EXPERIENCE WITH CALIFORNIA LAW ON REPORTING CT DOSE

Management and Reporting of Imaging Procedure Dose
Education Symposium: AAPM 2013
Indianapolis, Indiana

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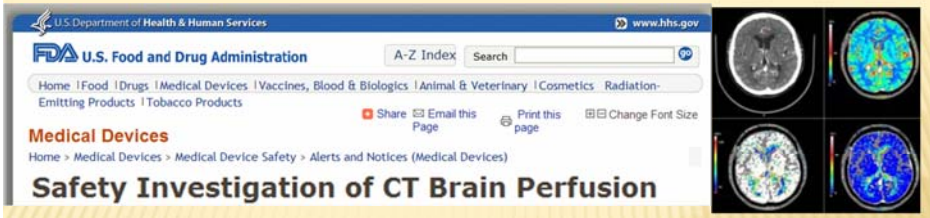
UC DAVIS
University of California, Davis

DISCLOSURES

- Co-investigator, University of California Dose Optimization and Standardization Endeavor (UC DOSE)
- User, Radimetrics eXposure software (as part of the UC DOSE consortium)

HISTORICAL PERSPECTIVES

- Rapid increase in the availability, capability, and use of CT over the last decade
- Contribution of dose burden by CT for medical imaging of ~50% for 15% of performed exams
- Radiation overdose incidents with CT brain perfusion exams, chiefly in California, resulting in 200+ overexposures in 18 months



October 2009

Cedars-Sinai, L.A.

EQUIPMENT AND/OR USER FAILURE.....

- 2 ½ year old boy
- 150 scans to same area over a period of 1 hour.....
- Acute erythema in area of scan (5-10 Gy)
- Cataracts, cancer, cognitive impairment are possible outcomes

RESULTING CALIFORNIA LEGISLATION

- Senate Bills 1237 & 38
  - Introduced by Alex Padilla

- Assembly Bill 510
  - Introduced by Bonnie Lowenthal

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 electronically send the study and technical factors to the picture archive and communication system (PACS)
  - 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
    - 0.5 Sv (50 rem) to an organ or tissue
    - 0.5 Sv (50 rem) shallow dose equivalent to the skin
  - 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

AB510

- Further clarifies SB1237
- Section 115111:
  - Nuclear Medicine 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

AB510

- Section 115112
  - Accreditation not required if:
    - Radiation treatment planning or delivery
    - Attenuation coefficients for Nuc Med studies
    - Image guidance for IR procedures
- Section 115113
  - Establishes dose levels for “any individual for whom a physician did not provide approval for the exam” (same dose levels as SB1237)
  - Establishes dose levels for “a CT x-ray for an examination that does not include the area of the body that was intended to be imaged by the ordering physician or radiologist”

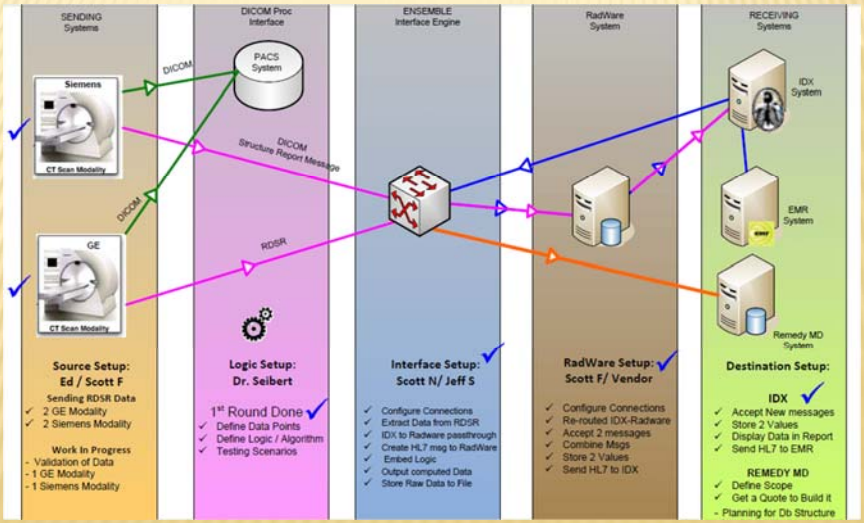
ISSUES

- Law does not indicate specifics of reporting $CTDI_{vol}$ and DLP…. Summed? By Series?
- Interpretation as to what “reporting” means
  - Access to PACS dose image adequate?
  - What about reconstruction/reformatting procedures that do not deliver dose?
- Failure to comply with law?

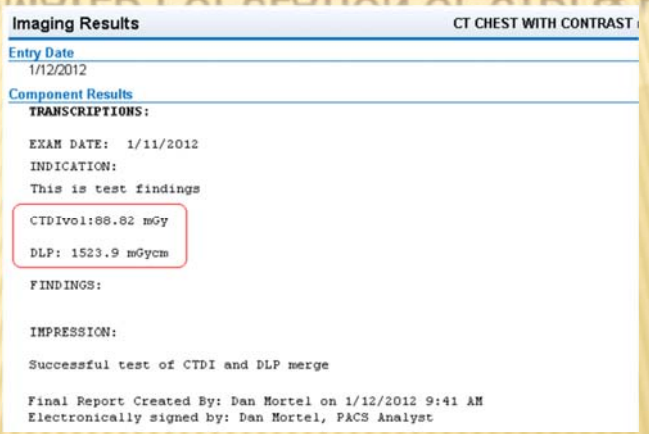
UC DAVIS PERSPECTIVE ON THE LAW

- Automate transfer of dose metrics to report
- Provide mechanism to report $CTDI_{vol}$ and DLP
- …… not as straightforward as initially thought
- RIS as repository of data?
- Alternate methods researched …..
- Final solution uses speech dictation system

UC DAVIS DOSE REPORTING AUTOMATION



AUTOMATED POPULATION OF CTDI & DLP



Imaging Results — CT CHEST WITH CONTRAST

Entry Date
1/12/2012

Component Results

TRANSCRIPTIONS:

EXAM DATE: 1/11/2012
INDICATION:
This is test findings

CTDIvol:88.82 mGy

DLP: 1523.9 mGycm

FINDINGS:

IMPRESSION:

Successful test of CTDI and DLP merge

Final Report Created By: Dan Mortel on 1/12/2012 9:41 AM
Electronically signed by: Dan Mortel, PACS Analyst

- 2 values only; multiple exams summed
- No explanatory information / text

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.

UC DOSE GUIDELINES

2. DOSE REPORTING (115111) effective July 1, 2012

B. Guidelines on How to Comply with this Section of the Law

1. Electronically send ("Push") the scanner's "Dose Report" or "Protocol Page" to your electronic archive (e.g. PACS),

AND one of the following (2 or 3):

2. Report $CTDI_{vol}$ and DLP ***for each series*** in the Radiology Report (see Appendix A).
   a. Include the anatomic area imaged (head, neck, chest, abdomen/pelvis, spine, extremity)
   b. Include the phantom size reference (32cm or 16cm).

OR

3. Attach the protocol page / dose sheet that includes the radiation dose for each series, to the radiology report.

UC DOSE GUIDELINES

2. DOSE REPORTING (115111) effective July 1, 2012

3. Do not add the $CTDI_{vol}$ and DLP values from different series. Adding them is misleading, inappropriate and may be inconsistent with the meaning of the law; reporting values separately for each series is unambiguous and recommended.

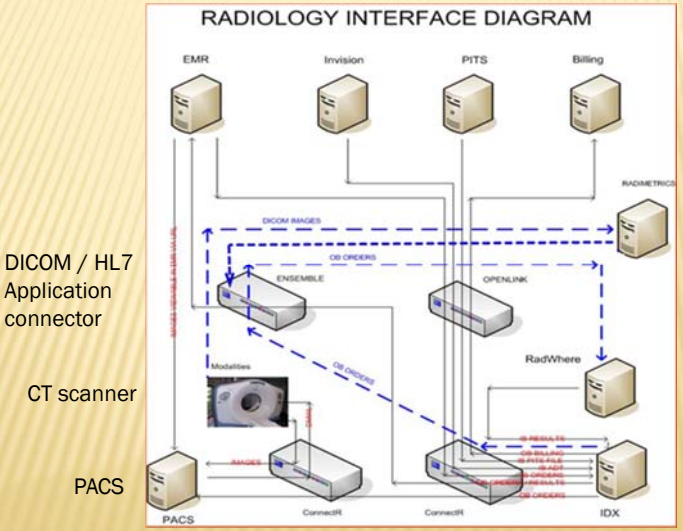
5. In the Radiology Report itself, the UC DOSE consortium recommends explanatory text accompany the reporting of the CTDIvol and DLP numbers.[4] Sample text might include:

The dose indicators for CT are the volume Computed Tomography (CT) Dose Index (CTDIvol) and the Dose Length Product (DLP), and are measured in units of mGy and mGy-cm, respectively. These indicators are not patient dose, but values generated from the CT scanner acquisition factors and may substantially underestimate or overestimate the absorbed dose based on patient size and other factors. A medical physicist or other qualified health professional should be consulted for specific questions regarding the radiation dose for this exam.

REPORTING CTDI & DLP IN REPORT…..

- UC Davis: following UC DOSE recommendations
- Automated solution to include values in report
  - Implementation of dose calculation engine
  - Extraction of series by series CT dose metrics
  - Provision of web-services calls and HL7 messaging
  - Inclusion of user defined message in speech engine
  - Creation of final report in RIS with dose metrics

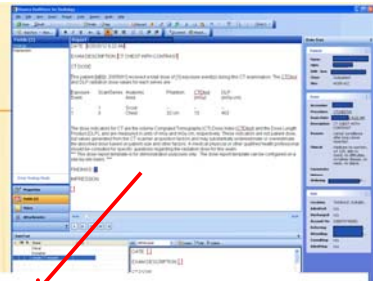
SYSTEMS INTEGRATION – DOSE REPORTING



IMPLEMENTATION CONSIDERATIONS

- Modifying radiologist templates to accept data
- Delays to extract dose data prior to dictation
- Exam splitting requiring assignment of accession numbers with same dose metrics
- Tabular data not handled by HL7 (formatting)
- Radiologists requesting minimal content

SINGLE ACQUISITION EXAM



CT DOSE:

[This patient [MRN: 2085681] received a total dose of [1] exposure event(s) during this CT examination. The CTDIvol and DLP radiation dose values for each series are:

Exposure Event	Scan/Series	Anatomic Area	Phantom	CTDIvol (mGy)	DLP (mGy-cm)
--	1	Scout	--	--	--
1	3	Chest	32 cm	13	402

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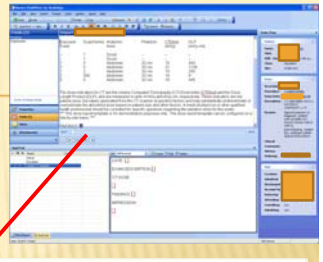
*** This dose report template is for demonstration purposes only. The dose report template can be configured on a site-by-site basis. ***

MULTIPLE ACQUISITION EXAM



Exposure Event	Scan/Series	Anatomic Area	Phantom	CTDIvol (mGy)	DLP (mGy-cm)
--	1	Scout	--	--	--
--	1	Scout	--	--	--
1	2	Abdomen	32 cm	18	343
2	3	Abdomen	32 cm	21	1136
1	2	Abdomen	32 cm	10	250
2	200	Abdomen	32 cm	18	9
5	3	Abdomen	32 cm	18	345

The dose indicators for CT are the volume Computed Tomography (CT) Dose Index (CTDIvol) and the Dose Length Product (DLP), and are measured in units of mGy and mGy-cm, respectively. These indicators are not patient dose, but values generated from the CT scanner acquisition factors and may substantially underestimate or overestimate the absorbed dose based on patient size and other factors. A medical physicist or other qualified health professional should be consulted for specific questions regarding the radiation dose for this exam.
*** This dose report template is for demonstration purposes only. The dose report template can be configured on a site-by-site basis. ***

EXAMPLE REPORTS

- Our radiologists want short reports
- No more "consult with Medical Physicist"

DOSE REPORT: This study involved (1) CT acquisition(s). The CTDIvol and DLP values are included below as required by state law:

1; Series: 3; Abdomen; 32 cm; CTDIvol=17.7 mGy; DLP=856.7 mGy-cm

For further information on CT radiation dose, see http://www.ucdmc.ucdavis.edu/radiology/RadiationDose.html

RADIATION DOSE:
This study involved (3) CT acquisition(s). The CTDIvol and DLP values are included below as required by state law:
1; Series: 2; Chest; 32 cm; CTDIvol=2.9 mGy; DLP=3 mGy-cm
2; Series: 3; Chest; 32 cm; CTDIvol=26.4 mGy; DLP=26 mGy-cm
3; Series: 5; Chest; 32 cm; CTDIvol=13.5 mGy; DLP=692 mGy-cm
For further information on CT radiation dose, see
http://www.ucdmc.ucdavis.edu/radiology/RadiationDose.html

TRAUMA CT DOSE REPORTING

- Sometimes the dose report is missing or late
- Either gets populated with single DLP value or nothing
- Problem is sorting scans after acquisition

Procedure:CT C-SPINE WITHOUT CONTRAST

Date:10/9/2012 3:50 AM

History: Trauma

Technique: Axial CT images of the cervical spine were obtained in bone and soft tissue algorithm. Coronal and sagittal reformatted images were also examined, in bone algorithm only.

Radiation dose:
Total DLP for CT brain and C-spine is 1178

Comparison: None

Findings:

There is no acute fracture of the cervical spine.

There is moderate collapse of the disk with diffuse annular bulging with kyphosis at C4-5 with partial uncovering of the left C4-C6 facet

EXAM: CT ABDOMEN + CT PELVIS, WITH CONTRAST

DATE OF STUDY: 10/9/2012 4:14 AM

CLINICAL INFORMATION: Signs/Symptoms or Diagnosis: Pain S/P Trauan
Special Instructions: IV Contrast only

TECHNIQUE: Helically acquired contrast enhanced multidetector CT of the abdomen and pelvis acquired in the portal venous phase, extending from the lung bases through the groins. Uneventful administration of 125 ml of Omnipaque 350 injected at a rate of 2.5 ml/sec. Images are reconstructed in the axial pane with subsequent reformatting in coronal and sagittal planes.

No P.O. contrast was administered.

DOSE REPORT:

COMPARISON: None.

FINDINGS:

EXAMPLE REPORTS WITH DOSE DATA

- Linked studies often have same dose data; others have different accession numbers

Radiation dose:

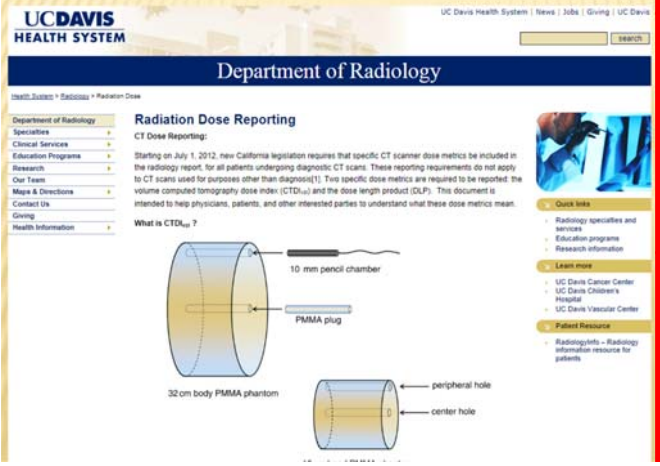
This study involved (3) CT acquisition(s). The CTDIvol and DLP values are included below as required by state law:

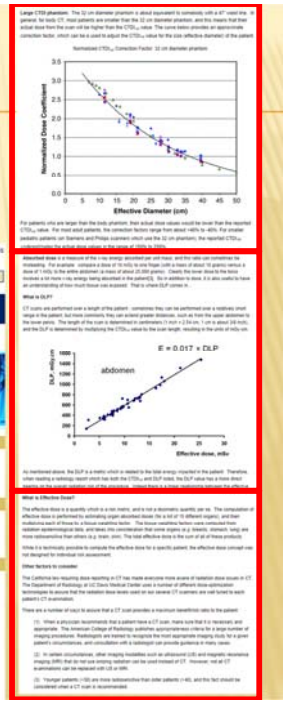
1; Series: ; Chest; 32 cm; CTDIvol=26.4 mGy; DLP=26 mGy-cm
2; Series: 2; Chest; 32 cm; CTDIvol=57.7 mGy; DLP=1312 mGy-cm
3; Series: 3; Abdomen; 32 cm; CTDIvol=16.1 mGy; DLP=635 mGy-cm

The following accession numbers are related to this dose report {3563977}:
3563978

WEBSITE FOR INFORMATION

- Reduce verbiage in report
- Currently “too technical”





AUDIT OF DOSE REPORT COMPLIANCE

CT audit for dose reporting: 9/15/2012 to 9/25/2012

9/15/2012	ACC#	Study	Report?	Complete?
	1	3552078 CT Chest	Yes	Yes
	2	3552012 CT Neck	Yes	Yes
	3	3551844 CT AbdPel	Yes	Yes
	4	3551788 CT Head	Yes	Yes
	5	3551820 CT Sinus/Facial	Yes	Yes
9/16/2012				
	6	3552581 CT AbdPel	Yes	Yes
	7	3552539 CT Head	Yes	Yes
	8	3552305 CT AbdPel	Yes	Yes
	9	3552295 CT Chest	Yes	Yes
	10	3552236 CT Head	Yes	Yes
	11	3552237 CT Neck	Yes	Yes
9/17/2012				
	12	3554345 CT lower extr	Yes	Yes
	13	3553710 CT Chest	Yes	Yes
	14	3538368 CT facial	Yes	Yes
	15	3538369 CT Head	Yes	Yes
	16	3544233 CT Abdo	Yes	Yes
	17	3552990 CT AbdPel	Yes	Yes
9/18/2012				
	18	3555977 CT Head	Yes	Yes
	19	3554605 CT Sinus/Facial	Yes	Yes
	20	3555116 CT AbdPel	Yes	Yes
	21	3508651 CT Chest	Yes	Yes
	22	3549664 CT Angio Chest	Yes	Yes
9/19/2012				
	23	3557544 CT Head	Yes	Yes
	24	3557545 CT C-spine	No	No
	25	3557546 CT Sinus/Facial	No	No
	26	3557548 CT L-spine	No	No
	27	3557333 CT Head	Yes	Yes
	28	3556877 CT Pelvis	No	No

September 15-25 (random audit)
83.4% compliance

October 9 (all scans audited)
91.5% compliance

November 29 (all scans audited)
95.4% compliance

Findings:

- Speech templates improperly set up
- Reports are sometimes not generated, and radiologists fail to populate dose
- Many studies do not result in patient dose (e.g. reconstructions)

UC DOSE GUIDELINES….

3. FACILITY ACCREDITATION (115112) Effective July 1, 2013

3B. Guidelines on How to Comply with this section of the Law

Get all equipment (inpatient /outpatient) accredited by one of the organizations approved by CMS/CDPH. The three approved accreditation bodies are:

1. The American College of Radiology CT accreditation program
   http://www.acr.org/accreditation/computed.aspx
2. The Joint Commission
   http://www.jointcommission.org/accreditation/diagnostic_imaging_centers.aspx
3. Intersocietal Commission for Accreditation of CT Laboratories (ICACTL)
   http://www.icactl.org/icactl/index.htm

DETERMINATION OF REPORTABLE DOSE

- Section 3 (115113)
  - + – An Effective Dose (E.D.) that exceeds 0.05 Sv (5 rem)
  - + – A dose in excess of 0.5 Sv (50 rem) to any organ or tissue
  - + – Shallow dose to the skin of 0.5 Sv (50 rem) to the skin
  - + – **Dose to fetus that is greater than 50 mSv (5 rem)**
- Reporting dose with the current limits is unlikely except for dose to the fetus in certain circumstances
- A medical physicist should be involved in any formal dose estimation

RECOMMENDATIONS:

4. MEDICAL EVENT REPORTING (115113) Effective July 1, 2013

- California Clinical and Academic Medical Physicists (C-CAMP)

http://aapm.org/government_affairs/documents/SB-1237Section3_v7.pdf

- *John M. Boone: University of California Davis*
- *Christopher Cagnon: University of California, Los Angeles*
- *Melissa Martin: Therapy Physics, Inc. Gardena, CA*
- *Michael McNitt-Gray: University of California, Los Angeles*
- *Thomas R. Nelson: University of California, San Diego*
- *J. Anthony Seibert: University of California Davis*

PATIENT EFFECTIVE DOSE ≥ 50 mSv

- Determine DLP with appropriate k-factor that would result in effective dose ≥ 50 mSv
- Two tables required
  - $CTDI_{vol}$ and DLP determined with 16 cm diameter phantom for pediatric body exams
  - $CTDI_{vol}$ and DLP determined with 32 cm diameter phantom for pediatric body exams

DLP VALUE: REPORTING THRESHOLDS

- $CTDI_{vol}$ and DLP with 16 cm phantom for pediatric body exam

DLP in mGy·cm

	0 year old	1 year old	5 year old	10 year old	adult
head & neck	3840	5880	8770	11900	16120
head	4540	7460	12500	15620	23800
neck	2940	4160	4540	6320	8470
chest	1280	1920	2770	3840	3570
abd/pelvis	1020	1660	2500	3330	3330
trunk (C/A/P)	1130	1780	2630	3570	3330

- $CTDI_{vol}$ and DLP with 32 cm phantom for pediatric body exam

DLP in mGy·cm

	0 year old	1 year old	5 year old	10 year old	adult
head & neck	3840	5880	8770	11900	16120
head	4540	7460	12500	15620	23800
neck	2940	4160	4540	6320	8470
chest	550	830	1200	3840	3570
abd/pelvis	440	720	1080	3330	3330
trunk (C/A/P)	490	770	1140	3570	3330

ORGAN DOSE THRESHOLD: 500 mSv

- "Cumulative $CTDI_{vol}$" if same anatomic region scanned multiple times (and organ included)
  - Scans with table movement
    - Pediatric: cumulative **$CTDI_{vol}$ ≥ 200 mGy**
    - Adult: cumulative **$CTDI_{vol}$ ≥ 250 mGy**
  - Scans with no table movement (e.g., neuroperfusion)
    - Pediatric: cumulative **$CTDI_{vol}$ ≥ 650 mGy**
    - Adult: cumulative **$CTDI_{vol}$ ≥ 650 mGy**

SKIN DOSE THRESHOLD: 500 mSv

- Want to identify scans resulting in a *peak* skin dose that exceeds 500 mGy (multiple scans with no table motion)
  - DLP tends to underestimate
  - $CTDI_{vol}$ tends to overestimate (30 to 100%)
- Use recommendations for organ dose threshold

FETAL DOSE THRESHOLD: 50 mSv

- This event may occur in certain clinical scenarios
  - Scans with table movement
    - Cumulative $CTDI_{vol}$ of abd/pelvis ≥ **25 mGy**
  - Scans with NO table movement (abd/pelvis perfusion)
    - Cumulative $CTDI_{vol}$ of abd/pelvis ≥ **65 mGy**

CURRENT SITUATION – DOSE REPORTING

- Since July 1, 2012, there have been no (0) reported CT overdose events to California DPH
  - Likely due to very high dose reporting requirements
  - Lower threshold dose limits needed?
- In the last month, 3 reportable therapy events
  - Wrong patient or wrong treatment site
- No cases referred for escalated enforcement action
  - Prior compliance history to be taken into account
- The state has not yet evaluated compliance to section 115111 and reporting CTDI & DLP .....

NEXT STEPS

- Work with the state on developing meaningful ways to report dose metrics and dose
- Educate technologists, radiologists, referring physicians, physicists, nurses, and general public
- UC DOSE Virtual Symposium on Radiation Safety and Computed Tomography was held May 8th-10th, 2013 to the state, national, and international audience; **still available on web**

SUMMARY

- California dose reporting law – national attention
- Resultant emphasis on CT dose and safety
- Compliance & oversight by state is imminent
- Non-compliance? Notice of Violation (NOV)
- Multiple NOV's: financial $$ penalties

WHERE TO GET INFORMATION.....

- State of California Radiologic Health Branch (www.cdph.ca.gov/programs/pages/radiologichealthbranch.aspx)
- UC DOSE (rorl.radiology.ucsf.edu)
- AAPM (aapm.org)