

FINAL STATEMENT OF REASONS

The information contained in the Initial Statement of Reasons (ISR) at the time of Public Notice remains unchanged with the exception of the following modifications.

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).
- 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:

- 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 The change is made because that section exists and is not proposed to be amended or repealed.
- 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.
 - Paragraphs (6) & (7): For grammatical purposes, a comma is added after the phrase “certificate number,” resulting in no regulatory effect.
 - 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.

- For grammatical purposes, a comma is added after the phrase “serial number,” resulting in no regulatory effect.
- 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.
 - The number “6” is changed to “six,” resulting in no regulatory effect.
 - A comma after the word “or” and before the phrase “in lieu” is added, resulting in no regulatory effect.
- 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 ~~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).
 - Paragraph (1) is revised to delete the word “of” after the word “date,” resulting in no regulatory effect.
 - Paragraph (3) is revised to:
 - Delete the word “of” after the word “date,”
 - Delete the comma found after the word “postmarked,”
 - Add a comma after the word “or” and before the phrase “if electronically received,” and
 - Add the word “the” after the phrase “if electronically received,” and before the word “date,” resulting in no regulatory effect.

Section 30315.36(d): A hyphen, without formatting, is inserted between “FDA” and “accepted” for consistency with existing text.

Section 30315.52:

- Subsections (a)(3) & (a)(4): the conjunction “and” is inserted between the provisions clarifying, as shown in existing text, that paragraphs (1) through (4) must be met.
- Subsection (a)(5): As discussed in the ISR, page 19, section 30315.52 is intended to apply to physicists conducting surveys of radiation machines used for interventional mammography, not just those machines subject to the federal MQSA requirements. As provided in section 30315.60(a)(4), as redesignated, an applicant may submit documentation in lieu of documentation demonstrating section 30315.52(a)(2) through (4) is met. Thus, section 30315.52(a)(5) is not needed, so it is deleted. A third additional 15-day public availability period was conducted during which no additional comments were received.
- Subsection (b):
 - The provision is revised to clarify time periods, and to supply a specific date in lieu of requesting the Office of Administrative Law to supply it. This provision was revised, due to a public comment, to alleviate a possible noncompliance event for physicists renewing under both the federal MQSA requirements and this requirement. The revision resulted in a confusing, overlapping time period. As now revised, the provision defers paragraphs (1) and (2) from taking effect for one year as recommended.
 - Paragraph (1) is further revised to clarify phraseology and is based on section 30403, a similar provision, requiring individuals certified or permitted under the Radiologic Technology Act (H&S Code § 27(f)) to obtain continuing education for purposes of renewing authorization. For punctuation and grammatical purposes, the comma found after the phrase “counted only once,” in the third

- sentence is deleted, and, regarding the 36-month time period, formatting is revised to ensure the phrase “36-month cycle” results.
- Due to comments regarding the last sentence of subsection (b)(1), the sentence was revised to remove the phrase “or attending an identical course” for consistency with the last sentence of 21 CFR 900.12(a)(3)(iii)(A). A fourth additional 15-day public availability period was conducted during which no additional comments were received.
 - As indicated in the ISR (page 19) regarding subsection (b), 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.
 - 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 as discussed above. 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.

- The Department proposes an effective date of July 1, 2020 allowing the one-year transition period to begin July 1, 2021.
- 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. Subsection (b)(1) is also revised for consistency with the discussion of subsection (b) in the 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. A second 15-day public comment period was conducted during which no additional comments on this provision were received.

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 (a)(1): punctuation at the end of paragraph (1) is changed to a semi-colon, without format change, for consistency with the official CCR because the initial text erroneously contained a colon. This change results in no regulatory effect.
- Subsection (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)."
 - Punctuation at the end of subparagraph (B) (repealed) is changed to a semi-colon, for consistency with subsection (a)'s punctuation usage.
- 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. A second 15-day comment period was conducted and no additional comments on this proposal were received.

- The word “sections” in subsection (c)(2) is changed to “section,” resulting in no regulatory effect.
- Due to comments, subsection (c)(2)(B) is revised to correct a grammatical error, resulting in no regulatory effect.
- 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:

- The struck out language found in the section title is deleted, and the underlined language is reformatted by removing the underlining, for consistency with the existing section’s title. No changes to the title were intended.
- Subsection (b) is revised, without formatting, for consistency with existing text by deleting “all” and capitalizing the word “radiation.”
- Subsection (b)(8)(C) is revised, without formatting, for consistency with existing text by inserting the word “sized” between “different” and “compression.”

Section 30316.20:

- Subsection (b):
 - The first sentence is revised by deleting the comma found after “each week,” resulting in no regulatory effect.
 - The third sentence is revised by underlining the comma found after “phantom,” and deleting the comma found after “thick,” resulting in no regulatory effect.
 - Paragraph (2) is revised by deleting the comma found after “contrast,” resulting in no regulatory effect.
- 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).
 - 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 (1), due to the repeal of paragraph (1) and the redesignation of paragraph (2) to paragraph (1), the meaning of the acronym “kVp” was

- inadvertently lost. Paragraph (1), as redesignated, is revised to provide the acronym's meaning ("kilovoltage peak"), resulting in no regulatory effect.
- Paragraph (2): Punctuation at the end of the sentence is changed to a semi-colon for consistency with subsection (e)'s punctuation usage, resulting in no regulatory effect.
 - 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 discussion below regarding paragraph 7.
 - 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).
 - Due to comments, the proposals clarify that the specified provisions apply only to screen-film imaging systems, and revised to maintain correct grammatical structure.
 - The word "that" found in the phrase "and that the difference..." is deleted, resulting in no regulatory effect.
 - In addition to the discussion of paragraph (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.
 - 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 30316.30

- Subsection (b): A comma, after the word "specks," is added, resulting in no regulatory effect.
- The existing authority note being deleted is corrected, without formatting, by removing reference to sections 114975 and 115000, resulting in no regulatory effect.

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).
- Subsection (a): the word “an” in the phrase “an radiation machine” in the initially proposed text, is changed, without any formatting, to “a” (“a radiation machine”) for consistency with the CCR.
- Subsection (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. With 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 provides 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: 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).”
- 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:

- Reference to “360319.20,” found on page 27 of the ISR, is corrected to “30319.20” since section 360319.20 does not exist and the material being referred to is found in the corrected citation.
- 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. An additional 15-day public comment period was conducted resulting in no comments on the proposal.
- Subsections (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 30317.70: The reference note is corrected, without formatting, to change “sections” to “section,” and to delete reference to section 123145, resulting in no regulatory effect.

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:

- The sentence on page 30 of the 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.

- 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.

Section 30319(a)(2): The formatted word “the” is deleted, without formatting, for consistency with the existing provision, resulting in no regulatory effect.

SUMMARY AND RESPONSE TO COMMENTS RECEIVED DURING THE INITIAL NOTICE PERIOD AND TWO ADDITIONAL 15-DAY COMMENT PERIODS.

The following is the list of people who commented on the initial proposed regulations (DPH-10-005) during the 45-day public comment period beginning on July 13, 2018 and ending at 5:00 p.m. on August 27, 2018. The Department received two letters containing comments as identified below. A public hearing was not held as no requests were received. A 15-day public availability comment period was conducted beginning on December 28, 2018 and ending at 5:00 p.m. on January 12, 2019. A second 15-day public availability comment period was conducted beginning on February 26, 2019 and ending at 5:00 p.m. on March 13, 2019. The Department received comments as identified below. A third 15-day public availability comment period was conducted beginning on August 29, 2019 and ending at 5:00 p.m. on September 13, 2019, during which one letter of comment was received. A fourth 15-day public availability comment period was conducted beginning on October 1, 2019 and ending at 5:00 p.m. on October 16, 2019, during which no additional comments were received.

List of Commenters during Initial 45-day Proceeding held from July 13, 2018 through August 27, 2018. (Written testimony)

1. Lucy Gariador, Director of Imaging – lfariador@Primehealthcare.com
2. Thomas Oshiro, Ph.D., DABR, Associate Professor - Radiological Sciences, UCLA David Geffen School of Medicine
3. Harvey B. Wolkov, MD, FACR, President, The California Radiological Society.

List of Commenters during the first 15-day Proceeding held from December 28, 2018 through January 12, 2019. (Written testimony)

- 2a. Thomas Oshiro, Ph.D., DABR, Associate Professor – Radiological Sciences, UCLA David Geffen School of Medicine

The second 15-day Proceeding held from February 26, 2019 through March 13, 2019 produced no comments.

List of Commenters during the third 15-day Proceeding held from August 29, 2019 and ending at 5:00 p.m. on September 13, 2019 produced one comment.

4. Cynthia H. McCollough, PhD, FAAPM, FACR, FAIMBE, President, American Association of Physicists in Medicine.

The fourth 15-day Proceeding held from October 1, 2019 and ending at 5:00 p.m. on October 16, 2019 produced no comments.

Summary of comments and responses

Note: The digit or digit and letter before the decimal point designation identifies the Commenter as listed above. The digit(s) after the decimal point indicate the identified comment from that commenter.

1.1. Asked if two entities (state/FDA) will provide inspections. How do we contact FDA or will they be notifying our Department?

Response: No changes to the proposal are made due to this comment. The proposal addresses state regulation, not federal regulation, and does not change who performs regulatory inspections. Both state and federal law require inspections by the respective governmental agency. For purposes of federal law, the Department performs federal inspections under contract with the U.S. Food and Drug Agency (FDA). During those federal inspections, Department inspectors also conduct the inspection for purposes of carrying out state law. Because this proposal focuses only on the Department's regulations under state law, the FDA is not involved with this proposal so it will not notify a California facility about this proposal.

2.1 Section 30315.10 (b)(5): Recommends defining "one hour of training" to be consistent with different institutional or accrediting agency definitions since some educational classes are often described as one hour, but a syllabus or course catalog may only have 50 minutes of instructional time. Suggested change: "*Continuing education unit*" means one hour of training as defined by the accrediting agency and received through either:

Response: The recommendation to clarify the meaning of "one hour" is accepted but to base that definition on the "accrediting agency" is rejected. The provision was revised for consistency with 17 CCR 30400(a)(4) and to clarify that one unit is a 50- to 60-minute period of time. An additional 15-day public proceeding was conducted and no additional comments on the revision were received.

2.2 Section 30315.10(b)(17): The definition refers to screening modalities and should clarify that it is for screening purposes and not to be misinterpreted as

testing of interventional systems, such as stereotactic breast biopsy systems, which is a different modality. Suggests: “*Mammographic modality*” means a technology for radiography of the breast for screening purposes such as screen-film mammography, digital mammography, full field digital mammography, and digital breast tomosynthesis.

Response: The recommendation is rejected because this proposal is not limited only to screening purposes, as are the FDA MQSA regulations. The ISR discussed the purposes of this proposal and that it is broader than federal requirements. Though the definition provides examples typically focusing on screening purposes, the term was not proposed to be amended because, as written, it is consistent with MQAA and this proposal’s intent to fully supersede the Rules of Good Practice (Reference 1) as discussed on page 7 of the ISR. Accepting the recommendation would be inconsistent with that intent.

- 2.3 Section 30315.36(a): should specify why the Department needs to obtain these records (most likely due to a deficiency). Deficiencies may pertain to image quality, medical record, or record keeping. Suggests revising to: Resulting from a significant deficiency in equipment performance, image quality or recordkeeping, the user shall, upon request by the Department, make mammograms and their written reports of results available to the Department and allow those mammograms and reports to be removed from the facility for the purpose of evaluating the mammography study.**

Response: The recommendation is rejected because it limits the Department’s ability to perform the review for other purposes such as for random image quality reviews, investigation of complaints, or unlicensed personnel performing mammography. As the provision indicates, such records must be provided when requested, and the reasons for that request would be specific to the individual facility.

The recommendation to change “mammogram image quality” to “mammography study” is rejected because the existing provision clearly states the evaluation’s purpose, whereas the recommended phrase is broad and subject to multiple interpretations as to the scope of “study.” The commenter provides no detail for consideration.

- 2.4 Section 30315.50 (a)(1): a physician with only the radiography supervisor and operator permit should not be involved in supervision of individuals who perform mammography unless they qualify under FDA 900.12 to interpret mammograms. In some cases, a physician who qualifies under the MQSA alternative standards may only qualify for the CA radiography supervisor/operator certificate. If the purpose of the rewording was to include these individuals, then I would suggest rewording to:**

Each physician, as defined in section 30315.10, supervising individuals who perform mammography shall meet the requirements specified in title 21, Code of Federal Regulations Section 900.12(a)(1) and:

(a) possess a current and valid radiology supervisor and operator certificate pursuant to section 30466 or

(b) possess a radiography supervisor and operator permit issued pursuant to section 30466.

Response: The recommendation is rejected because it misstates the proposal's purpose, as stated in the ISR, and merely restates the existing provision. Since the FDA regulations apply regardless of California law or regulation and are enforced by federal authorities or state agencies under a federal contract, there is no need to include it in the Department's regulation.

- 2.5 Section 30315.52 (b)(1):** this provision should also specify whether or not an attendee can obtain CEs for the same course every year. I'm assuming since the instructor isn't allowed to claim CEs, the attendees shouldn't either.

Commenter suggested change: *Have taught or completed at least 15 continuing education units in mammography. This continuing education shall include training appropriate to each mammographic modality evaluated by the medical physicist. Units earned through teaching or attending an identical course can be counted only once during the 36 months cycle; and...*

Response: The comment was initially accepted and an additional 15-day proceeding was conducted, during which no additional comments were received. However, see comment four, and its response, for further discussion.

- 2.6 Section 30315.52 (b):** provision should specify that reauthorization or renewals are also a part of the 36-month cycle. Suggests: *Within 36 months of obtaining initial or renewed authorization by the Department pursuant to section 30315.60, the mammography medical physicist shall:*

Response: The comment was accepted and an additional 15-day proceeding was conducted, during which no additional comments were received.

- 2.7 Section 30315.52(b)(2):** as with the MQSA regulations (2 facilities, 6 units over 24 months), some physicists may satisfy this federal standard - but not the CA standard (3 facilities, 9 units over 36 months) due to timing of their evaluations. For example, in year 1, a physicist does 0 units, 0 facilities. In year 2, they do 6 units and 2 facilities and in year 3, they do 0 units and 0 facilities. They would still be compliant with MQSA regs - but not California. I don't think it'll affect many physicists - but I think either a "grandfather clause" or having an effective date 1 year after publication would help alleviate this potential situation.

Response: The recommendation was accepted and an additional 15-day proceeding was conducted. No additional comments on this provision were received.

- 2.8 Section 30316.20(a) - (d): the tricky part of this section is splitting up the digital mammography and screen/film mammography parts. I think 30316.20 (a) – (d) are fine but each part needs to specify that the test is for film/screen. For example, 3016.20 (d) should be: *Each facility conducting film/screen mammography shall, prior to initial use and at intervals not to exceed six months:***

Response: The recommendation was accepted and an additional 15-day proceeding was conducted, except that, as it pertains to subsection (d)(3), the comment was rejected. Subsection (d)(3) is a compression test of the machine and is applicable to digital imaging systems. The compression paddle is used to compress the breast tissue to increase image quality by reducing geometric distortion. An additional 15-day proceeding was conducted during which no additional comments on this provision were received.

- 2.9 Section 30316.20(e)(1): this is for film/screen only and should read: *For film/screen mammography systems, the AEC can maintain film optical density within plus or minus 0.15 of the average of the optical densities measured using homogeneous breast-tissue equivalent material thicknesses of 2, 4, and 6 centimeters (cm)...***

Response: The comment is rejected because the provision expired October 28, 2002.

- 2.10 Section 30316.20(e)(5): this is for film/screen only and should read: *For film/screen mammography systems, the focal spot condition shall be evaluated by determining the mammography system resolution in accordance with the following and meet the specified criteria:***

Response: The recommendation was accepted and an additional 15-day proceeding was conducted. No additional comments on this provision were received.

- 2.11 Section 30316.20(e)(10): this is for film/screen only and could read: *For film/screen mammography systems, the uniformity of screen speed of all cassettes in the facility are tested, and that the difference between the maximum and minimum optical densities do not exceed 0.30. The optical density of the test films shall be no less than 1.4;***

Response: It appears the commenter is referring to subsection (e)(12), as recodified. The recommendation was accepted and an additional 15-day proceeding was conducted. No additional comments on this provision were received.

- 2.12 Section 30316.20(e)(13): Recommends accounting for systems other than molybdenum/molybdenum by adding For mammography systems with other anode/filter configurations, the radiation output rate unit shall comply with manufacturer's specifications.**

Response: The comment is rejected to maintain consistency with FDA's 21 CFR 900.12(e)(5)(x). As indicated in the ISR (pages 23 & 24), the changes to section 30316.20 are made to retain consistency with FDA's standards, not to propose new machine output standards. Such manufacturing standards are reserved to the FDA under the federal Radiation Control for Health and Safety Act of 1968 [Pub.L. No. 90-602].

- 2.13 Section 30316.20(e)(15): this is for film/screen only and could read: For film/screen mammography systems, calibration of the densitometer and sensitometer used by the facility meets the manufacturer's specifications;**

Response: The recommendation was accepted and an additional 15-day proceeding was conducted. No additional comments on this provision were received.

- 2.14 Section 30316.20(f): this is for film/screen only and could read: For film/screen mammography systems, each facility conducting mammography shall ensure that:**

Response: The recommendation was accepted and an additional 15-day proceeding was conducted. No additional comments on this provision were received.

- 2.15 Section 30316.61(b): Recommends the provision be changed to: Instrumentation used by the mammography medical physicist to measure the illumination as specified in section 30316(b)(13) shall be calibrated in units of lux or foot candles and shall meet manufacturer specifications. Calibration shall be verified at least once every 5 years with one of the following methods:**
- a. The light meter shall be calibrated at least every 5 years to a traceable national standard.**
 - b. Cross-comparison to a calibrated light meter is performed annually. The calibrated light meter used for comparison must be traceable to a national standard within 5 years.**

Response: Due to the comment, the Department reconsidered the usefulness of the existing provision. As indicated by the commenter, 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 provides 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.

Thus, the comment was rejected. However, an additional 15-day comment period was conducted and no additional comments were received.

- 2.16 Section 30316.22(a): Because there are new FDA approved phantoms for facility use, recommends adding: ACR Digital Mammography Phantom Model 086 produced by CIRS.**

Response: The comment is rejected because, as discussed in the ISR (pp. 24-25), this section is repealed.

- 2.17 Section 30317.20(a)(1): the unique ID number is redundant since the vendor's serial number is used for the FDA 2579 form which usually matches the California certificate. Having an additional unique number can make tracing a system more difficult especially when systems are sold and transferred. The serial numbers are affixed to the system by the vendor. Commenter suggested change:**
An inventory that identifies each radiation machine used for mammography by the machine's manufacturer, model, and serial number that is permanently affixed to the machine by the user.

Response: Due to the comment, the provision was revised to delete language not found in existing section 30317(g), nor was the language intended to be adopted.

However, the suggested rewording is rejected because the provision was adopted in 2007 to address facility requests for clarity regarding identification of the machine. The basic components of an X-ray machine include the control panel, generator, and the X-ray tube. Under FDA's manufacturing standards, each of these components must be labeled, and each one will have a unique serial number placed on the component by the manufacturer. Also, when a component is replaced, the new component's serial number changes. Facilities were continually confused as to which number should be used, and continually submitted change documentation. Thus, the 2007 adoption alleviated unnecessary submittals. The Department has received no indication of confusion since. An additional 15-day comment period was conducted during which no additional comments regarding this provision were received.

2a.1 30315.10(b)(3): Indicates there is a typographical error and should read as follows (bolded italic):

“Automatic Exposure Control” (AEC) means a device that automatically controls **one** or more technique factors in order to obtain at pre-selected locations a required quantity of radiation.

Response: Comment is accepted, resulting in no regulatory change. A second additional 15-day comment period was conducted, during which no additional comments were received.

2a.2 30315.10(b)(17): There could be some confusion arising with specifying both “digital mammography” and “full field digital mammography” (FFDM) since the terms are often interchangeable, creating issues when enforcing requirements for initial training and continuing education units. Recommends deleting “digital mammography”

Response: As indicated by the commenter, the two terms are “often” used interchangeably. The comment is rejected since the terms are not always interchangeable and the terms FFDM and “digital mammography” are still used within the healthcare industry separately. The provision provides a definition, with a few examples of types of modalities (as does 21 CFR 900.2(z)), and was adopted in 2003, and the Department has received no indication the provision has created enforcement confusion.

2a.3 30315.10(b)(29): Recommends rewording to:

“Quality assurance testing evaluation” means an evaluation of a facility's quality assurance testing **program** by a mammography medical physicist to ensure quality control testing is being performed in accordance with section 30316.20 excluding subsection (e) of section 30316.20.

Response: The comment is rejected to maintain consistency and clarity with section 30316.20 (Quality Assurance Testing), and section 30317.10 (Mammography Quality Assurance Program). The defined term addresses evaluation, by the physicist, as to

whether the required tests were performed properly by the facility, not the evaluation of the mammography quality assurance program itself.

2a.4 30315.10(b)(30): Recommends rewording to:

“Quality control technologist” means an individual meeting the requirements of section **30315.51** who is responsible for those quality assurance tasks specified in section 30317.10(d)

Response: The comment is rejected because section 30315.51 is being repealed and the subject matter is redesignated to section 30315.50, as discussed in the ISR (p. 18).

2a.5 30315.52(b)(1): The wording should be clarified so it indicates that 15 units need to be obtained - but within those 15 units - each ‘modality’ must be covered. Suggest rewording to:

Have taught or completed at least 15 continuing education units in mammography. This continuing education shall include **at least one continuing education unit** appropriate to each mammographic modality evaluated by the medical physicist

Response: The comment was received for purposes of the additional 15-day public comment period and not the initial proposal. As discussed in the ISR (page 19), the provision is intended to carry over, and to directly present, in the California Code of Regulations without substantive change, the incorporated federal provision found in section 30315.52(b), by removing the incorporation reference. However, due to the comment, a number of inconsistencies were noted.

A second additional 15-day comment period was conducted to ensure the proposed text met the Department’s intent, was consistent with the federal provision, and addressed the comment. No additional comments on the revision were received.

2a.6 30315.60(c)(2)(B): Recommends changing “physicists” (plural) to physicist (singular).

Response: The comment is accepted, resulting in no regulatory effect. A second additional 15-day comment period was conducted, during which no additional comments were received.

2a.7 30316.20(c)(1): Should be modified to specify that it is a screen-film QC test. Suggest rewording to:

When conducting screen-film mammography, test the residual fixer retained in the film to determine that it is no more than 5 micrograms per square centimeter.

Response: Though the comment was received for purposes of the additional 15-day public comment period and this existing provision was not proposed to be amended, the comment is rejected as unnecessary since fixer retention tests can only be performed on chemically processed film, as indicated in the existing provision, and only relates to screen-film mammography. The test addresses processing of photographic type film with chemicals to develop the image and the amount of fixer chemical retained in that film after processing, which affects the film's storage period before the image degrades due to film emulsion breakdown.

2a.8 30316.20(e)(1) Should be modified to specify that it is a screen-film QC test. Suggest rewording to:

When conducting screen-film mammography, the AEC can maintain film optical density within plus or minus 0.15 of the average of the optical densities measured using homogeneous breast-tissue equivalent material thickness of 2,4, and 6 centimeters (cm) and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility

Response: Though the comment was received for purposes of the additional 15-day public comment period and only nonsubstantial changes to this provision were proposed, the comment is rejected as unnecessary since film optical density can only be determined on film, as indicated in the existing provision, and only relates to screen-film mammography.

2a.9 30316.20(e)(13): Because this section applies only to Mo/Mo systems, recommends rewording to:

For molybdenum anode / molybdenum filter based systems, each machine produces, over 3.0 seconds, a minimum output of 7.0 mGy air kerma per second (800 milliroentgen (mR) per second) when operating at 28 kVp in the standard mammography (molybdenum/molybdenum) mode at any SID where the system is designed to operate and when measured by a detector with its center located 4.5 cm above the breast support surface with the compression paddle in place between the source and the detector.

Response: Though the comment was received for purposes of the additional 15-day public comment period and only nonsubstantial changes to this provision were proposed, the comment is rejected as unnecessary because it merely creates duplication by stating a testing parameter that the existing provision already provides. Further, because these machines could also have other target/filter combinations, the suggested wording could create confusion as to which combination must be used for determining output. The provision clearly states the testing parameters making the suggested wording unnecessary. The commenter also provided information about tungsten based systems. See comment 2.12.

3.1 Section 30315.33(a)(8)(C) should be revised to insert “or printer” after the word “processor.”

Response: The recommendation is rejected. Printers are used in digital imaging and its quality assurance program must follow that recommended by the image receptor manufacturer (§ 30316(e)(16), as recodified). That program component is evaluated during inspection so is not needed for purposes of determining if the mammography machine certificate will be issued.

- 3.2 Section 30315.52(b)(2) should be revised for consistency with 21 CFR 900.12(a)(3)(iii)(B). This provision, regarding “at least three facilities and a total of at least nine mammography systems,” should also be the same as FDA’s requirement.**

Response: The comment to make the provision the same as FDA’s was rejected. An additional 15-day proceeding was conducted providing additional discussion regarding the provision, during which no additional comments were received. See also the response to comment 2.7.

- 3.3 Section 30316(c)(3) and (4) should be revised for consistency with current state of practice in mammography, as specified.**

Response: The recommendation to insert language regarding the purposes of devices specified in paragraphs (3) and (4) of subsection (c) is rejected as unnecessary since the radiology community knows the purposes of, and how to use, the devices. Such devices have been in use since integration of X-ray for medical purposes occurred. The recommendation to revise paragraphs (1) and (2) is rejected as unnecessary since the substantive recommendation is rejected.

- 3.4. Section 30317.20(b) should be revised for consistency with FDA’s provisions regarding records.**

Response: The recommendations are rejected for the reasons discussed in the ISR (pp. 1 through 7). Existing provisions were adopted for purposes of being an AB under MQSA, but the Department is no longer an AB or performs the AB’s functions under MQSA. As discussed in the ISR, a facility performing screening or diagnostic mammography remains subject to MQSA requirements regardless of state regulations and laws.

- 4.1. Recommends section 30315.52(b)(1), last sentence, be revised for consistency with FDA’s equivalent provision by removing language disallowing training hours obtained through attending an identical course more than once during a 36-month cycle.**

Response: The recommendation was accepted and an additional 15-day proceeding conducted, during which no additional comments were received.

ALTERNATIVES DETERMINATION: In accordance with Government Code Section 11346.9(a)(4), the Department has determined that no alternative would be more effective in carrying out the purpose for which the regulation is proposed; or would be as effective and less burdensome to affected private persons than the proposed regulation; or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law. This determination is based on the following:

- The federal MQSA, implemented in 1994 by the FDA, established national processing standards for facilities providing screening or diagnostic mammography services. Under MQSA, states may be approved by FDA as an accreditation body (AB) for accrediting mammography facilities within the state in accordance with those processing standards.
- The CDPH, in 2003, adopted regulations to implement California's MQAA consistent with FDA's regulations and processes for purposes of functioning as an FDA-approved AB within the State of California.
- The CDPH, though no longer an FDA-approved AB, maintains a partnership with FDA through FDA's computer systems, inspection procedures, legal proceedings and certification cycles to which mammography facilities nationally are subject.
- This proposal retains and, in some instances, ties provisions, including processing standards, to MQSA regulations for consistency and clarity, and to which California facilities are intimately familiar.
- The CDPH received no comments identifying more effective, less burdensome, or more cost-effective alternatives to the proposal.

IMPOSITION OF LOCAL MANDATE

The Department has determined that the regulation would not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by part 7 (commencing with Section 17500) of division 4 of the Government Code, nor are there any other nondiscretionary costs imposed.

IMPACT ON BUSINESS

The Department has determined that the regulations would not have a significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.