform and/or fulfill its project implementation related service, warranty service and/or warranty obligations hereunder.
- 15.3 It is Customer's responsibility to notify Philips if any portion of the order is funded under the American Reinvestment and Recovery Act ("ARRA"). To ensure compliance with the ARRA regulation, Customer shall include a clause stating that the order is funded under ARRA on its purchase order or other document issued by Customer.
- 16. Excluded Provider. Philips represents and warrants that Philips, its employees and subcontractors, are not debarred, excluded, suspended or otherwise ineligible to participate in a federal health care program, nor have they been convicted of any health care related crime for the products and services provided under this Agreement (an "Excluded Provider"). Philips shall promptly notify Customer when it becomes aware that Philips or any of its employees or subcontractors, providing services hereunder, have become an Excluded Provider whereupon Customer may terminate this order by express written notice for product and services not yet shipped or rendered.

**Rev.:** 10 Page 24 of 43 Quotation #: 1-TY6NSD

- 17. General Terms. The following additional terms shall be applicable to the purchase of a product:
- 17.1 Force Majeure. Each party shall be excused from performing its obligations (except for payment obligation) arising from any delay or default caused by events beyond its reasonable control including, but not limited to, acts of God, acts of third parties, acts of any civil or military authority, fire, floods, war, embargoes, labor disputes, acts of sabotage, riots, accidents, delays of carriers, subcontractors or suppliers, voluntary or mandatory compliance with any government act, regulation or request, shortage of labor, materials or manufacturing facilities.
- 17.2 Bankruptcy. If Customer becomes insolvent, is unable to pay its debts when due, files for bankruptcy, is the subject of involuntary bankruptcy, has a receiver appointed, or has its assets assigned, Philips may cancel any unfulfilled obligations, or suspend performance; however, Customer's financial obligations to Philips shall remain in effect.
- 17.3 Assignment. Customer may not assign any rights or obligations in connection with the transactions contemplated by the quotation without the prior written consent of Philips, which consent shall not be unreasonably withheld, and any attempted assignment without such consent shall be of no force or effect.
- 17.4 Export. Customer shall assume sole responsibility for obtaining any required export authorizations in connection with Customer's export of the products from the country of delivery.
- 17.5 Governing Law. All transactions contemplated by the quotation shall be governed by the laws of the state where the equipment will be installed, without regard to that state's choice of law principles, and expressly excluding application of the Uniform Computer Information Transactions Act ("UCITA"), in any form. EACH PARTY, KNOWINGLY AND AFTER CONSULTATION WITH COUNSEL, FOR ITSELF, IT'S SUCCESSORS' AND ASSIGNS, WAIVES ALL RIGHT TO TRIAL BY JURY OF ANY CLAIM ARISING WITH RESPECT TO THIS AGREEMENT OR ANY MATTER RELATED IN ANY WAY THERETO.
- 17.6 Entire Agreement. These Terms and Conditions of Sale, the terms and conditions set forth in the quotation and the applicable Philips' product-specific warranty document constitute the entire understanding and agreement by and between the parties with respect to the transactions contemplated by the quotation, and supersede any previous understandings or agreements between the parties, whether written or oral, regarding the transactions contemplated by the quotation. The pricing in the quotation is based upon the terms and conditions in the quotation. No additional terms, conditions, consents, waivers, alterations, or modifications shall be binding unless in writing and signed by the parties. Customer's additional or different terms and conditions, whether stated in a purchase order or other document issued by Customer, are specifically rejected and shall not apply to the transactions contemplated by the quotation.
- 17.7 **Headings.** The headings in the quotation are intended for convenience only and shall not be used to interpret the quotation.
  17.8 **Severability.** If any provision of the quotation is deemed to be illegal, unenforceable, or invalid, in whole or in part, the validity and enforceability of the remaining provisions shall not be affected or impaired, and shall continue in full force and effect.
- 17.9 **Notices.** Notices or other communications shall be in writing, and shall be deemed served if delivered personally, or if sent by facsimile transmission, by overnight mail or courier, or by certified mail, return receipt requested and addressed to the party at the address set forth in the quotation.
- 17.10 **Performance**. The failure of Customer or of Philips at any time to require the performance of any obligation will not affect the right to require such performance at any time thereafter. Course of dealing, course of performance, course of conduct, prior dealings, usage of trade, community standards, industry standards, and customary standards and customary practice or interpretation in matters involving the sale, delivery, installation, use, or service of similar or dissimilar products or services shall not serve as references in interpreting the terms and conditions of the quotation.
- 17.11 **Obligations.** Customer's obligations are independent of any other obligations the Customer may have under any other agreement, contract, or account with Phillips. Customer will not exercise any right of offset in connection with the terms and conditions in the quotation or in connection with any other agreement, contract, or account with Phillips.
- 17.12 Additional Terms. The Product specific schedules listed below are incorporated herein as they apply to the equipment listed on the quotation and their additional terms shall apply solely to Customer's purchase of the products specified therein. If any terms set forth in a schedule conflict with terms set forth in these Terms and Conditions of Sale, the terms set forth in the schedule shall govern:
- (a) Schedule 1: Interventional X-Ray (iXR), Diagnostic X-Ray (DXR), Computed Tomography (CT), Magnetic Resonance (MR), Positron Emission Tomography (PET), Nuclear Medicine (NM), Radiation Oncology (PROS), Women's Healthcare (WHC), and Ultrasound Products (including Image Guided Intervention and Therapy (IGIT) products).

#### **LICENSED SOFTWARE**

#### 1. License Grant.

- 1.1 Subject to any usage limitations for the Licensed Software set forth on the product description of the quotation, Philips grants to Customer a nonexclusive and non-transferable right and license to use the computer software package ("Licensed Software") in accordance with the terms of the quotation. The License shall continue for as long as Customer continues to own the product, except that Philips may terminate the License if Customer is in breach or default. Customer shall return the Licensed Software and any authorized copies thereof to Philips immediately upon expiration or termination of this License.
- 1.2 The License does not include any right to use the Licensed Software for purposes other than the operation of the product. Customer may make one copy of the Licensed Software in machine-readable form solely for backup purposes. Philips reserves the right to charge for backup copies created by Philips. Except as otherwise provided under section 1.6, Customer may not copy, reproduce, sell, assign, transfer, or sublicense the Licensed Software for any purpose without the prior written consent of Philips. Customer shall reproduce Philips' copyright notice or other identifying legends on such copies or reproductions. Customer will not (and will not allow any third party to) decompile, disassemble, or otherwise reverse engineer or attempt to reconstruct or discover the product or Licensed Software by any means whatsoever.
- 1.3 The License shall not affect the exclusive ownership by Philips of the Licensed Software or of any trademarks, copyrights, patents, trade secrets, or other intellectual property rights of Philips (or any of Philips' suppliers) relating to the Licensed Software.
- 1.4 Customer agrees that only authorized officers, employees, and agents of Customer will use the Licensed Software or have access to the Licensed Software (or to any part thereof), and that none of Customer's officers, employees, or agents will disclose the Licensed Software, or any portion thereof, or permit the Licensed Software, or any portion thereof, to be used by any person or entity other than those entities identified on the quotation. Customer acknowledges that certain of Philips' rights may be derived from license agreements with third parties, and Customer agrees to preserve the confidentiality of information provided by Philips under such third party license agreements.
- 1.5 The Licensed Software shall be used only on the product(s) referenced in the quotation.
- 1.6 Customer may transfer the Licensed Software in connection with sale of the product to a healthcare provider who accepts all of the terms and conditions of this License; provided that Customer is not in breach or default of this License, the Terms and Conditions of Sale,

or any payment obligation to Philips.

#### 2. Modifications.

- 2.1 If Customer modifies the Licensed Software in any manner, all warranties associated with the Licensed Software and the products shall become null and void. If Customer or any of its officers, employees, or agents should devise any revisions, enhancements, additions, modifications, or improvements in the Licensed Software, Customer shall disclose them to Philips, and Philips shall have a non-exclusive royalty-free license to use and to sub-license them.
- 2.2 The Licensed Software is licensed to Customer on the basis that (i) Customer shall maintain the configuration of the products as they were originally designed and manufactured and (ii) the product includes only those subsystems and components certified by Philips. The Licensed Software may not perform as intended on systems modified by other than Philips or its authorized agents, or on systems which include subsystems or components not certified by Philips. Philips does not assume any responsibility or liability with respect to unauthorized modification or substitution of subsystems or components.

Quotation #: 1-TY6NSD

**Rev.:** 10

Schedule 1
Interventional X-Ray (iXR), Diagnostic X-Ray (DXR), Computed Tomography (CT), Magnetic Resonance (MR),
Positron Emission Tomography (PET), Nuclear Medicine (NM), Radiation Oncology (PROS), Women's Healthcare (WHC), and Ultrasound (US) products (including Image Guided Intervention and Therapy (IGIT) Products)

#### 1. Payment Terms.

Unless otherwise specified in the quotation, Philips will invoice Customer, and Customer will pay such invoice on receipt, as follows:

- 1.1 For Interventional X-Ray (iXR), Diagnostic X-Ray (DXR), Computed Tomography (CT), Magnetic Resonance (MR), Positron Emission Tomography (PET), Nuclear Medicine (NM), Radiation Oncology (PROS), and Women's Healthcare (WHC):
- (a) 10% of the purchase price shall be due with Customer's acceptance of the quotation.
- (b) 70% of the purchase price shall be due on delivery of the major components of the product. Product installation will not begin until Customer has paid this portion of the purchase price.
- (c) 20% of the purchase price shall be due when the product is available for first patient use. Available for first patient use means the product has been installed and substantially meets Philips' published specifications.
- 1.2 For Ultrasound(US) products (including IGIT Products):
- (a) 100% of the purchase price shall be due thirty (30) days from Philips' invoice date.
- 1.3 If the start of the installation is delayed for any reason beyond the control of Philips for more than thirty (30) days following the date that Philips notifies customer that the major components of the product are available for delivery, the unpaid portion of the purchase price shall be due on the thirty-first (31st) day following such date.
- 2. Cancellation. The quotation is subject to change or withdrawal prior to written acceptance by Customer. All purchase orders issued by Customer are subject to acceptance by Philips. If Customer cancels an order prior to product shipment, Customer shall pay a cancellation charge of fifteen percent (15%) of the net order price. Orders are non-cancellable for products shipped.

#### Delivery.

- 3.1 Philips will use reasonable efforts to ship the product to the Customer by: (a) by the mutually agreed upon shipment date; or (b) by the date stated in the quotation; or (c) as otherwise agreed in writing. Philips will ship the product according to Philips' standard commercial practices. Philips will deliver the equipment during normal working hours, 8:00 - 5:00 PM, in the time zone where the Customer is located. Philips may make partial shipments. Philips will pay shipping costs associated with product shipment.
- 3.2 Prior to the shipment of any product, Philips may change the construction or the design of the product without notice to the Customer so long as the function, footprint, and performance of the product are not substantially altered.
- 3.3 If Customer requests a delay in the date major components of the product are available for delivery, then Philips will place the product in storage and the unpaid portion of the purchase price shall be due. Customer will reimburse Philips for all storage fees incurred upon receipt of invoice.

#### 4. Additional Customer Installation Obligations for Magnetic Resonance.

- 4.1 Customer shall provide any and all Site preparation and shall be in compliance with all RF or magnetic shielding and acoustical suppression and building codes relevant to the product and its installation and use.
- 4.2 Customer's contractor or Customer's architect is required to provide detailed information on the proposed Helium Exhaust Pipe for their MRI system prior to installation to ensure safety specifications are being met. Required Details include:
- (a) Architectural drawing or sketch with complete dimensions including lengths, bending radii, bending angles, and pipe diameters for entire Helium Exhaust Pipe run from RF enclosure to discharge location.
- (b) Completed Helium Exhaust Pipe Verification Checklist (Provided by Local Philips Project Manager)
- (c) Picture showing the area where the Helium Exhaust Pipe will discharge.
- 4.3 Magnets will not be released for delivery unless and until Helium Exhaust Pipe details are provided for verification and have been confirmed to meet all life safety specifications.

#### 5. Additional Terms Related to Sales of IGIT Products.

- 5.1 As part of installation, Philips will connect the IGIT product to such DICOM compatible scanners as Customer may designate (in writing), including CT and MR scanners and, if ultrasound navigation is included in the product, an iU22 ultrasound system.
- 5.2 If Customer requires that Philips connect the IGIT product to more than two (2) scanners or other devices, then Philips shall invoice Customer and Customer shall pay for installation services at Philips' then-current daily service rate. Additionally, Customer shall (a) make the scanner(s) the Customer has designated available to Philips' installation representative. (b) create and provide a data set of the installation phantom on or before the installation date, and (c) have its IT representative available to assist in connecting the IGIT product to Customer's DICOM devices during the agreed installation time. If such installation and connection is delayed due to Customer failing in its obligations described in this section, then Philips may invoice Customer and Customer shall pay either for (a) any time that Philips spends waiting at the site for such obligation to be fulfilled, at Philips' then-current service rate, or (b) reasonable travel expenses if Philips has to reschedule such installation.
- 5.3 Training on the IGIT Product is not included with the purchase of the IGIT product unless it is separately identified on the quotation.

#### 6. Additional Terms Related to Sales of the Intellispace Breast Solution, including the MammoDiagnost VU.

- 6.1 Installation. Philips will install the Intellispace Breast Solution and perform installation tests on the application running with the hardware provided as part of the solution, including the MammoDiagnost VU. Philips also configures and provides interfaces to the equipment and information systems set forth in a statement of work signed by Philips and the Customer. Interfaces set forth in Subsection 6.2 below are Customer's responsibility and are not part of Parts installation deliverables.
  6.2 Customer's Interface Obligations for Third Party RIS and MIS Applications. Customer is responsible to develop and implement
- interfaces from the Licensed Software running on the client workstation to any third party Radiology Information System ("RIS") or Mammography Information System ("MIS") or to contract with the RIS and/or MIS vendor to have them perform these interface obligations on Customer's behalf. Interfacing the solution from the solutions server is not permitted. Philips shall provide Customer an API toolkit for the Licensed Software to aide Customer to perform such interface tasks. The successful and reasonably timely completion of these projects takes good faith efforts on the part of both Philips and Customer, especially when Customer has third party interfaces to develop and implement. A project implementation plan is based on completion dates mutually agreed by the parties that should be

Quotation #: 1-TY6NSD **Rev.:** 10 Page 27 of 43 reflective of the obligations of both parties. These dates are entered into the project implementation plan for this solution (the "Project Implementation Plan"). In the event Customer has not fulfilled its interface obligations by the dates set forth in the Project Implementation Plan, Customer will sign Philips' acceptance (MDIR) document for the Philips deliverables sold and pay the final payment described in Subsection 1.1(c), provided that Philips has installed the Philips deliverables and provided the interfaces Philips is responsible for pursuant to Subsection 6.1, and that the Philips deliverables substantially meet Philips' published specifications. 6.3 Prior Validation of Operating System Updates and/or Upgrades. Patches introduced by operating system oem's or upgrades to antivirus software can impact the performance and functionality of the applications that run on them and affect patient safety. Philips shall perform validation testing of certain Microsoft operating systems and MacAfee anti-virus software during the warranty period. Philips shall have no obligation to validate any other third party operating system or anti-virus software. Customer shall not install or use (a) operating system patches, updates or upgrades; (b) anti-virus updates (except to the DAT files, i.e., virus definitions); or, (c) upgrades to anti-virus search engines, collectively (a)-(b) prior to validation testing and approval by Philips ("Unauthorized Updates"). Philips shall have no liability, including, without limitation, for warranty claims, arising from use of the Licensed Software with Unauthorized Updates. In the event Philips discovers that Customer is using an Unauthorized Update with the Licensed Software, Philips shall have the right to require Customer to roll back to the most recently validated versions of operating systems and anti-virus, prior to performing any support. 6.4 Customer's Network Connectivity Obligations. Customer must have network connectivity between the IntelliSpace Breast solution server, the client workstation, and the optional DynaCAD server of not less than 1GB/s, and all three systems must be on the same subnet. A connection of no less than 100 MB/s is required between the IntelliSpace Breast solution and the hospital network. However for optimal performance a 1GB/s network between the IntelliSpace Breast and the hospital network is recommended. 6.5 RSN Warranty Condition Requirement. As a condition to receiving warranty service on this solution, Customer agrees it shall use

Philips Remote Service Network ("RSN") service to enable Philips to access the system to perform its support obligations.

Quotation #: 1-TY6NSD Rev.: 10 Page 28 of 43

## PHILIPS PRODUCT WARRANTY

#### COMPUTED TOMOGRAPHY (CT) SYSTEMS

This product warranty document is an addition to the terms and conditions set forth in the quotation to which this warranty document is attached. The terms and conditions of the quotation are incorporated into this warranty document. The capitalized terms herein have the same meaning as set forth in the quotation.

#### TWELVE (12) MONTH SYSTEM WARRANTY

Philips warrants to Customer that the Philips CT System (the "System") will be free from defects in material and manufacturing workmanship for a period of twelve (12) months after completion of installation or availability for patient use, whichever occurs first. If an X-ray tube, Chiller Unit, Power Conditioner Unit, CT Injector Unit, Option, Upgrade or Accessory is purchased from Philips, they will be covered by the special warranty set forth below.

#### PLANNED MAINTENANCE

During the warranty period, Philips service personnel will schedule planned maintenance visits, in advance, at a mutually agreeable time on weekdays, between 8:00 A.M. and 5:00 P.M., excluding Philips observed holidays.

#### SYSTEM OPTIONS, UPGRADES OR ACCESSORIES

Any commercially available options, upgrades, or accessories for the System which are delivered and/or installed on the System during the original term of the System warranty shall be subject to the same warranty terms contained in the first paragraph of this warranty, except that such warranty shall expire on the later of: a) upon termination of the initial twelve (12) month warranty period for the System on which the option, upgrade or accessory is installed, b) after ninety (90) days for parts only from the date of installation. Any commercially available options, upgrades, or accessories for the System which are delivered and/or installated on the System after the original term of the System warranty has expired shall be subject to the same warranty terms contained in the first paragraph of this warranty, except that such warranty shall expire the later of: a) after ninety (90) days for parts only from the date of installation, or b) on the twelve (12) month renewal date of any current service agreement then in effect on the System.

## X-RAY TUBE WARRANTY BRILLIANCE CT SERIES -MRC X-RAY TUBES:

The CT MRC X-ray Tube ("tube") warranty period is for twelve (12) months from the date of installation or availability for patient use, whichever occurs first. If a tube becomes inoperative or fails when operated within this twelve (12) month warranty period, upon return of the tube, Philips will provide a replacement tube at no additional charge. The replacement tube warranted for the balance of the original twelve (12) month warranty.

#### BRILLIANCE CT SERIES & MX8000 CT SERIES - AKRON OR CTR2112/ CTR2150 X-RAY TUBES:

The CT X-ray Tube ("Tube") warranty period is the shorter of twelve (12) months from the date of installation or 120,000 scan-seconds. If a tube becomes inoperative or fails when operated within published ratings, upon return of the tube, a prorated credit toward the purchase of a replacement tube from Philips will be issued as follows: Failure within the first 3,000 Scan-Seconds = 100% credit will be provided. Failure after the first 3,000 Scan-Seconds = tube credit will be prorated (See CT X-ray Tube Credit Proration Calculation below). Scan-Seconds are the number of seconds the System operates with the X-ray on.

> Brilliance CT Series & Mx8000 CT Series X-Ray Tube Credit Proration Calculation: Credit = 1 - Number of Scan-Seconds Used

Expressed in a percentage not to exceed 100%

#### ACQSIM CT, PQ2000S OR ULTRA-Z CT X-RAY TUBES

The CT X-ray Tube ("Tube") warranty period is the shorter of twelve (12) months from the date of installation or 100,000 exposures. If a tube becomes inoperative or fails when operated within published ratings, upon return of the tube a prorated credit toward the purchase of a replacement tube will be issued as follows: Failure within the first 3,000 exposures = 100% credit will be provided. Failure after the first 3,000 exposures = tube credit will be prorated (See CT X-ray Tube Credit Proration Calculation below). An Exposure is any 360 degree or partial angle rotation of the gantry scan frame with the X-ray on.

> ACQSIM CT. PQ2000s or ULTRA-Z CT X-ray Tube Credit Proration Calculation: Credit = 1 - Number of Exposures Made 100,000

Expressed in a percentage not to exceed 100%.

All claims under this Tube warranty must be made within sixty (60) days of failure, or fourteen (14) months of (1) the date of installation (if installation of the tube is performed by Philips) or (2) the delivery (if installation of the tube is not performed by Philips), which ever comes first.

CHILLER UNIT, POWER CONDITIONER UNIT OR INJECTOR UNIT WARRANTY

The System can be purchased with an optional Chiller Unit, Power Conditioner Unit or Injector Unit. If any of these Units are purchased with the System, Philips will include these Units under the twelve (12) month System warranty as an OEM Warranty pass through. Authorized representatives of the Original Equipment Manufacturer will perform warranty service on each of these units.

#### SYSTEM SOFTWARE AND SOFTWARE UPDATES

The software provided with the System will be the latest version of the standard software available for that system as of the 90th day prior to the date the System is delivered to Customer. Updates to standard software for the System that do not require additional hardware or equipment modifications will be performed as a part of normal warranty service during the term of the warranty. "Updates" shall mean changes to the right of the decimal point for the software shipped with the product

All software is and shall remain the sole property of Philips or its software suppliers. Use of the software is subject to the terms of a separate software license agreement. Customer must sign all such license agreements prior to or upon the delivery of the product. No license or other right is granted to Customer or to any other party to use the software except as set forth in the license agreements.

Any Philips maintenance or service software and documentation provided with the product and/or located at Customer's premises is intended solely to assist Philips and its authorized agents to install and to test the System, to assist Philips and its authorized agents to maintain and to service the System under a separate support agreement with Customer, or to permit Customer to maintain and service the System. Customer agrees to restrict the access to such software and documentation to Philips' employees and those of its authorized agents, and to authorized employees of Customer only.

WARRANTY LIMITATIONS
Philips' obligations under the System warranty are limited, at Philips' option, to the repair or the replacement of the System or a portion thereof, or to a credit or refund of a portion of the purchase price paid by Customer. Any refund will be paid to Customer when the System is returned to Philips. Certain of the parts used in the manufacture or installation of, or in the replacement parts for, this System may contain refurbished components. If such components are used, they will be subject to the same quality control and inspection procedures as new components. Any System warranty is made on condition that Philips receives written notice of a System defect during the warranty period, and within thirty (30) days following the discovery of the defect by Customer. Philips' obligations under the System warranty do not apply to any System defects resulting from: improper or inadequate maintenance or calibration by Customer or its agents; Customer or third party supplied software, interfaces, or supplies; use or operation of the product other than in accordance with loss, or damage in transit; improper site preparation; operation of the system outside its environmental, electrical, or performance specifications; unauthorized maintenance or Philips' applicable product specifications and written instructions; abuse, negligence, accident, modifications to the System; or to viruses or similar software interference resulting from the connection of the product to a network. Philips does not provide a warranty for any such third party products furnished to Customer by Philips; however, Philips shall use reasonable efforts to extend to Customer the third party warranty for the product. The obligations of Philips described above are Philips' only obligations and Customer's sole and exclusive remedy for a breach of a System warranty. Renote of the product and the term of this warranty. a System warranty. Repairs or replacement parts do not extend the term of this warranty.

THE WARRANTIES SET FORTH IN PHILIPS WARRANTY DOCUMENT WITH RESPECT TO THIS SYSTEM (INCLUDING THE SOFTWARE PROVIDED WITH THE SYSTEM) ARE THE ONLY WARRANTIES MADE BY PHILIPS IN CONNECTION WITH THE SYSTEM, THE SOFTWARE, AND THE TRANSACTIONS CONTEMPLATED BY THE QUOTATION, AND ARE EXPRESSLY IN LIEU OF ANY OTHER WARRANTIES, EXPRESS OR IMPLIED INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

Philips shall have full, free and safe access to the System and Customer's operation, performance and maintenance records for the System, on each scheduled or requested warranty service visit. Philips shall also have access to and use of any machine, service, attachment, features or other equipment required to perform the necessary service contemplated herein at no charge to Philips. Customer waives warranty service if it does not provide such access to the System and Customer's records. Should Philips be denied access to the

Quotation #: 1-TY6NSD Rev.: 10 Page 29 of 43 System and Customer's records at the agreed upon time, a charge equal to the appropriate hourly rate will be accepted by Customer for "waiting time."

in the event it is not possible to accomplish warranty service within normal working hours (8:00 A.M. to 5:00 P.M., Monday through Friday, excluding Philips observed holidays), or in the event Customer specifically requests that warranty service be performed outside of Philips normal working hours, Customer agrees to pay for such services at Philips standard service rates in effect. Customer Support Agreements are available for extended coverage.

in the event Customer transfers or relocates the System, all obligations under this warranty will terminate unless Customer receives the prior written consent of Philips for the transfer in the event customer delicates on relocation, the System must be inspected and certified by Philips as being free from all defects in material, software and workmanship and as being in compliance with all technical and performance specifications. Customer will compensate Philips for these services at the prevailing service rates in effect as of the date the inspection is performed. Any System, which is transported intact to pre-approved locations and is maintained as originally installed in mobile configurations, will remain covered by this

This warranty is subject to the following conditions: the System (a) is to be installed by authorized Philips representatives (or is to be installed in accordance with all Philips installation instructions by personnel trained by Philips), (b) is to be operated exclusively by duly qualified personnel in a safe and reasonable manner in accordance with Philips written instructions and for the purpose for which the products were intended, (c) is to be maintend and in strict compliance with all recommended and scheduled maintenance instructions provided with the System, and (d) Customer is to notify Philips immediately in the event the System at any time falls to meet its printed performance specifications.

LIMITATIONS OF LIABILITY AND DISCLAIMERS

The liability, if any, of Philips AND ITS AFFILIATES for damages whether arising from breach of the terms in the quotation, breach of warranty, negligence, indemnity, strict liability or other tort, or otherwise with respect to the products and services is limited to an amount not to exceed the price of the product or service giving rise to the liability.

IN NO EVENT SHALL PHILIPS OR ITS AFFILIATES BE LIABLE FOR ANY INDIRECT, PUNITIVE, INCIDENTAL, CONSEQUENTIAL, OR SPECIAL DAMAGES, INCLUDING WITHOUT LIMITATION, LOST REVENUES OR PROFITS, OR THE COST OF SUBSTITUTE PRODUCTS OR SERVICES WHETHER ARISING FROM BREACH OF THE TERMS IN THIS QUOTATION, BREACH OF WARRANTY, NEGLIGENCE, INDEMNITY, STRICT LIABILITY OR OTHER TORT. PHILIPS SHALL HAVE NO LIABILITY FOR ANY GRATUITOUS ADVICE PROVIDED TO THE CUSTOMER.

#### FORCE MAJEURE

Politips and Customer shall each be excused from performing its obligations arising from any delay or default caused by events beyond its reasonable control including, but not limited to: acts of God, acts of third parties, acts of the other party, acts of any civil or military authority, fire, floods, war, embargoes, labor disputes, acts of sabotage, riots, accidents, delays of carriers, subcontractors or suppliers, voluntary or mandatory compliance with any government act, regulation or request, shortage of labor, materials or manufacturing facilities.

Philips system specifications are subject to change without notice Document Number 4535 983 03551 999

Quotation #: 1-TY6NSD Rev.: 10 Page 30 of 43

## Non Disclosure Agreement for Philips Confidential Pricing Information

The parties specified below agree to the following terms:

#### A. Philips

po		
Name	Phillips Healthcare, a division of Phillips Electronics North America Corporation	
Address	22100 Bothell-Everett Highway, Bothell, WA 98021 United States of America	

#### B. Company

Name	UNIV OF CONNECTICUT HEALTH CENTER JOHN DEMSEY HOSP	
Address	263 FARMINGTON AVE FARMINGTON, CT 06030-1948	

#### C. Confidential Information

Authorized Purpose	To evaluate Philips' confidential information relating to pricing for imaging equipment ("Pricing") in connection with		
	the potential purchase of such imaging equipment.		
Period	Begins on the date Pricing is first disclosed and continues for 5 years from date Pricing is last disclosed.		

#### D. Philips Contact

Name	Stephen lametti
Title	
Telephone	(800) 833-3316
Fax	(845) 429-1138
e-mail	
Signature	

#### **Company Contact**

Name	
Title	
Telephone	
Fax	
e-mail	
Signature	

- The following terms and conditions (the "Agreement") apply to Pricing disclosed by Philips and its Affiliates ("Philips") to Company and its Affiliates ("Company"), in connection with the Authorized Purpose.
  - (a) Subject to Philips' prior written consent, Company may disclose, or request that Philips disclose, Pricing to Company's Affiliates that need to know the Pricing for carrying out the Authorized Purpose, provided they are advised of and agree to be bound by this Agreement. Company is responsible for any breach of this Agreement by its Affiliates.
  - (b) An Affiliate is any corporation, company, or other entity, that: (i) is under the Control of a party hereto; or (ii) has Control of a party hereto; or (iii) is under common Control with a party hereto. For this purpose "Control" means that more than fifty percent (50%) of the controlled entity's shares or ownership interest representing the right to make decisions for such are owned or controlled, directly or
- 2. Philips may disclose Pricing to Company with respect to the Authorized Purpose in writing, orally, or otherwise. All information is assumed to be Pricing, and confidential, if the confidential or proprietary nature is reasonable under the circumstances.
- 3. All Pricing disclosed by Philips shall remain Philips' the property. Company does not, by implication, estoppel, or otherwise, acquire any intellectual property right, title, or ownership, nor a license to any such intellectual property right, with respect to any Pricing disclosed by Philips hereunder.

ALL PRICING IS PROVIDED ON AN "AS IS" BASIS, WITHOUT ANY WARRANTY WHATSOEVER. PHILIPS SHALL HAVE NO LIABILITY WHATSOEVER RESULTING FROM THE USE OF THE INFORMATION PROVIDED.

- 4. Company shall:
  - (a) not use the Pricing for any purpose other than the Authorized Purpose;
  - (b) not disclose the Pricing to any third party;
  - (c) protect the Pricing against disclosure in the same manner and with the same degree of care with which Company protects its own confidential information but not less than a reasonable degree of care; and
  - (d) limit circulation of the Pricing to Company's employees as have a need to know in connection with the Authorized Purpose.

    These obligations shall survive the termination of this Agreement. Philips may terminate this Agreement at any time by means of a written notice to Company. Company shall return to Philips, or certify destruction of, all Pricing, immediately upon termination or expiration of this Agreement.
- 5. Information disclosed by Philips to Company pursuant to this Agreement shall not be confidential to the extent that the information:
  - (a) is or becomes part of the public domain without violation of this Agreement or any other obligation of confidentiality;
  - (b) is known by Company prior to disclosure by Philips;
  - (c) is lawfully obtained by Company from a third party without any breach of confidentiality or violation of law; or
  - (d) is developed by Company completely independently of any such disclosure by Philips.
- 6. If Company is required, pursuant to administrative or judicial action or subpoena, to disclose the Pricing, Company shall use its best efforts to maintain the confidentiality of the Pricing, e.g. by asserting in such action any applicable privileges. Immediately after gaining knowledge or receiving notice of such action or subpoena, Company shall notify Philips and give Philips the opportunity to seek any other legal remedies so as to maintain such Pricing in confidence, including a reasonable protective order.
- 7. Company may not transfer or assign any or all of its rights and/or obligations or delegate the performance of any or all of its obligations under this Agreement, directly or indirectly, through acquisition, merger or otherwise, without the prior written consent of Philips. Any transfer, assignment or delegation in contravention of the foregoing shall be void.
- 8. Company shall not disclose, export or release the Pricing in contravention of any applicable laws or regulations.
- 9. This Agreement shall be governed and construed in accordance with the laws of the State of New York, without giving effect to its conflict of laws provisions.
- 10. This Agreement contains the entire understanding of the parties and supersedes any previous understandings or agreements with respect to the subject matter hereof. This Agreement may be amended only in writing signed by authorized representatives of each party.

Pricina NDA ver1 - 8/9/07

Quotation #: 1-TY6NSD Rev.: 10 Page 31 of 43

# PHILIPS HEALTHCARE A division of Philips Electronics North America Corporation 22100 Bothell Everett Highway P.O. Box 3003 Bothell, Washington 98041-3003



Quotation #: 1-TY6NSD Rev. 10 Effective From: 08/08/2012 To: 09/22/2012 Presented By: Presented To: Tel: (800) 833-3316 Fax: (845) 429-1138 UNIV OF CONNECTICUT HEALTH CENTER Stephen lametti Account Manager JOHN DEMSEY HOSP 263 FARMINGTON AVE Tel: (800) 833-3316 Randal Herring **FARMINGTON, CT 06030-1948** Regional Manager Fax: Tel: Alternate Address: Date Printed: 08-Aug-12 Submit Orders To: 22100 Bothell Everett Hwy Bothell, WA 98021-8431 Tel: (800) 982-2011 Fax: (425) 487-8110

IMPORTANT NOTICE: Health care providers are reminded that if the transactions herein include or involve a loan or discount (including a rebate or other price reduction), they must fully and accurately report such loan or discount on cost reports or other applicable reports or claims for payment submitted under any federal or state health care program, including but not limited to Medicare and Medicaid, such as may be required by state or federal law, including but not limited to 42 CFR 1001.952(h).

Model	Month	ıs Qty	Service Plan
100017 Brilliance CT Big Bore Oncology Systems	48	1	SVC0931 Philips RightFit Service Agreement Support

	Home Office Use Only	
Site #	Start Date	End Date

## POINT OF SALE SERVICE CONTRACT SECTION

This quotation contains confidential and proprietary information of Philips Healthcare, a division of Philips Electronics North America Corporation ("Philips") and is intended for use only by the customer whose name appears on this quotation. It may not be disclosed to third parties without the prior written consent of Philips.

Philips Ultrasound Customer Services Ranked #1 by Customers in IMV ServiceTrakTM Survey in 2010 for 18th consecutive year

Quotation #: 1-TY6NSD

Rev.: 10

		Brilliance CT Big Bore Oncology Systems
Item #	Part#	Description
1	SVC0931	Philips RightFit Service Agreement Support
	Thank you for Support Service communication	the opportunity to provide this proposed Philips RightFit Service Agreement. Our ce Agreement offers you cooperative hands-on participation from Philips, and open ns.

#### LABOR:

- Second Response Labor Coverage. This includes labor and travel coverage from 8:00 am 5:00 pm. Monday Friday, excluding Philips published holidays. Labor is provided by Philips after the customer engineer has made an initial attempt to resolve equipment problems or concerns.
- Preferential Scheduling of service calls for service contract customers.
- On-site Response. At customer's request, Philips service goal is to be on-site within 4 hours.
- <u>Preferred rates for labor and travel</u>. This includes reduced hourly rates for labor and travel for corrective or planned maintenance outside of Service Agreement coverage hours.
- <u>Diagnostic Software License</u>. This includes a license granted by Philips to the customer to use Philips proprietary diagnostic software tools. The license is not transferable.
- <u>Service Documentation License</u>. This includes a license granted by Philips to the customer to use Philips proprietary service documentation. The license is not transferable
- <u>Customer Engineer Training</u> is required with the purchase of this service agreement in order for this contract to be valid. Training courses must be purchased separately. Travel and living expenses for trainees may also be purchased. Technical training addresses problem resolution, planned maintenance, safety, and other topics. The training is conducted at a Philips training center. Training course length and timing are determined by Philips.

#### PARTS:

- Standard parts coverage. This provides coverage on parts to maintain and repair the
  equipment including both hardware and software items.
- 10:30 am next day parts delivery. This provides UPS next day delivery by air, available in most areas. (Actual time depends on local shipper delivery schedule and delivery restrictions for oversized or hazardous parts).

#### LIFECYCLE:

- Operating system software and hardware reliability updates. This includes on-site or remote labor, travel and parts necessary to complete safety, performance and reliability modifications to existing equipment software or hardware.
- 25% discount on any items selected from Philips Life Solutions catalog, excluding power monitoring.

#### **CUSTOMER CARE SOLUTIONS CENTER:**

- 24/7 Technical telephone support.
- Clinical telephone support from 8:00 am 5:00 pm, Monday Friday.
- <u>Remote Services.</u> This supports remote system diagnostics and monitoring. Philips
  equipment is connected via an Internet secure single point of access network to our
  solutions center as described in the Terms and Conditions exhibit. Features may vary by
  equipment and software release level.

#### **SOLUTION ENHANCEMENTS:**

Quotation #: 1-TY6NSD Rev.: 10 Page 33 of 43

#### **Brilliance CT Big Bore Oncology Systems**

- <u>Philips Service Information</u>. This contains important service management reports through a secure Internet site. Information on equipment service status, historical service performance, engineer response time, and planned maintenance schedules is available.
- <u>Utilization Essentials</u>. This provides a compilation of workflow-related reports for visibility into system utilization and potential opportunities for business improvements. Availability dependent on system type and software release levels.
- Quarterly customer loyalty meetings. These include a review of current and future performance goals of Philips equipment and service.

#### 1.1 SVC00843 Tube Coverage Brilliance CT Big Bore Oncology-Medi

Multi-Slice CT Tube replacement as needed during the agreement term for the <u>Brilliance CT Big Bore Oncology</u> System. This coverage option is for medium usage which equates to approximately 30 patients per day, 10920 procedures per year and 215,000 scan seconds per year. Overage charges are determined by measuring scan seconds per year. Tube replacements will be performed during standard working hours (M-F: 8:00 a.m.-5 p.m.). If the actual scan seconds in any one year agreement period exceed 215,000, then at the annual anniversary of the agreement, a \$0.50 charge per each scan second in excess will apply. If the actual scan seconds in any one year agreement period exceed the agreement coverage by greater than twenty-five percent (25%), then at the anniversary of the contract, the CT Tube replacement coverage will be adjusted upward to the next coverage level for the remainder of the agreement term and previous year overage charges will be waived.

#### **Promotions**

With this new promotion, Philips will provide an additional six months of service with the purchase of a Primary, Uptime POS, Protection POS, or Support Service Agreement for your new or Diamond Select Philips CT system. The free six months includes the total service package of the agreement and all options purchased such as tubes, extended hours, etc. The additional six months of service will begin immediately following the end of the warranty period—the service payments will then begin at month 19. This is a limited time offer that expires December 31, 2012.

Quotation #: 1-TY6NSD Rev.: 10 Page 34 of 43

## **Brilliance CT Big Bore Oncology Systems**

Service Plan:

SVC0931 Philips RightFit Service Agreement Support

Quantity:

1

\*To commence at a time of system warranty expiration with the exception of In-Warranty Coverage and selected

Supplement Items Plans\*

Select Payment Terms Desired:

	36	elect Payment Terms Desired:	
Select Choice *	Payments Plans	Single System Net	Total Ne
	48 Monthly Payments at	\$6,680	\$6,680
Control of the Contro	16 Quarterly Payments at	\$20,039	\$20,039
	4 Yearly Payments at	\$80,157	\$80,157
	Single Payment at	\$320,628	\$320,628
* If no se	election is made, the default choice will be	monthly payments.	
	Prices ab	ove do not include any applicable sales taxes	
		nal equipment. If optional equipment is purchased please see attach ir Account Manager for amended service pricing.	ed Equipment
uying Gr	roup: NO CONTRACT	Contract #: NONE	
ddt'i Terr	ms.		
nd any sp		Group/Contract Number representing an agreement containing disc o that single quoted solution. If no Buying Group/Contract Number is noted solution.	
	oment system listed on purchase order/orders action is to be individually billed and paid.	represents a separate and distinct financial transaction. We unders	stand and agree that
or service	es performed outside the contract hours of cov	verage, Philips will request a Purchase Order before dispatching a F	ield Service
ngineer.			
		/e authorize payments 'in lieu of a Purchase Order' for the equipmen 	t as described in
		ver, due to our business/system limitations, we cannot issue a forma ad:	purchase order until
		Customer Agreement as Quoted d Philips representative, this document constitutes a contract and cu MITATIONS OF LIABILITY.	ustomer agrees to be
	BY: X		
	Customer Signature		
	Printed Name		
	Title	Date:	
	Ea	v Hoodenseton Hoo Only	
bilina by i		r Headquarters Use Only ntenance service for the equipment listed above in accordance with	all tarme
riiips by ii	is acceptance thereof, agrees to provide main	iteriance service for the equipment instead above in accordance with	an territa.
	Q:		
	Signature		

Quotation #: 1-TY6NSD Rev.: 10 Page 35 of 43

Date

Title

## **Service Agreement Terms and Conditions**

#### PHILIPS HEALTHCARE SERVICE AGREEMENT TERMS AND CONDITIONS

Philips Healthcare, a division of Philips Electronics North America Corporation ("Philips") will perform the services ("Services") listed below and on the above pages of this service agreement and any exhibits and attachments ("Exhibits") attached to it (together, the "Agreement") under the following terms and conditions:

1. SERVICE

During the term of this Agreement, unless otherwise set forth in the Exhibits, Philips will provide Customer the Services on the equipment identified so long as it remains under Customer's exclusive ownership or control ("Equipment"), at the location described ("Equipment Sile"), and for the prices set forth in this Agreement, including a Equipment quality performance planned maintenance as scheduled by Philips to include a general Equipment inspection and review of Equipment operation, calibrating the

Equipment as necessary, system lubrication and filter replacement or cleaning, completing minor operational and reliability field engineering change notices or updates and other remedial maintenance of a non-emergency nature. Philips will provide such planned maintenance during the Service Coverage hours (as defined in paragraph 3 below) at a time that

remedial mantenance of a non-entengency flactor. In the control of this multually agreed upon; and

b. Repair service, due to Equipment malfunction, as required. Repair service includes the cost of Philips replacement parts as required on an exchange (refurbished) or new part basis and labor to install Philips replacement parts. Replaced parts become Philips' property and may be promptly removed by Philips from the Equipment Site. The prices set forth in this Agreement are subject to change if (i) the Equipment is upgraded or reconfigured, or (ii) cryogens are included in this Agreement and the Consumer Price Index (CPI) for open market crude helium prices, as reported by the Bureau of Land Management (BLM), is increased by five percent (5%) or more during the term of this Agreement.

- a, servicing or replacing components of the Equipment other than those listed in the Exhibits;

- b. providing any service or parts specifically excluded under this Agreement;
  c. providing or paying the cost of any rigging, facility, structural alteration, or accessory incident to the Services or Equipment;
  d. servicing the Equipment if the Equipment Site or Equipment is contaminated with blood or other potentially infectious substances;
- e. any service necessary due to:

  - any service necessary due to:

    (1) a design, specification or instruction provided by Customer or Customer representative;

    (2) the failure of anyone other than Philips' subcontractor or Philips to comply with Philips' written instructions or recommendations;

    (3) any combining of the Equipment with a product or software of other manufacturers other than those recommended by Philips;

    (4) any alteration or improper storage, handling, use or maintenance of the Equipment by anyone other than Philips' subcontractor or Philips;

    (5) damage caused by an external source, regardless of nature;

    (6) any removal or relocation of the Equipment; or
- (7) neglect or misuse of the Equipment;
- (7) neglect or misuse of the Equipment;
  f. any cost of materials, supplies, parts or labor supplied by any party other than Philips or Philips' subcontractors;
  g. unless specifically included in this Agreement, the cost of consumable materials, including but not limited to cushions, knee supports, pads, magnetic media, cryogens, PET
  calibration sources, film, batteries, X-ray plates and cassettes or other supply items;
  h. the cost of reconditioning, rebuilds, and overhauls if reasonably necessary because repair by Philips cannot maintain the Equipment in satisfactory operating condition;
  i. providing software updates or upgrades, back-up copies of software, or the programming of custom code;
  j. unless specifically included in this Agreement, maintenance or repair, including the cost thereof, of third-party products including but not limited to HVAC systems and chiller

- k. unless specifically included in this Agreement, the cost of nuclear camera detector crystals, surface coils, flat panel detectors, magnet replacement, magnet refrigeration system (coldhead, compressor), chiller, power conditioners, power filters, surge suppressors, uninterruptible power supplies and evacuated devices such as x-ray tubes, image intensifiers, TV camera pick-up tubes and photo multiplier tubes

  I. disposal of hazardous, intectious, or biomedical waste or materials, whether or not generated from the Services; or
- m. service to Equipment that has exceeded its useful life (i.e., has reached end-of-life as identified by the original manufacturer), is classified as obsolete, is beyond economical repair, for which continued support by the original manufacturer or repair parts are no longer available, or that can no longer be maintained in a safe or effective manner as determined by Philips. Philips will use commercially reasonable efforts to Service Equipment that has exceeded its useful life, but if Philips determines that its ability to provide Service is hindered due to the unavailability of parts or trained personnel, then Philips may remove the item(s) of Equipment from this Agreement upon notice to the Customer and refund any Customer pre-payments for periods of Service Coverage terminated by Philips or terminate this Agreement as described in paragraph 7.

#### 3. COVERAGE

- a. Unless otherwise set forth in the Exhibits, Philips will provide Customer the Services Mondays through Fridays, 8:00 AM to 5:00 PM Customer local time, excluding Philips a. Unless otherwise set forth in the Exhibits, Philips will provide Customer the Services Mondays through Fridays, 8:00 AM to 5:00 PM Customer local time, excluding Philips observed holidays ("Service Coverage"). Unless otherwise set forth in the Exhibits, travel necessary to perform the Services during the Service Coverage hours is included. Subject to the availability of personnel and repair parts, Philips will provide, at Customer request and additional expense, service relating to certain excluded items (invoiced at Philips' then-current standard rates for material and labor) or service outside the Service Coverage hours (invoiced at Philips applicable rates for out-of-hours service of this type in effect for service contract customers with this Equipment, including round trip travel time). Customer will be charged a minimum of two hours on-site time plus applicable travel charges per service visit. Other travel expenses and overnight living expenses will be charged at accordance with Philips standards for business expense reimbursement of Philips' employees.

  b. If this Agreement includes Support or Assist coverage, then the terms and conditions of Exhibit 1 and its attachments are incorporated into this Agreement.

  c. If this Agreement includes Multi-Vendor Comprehensive Management coverage, then the terms and conditions of Exhibit 2 and its attachments are incorporated into this Agreement.

- d. If the Philips Technology Upgrades option is available for the Equipment and purchased or included in this Agreement, then the terms and conditions of Exhibit 3 are incorporated
- e. If an uptime guarantee is available for the Equipment and purchased or included in this Agreement, then the terms and conditions of Exhibit 4 are incorporated into this

#### 4. CUSTOMER RESPONSIBILITIES

- During the term of this Agreement, Customer will:

  a. assure that the Equipment Site is maintained in a clean and sanitary condition and that the Equipment is cleaned and decontaminated after contact with blood or other potentially b. dispose of any hazardous or biological waste generated as a result of Philips servicing the Equipment;
- c. maintain the Equipment Site and environment (including temperature and humidity control, incoming power quality, incoming water quality, and fire protection system) in a condition suitable for operation of the Equipment;
- d. operate the Equipment in accordance with the published manufacturer's operating instructions;
   e. make normal operator adjustments to the Equipment as specified in the published manufacturer's operating instructions;
- 1. provide:

  (1) Philips a secure location to store a Philips remote services ("PRS") network router (or a Customer owned router acceptable to Philips) for connection to the Equipment and Customer network and a Philips diagnostic site server ("DSS") for connection to any non-Philips Equipment subject to Multi-Vendor Comprehensive Management coverage; provided, however, that the PRS router and DSS remain Philips' property and are only provided during the term of this Agreement;

  (2) Philips and its vendors full and free access to the PRS router and DSS to enable Philips to remotely access the Equipment or non-Philips Equipment subject to Multi-Vendor Comprehensive Management coverage; and

  (3) Philips at each Equipment Site, at all times during the term of this Agreement, a dedicated broadband internet access node, including but not limited to public and stated internet access to the PRS and Customer property for Philips use in remote condeting of the Equipment
- private interface access, suitable to establish a successful connection to the Equipment through the PRS and Customer network for Philips use in remote servicing of the Equipment, remote assistance to personnel that operate the Equipment, performing real-time screen sharing with Customer's personnel, updating the Equipment software, transmitting automated status notification from the Equipment and regular uploading of Equipment data files (such as but not limited to error logs and utilization data for improvement of Philips products and services and aggregation into new services). Unless Philips determines in its sole discretion that the Equipment cannot be connected to the PRS, then Customer's failure to provide the access described in this paragraph 4(f) will constitute Customer's waiver of its rights to Services under this Agreement and any uptime guarantee provided with the Equipment or in
- the access described in this paragraph 4(f) will constitute Customer's waiver of its rights to Services under this Agreement and any uptime guarantee provided with the Equipment connection with this Agreement, if any;
  g. provide Philips service personnel full and free access to the Equipment at the scheduled service time. Customer's failure to provide such access at the scheduled time constitutes Customer's waiver of the scheduled planned maintenance service and voids Agreement coverage of Equipment mailtunctions until such time as planned maintenance service is completed. Customer agrees to pay Philips at the prevailing demand service rates for all time spent by Philips service personnel waiting for access to the Equipment;
  h. provide Philips service personnel access to safe and secure parking in an area close to the normal Equipment Site entrance/exit points and access to Customer's cafeteria,
- i. report cryogen readings for all Equipment covered by this Agreement into the Magnet Monitoring System at 1-800-722-9377 (option 8) each week if the Equipment is not connected the PRS. If an emergency cryogen fill is required due to a lack of such cryogen reporting, then Customer will be responsible for all costs and expenses associated with such
- is connect all Equipment located in a mobile unit to a fully functional and operating generator during transport. If such generator malfunctions, then Customer agrees to replace or pair the generator within two (2) business days. If generator repair goes beyond two (2) business days, then Customer will be responsible for all costs and expenses associated with

Page 36 of 43 Quotation #: 1-TY6NSD Rev.: 10

the resulting cryogen fill.

All payments under this Agreement are due thirty (30) days from the date of Philips' invoice until the Agreement amount and all applicable taxes and interest are paid in full. Customer will pay interest on any amount not paid when due at the lesser of 1.5% interest per month or the maximum rate permitted by applicable law.

e. EACUSABLE DELAYS
Philips is excused from performing under this Agreement when Philips' delay or failure to perform is caused by events beyond Philips reasonable control including, but not limited to, acts of third parties, acts of the other party, acts of any civil or military authority, fire, floods, war, terrorism, embargoes, labor disputes, acts of sabotage, riots, accidents, delays of carriers, subcontractors or suppliers, voluntary or mandatory compliance with any government act, regulation or request, shortage of labor, materials or manufacturing facilities, or Equipment being contaminated with blood or other potentially infectious material.

#### 7. TERM: TERMINATION

7. TERMI; TERMINATION

Except as otherwise provided in this paragraph 7, this Agreement is noncancelable by Customer and will remain in effect for the term specified in this Agreement.

a. Customer may cancel this Agreement upon 80 days written notice to Philips (i) representing that the Equipment is being permanently removed from the Equipment Site and that the Equipment is not being used in any other Customer or third party site, or (ii) specifically describing a material breach or default of the Agreement by Philips, provided that Philips may avoid such cancellation by curring the condition of breach or default within such 60 day notice period.

b. if Customer transfers ownership of the Equipment as part of the transfer of (i) Customer's business or a substantial amount of its assets to a third party or (ii) a mobile unit that

ment to such third party (as described in paragraph 16), then Customer will pay a cancellation fee

b. If Customer transfers ownership of the Equipment as part of the transfer of (i) Customer's business or a substantial amount of its assets to a third party or (ii) a mobile unit the houses the Equipment to a third party, in either case without assignment of this Agreement to such third party (as described in paragraph 16), then Customer will pay a cancellation for equal to thirty percent of the remaining balance of this Agreement within 30 days of when payment is due constitutes a default of this Agreement and all other agreements between Customer and Philips. In such an event, Philips may, at its option, (i) withhold performance under this Agreement and any or all of the other agreements until a reasonable time after all defaults have been cured, (ii) declare all sums due and to become due to be immediately due and payable under this Agreement and any or all of the other agreements, (iii) commence collection activities for all sums due or to become due to be immediately due and payable under this Agreement and any or all of the other agreements, (iii) commence collection activities for all sums due or to become due hereunder, including, but not limited to costs and expenses of collection, and reasonable attomey's fees, (iv) terminate this Agreement with 10 days notice to Customer, and (v) pursue any other remedies permitted by law.

d. If Philips determines that its ability to provide the Service Coverage is hindered due to the unavailability of parts or trained personnel, then Philips may terminate this Agreement upon notice to the Customer and provide Customer with a refund of any Customer pre-payments for periods of Service Coverage terminated by Philips.

b. WARRANT I DISCEMINE.

Philips' full contractual service obligations to Customer are described in this Agreement. Philips provides no warranties under this Agreement. All service and parts to support service under this Agreement are provided AS IS. NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE APPLIES TO ANYTHING PROVIDED BY PHILIPS' SUBCONTRACTOR OR PHILIPS.

9. LIMITATIONS OF LIABILITY AND DISCLAIMER

A. THE TOTAL LIABILITY, IF ANY, OF PHILIPS AND ITS AFFILIATES FOR ALL DAMAGES AND BASED ON ALL CLAIMS, WHETHER ARISING FROM BREACH OF CONTRACT, BREACH OF WARRANTY, NEGLIGENCE, INDEMNITY, STRICT LIABILITY OR OTHER TORT, OR OTHERWISE, ARISING FROM A PRODUCT, LICENSED SOFTWARE, AND/OR SERVICE IS LIMITED TO THE PRICE PAID HEREUNDER FOR THE PRODUCT, LICENSED SOFTWARE, OR SERVICE. THIS LIMITATION SHALL NOT APPLY TO THIRD PARTY CLAIMS FOR BODILY INJURY OR DEATH CAUSED BY PHILIPS' NEGLIGENCE OR PROVEN PRODUCT DEFECT. PHILIPS WILL HAVE NO LIABILITY

APPLY TO THIRD PARTY CLAIMS FOR BODIET INDUST OR DEATH CAUSED BY PHILIP'S REGISTENCE OR PROVEN PRODUCT DEFECT. PHILIP'S WILL PAVE NO LABELTY FOR ANY ASSISTANCE PHILIPS PROVIDES THAT IS NOT REQUIRED UNDER THIS AGREEMENT.

B. IN NO EVENT SHALL PHILIPS OR IT'S AFFILIATES BE LIABLE FOR ANY INDIRECT, PUNITIVE, INCIDENTAL, CONSEQUENTIAL, OR SPECIAL DAMAGES, INCLUDING WITHOUT LIMITATION, LOST REVENUES OR PROFITS, BUSINESS INTERRUPTION, LOSS OF DATA, OR THE COST OF SUBSTITUTE PRODUCTS OR SERVICES WHETHER ARISING FROM BREACH OF CONTRACT, BREACH OF WARRANTY, NEGLIGENCE, INDEMNITY, STRICT LIABILITY OR OTHER TORT.

#### 10. PROPRIETARY SERVICE MATERIALS

in connection with the installation, configuration, maintenance, repair and de-installation of the Equipment, Philips might deliver or transmit to the Equipment Site, along with the Equipment or separately, and store at the Equipment Site, attach to or install on the Equipment, and use certain proprietary service materials (including software, tools and written documentation) that have not been purchased by or licensed to Customer heavy consents to this delivery, transmission, storage, attachment, installation and use, and to the presence of Philips' locked cabinet or box in the Equipment Site for storage of this property, and to Philips' moved of all or any part of this property at any time, all without charge the presence of this property within the Equipment site will not be strateged to the property at any limit of this property of any license or other right to access, use or decompile this property. Any access to or use of this property and any decompilation of this property by anyone other than Philips' personnel is prohibited. Customer agrees that it will use all reasonable efforts to protect this property against damage or loss and to prevent any access to or use or decompilation of this property against damage or loss and to prevent any access to or use or decompilation of this property against damage or loss and to prevent any access to or use or decompilation of this property contrary to this prohibition. Customer also agrees to immediately report to Philips any violation of this provision known by Customer.

#### 11. THIRD PARTY MANAGEMENT

11. THIRD PARTY MANAGEMENT

If Customer has contracted with a third party service management organization, asset management company, maintenance management company, technology management company, maintenance insurance organization or the like ("Third Party Organization") for purposes of centralized billing and management of services provided to Customer, at Customer's written request, Philips will route invoices for payment of services rendered by Philips to such Third Party Organization and accept payment from them on Customer's behalf. Notwithstanding the above, Customer agrees that the services provided by Philips are subject solely to the terms and conditions set forth in this Agreement, and that Customer guarantees the payment of all monies due or that may become due under this Agreement in spite of any collateral arrangements Customer may have with such Third Party Organization or any payments. Customer have made to the Third Party Organization. Philips has no contractual relationship for the Services rendered to Customer except as set forth herein. To the extent that the parts and services Philips provides are not covered by Customer's arrangement with such Third Party Organization, Customer agrees to promptly pay for such parts and services on

The imposed to pay any federal, state or local tax imposed upon or measured by Philips' net income. Any other applicable tax will be invoiced to and payable by Customer, along with the Agreement Price in accordance with the payment terms set forth in this Agreement, unless Philips receives a tax exemption certificate from Customer which is acceptable to the taxing authorities.

#### 13. INDEPENDENT CONTRACTOR

13. INDEPENDENT CONTRACTOR
Philips is Customer's independent contractor. Philips' employees are under Philips' exclusive direction and control. Philips' subcontractor's employees are under Philips' subcontractor's exclusive direction and control. Nothing in this Agreement will be construed to designate Philips or any of Philips' employees or Philips' subcontractors or any of their employees as Customer employees, agents, joint venturers or partners. Customer will indemnify, defend, and hold hammless Philips and its officers, directors, and employees from any claims for loss, cost, damages, expense or liability (including reasonable attomeys fees) to the extent such claims result from Customer's or Customer's employees' act or omissions related to the services to be performed by Customer's employees under this Agreement.

if Section 1861 (v) (1) (l) of the Social Security Act applies to this Agreement, Subsections (i) and (ii) of that Section are made a part of this Agreement. In such an event, Philips agrees to retain and make available, and to insert the requisite clause in each applicable subcontract requiring Philips subcontractor to retain and make available, the contract(s), book(s), document(s), and record(s) to the person(s), upon the request(s) for the period(s) of time required by these Subsections.

ID. FIGURE 1
In the course of providing the Services to Customer, it is necessary for Philips to have access to, view and/or download computer files from the Equipment that might contain Personal Data. Personal Data includes information relating to an include both personal health information (e.g., mages, heart monitor data, medical record number) and non-health information (e.g., date of birth, gender). Philips will process Personal Data only to the extent necessary to fulfill its Service obligations under this Agreement.

#### 16. SUBCONTRACTS AND ASSIGNMENTS

Philips may subcontract to service contractors of Philips' choice any of Philips' service obligations to Customer or other activities performed by Philips under this Agreement. No such subcontract will release Philips from those obligations to Customer Customer may not assign this Agreement or the responsibility for payments due under it without Philips' prior express written consent, which will not be unreasonably withheld.

#### 17. SURVIVAL, WAIVER, SEVERABILITY, NOTICE, CHOICE OF LAW

17. SUKYIVAL, WAIVER, SEVERABILIT, NOTICE, CHOICE OF LAW
Customer's obligation to pay any money due to Philips under this Agreement survives expiration or termination of this Agreement. All of Philips' rights, privileges and remedies with respect to this Agreement will continue in full force and effect after the end of this Agreement. Either party's failure to enforce any provision of this Agreement is not a waiver of that provision or of such party's right to later enforce each and every provision. If any part of this Agreement is found to be invalid, the remaining part will be effective. Notices or other communications will be in writing, and will be deemed served if delivered personally, or if sent by facsimile transmission, by overnight mail or courier, or by certified mail, return receipt requested and addressed to the party at the address set forth on the face of this Agreement. The law of the state in which the Equipment is located will govern any interpretation of this Agreement and dispute between Philips and Customer without regard to the principles of choice of law.

18. ENTIRE AGREEMENT

This Agreement constitutes the entire understanding of the parties and supersedes all other agreements, written or oral, regarding its subject matter. No additional terms, conditions, consent, waiver, alteration, or modification will be binding unless in writing and signed by Philips' authorized representative and Customer. Additional or different terms and conditions, whether stated in a purchase order or other document issued by Customer, are specifically rejected and will not apply to the transactions contemplated by this Agreement. No prior proposals, statements, course of dealing, course of performance, usage of trade or industry standard will be part of this Agreement.

in executing this Agreement, the parties hereto acknowledge that they have read each of the terms and conditions hereof on behalf of their respective interests, that they know and understand the same, and that they have signed this Agreement as their own respective free acts and with the express authority to do so.

21594h v1 (rev060711)

Page 38 of 43 **Rev.:** 10 Quotation #: 1-TY6NSD

#### Exhibit 1

#### Support and Assist Coverage

This Support and Assist coverage Exhibit ("Exhibit") is an exhibit to and incorporated into the Philips Healthcare Service Agreement to which it is attached. Unless otherwise defined in this Exhibit, the capitalized terms used in this Exhibit have the same meanings as set forth in the Agreement. This Exhibit provides terms and conditions that are in addition to and may supersede the Agreement. In the case of a conflict between this Exhibit and the Agreement, this Exhibit shall supersede the Agreement and the terms and conditions herein shall govern with respect to the Support and Assist coverage.

#### 1. Training

If training is included with the Agreement, then Philips will admit the number of employees of Customer identified on the face of the Agreement ("Trainee(s)") into the next scheduled training course that relates to the Equipment identified in the quotation or Attachment A1 to this Exhibit where space is available, or to any subsequent scheduled course as the parties may agree. Philips will provide training to the Trainee(s) only to the extent service training for the Equipment is included in Philips' training course offerings then in effect and is included on the face of the Agreement. Training will be conducted at Philips' service training facilities, or through remote training options as defined by Philips for the applicable course. All travel and living expenses incurred by the Trainee(s) will be borne by Customer, unless otherwise indicated on the face of the Agreement. Philips reserves the right to cancel or reschedule courses.

Customer acknowledges and agrees that Philips' obligation to provide training hereunder is expressly subject to the Customer Non-Disclosure Terms and Conditions set forth in Attachment B1 to this Exhibit (which are incorporated into this Exhibit) and expressly contingent on each Trainee signing a Customer Employee Non-Disclosure Agreement set forth as Attachment C1 to this Exhibit. Trainee(s) must meet the minimum admission requirements set forth in the course syllabus, and must satisfy all prerequisites prior to admission. Philips makes no warranty that any Trainee will pass all or any portion of the training courses provided or that the training will result in any Trainee being qualified or able to troubleshoot and repair any or all possible malfunctions that may occur in the Equipment.

#### 2. Customer Service Documentation: Customer Diagnostic Software License

If software and documentation are included in the Agreement, then Philips hereby grants to Customer and Customer accepts from Philips a limited, non-exclusive and non-transferable license (the "License") to load and run the customer diagnostic software issued for the Equipment ("Diagnostic Software") and use customer service documentation issued for the Equipment ("Service Documentation") solely in conjunction with the maintenance, service and repair of the Equipment and at the Equipment Site, and subject to Customer Non-Disclosure Terms and Conditions and Customer Employee Non-Disclosure Agreement. Customer acknowledges that the Diagnostic Software and Service Documentation, and all trademarks, copyrights, patents, trade secrets, proprietary rights, or other property rights of Philips associated therewith, are and will remain the exclusive property of Philips.

The Diagnostic Software and Service Documentation are licensed by Philips for ultimate end use by government agencies only under the following conditions: (a) software and technical data rights in the Software and Documentation include only those rights customarily provided to end user customers as defined in the Agreement; (b) this customary commercial License in the Software and Documentation is provided in accordance with FAR 12.211 (Technical Data) and FAR 12.212 (Computer Software) and, for Department of Defense purchases, DFAR 252.227-7015 (Technical Data - Commercial Items) and DFAR 227.7202-3 (Rights in Commercial Computer Software or Computer Software Documentation); (c) if a federal government or other public sector customer has a need for rights not conveyed under these terms, it must negotiate with Philips to determine if there are acceptable terms for transferring such rights, and a mutually acceptable written agreement specifically conveying such rights must be executed by both parties.

#### 3. Parts Coverage

If Parts or Combination Pool coverage is not included in the Agreement, then Philips will sell parts to Customer at Philips' published list price. If Parts coverage is included in the Agreement, then the cost of parts used in corrective maintenance of the Equipment at the Equipment Site is included in this Exhibit, subject to the terms and conditions of the Agreement. Philips reserves the right to approve any Customer requests for parts.

Customer acknowledges and agrees that the inclusion of parts (in the case of Parts coverage) and the favorable parts pricing afforded Customer (in the case of Combination Pool coverage) under the Agreement is premised on Customer's agreement that all parts furnished pursuant the Agreement will only be used in the maintenance, service and repair of the Equipment at the Equipment Site. Customer may not resell or exchange such parts with any third party. If a replaced part is a recyclable part as indicated on Philips' published price book, Customer must immediately return to Philips the failed recyclable part for which the replacement part was furnished within 14 days of shipment of the replacement part. If the parts are resold or exchanged, or the failed part is not returned to Philips in the time stated, Customer will pay Philips, in addition to any other amounts due Philips, Philips' published list price for such parts plus freight. Unless priority parts delivery is included in the Agreement, all replacement parts ordered under this Exhibit will be shipped using Philips standard shipping priority prepaid subject to availability. Other freight arrangements will be at Customer's request and expense.

#### 4. On-Site Support Coverage

If Second Response or Combination Pool coverage is not included in the Agreement, then Philips will provide on-site labor to Customer at Customer's request at Philips' then-current standard hourly rates for demand service.

If Second Response coverage is included in the Agreement, then the cost of on-site labor for corrective maintenance of the Equipment at the Equipment Site is included in this Exhibit, subject to the terms and conditions of the Agreement. Philips' obligation to provide on-site labor is subject to Customer, through its Trainee, making a reasonable first attempt to service a particular item of Equipment prior to calling Philips for on-site labor support on such Equipment. If the Trainee cannot resolve the Equipment problem after such first attempt, then the Trainee must make a reasonable second attempt to resolve the Equipment problem by contacting Philips' remote technical assistance center. If the Equipment problem remains unresolved after such second attempt, then Philips will provide a Philips employee for on-site labor support, subject to the terms and conditions of the Agreement. The Trainee will be present during any and all visits to the Equipment Site by Philips for on-site labor support. If the Equipment requires any major component replacements, such as but not limited to, tubes, flat panel detectors, cold heads and the like, then Philips will take the lead in making such replacements. Second Response coverage does not include, and may not be used for, quality assurance audits unless otherwise stated on the face of the Agreement.

Quotation #: 1-TY6NSD Rev.: 10 Page 39 of 43

Customer acknowledges and agrees that the favorable labor pricing afforded Customer under the Agreement is for the monetary level stated on the face of the Agreement (in the case of Combination Pool coverage) or for the inclusion of on-site labor (in the case of Second Response coverage), and in either case on-site labor is only provided during Service Coverage Hours. Unless otherwise stated in the Agreement or this Exhibit, any travel time will be billed as on-site labor hours. Subject to the availability of personnel and repair parts, Philips will provide, at Customer request and additional expense, on-site labor outside labor coverage hours stated above (invoiced at Philips' applicable rates for out-of-hours service of this type, including round trip travel time).

Customer acknowledges and agrees that its eligibility for Second Response coverage and/or Parts coverage depends on Customer using the benefits of Second Response and Parts solely on the Equipment, and not on equipment similar to the Equipment; and on Customer meeting its responsibilities described under paragraph 7 if for any reason Customer loses eligibility for Second Response or Parts coverage, then the Agreement will convert into Philips then current lowest level full service agreement for the remainder of the term or until Customer, in Philips sole and reasonable discretion, becomes eligible for Second Response and Parts coverage. Such conversion will occur thirty (30) days from Philips notice to Customer of its ineligibility, unless Customer notifies and establishes with Philips that such ineligibility has been corrected before the expiration of such thirty day period. Upon such conversion, if any, Customer agrees to use the same method of payment used for Customer's purchase of the Services under the Agreement, agrees to abide by the standard terms and conditions of Philips then current lowest level full service agreement, including but not limited to its pricing, and agrees to execute any documentation or service agreement that may be required by Philips. Upon any such conversion, the Diagnostic Software License and Service Documentation to Philips.

#### 5. Combination Pool

If Combination Pool coverage is included in the Agreement, then Philips will provide, upon Customer's request, the monetary level of on-site labor and/or parts stated on the face of the Agreement for corrective maintenance of the Equipment at the Equipment Site under this Exhibit, subject to the terms and conditions of the Agreement, which includes this Exhibit. As Customer requests or uses either on-site labor or parts under Combination Pool coverage, the Combination Pool monetary level stated on the face of the Agreement will be reduced at Philips then current standard rates (in the case of on-site labor) and Philips then current published list price (in the case of parts). Customer may allocate the level of on-site labor or parts purchased by Customer between Equipment at the Equipment Site. Philips reserves the right to approve any Customer requests for parts. Combination Pool coverage expires on an annual basis, and no credit for any unused portion may be carried forward to the next year. If Combination Pool coverage is exhausted during any year of the term (as defined on the face of the Agreement), then Philips will sell on-site labor or parts to Customer at Philips' then current standard rates for demand service plus applicable travel charges per service visit (in the case of on-site labor) and Philips then current published list price (in the case of parts), and in both cases minus the discount, if any, indicated on the face of the Agreement. In the case of on-site labor, other travel expenses and overnight living expenses will be charged at actual cost in accordance with Philips' standards for business expense reimbursement of Philips' employees.

#### 6. Tubes and Image Intensifiers

If tubes and image intensifiers coverage is included in the Agreement, then Philips will provide and install replacement tubes and image intensifiers indicated on the face of the Agreement on the Equipment during the term subject to the following: (a) the terms of tubes and image intensifiers coverage included on the face of the Agreement; and (b) Customer maintaining the Equipment, at Customer's expense, so that the operation of the Equipment does not reduce the life of the tubes and image intensifiers, as determined by Philips. Customer's failure to adequately maintain the Equipment will constitute waiver of Philips' obligation to provide and install replacement tubes and image intensifiers until the Equipment is adequately repaired. If Customer has not chosen the tubes and image intensifiers coverage, but desires to purchase tubes and image intensifiers from Philips for installation by Customer's employees, Philips' standard tubes and image intensifiers warranty will be extended, provided Customer has maintained the Equipment in strict compliance with the planned and remedial maintenance requirements specified by Philips.

#### 7. Customer Responsibilities

In addition to the Customer Responsibilities described in the Agreement, Customer agrees to the following during the term:

- (a) Customer will assign the Trainee to perform the obligations of Customer described under the Agreement.
- (b) Customer will notify Philips if the Trainee's employment with Customer terminates or Customer assigns another trained employee to maintain or repair the Equipment. Philips may require the employee selected by Customer as the trained employee to attend training, subject to the terms and conditions of the Agreement, at Philips then current price minus the discount, if any, indicated on the face of the Agreement.
- (c) Customer further acknowledges and agrees that the inclusion of a Diagnostic Software License and Service Documentation License, inclusion of parts under Parts, inclusion of on-site labor support under Second Response and the favorable pricing afforded Customer under the Combination Pool coverage options of the Agreement are based on Customer maintaining the Equipment in strict compliance with the planned and remedial maintenance requirements specified by Philips, utilizing replacement parts and tubes and image intensifiers that meet or exceed Philips' specification for such parts, and that Customer exercises due diligence in the maintenance and/or repair of the Equipment. Failure to abide to these conditions may result in termination of any or all of the options specified above or in voiding any warranty provided herein or with any tubes and image intensifiers. Customer will provide Philips service personnel full and free access to the Equipment Site and Equipment to inspect for Customer's compliance with this paragraph 7.

#### 8. Termination

In addition to the termination rights described in the Agreement, Customer agrees to the following during the term:

Philips may immediately terminate this Exhibit or the Agreement and the License without liability to Customer by providing Customer written notice of termination on the happening of any of the following: (a) Customer no longer uses the Diagnostic Software or Service Documentation or no longer uses the Diagnostic Software or Service Documentation on the Equipment or at the Equipment Site; (b) Customer no longer owns sole and exclusive title to the Equipment or no longer leases the Equipment from a financing company; (c) Customer services medical equipment manufactured by Philips or a Philips' affiliate that Customer does not exclusively own or lease from a financing company; (d) someone other than Customer, Philips, or an authorized Philips distributor or dealer services the Equipment; (e) a competitor of Philips acquires an ownership interest in Customer; or (f) Customer or the Trainee(s) violates any condition or restriction set forth in Customer Non-Disclosure Agreement Terms and Conditions or Customer Employee Non-Disclosure Agreement. Customer must notify Philips immediately upon the happening of any of the above events.

Quotation #: 1-TY6NSD Rev.: 10 Page 40 of 43

Philips may terminate this Exhibit or the Agreement and the License without liability to Customer upon three days written notice to Customer in the event of any breach by Customer or Trainee(s) of any other term, covenant or condition herein.

Upon expiration or termination of this Exhibit or the Agreement, the License expires and Customer must immediately return the Philips' Diagnostic Software and Service Documentation and all copies or reproductions thereof to Philips at Customer's expense, unless the parties agree in writing upon an extension of the License. Such termination or expiration will not relieve Customer of any of its obligations incurred prior to such termination or expiration, and will not impair any of Philips' rights which have accrued prior to such date. The covenants of Customer contained herein will survive the expiration or termination of this Exhibit or the Agreement and the License. In addition to all other rights and remedies, Philips is entitled to seek injunctive relief for any breach by Customer of paragraphs 2, 8, or 10 of these terms and conditions.

#### 9. Warranty and Warranty Disclaimer

In addition to the warranty obligations described in the Agreement, Philips warrants that any replacement parts or special service tools and Service provided under this Exhibit will be free from defects in material and workmanship for a period of 90 days from the date of installation (when installed by Philips) or 30 days from the date the parts were delivered to Customer (when not installed by Philips). Certain items such as x-ray tubes, photomultiplier tubes, cathode-ray tubes, and high voltage transformers may carry separate warranties that are provided at the time of purchase. This warranty does not include any defect or failure to perform which is the direct or indirect result, in whole or in part, of accident, abuse, misuse, operation of the Equipment in which the part is installed outside of its environmental, electrical or performance specifications, power fluctuations or failures, fires, floods or other similar or dissimilar natural causes, or improper installation or calibration. Parts not meeting this warranty will be promptly returned to Philips for repair or replacement. THE WARRANITES STATED ABOVE ARE EXPRESSLY IN LIEU OF ANY OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING WITHOUT LIMITATION WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR NONINFRINGEMENT WITH RESPECT TO ANYTHING PROVIDED BY PHILIPS OR ITS SUBCONTRACTOR UNDER THIS EXHIBIT OR THE AGREEMENT. CUSTOMER'S SOLE AND EXCLUSIVE REMEDY FOR ANY BREACH OF THIS WARRANTY IS THE REPAIR OR REPLACEMENT OF A NON-CONFORMING PART AND THE REPAIR OF EQUIPMENT FOR ANY NON-CONFORMING SERVICE.

#### 10. No Solicitation

Customer agrees that during the term and for a period of one year thereafter it will not solicit to employ or hire any of the employees of Philips or any of its affiliates to maintain, service or repair the Equipment.

21594h v1 (rev 060711)

Quotation #: 1-TY6NSD Rev.: 10 Page 41 of 43

#### SUPPORT AND ASSIST COVERAGE

#### **CUSTOMER NON-DISCLOSURE TERMS AND CONDITIONS ATTACHMENT B1**

Agreement	Number	
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- 1. The capitalized terms herein have the same meaning as set forth in the Support and Assist coverage Exhibit to which these terms and conditions are attached.
- 2. Philips is the holder and owner of certain proprietary and trade secret information (hereinafter "Philips Proprietary Information"), relating to the installation, service, maintenance and repair of the products manufactured and sold by Philips including without limitation, the Software and Documentation and any work product or diagnostic results derived therefrom, any oral, written or electronically recorded information regarding the installation, service, maintenance, repair, construction, design, theory of operation, diagnostic tools, teaching materials, hardware schematics, electrical schematics, software of any nature in any form and on any media, repair analysis techniques or maintenance of any Philips equipment, service notes, safety bulletins, installation manuals, service manuals, service diagnostic tools and techniques, and any other corresponding information of Philips or any of its predecessors, successors, affiliates, subsidiaries or assigns.
- 3. Customer warrants that all Trainees attending any Philips training are employees of Customer. For the purpose of this Attachment B1 the term "employee", or other words contemplating the same relationship as "employee", will have the same definition as is contained within the Internal Revenue Service Code in effect at the time of this Attachment B1.
- 4. Prior to the disclosure or dissemination of any Philips Proprietary Information to Customer's Trainee(s), Customer must deliver an original copy of the signed Customer Employee Non-Disclosure Agreement (Attachment C1) to Philips prior to Customer's Trainee(s) attending any Philips training. The execution by Customer's Trainee(s) of the Customer Employee Non-Disclosure Agreement and its delivery to Philips is a CONDITION PRECEDENT to Philips' obligation to train or otherwise disclose or disseminate any Philips Proprietary Information to said Customer Trainee(s).
- 5. Customer will treat any Philips Proprietary Information that is received in strictest confidence and will refrain from disclosing or disseminating any of the Philips Proprietary Information without the prior express written consent of Philips except to those employees of the Customer who have executed the Customer Employee Non-Disclosure Agreement referenced above. Except as permitted under this Attachment B1, Customer will not directly or indirectly disclose, copy, access, run, perform, display, disassemble, decompile, reverse engineer, modify, adapt, translate, create derivative works, distribute, sublicense, sell, assign, or otherwise transfer all or any part of the Proprietary Information, or cause or permit the Proprietary Information or any part thereof, to be used by any persons other than the Trainees and only on the Equipment and at the applicable Equipment Site.
- 6. All information disclosed to Customer's Trainee(s) in connection with said training and all related information regarding Philips equipment which Customer may have access to is presumed to be Philips Proprietary Information, unless Philips advises Customer in writing that any such information need not be regarded or treated as confidential.
- 7. Customer hereby acknowledges and agrees that the use or disclosure of any of the Philips Proprietary Information by Customer's Trainee(s) for purposes other than the service, maintenance and repair of Philips equipment owned or leased by Customer without the prior express written consent of Philips is a breach of this Attachment B1 and an unauthorized use or disclosure of Philips' trade secrets or other proprietary rights. In the event of any such unauthorized use or disclosure, Philips will be entitled to compensation for all damages arising out of or resulting therefrom, including but not limited to all consequential damages and attorney's fees incurred by Philips. Considering the substantial investment that Philips has in the Philips Proprietary Information, Customer further agrees that a violation by or for it of any provision of this Attachment B1 or the Customer Employee Non-Disclosure Agreement by Customer's Trainee(s) will cause irreparable injury to Philips and that Philips will be entitled, in addition to any other rights and remedies it may have at law or in equity, to an injunction enjoining and restraining the Customer from doing or continuing to do any such violation or threatened violation of this Attachment B1. Customer hereby confers jurisdiction to enforce the provisions of this Attachment B1 upon the courts of any State of the United States. Customer also agrees to indemnify and hold Philips harmless from any damages resulting from Customer or Trainee's breach of this Attachment B1.
- 8. The obligations hereunder to maintain the confidentiality of Philips Proprietary Information will endure permanently. Customer may not assign this Attachment B1 nor may any party succeed to Customer's rights and obligations hereunder unless with the prior written approval of Philips. Customer further agrees that the terms and conditions of this Attachment B1 will inure to and be binding upon its affiliates, parent, subsidiaries, officers, directors, employees, agents, or other representatives and its negmitted assigns and successors.
- 9. Customer agrees that it will not directly or indirectly permit or authorize Customer's employees to utilize in any way any of the Phillips Proprietary Information except as permitted under this Attachment B1, except with the prior written consent of Phillips.

22185h v1 - Customer NDA - (rev060711)

Quotation #: 1-TY6NSD Rev.: 10 Page 42 of 43

## SUPPORT AND ASSIST COVERAGE

## **CUSTOMER EMPLOYEE NON-DISCLOSURE AGREEMENT ATTACHMENT C1**

		Agreement Number	
(Name of Employee)	(Custom	ner Name)	
(Residence Address)	(City)	(State)	(Zip)
In consideration of the training, Customer service documentation, and/o of Philips Electronics North America Corporation, ("Philips"), and in furth following terms and conditions:			
1. "Philips Proprietary Information" as used herein means information di or in my subsequent utilization of such information in the installation, se electronically recorded information regarding the installation, service, en teaching materials, hardware schematics, electrical schematics, softwar Philips equipment, service notes, safety bulletins, installation manuals, soft Philips or any of its predecessors, successors, affiliates, subsidiaries	rvice, maintenance and repai aintenance, repair, constructi re of any nature in any form a service manuals, service diag	r of Philips equipment, including without on, design, theory of design, theory of op and on any media, repair analysis techniq	limitation any oral, written or peration, diagnostic tools, jues or maintenance of any
2. I acknowledge that as part of Philips' training of me in the installation, substantial investment in the Philips Proprietary Information, including this training school and development of special troubleshooting and diagraphilips equipment. I further acknowledge that as part of the Philips training equipment, including training on how to set up and operate such equipments, system and subsystems in the Philips equipment. During the training proutside of Philips, including detailed schematic diagrams of Philips equiport for the equipment, system and subsystems, their potential trouble spots developed by Philips may be disclosed to me. Philips' troubleshooting methods and special codes to perform tests and analysis to that the Philips training will be extremely valuable and cannot be duplicat troubleshooting methods and protocols which Philips has developed three.	housands of man-hours of wo nostic methods and protocols ing I may be given extensive nent. As part of the training, I ogram, I may have disclosed pment; the Philips instructors and how to isolate and repair nethods and protocols for the help locate and repair partic ated elsewhere and that only	ork by Philips employees in the developm relating to the installation, service, main teaching regarding the theory of design may be taught to analyze the design and to me the Philips Proprietary Information may go through the schematics with me such trouble spots. Selected detailed m service and maintenance of its equipme plar malfunctions of components of Philip at the Philips training school will I have	nent of teaching materials for tenance and repair of and operation of Philips d details of operation of the which is not available and discuss the operation anufacturing instructions ant include detailed computer os equipment. I acknowledge
I agree that I will treat the Philips Proprietary Information in strictest c translate, create derivative works, disassemble, disseminate, lecture up Philips. This obligation to maintain the confidentiality of Philips Proprietation.	on, publish, copy or duplicate	any such information without the prior e	
4. Upon termination of my employment with my current employer ("Emp wherein my use of the Phillips Proprietary Information is no longer requir Proprietary Information then in my possession, custody or control. I agre notebooks, drawings, photographs, excerpts or any other documents reduring my employment with the Employer. In the event Employer does no required above, I will agree to immediately inform Phillips of these circun	red, I agree to turn over to a c ee that I will not retain any co lating in any way to the Philip not designate an employee o	designated individual employed by the El pies or reproductions of correspondence as Proprietary Information which are entr	mployer all Philips , memoranda, reports, usted to me at any time
5. I agree that for a period of one year from the date of termination or re or repair the type of Philips equipment on which I am being trained unles customer having an agreement similar to the agreement that permitted in	ss I become employed by Ph		
<ol><li>I hereby acknowledge that no license or right is granted hereby and n respect to or under any invention, patent application, patent, copyright, t Information.</li></ol>			
7. This Agreement and all matters relating to the construction, interpreta regard to principles of choice of law. 8. If any provision of this Agreement will be determined by a court of con affecting the remainder of this Agreement.			
(Employee's Signature)		(Date)	

Quotation #: 1-TY6NSD Rev.: 10 Page 43 of 43

#22184h v1 - Customer Employee NDA - (rev 060711)

## Attachment G: Current Rate Schedule

John Dempsey Hospital Chargemaster, FY 13

Charge Code	Rate	CPT Code
4200110	\$1,901.00	CPT 77761
4200111	\$952.00	CPT 77762
4200120	\$1,819.00	CPT 77776
4200121	\$1,153.00	CPT 77777
4200130	\$469.00	CPT 77280
4200132	\$1,079.00	CPT 77290
4200282	\$3,883.00	CPT 77295

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## STATE OF CONNECTICUT

# DEPARTMENT OF PUBLIC HEALTH Office of Health Care Access

October 31, 2012

VIA FAX ONLY

Jim Thibeault Director, Strategy and Planning John Dempsey Hospital 263 Farmington Avenue Farmington, CT 06030-3804

RE: Certificate of Need Application; Docket Number: 12-31791-CON

Acquisition of a Computed Tomography-Simulator

Dear Mr. Thibeault:

On October 2, 2012, the Office of Health Care Access ("OHCA") received your initial Certificate of Need ("CON") application filing on behalf of John Dempsey Hospital ("JDH or Applicant") for the acquisition of a Computed Tomography-Simulator ("CT Simulator"), with an associated total capital expenditure of \$1,600,000.

OHCA has reviewed the CON application and requests the following additional information pursuant to General Statutes §19a-638a(8):

#### Page 3

1. Please provide evidence that the Applicant did not need a CON for the existing simulator.

#### Page 5

2. Please discuss in detail the benefits of a CT Simulator.

## Page 6

- 3. Provide the past 3 years annual number of total cancer patient visits to the JDH.
- 4. Provide description of type of patients requiring this service.
- 5. Provide the number of simulations performed from July 1, 2012 to the most recently completed month.

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 reference "Docket Number: 12-31791-CON." Submit one (1) original and five (5) hard copies of your response. In addition, please submit a scanned copy of your response including all attachments on CD in an Adobe format (.pdf) and in an MS Word format.

If you have any questions concerning this letter, please feel free to contact me at (860) 418-7001.

Sincerely.

Paolo Fiducia

Associate Health Care Analyst

\*\*\*\*\*\*\*\*\*\*\*\*\*\* \*\*\* TX REPORT \*\*\* \*\*\*\*\*\*\*\*\*\*\*\*\*

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

## FAX SHEET

TO:	3 19 14113EAULT	_
FAX:	860 679 4451	
AGENCY:	JOHN DEMPSEY HOSPITAL	
FROM:	PAOLO FLOUCIA	
DATE:	10 31 12 TIME: 2:00 PM	••••
NUMBER O	F PAGES: 3 (including transmittal sheet	

Comments: 12-31791- CON

COMPLETENESS LETTER



November 6, 2012

NOV - 62012

Mr. Paolo Fiducia
Associate Health Care Analyst
State of Connecticut
Department of Health Care Access
410 Capital Ave. – MS#13HCA
P.O. Box 340308
Hartford, CT. 06134-0308

Re: Certificate of Need Application: Docket Number: 12-31791-CON Acquisition of a Computed Tomography-Simulator

Dear Mr. Fiducia:

On October 31, 2012, John Dempsey Hospital received a request for additional information pertaining to our Certificate of Need Application for the Acquisition of a computed Tomography-Simulator (CT-Simulator). The following are our responses to the 5 questions:

#### Page 3:

Question 1: Please provide evidence that the Applicant did not need a CON for the existing simulator:

**Response:** Our records show that the existing Varian Ximatron Simulator was purchased on Sept. 15, 1990 and installed in early 1991 for a cost of \$399,900. This was under the then existing CON threshold of \$400,000 and deemed not to require a CON at the time of the purchase.

#### Page 5:

Question 2: Please discuss in detail the benefits of a CT Simulator

Response: The following are the benefits associated with a CT Simulator:

- A CT Simulator produces high-quality 3D image sets essential for performing radiation therapy planning used to treat cancer patients, and has been considered a standard of practice since the 1990's.
- A CT Simulator is designed with a large physical bore to accommodate the immobilization and positioning devices required for radiation therapy.

- A CT Simulator is equipped with a large field of view to image the entire external contour of the radiation therapy patient, which is necessary to perform custom treatment calculations.
- A CT Simulator is used to visualize and delineate various structures within the body, allowing for highly conformal therapy which delivers a maximum dose to the tumor while avoiding critical structures, as the current accepted best practice.
- A CT Simulator is capable of producing 4D images synchronized with respiratory motion, necessary for performing body stereotactic radiation therapy.
- A CT Simulator will reduce turnaround time and provide an overall improved experience for radiation therapy patients, as they will be positioned, stabilized with devices, imaged and evaluated efficiently all on one machine, in the Radiation Oncology Department where the treating physician and support staff are based.
- A CT Simulator will improve accuracy and patient comfort for brachytherapy procedures, since the applicator insertion, imaging and planning are all performed in one location.

#### Page 6:

Question 3: Provide the past 3 years annual number of total cancer patient visits to the JDH:

**Response:** The following table shows the number of Cancer Center Patient Visits for the past 3 fiscal years:

,	<b>FY 2010</b> 7/01/09 – 6/30/10	<b>FY 2011</b> 7/01/10 -6/30/11	<b>FY 2012</b> 7/01/11 – 6/30/12
Inpatient discharges Outpatient Visits Radiation Oncology Visi	1,073 36,248 ts 9,174	972 32,696 8,308	873 32,234 8,570
Annual Totals	46,495	41,976	41,677

#### Page 6:

Question 4: Provide description of type of patients requiring this service.

#### Response:

All patients undergoing radiation therapy require imaging with a CT Simulator. This includes both curative and palliative cases, external beam and brachytherapy treatments, and all body sites including, but not limited to extremities, breast, prostate, lung, gynecological cancers, central nervous system and colorectal patients

Uncommon exceptions include treatments to skin surface and a limited subset of emergency patients for whom it may be possible to proceed in the absence of images from a CT Simulator.

#### Page 6:

Question 5: Provide the number of simulations performed from July 1, 2012 to the most recently completed month.

**Response:** The following table shows the number of simulations performed from July 1, 2012 through Sept. 30, 2012 – the first completed quarter of our FY 2013.

Total Simula Fiscal Year	ntions per Qua Quarter 1	arter Quarter 2	Quarter 3	Quarter 4	Total per FY
2010	155	158	190	145	648
2011	123	163	174	154	614
2012	140	156	186	204	686
2013	164				

Although the 164 simulations performed in the first quarter of FY 2013 shows an increase of 24 simulations over the 140 simulations performed in the first quarter of FY 2012, a 17.1% increase, we do not anticipate the rate of growth will continue at this pace. For the entire fiscal year, we projected an overall annual growth rate of 1% for FY 13. Due to the quarterly fluctuations in simulations we have historically experienced, we continue to project a 1% increase over FY 12.

Submitted by:

James S. Thibeault

Director, Strategy and Planning



## STATE OF CONNECTICUT

# DEPARTMENT OF PUBLIC HEALTH Office of Health Care Access

December 5, 2012

VIA FAX ONLY

Jim Thibeault Director, Strategy and Planning John Dempsey Hospital 263 Farmington Avenue Farmington, CT 06032

RE:

Certificate of Need Application; Docket Number: 12-31791-CON

John Dempsey Hospital

Acquisition of a Computed Tomography-Simulator Notification Deeming the CON Application Complete

Dear Mr. Thibeault:

This letter is to inform you that, pursuant to Section 19a-639a(d) of the Connecticut General Statutes, the Office of Health Care Access ("OHCA") has determined that the above-referenced application has been deemed complete as of December 4, 2012. The date of December 4, 2012, also begins the ninety-day review period of the application.

If you have any questions regarding this matter, please feel free to contact me at (860) 418-7015.

Sincerely.

Paolo Fiducia

Associate Health Analyst,

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

## FAX SHEET

TO:	JIM THIBEAULT	
FAX:	860 679 4451	
AGENCY:	JOHN DSMPSEY HOSPITAL	
FROM:	PAOLO FIDUCIA	
DATE:	12/5/12 TIME: 10 AV	
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Comments: 12-31791-60N

NOTIFICATION DEEMING THE CON APPLICATION COMPLETE