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 45-day public comment period, which ended on August 27, 2018. Additional discussion to the Initial Statement of Reasons (ISR) and documents relied upon, identified below, are added to the rulemaking file.

Documents Relied Upon: For purposes of Government Code section 11347.1, this document, "Supplemental Statement of Reasons," is added to the rulemaking file, deemed a document relied upon, and designated as **Reference 4.**

ISR: Additional discussion is provided as follows:

- **Section 30315.33:**
  The phrase "proposed section 30315.20(c)" in the sentence, on page 17 of the ISR, discussing proposed subparagraph (D) of paragraph (8) of subsection (a), is changed to "section 30315.20(c)." The change is made because that section exists and is not proposed to be amended or repealed.

- **Section 30315.52(b):**
  As indicated in the ISR (page 19), 21 CFR 900.12(a)(3)(iii) and (iv) are intended to be written directly into section 30315.52. Subsection (b)(1) addresses 21 CFR 900.12(a)(3)(iii)(A), and subsection (c) addresses 21 CFR 900.12(a)(3)(iii)(C). Regarding 21 CFR 900.12(a)(3)(iii)(B) (proposed subsection (b)(2)), the federal provision requires surveys of at least two facilities and six mammography systems in a two-year period. Because the Department's issued authorization is valid for three years (17 CCR 30315.60(b), as recodified in this proposal), this proposal would require surveys of at least three facilities and nine mammography systems in a three-year period, and was determined by annualizing the federal provision (e.g., survey at least one facility and three mammography systems per year) and applying those annual values to a three-year period (e.g. three facilities and nine systems per three-year period). See also the discussion of the changes to the proposed regulation text.

  The federal provision, 21 CFR 900.12(a)(3)(iv), currently incorporated by reference in section 30315.52(b) is addressed in section 30315.60(c)(2), as recodified in this proposal.

- **Section 30315.60(a)(2):**
  The reference to "subsection (4)" found on page 19 of the ISR regarding subsection (a)(2) is changed to be a reference to "subsection (a)(4)."

- **Section 30316.20(e)(7):**
  In addition to the discussion of subsection (e)(7) on pages 23 and 24 of the ISR, the existing clauses of section 30316.20(e)(7)(B), as published in the CCR, are incorrectly designated as "(1)", "(2)", etc. Section 30316.20(e)(7) (subsection (e)(5), as redesignated) is revised to delete expired subparagraph (A), and to restructure the subsection using applicable designators for consistency with the accepted CCR structure.

- **Section 30316.60:**
  On page 25 and 26 of the ISR, the reference to "Subsection (b)(1)" is revised to be a reference to "subsection (a)(1)" as the calibration record requirement is found in subsection (a)(1).

- **Section 30316.61:**
  On page 26 of the ISR, the reference to "section 30316.60(b)(1)" is revised to be a reference to "section 30316.60(a)(1)" as the calibration record requirement is found in section 30316.60(a)(1).

- **Section 30317:**
  On page 26 of the ISR, the reference to "section 30317.20(b)(1)" regarding the redesignation of subsection (g) is revised to be a reference to "section 30317.20(a)(1)" where this proposal relocates the inventory requirement.

- **Section 30317.10:**
  On page 26 of the ISR, the reference to "section 30317.10(a) and (b)" regarding subsection (b)(5) is revised to be a reference to "section 30317(a), (b) and (c)."

- **Section 30317.20(b) *&* (c):**
  As indicated on page 28 of the ISR, subsection (b) is needed to inform the user how long the records must be maintained, and subsection (c) is needed to ensure only qualified individuals are allowed to perform mammography. These provisions are recodified from existing section 30319.20(a), and revised to change the recordkeeping period from two years to the next Department inspection to determine if the user complies with section 30315.50. Pursuant to Health and Safety Code section 115085, the average inspection frequency for mammography X-ray units is once each year. Thus, these records are reviewed annually, removing the need to review records that were reviewed the prior year. By tying the record retention period to the inspection frequency, fewer records will need to be retained.

- **Section 30318.11:**
  The sentence on page 30 of ISR addressing "existing subsection (a)(5)" is deleted. Because this proposal now includes mammography procedures not subject to

federal MQSA and that this section addresses mobile mammography, newly added subsection (a)(2), discussed below regarding revision to proposed text, retains existing subsection (a)(5) for use that is subject to that federal law. This allows the patient to have confidence the provider has met both federal and state requirements, can produce quality mammograms, and is regularly inspected.

Regulation Text: Additional changes are proposed as follows:

Section 30315.10:

- Subsection (b)(5) is revised due to comments, and for consistency with 17 CCR 30400(a)(4).
- Subsection (b)(7): The phrase "performance of-the individual" (existing clause (C) of paragraph (11)) is changed to "performance of the individual" to remove an incorrect strikeout of a space, resulting in no regulatory effect.
- Subsection (b)(30) is revised to correctly reference the location where the responsibilities of a quality control technologist are specified: namely, section 30317.10(d).

Section 30315.22:

- Subsection (a)(1) is revised for clarity by removing unnecessary verbiage, resulting in no regulatory effect.
- Subsection (a)(4) is revised to clarify where the specific requirement to designate a lead supervising physician is found.

Section 30315.33:

- Subsection (a) is clarified by including citation to section 30315.23 regarding renewal of a mammography machine certificate because the content in this section is used for both initial applications and renewal applications, as stated in sections 30315.22(a)(1) and 30315.23(a). Additional revisions are made for clarity as follows:
    - Paragraph (1) is revised to include the physical address of the user. Though some duplication of addresses may occur, this is needed to ensure the issued mammography machine certificate and other correspondence reaches the user. Many users are located within large university, college or hospital campuses with numerous buildings, each having their own mailing and physical address.
    - Paragraph (8):
        - Subparagraph (A) is revised to require identification of the mammographic modality of the mammography system. This is needed to determine if the facility's mammography medical physicist has met the additional eight-hour training requirement (section 30315.52(c), as recodified in this proposal), whether the specific mammography system evaluation (subparagraph (E)) is appropriate, and, if used in a mobile

setting, whether the quality control procedure (section 30318.10(b)) is appropriate.
    - Subparagraph (B) is revised, and new paragraph (9) added, to restore existing paragraphs (8) and (15)(B) for consistency with section 30318.10(a), which requires the person providing mammography in a mobile setting, to notify the Department prior to performing mammography at locations that were not identified on the application. If the existing provisions were not restored, more notifications than needed would likely occur.
    - Subparagraph (D) is amended to include mammography machines used for research purposes. Mammography machine certification is not limited to screening, diagnostic, or interventional mammography making this change necessary. Grammatical correction of "and/or" is also made to clarify it means any combination of the indicated types of mammography. This is needed because mammography X-ray equipment may be designed to be used for more than one of the identified types of mammography, or it may be designed for only one type of mammography procedure. Thus, the user would identify all types of mammography for which the machine may be used.
    - Subparagraph (E) is amended for clarity. As presented in the original proposal, this subsection could be interpreted as requiring a mammography medical physicist to submit the application. As revised, subparagraph (E) clarifies that a mammography medical physicist is responsible for the evaluation report or the survey report and the application is to be submitted by the user. This is necessary to clearly identify who is responsible for completing the required documentation.
  - New paragraph (9) is added as discussed regarding paragraph (8)(B).
  - Paragraph (9) is redesignated to paragraph (10), due to addition of new paragraph (9), and clarified by using only one term, "user," instead of two terms, "user" and "applicant," to refer to the applicant.
- Existing subsection (a)(9)(C)1:
  - As presented in the initially proposed text, the existing provisions in section 30315.33, shown in strikeout format, are proposed to be repealed.
  - However, the structural designator for subsection (a)(9)(C)1. is not shown in strikeout format. The designator is now shown in double strike-out, resulting in no regulatory effect, for consistency with this proposal.

Section 30315.34:

- Subsection (b) is amended to remove the phrase, "of its mailing" as it is no longer needed due to addition of subsection (d).
- New subsection (d) is needed to inform applicants when the time periods or events specified in subsections (a) through (c) begin. This maintains consistency with other

provisions addressing application processes; namely, proposed section 30315.60(e)(1), and other similar existing provisions (17 CCR 30405).

Section 30315.52:

- Due to comments, subsection (b) is amended to provide a one year transition period for individuals renewing their authorization, who also are maintaining their authorization under federal MQSA provisions. Currently, existing section 30315.60(e)(4) requires the individual to, in part, provide documentation of complying with 21 CFR 900.12(a)(3)(iii), incorporated by reference in existing section 30315.52(b). This proposal places those federal provisions directly into the California Code of Regulations by removing the incorporation reference (proposed section 30315.52(b)) but annualizes the survey requirements for a three year period instead of a two year period. See the additional discussion in this document regarding section 30315.52 and these survey requirements. As indicated by a commenter, this proposal could result in some individuals meeting federal MQSA provisions but not California's provisions. However, the survey requirement start date under 21 CFR 900.12(a)(3)(iii)(B) is determined by each individual facility using criteria specified in those federal provisions, resulting in a variable start date for the mammography medical physicist based on each individual facility. Thus, because this proposal sets a specific date based on the individual, not the facility, the revision will allow individuals, subject to both federal and state provisions, to adjust to these cycle differences. This one year transition period is not applied to the continuing education (CE) requirement (21 CFR 900.12(a)(3)(iii)(A)) or the eight-hour additional training (21 CFR 900.12(a)(3)(iii)(C)) because the three-year cycle period for CEs under both this proposal (30315.52(b)(1)) and the federal provision is the same. The additional training provision (30315.52(c)) occurs only when the individual begins surveying a new mammographic modality, other than one for which they already qualified for, and is much less affected by cycle differences.
    - Because the Department cannot determine the effective date of this proposal for purposes of the one year transition period, the Department proposes to authorize the Office of Administrative Law to insert the date for clarity.
- Due to comments, subsection (b)(1) is amended for consistency with 21 CFR 900.12(a)(3)(iii)(A) and to remove unnecessary words for clarity.
- Regarding 21 CFR 900.12(a)(3)(iv), incorporated by reference in existing subsection (b), see the above additional ISR discussion of section 30315.52(b) and the below discussion regarding section 30315.60(c)(2).

Section 30315.60:

- Subsections (a)(1) and (c)(1) are amended to:
    - Allow an applicant to submit either their social security number (SSN) or individual taxpayer identification number (ITIN). Pursuant to Statutes of 2018, chapter 838, Family Code section 17520 was amended to require specified government organizations to collect SSNs or ITINs for applicable licenses.

Thus, this provision is amended for consistency with that statute, and to reduce volume by using acronyms.
    - Delete reference to a fax number and insert “email address” since use of email has become a major communication method and that FAX use has greatly diminished.
- Subsection (c)(2):
    - Currently, this provision, as recodified in this proposal, requires the individual to provide documentation of complying with 21 CFR 900.12(a)(3)(iii) and (iv), incorporated by reference in existing section 30315.52(b). This proposal places those federal provisions directly into the California Code of Regulations by removing the incorporation reference (proposed sections 30315.52(b) & (c)) but the initially proposed text failed to carry over the existing provision on how to reestablish qualifications addressed in 21 CFR 900.12(a)(3)(iv).
    - New proposed language and subparagraphs (A) and (B) are added to clarify how to reestablish qualifications. Regarding differences in the number of required surveys, and the two- and three-year cycles in section 30315.52(b), in this proposal as compared to 21 CFR 900.12(a)(3)(iv), see the discussion in the ISR (p. 19) and the additional discussions of section 30315.52(b) in this document.
- Subsection (f) is amended by changing 10 days to 30 days to allow time for review of applications. This also maintains consistency with other similar authorization processes (e.g., 17 CCR 30405(b)(1) & 30531(b)(1)).

Section 30316.20:

- Subsection (d):
    - As initially proposed, these existing provisions were not being amended so the phrase “No Change to Text” was used to shorten the length of the proposed text. Due to acceptance of received comments, the unchanged text is now added in normal text (i.e., without use of any change methodology) and changes addressing the comment are shown using the method specified on page one of the proposed regulation text (i.e., double ~~strikeout~~; double <u>underline</u>).
    - Paragraphs (1) and (2), due to comments, are revised to clarify the provision applies only to screen-film imaging systems. The provisions are also revised to maintain correct grammatical structure. Though the comments recommended limiting the entire subsection (d) to screen-film imaging systems, the compression test in paragraph (3) is not revised since compression capability applies regardless of the imaging receptors (e.g. screen-film or digital) the equipment is designed for.
- Subsection (e):
    - Paragraph (5), due to comments, is revised to clarify the provision applies only to screen-film imaging systems and to maintain correct grammatical structure. See also the additional ISR discussion above regarding this provision.

        - Subparagraph (C) is revised to correctly cite to the intended provision (paragraph (5)) and for consistency with 21 CFR 900.12(e)(5)(iii)(A)(3).
    - Paragraphs (10) and (15), as redesignated from paragraphs (12) and (18), respectively:
        - As initially proposed, these existing provisions were not being amended so the phrase “No Change to Text” was used to shorten the length of the proposed text. Due to acceptance of received comments, the unchanged text is now added in normal text (i.e., without use of any change methodology) and changes addressing the comment are shown using the method specified on page one of the proposed regulation text (i.e., double ~~strikeout~~; double underline).
        - Due to comments, the proposals clarify that the specified provisions apply only to screen-film imaging systems, and revised to maintain correct grammatical structure.
- Subsection (f):
    - Due to comments, the proposal clarifies that the specified provisions apply only to screen-film imaging systems.
- Existing subsection (h), proposed to be repealed, in the initially proposed text was shown as left justified, and is now shown indented for presentation consistency, resulting in no regulatory effect.

Section 30316.61(b): Due to comments regarding calibration of instrumentation used to measure illumination, the Department reconsidered the usefulness of the existing provision. Received comments pointed out that light meter calibration is not as critical as radiation meter calibration, and some vendors do not provide adequate specifications or a calibration process for their light meters. The commenter provided a possible calibration verification process similar to radiation meter calibrations that rely on a traceable national standard (17 CCR 30315.10(b)(36), as redesignated in this proposal).

The light meter is used to determine if the mammography system meets the light output requirement in section 30316(b)(13) (equivalent to 21 CFR 900.12(e)(5)), applicable to a system with a light beam that passes through the X-ray beam limiting device. The purpose of the light is so that the operator can visualize where the body part is in relation to the X-ray field, thereby irradiating the intended body part. In general radiographic X-ray equipment, the X-ray beam limiting device (i.e. collimator) can vary the size of the X-ray field to accommodate different sizes of image receptors and can further collimate the field to eliminate or greatly reduce radiation exposures to body parts not intended to be irradiated.

In mammography X-ray equipment, the X-ray beam limiting device is commonly a fixed aperture device, without a light beam, and the imaging receptor contains markings delineating the X-ray field, eliminating the need for a light. Further, standard mammography practice is to ensure the entire image receptor is exposed by radiation or

electronically masked to limit extraneous light coming through the image display, for both film and digital images, so the interpreting physician can properly interpret the mammogram. This practice generally begins with standards such as those found in 21 CFR 900.12(b)(5) & (b)(15). Based on the Department's annual inspection of all mammography equipment, very few equipment provide such illumination making the recommended calibration process a heavy and costly burden without benefit. Because the provision is no longer useful nor critical to patient radiation safety or image quality, the provision is proposed to be repealed.

Section 30317.10:

- Punctuation at the end of subsection (d)(1) is revised for consistency with the other subsection's provisions, resulting in no regulatory effect.

Section 30317.20

- Subsection (a)(1) is revised to delete language not found in existing section 30317(g), nor was the language intended to be adopted.
- Due to the addition of subsection (a)(5), punctuation found at the end of subsections (a)(3) and (a)(4) are revised for consistency, resulting in no regulatory effect.
- New subsection (a)(5) is added to require documentation that each radiation machine used for mammography, if subject to MQSA, is accredited. This is needed to verify that only accredited machines are used, and, if not accredited when required, to inform FDA of such use.

Section 30318.10:

- Subsection (a)(1) is revised to require the physical and mailing address of the user. This is needed so Department staff can perform on-site inspections of records and to effectively communicate as needed.

Section 30318.11

- New subsection (a)(2) is added to retain existing subsection (a)(5), and to clarify that a copy of the certificate need be posted only if subject to federal MQSA.
- Paragraph designators are revised due to addition of paragraph (2) to maintain a coherent structure.