

## **INITIAL STATEMENT OF REASONS**

### **Summary of the Proposed Regulatory Action**

This proposal would amend the Requirements for the Use of X-ray in Mammography in title 17, California Code of Regulations (17 CCR) sections 30315.10 through 30320.90 by removing components of accreditation processes adopted for purposes of maintaining U.S. Food & Drug Administration (FDA) approval as an Accreditation Body (AB) under the federal Mammography Quality Standards Act (MQSA). The proposal would clarify and emphasize state processes, reorganize regulatory structure and update mammography X-ray equipment standards for consistency with MQSA standards. It would also address standards applicable to the performance of interventional mammography that is not subject to federal MQSA standards. Nonsubstantial changes are also made.

### **Policy Statement Overview**

*Problem Statement:* Currently, Department regulations continue to follow the federal MQSA accreditation process for certification of mammography service providers by FDA. These regulations were adopted when the Department was an FDA-approved Accreditation Body (AB) and performed those federal accreditation functions. However, the Department is no longer AB and no longer performs those federal functions. For a facility to provide, or continue to provide, mammography services, it must apply for, or renew, federal certification following the federal accreditation process, in addition to completing the state's process, under the California Mammography Quality Assurance Act (MQAA), for certifying X-ray machines used for mammography. Because the Department's regulations were developed for carrying out the federal accreditation process, the regulations are silent in how the state's MQAA machine certification process functions. Due to the differences between the federal and state processes and the regulatory silence regarding the state's machine certification process, mammography providers become confused resulting in diverting facility staff away from providing patient procedures, to regulatory issues, which in turn could reduce access to mammography services. As it pertains to interventional mammography that is not subject to the federal MQSA, current requirements are seldom appropriate, creating regulatory and enforcement confusion and inconsistencies that could also reduce access to these procedures. By amending the current regulations, facilities can focus on providing accessible and consistent patient care rather than on regulatory issues.

*Objectives:* Broad objectives of this proposed regulatory action are to:

- Reduce possible barriers to consistent and accessible mammography services by repealing the facility accreditation processes previously adopted for federal MQSA purposes.
- Clarify and emphasize the approval processes specific to the MQAA by restructuring existing regulations.
- Ensure standards for performance of interventional mammography are appropriate and consistent by clearly addressing it in regulation.
- Ensure and maintain public health and safety by removing regulatory barriers.
- Update existing regulations for clarity and consistency with current federal and state legislation.

*Benefits:* Anticipated benefits from this proposed regulatory action are:

- Increased patient care consistency between all mammography facilities.
- Increased access to mammography services.
- Increased clarity of approval processes for new providers of screening, diagnostic, and interventional mammography.
- Continued protection of the public health and safety.
- Updated, clear, and consistent regulations.

*Evaluation as to whether the proposed regulations are inconsistent or incompatible with existing state regulations:* The Department evaluated this proposal and determined that, if adopted, it will not be incompatible with existing state regulations or duplicative of federal requirements. This evaluation included a review of the Department's existing general regulations and federal regulations specific to mammography. An Internet search of other state agency regulations determined that no other state regulation addresses the same subject matter.

### **Background/Authority**

The Radiation Control Law (RCL), Health and Safety Code (H&S Code), sections 114960 et seq., authorizes the Department to promulgate regulations regarding sources of ionizing radiation for the protection of the health and safety of the public and radiation workers. The Radiologic Technology Act (RT Act), H&S Code 27(f)<sup>1</sup>, authorizes the Department to promulgate regulations regarding certification and permitting of individuals who use X-rays on human beings for diagnostic or therapeutic purposes. The Mammography Quality Assurance Act of 1992 (MQAA), Statutes 1992, chapter 870, requires the Department to adopt registration and certification requirements for mammography equipment and individuals performing mammography. (H&S Code 115060(e) and 106965.) The regulations that implement, interpret, and make specific the provisions of the RCL pertaining to MQAA (registration and certification of mammography equipment) are in 17 CCR 30315.10 through 30320.90<sup>2</sup>, hereinafter referred to as "Article 4.5". The regulations that implement, interpret, and make specific the provisions of the RT Act pertaining to MQAA (certification of persons who apply X-ray to humans) are in 17 CCR, Division 1, Chapter 5, Subchapter 4.5 (commencing at section 30400). This proposal makes no changes to the RT Act regulations.

The governor of this state signed into law the Mammography Quality Assurance Act of 1992 (Stats. 1992, ch. 870, § 2 (AB 2841)), which required individuals that perform mammography be certified pursuant to the RT Act, incorporated the May 1990 version of Appendix B of the "Rules of Good Practice for Supervision and Operation of Mammographic X-ray Equipment" (Rules of Good Practice) (Reference 1), as approved by the Radiologic Technology Certification Committee (RTCC), until registration and

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<sup>1</sup> This short format "H&S Code 27" for a given Health and Safety Code section will be used throughout this document for brevity. For example, "H&S Code 27" means California Health and Safety Code section 27.

<sup>2</sup> The short format "17 CCR 30315.10" for a given regulation found within title 17, California Code of Regulations will be used throughout this document for brevity.

certification regulations for mammography equipment were adopted, and, among other requirements, specified financial penalties for violations of the RT Act and RCL. RTCC is the Department’s consultant regarding the RT Act as specified in H&S Code 114855.

In 1993, the President of the United States signed into law the Mammography Quality Standards Act of 1992 (MQSA) [Pub. L. No. 102-539]. The FDA issued interim regulations (58 Fed. Reg. 67558 (Dec. 21, 1993), amended by 59 Fed. Reg. 49808 (Sep. 30, 1994)) to implement MQSA. Those regulations established congressionally mandated uniform, national quality standards for mammography. MQSA requires that, to provide mammography services after October 1, 1994, persons providing such services are accredited by an approved accreditation organization and obtain a certificate from the Secretary of Health and Human Services. MQSA was reauthorized as the Mammography Quality Reauthorization Standards Act of 1998 [Pub.L. No. 105-248]. The FDA has issued final regulations (62 Fed. Reg. 55852 (Oct. 28, 1997), as amended by 63 Fed. Reg. 56555 (Oct. 22, 1998) and 64 Fed. Reg. 32404 (June 17, 1999)) that supersede and clarify the interim regulations. The final regulations are codified in Title 21, Code of Federal Regulations, Part 900 (21 CFR 900).

**Major differences between federal MQSA and California MQAA**

Though MQSA and MQAA were both enacted within months of each other by Congress and the California Legislature, respectively, there are major differences in how each achieves its goal of ensuring citizens receive quality mammograms for the early detection of breast cancer. Federal MQSA accreditation and certification process is discussed after the following table that presents these major differences.

<b>Federal MQSA</b>	<b>State MQAA</b>
Establishes national quality standards for <b>facilities</b> providing mammography services.	Requires the Department to adopt certification requirements for mammography <b>equipment</b> .
Defines “mammography” to mean radiography of the breast.  <b>Excludes</b> radiography of the breast performed during invasive interventions <b>or</b> radiography of the breast performed with an investigational mammography radiation device.	Defines “mammography” to mean the creation of an X-ray image of the human breast.  <b>Includes</b> radiography of the breast performed for interventional purposes <b>and</b> radiography of the breast performed with an investigational mammography device.
Requires <b>facilities</b> performing mammography for screening or diagnostic purposes to be certified by the FDA.	Requires <b>X-ray equipment</b> used to perform mammography for screening, diagnostic and interventional purposes to be certified by the Department.

To be eligible for certification, a mammography <b>facility</b> is required to be accredited by an FDA-approved AB.	To be eligible for certification, a mammography <b>machine</b> is required to be registered with the Department.
To be approved by FDA as an AB, a state agency or private entity is required to establish and administer an accreditation program, meeting the requirements specified in 21 CFR 900 Subpart A, that will ensure that accredited facilities can meet the requirements specified in 21 CFR 900 Subpart B.	No equivalent AB-type process.
Requires physicians who interpret mammograms to meet specific requirements.	<p>MQAA does not give the Department regulatory authority over interpretation of mammograms. Establishment of existing requirements for interpreting physicians is accomplished via status as an FDA-approved AB. Absent FDA approval as an AB, authority over interpretation of mammograms is authorized only under the Medical Practice Act, administered by the Medical Board of California.</p> <p>Under the RT Act, physicians who administer or supervise administration of X-ray must be certified or permitted by the Department. (H&amp;S Code 27(f); 17 CCR 30400 through 30468.)</p>

**Federal MQSA Accreditation and Facility Certification Process**

Under MQSA, screening and diagnostic mammography services can only be provided by facilities that are certified by FDA as meeting MQSA and regulations promulgated thereunder. MQSA does not apply to interventional mammography, which is discussed later in this document. In part, the MQSA requires:

- Accreditation of mammography facilities by private, nonprofit organizations or state agencies that have the standards established by FDA for entities that accredit facilities. Such entities are called “accreditation bodies” and must be approved by FDA and undergo direct federal audits.
- An annual mammography facility physics survey, consultation, and evaluation performed by a qualified medical physicist.
- Annual inspection of mammography facilities by FDA-certified federal or state inspectors.
- Establishment of initial and continuing qualification standards for physicians interpreting mammograms, individuals performing mammography, and medical physicists performing equipment surveys.

- Establishment of quality standards for mammography equipment and practices, including quality assurance and quality control programs.
- Standards governing recordkeeping for patient files and requirements for reporting and patient notification by physicians.

Before a facility can begin to perform mammography, the facility must start the accreditation process by applying to an AB. The AB reviews the facility's application regarding the following:

- Specific facility information regarding location, addresses, persons of contact, and accreditation and certification history if applicable.
- Qualifications of physicians who interpret mammograms, mammographers, and medical physicists.
- Specific X-ray equipment information.
- Specific information regarding quality control and assurance programs.
- Other information as may be found in the AB's standards.

Once the AB is satisfied the facility can meet both MQSA regulations and the AB's standards, the AB recommends to FDA that the facility be issued an Interim authorization, valid for up to six months. Upon receipt of the FDA Interim authorization, the facility may then begin performing mammography and must select mammograms meeting certain criteria and submit to the AB those mammograms for clinical image review (CIR). The AB then reviews those mammograms to determine if the mammograms meet specific FDA-accepted attributes. If the facility fails the CIR process, the facility enters the "Provisional" process whereby their Interim authorization can be extended for a limited time so the facility can submit additional mammograms into the CIR process. If the facility passes the CIR process, the AB recommends to FDA the facility be certified. If FDA issues the certification, it is valid for three years beginning on the date FDA issued the Interim authorization.

### **Existing California Regulations**

Existing Article 4.5 was adopted in 2003 to more fully implement California's MQAA and to maintain Department status as an AB under federal MQSA. The regulations married the requirements and processes for implementing MQAA and establishing an accreditation process for purposes of MQSA. Under MQSA, private entities have the ability to also become an AB. Because of that ability, a facility in California, to comply with federal MQSA, could apply for federal certification to either the Department or the American College of Radiology (ACR), a private entity and an AB. Existing Article 4.5 accounts for those facilities applying to ACR for FDA certification. However, though a facility could apply to ACR for federal purposes, the facility, for State purposes, must also apply to the Department for mammogram certification as required by California's MQAA.

As adopted, Article 4.5 established processes necessary for carrying out MQSA accreditation so a facility could obtain FDA certification. The Interim Facility Accreditation Certificate (IFAC) (17 CCR 30315.10(b)(18)) was issued simultaneously with FDA's issuance of the federal provisional facility certificate. The IFAC was a temporary document issued upon meeting the criteria in existing 17 CCR 30315.24

allowing the facility to obtain mammograms for CIR by either the Department or ACR for purposes of FDA certification. The Facility Accreditation Certificate (FAC) (17 CCR 30315.10(b)(14)) was issued simultaneously with FDA's issuance of the federal facility certificate indicating the passage of CIR via existing 17 CCR 30315.35 or ACR's accreditation process. The validity period of these documents were tied to FDA-issued document dates. Those dates vary based on where in the accreditation or certification process the applicant is and the circumstances that impact that process, regardless of which AB (Department or ACR) the facility applied to.

FDA's computer system maintains information on all certified facilities in the United States and on those facilities that have applied for an FDA certificate issued pursuant to 21 CFR 900.11(b)(1). FDA requires ABs to submit facility data through that computer system and includes whether the AB has determined the facility meets both MQSA and

AB requirements. Thus, by use of that system, when the Department issued the IFAC or when ACR issued its equivalent document, the FDA issued a provisional certificate to the facility at the same time. This also occurred simultaneously for issuance of the Department-issued FAC and the FDA-issued certificate.

In addition to the federal MQSA accreditation and certification process, the facility or applicant must comply with state processes. These processes are registration of the radiation machine pursuant to 17 CCR 30108 through 30146, and mammogram certification pursuant to H&S Code 114850(q) as enacted under MQAA. Under MQAA, the document specified in H&S Code 115115(b), "Mammography X-ray Equipment and Facility Accreditation Certificate" (MXEFAC), is issued and required to be posted on the particular radiation machine. Thus, existing Article 4.5 ensured a facility could comply with both federal and state requirements concurrently instead of linearly. This greatly reduced the facility's compliance burden to meet all requirements and more quickly provide mammography services. The Department established the IFAC and FAC to coincide with, and for purposes of, federal processes and the Department then automatically issued the MXEFAC for purposes of mammogram certification and posting on the machine under MQAA.

### **Interventional Mammography**

California's MQAA is broader in scope than federal MQSA because the federal regulations do not apply to use of a radiation machine for purposes of obtaining tissue samples to determine the presence of cancer or to localize, for surgical excision, tissue suspected of being cancerous. Mammography performed for such purposes is called interventional mammography. (17 CCR 30315.10(b)(19).)

Because Article 4.5 was adopted for purposes of both renewing the Department's AB status with FDA and for clarifying and implementing MQAA, as it pertains to the narrower scope of MQSA, Article 4.5 only addresses screening and diagnostic mammography. Exclusion of interventional mammography within existing Article 4.5 is accomplished by use of terminology and tying requirements to only facilities performing screening or diagnostic mammography. This exclusion results in bifurcated processes and standards as follows:

- Standards and processes applicable to screening and diagnostic mammography are found in Article 4.5, and subject to federal MQSA;
- Standards and processes applicable to interventional mammography are found in Appendix B of the “Rules of Good Practice” as specified in H&S Code 115115, but are not subject to federal MQSA (Reference 1).

In 2004, the Department withdrew from FDA’s mammography facility accreditation program for fiscal reasons. The ACR was then approved by the FDA to take over the accreditation of mammography facilities in California. Currently, the Department provides mammogram certification pursuant to MQAA by requiring each facility performing screening or diagnostic mammography to meet the provisions of Article 4.5 and, for facilities using radiation machines for interventional mammography, the provisions of Appendix B of the Rules of Good Practice (Reference 1).

This proposal now addresses interventional mammography so that all standards and processes regarding screening, diagnostic, and interventional mammography are addressed in regulation. Both terminology and requirement changes are proposed so as to fully implement California’s MQAA within regulation. For example, existing Article 4.5 uses the word “mammography” in numerous provisions but the scope of the provision is limited via terminology to screening and diagnostic mammography as encompassed by federal MQSA. By removing those limitations, the scope of this proposal broadens the scope of the regulations to encompass mammography as defined by California MQAA. Therefore, it is the Department’s intent that this proposal will result in regulations that supersede the Rules of Good Practice (Reference 1) in accordance with H&S Code 115100(b) so as to address screening, diagnostic and interventional mammography.

Because of the dual regulatory oversight of mammography, in general, by both the FDA, under MQSA, and the Department, under MQAA, this proposal also repeals a number of provisions formerly adopted only for purposes of MQSA and for the Department to remain an AB. Even though a provision may be repealed in this proposal, facilities providing screening or diagnostic mammography services remain subject to the equivalent provision under federal regulations. Thus, this proposal results in increasing clarity of State processes and requirements, removes components of federally-related accreditation processes, reduces, where appropriate, the dual regulatory oversight required under both State and federal law, revises regulatory structure, and updates mammography machine standards.

The authority and reference citations of sections being amended, resulting in nonsubstantial changes pursuant to title 1, California Code of Regulations section 100, reflect the:

- Numbering system implemented by the 1995 recodification of the H&S Code, and
- Reorganization of the Department of Health Services into the Department of Health Care Services and the California Department of Public Health, pursuant to SB 162. (Stats. 2006, Ch. 241.)

### **Specific Discussion of Proposed Changes**

The proposed changes are explained as follows:

**Adopt section 30315.05.** This proposed section is intended to:

- Reduce revision efforts of existing provisions written from the federal MQSA and AB perspective for grammatical and contextual usage.
- Reduce interpretive confusion by the public and staff.
- Clarify that the proposal is not intended to sanction noncompliance, or allow circumvention of requirements due to regulatory perspective.

As presented above regarding the differences between MQSA and MQAA, MQSA focuses on a “facility” resulting in certification of a facility and the standards the facility must meet. Existing Article 4.5 focuses on placing mandates on a facility even though that term is defined as an inanimate object (e.g. a building) in accordance with MQSA. It leaves it unclear who controls the facility; that is, the actual person or persons.

On the other hand, California MQAA focuses on the actual person; that is, the user. MQAA amended two existing laws; the Radiation Control Law (RCL), and the Radiologic Technology Act (RT Act). Under RCL’s regulations, mandates are placed on persons (H&S Code 114985(c)) who possess sources of ionizing radiation. These persons are called “users.” User, for possessors of radiation machines, means any person who has registered or who otherwise possesses a source of radiation which is subject to registration. (17 CCR 30100(z).) To revise Article 4.5 so it is grammatically consistent with RCL regulation would require major editing that would increase confusion between federal MQSA regulations and California MQAA regulations. Therefore, this proposed section is needed to both clarify the regulatory perspective of Article 4.5 provisions as to how it implements, and makes specific MQAA and to prevent or reduce interpretive confusion as to who must comply with the provisions.

Additionally, Article 4.5 contains provisions with phrases that are grammatically correct with common English usage. Thus, this proposal clarifies how to treat contextual usage of defined terms. Language is included to inform the public that this proposal or change in perspective, from federal to state view, is not intended to allow the performance of mammography in violation of the cited laws or regulations. This is needed to clarify the Department’s intent.

**Amend section 30315.10.** Subsections are redesignated as necessary to maintain a coherent structure.

Repeal subsections (b)(2) and (b)(3) as the terms are no longer used. Regarding subsection (b)(2), the term was adopted for purposes of maintaining AB status. Because the meaning includes the interpretation of mammograms and the Department does not have authority over that activity, unless the Department was an FDA-approved AB, the term is deleted. Regarding subsection (b)(3), this term is used for purposes of the term “serious adverse event” and section 30317.70, both adopted to maintain FDA-approved AB status. It is deleted for the reasons discussed in section 30317.70.

Redesignate subsections (b)(4), (b)(5) and (b)(6) as (b)(2), (b)(3) and (b)(4), respectively, to maintain coherency.

Repeal subsection (b)(7) because that term is not used in existing Article 4.5 and is not used in this proposal.

Repeal subsection (b)(8) as that term is no longer used. See the discussion regarding section 30315.35.

Repeal subsection (b)(9) as that term is no longer used. See the discussion regarding section 30317.70.

Redesignate subsection (b)(10) as (b)(5) to maintain a coherent structure.

Proposed subsection (b)(6) is needed for clarifying activities that are subject to federal MQSA requirements. Certain provisions apply exclusively to mammography systems used to perform diagnostic mammography. The meaning is based on the term “diagnostic mammography” found in the “ACR 1999 Mammography Quality Control Manual” published by the American College of Radiology (ACR) (Reference 2, page 335). The ACR is approved by FDA to accredit mammography facilities in the State of California subject to federal MQSA.

Redesignate subsection (b)(11) as (b)(7) to maintain a coherent structure and amended for clarity and consistency with proposed subsection (b)(20) and the changes to sections 30315.50 and 30315.51. Paragraphs (A) and (B) were initially adopted for uniformity with 21 CFR 900.2(o) used within 21 CFR 900.12(a)(1) and (a)(2), pertaining to personnel qualifications. However, during rulemaking, personnel qualification requirements were modified as specified in existing sections 30315.50 and 30315.51. Those provisions do not use the term “direct supervision” and this proposal also does not use that term. Therefore, paragraphs (A) and (B) are deleted as unnecessary. Paragraph (C) is redesignated as subsection (b)(7) and amended for consistency with proposed subsection (b)(20).

Redesignate subsection (b)(12) and (b)(13) as (b)(8) and (b)(9), respectively, to maintain a coherent structure. Proposed subsection (b)(9) changes the meaning of “facility” to pertain only to mammogram certification as defined in H&S Code 114985(q). Paragraphs (A) and (B) are deleted for the reasons discussed in deleting the meaning of “activities” in existing subsection (b)(2) and in revising the meaning of “mammography” in proposed subsection (b)(18).

Repeal subsection (b)(14) for the reasons discussed regarding sections 30315.20 and 30315.22.

Redesignate subsection (b)(15) and (b)(16) as (b)(10) and (b)(11), respectively, to maintain a coherent structure.

Repeal subsection (b)(17) because this proposal deletes the concept of “Interpreting

physician” as discussed regarding section 30315.50.

Repeal subsection (b)(18) since the Department no longer issues an IFAC. The IFAC was used for purposes of obtaining FDA approval as an AB. See also the discussion regarding sections 30315.20 and 30315.22.

Redesignate subsection (b)(19) and (b)(20) as (b)(12) and (b)(13), respectively, to maintain a coherent structure and to amend the meaning of “interventional mammography.” It is amended to remove the reference to therapeutic procedures. Those types of procedures are not considered interventional in nature because the presence of cancer has been confirmed by procedures such as breast biopsy, which are for the purpose of confirming the presence of cancer.

Repeal subsection (b)(21) for consistency with this proposal. See the discussion regarding proposed subsection (b)(14) and section 30317.10(a).

Adopt proposed subsection (b)(14) to define the term “Lead supervising physician” (LSP). Under federal MQSA, and existing Article 4.5, the Lead Interpreting Physician is the overseer of the quality assurance (QA) program to ensure quality mammography is provided to the public. (17 CCR 30317(c), 30317.10(a), 30317.20(a), and 30317.30(a).) This oversight included analysis of an interpreting physician’s interpretive accuracy. (17 CCR 30317.60(d).) This proposal modifies this oversight structure by replacing the concept of “lead interpreting physician” with “lead supervising physician” (LSP). This modification is necessary because, absent FDA-approved AB status under the federal MQSA, the Department does not have authority over who can interpret a mammogram. That authority, under state law, is given to the Medical Board of California. However, because QA, and its oversight, remains within the Department’s authority under the California MQAA, an MQSA-equivalent QA oversight structure is maintained by use of the LSP concept. This concept, and the requirement that the LSP meet proposed section 30315.50(a)(1), is based on the federal MQSA, the Rules of Good Practice as referenced in H&S Code 115100 and 115115, and, including consistency with, the RT Act regarding supervision of mammography. (H&S Code 106965(b), 106980(a), 107110, and 114850(g), (h)(1), and (i).) See the additional discussion regarding section 30317.10(b). This proposal makes no changes to regulations implemented under the RT Act.

Redesignate subsection (b)(22) and (b)(23) as (b)(15) and (b)(16), respectively, to maintain a coherent structure.

Redesignate subsection (b)(24) as (b)(17) to maintain a coherent structure and amend to include other mammography modalities introduced into use since Article 4.5 was adopted.

Redesignate subsection (b)(25) as (b)(18) to maintain a coherent structure. It is amended to clarify that the term does not distinguish between interventional mammography, research mammography, screening mammography, or diagnostic mammography. Federal MQSA (21 CFR 900(aa)), does not include interventional or research mammography.

As discussed previously, existing Article 4.5 applies only to screening and diagnostic mammography both for purposes of being an FDA-approved AB and for purposes of implementing California's MQAA. Interventional mammography is subject to Appendix B of the Rules of Good Practice (Reference 1). Because this proposal removes certain MQSA accreditation components within existing Article 4.5 and increases the clarity of State MQAA processes, clarification of the term "mammography" now makes radiation machines used only for interventional mammography subject to, with exceptions, all provisions in this proposal. Thus, the Rules of Good Practice are fully superseded. See also the discussion regarding the terms "diagnostic mammography" and "screening mammography."

Proposed subsection (b)(19) is needed to identify the issued document for purposes of "mammogram certification" defined in H&S Code 114985(q). The proposed term is used instead of the term "Mammography X-ray Equipment and Facility Accreditation Certificate" that is used in H&S Code 115115(b), to avoid confusing "mammogram certification" pursuant to the California MQAA with the facility accreditation and certification documents issued by FDA pursuant to the federal MQSA. See the discussion in section 30315.20 regarding posting of this certificate for purposes of H&S Code 115115(b).

Repeal subsection (b)(26) because "mammography medical outcomes audit" requirements are deleted. See the discussion regarding section 30317.60.

Adopt proposed subsection (b)(20) to distinguish the requirements for medical physicists to conduct mammography surveys from the requirements for medical physicists to conduct other surveys such as radiation therapy surveys (17 CCR 30312(b)(5)). This proposed term replaces, and is based on, "medical physicist" currently defined in existing subsection (b)(29). See also the discussion regarding section 30315.52.

Redesignate subsection (b)(27) as (b)(21) to maintain a coherent structure and amend to make nonsubstantial punctuation corrections in paragraph (B).

Redesignate subsection (b)(28) as (b)(22) to maintain a coherent structure. It is amended for clarity and consistency with the equivalent term in 21 CFR 900.2(bb) and proposed subsection (b)(20).

Repeal subsection (b)(29) for the reason discussed regarding proposed subsection (b)(20).

Adopt proposed subsection (b)(23) as discussed regarding current subsection (b)(30) and section 30318.10.

Repeal subsection (b)(30) by replacing it with the term "mobile mammography" for consistency with common usage, H&S Code 115060(e)(3), and to avoid confusion with Medicare's requirements for mobile health service providers. See the additional discussion regarding proposed 30318.10.

Redesignate subsection (b)(31) as (b)(24) to maintain a coherent structure and amend it to clarify the meaning of the term as used in this proposal, and for consistency with this proposal's revised perspective regarding radiation machines used to "perform" mammography instead of regarding requirements for facilities that "provide" mammography services.

Repeal subsection (b)(32) because the term is not used in existing Article 4.5 or this proposal.

Repeal subsection (b)(33) because the term is no longer needed due to the repeal of section 30317.40.

Redesignate subsection (b)(34) as (b)(25) to maintain a coherent structure and amend it to specify that the phantom used for QA testing must be an FDA-approved test object.

Since the Department is no longer an AB, it no longer approves phantoms pursuant to 21 CFR 900.3(d). See also the discussion regarding section 30316.22.

Redesignate subsection (b)(35) and (b)(36) as (b)(26) and (b)(27), respectively, to maintain a coherent structure.

Adopt proposed subsection (b)(28) to clarify the meaning of "Physician" as used in this proposal and for consistency with RT Act provisions and its regulations. (H&S Code 106965(b), 106980(a), 107110, 114850(g) and (h)(1); 17 CCR 30400 et seq.) See also the discussion regarding section 30315.50.

Repeal subsection (b)(37) because the term "positive mammogram" is only used in sections 30317.30 and 30317.60 which are repealed making the term unnecessary since it is no longer used.

Repeal subsection (b)(38) because it is replaced with the term "quality control technologist" for the reason discussed in proposed subsection (b)(30).

Redesignate subsection (b)(39) as (b)(29) to maintain coherency and consistency with the replacement of "medical physicist" with "mammography medical physicist." A nonsubstantial punctuation correction is made.

Adopt proposed subsection (b)(30) for consistency with accepted usage of the phrases "quality assurance" and "quality control." Quality assurance means the planned and systematic activities implemented in a quality system so that quality requirements for a service will be fulfilled. Quality control means the observation techniques and activities used to fulfill requirements for quality. This proposal is also based on the same term defined in 21 CFR 900.2(qq) and the existing term of "quality assurance technologist."

Redesignate subsection (b)(40) as (b)(31) to maintain a coherent structure.

Adopt proposed subsection (b)(32) to specify the meaning of "screening mammography" as used in this proposal. This is needed to specify requirements that apply exclusively to mammography systems used to perform screening mammography. The meaning is based on term "screening mammography" in the "ACR 1999 Mammography Quality Control Manual" published by the American College of Radiology, the body approved by FDA to accredit mammography facilities in the State of California (Reference 2, page 339). However, the meaning is revised to include all persons because breast cancer can occur in any person. See also the discussions

regarding “mammography” in proposed subsection (b)(18).

Repeal subsections (b)(41) and (b)(42) as discussed regarding section 30317.70.

Redesignate subsection (b)(43) as (b)(33) to maintain a coherent structure.

Redesignate subsection (b)(44) as (b)(34) to maintain a coherent structure.

Redesignate subsection (b)(45) as (b)(35) to maintain a coherent structure and amend it for consistency with the terminology change of “medical physicist” to “mammography medical physicist.”

Redesignate subsection (b)(46) as (b)(36) to maintain a coherent structure.

**Repeal and Adopt section 30315.20.** The title is changed to accurately reflect the contents of this section.

As discussed previously regarding existing Article 4.5, issuance of documents and prohibitions necessary for maintaining MQSA accreditation and to implement California MQAA for screening and diagnostic mammography were tied to federally issued documents, time frames and prohibitions. Because this proposal removes certain federal MQSA accreditation components, it increases clarity of California’s process of mammogram certification as enacted under MQAA.

Existing provisions are repealed since the Department no longer accredits facilities to be eligible for FDA certification. The documents identified in this section were issued for purposes of accreditation under MQSA while the Department was an AB. Because the Department is no longer an AB, the indicated documents are no longer issued. The proposal clarifies that a mammography machine certificate is now issued to signify approval of the machine for mammography as mandated under MQAA. However, repealing these provisions will have no health and safety impact since facilities providing screening or diagnostic mammography services remain subject to the federal accreditation and certification requirements.

Adopt proposed subsection (a) to specify the provisions for mammogram certification, defined in H&S Code 114985(q), that were implemented through the Department’s former mammography facility accreditation process. Under MQAA, the “Mammography X-ray Equipment and Facility Accreditation Certificate” (MXEFAC) required by H&S Code 115115(b) to be posted on the radiation machine is the document that signifies to the public that the Department has determined that the machine dedicated to or used for mammography meets the MQAA standards. As discussed regarding proposed section 30315.10(b)(19), it is proposed that the document “mammography machine certificate” (MMC) be issued in lieu of the MXEFAC so as to avoid confusion with federal MQSA terminology of FAC. Congress’s enactment of MQSA focuses on certification of a facility whereas the California Legislature’s enactment of MQAA focuses on certification of a machine resulting in similar terminology but different meanings. This proposal, because it implements MQAA, must be consistent with

MQAA but is intended to avoid confusion with federal MQSA. Therefore, in lieu of issuing the MXEFAC document identified in H&S Code 115115(b), these proposed regulations substitute that document with the MMC to avoid confusion with federal MQSA regulations and FDA-issued documents. Lastly, because of the substitution of MXEFAC with MMC, it is necessary to inform the industry that posting of the MMC on the radiation machine satisfies the posting requirement of H&S Code 115115(b).

Adopt proposed subsection (b) to specify the period for which an MMC shall be valid. Existing subsection (c) states the validity period is three years. Mammogram certification is contingent on compliance with registration requirements (H&S Code §114985(q)). Registration of radiation machines is a two-year cycle. (17 CCR 30108 through 30146.) However, federal MQSA facility certification is a three-year cycle. The Department, as both an AB under federal MQSA and a certifier of the radiation machine under California MQAA, adopted Article 4.5 for consistency with federal processes and internally dealt with these different authorization cycles by communication via FDA's computer system and the Department's database. This ensured facilities maintained compliance with both federal and state laws and regulations.

Though the Department is no longer an AB under MQSA, communication via FDA's computer system continues to allow staff to assist facilities in complying with all authorization cycles. Therefore, because use of radiation machines used for screening or diagnostic mammography is subject to both federal and State provisions that have differing authorization cycles, this proposal ties validity of the MMC to the federal MQSA authorization cycle but subject to registration. When the radiation machine will be used to perform screening or diagnostic mammography, the MMC expiration date will coincide with the FDA's expiration date as found on the facility's provisional certificate or the facility's certification. FDA's provisional certificate is valid for up to six months while the facility is undergoing the CIR process. FDA's facility certificate, issued upon passage of CIR, is valid for three years from the date of provisional authorization allowing the facility to begin CIR. Because of these differing authorization cycles, proposed language as to when the document becomes invalid is needed to both inform the user and for consistency with H&S Code 114850(i). Even though radiation machines used for interventional mammography are not subject to federal MQSA, the MMC expiration date will be three years and tied to registration so as to achieve uniform and consistent Department processes.

Adopt proposed subsection (c) to inform the user of federal requirements for the certification of facilities pursuant to 21 CFR 900.11(a). It also allows the Department to take prompt action against a facility performing screening or diagnostic mammography that is not complying with federal law and to inform FDA. Though the Department is not an MQSA AB, Department inspectors, under contract, perform federal inspections and, thus, participate in this nationwide program for obtaining and maintaining quality mammography for the public. Providing such mammography services illegally places the public at a great risk because the equipment, personnel, and QA programs have not been evaluated to determine if they meet the appropriate federal and state standards.

**Repeal and Adopt section 30315.22.** The title is changed to reflect the contents of this amended section. Existing provisions are repealed and readopted for consistency and clarity with proposed changes.

Repeal subsection (a) since the Department no longer issues FACs. The effect of repealing this subsection will have no impact on the use of X-ray in mammography for facilities providing screening or diagnostic services because such facilities remain subject to federal MQSA.

Adopt proposed subsection (a) to specify the requirements a user shall meet to be eligible for mammogram certification, defined in H&S Code 114985(q), that were implemented through the Department's former mammography facility accreditation process. This subsection is needed so an applicant knows what must be submitted for the Department to determine if quality mammograms can be produced. It also makes it possible for a user to meet the posting provisions specified in H&S Code 115115(b). See also the discussion regarding proposed section 30315.20(a) and the discussion of "mammography machine certificate" in proposed section 30315.10(b)(19).

Proposed subsection (a)(1) references section 30315.33 to maintain a clear presentation of those items the applicant must submit for eligibility.

Proposed subsection (a)(2) is needed to ensure that the radiation machine is registered before the Department issues an MMC for consistency with H&S Code 114985(q).

Proposed subsection (a)(3) is needed to ensure that the radiation machine is specifically designed for mammography pursuant to H&S Code 115060(e)(1). See the discussion regarding sections 30316 and 30316.20(e).

Proposed subsection (a)(4) is needed to ensure that the user has designated an LSP who is responsible for establishing and maintaining the user's mammography QA program as specified in section 30317.10. See also the discussion regarding "lead supervising physician" in proposed sections 30315.10(b)(14) and 30317.10(a).

Proposed subsection (a)(5) is needed to ensure that the user is capable of meeting the requirements for a QA program specified pursuant to H&S Codes 115060(e)(2), 115100(b), and 115115. See also the discussion regarding proposed section 30317.10.

**Repeal and Adopt section 30315.23.** The title is changed to reflect the contents of this amended section.

Repeal subsection (a) since the Department no longer renews mammography FACs for purposes of federal MQSA. Repealing this subsection will have no impact on facilities providing screening or diagnostic mammography services because such facilities remain subject to the federal MQSA.

Adopt proposed subsection (a) to specify the requirements for renewing an MMC. These requirements were implemented through the Department's former

mammography facility accreditation processes. See also the discussions regarding section 30315.20(b) addressing the certificate's validity period and the meaning of "mammography machine certificate" in proposed section 30315.10(b)(19).

Proposed subsection (a)(1) is needed to ensure that a user will apply for an MMC renewal far enough in advance to continue using the radiation machine into the next certification period without interruption. The time period needed for renewal is significantly less than seven months since the renewal process for an MMC does not include the CIR that was required in section 30315.35 formerly adopted to maintain FDA-AB status. The Department determined, based upon experience processing applications for renewing an FAC that sixty days provides more than enough time to complete the renewal process for an MMC.

Subsection (a)(1) also informs the user to update information to account for changes since initial or last renewal of the certificate to ensure the Department has current information. Based on staff experience processing applications for renewing FACs, a majority of the personnel information required for renewal remains unchanged at the time of renewal.

Proposed subsection (a)(2) is needed to ensure the facility will continue to provide quality mammography.

**Repeal section 30315.24.** This section is repealed since the Department no longer issues IFACs for purposes of maintaining FDA-approved AB status.

**Repeal and Adopt section 30315.33.** The title is changed to reflect the contents of this amended section. Existing subsection (a) is repealed and the section restructured to maintain consistency with this proposal.

Proposed subsection (a) carries forward some of the existing provisions and is needed to specify the information needed by the Department to issue an MMC pursuant to section 30315.22 as follows:

- Paragraph (1) is needed to identify the applicant to whom a certificate will be issued and the mailing address is needed to know where to mail the certificate and for notification pursuant to section 30315.34.
- Paragraph (2) is needed to provide the Department with a single contact person. This reduces confusion for the facility and the Department when scheduling inspections or other needed communication such as submitting records and mammograms for review pursuant to section 30315.36.
- Paragraph (3) is redesignated from existing subsection (a)(5) without change.
- Paragraphs (4) and (5) are needed to verify the applicant complies with section 30317.10(a) regarding the LSP and the quality control (QC) technologist. See also the discussion regarding section 30317.10(a).
- Paragraph (6) is needed to verify the applicant complies with section 30315.50(a)(1). The number and expiration date shown on the certificate or permit issued pursuant to section 30466 is needed to verify each physician who may supervise individuals performing mammography holds the appropriate authorization.

- Paragraph (7) is needed to verify the applicant complies with section 30315.50(a)(2). The certificate number and expiration date shown on the certificate issued pursuant to section 30455.1 is needed to verify each individual performing mammography holds the appropriate authorization.
- Paragraph (8) is needed to ensure that the radiation machines used for mammography meet this proposal and to identify the machine on which the MMC will be posted. Subparagraphs (A) through (C) are needed to perform on-site inspections and to provide additional verification the radiation machine is registered. In addition, this information is needed to determine if the user is required to meet the additional requirements for mobile mammography specified in section 30318.10. A copy of the survey report specified in proposed section 30316.60 is needed for the Department to determine if each mammography system meets the requirements in proposed sections 30316 and 30316.20. Subparagraph (D) is needed to determine if the radiation machine is subject to federal MQSA, to verify federal certification status, when applicable, and to ensure compliance with proposed section 30315.20(c). Subparagraph (E) is redesignated from existing subsection (a)(16) and revised for consistency with this proposal.
- Paragraph (9) is redesignated from existing subsection (a)(23) and revised for consistency with this proposal.

**Amend section 30315.34.** This section was originally adopted in 2003 to address the former Permit Reform Act (PRA) that was repealed by the Legislature in 2003 (Statutes of 2003, chapter 229). Though the PRA was repealed, the Department is maintaining this section, as revised, to clearly inform applicants of processing times and what is expected of the applicant.

Subsection (a) is amended to delete reference to the FAC, which is no longer issued, and replace it with MMC for consistency with this proposal. Terminology in paragraphs (1) and (2) are revised for consistency with section 30315.33 terminology regarding applications.

Subsection (b) is amended to clarify when the 30 day response time begins and to correct a punctuation error resulting in no regulatory effect.

Subsection (c) is amended for consistency with application terminology and to revise the reference to what document is issued. The six month time frame is changed to 30 days since the process to obtain the Department-issued MMC excludes the CIR process required under federal MQSA and as found in existing section 30315.35. Based on staff experience and for consistency with radiation machine registration requirements pursuant to section 30108, 30 calendar days after receipt of an acceptable application is sufficient for processing an MMC application.

Existing subsection (d) is repealed as those processing time frames were based on activities of the early 2000's.

**Repeal section 30315.35.** This section was adopted to maintain FDA-approved AB status under federal MQSA and is repealed to remove duplicative processes. Facilities providing screening or diagnostic mammography services remain subject to CIR under federal MQSA, as required for accreditation by an FDA-approved AB, and use of radiation machines for interventional mammography is not subject to CIR.

**Amend section 30315.36.** Amend subsection (a) for consistency with MQAA and to clarify that mammography review requirements apply to all users, whether or not they are accredited under the federal MQSA. Amend subsections (b) and (c) by changing “facility” to “user” for consistency with MQAA. Grammatical changes are made resulting in no regulatory effect. Amend subsection (c)(3)(A) to coincide with the repeal of section 30315.35. Amend subsection (c)(3)(B)3. since the California Department of Public Health is the successor to the Department of Health Services of the State of California.

**Repeal and Adopt section 30315.50.** The title is changed to reflect the contents of this amended section. Subsection (a) is deleted and proposed subsection (a)(1) is adopted for consistency with this proposal’s removal of certain components adopted for purposes of maintaining FDA-approved AB status under federal MQSA. As discussed regarding section 30315.10(b)(14), the Department does not have authority over who can interpret a mammogram unless so authorized as an AB. Since the Department is no longer an AB under federal MQSA, this proposal replaces the requirements for physicians interpreting mammograms with requirements for physicians who supervise individuals performing mammography for consistency with the RT Act. However, this amendment will have no impact since the performance of screening and diagnostic mammography and interpretation of mammograms remain subject to federal MQSA.

Proposed subsection (a)(2) (redesignated from section 30315.51 with modification) is needed to clarify the criteria persons performing mammography must meet for consistency with the RT Act. See also discussion regarding section 30315.51.

**Repeal section 30315.51.** This section is no longer needed since subsection (a)(1) is redesignated to section 30315.50(a)(2). Subsection (a)(2) is deleted for consistency with this proposal to remove provisions adopted for purposes of maintaining AB status with FDA under federal MQSA. Because this proposal is also addressing interventional mammography, which is not subject to federal MQSA, deletion clarifies that an individual performing interventional mammographic examinations is not subject to 21 CFR 900.12(a)(2). However, individuals performing screening or diagnostic mammography in California remain subject to federal MQSA requirements of 21 CFR 900.12(a)(2).

**Repeal and Adopt section 30315.52.** The title is changed for consistency with the name change of the medical physicist to mammography medical physicist as discussed regarding section 30315.10(b)(20). The section is repealed and readopted to more clearly present the provisions due to terminology changes as proposed in section 30315.10.

Proposed subsection (a), as proposed to be readopted, is identical to existing subsection (a) except revisions are made as follows. The effect of any change is noted:

- Paragraph (1) – no change is made.
- Paragraph (2) – changes are made resulting in no regulatory effect.
- Paragraph (3) – changes are made resulting in no regulatory effect.
- Paragraph (4) – grammatical changes are made resulting in no regulatory effect. Existing provision regarding experience obtained after April 28, 1999 is deleted as unnecessary since the provision is in full effect and duplicative of the cited provisions.
- Paragraph (5) – Existing provisions addressing training prior to April 28, 1999 are deleted as unnecessary since there are no longer any active medical physicists who were authorized by the Department under those provisions.

Existing subsection (b) currently incorporates by reference 21 CFR 900.12(a)(3)(iii) and (iv) requiring the medical physicist to maintain their qualifications by completing a certain number of continuing education units, conducting a certain number of facility surveys, and, before conducting a survey in a new mammography modality of which the physicist has not received training on, to complete eight hours of training in that new modality. The provisions as incorporated are now written directly into section 30315.52 and designated as subsections (b) and (c) with grammatical changes resulting in no regulatory effect.

Though the provisions of 21 CFR 900.12(a)(3)(iii) and (iv) were adopted for purposes of screening and diagnostic mammography, the Department proposes to also apply these standards to physicists conducting surveys of radiation machines used for interventional mammography. This is based on FDA's national standards and industry standards to ensure physicists maintain competency in performing surveys of all mammography machines and to ensure quality mammography is not compromised due to errors caused by inadequately trained physicists.

**Amend section 30315.60.** This section is amended to maintain consistency with this proposal and to clarify Department actions relating to processing applications.

Subsection (a) is amended for consistency with the changes to subsections (g) through (k). See discussion of those subsections. A nonsubstantial punctuation correction is made.

Subsection (a)(2) is amended by deleting subparagraph (B) and restructuring the sentence for grammatical purposes resulting in no regulatory effect. Subparagraph (B) is deleted as unnecessary since it is addressed in subsection (4), as redesignated.

Subsection (a)(3) is deleted as unnecessary since it applies to, and is addressed in, the alternative found in subsection (a)(4), as redesignated, and to renewal applications as discussed in subsection (c), as redesignated.

Subsection (a)(4), redesignated (a)(3), is amended to reduce the number of reports the applicant must submit. The Department has determined that only one survey report is

needed for review because all survey reports as specified in section 30316.60 contain the same information. Reference to medical physicist is changed to mammography medical physicist for consistency with the changes discussed regarding section 30315.10(b)(20). The provision requiring certain language and data is deleted as unnecessary since the report, under section 30316.60, must contain certain information, which is more useful in determining the applicant's competency. A nonsubstantial grammatical correction is made.

Subsection (a)(5) is deleted since the information required is of no practicable value because the instruments and methods used by the applicant are maintained by the mammography medical physicist conducting the survey and providing direct supervision of the applicant. In addition, the Department has determined that it can ensure that a mammography medical physicist is using the appropriate equipment and methods for performing surveys by comparing the Department's inspections results with those in the survey reports.

Subsection (a)(6), redesignated (a)(4), is amended for consistency with FDA's changes to 21 CFR 900 (67 FR 5467 (Feb. 6, 2002)) since Article 4.5 was adopted. Reference to subsection (a)(3) is deleted since that provision is deleted resulting in no regulatory effect.

Subsection (b) is repealed as unnecessary. This subsection addressed the alternative qualification pathway of those physicists approved under FDA's interim regulations and who had completed certain requirements prior to April 28, 1999. This pathway is proposed to be deleted as discussed regarding section 30315.52(a)(5). Thus, subsection (b) is deleted since the alternative pathway is deleted resulting in no regulatory effect.

Subsection (c) is deleted since this proposal now applies to all radiation machines used to perform interventional mammography or research mammography. Though this proposal would accept surveys of radiation machines used to perform interventional or research mammography, acceptance is only for purposes of California MQAA, not for purposes of federal MQSA. FDA continues to exclude such surveys for purposes of qualifying a medical physicist under federal MQSA.

Subsection (d) is redesignated as (b) to maintain a coherent structure.

Subsection (e), redesignated (c), is amended to clarify when the renewal application must be submitted. Thirty days prior to expiration of authorization is proposed for consistency with the application processes found in 17 CCR 30403.5 and 30456.2(b). The Department has determined through experience that thirty days is sufficient for processing renewal applications. The word "and" is added at the end of the provision for grammatical purposes and consistency with the restructuring of provisions resulting in no regulatory effect.

Subsection (e)(2) is deleted to coincide with the deletion of subsection (a)(5) resulting in no regulatory effect.

Subsection (e)(3) is deleted as unnecessary since subsection (e)(4), redesignated subsection (c)(2), addresses this information resulting in no regulatory effect.

Subsection (e)(4), redesignated subsection (c)(2), is amended for consistency with the restructuring of section 30315.52(b) resulting in no regulatory effect.

Subsection (f) is redesignated (d) to maintain a coherent structure and to make nonsubstantial grammatical corrections resulting in no regulatory effect. Subsection (d)(1), as redesignated is amended for consistency with the restructuring of section 30315.52(b) resulting in no regulatory effect. Proposed subsection (d)(6) is needed to clearly inform individuals that they are subject to section 30105 addressing deliberate misconduct as defined in that section.

Subsections (g) through (k) were originally adopted to address the former PRA that was repealed by the Legislature in 2003 (Statutes of 2003, chapter 229). Though the PRA is no longer effective, the Department believes that the public benefits in knowing what to expect when applying for authorization. Proposed revisions are based on the processing provisions of 17 CCR 30405 for consistency as follows:

- Proposed subsection (e) is needed to clarify the start time of processing the application. Currently, the section does not provide a start time. This proposal is based on 17 CCR 30405(a).
- Subsections (g) through (j) are redesignated (f) through (i), respectively, and amended to maintain a coherent structure and to ensure cross references remain properly connected due to restructuring resulting in no regulatory effect.
  - A punctuation correction is made in subsection (g), as redesignated, resulting in no regulatory effect.
- The words “complete” and “incomplete” are revised for consistency with terminology regarding eligibility. Under the former PRA, terminology established when an application was complete, which then established the historical processing times found in subsection (k).
- Subsection (k) is deleted as it is no longer useful since it is based on processing activities of the early 2000’s.

**Amend section 30316.** The section title is amended for consistency with the contents of the section resulting in no regulatory effect.

Amend subsection (a) to include radiation machines that have been modified or equipped with special attachments because these machines are needed to perform interventional mammography. Subsection (a) was adopted to correspond to 21 CFR 900.12(b)(1), which applies only to radiation machines used to perform screening or diagnostic mammography whereas this proposal addresses radiation machines used to perform all types of mammography, including interventional mammography. This amendment will have no effect regarding radiation machines used to perform screening or diagnostic mammography since such use remains subject to federal MQSA. A nonsubstantial punctuation correction is made.

Amend subsection (b)(8) to delete an obsolete date, correct grammar and restructure paragraph (8) to maintain a coherent structure. This results in no regulatory effect.

Amend subsection (b)(9) to include a clarifying phrase regarding the technical components of mAs and to correct a typographic error. This results in no regulatory effect.

Amend subsection (b)(10) for consistency with usage of the phrase “AEC mode” found in subsections (b)(11) and (b)(12). This results in no regulatory effect.

Amend subsection (b)(12) for consistency with general industry terminology since a screen-film system uses screen-film image receptors. This results in no regulatory effect.

Amend subsection (b)(13) for consistency with 21 CFR 900.12(b)(5). This results in no regulatory effect.

Amend subsection (c) for consistency with terminology usage in this proposal. This results in no regulatory effect. Subsection (c)(1) is deleted based on Department inspection experience regarding the availability of a minimum number of image receptors. This provision was adopted to assist facilities in operating quickly and efficiently as specified in H&S Code 115060(f). It also addressed film and screen manufacturer recommendations that cassettes should not be used for a minimum period of time after being loaded so that air between the film and the screen can bleed out. This delay ensures good film/screen contact, which directly impacts the quality of the mammogram. It further provides the facility with additional image receptors in case one is damaged. However, technological advances since the original adoption in 2003 resulted in a majority of mammograms being obtained via digital imaging and film and screen manufacturers have modified cassettes so as to nearly eliminate the time needed to ensure good film/screen contact. Further, based on experience obtained during annual Department inspections this provision is no longer needed. Therefore, it is deleted and the subsection is restructured to maintain a coherent structure.

Subsection (c)(5), redesignated to (c)(4), is amended for consistency with the deletion of references to interpretation of mammograms as discussed regarding terminology changes in section 30315.10.

Repeal subsection (d) and redesignate record keeping requirements to section 30317.20. See section 30317.20 for discussion.

**Amend section 30316.10.** The title is amended to clearly indicate the content of the section resulting in no regulatory effect.

Subsection (b) is amended for consistency with the terminology change regarding medical physicists as discussed regarding section 30315.10(b)(20).

Subsections (c) and (d) are repealed since they were adopted for maintaining FDA-

approved AB status and apply to radiation machines used for mammography in facilities accredited pursuant to MQSA. The processes and documents issued for radiation machines certified pursuant to MQAA are discussed in sections 30315.20, 30315.22, 30315.23 and 30315.33. Installation of a new radiation machine is addressed in section 30315.20(a). The new machine must be certified pursuant to section 30315.22 before being used for mammography. The provision regarding the installation of a new processor is deleted because it is duplicative of section 30316.20(a) that requires each film processor used to develop mammograms to be adjusted and maintained to meet the technical development specifications for the mammography film in use.

Subsection (e) is redesignated (c) and amended for consistency with the repeal of section 30319.20 and the amendments in section 30317.20 regarding records. A nonsubstantial punctuation correction is made.

**Amend section 30316.20.** Subsections (b) and (b)(3) are amended for consistency with the repeal of section 30316.22 and the amendment of the term “phantom” in section 30315.10(b)(25). See sections 30316.22 and 30315.10(b)(25) for discussion. Subsection (b) is also amended to clarify that the phantom image must be processed in the film processor that may be used to develop mammograms. This requirement is found in existing section 30316.40 and is placed in this section for clarity. Nonsubstantial punctuation corrections are also made in subsection (b). Subsection (b)(1) is amended for consistency with 21 CFR 900.12(e)(1) resulting in reducing the required test image optical density from 1.40 to 1.20. This reduction is needed for consistency with FDA’s requirements and ABs nationally. Subsections (b)(1) and (b)(2) are also amended to more clearly state the provisions.

Subsection (d)(1) is amended to reduce the optical density value of 1.4 to 1.20 for consistency with changes to subsection (b)(1).

Subsection (e) is amended for consistency with the terminology change regarding medical physicist as discussed in section 30315.10(b)(20). Subsection (e)(1) is deleted since these requirements are no longer in effect. Subsection (e)(2) is redesignated (e)(1) to maintain a coherent structure resulting in no regulatory effect.

Existing subsection (e)(3) is deleted since the Department has determined through its inspection experience that AEC density controls now commonly function as intended by their manufacturers and therefore no longer need verification of their accuracy through the tests specified in this subsection.

Subsection (e)(4) is redesignated to (e)(2) and amended to remove duplicative criteria already specified in subsection (b) and to maintain consistency with the changes to subsection (b).

Subsections (e)(5) and (e)(6) are redesignated to subsections (e)(3) and (e)(4), respectively, to maintain a coherent structure resulting in no regulatory effect.

Subsection (e)(7)(A) is deleted since the requirement is no longer in effect. Subsection

(e)(7)(B) and its provisions are redesignated subsection (e)(5) and restructured to maintain a coherent structure. This change results in no regulatory effect.

Subsections (e)(8) through (e)(12) are redesignated subsections (e)(6) through (e)(10) to maintain a coherent structure resulting in no regulatory effect.

Subsection (e)(13) is redesignated subsection (e)(11) and amended for consistency with the restructuring of the section resulting in no regulatory effect.

Subsection (e)(14) is redesignated subsection (e)(12) to maintain a coherent structure resulting in no regulatory effect.

Subsection (e)(15) is deleted since the requirements are no longer in effect.

Subsection (e)(16) is redesignated to subsection (e)(13) to maintain a coherent structure, delete an obsolete date and to correct grammar resulting in no regulatory effect.

Subsections (e)(17) and (e)(18) are redesignated to subsections (e)(14) and (e)(15), respectively, to maintain a coherent structure resulting in no regulatory effect.

Subsection (e)(19) is redesignated to subsection (e)(16) and amended for consistency with the restructuring of this section to maintain a coherent structure resulting in no regulatory effect.

Subsection (f)(3) is amended to delete language formerly adopted for purposes of maintaining FDA-approved AB status as based on FDA's guidance. Though this language is deleted, facilities performing screening or diagnostic mammography remain subject to MQSA and the requirements of their AB. Facilities using radiation machines for interventional mammography are not subject to MQSA and the Department is not proposing to place that requirement on such use.

Subsection (g) is amended and subsection (h) is repealed for consistency and clarity with the restructuring of this section and to present the provisions more clearly resulting in no regulatory effect.

Subsections (i) and (j) are redesignated subsections (h) and (i), respectively, to maintain a coherent structure and make a punctuation correction resulting in no regulatory effect. Subsection (i), as redesignated, is amended for consistency with the repeal of section 30319.20 and amendment of section 30317.20 regarding records.

**Repeal section 30316.22.** This section is repealed since the Department is no longer an AB authorized to specify the phantom used in the facility accreditation process. Also, certain phantoms specified in this section are no longer in production and newer phantoms have been approved by the FDA since the provisions were adopted. This will allow facilities providing screening or diagnostic mammography services and users possessing a radiation machine used for interventional mammography to use any

phantom approved by the FDA for mammography quality control. See also the discussion of “phantom” in section 30315.10(b)(25).

**Repeal and Adopt section 30316.30.** The existing provisions are deleted and rewritten to present the scoring protocol more clearly. Proposed subsection (a) is needed to inform facilities subject to federal MQSA that since the Department is no longer an AB the facility must comply with the requirements the facility’s AB has established pursuant to 21 CFR 900.4(d)(3) for mammography systems used to perform screening or diagnostic mammography.

Proposed subsection (b) is needed to specify the minimum phantom image score required for mammography systems used to perform interventional mammography. The minimum phantom image score is based on both the standard established by the ACR in their “1999 Stereotactic Breast Biopsy Quality Control Manual (Reference 3, pages 21-27) and Appendix B of the Rules of Good Practice (Section III.C.6.a) (Reference 1). This change has no impact since these phantom image scores were implemented for interventional mammography through Appendix B requirements.

Proposed subsections (b)(1) through (b)(3) is needed to specify how to score the image to determine if the image meets the scoring values. This protocol is based on ACR’s standard. This change has no impact since the Department applied the protocol on mammography systems used to perform interventional mammography pursuant to Appendix B of the Rules of Good Practice (Reference 1).

**Repeal section 30316.40.** This section is repealed because it is redesignated to section 30316.20(b). This provides clarity by placing the requirement to process a phantom image using the film processor used to process mammograms in the same place the phantom image test requirement is found.

**Repeal section 30316.50.** This section requires certain information to be placed on the actual mammogram and was adopted to maintain FDA-approved AB status under federal MQSA. A mammogram is a patient record as defined in H&S Code 123105(d) as it is a record relating to the health history, diagnosis, or condition of a patient. Because the RCL, via mammogram certification as defined in H&S Code 114985(q), focuses on certification of the machine and not on patient records, this section is repealed. However, for the use of X-ray in mammography by facilities providing screening or diagnostic mammography, there will be no regulatory impact since those facilities remain subject to federal MQSA. The Department is not proposing to impose these provisions on interventional mammography since such use has never been subject to the provisions and patient records are already addressed in H&S Code 123100 et seq.

**Amend section 30316.60.** The title is changed to reflect the contents of this amended section. Subsections (a) and (b) are amended for consistency with the terminology change of “medical physicist” to “mammography medical physicist” as discussed in section 30315.10(b)(20). Subsection (b)(1) is amended to delete the requirement that the calibration record be included with the survey report since the calibration record is

not useful to the user and the Department uses its inspection results to better evaluate the physicist's performance. Subsection (c) is amended for consistency and clarity with placing the applicable provision into a new location resulting in no regulatory effect. Subsection (d) is amended for consistency with deletion of the calibration documentation in subsection (b)(1), proposed section 30315.05, and the re-designation of record keeping requirements to section 30317.20 from 30319.20 resulting in no regulatory effect.

**Amend section 30316.61.** The title is changed for consistency with terminology change as discussed in section 30315.10(b)(20). The requirements for maintaining the calibration record is deleted for the reasons discussed regarding section 30316.60(b)(1).

**Repeal section 30317.** This section is repealed for consistency with this proposal and the provisions redesignated as follows. For discussion, refer to the redesignated section:

- Subsection (a) – Section 30317.10(b)(5).
- Subsection (b) – Section 30317.10(b)(5) and (d).
- Subsection (c) – Section 30317.10(b)(1) and (4).
- Subsection (d) – Section 30317.10(b)(3).
- Subsection (e) – Section 30317.10(b)(3).
- Subsection (f) – Section 30317.10(c).
- Subsection (g) – Section 30317.20(b)(1).

**Repeal and Adopt section 30317.10.** Existing subsection (a) is repealed and re-adopted to present the provisions more clearly.

Subsection (a) is needed to clearly inform the user of their responsibility to the Department, and, more importantly, to the public, for ensuring quality mammography is provided. The Department continues to encounter users that attempt to redirect their responsibility to others that perform tasks for the user. This proposal clarifies that though certain individuals are to carry out certain tasks, the user is ultimately responsible to ensure those tasks are performed properly.

Subsection (b) is needed to maintain consistency with this proposal by ensuring the user has designated a physician to oversee the mammography QA program. As discussed regarding section 30315.10(b)(14), both federal MQSA and existing Article 4.5 require QA program oversight to ensure quality mammography is provided to the public. Those responsibilities of the LSP as found in existing regulations are more clearly presented as follows:

- Subsection (b)(1) addresses existing section 30317(c)
- Subsection (b)(2) addresses existing section 30317.10(a)
- Subsection (b)(3) addresses existing section 30317(d) and (e)
- Subsection (b)(4) addresses existing section 30317(c)
- Subsection (b)(5) addresses existing section 30317.10(a) and (b)

Subsection (c) is redesignated from section 30317(f) resulting in no regulatory effect.

Subsections (d) and (d)(1) address existing section 30317(a) and (b) and clarify that the QA procedure found in section 30318.10(b) falls within the QC technologist's responsibility. The tests in section 30318.10(b) are the same tests performed under section 30316.20(a) and (b).

Subsection (d)(2) is needed to clarify who must perform the tests for mammography systems using image receptor modalities other than film-screen systems (i.e. digital systems) pursuant to existing section 30316.20(e)(19). Pursuant to section 30316.20(e), the mammography medical physicist is required to verify the QA program for digital systems used within the facility meets the QA program recommended by the image receptor manufacturer. However, existing regulations fail to clarify that the recommended tests must be performed and who must perform them and only require the physicist to verify the QA program meets the manufacturer's recommendation. Thus, subsection (d)(2) makes it clear that the tests must be performed and the QC technologist must ensure they are performed.

Subsection (d)(3) is needed to ensure the technique chart is always available since these charts can be lost by the operator or removed from posting locations without replacement.

Subsection (d)(4) addresses existing section 30317.30(a)(5) and is revised to remove the date of publication for Title 29, Code of Federal Regulations, section 1910.1030. The date is removed because the employer is subject to those provisions at all times making the date irrelevant. That provision addresses an employer's responsibility to their employee regarding exposure to blood borne pathogens.

**Repeal and Adopt section 30317.20.** The title is changed to reflect the contents of this section; namely, record keeping requirements. Currently, subsection (a) specifies the contents and documents of the QA manual. How long those documents must be maintained is found in section 360319.20. These provisions are proposed to be repealed as unnecessary for the following reasons:

- The QA manual served to centralize records. It is basically a compilation of QA records documenting performance of QA tests. The Rules of Good Practice was developed in the late 1980's and approved by the RTCC in 1990 (Reference 1). Those Rules were adopted when MQAA was enacted in 1992. Since enactment of both MQAA and federal MQSA, facility records of QA tests, equipment, and corrective actions has become more centralized and are now in electronic format making the concept of a "manual" obsolete.
- The proposed record keeping provisions maintain the essential records, consistent with the Rules of Good Practice, showing QA test performance and maintains the ability of Department inspectors to evaluate the outcomes of that performance and, if problems found, to evaluate the records and assist the facility in focusing on causes for correction (Reference 1).

Subsection (a)(1) (formerly section 30319.20(c)) is needed to verify all radiation

machines subject to registration are registered and that the user can account for all radiation sources.

Subsection (a)(2) (formerly section 30319.20(a)) is needed to ensure the user has used qualified individuals in evaluating the indicated equipment and that the equipment can provide quality mammograms.

Subsection (a)(3) (formerly section 30319.20(a)) is needed to ensure the required surveys are performed and that the equipment continues to meet the indicated standards.

Subsection (a)(4) (formerly section 30319.20(a)) is needed to determine if tests are performed, problems corrected, and the mammography QA program is effective.

Subsection (b) (formerly section 30319.20(a)) is needed to inform the user how long the records must be maintained.

Subsection (c) (formerly section 30319.20(a)) is needed to ensure only qualified individuals are allowed to perform mammography.

**Repeal section 30317.30.** This section was adopted for purposes of maintaining AB status under federal MQSA. It is now repealed because the Department is no longer an AB. Repealing this section will have no impact on facilities providing screening or diagnostic mammography services since such facilities remain subject to federal MQSA. Facilities using radiation machines for interventional mammography are not subject to MQSA and the Department is not proposing to place that requirement on such use. However, subsection (a)(5) is redesignated to section 30317.10(d)(4) as it addresses disinfection of equipment due to blood borne pathogens. See section 30317.10(d)(4) for discussion.

**Repeal section 30317.40.** This section was adopted for purposes of maintaining AB status under federal MQSA. It is now repealed because the Department is no longer an AB. Repealing this section will have no impact on facilities providing screening or diagnostic mammography services since such facilities remain subject to federal MQSA. Facilities using radiation machines for interventional mammography are not subject to MQSA and the Department is not proposing to place that requirement on such use since the content relates to interpretation of a mammogram to determine if an intervention is necessary.

**Repeal section 30317.50.** This section was adopted for purposes of maintaining AB status under federal MQSA. It is now repealed because the Department is no longer an AB. Repealing this section will have no impact on facilities providing screening or diagnostic mammography services since such facilities remain subject to federal MQSA. Facilities using radiation machines for interventional mammography are not subject to MQSA and the Department is not proposing to place that requirement on such use. However, medical record retention and patient access to medical records remain in effect as provided in H&S Code sections 123100 et seq.

**Repeal section 30317.60.** This section was adopted for purposes of maintaining AB status under federal MQSA. It is now repealed because the Department is no longer an AB. Repealing this section will have no impact on facilities providing screening or diagnostic mammography services since such facilities remain subject to federal MQSA. Facilities using radiation machines for interventional mammography are not subject to MQSA and the Department is not proposing to place that requirement on such use.

**Repeal section 30317.70.** This section was adopted for purposes of maintaining AB status under federal MQSA. It is now repealed because the Department is no longer an AB. Repealing this section will have no impact on facilities providing screening or diagnostic mammography services since such facilities remain subject to federal MQSA. Facilities using radiation machines for interventional mammography are not subject to MQSA and the Department is not proposing to place that requirement on such use. However, the Department continues to accept complaints from the public and evaluates those complaints on a case-by-case basis.

**Amend section 30318.10.** The title is changed to reflect the contents of this amended section. Subsection (a) is amended for consistency with deletion of the term “mobile service provider” in existing section 30315.10(b)(30) and the proposed term of “mobile mammography” in section 30315.10(b)(23). This terminology change maintains consistency with mammography industry usage. Additional grammatical revisions are made for clarity resulting in no regulatory effect. Paragraph (1) is amended for consistency with proposed section 30315.05. Paragraph (2) is amended because the Department no longer accredits facilities under federal MQSA. The name and telephone number of a contact person for the user is proposed and is needed so Department inspectors can contact a person who has the applicable knowledge regarding the submitted notice. Paragraph (4) is amended to assist inspectors in accessing registration databases and files to ensure the mammography machine is registered as required by H&S Code 114985(q). The existing requirement is no longer needed since the user’s contact person has this information available if requested. Paragraph (5) is amended to identify the mammography machine and ensure it has been evaluated by the mammography medical physicist for determining it meets section 30316. The existing provision is not needed since the user’s contact person informs inspectors during an inspection where each room is located.

Existing subsections (b), (c) and (d) are deleted, and the provisions restructured into proposed subsection (b) and revised for clarity. As revised, the proposal clarifies that the provision applies to screen-film mammography since the standards do not apply to digital imaging. It also clarifies that the individual operating the radiation machine is to determine the applicable standards are met since mobile mammography, in general, is carried out by only one person.

Subsection (e) is deleted and replaced with proposed subsection (c) to clarify what records must be kept and where those records are located so Department inspectors can evaluate the records. This provision is redesignated from section 30318.11(b). Evaluation of these records is needed for determining if problems have been addressed and whether quality mammography is compromised.

**Repeal and Adopt section 30318.11.** The title is changed to reflect the contents of this amended section and consistency with this proposal.

Subsection (a) is repealed and readopted to more clearly present the provisions and for consistency with this proposal. Proposed paragraphs (1) through (3) are redesignated from existing subsections (a)(1) through (a)(3). Existing subsection (a)(4) is deleted since it is addressed in section 30315.20(a). Existing subsection (a)(5) is deleted since an AB and FDA under federal MQSA may establish its own posting requirement. Existing subsections (a)(6) through (8) are deleted and addressed in section 30317.20. See that section for discussion.

Existing subsection (b) is redesignated to proposed section 30318.10(c). See that section for discussion.

**Amend section 30319.** Subsection (a) is amended for consistency with this proposal to increase clarity of mammogram certification under California's MQAA instead of accreditation under federal MQSA.

Subsection (a)(1) is amended for consistency with the changes to section 30315.22 and increasing clarity of state requirements as opposed to federal requirements.

Subsection (a)(2) is deleted since only one entity is approved by FDA to accredit mammography facilities within the state of California.

Subsection (a)(3) is redesignated (a)(2), and changed for clarity resulting in no regulatory effect. A nonsubstantial grammatical correction is made.

Subsections (a)(4) through (a)(6) are deleted as unnecessary since they specify information that would be reported pursuant to subsection (a)(1).

Subsection (a)(7) is deleted for consistency with the changes to section 30316.10.

Subsection (a)(8), redesignated (a)(3), is amended since an unsatisfactory image quality report from the AB may require the Department to invoke section 30315.36 regarding mammography reviews so as to determine if quality mammography is compromised.

Subsection (a)(9) is deleted as unnecessary since it would be reported pursuant to subsection (a)(1).

Subsection (b) is amended for consistency with terminology changes in this proposal and to also require the name and signature of the LSP, as defined in section 30315.10(b)(14) and as discussed in that proposed provision. Requiring the LSP's name and signature is needed since the LSP is the overseer of the QA program to ensure produced mammograms are of high quality. This further ensures the user and LSP maintain communication and can address any issues that may compromise quality mammography.

**Repeal section 30319.20.** This section is repealed and the provisions are addressed in section 30317.20. See that section for discussion.

**Amend section 30320.90.** The section is amended for consistency with this proposal to increase clarity of mammogram certification under California's MQAA instead of accreditation under federal MQSA.

Subsection (a) is amended for consistency with the terminology changes regarding issued documents.

Subsections (a)(3) and (a)(4) are revised to delete the reference to CIRs since those provisions are proposed to be deleted.

Subsection (a)(7) is amended to be specific for mammogram certification since the Department no longer accredits mammography facilities.

Subsection (a)(8) is deleted to coincide with the repeal of section 30317.50.

Subsection (a)(9) is redesignated (a)(8) and amended to coincide with the redesignation of section 30316.20(e)(10) to section 30316.20(e)(8).

Subsection (a)(10) is redesignated (a)(9) and amended to coincide with the redesignation of section 30316.20(b)(3) to section 30316.30.

Subsection (a)(11) is deleted to coincide with the repeal of section 30317.30.

Subsection (a)(12) is redesignated (a)(10) to maintain a coherent structure and make a nonsubstantial grammatical correction.

#### **Documents Relied Upon (11346.2(b)(3))**

1. Rules of Good Practice for Supervision and Operation of Mammographic X-Ray Equipment, State of California, Department of Health Services, May 1990.
2. 1999 Mammography Quality Control Manual, American College of Radiology, pages 335 and 339.
3. 1999 Stereotactic Breast Biopsy Quality Control Manual, American College of Radiology, pages 21-27.

#### **ECONOMIC IMPACT ASSESSMENT**

The Department has determined that the regulations affect the following as described:

- **The creation or elimination of jobs within the State of California.** This proposal is unlikely to create or eliminate jobs as it clarifies and restructures provisions for consistency with current practices.
- **The creation of new businesses or the elimination of existing businesses within the State of California.** This proposal is unlikely to create new businesses or eliminate existing businesses as it clarifies and restructures provisions for consistency with current practices.

- **The expansion of businesses currently doing business within the State of California.** This proposal will not result in expansion of businesses as it clarifies and restructures provisions for consistency with current practices.
- **The health and welfare of California residents, worker safety, and the environment.** This proposal increases benefits to residents by certifying only those radiation machines that are capable of providing quality mammography for the detection of breast cancer. This proposal increases benefits to worker safety by clarifying QA tests and responsible persons over such tests. This proposal would not significantly affect the state's environment because the radiation energy emitted from the use of X-ray equipment dissipates to normal atomic structures without environmental contamination.

**Small Business Determination (11346.2(b)(4)(B)):** The Department has determined that there would be an effect on small businesses subject to these regulations because small businesses are currently required to comply with the regulations.

**REASONABLE ALTERNATIVES (11346.2(b)(4)(A); (11346.5(a)(13)):**

The Department must determine that no reasonable alternative considered by the Department, or that has otherwise been identified and brought to the attention of the Department, would be more effective in carrying out the purpose for which the action is proposed; would be as effective and less burdensome to affected private persons than the proposed action; or would be more cost-effective to affected private persons and equally effective in addressing the provisions of MQAA.

Alternatives considered in this proposal are discussed or addressed in the detailed discussion of each regulation section.

**SIGNIFICANT ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS:**

The Department has determined that the proposed regulatory action would have no significant adverse economic impact on California business enterprises and individuals, including the ability of California businesses to compete with businesses in other states. The Department estimates no significant adverse economic impact because the proposed regulatory action clarifies and restructures provisions for consistency with current practices.

**LOCAL MANDATE**

The Department has determined that the proposed regulation action 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.