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

MARK B HORTON, MD, MSPH
Director

EDMUND G. BROWN JR.
Governor

Information Notice Regarding Senate Bill (SB) 1237, California Health and Safety (H&S) Code Section 115113

Date: January 14, 2011

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

Subject: SB 1237, H&S Code Section 115113 Questions and Answers (Q&A)

This Q&A only applies to H&S Code Section 115113, recently enacted by SB 1237 (Padilla, Chapter 521, Statutes of 2010), which added reportable events from the use of X-ray CT and therapy. H&S Code Section 115113 became effective January 1, 2011.

This legislation was enacted in response to multiple events where patients were exposed to excessive radiation by diagnostic CT scanners. The intent of the law is to prevent such events. However, if excessive exposures do occur, systems need to be alerted and corrected as expeditiously as possible so that patients can be assured that they are receiving quality medical care.

Q&A

H&S Code Section 115113(a) Except for an event that results from patient movement or interference, a facility shall report to CDPH an event in which the administration of radiation results in and of the following:

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

   This means the patient moves voluntarily or involuntarily, or the patient's family causes interference.

   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.

H&S Code Section 115113(a)(1) Repeating of a CT examination, unless otherwise ordered by a physician or a radiologist, if the following dose values are exceeded:
(A) 0.05 Sv (5 rem) effective dose equivalent.
(B) 0.5 Sv (50 rem) to an organ or tissue.
(C) 0.5 Sv (50 rem) shallow dose equivalent to the skin.

2. **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 image non-diagnostic.

3. **After reviewing H&S Code Section 115113(a)(1), it appears that all the dose values referenced in this Section have to be exceeded, to trigger the reporting requirement for a repeat CT examination. Is this true?**

   If the CT examination is repeated, all dose values listed in this subsection would need to be exceeded before mandatory reporting is required.

4. **Assume that a CT scanner breaks during a procedure and the technical factors are high enough to 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, and with the assumption that the exposure occurred as planned.

H&S Code Section 115113(a)(2) CT X-ray irradiation of a body part other than that intended by the ordering physician or a radiologist if one of the following dose values is exceeded:
(A) 0.05 Sv (5 rem) effective dose equivalent.
(B) 0.5 Sv (50 rem) to an organ or tissue.
(C) 0.5 Sv (50 rem) shallow dose equivalent to the skin.

5. **After reviewing H&S Code Section 115113(a)(2), it appears that if any of the dose criteria is exceeded and the wrong body part has been irradiated, the event is required to be reported. Is this correct?**

Yes. If a CT irradiates the wrong body part and any of the dose criteria is exceeded, then the facility must report the event.

6. **H&S Code Section 115113(a)(2) does not define "body part other than that intended by the ordering physician or a radiologist." How is this defined?**

   Reporting is required if the intended body part is not imaged. It is recognized that body parts that are adjacent or opposite to the intended body part will receive some exposure, but this is not reportable.

H&S Code Section 115113(a)(3) 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.

7. **What defines "unanticipated" in Section 115113(a)(3)?**

   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 system to fail. If this unanticipated event occurs, then it must be reported.

8. **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.

9. **Section 115113(a)(3) 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.

H&S Code Section 115113(a)(4) A CT or therapeutic dose to an embryo or fetus that is greater than 50 mSv (5 rem) dose equivalent, resulting from radiation to a known pregnant individual, unless the dose to the embryo or fetus was specifically approved, in advance, by a qualified physician.

10. A known pregnant female received in excess of 50 mSv (5 rem) from a CT or radiation therapy. and the procedure was not approved by a physician. The embryo or fetus dose did not receive 50 mSv (5 rem). Does this still require reporting?

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

11. 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

H&S Code Section 115113(a)(5) Therapeutic ionizing radiation administered to the wrong individual, or wrong treatment site.

12. What defines "a wrong treatment site" in Section 115113(a)(5)?

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.

13. Does Section 115113(a)(5) apply to each therapy fraction, or the entire treatment?

This applies to each treatment fraction.

H&S Code Section 115113(a)(6) The total dose from therapeutic ionizing radiation administered differs from the prescribed dose by 20 percent or more. A report shall not be required pursuant to this paragraph in any instance where the dose administered exceeds 20 percent of the amount prescribed in a situation where the radiation was utilized for palliative care for the patient. The radiation oncologist shall notify the referring physician that the dose was exceeded.

14. H&S Code Section 115113(a)(6) 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.

15. Who determines palliative care?

Palliative care is determined by the patient's physician.

H&S Code Section 115113(b) The facility shall, no later than five business days after discovery of an event described in subdivision (a), provide notification of the event to CDPH 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.

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

You may also be required to report to other agencies, due to additional regulatory obligations.

17. 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 enforcement action will be taken.

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

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.

19. If an event is reported to CDPH, 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.

20. How should the facility notify CDPH 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 plan
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.

Notify CDPH 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 Q&A about SB 1237, H&S Code Section 115113

21. H&S Code Section 115113 references both studies and examinations. What is the difference between the terms?

In this instance, these terms are interchangeable.

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

CDPH does not have the authority to waive any of the requirements specified in this law.

23. 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.

24. If CT is only used for radiation therapy planning, are we required to comply with this law?

According to the FDA (Title 21, Code of Federal Regulations [CFR] 892.1750), a CT is defined as a diagnostic X-ray system. By definition, CTs used for radiation

therapy planning is defined as radiation therapy simulation systems (21 CFR 892.5840), and so are not subject to this new reporting requirements.

If a CT scanner is used for both simulation and diagnostic, then the diagnostic usage is subject to this law.

25. 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. Beginning in July 2012, patient radiation index values will be required to be reported in accordance with H&S Code Section 115111.

26. H&S Code 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).

27. 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.

28. Our CT does not report effective dose, organ dose, or skin dose. Can we calculate a CTDIvol 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 CTDIvol 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

29. Our CT does not display CTDIvol or DLP dose index values. Do we need to comply with the requirements of the law?

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

30. 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

31. 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.

For specific questions concerning this law:

Toll-free: (877)-818-2890
Email: RHB_SB1237@cdph.ca.gov