

SECOND SUPPLEMENTAL STATEMENT OF REASONS

The California Department of Public Health (Department) has instituted additional changes to these proposed regulations which are discussed below. These changes are either initiated by the Department or in response to comments that were received during the first 15-day availability period, which ended on January 12, 2019. Additional documents relied upon, identified below, are added to the rulemaking file.

Documents Relied Upon: For purposes of Government Code section 11347.1, this document, “Second Supplemental Statement of Reasons,” is added to the rulemaking file, deemed a document relied upon, and designated as **Reference 5**.

Regulation Text: Additional changes are proposed as follows:

Section 30315.10:

- Subsection (b)(3) is revised due to comments identifying a drafting error as compared to the existing provision. The word “on” in the initially proposed regulation text should be “one” as shown in the California Code of Regulations. However, the correction is presented only as existing text (i.e., no formatting) in lieu of use of the change methodology identified on page one of the regulation text document.
- No other additional changes to this section are proposed.

Section 30315.52:

- Subsection (b)(1) is revised for consistency with the discussion of subsection (b) in the Initial Statement of Reasons (ISR) (p. 19). Due to comments, the inconsistency was identified and corrected, addressing the comment. A grammatical error is also corrected, resulting in no regulatory effect.
- Subsection (c) is revised for consistency with the ISR’s discussion of subsection (b) (p. 19) and the cited federal provision. The added defined term is based on the FDA’s definition in 21 CFR 900.2(dd) (Mammography unit or units), and needed to maintain consistency as discussed in the ISR.
- No other additional changes to this section are proposed.

Section 30315.60:

- Due to comments, subsection (c)(2)(B) is revised to correct a grammatical error, resulting in no regulatory effect.
- No other additional changes to this section are proposed.