

UC-DOSE University of California Health System

Recommendations for Compliance with California Senate Bill 1237 and related pending legislation June 15, 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. This bill takes effect on July 1, 2012, will be enforced by the California Department of Public Health Radiologic Health Branch, and requires the reporting of CT radiation dose in the patient's radiology report; this can be accomplished by inserting the dose information into the radiology report or attaching the protocol sheet that includes the dose (dose sheet from PACS). 3,4

This document outlines our interpretation of the requirements for complying with the law and provides guidelines for UC radiologists, physicians, technologists and other clinical personnel with information on the details of what must be reported (Section 2 of this document); explains the accreditation provisions in the law (Section 3); describes compliance requirements for reporting overdoses (Section 4); and includes a Glossary of CT radiation dose terms (Section 5). The Appendix includes several examples of reporting dose for a few different types of CT exams on scanners by the major manufacturers. Members of the UC-DOSE team are listed at the end of the document.

At this time, there is a separate bill under consideration before the legislature (AB 510) that would change some of the reporting requirements - these have not been incorporated into this document (except where referenced as guidance), but we will issue an update if/when that bill passes.

• It should be noted that the radiation dose values required to be recorded by this bill (CTDI and DLP) are based on a dose emitted by the machine and absorbed by a plastic <u>phantom</u> used during calibration of the equipment, and not a direct measure of dose for that particular patient. We believe it would be ideal to provide a patient dose estimate in the medical record, but methods to do so are still under development. In a future version of this document we will provide a strategy that takes into account dose measures, currently under development (such as the size specific dose estimate, or <u>SSDE</u> and effective dose, <u>E</u>) that do take into account patient size, body region imaged and other factors.

¹Padilla A. California Senate Bill 1237 (2010) Chaptered. 2010;

http://www.leginfo.ca.gov/pub/09-10/bill/sen/sb_1201-1250/sb_1237_bill_20100929_chaptered.pdf

² CDPH. Radiologic Equipment. 2012;

http://www.cdph.ca.gov/certlic/radquip/Pages/RadiologicEquipment.aspx.

The requirement to put the information in the "radiology report" or patient record is made explicit in AB 510: (d) Subject to subdivision (e), the radiology report of a CT study shall include the dose of radiation by either recording the dose within the patient's radiology report or attaching the protocol page that includes the dose of radiation to the radiology report. http://www.leginfo.ca.gov/pub/11-12/bill/asm/ab_0501-0550/ab_510_bill_20120416_amended_sen_v94.html

⁴ See Q&A No. 7 in "Information Notice Regarding California Health and Safety Code, Section 115111 and 115112: http://www.cdph.ca.gov/certlic/radquip/Documents/RHB-SB1237-2012-05-02-FAQ.pdf

The major provisions of the law are as follows:

- Commencing July 1, 2012, SB1237 (Section 115111) requires hospitals and clinics that use computed tomography (CT) X-ray systems for human use to record in the radiology report the dose of radiation on every CT study produced during the administration of a CT examination. CT studies used for therapeutic radiation treatment planning as well as PET/CT or SPECT/CT studies used for attenuation correction only and not for diagnosis, shall not be required to record the dose.
- Commencing July 1, 2013, SB1237 (Section 115112) requires that *CT X-ray systems* shall be accredited by an organization that is approved by the U.S. Centers for Medicare and Medicaid Services (CMS), an accrediting agency approved by the Medical Board of California, or the State Department of Public Health (CDPH).
- Commencing July 1, 2012 SB1237 (Section 115113) also requires facilities to report certain information, under specific conditions, to the California Department of Public Health regarding radiation exposures to the patient and the patient's treating physician. (Note: SB38 clarified these reporting requirements as commencing on July 1, 2012 and this was not noted on the first version of this document dated May 21, 2012.)

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Members of the <u>UC Dose Team</u>

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

Prompted by CT radiation overexposures, California State Senator Alex Padilla (D-Pacoima), authored legislation (SB 1237) requiring California facilities that use CT to: 1) notify patients and their doctors of exposure events meeting certain conditions, 2) to report these events to the state faster and 3) record the doses in the patient's medical record. The Governor signed SB1237 into law in September 2010. Senate Bill 38 (SB38) provided a clarification on when section 3 (115113) would go into effect (July 1, 2012). Assembly Bill (AB) 510 is pending at this time and would modify some of the reporting requirements.

A. Major Provisions

Effective July 1, 2012 a person that uses a computed tomography (CT) X-ray system for human use shall:

- 1. Record the radiation dose on every CT study produced during a CT examination.
- 2. Electronically send each CT study and protocol page listing technical factors and radiation dose to the Picture Archiving and Communications System (PACS).
- 3. Have a medical physicist verify annually that displayed doses in PACS are within 20 percent of the true measured dose (unless the facility is accredited).
- 4. Include the radiation dose within the patient's radiology report by either:
 - a. Recording the radiation dose in the radiology report,
 - b. Attaching the protocol page that includes the radiation dose to the radiology report.
- 5. This provision is limited to CT systems capable of calculating and displaying the dose.
- 6. Dose is defined in the following ways:
 - a. The computed tomography index volume (CTDI_{vol}) <u>and</u> dose length product (DLP). (See the Glossary.)
 - b. The dose unit as recommended by the American Association of Physicists in Medicine (AAPM).⁵

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.

C. Recommendations for recording

1. The law does not explicitly state how the dose is to be reported, however, reporting the CTDIvol and DLP by series and anatomic area meets the letter of the law for reporting and is the only meaningful way for these

⁵ The AAPM has <u>not</u> made any recommendations on a dose unit to-date.

- measures to be reported. In addition, these are the elements required to make estimates of effective dose or local tissue/organ dose, such as for section 115113 (see below).
- 2. It is not necessary or meaningful to report the dose for the scout or topogram (these are much smaller than doses from the regular series).
- 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.
- 4. For patients who undergo several exams at the same time (i.e., chest-abdomen-pelvis) the dose from all of these should be included within a single dose report, and should not be divided even if separate interpretations are generated. This single report can be included in one of the interpretations (for example the chest report) and then referred to in other reports, or a duplicative summary could be included with all of the interpretations where it is stated that a single summary will be provided for the entire imaging exam done at that time.
- 5. In the Radiology Report itself, the UC DOSE consortium recommends explanatory text accompany the reporting of the CTDIvol and DLP numbers. 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.

Examples for reporting, including suggested text, are provided in the Appendix.

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

3A. Major Provisions

Effective July 1, 2013, facilities that furnish *CT X-ray services shall* be accredited by an organization that is approved by the U.S. Centers for Medicare and Medicaid Services (CMS), an accrediting agency approved by the Medical Board of California, or the State Department of Public Health (CDPH).

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. Inter-societal Commission for Accreditation of CT Laboratories (ICACTL) http://www.icactl.org/icactl/index.htm

⁶This text is not required by law, but will be helpful to patients and physicians.

4. MEDICAL EVENT REPORTING (115113) Effective July 1, 2012⁷

4A. Major Provisions

- 1. A facility shall report administration of radiation (except from patient movement or interference) as a result of:
 - a. A repeat CT examination (unless otherwise ordered by a physician) *if all of the following dose values* are exceeded:⁸
 - i. 0.05 Sv (50 mSv, 5 rem) effective dose equivalent.
 - ii. 0.5 Sv (500 mSv, 50 rem) to an organ or tissue.
 - iii. 0.5 Sv (500 mSv, 50 rem) shallow dose equivalent to the skin.
 - b. CT irradiation of an anatomic area that does not include the intended anatomic area of a body part (other than that ordered by a physician) if *one* of the following dose values are exceeded:⁹
 - i. 0.05 Sv (50 mSv, 5 rem) effective dose equivalent.
 - ii. 0.5 Sv (500 mSv, 50 rem) to an organ or tissue.
 - iii. 0.5 Sv (500 mSv, 50 rem) shallow dose equivalent to the skin.
 - c. A CT or therapeutic exposure that results in <u>unanticipated</u> permanent functional damage to an organ or a physiological system, hair loss, or erythema, as determined by a qualified physician.
 - d. A CT or therapeutic dose to an embryo or fetus that is greater than 50 mSv (5 rem) dose equivalent that is the result of radiation <u>to a known pregnant individual</u> unless a qualified physician specifically <u>approved</u> the dose to the embryo or fetus <u>in advance</u>.
 - e. Therapeutic ionizing irradiation of the <u>wrong individual</u>, or <u>wrong treatment site</u>. Reporting is not required if adjacent body parts are irradiated during the same treatment.
 - f. Administration of a dose that exceeds by 20% the dose prescribed for therapeutic ionizing radiation:

A report <u>shall not be</u> required pursuant to this paragraph in any instance where the dose administered exceeds 20% of the amount prescribed in a situation where the radiation was utilized for palliative care for the specific patient. The radiation oncologist shall notify the referring physician that the dose was exceeded.

g. The Facility <u>shall</u> notify the department (CDPH) no later than *five business days* after discovery of an event described in (a); and, 1) provide notification of the event to the department and the referring physician of the person subject to the event; and 2) provide written notification to the person who is the subject of the event no later than *15 business days* after discovery of the event described in (a).

⁸ CDPH interpretation of this provision is that all three conditions (effective dose> 50 mSv, organ dose> 500 mSv AND skin dose > 500 mSv) have to be met before this becomes a reportable event. See Question & Answer No.3: CDPH. Information Notice Regarding Senate Bill (SB) 1237, California Health and Safety (H&S) Code Section 115113. 2011. http://www.cdph.ca.gov/certlic/radquip/Documents/RHB-SB1237-FAQ.PDF

 $^{^7}$ SB38 clarified the date the medical reporting provisions went into effect as July 1, 2012.

Pending legislation (AB510) proposes to revise this condition to specify "an examination that does not include the intended area of the body" rather than "body part" and that reporting is required if "at least one" of the specified dose values is exceeded. http://www.leginfo.ca.gov/pub/11-12/bill/asm/ab_0501-0550/ab_510_bill_20120416_amended_sen_v94.html

h. The information required pursuant to this section shall include, but not be limited to, information regarding each substantiated adverse event, as defined in Section 1279.1.a. report to CDPH may also require compliance information history.¹⁰

4B. Recommendations on How to Comply with this section of the Law¹¹

- 1. Review protocols to ensure that:
 - a. These dose limits are generally not exceeded in routine practice.
 - b. Identify all protocols that have the potential to exceed these limits and monitor them closely.
 - c. Establish procedures to ensure that the proper protocol is used on the correct patient.
 - d. Institute internal reporting policies to identify when an exam has met the criteria of:
 - i. Repeated for any reason that does not include ordering by a physician, or
 - ii. Repeated due to patient motion or "interference."
 - e. Develop alert mechanisms and protocols for investigating when any of the criteria in (d) is met.
- 2. When a body part is irradiated other than that ordered by a physician:
 - a. Determine whether a detailed dose estimate is required to assess whether the reporting limits were exceeded.
 - b. Initiate an investigation into the protocol that was used in the CT examination.
- 3. Pregnant Patient Protocols.
 - a. Ask all females of reproductive age if they are pregnant or could be pregnant and have all protocols specifically approved by a physician before the exam.
 - b. Create an alert and notification system in the case that a known pregnant patient is scanned and a physician did not approve the scan.
 - c. Investigate the protocol and exam parameters to determine if the fetal dose values were exceeded.

5. GLOSSARY

Radiation Dose Measures

CTDI_{vol} –Volume Computed Tomography Dose Index (CTDI_{vol}) is a dose index that represents scanner output as measured in a cylindrical test object (referred to as a phantom); it is expressed in units of mGy.

DLP – Dose Length Product (DLP) is calculated by multiplying the $CTDI_{vol}$ (mGy) by the scan length (cm) and is expressed in units of mGy-cm.

[Note: $CTDI_{vol}$ and DLP are based on a measurement made using an acrylic phantom (32 cm or 16 cm diameter) and do not directly represent the radiation dose that will be absorbed by the patient. Individual patient doses derived from these values will depend on the patient size and can substantially underestimate or overestimate the actual dose. A medical physicist should be consulted on questions regarding the specific absorbed dose for this exam. If the patient size is very different from the assumed phantom size, the dose can be over or underestimated by as much as a factor of two.]

Effective Dose [E] –The effective dose, E or ED, originally defined by the International Commission on Radiological Protection (an international scientific group), is calculated by multiplying actual organ doses by "risk weighting factors" (which approximate each organ's relative radiosensitivity to developing cancer based on epidemiological studies) and adding up the total of all the numbers—the sum of the products is the "effective whole-body dose" or just "effective dose."

Phantom—a phantom is an acrylic cylinder used to measure the dose of the x-ray beam from a particular piece of equipment. Phantoms for routine calibration of equipment come in two sizes 16 cm typically used to calculate doses to the head and 32 cm used to calculate doses to the body. In some scanners, the 16cm is used in pediatric protocols to represent a child's abdomen.

Size Specific Dose Estimate [SSDE] –Is an estimate of patient dose that takes into consideration corrections based on the size of the patient using linear dimensions measured on the patient or the patient's image. ¹³

¹² ICRP Publication 92 (2003): http://www.icrp.org/publication.asp?id=ICRP%20Publication%2092; updated 2007 (ICRP Publication 103) version: http://www.icrp.org/publication.asp?id=ICRP%20Publication%20103

¹³ AAPM (American Association of Physicists in Medicine) Report Number 204: Size Specific Dose Estimates (SSDE) in Pediatric and Adult Body CT Examinations: http://www.aapm.org/pubs/reports/rpt 204.pdf

APPENDIX A

Examples for Section 1 - 115111 - Recommendations for CT Dose Reporting

For each example, the recommendation is to report the <u>exposure event number</u>, <u>scan series</u> (as reported on the patient protocol page or dose report), <u>anatomic area</u>, <u>phantom size</u> and <u>CTDIvol and DLP values</u>. We suggest using a tabular format that matches the recorded information on the dose sheet, allowing a direct connection to the dose sheet.

Protocol pages may differ between scanner manufacturers and series numbers are sometimes printed out of order. However, in all dose reports, each of the exposure events (CT radiographs, axial or sequential series, helical series, timing studies, etc.) that involve X-ray exposures are recorded in the patient dose report, samples of which are shown below. Imaging reconstructions that do not involve additional radiation to the patient (reformats, 3-D recons, reconstructions with different reconstructed image widths, etc.) have not been included in this report, as they do not represent any additional patient exposure, and these should not be recorded. Consult with your manufacturer's Operator Manual for details regarding your equipment's patient protocol page or dose report.

I - Single Anatomic area, single series

A. Equipment--General Electric

	Dose Report									
Series	Type	Scan Range (mm)	CTDIvol (mGy)	DLP (mGy-cm)	Phantom cm					
1	Scout	-	-	_	-					
2	Helical	I18.000-I313.000	6.20	211.63	Body 32					

This patient [Patient Name or MRN] received a total of [1] exposure event 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	32 cm		
1	2	Abdomen	32 cm	6.20	211.63

	Dose Report										
Series	Type	Scan Range (mm)	CTDIvol (mGy)	DLP (mGy-cm)	Phantom cm						
1	Scout	=	-	-	=						
2	Axial	I10.500-S118.252	55.53	718.68	Head 16						

This patient [Patient Name or MRN] received a total of [1] exposure event 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	2	Head	16 cm	55.52	718.68

B. Equipment--Siemens

	Scan	ΚV	mAs / ref.	CTDIvol mGy	DLP mGycm	TI s	cSL mm
Patient Position F-SP SUPINE Contrast	1	100				5.3	0.6
ABD/PEL W/C	2	120	168 / 220	11.39(a)	426.69	0.5	1.2

Patient [Patient Name or MRN] received a total of [1] exposure event 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				
1	2	Abdomen/Pelvis	32 cm*	11.39	426.69

^{*}Body phantom represented by "a" next to CTDIvol.

II – Multiple Series with Multiple Anatomic Areas

A. Equipment—Toshiba

	Exposure Time	CTDIvol(mGy)	DLP(mGycm)	SD
SCANOSCOPE[2]	13.70			
HEL ICAL_CT	11.34	19.80 (Body)	662.90 (Body)	15 . 00
HEL ICAL_CT	15. 41	20.40 (Body)	700.90 (Body)	20.00
HEL ICAL_CT	9. 53	20.40 (Body)	473.50 (Body)	20.00

This patient [Patient Name or MRN] received a total of [3] exposure events 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	Helical_CT	Abdomen	32 cm	19.80	622.90
2	Helical_CT	Abdomen/pelvis	32 cm	20.40	700.90
3	Helical_CT	Pelvis	32 cm	20.40	473.50

^{*}Anatomic area is based on the ordered protocol

B. Equipment—Phillips

	Description	Scan	MAS	kV	CIDIvol.	DLP	Phanton
		Mode			[mGy]	(mGy*cm)	Type [cn]
2	SCOUT	Survieu	1	120	0.10	7.5	16 CM
2	SCOUT	Surview	1	120	0.10	7.5	16 CH
3	CAPSXS NO PACS	Helical	243	120	16.47	1262.7	32 CH
9	ABDOMIN DELAY	Helical	248	120	16.77	638.2	32 CH

This patient [Patient Name or MRN] received a total of [2] exposure events 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)
	2	Scout	16 cm		
	2	Scout	16 cm		
1	3	Chest/Abdomen/Pelvis	32 cm	16.46	1262.70
2	9	Abdomen	32 cm	16.77	638.20

^{**}Body phantoms unless otherwise specified are always 32cm.

III - Multiple Series in Same Anatomic Areas

A. Equipment—General Electric

	Dose Report									
Series	Туре	Scan Range (mm)	CTDIvol (mGy)	DLP (mGy-cm)	Phantom cm					
1	Scout	-	-	-	-					
200	Axial	1222.750-1222.750	14.44	7.22	Body 32					
2	Helical	1210.500-1469.250	19.13	583.75	Body 32					
2	Helical	S0.750-I319.250	12.87	471.39	Body 32					
2	Helical	1210.500-1681.125	21.45	1108.77	Body 32					
5	Helical	1219.250-1478.000	19.20	585.75	Body 32					

This patient [Patient Name or MRN] received a total of [5] exposure events 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	200	Abdomen	32 cm	14.44	7.22
2	2	Abdomen	32 cm	19.13	583.75
3	2	Abdomen	32 cm	12.87	471.39
4	2	Abdomen	32 cm	21.45	1108.75
5	5	Abdomen	32 cm	19.20	585.75

B. Equipment Type—Siemens

	Scan	kV	mAs / ref.	CTDIvol* mGy	DLP mGytm	TI	cSL mm
Patient Position F-SP							
Topogram	1	100	39 mA	0.10 L	1	1.5	0.6
Topogram	2	100	39 mA	0.10 L	3	3.5	0.6
PreMonitoring	3	100	50	1.49 L	1	0.28	10.0
PreMonitoring	4	100	50	1.49 L	1	0.28	10.0
PreMonitoring Contrast	5	100	50	1.49 L	1	0.28	10.0
Monitoring	6	100	50	5.96 L	6	0.28	10.0
I_Embolism	100	100	206 / 150	6.85 L	214	0.28	0.6
I_Embolism	11D	100	140 / 150	4.68 L	55	0.28	0.6

This patient [Patient Name or MRN] received a total of [6] exposure events 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	Topogram		-	
	2	Topogram			
1	3	Chest	32 cm	1.49	1.00
2	4	Chest	32 cm	1.49	1.00
3	5	Chest	32 cm	1.49	1.00
4	6	Chest	32 cm	5.96	6.00
5	10D	Chest	32 cm	6.85	214.00
6	11D	Chest	32 cm	4.68	55.00

^{*}Phantom size represented by "L" next to CTDI_{vol}.

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