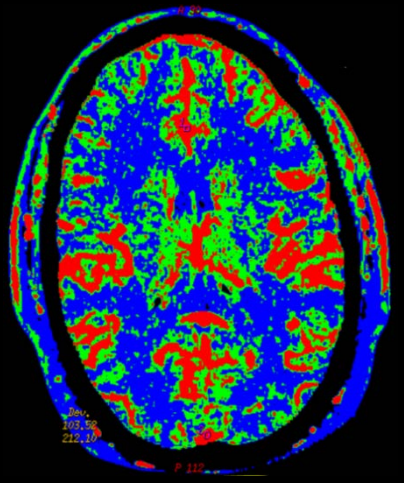
The California CT Dose Law:
History, Implementation, Implications, and Benefits

John M. Boone, Ph.D., FAAPM, FSBI, FACR
Professor and Vice Chair (Research) of Radiology
Professor of Biomedical Engineering
Department of Radiology

The California CT Dose Law:

- History
- Details
- Implementation
- Implications
- Benefits
- Summary



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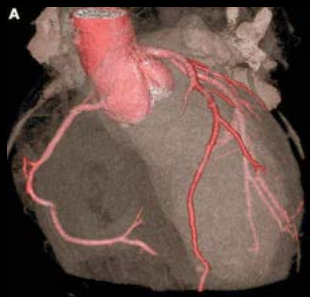
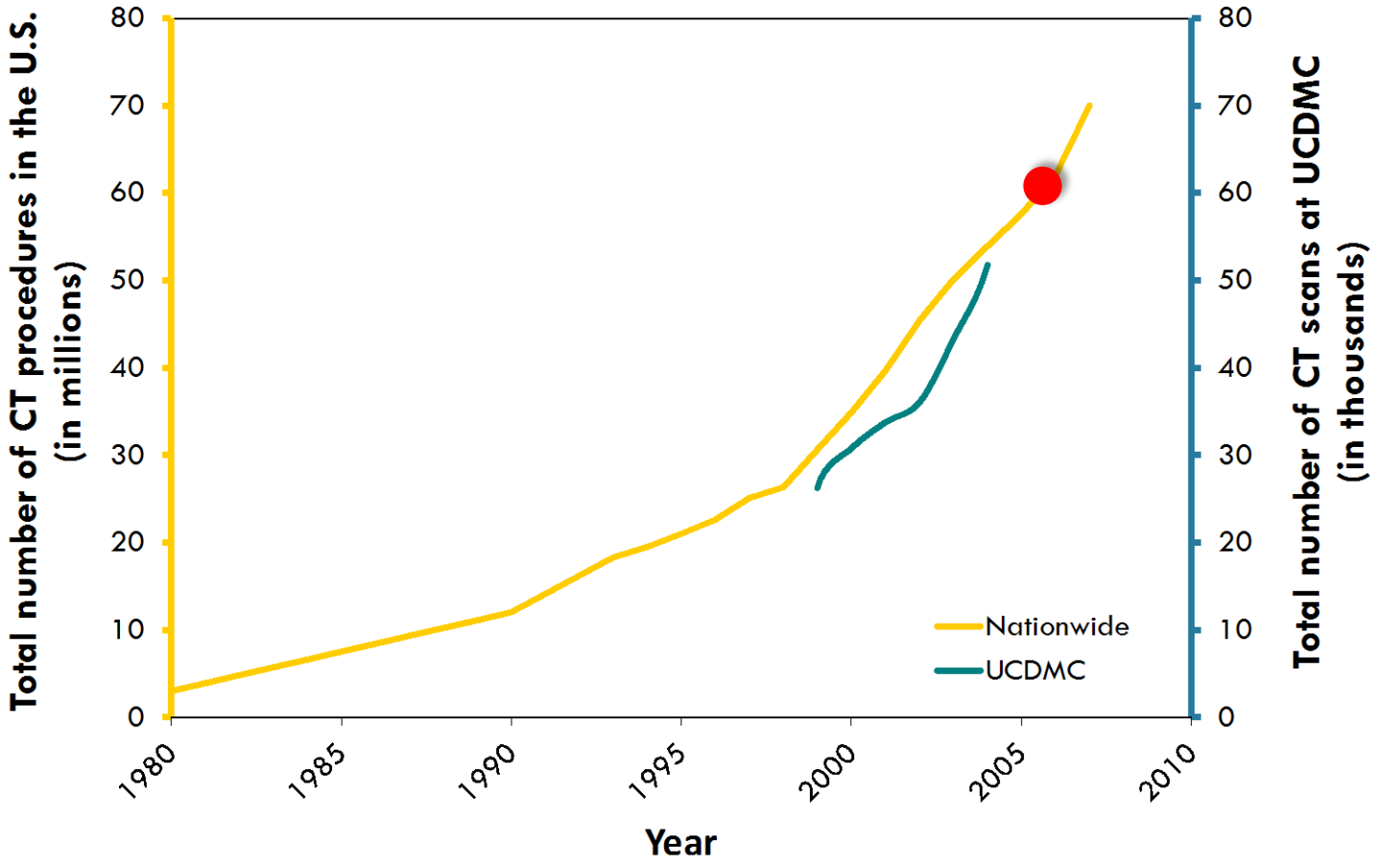


A

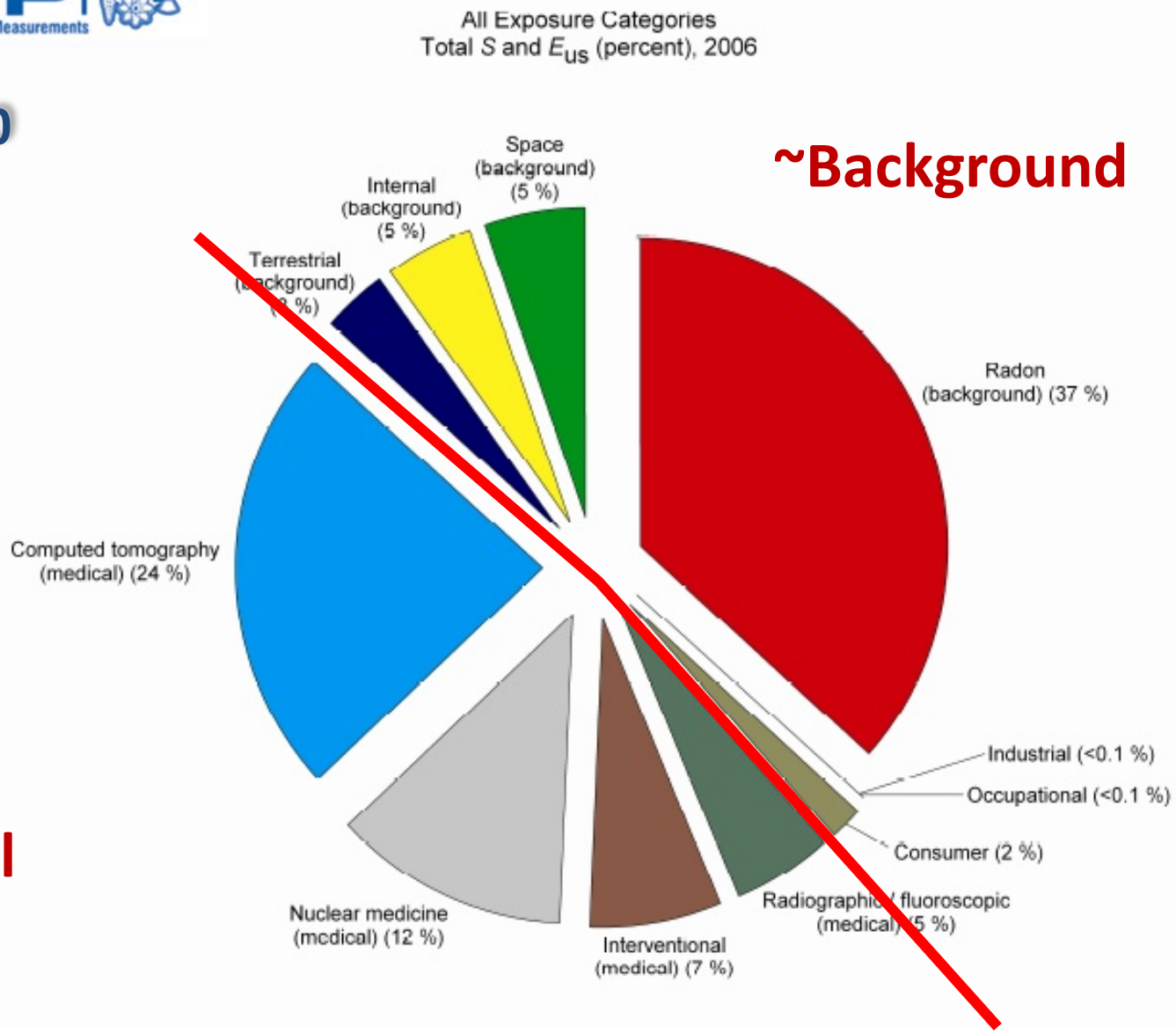
Use of CT: Locally and Nationally



Boone, J M et al *J Am Col Radiology*, 2008; 5(2): 132–138
Brenner, D J et *New Eng J Med*, 2007; 357: 2277-2284

NCRP
National Council on Radiation Protection & Measurements

NCRP 160



~Background

Medical

The radiation from CT has caught the eye of the public

FDA Public Health Notification:
Reducing Radiation Risk from Computed Tomography for Pediatric and Small Adult Patients

FDA: Medical devices can shock in CT scans

The surprise alert cites six confirmed cases of problems.

Virtually all of these people are already ineligible for MRI scans – another popular imaging technology – because metal parts in their devices can't be exposed to MRI

Hospital radiation overdoses probed

By Alan Zarembo
Los Angeles Times

LOS ANGELES – Every time a patient receives a computerized tomography scan, an array of numbers appears on the computer screen before a technician.

The numbers include the radiation dose.

"It's in your face on the screen," said Dr. Donald Rucker, chief medical officer for Siemens, a manufacturer of CT scanners.

Beginning in February 2008, each time a patient at Cedars-Sinai Medical Center received a CT brain perfusion scan – a state-of-the-art procedure used to diagnose strokes – the dose displayed would have been eight times higher than normal.

No medical imaging procedure would use so much radiation, which one expert said is on par with the levels used to blast tumors.

"It's pretty mystifying to me."

DAVID BRENNER,
director of the Center for Radiological Research at Columbia University Medical Center, as to how the radiation doses could have gone unnoticed for 18 months

ment of Public Health are investigating the overdoses. Cedars-Sinai has released only basic information, saying the overdoses stemmed from an error made when the hospital reconfigured a scanner to improve doctors' ability to see blood flow in the brain.

The CT machine in question was used to perform several types of scans, each of which has its own set of computerized instructions, or protocol. To change the instructions for brain perfusion scans, the hospital had to bypass the protocol that came installed on the machine. Other types of scans

tor dose levels, and some hospitals conduct checks before every scan.

"There are other places where the techs might be operating more as button pushers," said Dr. Geoffrey Rubin, a professor of radiology at Stanford University. "The user becomes a little blind to these numbers."

The overdoses also could have been caught during periodic calibrations of the machines, when radiation levels are tested directly.

Najmedin Meshkati, a professor of industrial and systems engineering at the University of Southern California, said the overdoses point to a problem well-documented in medicine – the need for multiple backup systems to catch mistakes.

As a result of the radiation overdoses, the FDA issued an alert that raised the possibility that CT scanners at other hospitals could be set wrong – with nobody noticing

CT scans in children linked to cancer

By Steve Sternberg, USA TODAY

Each year, about 1.6 million children in the USA get CT scans to th abdomen — and about 1,500 of those will die later in life of radiation cancer, according to research out today.

What's more, CT or computed tomography scans given to kids are t calibrated for adults, so children absorb two to six times the radiatio produce clear images , a second study shows. These doses than the sorts of doses that people at Three Mile Island were Brenner of Columbia University says. "Most people got a tenth the dose of a CT."

Radiation-induced temporary hair loss as a radiation damage only occurring in patients who had the combination of MDCT and DSA

Eur Radiol (2005) 15:41–46

BEIR VII: Health Risks from Exposure to Low Levels of Ionizing Radiation

Risk of cancer from diagnostic X-rays: estimates for the UK and 14 other countries

Amy Berrington de González, Sarah Darby

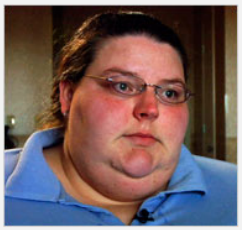
Mad River Hospital

Humboldt Online

Get the News... Not the Paper

Radiation Overdoses Point Up Dangers of CT Scans

Written by Humboldt Online Editor on 16 October 2009



New York Times Raven Knickerbocker, then an X-ray technologist at Mad River Community Hospital in Arcata, Calif., activated a CT scan 151 times on the same area of the head of 2 ½-year-old Jacoby Roth, investigators concluded.

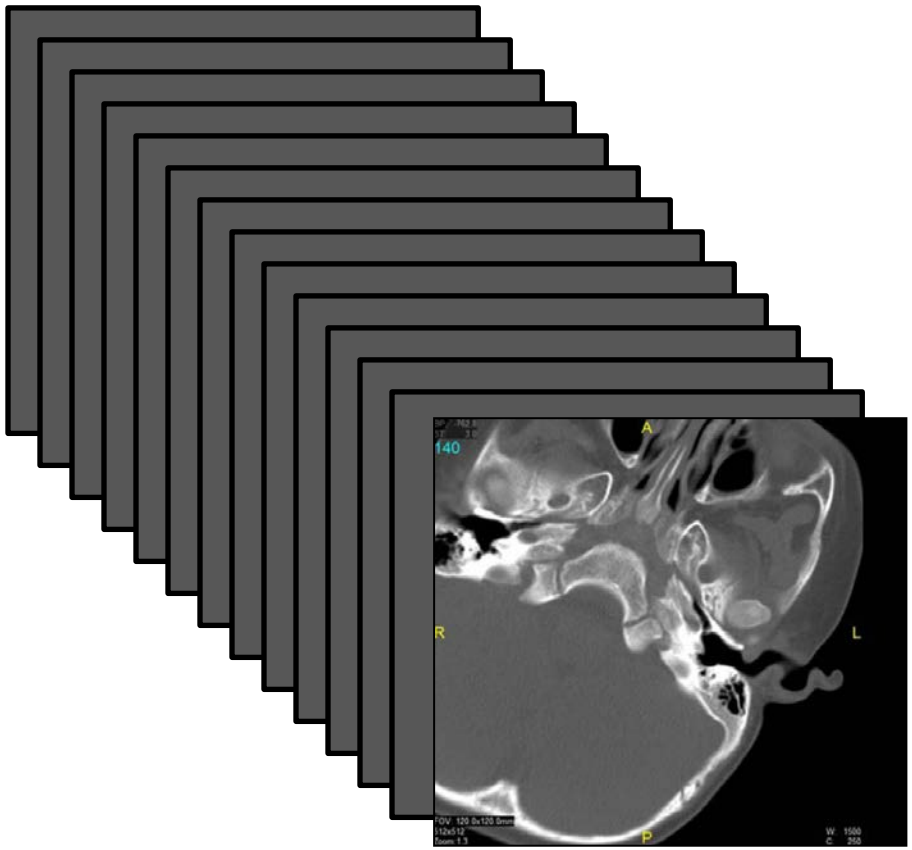
California hospital fined $25,000 for pediatric CT radiation overdose

By Cynthia E. Keen
AuntMinnie.com staff writer
March 24, 2009

Parents sue California hospital over pediatric CT radiation overdose

By Cynthia E. Keen
AuntMinnie.com staff writer
November 20, 2008

A rural California hospital is being sued by parents of a child who underwent a CT exam during an emergency department visit for a neck injury. The parents allege that their 23-month-old boy received radiation burns and has permanent chromosomal damage due to excessive radiation exposure from the CT scan, which took over an hour to perform.

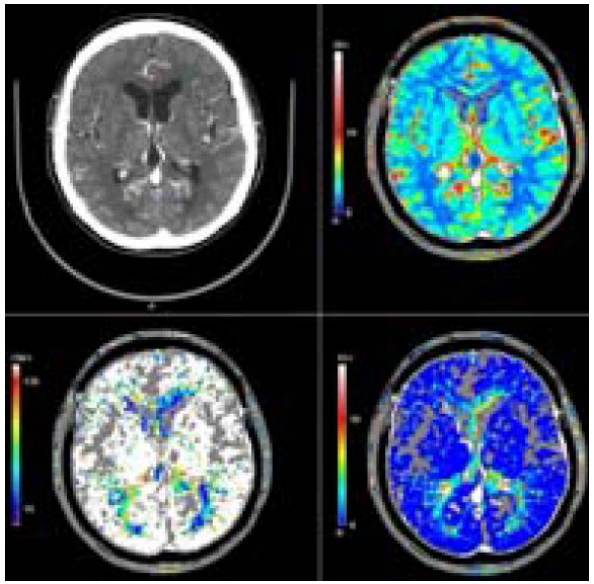


150 CT scans of the same area + one scout view

Equipment and/or user failure…..

- 2 ½ year old boy
- January 2008
- 150 scans to same area in ~1 hour…..
- Prompt erythema in area of scan (5-10 Gy)

Cedars-Sinai Medical Center



U.S. Department of Health & Human Services www.hhs.gov

FDA U.S. Food and Drug Administration A-Z Index Search go

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Medical Devices

Home > Medical Devices > Medical Device Safety > Alerts and Notices (Medical Devices)

Safety Investigation of CT Brain Perfusion Scans: Update 12/8/2009

Cedars-Sinai Medical Center

- >150 cases: CT Overdose during Head CT perfusion
- Other cases in West Virginia and Arkansas
- Mostly on GE CT scanners
- Lawyers!


Mad River Hospital
Cedars-Sinai Medical Center
© geology.com

Resulting California Legislation

- Senate Bills 1237 & 38
  - Introduced by Alex Padilla

- Assembly Bill 510
  - Introduced by Bonnie Lowenthal

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Senate Bill 1237

- Effective July 1, 2012
- Adds sections 115111, 115112 and 115113 to the state Health and Safety code for Public Health

SB1237 – Section 115111

- Requires those responsible for CT system operation:
  - **To record the dose of radiation for every CT study produced during an exam**
  - **To have on an annual basis, a medical physicist verify displayed doses within 20% of the true measured dose**
  - **To record the CT dose metrics in the radiology report**
    - **Volume computed tomography dose index ($CTDI_{vol}$)**
    - **Dose length product (DLP)**

SB1237 – Section 115112

- Requires “facilities that furnish CT X-ray services ***shall be accredited*** by an organization that is approved by the federal Centers for Medicare and Medicaid Services, and accrediting agency approved by the Medical Board of California, or the State Department of Public Health”
- Date of required compliance: July 1, 2013

SB1237 – Section 115113

- Requires a report be sent to CA Dept of Health Services:
  - Repeating a CT exam, unless ordered by a physician or radiologist or movement / interference of patient, if the following dose values are exceeded:
    - 0.05 Sv (5 rem) effective dose equivalent (50 mSv)
    - 0.5 Sv (50 rem) to an organ or tissue (500 mSv)
    - 0.5 Sv (50 rem) shallow dose equivalent to the skin (500 mSv)
  - Irradiating a body part other than the intended body part (with the same dosage requirements as above)

SB1237 – Section 115113

- Requires a report be sent to CA Dept of Health Services:
  - If an exam results in unintended patient harm (organ damage or erythema), as determined by a physician
  - Radiation exposure greater than 50 mSv (5 rem) to a fetus or embryo of a known pregnant individual unless approved by a physician
  - Irradiating the wrong person or wrong site
  - Delivered dose is >20% of the *prescribed* dose

AB 510

- Further clarifies SB1237
- Section 115111:
  - Nuclear Medicine PET/CT & SPECT/CT scanners* excluded
  - **Technical factors and dose shall be electronically sent to PACS**
  - **Displayed dose verified by physicist for typical adult brain, adult abdomen, and pediatric brain protocols – within 20% of measured dose**
  - Dose reporting is limited to systems capable of reporting dose
  - Dose report shall be included in “interpretive report”, not just “Radiology report”, to account for other departments using CT

The California CT Dose Law:

- History
- Details (behind the scene)
- Implementation
- Implications
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- Summary

Sacramento State Capital Building

Alex Padilla

California Consumer Attorneys Association (~)

California Hospital Association

California Radiological Association (CRS)

American College of Radiology (ACR)

115111. (a) Commencing July 1, 2012, subject to subdivision (e), a person that uses a computed tomography (CT) X-ray system for human use shall record the dose of radiation on every diagnostic CT study produced during a CT examination in the patient's record, as defined in Section 123105. CT studies used for therapeutic radiation treatment planning or delivery or for calculating attenuation coefficients for nuclear medication studies shall not be required to record the dose.

(b) The facility conducting the study may send electronically each CT study and protocol page that lists the technical factors and dose of radiation to the electronic picture archiving and communications system.

(c) (1) Until July 1, 2013, the displayed dose shall be verified

(f) For the purposes of this section, dose of radiation shall be defined as one of the following:

(1) The computed tomography index volume (CTDI vol) and dose length product (DLP), as defined by the International Electrotechnical Commission (IEC) and recognized by the federal Food and Drug Administration (FDA).

(2) The dose unit as recommended by the American Association of Physicists in Medicine.

recording the dose within the patient's report or attaching the protocol page that includes the dose of radiation to the report.

(e) The requirements of this section shall be limited to CT systems capable of calculating and displaying the dose.

(f) For the purposes of this section, dose of radiation shall be defined as one of the following:

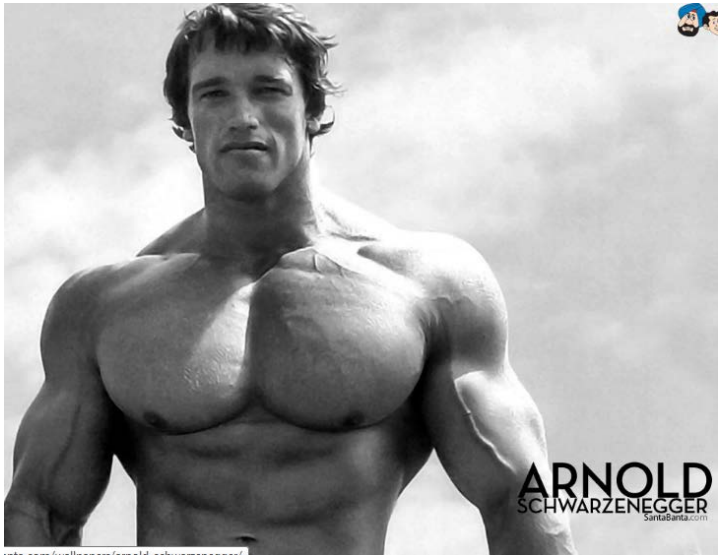
(1) The computed tomography index volume (CTDI vol) and dose length product (DLP), as defined by the International Electrotechnical Commission (IEC) and recognized by the federal Food and Drug Administration (FDA).

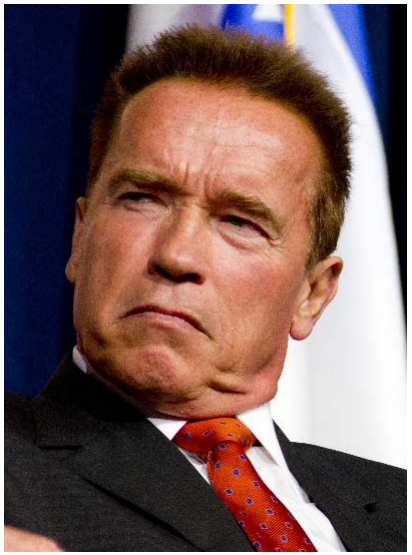
(2) The dose unit as recommended by the American Association of Physicists in Medicine.

(g) For purposes of this section, "CT X-ray system" means the same as provided in Section 892.1750 of Title 21 of the Code of Federal Regulations.

CA Legislative Activities

- Sen. Padilla introduced SB 1237 in Feb 2010
  - Radiation Control: Health Facilities and Clinics
- Governator signed bill on September 29, 2010





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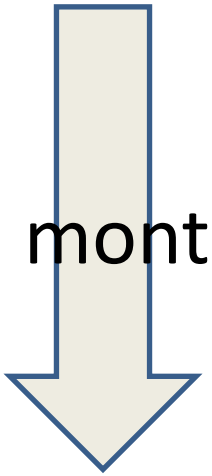
September 29, 2010



22 months

July 1, 2012

Legislation

California Health and Safety Code Section 115111

RADIOACTIVE MATERIALS LICENSING SECTION	REGISTRATION & CERTIFICATION SECTION	INSPECTION COMPLIANCE & ENFORCEMENT SECTION	INSPECTION COMPLIANCE & ENFORCEMENT SECTION	FINANCIAL OPERATIONS & ANALYSIS SECTION	STRATEGIC PLANNING & QUALITY ASSURANCE SECTION
Steve Hsu	Frieda Taylor	Radioactive Materials John Fassell	Radiation Machines Lisa Russell	Karen Hobson	Jerry Hensley
580-630-3801-003 (916) 440-7940	580-630-3801-002 (916) 650-6702	580-630-3801-001 (916) 445-2196	580-630-3801-006 (916) 440-7925	580-630-4801-001 (916) 440-7997	580-630-3801-004 (916) 440-7931

California Radiological Health Branch
Inspection Compliance and Enforcement Section
(Radiation Machines)

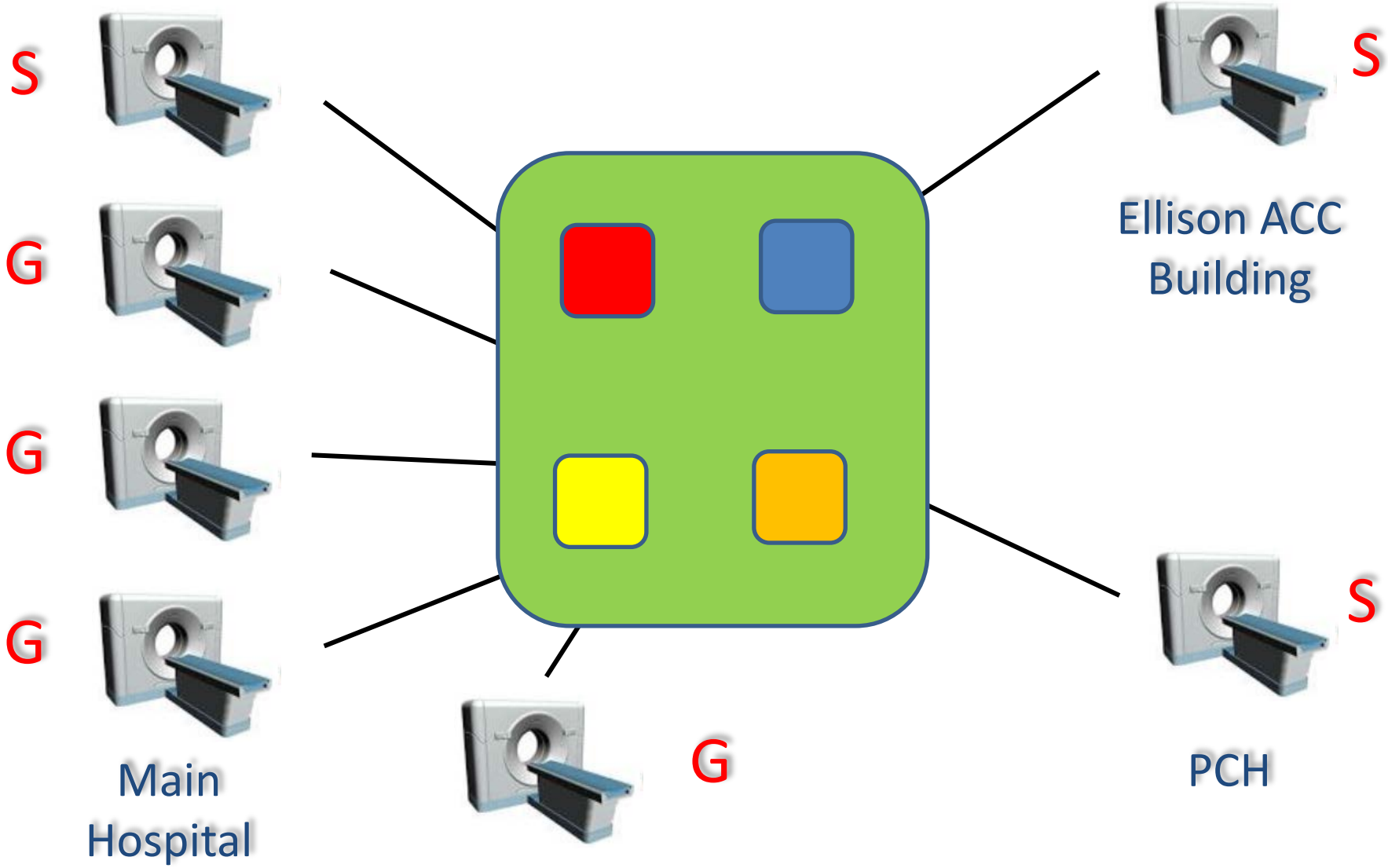
Jerry Hensley Lisa Russell

C-CAMP

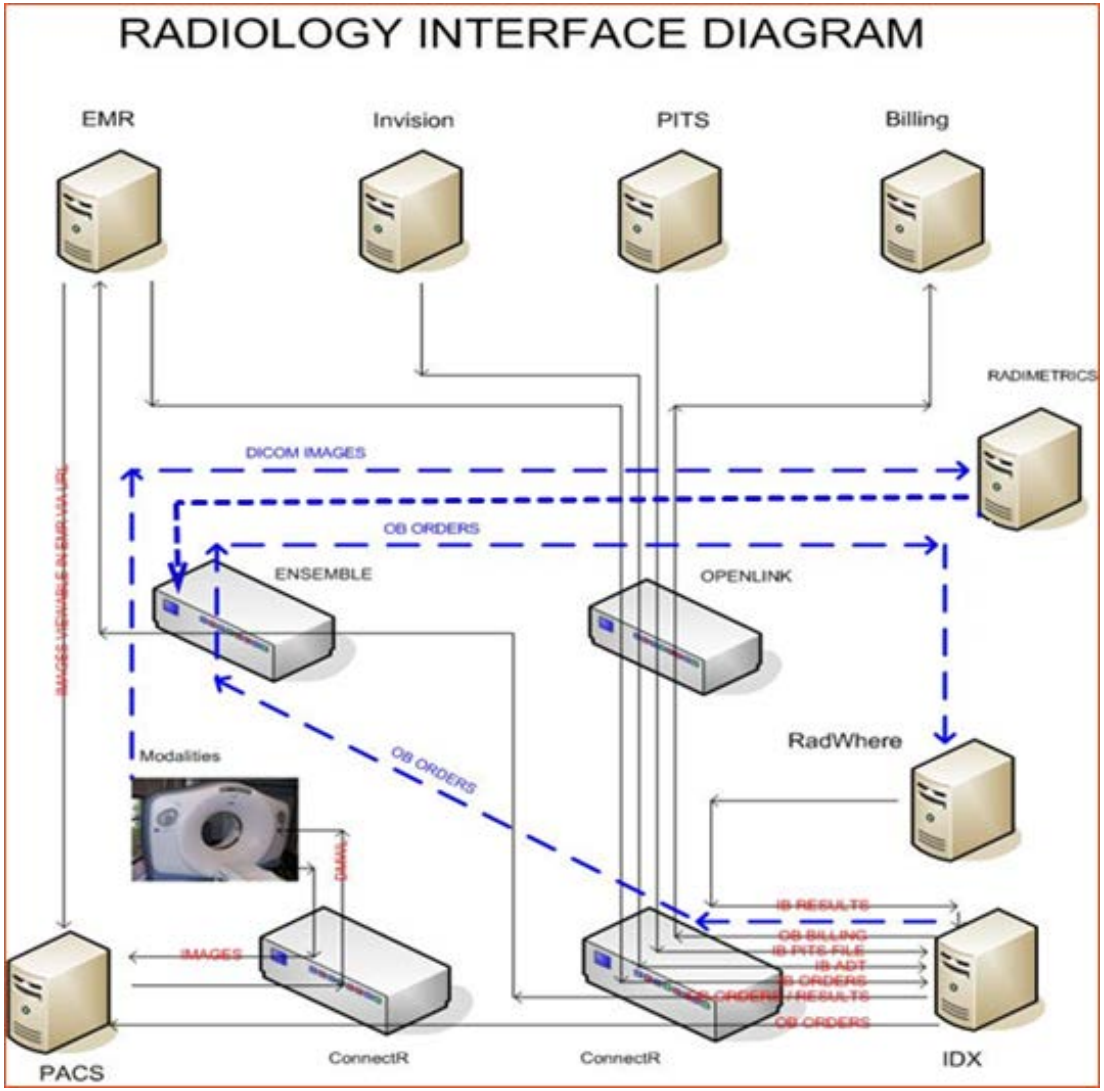
California clinical & academic medical physicists

Tony Seibert
John Boone
Linda Kroger
Mike McNitt-Gray
Chris Cagnon
Melissa Martin
Tom Nelson

UC Davis Home Grown Attempt



UC Davis Home Grown Attempt



DICOM / HL7 Application connector

CT scanner

PACS

Broker & DICOM processor

PACS/RIS Broker

Dose Calculation Software

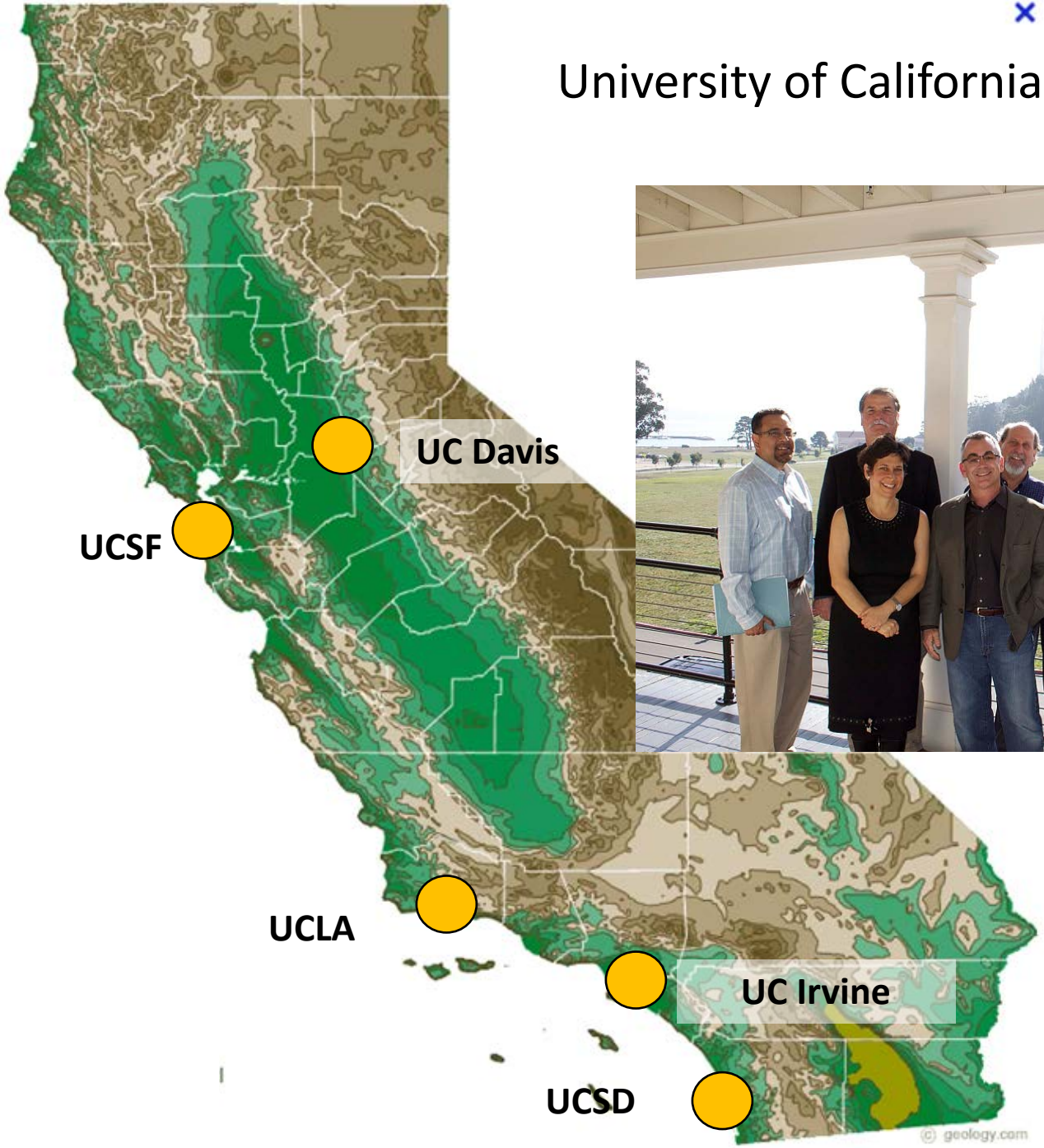
Speech Recognition

RIS

UC DOSE

Dose Optimization and Standardization Endeavor

University of California DOSE consortium



UC San Francisco
UC Davis
UC Irvine
UC Los Angeles
UC San Diego

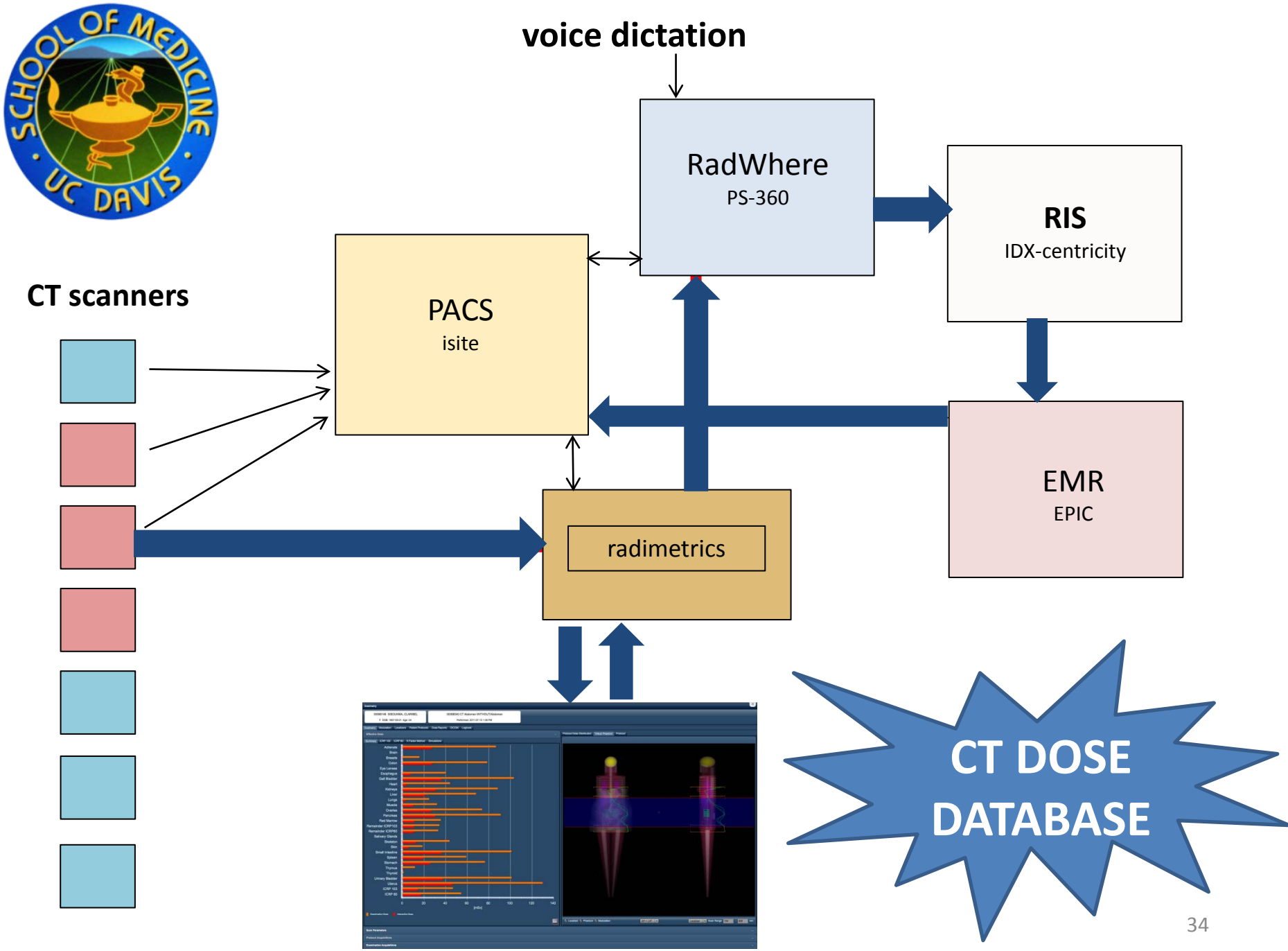
Dose Reporting Software Vendors

A B C D

UC San Francisco
UC Davis
UC Irvine
UC Los Angeles
UC San Diego

B

- CTDIvol
- DLP
- Eff Diameter
- Water-equiv Diameter
- SSDE
- Organ dose


voice dictation
RadWhere
PS-360
RIS
IDX-centricity
CT scanners
PACS
isite
EMR
EPIC
radimetrics
CT DOSE
DATABASE

The Structured Dose Report with Radimetrics Feed

Report: Gaga, Lady – MRN: 1234567

EXAM DATE [5/24/2012 12:35 pm]

INDICATION:
[]

DOSE:
[This was an abdomen-pelvis CT examination with two series, one with and one without contrast. Estimates of the radiation dose metrics that you received are:

Series 1: (no contrast)
CTDIvol = 12.4 mGy
DLP = 496 mGy-cm

Series 2: (with contrast)
CTDIvol = 13.2 mGy
DLP = 577 mGy-cm

These doses are {lower} {typical} {higher} than other patients having this same CT study]

FINDINGS:
[]

IMPRESSION:

[]

text and format are up for discussion

PRIMER ON CT DOSE METRICS FOR RADIOLOGISTS:

PREPARATION FOR INTERPRETING THE CT DOSE REPORT

John M. Boone, Ph.D., FAAPM, FSBI, FACR
Professor and Vice Chair of Radiology
University of California Davis Medical Center

The Structured Dose Report with Radimetrics Feed

Report: Gaga, Lady – MRN: 1234567

EXAM DATE [5/24/2012 12:35 pm]

INDICATION:
[]

DOSE:
[Dose information for this CT examination:

Series 1: (no contrast)
CTDIvol = 12.4 mGy
DLP = 496 mGy-cm

Series 2: (with contrast)
CTDIvol = 13.2 mGy
DLP = 577 mGy-cm

UC Davis Health System CT scanners are accredited by the American Board of Radiology, and employ modern techniques for CT dose reduction, including protocol review, automatic exposure control, and iterative reconstruction techniques. These features assure that radiation dose levels in CT are optimized and are consistent with state of the art CT practice.]

FINDINGS:
[]

IMPRESSION:

[]

text and format are up for discussion

The Structured Dose Report with Radimetrics Feed

Report: Gaga, Lady – MRN: 1234567

EXAM DATE [5/24/2012 12:35 pm]

INDICATION:
[]

DOSE:
[There were two exposure events in this study:
Series 1: CTDI=12.4, DLP=496, 32 cm
Series 2: CTDI=13.2, DLP=577, 32 cm
See www.ucdavis.edu/CTdose for further information.]

FINDINGS:
[]

IMPRESSION:

[]

Recommendations for compliance

- UCDOSE consortium of UC Medical Centers

UNIVERSITY OF CALIFORNIA

BERKELEY • DAVIS • IRVINE • LOS ANGELES • MERCED • RIVERSIDE • SAN DIEGO • SAN FRANCISCO SANTA BARBARA • SANTA CRUZ

UC-DOSE
University of California Health System
Recommendations for Compliance with California Senate Bill 1237 and related pending legislation
May 10, 2012

1. EXECUTIVE SUMMARY

The UC-DOSE project (University of California Dose Optimization and Standardization Endeavor) was funded by the University of California Office of the President (UCOP) to standardize and optimize computed tomography (CT) protocols across the University of California Medical Centers, and to develop a consistent solution for responding to California Senate Bill 1237.[1] This bill takes effect on July 1, 2012, will be enforced by the California Department of Public Health Radiologic Health Branch,[2] and requires the reporting of CT radiation dose, and the reporting of overdoses in particular settings.

DLP value: reporting thresholds

Effective Dose = DLP × k

Effective Dose / k = DLP

SIIM Regional Meeting: Practical Imaging Informatics

October 24, 2011 | Hyatt Regency San Francisco

Program Agenda

March 22, 2012 SIIM meeting in Long Beach

GRAND BALLROOM A

8:00 am – 9:00 am	**Registration and Continental Breakfast** Grand Ballroom A Foyer
8:45 am	**Welcome Remarks** *Elizabeth A. Krupinski, PhD, FSIIM*, University of Arizona Chair, Society for Imaging Informatics in Medicine
8:55 am	**Radiation Dose Monitoring in California** *J. Anthony Seibert, PhD, FSIIM*, University of California, Davis
9:00 am – 9:45 am	**Radiation Dose in a Clinical Environment: Benefit and Risk – The User's Perspective** *John M. Boone, PhD*, University of California, Davis *Robert G. Gould, ScD*, University of California, San Francisco *Rebecca Smith-Bindman, MD*, University of California, San Francisco
9:45 am – 10:30 am	**Acquiring, Mining, and Reporting the Radiation Dose Data – The Vendor's Perspective** *Mike Battin*, COO, PHS Technologies Group *Gregory Couch*, President & CEO, Radimetrics, Inc. *Philip Zarboulas*, Partner, Primordial Design, Inc.
10:30 am – 11:00 am	**Morning Break and Visit the Exhibits**
11:00 am – 11:45 am	**The California Dose Reporting Law: Implications and FAQ – The Government's Perspective** *Jerry Hensley, CHP*, Chief, X-Ray Inspection, Compliance and Enforcement, California Department of Public Health *Lisa Russell*, Inspector, Compliance and Enforcement, California Department of Public Health

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Other states are looking at the California CT Dose law

Connecticut

Texas

……

Adoption of CA laws…

The Joint Commission

Joint Commission Requirement

Revised Requirements for Diagnostic Imaging Services

APPLICABLE TO HOSPITALS AND CRITICAL ACCESS HOSPITALS

Effective July 1, 2014

Provision of Care, Treatment, and Services (PC)

Standard PC.01.02.15
The [critical access] hospital provides for diagnostic testing.

Elements of Performance for PC.01.02.15

C 5. ◎ For [critical access] hospitals ~~in California~~ that provide diagnostic computed tomography (CT) services: The [critical access] hospital documents in the patient's medical record the radiation dose *(CTDIvol or DLP) on every study produced during a CT examination. Ⓜ 3

C 6. For [critical access] hospitals ~~in California~~ that provide diagnostic computed tomography (CT) services: The interpretive report of a diagnostic CT study includes the volume computed tomography dose index (CTDIvol) or dose-length product (DLP) radiation dose. * The dose is either recorded in the patient's interpretive report or included on the protocol page~~, which is then attached to the interpretive report~~. Ⓜ

Standard PI.02.01.01
The [critical access] hospital compiles and analyzes data.

Elements of Performance for PI.02.01.01

A 6. For [critical access] hospitals that provide diagnostic computed tomography (CT) services: The [critical access] hospital compiles and analyzes data on patient CT radiation doses and compares it with external benchmarks, when such benchmarks are available.

Standard PC.01.03.01
The [critical access] hospital plans the patient's care.

Elements of Performance for PC.01.03.01

A 25. For [critical access] hospitals that provide diagnostic computed tomography (CT) services: The [critical access] hospital establishes imaging protocols based on current standards of practice, which address key criteria including clinical indication, contrast administration, age (to indicate whether the patient is pediatric or an adult), patient size and body habitus, and the expected radiation dose range. (*See also* PI.01.01.01, EP 46) 3

Solutions for Dose Reporting

- Fully integrated software – reporting automatic
  - CTDIvol & DLP automatically are stored
  - Can break out each series DLP & CTDIvol
  - Data base of CT dose information available
- Radiologist Dictation
  - Wastes radiologist's time
  - reduces accuracy of data in report
  - consolidation of metrics bad practice*
  - no data base of CT dose is produced

*Summed DLP and maximum CTDIvol

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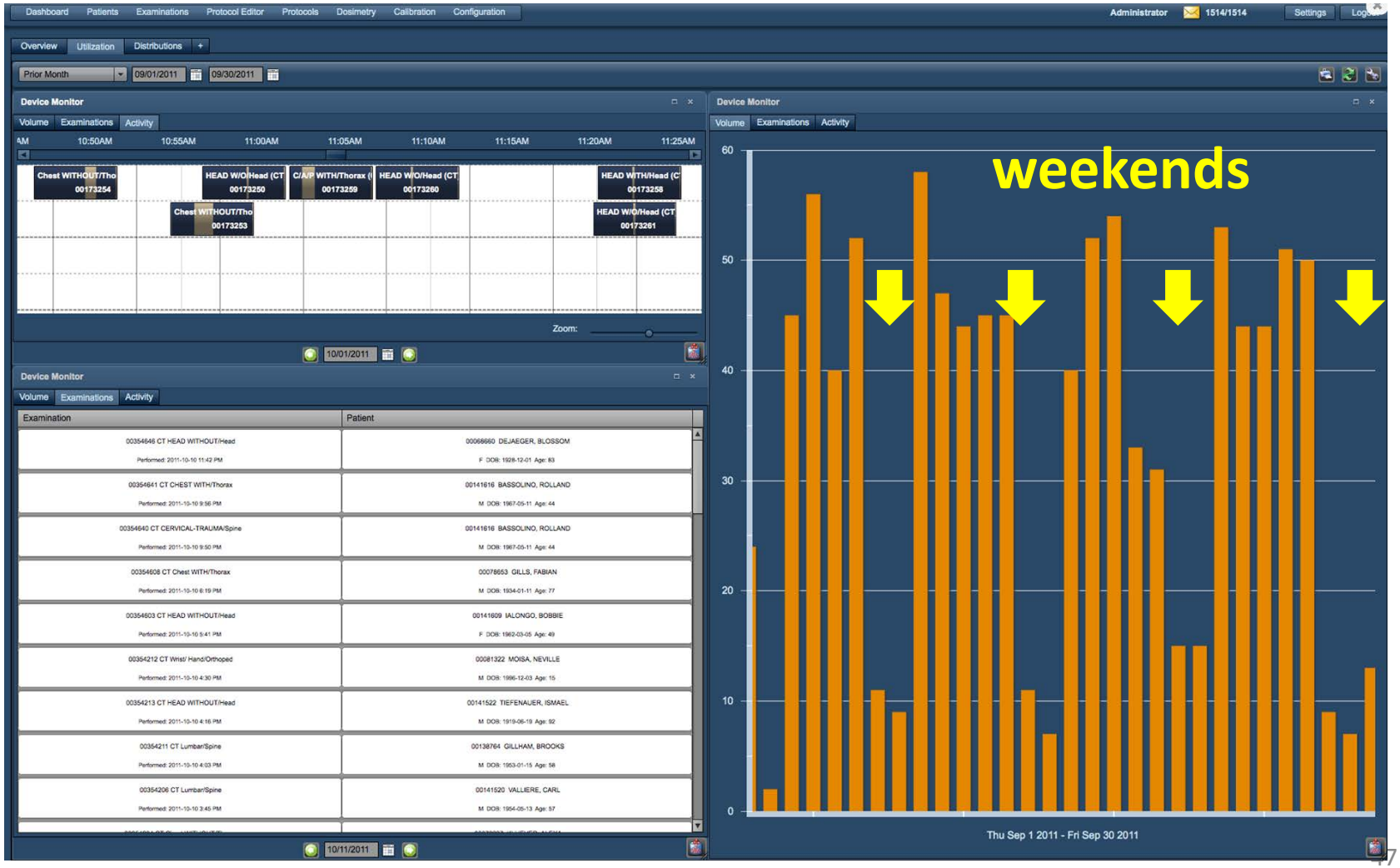
Software based analysis of CT doses

CT scans per day



Software based analysis of CT doses

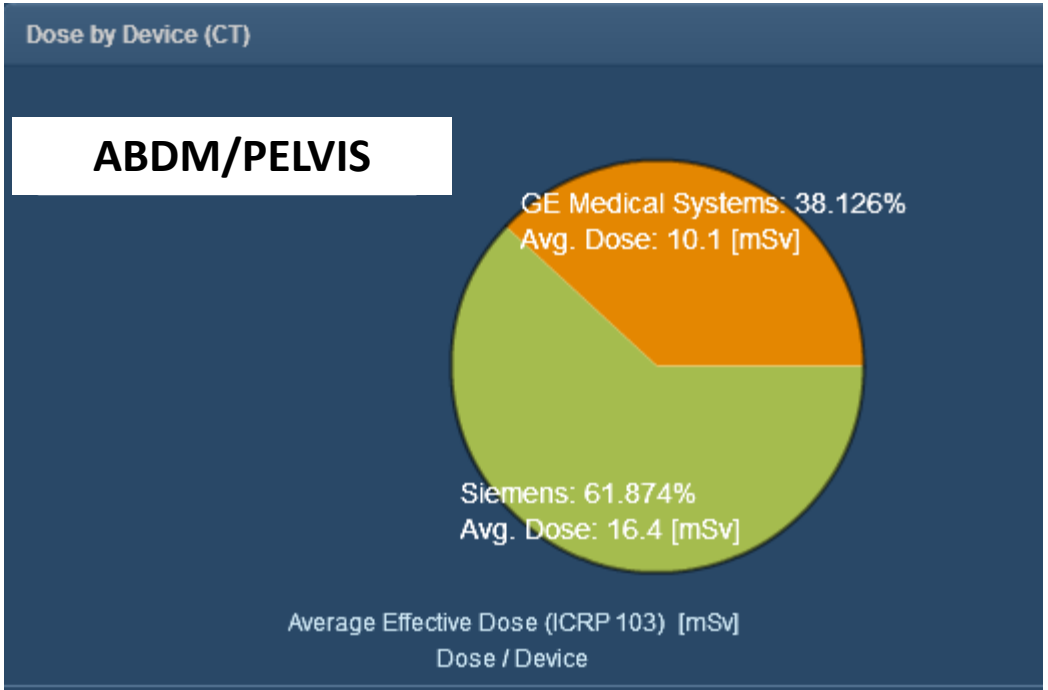
Individual patient's cumulative effective dose by organ

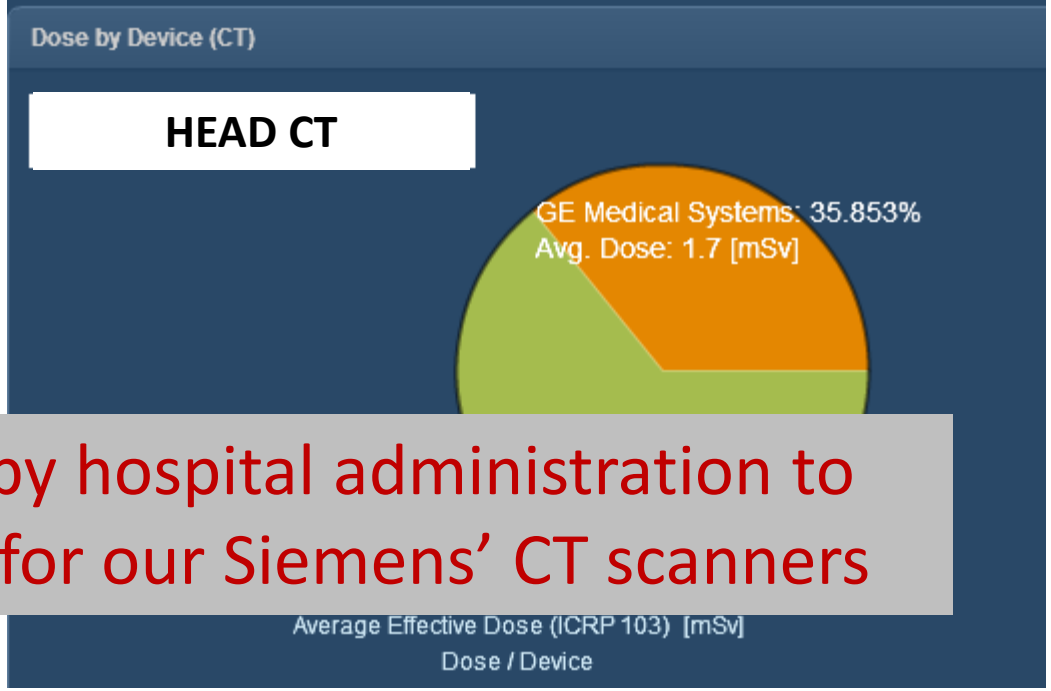
Software based analysis of CT doses

Break-down of CT procedures for different CT scanners

Dose by scanner type

Software based analysis of CT doses

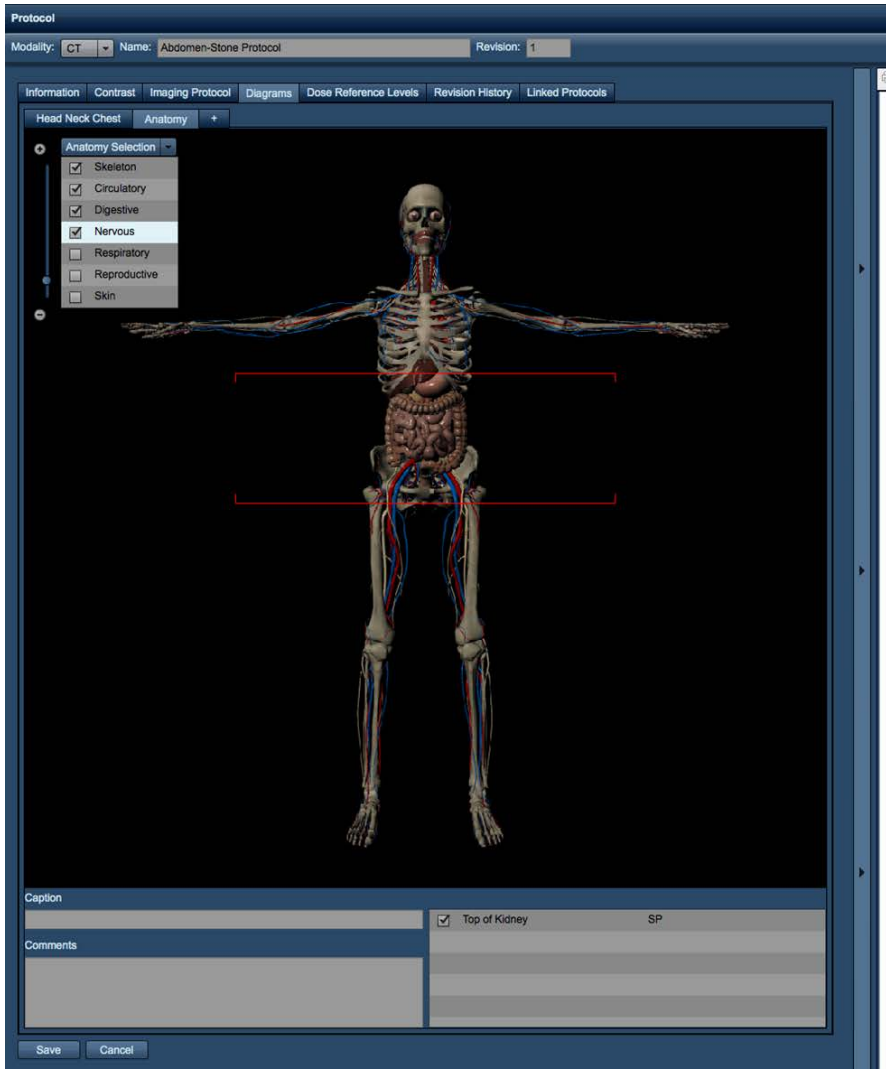


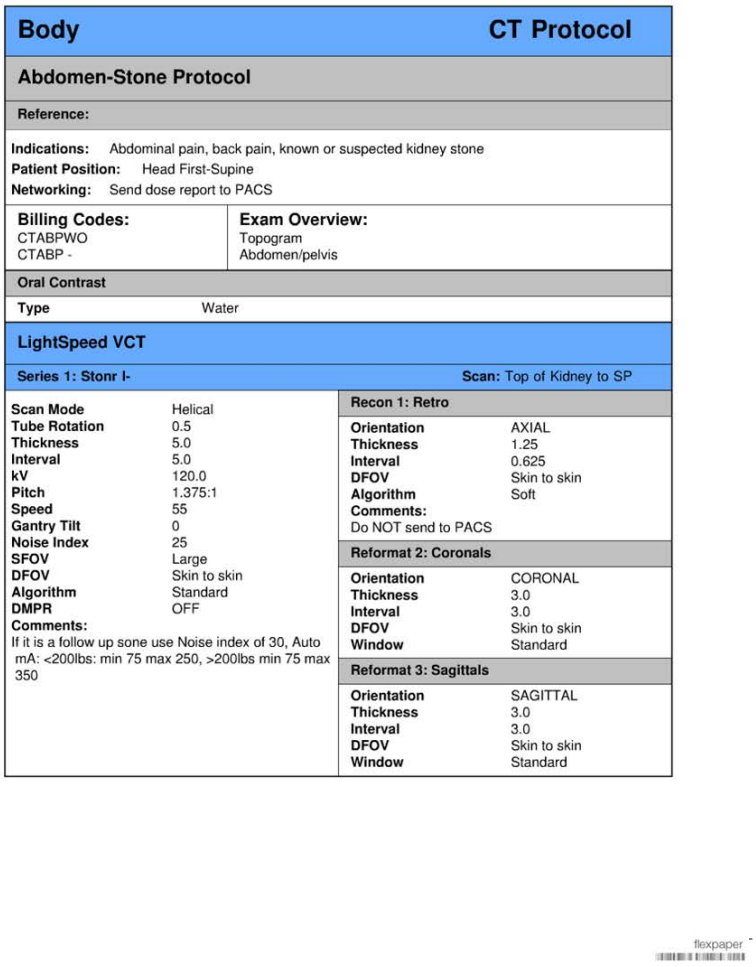


Used this data to lobby hospital administration to purchase IR software for our Siemens' CT scanners

Software based analysis of CT doses

CT protocol review





Body — **CT Protocol**

Abdomen-Stone Protocol

Reference:

Indications: Abdominal pain, back pain, known or suspected kidney stone
Patient Position: Head First-Supine
Networking: Send dose report to PACS

Billing Codes:	Exam Overview:
CTABPWO	Topogram
CTABP -	Abdomen/pelvis

Oral Contrast

Type	Water

LightSpeed VCT

Series 1: Stonr I- — **Scan:** Top of Kidney to SP

Scan Mode	Helical
Tube Rotation	0.5
Thickness	5.0
Interval	5.0
kV	120.0
Pitch	1.375:1
Speed	55
Gantry Tilt	0
Noise Index	25
SFOV	Large
DFOV	Skin to skin
Algorithm	Standard
DMPR	OFF

Comments:
If it is a follow up sone use Noise index of 30, Auto mA: <200lbs: min 75 max 250, >200lbs min 75 max 350

Recon 1: Retro

Orientation	AXIAL
Thickness	1.25
Interval	0.625
DFOV	Skin to skin
Algorithm	Soft

Comments:
Do NOT send to PACS

Reformat 2: Coronals

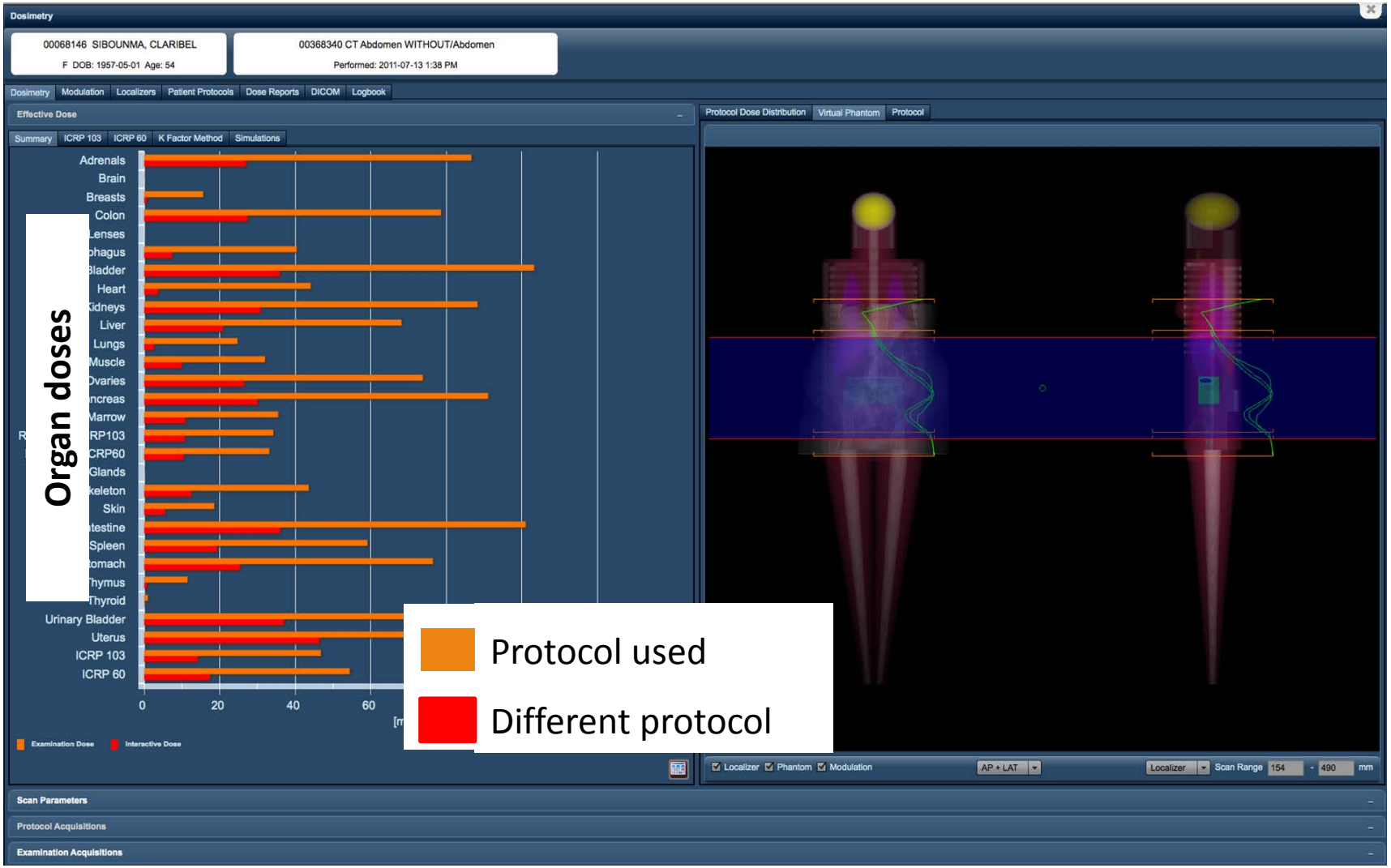
Orientation	CORONAL
Thickness	3.0
Interval	3.0
DFOV	Skin to skin
Window	Standard

Reformat 3: Sagittals

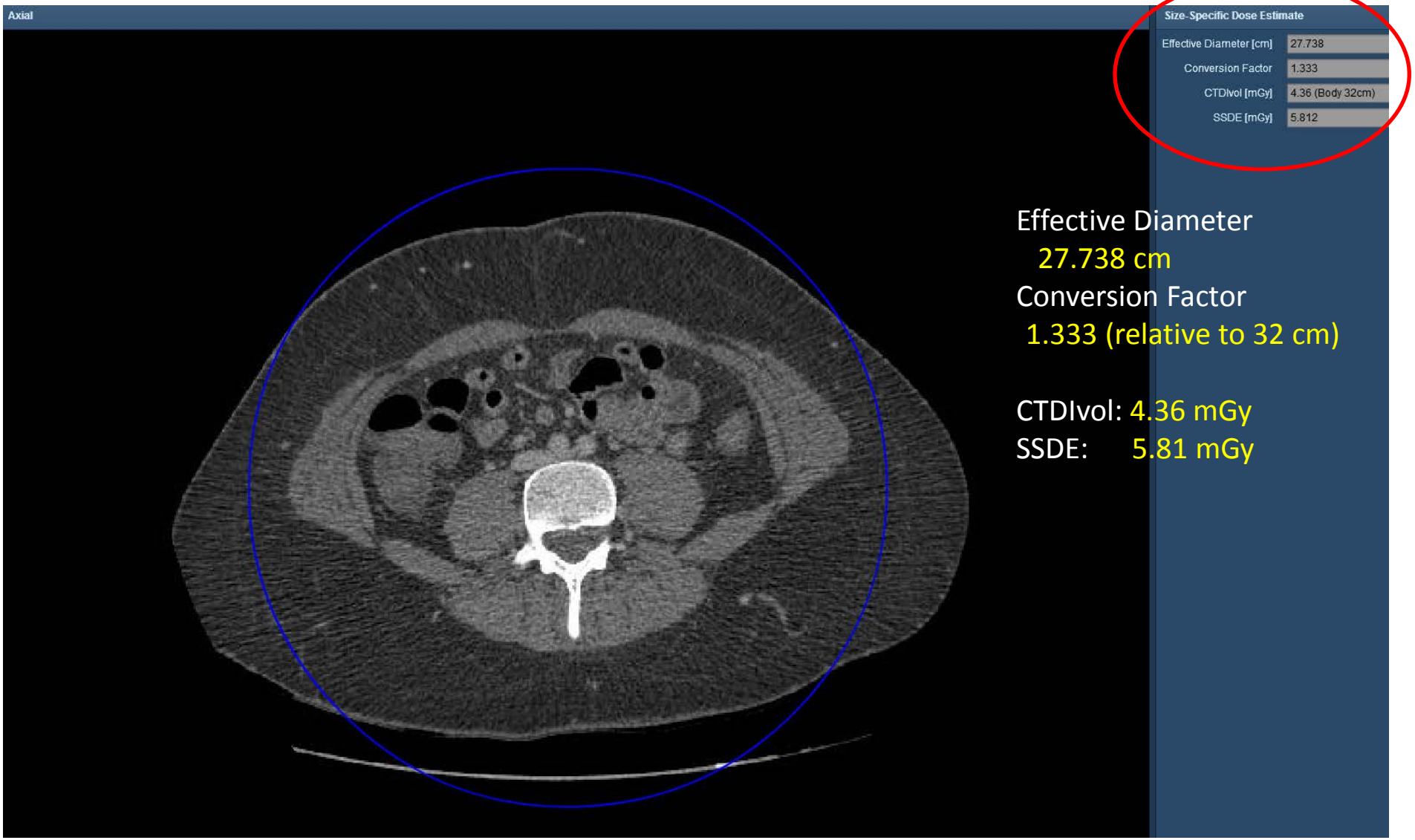
Orientation	SAGITTAL
Thickness	3.0
Interval	3.0
DFOV	Skin to skin
Window	Standard

Software based analysis of CT doses

Protocol review: “What IF” scenarios



SSDE modification to CTDIvol

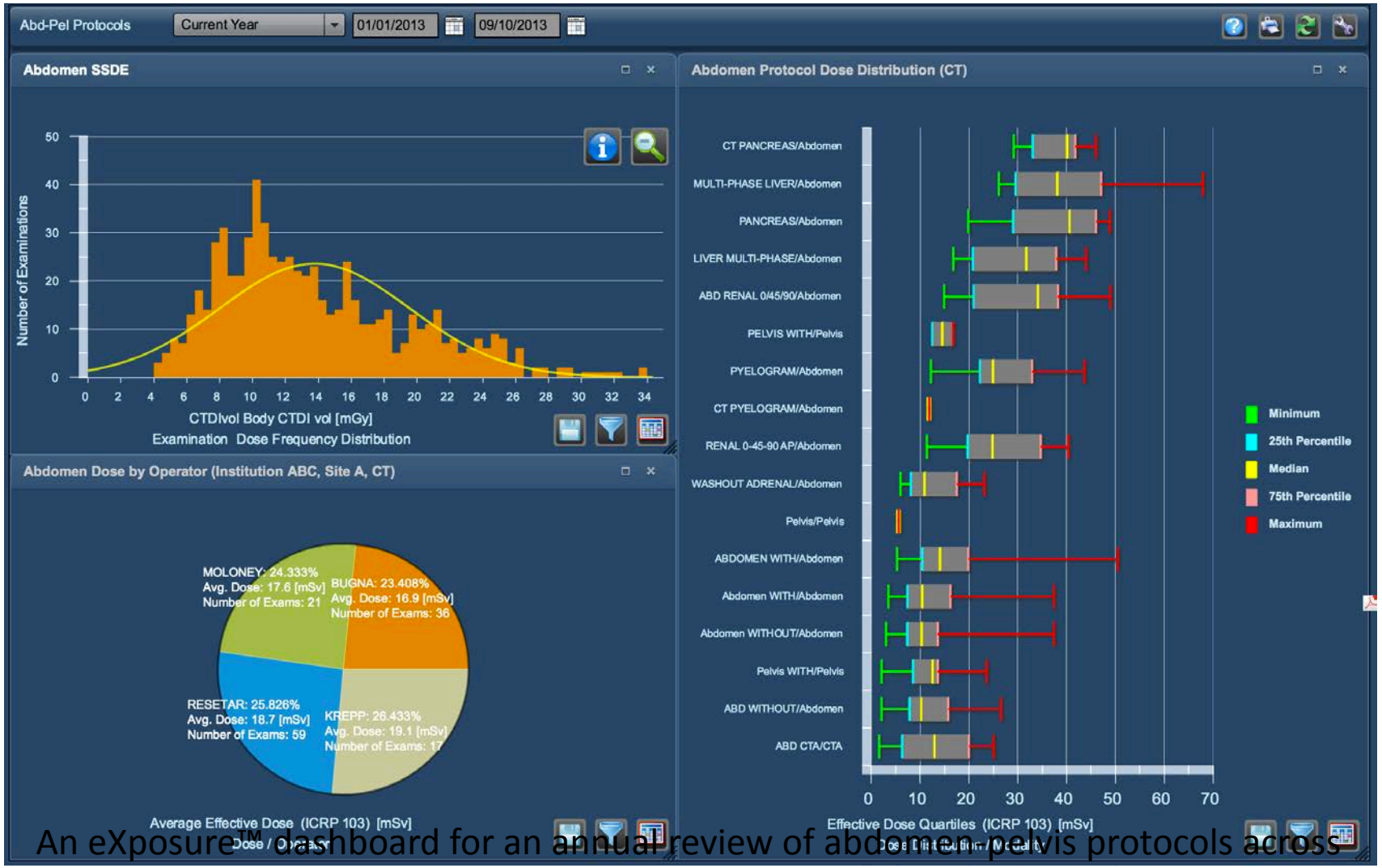


Effective Diameter
27.738 cm
Conversion Factor
1.333 (relative to 32 cm)

CTDIvol: 4.36 mGy
SSDE: 5.81 mGy

Software based analysis of CT doses

Protocol review across sites (abd-pelvis)

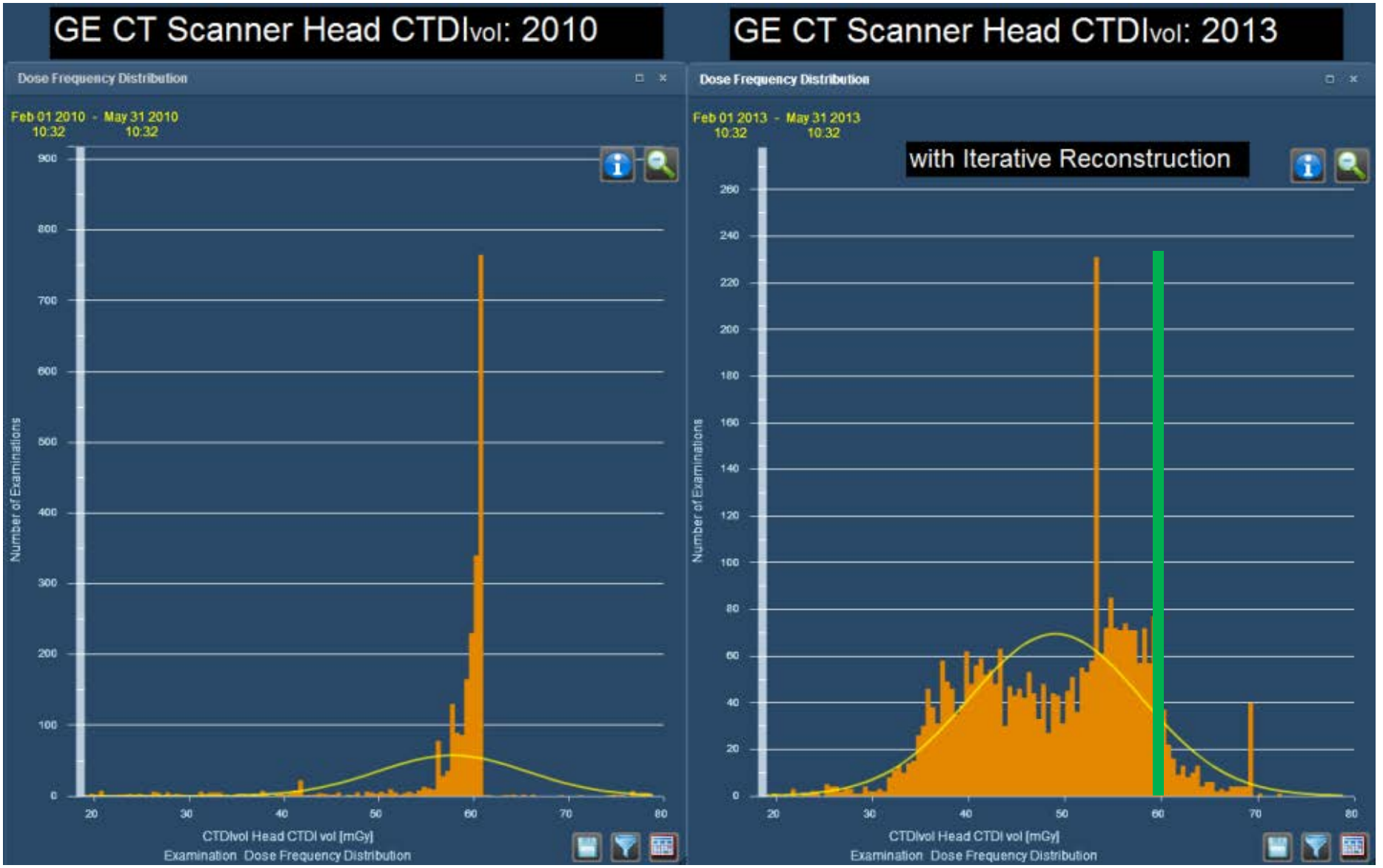


An eXposure™ dashboard for an annual review of abdomen-pelvis protocols across multiple sites.

Software based analysis of CT doses

Dose Alerts for patients with high doses

Before & After implementation of IR Software



The California CT Dose Law:

- History
- Details
- Implementation
- Implications
- Benefits
- Summary

The California CT Dose Law

lessons

MP's ⟷ state legislators

MP's ⟷ state regulators

Local MP alliances can be very useful

The law was intended to solve problem X

But ended up solving problem Y

SB1237 forced us to do what we should have been doing

The California CT Dose Law:

History

Details

Implementation

Implications

Benefits

Summary