State of California—Health and Human Services Agency
California Department of Public Health

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Information Notice Regarding California Health and Safety Code, Section 115111, 115112, and 115113

Date: July 17, 2012

To: Facilities Using X-Ray Computed Tomography (CT) Equipment

Subject: Assembly Bill 510, Senate Bill 1237, and Senate Bill 38 (California Health and Safety Code Sections 115111, 115112, & 115113) Questions and Answers (Q&A)

This Q&A only applies to Health and Safety Code sections 115111 and 115113 which became effective July 1, 2012, and section 115112 which becomes effective July 1, 2013.

Text of Health and Safety Code Sections 115111, 115112, and 115113

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 annually by a medical physicist for the facility's standard adult brain, adult abdomen, and pediatric brain protocols, to ensure the displayed doses are within 20 percent of the true measured dose measured in accordance with subdivision (f).

(2) A facility that has a CT X-ray system that is accredited by an organization that is approved by the federal Centers for Medicare and Medicaid Services, an accrediting agency approved by the Medical Board of California, or the State Department of Public Health may elect not to perform the verification described in paragraph (1).

(d) Subject to subdivision (e), the interpretive report of a diagnostic CT study shall include the dose of radiation by either 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.

115112. (a) Except as provided in subdivision (b), commencing July 1, 2013, CT X-ray systems shall be accredited by an accrediting organization that is approved by the federal Centers for Medicare and Medicaid Services, an accrediting organization approved by the Medical Board of California, or the State Department of Public Health. A facility that is subject to accreditation may elect to have the CT X-ray system accredited pursuant to a single accreditation survey that includes the CT service by the accrediting organization.

(b) A CT X-ray system shall not be subject to accreditation if any of the following apply:

(1) The system is used for therapeutic radiation treatment planning or delivery.

(2) The system is used for calculating attenuation coefficients for nuclear medicine studies.

(3) The system is dedicated for image guidance for interventional radiologic procedures.

115113. (a) Except for an event that results from patient movement or interference, a facility shall report to the department an event in which the administration of radiation results in any of
the following:

(1) Repeating of a CT examination, unless otherwise ordered by a physician or a radiologist, if one of the following dose values is exceeded:

(A) 0.05 Sv (5 rem) effective dose.

(B) 0.5 Sv (50 rem) to an organ or tissue.

(C) 0.5 Sv (50 rem) shallow dose to the skin.

(2) A CT X-ray examination for any individual for whom a physician did not provide approval for the examination if one of the following dose values is exceeded:

(A) 0.05 Sv (5 rem) effective dose.

(B) 0.5 Sv (50 rem) to an organ or tissue.

(C) 0.5 Sv (50 rem) shallow dose to the skin.

(3) 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 if one of the following dose values is exceeded:

(A) 0.05 Sv (5 rem) effective dose.

(B) 0.5 Sv (50 rem) to an organ or tissue.

(C) 0.5 Sv (50 rem) shallow dose to the skin.

(4) CT or therapeutic exposure that results in unanticipated permanent functional damage to an organ or a physiological system, hair loss, or erythema, as determined by a qualified physician.

(5) A CT or therapeutic dose to an embryo or fetus that is greater than 50 mSv (5 rem) dose, that is a result of radiation to a known pregnant individual unless the dose to the embryo or fetus was specifically approved, in advance, by a qualified physician.

(6) Therapeutic ionizing irradiation of the wrong individual or the wrong treatment site, excluding the area of the body that was intended to be irradiated.

(7) The total dose from therapeutic ionizing radiation delivered differs from the prescribed dose by 20 percent or more. A report shall not be required pursuant to this paragraph in any instance if the dose administered exceeds 20 percent of the amount prescribed in a situation if the radiation was utilized for palliative care for the specific patient. The radiation oncologist shall notify the referring physician that the dose was exceeded.

(b) The facility shall, no later than five business days after the discovery of a therapeutic event described in paragraphs (3) to (7), inclusive, of subdivision (a) and no later than 10 business days after discovery of an event described in paragraphs (1) to (4), inclusive, of subdivision (a), provide notification of the event to the department and the referring physician of the person subject to the event and shall, no later than 15 business days after discovery of an event described in subdivision (a), provide written notification to the person who is subject to the event.

(c) This section shall become inoperative on the effective date of the act that added this subdivision, and shall remain inoperative until July 1, 2012.

Questions and Answers

Dose Display and Dose Recording

1. **If our CT is used for radiation therapy planning, radiation therapy image guidance, image guidance for radiological interventional procedures, or to create CT/Positron Emission Tomography (PET) or Single-Photon Emission Computer Tomography (SPECT) attenuation coefficients, are we required to comply with this law?**

   Section 115111 states that CT studies used for therapeutic radiation treatment planning or delivery or for calculating attenuation coefficients for nuclear medicine studies shall not be required to record the dose. There is no exception from the dose recording requirements for CT systems dedicated to image guidance for intervention radiological procedures.

   If a hybrid (PET/CT or SPECT/CT) scanner is used with the intention to produce diagnostic CT images independent of attenuation coefficients, then the diagnostic usage must comply with this law.

2. **Our CT calculates and displays the dose index values $CTDI_{vol}$ and DLP; however we cannot electronically send the dose index values to the PACS. How do we comply with the law's requirement to record the dose index values?**

   Contact your CT manufacturer or PACS vendor to determine a functional method for transferring the data. You may record this information manually or via any other data storage mechanism; the electronic transfer of data to a PACS is optional.

3. **Some protocols require patients to have multiple CT scans. Are we required to record the dose index values in the PACS or radiology report for each scan, or can we record the highest values, average the values, or sum the values?**

   The dose index values reported by the CT may be used to calculate a patient's approximate radiation exposure. The facility has multiple options to record the dose index values for CT scans of the same body area.

   If there are multiple sequences of the same body part, for example a three phase abdomen, you may report the values in a few different ways to meet the requirements:
   - each CTDIvol and DLP value displayed may be reported;
   - the CTDIvol and the DLP may be summed and only the results reported; or
   - the highest CTDIvol and the DLP may be reported as well as the number of sequences performed to which the maximum values apply.

   You may use one of these methods for CTDIvol and another for DLP.

   If you perform scans for different areas of the body during a single examination, each area of the body needs the dose index values recorded separately if the CT system is capable of displaying the values separately.

4. **How do we verify that the displayed dose values are accurate?**

   There are industry standards on how to verify that the displayed dose index values are accurate. CDPH will accept American Association of Physicists in Medicine (AAPM) guidance, and will review other methods during the inspection process. Appropriate phantoms must be used to verify displayed dose index values for the facility's standard adult brain, adult abdomen, and pediatric brain protocols.

5. **Displayed dose value accuracy must be verified annually until July 1, 2013, or until the CT system has been accredited. How will the Department determine compliance?**

   The accuracy should be verified at 12 month intervals that allows the facility to have the verification measurements performed at any time between July 1, 2012,

and June 30, 2013. Facilities may choose to have the verification performed at shorter intervals and/or to continue to perform this verification for a CT system that has been accredited.

6. **The law states that the dose of radiation must be included in the interpretive report. What does "interpretive report" mean and who must generate the report?**

   The interpretive report is the documented interpretation of the diagnostic CT examination. This interpretation may be performed by any licensed physician; this requirement is not limited to reports created by a radiologist.

7. **We send our dose index values to the PACS, and the physician interpreting the image reviews the dose index values. Do we still need to dictate or attach the dose report to the interpretive report?**

   Yes. Attaching the dose report to the interpretive report may be construed as either a hard copy of the data or a computer link to the website with the dose report provided the dose index values are retrievable by the referring physician. The dose values must be available to the patient as part of the medical record consistent with HIPPA requirements and applicable State law.

8. **Our CT calculates but does not display $CTDI_{vol}$ or DLP dose index values on the console. Do we need to comply with the requirements of the dose recording law?**

   That depends on the machine's capability.

   Contact your CT manufacturer or service engineer to see if the equipment software can be upgraded to add this feature.

   Certain older CT X-ray systems may be incapable of calculating and displaying these values. Requirements in Section 115111 are limited to systems that are capable.

Accreditation

9. **Our facility is accredited by an organization that is approved by the Centers for Medicare and Medicaid Services (CMS) that does not provide specific accreditation for CT services. Must I obtain this additional accreditation?**

   Yes. However, a facility that is subject to accreditation may elect to have the CT X-ray system accredited pursuant to a single accreditation survey that includes the CT service by the accrediting organization.

10. **If our CT is used for radiation therapy planning, radiation therapy image guidance, image guidance for radiological interventional procedures, or to create CT/Positron Emission Tomography (PET) or Single-Photon Emission Computer Tomography (SPECT) attenuation coefficients, are we required to comply with this law?**

    Section 115112 states that A CT X-ray system shall not be subject to accreditation if any of the following apply:
    (1) The system is used for therapeutic radiation treatment planning or delivery.
    (2) The system is used for calculating attenuation coefficients for nuclear medicine studies.
    (3) The system is dedicated for image guidance for interventional radiologic procedures.

Event Reporting

11. **If our CT is used for radiation therapy planning, radiation therapy image guidance, image guidance for radiological interventional procedures, or to create CT/Positron Emission Tomography (PET) or Single-Photon Emission Computer Tomography (SPECT) attenuation coefficients, are we required to comply with this law?**

    All uses are subject to the reporting requirements stated in Section 115113.

12. **What does "patient movement or interference" mean?**

    This means the patient moves, voluntarily or involuntarily, or the patient's family or caregiver causes interference, during a CT which would otherwise result in a reportable event.

    If normal procedures are followed and a CT is repeated due to abnormal patient anatomy or tissue damage, then this should be considered patient interference.

13. **What does "repeating a CT examination unless otherwise ordered by a physician or radiologist" mean?**

    This means that a technologist must repeat an examination due to instrument malfunction, wrong technical factors, incorrect positioning, or miscommunication, which render the images non-diagnostic without having sought physician or radiologist approval prior to performing the repeated scan.

    If a physician or radiologist has been consulted and the repeat was authorized, the event is not reportable; however, all dose values must be recorded.

14. **Assume that a CT scanner breaks during a procedure or a power outage occurs and the scan was not completed or was lost, and the technical factors are high enough to potentially exceed the dose values referenced in**

this subsection. The actual patient exposure time is unknown. How do we calculate radiation doses?

If the image was being saved during the exposure, the technical factors may have been stored that capture the actual scan time.

If no data is available, the radiation dose may be calculated using the technical factors set into the CT prior to the failure or retrieved from the CT protocol selected, and with the assumption that the exposure occurred as planned.

15. **Would an event described above be reportable?**

    You would be required to report if the dose values for the incomplete or lost scans exceeded the threshold values because the event was not the result of patient movement or interference (on behalf of the patient). Only the incomplete or lost portion of the study would be used to calculate the effective dose and compare to the threshold values as the second (complete) study was the appropriately accomplished diagnostic test ordered.

16. **After reviewing (a)(1), (a)(2), and (a)(3) of Section 115113, it appears that the event must be reported if <u>any</u> of the dose criteria is exceeded under any of the following conditions: (1) the CT is repeated without a physician order, (2) an individual received a CT for which the was no physician approval, or (3) an area of the body that was not intended to be imaged received a CT. Is this correct?**

    Yes. If a CT is repeated, is performed on an individual for which there was no physician approval, or irradiates the wrong body part <u>AND ANY</u> of the dose criteria is exceeded, then the facility must report the event.

17. **Is the dose additive over CT scans performed on consecutive days or weeks to determine whether a reportable event has occurred?**

    No. The law does not address CT scans performed over time, but applies to those scans performed during a single examination.

18. **Am I required to adjust CT radiation exposures for patient age, weight, and size when I calculate radiation exposures?**

    The law does not require that the radiation exposures be calculated for the age, weight, and size of each patient. The use of generic patient information is allowed for dose calculations. However, CDPH recommends that at a minimum, dose calculations be specific to infant, child, or adult.

19. **Our CT does not report effective dose, organ dose, or skin dose. Can we calculate a $CTDI_{vol}$ or DLP dose index value that is comparable and use this**

as an indicator, to know the dose values referenced in this Section have been exceeded?

Yes. The California Clinical and Academic Medical Physicists (C-CAMP) drafted generic DLP and $CTDI_{vol}$ criteria that will indicate when the dose values referenced in this law have been met. This will be available on the AAPM website: www.aapm.org

20. How do I calculate effective dose equivalent, organ dose, or skin dose?

Acceptable patient dose estimates can be achieved through several methods. If a dose reporting threshold has been exceeded and requires reporting, CDPH recommends that you contact a medical physicist to assist in performing these calculations. CDPH recommends that you contact a local chapter of the AAPM for a list of references. Below is a list of industry accepted methodologies. If the method you wish to use is not referenced below, contact CDPH for assistance.

AAPM Report No. 96, "The Measurement, Reporting, and Management of Radiation Dose in CT" 2008 http://www.aapm.org/pubs/reports/RPT_96.pdf

AAPM Report No. 111, "Comprehensive Methodology for the Evaluation of Radiation Dose in X-Ray Computed Tomography" 2010

ImPACT Computer Code http://www.impactscan.org/ctdosimetry.htm

CT-Expo
Dr. Georg Stamm
E-mail: stamm.georg@mh-hannover.de
http://www.mh-hannover.de/fileadmin/kliniken/diagnostische_radiologie/download/ct-expo-e.zip

International Commission on Radiological Protection (ICRP) Publication 103 (2007) http://www.icrp.org/

Note: ICRP 103 is recommended but CDPH will accept ICRP 60 for a limited time.

21. Does CDPH need to approve dose calculation methodology or settings?

CDPH will not approve a facility's dose calculations or methodologies. However, CDPH will review methodologies during inspections or investigations, to ensure they reflect a reasonable approach for estimating dose values.

22. How can we demonstrate that hair loss, erythema, or permanent functional damage was not "unanticipated"?

If the patient received instructions concerning the risks and potential consequences of a procedure, and has given consent prior to the procedure being performed, then the facility has met the definition of an anticipated event.

Due to age, health status, or confounding medical conditions the radiation exposure(s) can cause organs or physiological systems to fail. If this unanticipated event occurs, then it must be reported.

23. Hair loss or erythema is usually a transient event. Do we report all unanticipated events or just permanent events?

Report all unanticipated hair loss or erythema episodes.

24. Section 115113(a)(4) references unanticipated permanent functional damage. Is a facility required to report radiation-induced cataracts, if they are repaired?

Yes, if the cataracts are found by a qualified physician to have been an unanticipated consequence of the procedure.

25. A patient with a known pregnancy received in excess of 50 mSv (5 rem) from a CT or radiation therapy AND the procedure was not approved in advance by a physician. The embryo or fetus did not receive 50 mSv (5 rem). Does this exposure require reporting?

No. Reporting is only required if the dose to the embryo or fetus exceeds the threshold.

26. A female receives a CT examination or radiation therapy. Later she discovers that she was pregnant at the time of the CT examination. The calculated radiation exposure to the embryo or fetus radiation exceeded 50 mSv (5 rem). Must the facility report the event?

No. However, although not required by this law, if an embryo or fetus exceeds this dose and the individual later discovers that she is pregnant, the patient and patient's physician should be notified. The U.S. Centers for Disease Control and Prevention indicates additional risk to an embryo or fetus if the exposure exceeds 50 mSv (5 rem). http://www.bt.cdc.gov/radiation/prenatalphysician.asp

27. What defines "a wrong treatment site" in Section 115113(a)(6)?

If a "geometric miss" occurs (prescribed tumor volume is not irradiated), it must be reported. It is recognized that body parts that are adjacent to the treatment volume will be exposed to radiation, but this is not a reportable event.

28. Does Section 115113(a)(6) apply to each therapy fraction, or the entire treatment?

This applies to each treatment fraction.

29. Section 115113(a)(7) requires reporting if the therapy radiation dose administered differs from the prescribed dose by 20 percent or more. Does this apply to each fraction, or the entire treatment?

This applies to the entire treatment. The California Department of Public Health (CDPH) recognizes that the treating physician routinely modifies treatment plans based on progress, and this should not be construed as a reportable event.

Do not report an event if radiation therapy is terminated by the patient.

30. Who determines whether a treatment is rendered for palliative care?

Palliative care is determined by the patient's physician.

31. If an event is reported to CDPH Radiologic Health Branch (RHB), are we required to notify any other agencies?

Although not specifically required by this section of the law, you may also be required to report certain events to other agencies due to your regulatory obligations to those agencies.

32. We reported an event, but follow-up information revealed that we were not required to report the event. Can we retract the reporting of the event?

CDPH will evaluate the supplemental information, and if the change is supported, then no additional action will be taken.

33. We did not identify a reportable event in a timely manner. Are we in violation of the new reporting requirements?

Yes. You are obligated to report in a timely fashion. If reporting is delayed, then CDPH will evaluate the circumstances and determine a fair course of action, the goal being public health protection.

34. How soon after an event that does not involve palliative care must the facility notify CDPH RHB?

The facility must report events related to radiation therapy no later than five business days after the discovery of a therapeutic event. The facility must report events related to CT no later than 10 business days after discovery of the event.

35. How soon after an event must the facility notify the referring physician of the person (patient) subject to any event?

The facility must report events related to radiation therapy no later than five business days after the discovery of a therapeutic event. The facility must report events related to CT no later than 10 business days after discovery of the event.

36. How soon after an event that does not involve palliative care must the facility notify the person (patient) subject to an event?

The person/patient must be notified in writing no later than 15 business days after discovery of an event.

37. What does "discovery of an event" mean?

An event is considered to have been discovered when the registrant becomes aware of a potentially reportable situation and initiates investigation and assessment to confirm the status of the event as either reportable or not reportable.

38. What reporting is required for events that involve palliative care?

Only the report to the referring physician is required.

A report to CDPH RHB or to the patient shall not be required in any instance if the dose administered exceeds 20 percent of the amount prescribed in a situation if the radiation was utilized for palliative care for the specific patient. The radiation oncologist shall notify the referring physician that the dose was exceeded.

39. How should the facility notify CDPH RHB of an event?

The information provided to CDPH should include the following:

1. Person making report, job title, contact information
2. Date(s) of event
3. Facility information
4. Radiation generating equipment specifics (i.e. manufacturer, model number, and software version)
5. Radiation generating equipment settings
6. Operator's name
7. Patient's physician name and contact information
8. Copy of physician's order for CT or radiation therapy treatment
9. Explanation as to reason for reporting event
10. Copies of internal investigation reports (include cause and corrective action to prevent reoccurrence)

11. Patient dose calculations (include methodology)
12. Copies of letters sent to the patient and physician.

If you feel that you will be unable to comply with the required reporting timeframes specified in Section 115113(b) because you do not have complete information regarding items 10, 11, or 12, you may submit preliminary findings and provide additional documentation at a later date.

Notify CDPH RHB via letter to the following address:

Chief, X-Ray ICE
Event Notification
Radiologic Health Branch
California Department of Public Health
P.O. Box 997414, MS 7610
Sacramento, CA 95899-7414

Overnight
Chief, X-Ray ICE
Event Notification
Radiologic Health Branch
California Department of Public Health
1500 Capitol Avenue, MS 7610
Sacramento, CA 95814

General Questions

40. The law references both studies and examinations. What is the difference between the terms?

An examination may consist of one or more studies, or scans, during a single appointment.

41. We do not have time to implement this law. Are we required to meet its mandates? Can compliance be waived?

Yes, you are required to meet the mandates on the dates specified in the law. CDPH does not have the authority to waive or delay implementation of any of the requirements specified in this law.

42. We have a conebeam CT machine. Must we comply with these new sections of the law?

That depends on the use of the system. The law applies to medical diagnostic use of CT. It does not apply to those devices approved for and used as dental extra-oral x-ray devices which are defined in 21 CFR Section 872.1800. Therefore, users

of extra-oral x-ray devices used exclusively in dentistry are not subject to these sections of the law.

43. Accepted industry practice is to report skin or organ dose in rads or Grays. Can we assume that 1 rad = 1 rem and 1 Gy = 1 Sv?

Yes.

44. Do I need to calculate effective dose equivalent, organ dose, or skin dose for every patient to comply?

This law does not require that radiation exposures be calculated for every patient. Patient radiation index values must be reported in accordance with Section 115111.

45. Section 115113 references "effective dose equivalent". However, literature for medical radiation exposure references "effective dose". What is the difference?

"Effective dose equivalent" can be used interchangeably with "effective dose", as defined by the American Association of Physicists in Medicine (AAPM) or the International Electrotechnical Commission (IEC).

46. If an event is reported to CDPH RHB, what information will be released to the public?

In accordance with state and federal patient information disclosure laws, CDPH will not disclose patient identifying information.

CDPH is a public agency and is committed to openness and transparency. Disclosure is governed by the Public Records Act, and under the provisions of this law, CDPH must disclose non-confidential information.

CDPH may contact equipment manufacturers, the U.S. Food and Drug Administration (FDA), the Conference of Radiation Control Program Directors, equipment registrants, and professional organizations, if issues are identified that could result in adverse impacts from radiation exposure. However, CDPH strictly complies with laws and regulations that protect patient confidentiality.

Additional questions regarding implementation may be directed to CDPH by email to RHB_SB1237@cdph.ca.gov