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

Date: May 2, 2012

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

Subject: Senate Bill 1237 and Senate Bill 38 (California Health and Safety Code Section 115111) Questions and Answers (Q&A)

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

These FAQs will be impacted if AB 510 is signed into law. RHB will post revised information in that event.

This legislation was enacted following multiple events involving patients who were exposed to excessive radiation by diagnostic CT scanners.

**Questions and Answers**

- 1. If our CT is used for radiation therapy planning, radiation therapy image guidance, 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?**

According to the U.S. Food and Drug Administration (Title 21, Code of Federal Regulations (21 CFR) section 892.1750), a CT is defined as a diagnostic X-ray system. CT used for radiation therapy planning is defined as radiation therapy simulation systems (21 CFR 892.5840), and is not subject to these new reporting requirements.

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

- 2. Our facility has a CT that calculates and displays dose index values, but we do not have an electronic picture archiving and communication system (PACS). How do we comply with the law's requirement that we record the dose index values?**

The law requires that all images be sent to the PACS.

- 3. 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. Can we request an exemption from the law?**

CDPH cannot grant exemptions to State laws. Contact your CT manufacturer or PACS vendor to determine a functional method for transferring the data.

- 4. 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; therefore, the facility has multiple options to record the dose index values for CT scans of the same body area. You may report values for each scan or report the number of scans and the highest values. If you perform scans for different areas of the body, each area of the body needs the dose index values recorded separately.

- 5. 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. CDPH recommends that appropriate phantoms be used to verify displayed dose index values for the facility's standard adult brain, adult abdomen, and pediatric brain protocols.

- 6. Displayed dose value accuracy must be verified annually until the facility has been accredited. How will the Department determine compliance?**

The accuracy should be verified at 12 month intervals, however, the Department realizes that this may not always be scheduled on exactly the anniversary date of the previous verification; therefore an occasional period of up to 14 months between verifications is acceptable. Facilities may choose to have the verification

performed at shorter intervals and/or to continue to perform this verification for a CT system in a facility that has been accredited.

**7. The law states that the dose of radiation must be included in the radiology report. What does “radiology report” mean and must the radiology report be created by a radiologist?**

The radiology 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.

**8. 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 radiology report?**

Yes. Attaching the dose report to the radiology 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.

**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 systems. Must I obtain this additional accreditation?**

No. The law requires facility accreditation and does not address CT system specific accreditation.

Additional questions regarding implementation of SB 1237 or SB 38 may be directed to CDPH by email to [RHB\\_SB1237@cdph.ca.gov](mailto:RHB_SB1237@cdph.ca.gov)