Information Notice Regarding

California Health and Safety Code (HSC), Sections 115111, 115112, and 115113

Date: February 5, 2025

To: Facilities Using X-Ray Computed Tomography (CT) Equipment, and Reporting of Certain Radiation Administration events involving CT X-ray systems or radiation (X-ray) therapy

Subject: Health and Safety Code (HSC) §§ 115111, 115112, & 115113 Questions and Answers (Q&A)

This Q&A only applies to HSC §§ 115111, 115112, and 115113. These laws require, in part:

- A person that uses a computed tomography (CT) X-ray system for human use to record the dose of radiation on every diagnostic CT study produced during a CT examination in the patient's record. Exceptions apply. See HSC 115111.
- CT X-ray systems to be accredited by specific organizations. Exceptions apply. See HSC 115112.
- Facilities to report certain radiation administration events involving CT X-ray systems or radiation (X-ray) therapy. See HSC 115113.

Questions and Answers

Dose Display and Dose Recording

1. **If our CT unit 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 interventional 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 unit 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 unit 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 unit 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 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 until the CT system has been accredited. 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 unit 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 unit manufacturer or service engineer to see if the equipment software can be upgraded to add this feature.

   Certain older CT units 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 unit accredited pursuant to a single accreditation survey that includes the CT service by the accrediting organization.

10. **If our CT unit 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 the accreditation requirement?**

    No. Section 115112(b) exempts CT units used for those purposes from the accreditation requirement

Event Reporting

11. If our CT unit 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 the reporting requirement?

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 examination which would otherwise result in a reportable event.

If normal procedures are followed and a CT examination 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 unit prior to the failure or retrieved from the CT examination 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 any of the dose criteria is exceeded under any of the following conditions: (1) the CT examination is repeated without a physician order, (2) an individual received a CT examination for which the was no physician approval, or (3) an area of the body that was not intended to be imaged received a CT examination. Is this correct?**

    Yes. If a CT examination is repeated, is performed on an individual for which there was no physician approval or irradiates the wrong body part AND ANY 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 unit 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: AAPM Report No 96-5.qxd (refer to pages 6-9)

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, CDPH recommends that you contact a medical physicist to assit in performing these calculations.

    AAPM Report No. 96, The Measurement, Reporting, and Management of Radiation Dose in CT 2008

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

AAPM Report No. 246, Estimating Patient Organ Dose with Computed Tomography : a Review of Present Methodology and Required DICOM Information
ImPACT Computer Code

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)

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). Radiation and Pregnancy: Information for Clinicians | Radiation Emergencies | CDC

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

This applies to each treatment fraction.

28. 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 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.

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

Palliative care is determined by the patient's physician.

30. 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.

31. 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.

32. 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.

33. 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.

34. 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.

35. 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.

36. 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.

37. 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.

38. 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 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 email or letter to the following address:

Email: rhbxrayinspectionchief@cdph.ca.gov

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

39. 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.

40. We have a cone beam 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 Title 21, Code of Federal Regulations (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.

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

Yes.

42. 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.

43. 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).

44. 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 rhbxrayinspectionchief@cdph.ca.gov