Patient Dose Tracking for Imaging Studies

David E. Hintenlang, Ph.D., DABR University of Florida



Conflict of Interest Statement

No affiliation or financial interests in any of the commercial products or enterprises discussed as part of this presentation.



Introduction to Patient Dose Tracking (PDT)

Why Patient Dose Tracking (PDT)? What Dose Metrics are useful/attainable? How are dose metrics obtained?

- Where are dose metrics recorded?
- When is PDT required?
- What tools are available to assist with PDT?



Overview

- Motivation
- Dose Metrics
- PDT "Requirements"
 - Regulatory
 - Accreditation
- Strategies & Tools for PDT
- Examples of Commercial Products



Why track Patient Dose?

- Regulatory requirements
- Accreditation requirements
- Liability and Public Relations
- Research
- Quality Assurance
- Awareness & Patient Safety
- Individual Patient cumulative dose record
- PQI

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Patient Dose Metrics

- Dose
 - Organ Dose (Gy) /Equivalent Dose (Sv)
 - Effective Dose (Sv)
- Dose Surrogates
 - Cumulative Exposure Time (min)
 - Entrance Air Kerma (Gy)
 - Dose Area Product (Gy- cm²)
 - Cumulative Dose (Gy)
 - Peak Skin Dose (Gy)
 - CTDI (Gy)
 - Dose Length Product (Gy-cm)
 - Size Specific Dose Estimate (Gy)



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Individual Patient Dose Measurement

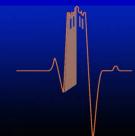
- Measurement of Patient Dose Difficult
 - Dosimeters
 - Computational Predictions
- Dose Surrogates Easier to obtain
 - Easier measurement
 - Difficult interpretation for radiation detriment
 - Not uniformly defined or applied
- Depend on biological endpoint



The dosimetry parameter that best represents the stochastic radiation detriment to a patient is

23%	a.	Cumulative Dose
17%	b.	CTDI _{vol}
13%	С.	Dose Area Product
30%	d.	Dose Length Product
17%	e.	Effective Dose





Answer: e. Effective Dose

Ref: Miller, et.al. Quality Improvement Guidelines for Recording Patient Radiation Dose in the Medical Record, J. Vasc. Interv. Radiology, 15:423-429, 2004.



Requirements & Recommendations

Federal

- 21CFR 803: Reporting of skin damage to fluoroscopic equipment manufacturers
- FDA Recommendations for Interventional Procedures
- States
 - CA, TX, OH.....?
 - Fluoro and CT
- Other
 - Individual Health Care Systems
 - Veterans Health Administration & NIH
 - American College of Radiology , Dose Index Registry
 - The Joint Commission

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Sample Recommendations for Dose Metrics

- California: Effective Dose, Skin Dose
- Texas:
 - Reference Levels
 - Fluoro: Air kerma, or other estimates of skin dose
 - CT: CTDI_{vol}, DLP
- VHA:
 - Cumulative fluoro time
 - Cumulative air kerma or skin dose
 - Dose-area-product



Recorded PDT Metrics likely dictated by regulatory and accreditation bodies



Requirements : California

• Senate Bill 1237

- Report to DHS scans that are repeated or wrong body part resulting in:
 - Effective Dose > 0.05 Sv
 - Dose > 0.5 Sv to any organ or tissue
 - Shallow dose to skin > 0.5 Sv
- Some exceptions
- Implementation: Reference levels for CTDIvol and DLP
- Exam and patient specific
 - i.e. Cumulative CTDIvol of 650 mGy for any → expected to exceed skin reporting threshold of 500 mSv



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Requirements : Texas

- 25 TAC 289.227 Effective May 1, 2013
- Radiation Protocol Committee for
 - Fluoroscopically-Guided Interventional Procedures
 - CT Systems
 - Methods to monitor radiation output
 - Establish Reference Levels for radiation output
 - Actions for when reference level is exceeded
 - Do not need to determine patient dose for each procedure

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Requirements: Texas

- Fluoroscopy
 - Make and maintain a record of radiation output information so the radiation dose to the skin may be estimated....
 - To include:
 - Cumulative air kerma or dose area product (if available on system) or
 - Fluoro mode, Cumulative exposure time & number of recorded exposures.
- CT
 - Make and maintain a record of radiation output information so the radiation dose to the skin may be estimated....
 - CTDIvol and DLP (if system capable of calculating and displaying) or

ENGINEERS for LIFE AAPM TG 111 Recommendations

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Proposed: Ohio 3701: 1-66-07 (3/3/2014)

- Fluoro: Interventional, cardiac cath pediatric, pregnant patients
- Record cumulative air kerma or DAP for each exam

or

• Mode of operation, Cumulative fluoro exposure time, and number of radiographs



The State of Texas requires monitoring of patient doses for





Answer: b. Fluoroscopy and CT

Ref: 25 Texas Adminstrative Code §289.227 "Use of Radiation Machines in the Healing Arts" May 2013.



Proposed: The Joint Commission

- Prepublication Standards: Diagnostic Imaging Services Requirements ; Provision of Care, Treatment, and Services (PC) – Effective July 1, 2014
- PC.01.02.15 ; C5
- For ...diagnostic CT....documents in the patient's medical record the radiation dose (CTDIvol or DLP) on every study produced during a CT examination.
- PC.01.02.15 ; C6
- For... diagnostic CT.. The interpretive report of a diagnostic CT study includes the CTDIvol or DLP radation dose. The Dose is either recorded in the patient's interpretive report or included on the protocol page.



- Only applicable for systems calculating and displaying radiation doses.
- Not applicable to systems for rad therapy treatment planning or dental cone beam CT



Proposed: The Joint Commission

- Prepublication Standards: Diagnostic Imaging Services Requirements ; Performance Improvement (PI) – Effective July 1, 2014
- PI.02.01.01; A6
- The hospital compiles and analyzes data on patient CT radiation doses and compares it with external benchmarks, when such benchmarks are available.
 - i.e. collection of data where pre-identified radiation dose limits are exceeded.



Observations on proposed TJC standards

 Draft requirement for electronic transmission of protocol identifying radiation dose to PACS was removed from the standard.

 Expect a parallel set of Fluoroscopy standards in Phase 2 – 2015 Implementation.



Effective July 1, 2014, The Joint Commission accreditation will require documentation of each patient's radiation dose (CTDI_{vol} or DLP)

10%	a.	in the patient medical record.
33%	b.	by electronic transmission to the EMR.
20%	C.	by electronic transmission to the hospital's electronic PACS.
20%	d.	for diagnostic CT and dental cone beam CT systems.
17%	e.	by a diagnostic medical physicist



Answer: a. in the patient medical record.

Ref: TJC Prepublication Standard PC.01.02.15



Generation& Recording of Dose Metrics

- Measured vs Predicted
 - DAP: measured
 - Cumulative Air Kerma/Skin Dose: Measured
 - CTDI : Predicted
 - DLP: Predicted
- Recording Methods
 - Manual
 - DICOM Radiation Dose Structure Report RDSR

Or other electronic transfer formats

Optical Character Recognition (OCR) from images



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Formats & Imaging Modalities

- DICOM Radiation Dose Structured Report
 - RDSR
- DICOM Modality Performed Procedure Step
 - MPPS
- IHE profile Radiation Exposure Monitoring

Digital Modalities these are typically provided for:

- CT
- Fluoro:
 - Interventional Radiography
 - Cardio-Vascular
 - Mobile C-Arms
- Radiography
- Mammography



Options for Legacy Equipment

- Manual entry / Logs
- Image Headers
- OCR from Images



Dose Tracking Applications

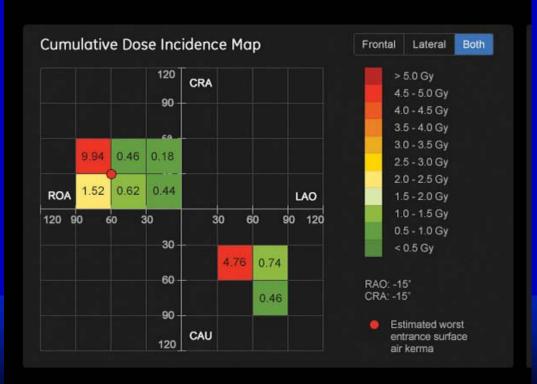
- Cumulative dose tracking throughout a health system (multiple modalities and procedures).
- Analysis to optimize image quality and minimize patient risk
- Compliance and Reporting:
 - Internal
 - Patients
 - Governing & regulatory authorities

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Patient Dose Tracking

- Threshold dose notifications
- Cumulative dose history prior to exams





Trend Analysis

- Dose comparisons as a function of
 - Modality
 - Protocol
 - Sites
 - Patient populations
 - Time
 - Etc.



Compliance Reporting

• Periodic Summary Reports

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Customized Diagnostic Reference Levels

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Communication with other systems

- PACS
- RIS
- HIS
- EMR
- ACR DIR



Dose tracking software systems can integrate dose information from each of the following methods <u>except</u>

40%	а.	DICOM MPPS
17%	b.	DICOM R <mark>DSR</mark>
10%	с.	HE Profile REM
20%	d.	NEMA OS-3- <mark>2012</mark>
13%	e.	OCR



Answer: d. NEMA OS 3-2012

Ref: Manufacturer Websites listed at end of presentation



Commercial Solutions for Dose Tracking

- Broad range of capabilities
 - Basic information recording
 - Advanced analysis and interactive notification
- Multi-modality
- Transmission of dose information from imaging device or PACS
- Integration with PACS, RIS, & EMR
- Analysis and Reporting
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Commercial PDT Tools

• Basic

Custom

Dedicated System



Basic Dose Tracking

- Integrated with an existing system
- Example: Meditech
 - Integrated information system
 - Many aspects of health care
 - Includes a RIS and interfaces with PACS
 - RDSR's flow into Meditech
 - Subsequently recorded in patient record



Custom Applications

- Designed to meet specific needs
- Example: Primordial
 - Customized applications in radiology
 - Provide wide variety of Radiology services
 - Departmental workflow, communications, QC,...
 - Integration of PACS, RIS, and EMR

Radiation Dose Monitoring – Customizable Application

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Dedicated Dose Tracking Software

Integrate dose metrics from imaging systems or PACS typical formats: DICOM RDSR preferred Integrate with PACS, RIS, EMR **Analysis capabilities Selection of Reference Doses** Automated notification



Examples of Dedicated Dose Tracking Systems

- DoseMonitor (PACS Health)
- DoseTrack (Sectra)
- DoseWatch (GE)
- RADAR360 (MedPhys360)
- Radimetrics/eXposure(Bayer)



Common Features

- DICOM or IHE standards for interfaces
- Single server web-based applications
- Interface with multiple modalities
 - CT, Mammo, DR, Interventional vascular, Cardiac angiography, mobile C-arms
- HL7 Interface with PACS
- Customization for Ref. dose alerts
- Provide Near-time dose feedback
- Upload to ACR Dose Index Registry
- SSDE Prediction Based on patient EMR data

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DOSEMONITOR®

by PHS Technologies Group

- 2012
- Single server, browser based design
- Direct integration with RIS, EMR, ACR DIR
- Supports CT, Mammo, DR, IV, CA





Features and Capabilities:

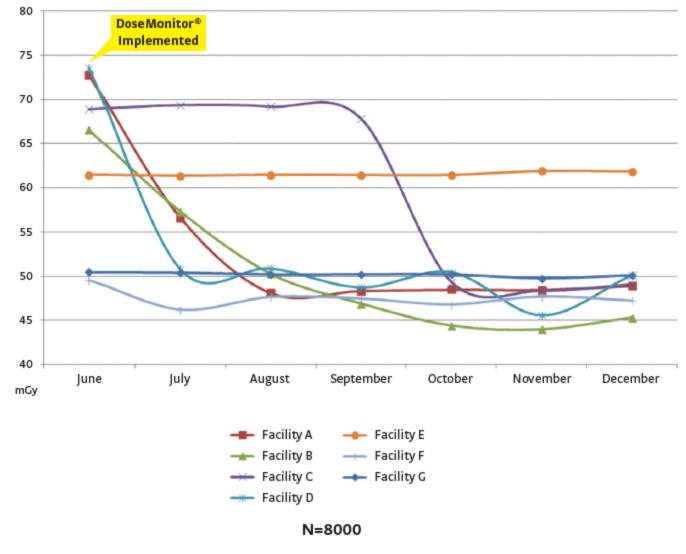
- Patient historical dose repository
- Customizable alerts and notifications
- Dose data exportable to dictation
- Reporting sort by
 - Technologist
 - Procedure
 - Physician



8000 studies over 6 months

Single Health System Multi-Facility Comparison

CT Head WO Contrast Average CTDI





RADAR360 by MedPhys360

- Radiation Dose Analyzing & Reporting
- Queries PACS for CT data
- CTDI & DLP Analyis
- Protocol Management
- Pediatric Techniques Evaluation
- Customizable designed to be affordable





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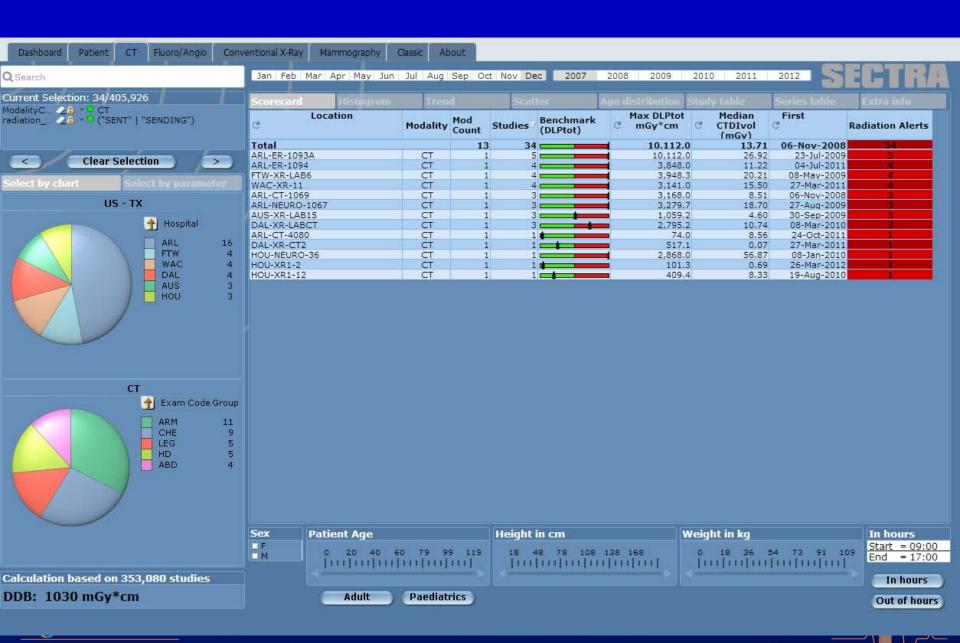


DoseTrack by Sectra

- Cloud based dose monitoring
- Supports CT, Mammo, DR, IV, CA
- Alerts when thresholds exceeded
 - i.e. User defined Dose Reference Levels
- Fluoro cumulative dose maps
- Analysis:
 - Patient specific
 - Dose profiles for imaging systems

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Radimetrics

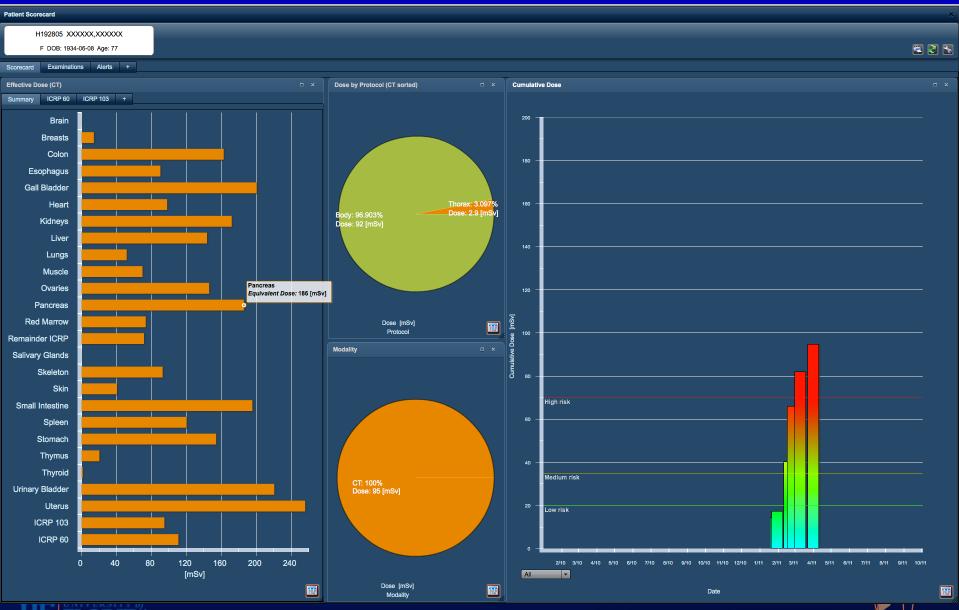
Radimetrics (eXposure) by Bayer

- Stand alone system- in house server
- Integrates with PACS & RIS
- Patient Score Card

 Cumulative dose tracking
- CT Dosimetry Prediction
 - Monte Carlo simulation engine
 - Organ doses
 - Effective dose
 - Protocol evaluation

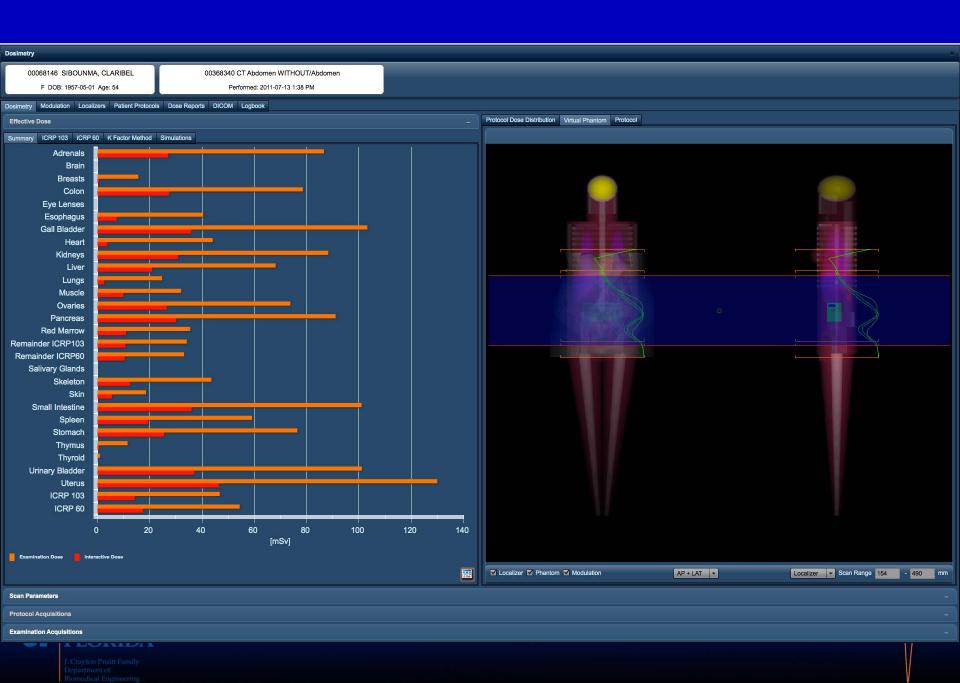
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Radimetrics

- Protocol Management
 - Supports multiple scanners
 - Tracks & authorizes revisions
 - Set uniform dose reference levels (CTDI, DLP, E, Organ Dose)
- Reporting
 - Customizable dashboard
 - Select items of items of interest
 - Pateint Scorecard integrates with most EMR systems
- Productivity
 - Monitoring & Analysis of equipment utilization
 - Integrates with Contrast dose management tools



DoseWatch – GE HealthCare

- Multi-modality
- Not vendor specific
- Centralized system- web-based interface
- Integrates with RIS and EMR
- Tracking and statistical analysis
 - Identifies dose outliers
 - Email notification



DoseWatch

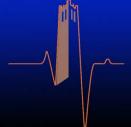
- Reporting
 - By device, operator or protocol
 - User defined thresholds
 - Email notifications
- Trend analysis
 - Baselines for procedures
 - Benchmark for improvements/optimization



DoseWatch

- Legacy systems
 - Extracts dose info from OCR on dose report images
- CT : Size Specific Dose Estimate (SSDE)
 - Per AAPM TG 204
 - Based on scout images
- Fluoroscopy: Incidence Map



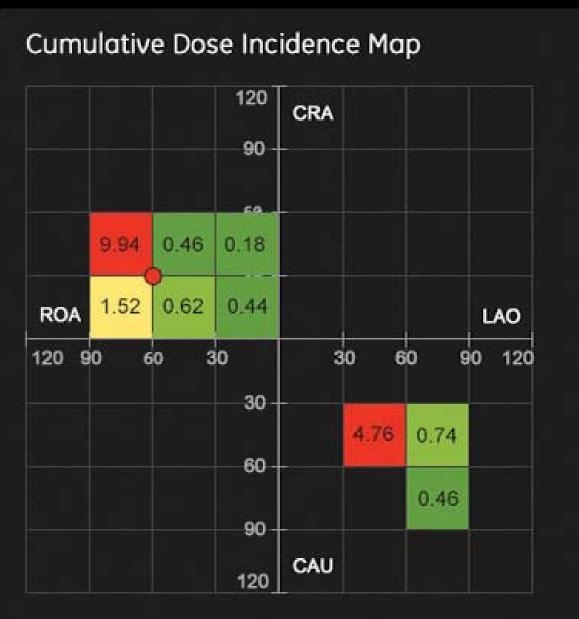


SSDE











Effectiveness & Advances

- Demonstrated reduction in patient doses
 Even without extensive analysis
- Seamlessly satisfy recording requirements
- Management of doses, equipment, training
- Endless PQI possibilities
- Development of Real-Time Dose Monitoring
 - Fluoroscopy
 - Real-time integration & body mapping of fields using RDSR



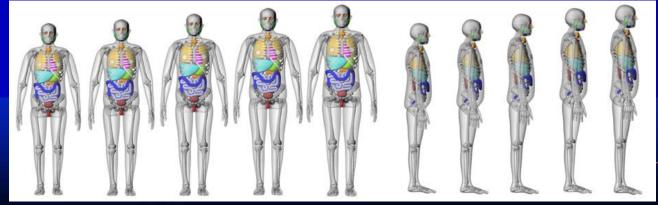
Real-Time Skin Dose Mappng

• RDSR – Radiation Dose Structured Report

• Collaboration with UF, UF Health Jacksonville and Columbia University Medical Center in NYC

•PI : Wesley Bolch, Ph.D.





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The cumulative dose incidence map provides

13%	а.	A planar represention of the surface air kerma distribution
20%	b.	A summary of the DAP per study
23%	C.	A visualization of cumulative organ doses through the body
13%	d.	The variation of a facilities cumulative delivered dose over time
30%	e.	A correlation of the number of studies performed with cumulative dose
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Ref: Manufacturer Websites listed at end of presentation



Summary

- Evolving Industry
 - Expect increasing numbers & advanced capabilities
- Products are readily customized to users needs
- Patient population or individual based applications
- Valuable QA tools
- Support regulatory focus & compliance
- Dose metrics not uniform across modality
 - Unavailable for legacy equipment
 - Integration of patient dose ?
- Integrate with other systems (PACS, EMR, RIS, HIS...)
- Difficult to track across health care systems



References

- 25 Texas Adminstrative Code §289.227 "Use of Radiation Machines in the Healing Arts" May 2013.
- VHA Handbook 1105.04, "Fluoroscopic Safety", Department of Veterans Affairs, Veterans Health Administration, Washington, DC 20420, July 2012.
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- Hospitals & Health Networks, Radiation dose management: A Patient Safety priority, Gatefold, 2013.
- The Joint Commission: Prepublication Standards: Diagnostic Imaging Services Requirements; Provision of Care, Treatment, and Services, Dec 2013.
- 2014 Ambulatory Care, Critical Access Hospital, and Hospital Comprehensive Accreditation Manual March 2014.

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Commercial Product Web-Sites and Descriptions

- http://www.dosemonitor.com/
- http://www.radimetrics.com/
- http://www.sectra.com/medical/
- <u>http://www.primordialdesign.com/</u>
- <u>http://www3.gehealthcare.com/en/Products/</u>
 <u>Dose Management/DoseWatch</u>
- <u>http://medphys360.com</u>

