

Title 17
Division 1. State Department of Health Services
Chapter 5. Sanitation (Environmental)
Subchapter 4. Radiation
Group 3. Standards for Protection Against Radiation
Article 4.5. Requirements for the Use of X-Ray in Mammography

Adopt Section 30315.05 within Article 4.5 to read as follows:

§ 30315.05. References to Facility.

Except when grammatical and contextual usage dictates otherwise, any reference to “facility” within this Article shall refer to a “user” as defined in section 30100. When contextual usage so dictates, “facility” shall have the meaning specified in section 30315.10. This section may not be construed to allow the performance of mammography in violation of the Act or this regulation, as defined in section 30100, the Radiologic Technology Act as defined in Health and Safety Code section 27(f), or any federal law or regulation pertaining to mammography.

NOTE: Authority cited: Sections 114975, 115060 and 131200, Health and Safety Code. Reference: Sections 115060, 131050, 131051 and 131052, Health and Safety Code.

Amend section 30315.10 to read as follows:

§ 30315.10. Definitions.

- (a) The definitions in section 30100 shall apply to this article.
- (b) As used in this article:
 - (1) “Action limit” means the minimum or maximum value of a quality assurance measurement representing acceptable performance.
 - (2) ~~“Activities” means the operation of a mammography system to produce the mammogram, the initial interpretation of the mammogram and the maintenance of the viewing conditions for that interpretation.~~
 - (3) ~~“Adverse event” means an undesirable experience associated with mammography activities such as:~~

- ~~(A) Poor image quality;~~
- ~~(B) Failure to send mammography reports within 30 calendar days from the date of the mammographic examination to the referring physician or to the patient; and~~
- ~~(C) Use of personnel that do not meet the applicable requirements of sections 30315.50, 30315.51 or 30315.52.~~

~~(4)~~(2) “Air kerma” means the kerma, measured in Gray (Gy), in a given mass of air.

~~(5)~~(3) “Automatic exposure control” (AEC) means a device that automatically controls one or more technique factors in order to obtain at pre-selected locations a required quantity of radiation.

~~(6)~~(4) “Average glandular dose” means the value in millirad (mrad) or milligray (mGy) for a given breast or phantom thickness that estimates the average absorbed dose for the glandular tissue extrapolated from free air exposures and based on fixed filter thickness and target material.

~~(7) “Category I” means medical educational activities that have been designated as Category I by the Accreditation Council for Continuing Medical Education, the American Osteopathic Association, or a state medical society.~~

~~(8) “Clinical image review” means the process whereby the mammograms produced by a specific mammography system are evaluated for image quality.~~

~~(9) “Consumer” means an individual who chooses to comment on or complain in reference to a mammographic examination, including the patient or representative of the patient, such as a family member or referring physician.~~

~~(10)~~(5) “Continuing education unit” means ~~one hour~~50 to 60 minutes of training received through either:

(A) Face-to-face interaction between instructor(s) and student(s), as when the instructor provides a lecture, conducts demonstrations, or reviews student performance; or

(B) The administration and correction of student examinations by an instructor(s) with subsequent feedback to the student(s).

(6) “Diagnostic mammography” means the mammographic examination of patients who, by virtue of symptoms, physical findings, or screening mammography, are considered to have a substantial likelihood of having breast disease.

~~(11)(7)~~ “Direct supervision” means that a ~~the oversight of operations that include the following:~~

~~(A) During joint interpretation of mammograms, the supervising interpreting physician reviews, discusses, and confirms the diagnosis of the physician being supervised and signs the resulting report before it is entered into the patient's record.~~

~~(B) During performance of a mammographic examination, the supervising mammographic radiologic technologist is physically present to observe, and correct, as needed, the performance of the individual who is performing the mammographic examination.~~

~~(C) During performance of a survey, the supervising mammography medical physicist who is conducting the survey is physically present to observe, and correct, as needed, the performance of the individual who is performing any portion of the survey.~~

~~(12)(8)~~ “Established operating level” means the value of a particular quality assurance parameter that has been established as an acceptable normal level by the facility's quality assurance program.

~~(13)(9)~~ “Facility” means a hospital, outpatient department, clinic, radiology practice, an office of a physician, mobile setting, or other place or building in which a person conducts mammography.

~~(A) Mammography activities; and/or~~

~~(B) Interventional mammography or research mammography.~~

~~(14) “Facility accreditation certificate” means a document issued by the Department authorizing a facility to perform mammography.~~

~~(15)(10)~~ “FDA” means the United States Food and Drug Administration.

~~(16)(11)~~ “Image receptor” means any device that transforms incident X-ray photons either into a visible image or into another form that can be made into a visible image by further transformations.

~~(17) “Interpreting physician” means a licensed physician who interprets mammograms and meets the requirements of section 30315.50.~~

~~(18) “Interim Facility Accreditation Certificate” means a document issued by the Department pursuant to section 30315.24.~~

~~(19)~~(12) “Interventional mammography” means the creation of a mammogram during invasive interventions for localization, or biopsy procedures, ~~or therapeutic procedures.~~

~~(20)~~(13) “Kerma” means the sum of the initial energies of all the charged particles liberated by uncharged ionizing particles in a material of given mass.

~~(21) “Lead interpreting physician” means the interpreting physician designated either by the person who owns or leases the facility, or an authorized agent of that person to ensure that the facility’s quality assurance program meets all of the requirements of this article.~~

(14) “Lead supervising physician” means the physician designated by the user to establish and maintain the user’s mammography quality assurance program and who meets the requirements of section 30315.50(a)(1).

~~(22)~~(15) “Mammogram” means an X-ray image of the human breast.

~~(23)~~(16) “Mammographic examination” means the performance of mammography on a human being.

~~(24)~~(17) “Mammographic modality” means a technology for radiography of the breast such as screen-film mammography, digital mammography ~~and xeromammography~~, full field digital mammography, and digital breast tomosynthesis.

~~(25)~~(18) “Mammography” means the procedure for creating a mammogram for the purposes of screening, diagnostic, interventional or research mammography.

(19) “Mammography machine certificate” means the certificate issued pursuant to sections 30315.22 or 30315.23 authorizing use of the particular radiation machine for mammography.

~~(26) “Mammography medical outcomes audit” means a systematic collection of mammography results and the comparison of those results with outcome data.~~

(20) “Mammography medical physicist” means an individual authorized pursuant to section 30315.60 to conduct mammography surveys.

~~(27)~~(21) “Mammography system” means a system that includes all of the following:

- (A) A radiation machine used as a source of radiation to produce a mammogram;
- (B) An imaging receptor used for the formation of a latent image of a mammogram, or for converting X-ray photons to a digital signal;
- (C) A processing device for changing a latent image of a mammogram or a digital signal to a visual image that can be used for diagnostic or therapeutic purposes; and
- (D) A viewing device, such as a view box or computer monitor, used to visually evaluate a mammogram.

~~(28)~~(22) “Mammography system evaluation” means an evaluation of ~~the a~~ mammography system conducted by a mammography medical physicist to ensure for the purpose of making a preliminary determination as to whether the system is in compliance with sections 30316 and 30316.20(e).

~~(29) “Medical physicist” means an individual trained in performing mammography system evaluations, quality assurance testing evaluations and surveys.~~

(23) “Mobile mammography” means mammography performed in a mobile setting.

~~(30) “Mobile service provider” means a person who performs mammography in a mobile setting.~~

~~(31)~~(24) “Mobile setting” means a setting in which mammography is performed with a radiation machine that is ~~fixed or used exclusively in a mobile vehicle or unit,~~ or is transported to a different location for the purpose of ~~providing~~ performing mammography, but does not include a radiation machine moved from room to room within a facility.

~~(32) “Multi-reading” means two or more physicians interpreting the same mammogram, at least one of whom meets the requirements of section 30315.50.~~

~~(33) “Overall assessment of findings” means the results of an interpreting physician's evaluation of mammograms produced during a mammographic examination and categorized using the assessment categories specified in section 30317.40(a)(4).~~

~~(34)~~(25) “Phantom” means ~~a~~an FDA-approved test object used to simulate radiographic characteristics of compressed breast tissue and containing components that radiographically model aspects of breast disease and cancer.

~~(35)~~(26) “Phantom image” means a radiographic image of a phantom.

~~(36)~~(27) “Physical science” means physics, chemistry, radiation science (including medical physics and health physics), and engineering.

(28) “Physician” means an individual possessing a current and valid license to practice as a physician and surgeon or as an osteopathic physician and surgeon pursuant to the California Medical Practice Act specified in Business and Professions Code Section 2000 et seq.

~~(37) “Positive mammogram” means a mammogram that has an overall assessment of findings that are either “suspicious” or “highly suggestive of malignancy.”~~

~~(38) “Quality assurance technologist” means an individual who meets the requirements of section 30315.51 and has experience performing or assisting in the performance of quality assurance tests specified in section 30316.20(a) through (d) and (f)~~

~~(39)~~(29) “Quality assurance testing evaluation” means an evaluation of a facility's quality assurance testing by a mammography medical physicist to ensure quality assurance testing is performed in accordance with section 30316.20, excluding subsection (e) of section 30316.20.

(30) “Quality control technologist” means an individual meeting the requirements of section 30315.50(a)(2) who is responsible for those quality assurance tasks specified in section 30317.10(d).

~~(40)~~(31) “Research mammography” means the creation of a mammogram with an investigational mammography device as part of a scientific study conducted in accordance with FDA's investigational device exemption regulations in part 812 of title 21, Code of Federal Regulations.

(32) "Screening mammography" means a mammographic examination of asymptomatic persons in an attempt to detect breast cancer when it is small, nonpalpable and confined to the breast.

~~(41) "Serious adverse event" means an adverse event that may significantly compromise clinical outcomes, or an adverse event for which appropriate corrective action was not taken in a timely manner.~~

~~(42) "Serious complaint" means a report of a serious adverse event.~~

~~(43)~~(33) "Source-to-image receptor distance" (SID) means the distance from the X-ray source to the center of the input surface of the image receptor.

~~(44)~~(34) "Standard breast" means a 4.2 cm thick compressed breast consisting of 50 percent glandular and 50 percent adipose tissue.

~~(45)~~(35) "Survey," in lieu of the definition found in title 10, Code of Federal Regulations, section 20.1001 incorporated by reference in section 30253, means the on-site performance of a mammography system evaluation and a quality assurance testing evaluation by a mammography medical physicist.

~~(46)~~(36) "Traceable to a national standard" means that the instrument used to quantitatively measure radiation has been calibrated at:

(A) The National Institute of Standards and Technology (NIST); or

(B) A calibration laboratory that participates in a proficiency program with NIST at least once every two years during which the calibration laboratory achieves agreement within plus or minus 3.0 percent of the NIST standard at mammography energy levels.

~~NOTE: Authority cited: Sections 100275 and 115060, Health and Safety Code.
Reference: Section 115060, Health and Safety Code.~~

~~NOTE: Authority cited: Sections 114975, 115060 and 131200, Health and Safety Code.
Reference: Sections 115060, 131050, 131051 and 131052, Health and Safety Code.~~

Repeal and Adopt section 30315.20 to read as follows:

§ 30315.20. Facility Accreditation Certificate and Interim Facility Accreditation Certificate. Mammography Machine Certificate and Facility Certification Certificate.

(a) A radiation machine may be used for mammography only if the machine is posted with a current and valid mammography machine certificate. Posting of this certificate shall satisfy the posting requirement specified in Health and Safety Code section 115115(b).

(b) The mammography machine certificate shall be valid up to and including the date of expiration stated on the certificate, provided registration of the radiation machine, pursuant to Group 1.5 of this subchapter, is current and valid. If registration expires or becomes invalid prior to the expiration date specified on the mammography machine certificate, the certificate shall be invalid pending renewal or reinstatement of registration.

(c) Screening or diagnostic mammography may be performed only in a facility possessing a current and valid facility certification certificate issued by the FDA pursuant to title 21, Code of Federal Regulations, section 900.11(a).

~~(a) Except for persons only performing interventional mammography or research mammography, a person shall not perform mammography activities unless performed in a facility that:~~

~~(1) Possesses a current and valid Facility Accreditation Certificate or an Interim Facility Accreditation Certificate; and~~

~~(2) Meets the requirements of this subchapter.~~

~~(b) An Interim Facility Accreditation Certificate shall be valid for six months beginning on the date of issuance.~~

~~(c) A Facility Accreditation Certificate shall be valid for three years beginning on the date of issuance.~~

~~NOTE: Authority cited: Sections 100275 and 115060, Health and Safety Code.~~

~~Reference: Section 115060, Health and Safety Code.~~

NOTE: Authority cited: Sections 114975, 115000, 115060 and 131200, Health and Safety Code. Reference: Sections 115060, 115115, 131050 and 131051, Health and Safety Code.

Repeal and Adopt section 30315.22 to read as follows:

§ 30315.22. Eligibility for a Facility Accreditation Certificate. Eligibility for a Mammography Machine Certificate.

(a) To be eligible for a mammography machine certificate, the user, as defined in section 30100, shall pass a Department review verifying that the:

(1) Information specified in section 30315.33 has been submitted;

(2) Radiation machine is registered pursuant to section 30108;

(3) Mammography system meets the requirements in sections 30316 and 30316.20(e);

(4) User has designated a lead supervising physician pursuant to section 30317.10(b); and

(5) Mammography quality assurance program is capable of meeting the requirements in section 30317.10.

~~(a) To be eligible for a Facility Accreditation Certificate a facility shall:~~

~~(1) Submit the application described in section 30315.33;~~

~~(2) Comply with section 30108;~~

~~(3) Pass a Department inspection verifying that:~~

~~(A) Physicians interpreting mammograms meet the requirements of section 30315.50;~~

~~(B) Mammographic radiologic technologists meet the requirements of section 30315.51;~~

~~(C) Medical physicists meet the requirements of section 30315.52;~~

~~(D) Mammography systems meet the requirements of section 30316;~~

~~(E) The mammography quality assurance program is capable of meeting the requirements of section 30317.10;~~

~~(F) By following the procedure specified in section 30316.20(b), phantom images of a phantom that meets the requirements of section 30316.22 produced by all mammography systems, meet the criteria specified in section 30316.20(b)(1) through (3);~~

~~(G) By use of the facility's proposed technique factors for a standard breast, the average glandular dose for each radiation machine used for mammography does not exceed the value specified in section 30316.20(e)(10);~~

~~(H) The quality assurance manual meets the requirements of section 30317.20;~~

~~(I) The mammography procedures manual meets the requirements of section 30317.30;~~

~~(J) The facility is capable of ensuring mammograms and mammographic examination reports meet the requirements of sections 30316.50 and 30317.40;~~

~~(K) The facility is capable of conducting a mammography medical outcomes audit that meets the requirements of section 30317.60;~~

~~(L) The facility has a consumer complaint procedure that meets the requirements of section 30317.70; and~~

~~(M) The requirements of Group 3 of this regulation are met.~~

~~(4) After receipt of an interim facility accreditation certificate issued pursuant to section 30315.24, for each machine that will be used to perform mammography, pass a clinical image review conducted by the Department pursuant to section 30315.35, or conducted by an entity approved by the FDA pursuant to 42 United States Code Section 263b(e)(1)(A); and~~

~~(5) After receipt of an interim facility accreditation certificate issued pursuant to section 30315.24, possess a current and valid certificate issued by FDA pursuant to title 21, Code of Federal Regulations, section 900.11(b).~~

~~NOTE: Authority cited: Sections 100275 and 115060, Health and Safety Code.
Reference: Section 115060, Health and Safety Code.~~

~~NOTE: Authority cited: Sections 114975, 115000, 115060 and 131200, Health and Safety Code. Reference: Sections 115060, 131050 and 131051, Health and Safety Code.~~

Repeal and Adopt section 30315.23 to read as follows:

§ 30315.23. Renewal of a Facility Accreditation Certificate. Renewal of a Mammography Machine Certificate.

(a) To renew a mammography machine certificate, the user shall:

(1) Sixty days prior to the expiration date shown on the mammography machine certificate, submit to the Department the application described in section 30315.33. The information in the application shall be updated to account for any changes that have occurred since initial issuance or the most recent renewal of the certificate; and

(2) Prior to the expiration date shown on the mammography machine certificate, pass the Department review specified in section 30315.22.

~~(a) To renew a Facility Accreditation Certificate, a facility shall:~~

~~(1) Seven months prior to the expiration date of the facility accreditation certificate submit the facility application described in section 30315.33;~~

~~(2) For each radiation machine that will be used for mammography, either:~~

~~(A) Pass a clinical image review conducted by the Department pursuant to section 30315.35(c) prior to the expiration date of the current facility accreditation certificate; or~~

~~(B) Have the machine's accreditation renewed by an entity approved by FDA pursuant to 42 United States Code Section 263b(e)(1)(A); and
(3) Possess a current and valid certificate issued by FDA pursuant to title 21, Code of Federal Regulations, section 900.11(b).~~

~~NOTE: Authority cited: Sections 100275 and 115060, Health and Safety Code.
Reference: Section 115060, Health and Safety Code.~~

NOTE: Authority cited: Sections 114975, 115000, 115060 and 131200, Health and Safety Code. Reference: Sections 115060, 131050 and 131051, Health and Safety Code.

Repeal section 30315.24.

§ 30315.24. Interim Facility Accreditation Certificate.

~~An interim facility accreditation certificate shall not be issued until a facility has complied with section 30315.22(a)(1) through (3) and has obtained a provisional certificate issued by FDA pursuant to title 21, Code of Federal Regulations, section 900.11(b)(2).~~

~~NOTE: Authority cited: Sections 100275 and 115060, Health and Safety Code.
Reference: Section 115060, Health and Safety Code.~~

Repeal and Adopt section 30315.33 to read as follows:

§ 30315.33. Complete Facility Application. Acceptable Application for a Mammography Machine Certificate.

(a) An application submitted for compliance with sections 30315.22 and 30315.23 shall be considered acceptable if the application contains the following information:

- (1) The name and mailing and physical address of the user;
- (2) The name and telephone number of a contact person for the user;
- (3) The registration number issued by the Department pursuant to section 30108 and the expiration date of registration;
- (4) The name of the lead supervising physician designated by the user;

(5) The name of the quality control technologist designated by the lead supervising physician;

(6) For each physician who may supervise individuals performing mammography, the name, certificate number, and expiration date as shown on the certificate or permit issued pursuant to section 30466;

(7) For each individual who may perform mammography, the name, certificate number, and expiration date shown on the certificate issued to the individual pursuant to section 30455.1;

(8) For each mammography system that may be used for mammography:

(A) The manufacturer, model, mammographic modality, serial number, and unique identification number of the radiation machine required pursuant to section 30317.20(a)(1);

(B) Whether the machine will be used in a mobile setting. If the machine will not be used in a mobile setting, the designated room number within the facility where the machine is installed or fixed;

(C) The manufacturer, model, and location of each film processor that may be used to process mammograms;

(D) Whether the machine will be used for screening, diagnostic, research, or interventional mammography, or any combination thereof; and

(E) A copy of the report indicating the results of a mammography system evaluation performed by a mammography medical physicist less than six months prior to the date of the application, or, in lieu thereof for renewal applications, a copy of the report indicating the results of a survey performed less than 12 months, by a mammography medical physicist, prior to the date of the renewal application. If the mammography system evaluation report or the survey report identifies deficiencies or recommendations for improvements in facility operations, provide:

1. A list and description of corrective actions taken and the date corrections were achieved;

2. Copies of work invoices;

3. Documentation that those corrective actions were taken and those actions corrected the deficiencies or that those recommendations were followed; and

(9) If the applicant will perform mammography in a mobile setting:

(A) The physical address of each location where mammography will be performed;

(B) For each location where mammography will be performed, the name and telephone number of the responsible person who is allowing the service to be provided at the location;

(C) Whether the mammograms will be processed with an on-board processor or at specific locations. If the facility will process mammograms at specific locations, the physical address of each location where mammograms will be processed;

(D) Whether the radiation machine is used in a mobile vehicle or is transported to the use location and moved to where mammographic examinations will be performed. If the radiation machine is moved to where mammographic examinations will be performed, the designated room number within the physical building at each location of use; and

(E) A description of the quality assurance tests that will be performed each time the radiation machine is relocated.

(10) The signature, title, and date of signature, of the user and the user's designated lead supervising physician.

~~(a) An application submitted for compliance with sections 30315.22 or 30315.23 shall be considered complete if the application contains the following:~~

~~(1) The legal name of the applicant, the mailing address, and the telephone number;~~

~~(2) The name under which the applicant's facility does business and, if doing business under a fictitious name, a copy of the applicant's fictitious name permit;~~

~~(3) The name of the contact person for the facility;~~

~~(4) The facility location address and mailing address if different from location address.~~

~~(5) The registration number issued by the Department pursuant to section 30108 and the expiration date of registration;~~

~~(6) The applicant's federal employer identification number and California taxpayer identification number;~~

~~(7) If the facility is accredited by an entity approved by the FDA pursuant to 42 United States Code Section 263b(e)(1)(A), the name of that entity.~~

~~(8) If the applicant requests approval to perform mammography in a mobile setting:~~

~~(A) The physical address of each location where mammography will be performed;~~

~~(B) For each location where mammography will be performed, the name and telephone number of the responsible person who is allowing the service to be provided at the location;~~

~~(C) Whether the mammograms will be processed with an on-board processor or at specific locations. If the facility will process mammograms at specific locations, the physical address of each location where mammograms will be processed;~~

~~(D) Whether the radiation machine is fixed or used, exclusively, in a mobile vehicle or is transported to the use location and moved to where mammographic examinations will be performed. If the radiation machine is moved to where mammographic examinations will be performed, the designated room number within the physical building at each location of use; and~~

~~(E) A description of the quality assurance tests that will be performed each time the radiation machine is relocated.~~

~~(9) Responses to the following questions:~~

~~(A) "Have you ever performed mammography authorized pursuant to a certificate issued by FDA?" If the answer is yes, provide in your response the names under which mammography was performed;~~

~~(B) "If you have been certified by FDA to perform mammography, has that certificate ever been revoked or suspended, or has FDA ever denied to renew that certificate?" If the answer is yes, provide in your response the following:~~

~~1. The identity of any specific radiation machine(s) that failed to pass clinical image review;~~

~~2. The dates of failure;~~

~~3. The actions taken to correct any clinical image review deficiencies including physician or technologist training, radiation machine or processor repair and acquisition of replacement equipment or image receptors;~~

~~4. Whether the radiation machine passed the clinical image review subsequent to actions taken as identified in subsection (a)(9)(B)3 and when;~~

~~5. If, within the three years prior to the date of application, any radiation machine used for mammography identified in subsection (a)(15) failed clinical image review during a time when accredited by an entity approved by the FDA pursuant to 42 United States Code Section 263b(e)(1)(A), copies of the failure reports; and~~

~~6. If accreditation issued by an entity approved by the FDA pursuant to 42 United States Code Section 263b(e)(1)(A), was suspended or revoked, a description of the circumstances that led to suspension or revocation.~~

~~(C) "Is any interpreting physician you seek to allow to interpret mammograms currently under a Department directed plan of corrective action for interpretation done at some other facility?" If the answer is yes, provide in your response the following:~~

~~1. The name and medical license number of the interpreting physician; and~~

2. The facility's name and registration number where the interpreting physician was required to complete a directed plan of corrective action.

~~(10) The name of the individual designated as the lead interpreting physician.~~

~~(11) The name, medical license number, certificate number and expiration date as shown on the individuals certificate issued pursuant sections 30466(d) or 30467 of each physician who will interpret mammograms produced by the facility;~~

~~(12) The name, certificate number and expiration date of certification shown on the certificate issued pursuant to section 30455.1 for each mammographic radiologic technologist who will perform mammographic examinations for the facility;~~

~~(13) The name of each medical physicist who will perform the tests specified in section 30316.20(e) for the facility;~~

~~(14) The name of the quality assurance technologist;~~

~~(15) For each radiation machine that will be used to perform mammographic examinations:~~

~~(A) The machine's manufacturer, model number, and the facility's radiation machine identification number as specified in section 30317(g);~~

~~(B) Whether the machine will be used in a mobile setting. If the machine will not be used in a mobile setting, the designated room number within the facility where the machine is installed or fixed;~~

~~(C) Whether the machine is a screen film, xeromammography or digital system. If the machine is a screen film system, the name of the manufacturer of the screen and film, and the type of screen and film used; and~~

~~(D) If the machine requires a screen film image receptor, a phantom image of a phantom that meets the requirements of section 30316.22.~~

~~(16) A copy of the report indicating the results of a mammography system evaluation performed less than 6 months prior to the date of the application by a medical physicist or in lieu thereof for renewal applications, a copy of the report indicating the results of a survey performed less than 12 months prior to the date of the renewal application by a medical physicist and if the mammography system evaluation report or the survey report identifies deficiencies or recommendations for improvements in facility operations:~~

~~(A) A list and description of corrective actions taken and the date corrections were achieved;~~

~~(B) Copies of work invoices;~~

~~(C) Documentation that those corrective actions were taken and those actions corrected the deficiencies or that those recommendations were followed.~~

~~(17) For each film processor that is used to process mammograms:~~

~~(A) The make and model number; and~~

~~(B) Whether the processor uses extended processing or standard processing.~~

~~(18) If this is a renewal application, the number of the following procedures performed in the previous year:~~

~~(A) Screening procedures;~~

~~(B) Diagnostic procedures;~~

~~(C) The total number of screening and diagnostic procedures;~~

~~(D) Biopsy procedures;~~

- ~~(E) Needle localization procedures; and~~
- ~~(F) Therapeutic procedures.~~
- ~~(19) If this is a renewal application, the identification number and expiration date shown on the FDA certificate issued to the applicant's facility;~~
- ~~(20) Whether the applicant participates or intends to participate in either the Breast Cancer Early Detection Program or the Breast and Cervical Cancer Control Program of the Department or any of their successors;~~
- ~~(21) If the applicant is a Medi-Cal provider, the nine-digit Medi-Cal number used to bill for mammographic examinations performed at the facility's location;~~
- ~~(22) If the applicant is a Medicare provider, the nine-digit Medicare number used to bill for mammographic examinations performed at the facility's location;~~
- ~~(23) Name, title, signature and date of signature of the applicant and lead interpreting physician.~~

~~NOTE: Authority cited: Sections 115060, 131051, and 131200, Health and Safety Code. Reference: Section 115060, Health and Safety Code.~~

NOTE: Authority cited: Sections 114975, 115000, 115060, and 131200, Health and Safety Code. Reference: Sections 115060, 131050 and 131051, Health and Safety Code.

Amend section 30315.34 to read as follows:

§ 30315.34. Application Processing Times.

(a) Within 30 calendar days of receipt of an application for or renewal of a facility accreditation certificate mammography machine certificate pursuant to sections 30315.22 or 30315.23, the Department shall:

- (1) Notify the applicant that the application is ~~complete~~ acceptable; or
- (2) Notify the applicant that the application is ~~incomplete~~ not acceptable and identify what is required for the Department to consider it ~~complete~~ acceptable.

(b) Unless the applicant responds to the notification in subsection (a)(2) within 30 calendar days, the application shall be deemed withdrawn and the applicant may reapply by submitting a new application.

(c) Within ~~six months~~ 30 calendar days of receipt of a ~~complete~~ an acceptable application, the Department shall issue or deny the ~~facility accreditation certificate~~ mammography machine certificate.

(d) For purposes of this section:

(1) Receipt of an application for or renewal of a mammography machine certificate pursuant to sections 30315.22 or 30315.23 shall be deemed to occur on the date the application, information, or documents are received by the Department;

(2) An application is considered acceptable when all documents and information required to be submitted on or with the application have been received by the Department, so as to allow the Department to determine if the applicant meets the requirements pursuant to sections 30315.22 or 30315.23; and

(3) Written notifications by the Department to applicants shall be deemed to occur on the date the notification is postmarked or, if electronically received, the date of receipt as indicated on the electronic communication.

~~(d) The Department's time periods for processing an application for or renewal of a facility accreditation certificate from receipt of the initial application to the date the final decision is made, are as follows:~~

~~(1) The median time is five and one-half months;~~

~~(2) The minimum time is four months;~~

~~(3) The maximum time is 12 months.~~

~~NOTE: Authority cited: Sections 100275 and 115060, Health and Safety Code. Reference: Section 15376, Government Code.~~

NOTE: Authority cited: Sections 114975, 115000, 115060 and 131200, Health and Safety Code. Reference: Sections 115060, 131050 and 131051, Health and Safety Code.

Repeal section 30315.35.

§ 30315.35. Clinical Image Review.

~~(a) After receipt of an interim facility accreditation certificate issued pursuant to section 30315.24, applicants for a facility accreditation certificate shall:~~

~~(1) Select mammograms in accordance with the criteria specified in title 21, Code of Federal Regulations, section 900.4(c)(4); and~~

~~(2) Within 75 calendar days of the date of issuance as shown on the interim facility accreditation certificate, submit those mammograms for clinical image review.~~

~~(b) If the mammograms fail the review, additional mammograms may be submitted if the resubmission is made no less than 75 calendar days prior to the expiration date of the interim facility accreditation certificate.~~

~~(c) Applicants for renewal of a facility accreditation certificate shall:~~

~~(1) Select mammograms in accordance with the criteria specified in title 21, Code of Federal Regulations, section 900.4(c)(4); and~~

~~(2) Submit those mammograms for clinical image review no less than 75 calendar days prior to the expiration date of the facility accreditation certificate.~~

~~(d) Mammograms submitted pursuant to this section shall meet the FDA-accepted attributes as specified in title 21, Code of Federal Regulations, section 900.4(c)(2).~~

NOTE: Authority cited: Sections 100275 and 115060, Health and Safety Code.
Reference: Sections 115060, 115100 and 115115, Health and Safety Code.

Amend section 30315.36 to read as follows:

§ 30315.36. Mammography Review.

(a) ~~Each facility possessing a facility accreditation certificate~~The user shall, upon request, make mammograms and their written reports of results ~~specified in section 30317.40(a)~~ available to the Department and allow those mammograms and reports to be removed from the facility for the purpose of evaluating mammogram image quality.

(b) For sample sizes of two mammographic examinations:

(1) If one mammographic examination fails the review, the ~~facility~~user shall submit a plan of corrective action, acceptable to the Department, addressing those areas that resulted in the failure and satisfactorily complete that plan; or

(2) If both mammographic examinations fail the review, the ~~facility~~user shall satisfactorily complete a plan of corrective action, as directed by the Department, addressing those areas of the review that resulted in the failure. The ~~facility~~user shall be subject to additional review using a larger sample.

(c) For sample sizes greater than two mammographic examinations:

(1) If 20 percent of the mammographic examinations fail the review, the ~~facility~~user shall submit a plan of corrective action, acceptable to the Department, addressing those areas that resulted in ~~the~~ failure and satisfactorily complete that plan;

(2) If 40 percent of the mammographic examinations fail the review, the ~~facility~~

user shall satisfactorily complete a plan of corrective action, as directed by the Department, addressing those areas of the review that resulted in the failure; or

(3) If 80 percent or more of the mammographic examinations fail the review, the ~~facility~~ user shall cease the performance of mammography and submit to an additional review and:

(A) If 70 percent or more of the mammographic examinations pass this additional review, the ~~facility~~ user may restart the performance of mammography after satisfactorily completing a plan of corrective action as directed by the Department and shall, within 75 calendar days of notification that the mammograms passed the review, submit additional ~~mammograms in accordance with section 30315.35(a)(1)~~ as directed by the Department; or

(B) If less than 70 percent of the mammographic examinations pass this additional review, the ~~facility~~ user shall not restart the performance of mammography and shall notify every patient who had a mammogram at the facility during the two-year period preceding the date of failure. The notification shall be approved by the Department prior to mailing and include:

1. The name of the patient;
2. The date the patient's mammogram was performed;
3. The statement, "~~The Department of Health Services of the State of California~~

The California Department of Public Health has conducted a review of the mammograms produced by (the name of the facility) and has determined that the mammograms do not meet the standards set by the Department. Therefore, we strongly advise you to consult with your physician as soon as possible regarding a repeat mammographic examination."

(d) Mammograms reviewed pursuant to this section shall meet the FDA-accepted attributes as specified in title 21, Code of Federal Regulations, section 900.4(c)(2).

~~NOTE: Authority cited: Sections 100275 and 115060 and 131200, Health and Safety Code. Reference: Sections 115060, 115100 and 115115, Health and Safety Code.~~

NOTE: Authority cited: Sections 114975, 115000, 115060 and 131200, Health and Safety Code. Reference: Sections 115060, 115100, 115115, 131050 and 131051, Health and Safety Code.

Repeal and Adopt section 30315.50 to read as follows:

§ 30315.50. Interpreting Physician Personnel Requirements.

(a) Each user possessing a radiation machine used for mammography shall ensure that:

(1) Each physician, as defined in section 30315.10, supervising individuals who perform mammography possesses either a current and valid radiology supervisor and operator certificate or a radiography supervisor and operator permit issued pursuant to section 30466; and

(2) Each individual performing mammography possesses a current and valid mammographic radiologic technology certificate issued pursuant to section 30455.1.

(a) An interpreting physician for a facility shall:

(1) Possess a current and valid radiology supervisor and operator certificate issued pursuant to sections 30467 or 30466(d); and

(2) Meet the requirements specified in title 21, Code of Federal Regulations, section 900.12(a)(1).

~~NOTE: Authority cited: Sections 100275 and 115060, Health and Safety Code. Reference: Section 115060, Health and Safety Code.~~

NOTE: Authority cited: Sections 114975, 115000, 115060 and 131200, Health and Safety Code. Reference: Sections 115060, 131050, and 131051, Health and Safety Code.

Repeal section 30315.51.

§ 30315.51. Personnel Requirements for Individuals Who Perform Mammography.

~~(a) Mammographic examinations shall not be performed unless the individual who performs the mammographic examination:~~

~~(1) Possesses a current and valid mammographic radiologic technology certificate issued pursuant to section 30455.1; and~~

~~(2) Meets the requirements specified in title 21, Code of Federal Regulations, section 900.12(a)(2).~~

NOTE: Authority cited: Sections 100275 and 115060, Health and Safety Code.
Reference: Sections 115060 and 115115, Health and Safety Code.

Repeal and Adopt section 30315.52 to read as follows:

§ 30315.52. Medical Physicist Requirements. Authorized Mammography Medical Physicist.

(a) Before conducting surveys, as defined in section 30315.10, a mammography medical physicist shall:

(1) Be authorized by the Department pursuant to section 30315.60;

(2) Have been awarded a master's degree or higher in a physical science from an accredited institution, with no less than 20 semester hours or 30 quarter hours of college undergraduate or graduate level physics;

(3) Have completed 20 hours of documented specialized training in conducting mammography surveys; and

(4) Have performed surveys of at least one facility and a total of at least ten mammography systems under the direct supervision of a mammography medical physicist who has renewed their authorization pursuant to section 30315.60(c). In no case may more than one survey of a specific mammography system performed within a period of 60 calendar days be counted towards the total number of mammography systems surveyed. The period of time spent in meeting the survey requirement may be counted toward meeting the 20-hour training requirement in subsection (a)(3).

(b) On and after July 1, 2021, the mammography medical physicist shall, in the 36 months immediately preceding the expiration date of the authorization:

(1) Have taught or completed at least 15 continuing education units in mammography. This continuing education shall include hours of training appropriate to each mammographic modality evaluated by the medical physicist. Units earned through teaching a specific course can be counted only once, even if the course is taught multiple times during the 36-month cycle; and

(2) Have conducted surveys of at least three facilities and a total of at least nine mammography systems. No more than one survey of a specific facility conducted

within a 10-month period or a specific system conducted within a 60 calendar day period may be counted towards this requirement.

(c) Before a mammography medical physicist may begin independently conducting surveys of a new mammographic modality, that is, a mammographic modality other than one for which the physicist received training to qualify under subsection (a), a mammography medical physicist shall receive at least eight hours of training in surveying units of the new modality. For purposes of this subsection, "units" means an assemblage of components for the production of X-rays for use during mammography, including, at a minimum, an X-ray generator, an X-ray control, a tube housing assembly, a beam limiting device, and the supporting structures for these components.

~~(a) A medical physicist for a facility shall:~~

~~(1) Be authorized by the Department pursuant to section 30315.60;~~

~~(2) Have a masters degree or higher in a physical science from an accredited institution, with no less than 20 semester hours or 30 quarter hours of college undergraduate or graduate level physics;~~

~~(3) Complete 20 hours of documented specialized training in conducting surveys of mammography facilities; and~~

~~(4) Conduct a survey of at least one mammography facility and a total of at least ten mammography radiation machines under the direct supervision of a medical physicist who has already met the requirements of this section, but in no case may more than one survey of a specific radiation machine conducted within a period of 60 calendar days be counted towards the total number of radiation machines surveyed. The period of time spent in meeting the survey requirement may be counted toward meeting the 20-hour training requirement in subsection (a)(3). After April 28, 1999, experience conducting surveys shall be acquired under the direct supervision of a medical physicist who meets the requirements of subsections (a)(1) through (4) and (b); or~~

~~(5) In lieu of subsections (a)(2) through (4), qualify as a medical physicist under Title 21, Code of Federal Regulations, section 900.12(a)(3), as published in the December 21, 1993 Federal Register (58 Fed.Reg. 67571) and have retained that qualification by maintenance of the active status of any licensure, approval, or certification required under those regulations and prior to April 28, 1999:~~

~~(A) Received a bachelor's degree or higher in a physical science from an accredited institution with no less than 10 semester hours or equivalent of college undergraduate or graduate level physics;~~

~~(B) After meeting the requirements of subsection (a)(5)(A), completed forty hours of documented specialized training in conducting surveys of mammography facilities; and~~

~~(C) After meeting the requirements of subsection (a)(5)(A), conducted surveys of at least one mammography facility and a total of at least 20 mammography radiation machines but in no case may more than one survey of a specific radiation machine conducted within a period of 60 calendar days be counted towards the total radiation machine survey requirement. The period of time spent in meeting the survey requirement may be counted toward meeting the 40-hour training requirement in subsection (a)(5)(B).~~

~~(b) A medical physicist for a facility shall meet the requirements specified in title 21, Code of Federal Regulations, section 900.12(a)(3)(iii) and (iv).~~

~~NOTE: Authority cited: Sections 100275, 115060 and 115100, Health and Safety Code. Reference: Sections 115060, 115100 and 115115, Health and Safety Code.~~

NOTE: Authority cited: Sections 114975, 115000, 115060 and 131200, Health and Safety Code. Reference: Sections 115060, 115100, 131050 and 131051, Health and Safety Code.

Amend section 30315.60 to read as follows:

§ 30315.60. Authorization and Renewal of Authorization to Conduct Mammography Surveys, Revocation and Suspension of Authorization and Application Processing Times.

(a) To be eligible for authorization to conduct mammography surveys, an individual shall submit ~~a complete~~ an acceptable application consisting of the following:

(1) Name, social security number (SSN) or individual taxpayer identification (ITIN) (pursuant to the authority found in sections 100275 and 115100 of the Health and Safety Code and as required by section 17520 of the Family Code, providing the ~~social security number~~ SSN or ITIN is mandatory. The ~~social security number~~ SSN or ITIN will be used for purposes of identification), mailing address, and daytime telephone number and ~~FAX number~~ email address;

(2) Documentation that the applicant meets the requirements of:

~~(A) Sections 30315.52(a)(2) through (4); or~~

~~(B) Section 30315.52(a)(5).~~

~~(3) Documentation that the applicant meets the requirements of section 30315.52(b);~~

~~(4)(3) Three sample survey reports, meeting the requirements of section 30316.60, A copy of a survey report indicating the name of the mammography medical physicist providing direct supervision and that the applicant performed all tests and the evaluations specified in section 30316.60; Each report shall include language and data that establishes that all tests were performed to determine if the facility meets the requirements of this article and that, if a test method is specified, the test method was followed; and or~~

~~(5) The following information:~~

~~(A) Manufacturer, model and serial number of the phantom used to produce phantom images;~~

~~(B) Whether the type of system resolution tool used to evaluate system resolution is a bar pattern or, until October 28, 2002, a star pattern;~~

~~(C) Method used to evaluate kVp;~~

~~(D) Method used to evaluate compression;~~

~~(E) Type of instruments used to determine average glandular dose and a copy of the most recent calibration report for that instrument indicating that it complies with section 30316.61;~~

~~(F) Whether aluminum filters used to determine the radiation machine's half-value layer of the useful beam is type 1100 or type 1145;~~

~~(G) Manufacturer, model and serial number of the densitometer, sensitometer and photometer used during surveys; and~~

~~(H) A list of equipment used to evaluate the mammography system for artifacts and the radiation machine's AEC performance; or~~

~~(6)(4) In lieu of subsections (a)(2) and (3), a copy of the letter issued to the applicant by the FDA, or a certifying agency approved by the FDA pursuant to title 21, Code of Federal Regulations, section 900.21, stating that the applicant met the requirements of title 21, Code of Federal Regulations, section 900.12(a)(3).~~

~~(b) Individuals approved by use of subsection (a)(2)(B) shall not provide direct supervision.~~

~~(c) Surveys of radiation machines used to perform interventional mammography or research mammography shall not be used to comply with this section.~~

~~(d)~~(b) Authorization shall be valid for three years.

~~(e)~~(c) To be eligible for renewal of authorization to conduct mammography surveys an individual shall, 30 days prior to the expiration date of their authorization, submit a complete to the Department an application consisting that includes all of the following:

(1) Name, ~~social security number~~ SSN or ITIN (pursuant to the authority found in sections 100275 and 115100 of the Health and Safety Code and as required by section 17520 of the Family Code, providing the ~~social security number~~SSN or ITIN is mandatory. The ~~social security number~~SSN or ITIN will be used for purposes of identification), mailing address, and daytime telephone number and ~~FAX number~~email address; and

~~(2) The following information:~~

~~(A) If changes to the information submitted pursuant to subsection (a)(5) have occurred, the updated information;~~

~~(B) A copy of the most recent calibration report for the instrument used to determine average glandular dose.~~

~~(3) Documentation indicating that at least 8 hours of training in surveying radiation machines were received for each new mammographic modality; and~~

~~(4)~~(2) Documentation that the applicant meets requirements of section 30315.52(b) and (c). If the applicant fails to meet those requirements, the applicant may not perform mammography surveys without the supervision of a mammography medical physicist with current and valid authorization. To reestablish qualifications for renewal of authorization to independently perform mammography surveys, the applicant shall:

(A) For failure to meet section 30315.52(b)(1), obtain a sufficient number of continuing education units to bring their total units up to the required 15 in the previous three years; and

(B) For failure to meet section 30315.52(b)(2), complete a sufficient number of surveys under the direct supervision of a mammography medical physicist to bring their

total surveys up to the required three facilities and nine units in the previous 36 months. No more than one survey of a specific facility within a 10-month period or a specific system conducted within a 60 calendar day period may be counted towards the total mammography unit survey requirement.

(f)(d) Authorization to conduct mammography surveys may be revoked, suspended, amended or restricted for any of the following:

(1) Failure to comply with section 30315.52(b) or (c);

(2) Knowingly conducting or performing mammography system evaluations, quality assurance testing evaluations or surveys that cause or would have caused, if not detected, a facility to be in violation of any provision of the Act, any regulation promulgated pursuant to the Act, any provision of the Radiologic Technology Act, as defined in Health and Safety Code section 27, any regulation promulgated pursuant to the Radiologic Technology Act, or any order of the Department;

(3) Knowingly ~~submits~~ submitting to the Department false, incorrect or fraudulent information;

(4) ~~Failure~~ Failing to inform a facility that a violation of this article has occurred when the medical physicist knows of the violation; ~~or~~

(5) Procuring authorization by fraud, or misrepresentation, or because of mistake; or

(6) Engaging in deliberate misconduct as specified in section 30105.

(e) For purposes of this section:

(1) Receipt of an application pursuant to this section shall be deemed to occur on the date the application, information, or documents are received by the Department;

(2) An application is considered acceptable when all documents and information required to be submitted on or with the application have been received by the Department, so as to allow the Department to determine if the applicant meets the eligibility requirements pursuant to subsection (a); and

(3) Written notification by the Department to applicants shall be deemed to occur on the date the notifications are postmarked, or if electronically received, date of receipt as indicated on the electronic communication.

~~(g)~~(f) Within ~~40~~30 calendar days of receipt of an application for or renewal of authorization, the Department shall:

(1) Notify the applicant that the application is ~~complete~~ acceptable; or

(2) Notify the applicant that the application is ~~incomplete~~ not acceptable and identify what is required for the Department to consider it ~~complete~~ acceptable.

~~(h)~~(g) Unless the applicant responds to the notification in subsection ~~(g)(2)~~(f)(2) within 30 calendar days, the application shall be deemed withdrawn.

~~(i)~~(h) Within 30 calendar days of receipt of a ~~complete~~ an acceptable application, the Department shall issue or deny the authorization.

~~(j)~~(i) Any applicant deemed by the Department to have withdrawn an application pursuant to subsection ~~(e)~~(g) may reapply by submitting a new application.

~~(k)~~ The Department's time periods for processing an application for authorization from receipt of the initial application to the date the final decision is made, are as follows:

(1) The median time is 30 calendar days;

(2) The minimum time is seven days;

(3) The maximum time is 90 calendar days.

~~NOTE: Authority cited: Sections 100275, 115060 and 115100, Health and Safety Code. Reference: Sections 115060, 115100 and 115115, Health and Safety Code; and Section 15376, Government Code.~~

NOTE: Authority cited: Sections 114975, 115060, 115100 and 131200, Health and Safety Code. Reference: Sections 115060, 115100, 131050 and 131051, Health and Safety Code.

Amend section 30316 to read as follows:

§ 30316. Mammography System Requirements.

(a) A radiation machine designed for general purpose radiography, or special nonmammography procedures ~~or that has been modified or equipped with special attachments for mammography~~ shall not be used for mammography.

(b) Radiation machines used for mammography shall:

(1) through (7) *No change to text.*

(8) Incorporate a compression device that:

~~(A) Effective October 28, 2002,~~ provides:

~~1.(A)~~ An initial power-driven compression activated by hands-free controls operable from both sides of the patient; and

~~2.(B)~~ Fine adjustment compression controls operable from both sides of the patient.

~~(B)(C)~~ Provides different sized compression paddles that match the sizes of all full-field image receptors provided for the system. Compression paddles for special purposes, including those smaller than the full size of the image receptor (for “spot compression”) may be provided but shall be exempt from the requirements of ~~subsection (b)(8)(C), paragraph (D); and~~

~~(C)(D)~~ Except as provided in ~~subsection (b)(8)(D) paragraph (E),~~ provides a compression paddle that is flat and parallel to the image receptor holder assembly and does not deflect from parallel by more than 1.0 cm at any point on the surface of the compression paddle when compression is applied. The chest wall edge of the compression paddle shall be straight and parallel to the edge of the image receptor. The chest wall edge shall not appear on the image;

~~(D)(E)~~ If the compression paddle is intended by the manufacturer's design to not be flat and parallel to the image receptor holder assembly during compression, the paddle shall meet the manufacturer's design specifications and maintenance requirements; and

~~(E)(F)~~ If the chest wall edge is bent upward for patient comfort, the edge shall not appear on the image.

(9) Provide manual selection of milliamperere-seconds (mAs) or at least one of its component parts (milliamperes (mA) and/or time), and;

(10) Indicate kVp, mA and time and/or mAs before the exposure begins, or when AEC mode is used, the technique factors that are set prior to the exposure;

(11) When the AEC mode is used, indicate the actual technique factors (kVp and mAs or mA and time) used, after completion of the exposure;

(12) If it is a used with screen-film system image receptors, provide an AEC mode that is operable in all combinations of equipment configuration provided on that unit, such as grid, nongrid, magnification, nonmagnification and various target-filter combinations, and:

(A) through (D) *No change to text.*

(13) If equipped with a light beam that passes through the X-ray beam-limiting device, the light provides an average illumination of no less than 160 lux (15 foot candles) at the lesser of:

~~(A)~~ 100 centimeters; or

~~(B)~~ The the maximum source-to-image-distance the machine can obtain.

~~(c)~~ A ~~facility shall not perform mammography~~ Mammography using a screen-film mammography system shall not be performed unless:

~~(1)~~ There are at least four image receptors of 18 x 24 centimeters (cm) and at least four image receptors of 24 x 30 cm available for use by the person performing mammographic examinations;

~~(2)~~(1) The X-ray film and intensifying-screens are designated by the film manufacturer and the screen manufacturer as appropriate for mammography and the X-ray film matches the screen's spectral output as specified by the screen manufacturer;

~~(3)~~(2) Chemical solutions used for processing mammograms are capable of developing the film so as to meet the minimum requirements specified by the film manufacturer;

~~(4)~~(3) Special lights for film illumination, or hot lights, that are capable of producing light levels greater than that provided by the view box are available; and

~~(5)~~(4) Film masking devices that can limit the illuminated area to a region equal to or smaller than the exposed portion of the film are available ~~to all physicians interpreting mammograms for~~ in the facility.

~~(d)~~ Documentation demonstrating compliance with this section shall be maintained in accordance with section 30319.20.

~~NOTE: Authority cited: Sections 100275 and 115060, Health and Safety Code.
Reference: Sections 115060, 115100 and 115115, Health and Safety Code.~~

NOTE: Authority cited: Sections 114975, 115000, 115060 and 131200, Health and Safety Code. Reference: Sections 115060, 131050 and 131051, Health and Safety Code.

Amend section 30316.10 to read as follows:

§ 30316.10. Evaluations of New, Reassembled, Replaced or Repaired Equipment.

(a) *No change to text.*

(b) The evaluation to determine if equipment specified in subsections (a)(1) through (3) are in compliance with subsection (a) shall be performed by a mammography medical physicist or an individual under the direct supervision of a mammography medical physicist.

~~(c) To use a new radiation machine, a facility shall:~~

~~(1) Possess a current and valid facility accreditation certificate issued pursuant to section 30315.22 or interim facility accreditation certificate issued pursuant to section 30315.24;~~

~~(2) Submit the results of tests with measurements and calculated data used to establish compliance with subsection (a), the information specified in section 30315.33(a)(1), (a)(4), (a)(7), (a)(15), (a)(17) and (a)(23) and the calibration record required in section 30316.61(a); and~~

~~(3) Pass a clinical image review conducted by an entity approved by FDA pursuant to 42 United States Code Section 263b(e)(1)(A) or by the Department in which mammograms shall:~~

~~(A) Be selected in accordance with the criteria specified in title 21, Code of Federal Regulations, section 900.4(c)(4);~~

~~(B) Be submitted within 75 calendar days of being notified by the Department that subsections (c)(1) and (2) have been met; and~~

~~(C) Meet the FDA accepted attributes as specified in title 21, Code of Federal Regulations, section 900.4(c)(2).~~

~~(d) To use a radiation machine that was disassembled and reassembled for mammography, a facility shall:~~

~~(1) Possess a current and valid facility accreditation certificate issued pursuant to section 30315.22 or interim facility accreditation certificate issued pursuant to section 30315.24;~~

~~(2) Submit the results of tests with measurements and calculated data used to establish compliance with subsection (a), the information specified in section 30315.33(a)(1), (a)(4), (a)(7), (a)(15), (a)(17) and (a)(23) and the calibration record required in section 30316.61(a); and~~

~~(3) Submit a mammography system evaluation performed by a medical physicist or an individual under the direct supervision of a medical physicist.~~

~~(e)(c) Documentation of the tests performed, the analysis of data obtained, corrective actions, and the effectiveness of those actions taken pursuant to this section shall be maintained in accordance with section 30317.20 ~~30319.20~~.~~

~~NOTE: Authority cited: Sections 100275 and 115060, Health and Safety Code.
Reference: Sections 115060, 115100 and 115115, Health and Safety Code.~~

NOTE: Authority cited: Sections 114975, 115000, 115060 and 131200, Health and Safety Code. Reference: Sections 115060, 115115, 131050 and 131051, Health and Safety Code.

Amend section 30316.20 to read as follows:

§ 30316.20. Quality Assurance Testing.

(a) *No Change to Text.*

(b) Each facility using screen-film systems for mammography shall, each week in which mammography is performed, produce an image of a phantom ~~that meets the requirements of section 30316.22~~. The test shall be performed prior to mammography on the day the test is performed using film processors that may be used to develop

mammograms. Before exposing the phantom, an acrylic disc measuring one centimeter in diameter and four millimeters thick shall be placed on the phantom in the image area so it will not obscure details in the phantom and where it cannot cast a shadow on any portion of the AEC detector. The phantom shall then be exposed using the mammography film of the type used clinically and the techniques used for clinical images of a standard breast. The resulting phantom image shall meet the following:

~~(1) The center of the image has an optical density (OD) of at least 1.40 and once an established operating level is determined, the difference does not change by more than plus or minus 0.20 OD when compared to the established operating level~~ The optical density (OD) at the center of the phantom image is at least 1.20 and did not change by more than plus or minus 0.20 from the established operating level;

~~(2) The difference between the OD measured inside the image of the disc and the OD measured adjacent to the image of the disc is at least 0.40 and once an established operating level is determined, the difference does not change by more than plus or minus 0.05 OD when compared to the established operating level~~ The optical density difference between the background of the phantom image and the test object added to assess image contrast did not change by more than plus or minus 0.05 from the established operating level; and

~~(3) Obtains a score of at least 4.0 for fibers, 3.0 for specks and 3.0 for masses using the phantom image scoring protocol in~~ The phantom image meets the minimum scores required pursuant to section 30316.30.

(c) *No Change to Text.*

(d) Each facility conducting mammography shall, prior to initial use and at intervals not to exceed six months:

(1) When conducting screen-film mammography, determine ~~Determine~~ that the optical density attributable to darkroom fog does not exceed 0.05, by performing a test which uses mammography film of the type used clinically in the facility in which the film is exposed such that the film has a mid-density of no less than ~~4.4~~ 1.2 OD, and is exposed to typical darkroom conditions for two minutes while such film, with one-half of

the film covered, is placed on the counter top, emulsion side up. If the darkroom has a safelight used for mammography film, it shall be on during this test;

(2) When conducting screen-film mammography, conduct Conduct testing on all cassettes used for mammography in the facility for screen-film contact using 40 mesh copper screen during which the entire area of the cassette that may be clinically exposed shall be tested; and

(3) Determine that the X-ray system is able to compress the breast with a force of at least 25 pounds and maintain this compression for at least 15 seconds, except that for systems with automatic compression, the maximum force applied without manual assistance shall be greater than 25 pounds and shall not exceed 45 pounds.

(e) Each facility conducting mammography shall, annually, ensure that a mammography medical physicist verifies that:

~~(1) Until October 28, 2002, the automatic exposure control (AEC) can maintain film optical density within plus or minus 0.30 of the average of the optical densities measured using homogeneous acrylic thicknesses of 2, 4, and 6 centimeters and the kilovoltage peak (kVp) is varied appropriately for such thicknesses over the kVp range used clinically in the facility. Each image of the homogenous acrylic shall have an optical density (OD) of at least 1.20. If the AEC cannot meet this requirement, a chart shall be posted that specifies appropriate techniques (kVp and density control settings) for different breast thicknesses and compositions so that optical densities within plus or minus 0.30 of the average under phototimed conditions can be produced;~~

~~(2) After October 28, 2002,~~ (1) The AEC can maintain film optical density within plus or minus 0.15 of the average of the optical densities measured using homogeneous breast-tissue equivalent material thicknesses of 2, 4, and 6 centimeters (cm) and the kilovoltage peak (kVp)kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility. Each image of the homogenous breast-tissue equivalent material shall have an OD of at least 1.20;

~~(3) When the AEC mode is used and the OD is increased or decreased from the normal or baseline setting, the net overall change in OD across the range of clinically used density control settings shall exceed the OD range established under subsection~~

~~(e)(12) and if that net overall change in OD is equal to or greater than the maximum difference in OD allowed under subsection (e)(12), this change shall be distributed over a minimum of two density control settings removed from the normal or baseline setting;~~

~~(4)(2) By using the protocol specified in subsection (b), the mammography system, if a screen-film system, can produce a phantom image that meets the criteria specified in subsection (b); the following:~~

~~(A) The center of the image has an OD of at least 1.40;~~

~~(B) The difference between the OD measured inside the image of the disc and the OD measured adjacent to the image of the disc is at least 0.40; and~~

~~(C) Obtains a score of 4.0 for fibers, 3.0 for specks and 3.0 for masses using the phantom image scoring protocol in section 30316.30.~~

~~(D) The difference between the OD measured inside the image of the disc and the OD measured adjacent to the image of the disc is at least 0.40 and the difference is not more than plus or minus 0.05 OD when compared to the facility's established operating level.~~

~~(5)(3) No Change to Text.~~

~~(6)(4) No Change to Text.~~

~~(7) The focal spot condition meets one of the following:~~

~~(A) Until October 28, 2002, the measured focal spot length (dimension parallel to the anode cathode axis) and width (dimension perpendicular to the anode cathode axis) shall be within the tolerance limits specified in Table 1. If a star pattern is used to evaluate focal spot condition, the star pattern shall, for evaluation of the large focal spot, be no larger than 1.5 degrees and, for evaluation of the small focal spot, be no larger than 1.0 degree.~~

Table 1

Focal Spot Tolerance Limit

Nominal Focal Spot Size (mm)	Maximum Measured Dimensions	
	Width (mm)	Length (mm)
0.10	0.15	0.15
0.15	0.23	0.23

0.20	0.30	0.30
0.30	0.45	0.65
0.40	0.60	0.85
0.60	0.90	1.30

~~(B)~~(5) For screen-film mammography, theThe focal spot condition shall be evaluated by determining the mammography system resolution in accordance with the following and meet the specified criteria:

~~(1)~~(A) Each mammography system used for mammography, in combination with the mammography screen-film combination used in the facility, shall provide a minimum resolution of 11 cycles/millimeter (mm) (line-pairs/mm) when a high contrast resolution bar test pattern is oriented with the bars perpendicular to the anode-cathode axis, and a minimum resolution of 13 line-pairs/mm when the bars are parallel to that axis;

~~(2)~~(B) The bar pattern shall be placed 4.5 cm above the breast support surface, centered with respect to the chest wall edge of the image receptor, and with the edge of the pattern within 1 cm of the chest wall edge of the image receptor;

~~(3)~~(C) When more than one target material is provided, the measurement in paragraph (5)~~subsection (e)(7)(A)~~ shall be made using the appropriate focal spot for each target material;

~~(4)~~(D) When more than one source-image-distance (SID) is provided, the test shall be performed at the SID most commonly used clinically; and

~~(5)~~(E) Test kVp shall be set at the value used clinically by the facility for a standard breast and shall be performed in the AEC mode, if available. If necessary, a suitable absorber may be placed in the beam to increase exposure times. The screen-film cassette combination used by the facility shall be used to test for this requirement and shall be placed in the normal location used for clinical procedures.

~~(8)~~(6) *No Change to Text.*

~~(9)~~(7) *No Change to Text.*

~~(10)~~(8) *No Change to Text.*

~~(11)~~(9) *No Change to Text.*

~~(12)~~(10) For screen-films systems, theThe uniformity of screen speed of all cassettes in the facility are tested, and that the difference between the maximum and minimum optical densities do not exceed 0.30. The optical density of the test films shall be no less than 1.4;

~~(13)~~(11) During the uniformity of screen speed test specified in ~~subsection (e)~~~~(12)~~paragraph (10), system artifacts are evaluated with a high-grade, defect-free sheet of homogeneous material large enough to cover the mammography cassette and performed on all cassette sizes used in the facility using a grid appropriate for the cassette size being tested. The optical density of the test films shall be no less than 1.4;

~~(14)~~(12) *No Change to Text.*

~~(15) Until October 28, 2002, each machine produces, over 3.0 seconds, a minimum output of 4.5 mGy air kerma per second (513 milliroentgen (mR) per second) when operating at 28 kVp in the standard mammography (molybdenum/molybdenum) mode at any SID where the system is designed to operate and when measured by a detector with its center located 4.5 cm above the breast support surface with the compression paddle in place between the source and the detector;~~

~~(16) After October 28, 2002, each~~(13) Each machine produces, over 3.0 seconds, a minimum output of 7.0 mGy air kerma per second (800 milliroentgen (mR) per second) when operating at 28 kVp in the standard mammography (molybdenum/molybdenum) mode at any SID where the system is designed to operate and when measured by a detector with its center located 4.5 cm above the breast support surface with the compression paddle in place between the source and the detector;

~~(17)~~(14) *No Change to Text.*

~~(18)~~(15) For screen-film systems, theThe calibration of the densitometer and sensitometer used by the facility meets the manufacturer's specifications; and

~~(19)~~(16) For systems with image receptor modalities other than screen-film, the quality assurance program meets the quality assurance program recommended by the image receptor manufacturer, except that the maximum allowable dose shall not exceed

the maximum allowable dose for screen-film systems specified in subsection ~~(e)(10)~~paragraph (8).

(f) Each facility conducting screen-film mammography shall ensure that:

(1) and (2) *No Change to Text.*

(3) All view boxes used to score phantom images and interpret mammograms are cleaned each week. ~~If the view box used to interpret mammograms is at a different location than where the mammograms are taken, the facility shall ensure that~~ documentation establishing the following is available to personnel and Department inspectors:

~~(A) Physical location(s) where the mammograms produced by the facility are interpreted;~~

~~(B) For each location, the individual responsible for ensuring the view boxes are cleaned at intervals not to exceed seven calendar days; and~~

~~(C) A log indicating the date and who cleaned the view boxes.~~

(g) After completion of the tests specified in subsections (a), ~~(b)~~, ~~(d)~~ and ~~(e)(4)~~ ~~(10)~~, and ~~(19)~~, through (f), the test results shall be compared to the corresponding specified action limits. For non-screen-film modalities, the test results shall be compared to the manufacturer's recommended action limits. If the test results fall outside of the action limits, the source of the problem shall be identified and corrective actions shall be taken:

(1) Before any further examinations are performed or any clinical films are processed using a component of the mammography system that failed any of the tests described in subsections (a), (b), (d), or (e)(10); and

(2) Within 30 days of the test date for all other tests specified in this section.

~~if any of the test results fail to meet the specified criteria, the source of the problem shall be identified and corrective actions shall be taken before any further mammographic examinations are performed or any films are processed using the component of the mammography system that failed the test.~~

(h) Each facility conducting mammography shall, if any of the results of the tests specified in subsections ~~(c)~~, ~~(e)(1) through (3)~~, ~~(5) through (9)~~ and ~~(11) through (18)~~ and

~~(f) fall outside the action limits, identify the source of the problem and take corrective actions within 30 days of the test date.~~

(i~~h~~) *No Change to Text.*

(j~~i~~) Documentation of the tests performed, the analysis of data obtained, corrective actions, and the effectiveness of those actions taken pursuant to this section shall be maintained in accordance with section ~~30319.20~~30317.20.

~~NOTE: Authority cited: Sections 100275 and 115060, Health and Safety Code. Reference: Sections 115060, 115100 and 115115, Health and Safety Code.~~

NOTE: Authority cited: Sections 114975, 115000, 115060 and 131200, Health and Safety Code. Reference: Sections 115060, 115100, 115115, 131050 and 131051, Health and Safety Code.

Repeal section 30316.22:

§ 30316.22. Acceptable Phantoms.

- ~~(a) A phantom shall not be used unless it is approved by the FDA and is:~~
- ~~(1) Mammographic Accreditation Phantom Model 156 produced by Radiation Measurement, Inc.;~~
 - ~~(2) Mammographic Accreditation Phantom Model 18-220 produced by Nuclear Associates; or~~
 - ~~(3) Equivalent in thickness to a standard breast and:
 - ~~(A) Contains six nylon fibers with the following diameters:
 - 1. 1.56 millimeters (mm);
 - 2. 1.12 mm;
 - 3. 0.89 mm;
 - 4. 0.75 mm;
 - 5. 0.54 mm;
 - 6. 0.40 mm;~~
 - ~~(B) Contains five aluminum oxide speck groups, each containing six specks and each speck in the group has the same diameter. The diameter of the specks shall be:
 - 1. 0.54 mm;
 - 2. 0.40 mm;
 - 3. 0.32 mm;
 - 4. 0.24 mm;
 - 5. 0.16 mm; and~~
 - ~~(C) Contains five nylon masses with decreasing diameters and the following thicknesses:
 - 1. 2.00 mm;~~~~

- 2. 1.00 mm;
- 3. 0.75 mm;
- 4. 0.50 mm;
- 5. 0.25 mm.

NOTE: Authority cited: Sections 100275 and 115060, Health and Safety Code.
Reference: Sections 115060, 115100 and 115115, Health and Safety Code.

Repeal and Adopt section 30316.30 to read as follows:

§ 30316.30. Phantom Image Scoring Protocol.

(a) Each screen-film mammography system used to perform screening or diagnostic mammography shall achieve at least the minimum phantom image score specified through the protocol established by the facility's accreditation body in accordance with title 21, Code of Federal Regulations Section 900.4(d)(3).

(b) Each screen-film mammography system not subject to subsection (a) shall achieve a minimum phantom image score of at least 4.0 for fibers, 3.0 for specks, and 3.0 for masses by using the following protocol:

(1) For fibers: Begin with the largest fiber and move down in size, adding one point for each full fiber until a score of zero or one half is given, then stop. If the entire length of the fiber can be seen and its location and orientation are correct, that fiber receives a score of one. If at least half, but not all, of the fiber can be seen and its location and orientation are correct, that fiber receives a score of one half. If less than one half of a fiber can be seen or if the location or orientation is incorrect, that fiber receives a score of zero. After determining the last fiber to be counted, look at the overall background for artifacts. If there are background objects that are fiber-like in appearance and are of equal or greater brightness than the last visible half or full fiber counted, subtract the last half or full fiber scored.

(2) For speck groups: Begin with the largest speck group and move down in size adding one point for each full speck group until a score of one half or zero is given, then stop. If at least four of the specks in any group are visualized, the speck group is scored as one. If two or three specks in a group are visualized, the score for the group

is one half. If one speck or no specks from a group are visualized, the score is zero. After determining the last speck group to receive a full or one-half point, look at the overall background for artifacts. If there are speck-like artifacts within the insert region of the phantom that are of equal or greater brightness than individual specks counted in the last visible half or full speck group counted, subtract the artifact speck from the observed specks, one by one. Repeat the scoring of the last visible speck group after these deductions.

(3) For masses: Begin with the largest mass and add one point for each full mass observed until a score of one half or zero is assigned, then stop. Score one for each mass that appears as a minus density object in the correct location that can be seen clearly enough to observe round, circumscribed borders. Score one-half if the mass is clearly present in the correct location, but the borders are not visualized as circular. After determining the last full or half mass to be counted, look at the overall background for artifacts. If there are background objects that are mass-like in appearance and are of equal or greater visibility than the last visible mass, subtract the last full or half point assigned from the original score.

~~(a) This section shall apply only to screen film mammography systems.~~

~~(b) Phantom images shall be scored in accordance with the following protocol.~~

~~Each of the following object groups shall be scored separately and shall meet the criteria specified in section 30316.20(b)(3) and (e)(4):~~

~~(1) Score the fibers as follows:~~

~~(A) Begin with the largest fiber and move down in size, adding one point for each full fiber until a score of zero or one half is given, then stop.~~

~~(B) If the entire length of the fiber can be seen and its location and orientation are correct, that fiber receives a score of one.~~

~~(C) If at least half, but not all, of the fiber can be seen and its location and orientation are correct, that fiber receives a score of one half.~~

~~(D) If less than one half of a fiber can be seen or if the location or orientation is incorrect, that fiber receives a score of zero.~~

~~(E) After determining the last fiber to be counted, look at the overall background for artifacts. If there are background objects that are fiber-like in appearance and are of equal or greater brightness than the last visible half or full fiber counted, subtract the last half or full fiber scored.~~

~~(2) Score the speck groups as follows:~~

~~(A) Begin with the largest speck group and move down in size adding one point for each full speck group until a score of one half or zero is given, then stop.~~

~~(B) If at least four of the specks in any group are visualized, the speck group is scored as one.~~

~~(C) If two or three specks in a group are visualized, the score for the group is one half.~~

~~(D) If one speck or no specks from a group are visualized, the score is zero.~~

~~(E) After determining the last speck group to receive a full or one-half point, look at the overall background for artifacts. If there are speck-like artifacts within the insert region of the phantom that are of equal or greater brightness than individual specks counted in the last visible half or full speck group counted, subtract the artifact speck from the observed specks, one by one. Repeat the scoring of the last visible speck group after these deductions.~~

~~(3) Score the masses as follows:~~

~~(A) Begin with the largest mass and add one point for each full mass observed until a score of one-half or zero is assigned, then stop.~~

~~(B) Score one for each mass that appears as a minus density object in the correct location that can be seen clearly enough to observe round, circumscribed borders.~~

~~(C) Score one-half if the mass is clearly present in the correct location, but the borders are not visualized as circular.~~

~~(D) After determining the last full or half mass to be counted, look at the overall background for artifacts. If there are background objects that are mass-like in appearance and are of equal or greater visibility than the last visible mass, subtract the last full or half point assigned from the original score.~~

~~NOTE: Authority cited: Sections 100275 and 115060, Health and Safety Code.
Reference: Sections 115060, 115100 and 115115, Health and Safety Code.~~

~~NOTE: Authority cited: Sections 114975, 115000, 115060 and 131200, Health and Safety Code. Reference: Sections 115060, 115115, 131050 and 131051, Health and Safety Code.~~

Repeal section 30316.40:

§ 30316.40. Processing of Mammograms and Phantom Images.

~~Each facility possessing a facility accreditation certificate and conducting screen-film mammography shall process phantom images in the processor(s) designated by the facility to process mammograms.~~

~~NOTE: Authority cited: Sections 100275 and 115060, Health and Safety Code.
Reference: Sections 115060, Health and Safety Code.~~

Repeal section 30316.50:

§ 30316.50. Mammographic Image Identification.

- ~~(a) The following information shall be placed on each mammogram in a permanent, legible manner that does not obscure anatomic structures:~~
- ~~(1) Name of patient and an additional patient identifier;~~
 - ~~(2) Date of examination;~~
 - ~~(3) View and laterality, which shall be indicated on the image in a position near the axilla using the abbreviations specified in subsections (b) and (c);~~
 - ~~(4) Facility name, city, state and zip code of the facility that performed the mammogram;~~
 - ~~(5) Technologist identification;~~
 - ~~(6) Identification of the cassette/screen used in producing the mammographic image; and~~
 - ~~(7) Radiation machine identification if there is more than one radiation machine used for mammography at the facility.~~
- ~~(b) The following abbreviations shall be used to indicate laterality:~~
- ~~(1) Right: "R";~~
 - ~~(2) Left: "L".~~
- ~~(c) At a minimum, the following abbreviations shall be used to indicate the view:~~
- ~~(1) Craniocaudal: "CC";~~
 - ~~(2) Mediolateral oblique: "MLO";~~
 - ~~(3) Mediolateral: "ML";~~
 - ~~(4) Lateromedial: "LM";~~
 - ~~(5) Lateromedial oblique: "LMO".~~

NOTE: Authority cited: Sections 100275 and 115060, Health and Safety Code.
Reference: Sections 115060, 115100 and 115115, Health and Safety Code.

Amend section 30316.60 to read as follows:

§ 30316.60. ~~Medical Physicist Survey Reports.~~

(a) Each facility conducting mammography shall undergo an annual survey by a mammography medical physicist or an individual under the direct supervision of a mammography medical physicist, and shall obtain a survey report, dated and signed by the mammography medical physicist and, if an individual performed the survey under the direct supervision of a mammography medical physicist, the individual being supervised, showing:

(1) The results with measurements and calculated data used for the mammography system evaluation ~~and the calibration record required in section 30316.61(a);~~

(2) The results of the quality assurance testing evaluation, as well as written documentation of any corrective actions taken and their results; and

(3) Written recommendations for corrective actions according to all results required to be in the report, if applicable.

(b) The survey report, specified in subsection (a), shall be obtained within 30 calendar days of the date the mammography medical physicist performed and completed the survey. A facility shall require the mammography medical physicist to notify them within 72 hours of the date the tests were performed of any deficiencies that involve any of the items listed in subsection (g) of section 30316.20.

(c) The survey report shall identify each radiation machine by the facility's radiation machine identification number as specified in section ~~30317(g)~~30317.20(a)(1).

(d) The survey report; and ~~reviews, and calibration documentation~~ required by this section shall be maintained by the user in accordance with section ~~30319.20~~30317.20.

~~NOTE: Authority cited: Sections 115060, 131051, and 131200, Health and Safety Code. Reference: Sections 115060 and 115100, Health and Safety Code.~~

NOTE: Authority cited: Sections 114975, 115060 and 131200, Health and Safety Code. Reference: Sections 115060, 115100, 131050 and 131051, Health and Safety Code.

Amend section 30316.61 to read as follows:

§ 30316.61. Instruments Used by Mammography Medical Physicists.

(a) Instruments used by mammography medical physicists to measure the air kerma or air kerma rate from a radiation machine used for mammography shall be calibrated at least once every two years and each time the instrument is repaired. The instrument calibration shall be traceable to a national standard and calibrated with an

accuracy of plus or minus 6.0% (95% confidence level) in the mammography energy range. ~~The calibration record shall be maintained in accordance with section 30319.20.~~

~~(b) Instrumentation used by the medical physicist to measure the illumination as specified in section 30316(b)(13) shall be calibrated in units of lux or foot candles and shall meet manufacturer specifications.~~

~~NOTE: Authority cited: Sections 100275 and 115060, Health and Safety Code.
Reference: Sections 115060 and 115100, Health and Safety Code.~~

NOTE: Authority cited: Sections 114975, 115000, 115060 and 131200, Health and Safety Code. Reference: Sections 115060, 115100, 131050 and 131051, Health and Safety Code.

Repeal section 30317:

§ 30317. General Facility Requirements.

~~(a) The facility shall designate a quality assurance technologist.~~

~~(b) Tests specified in section 30316.20(a) through (d) and (f) shall be performed by the quality assurance (QA) technologist or by other personnel qualified to perform the tasks. When other personnel are utilized for these tasks, the QA technologist shall ensure that the specified tests are performed correctly. The QA technologist shall maintain documentation of training received by the other personnel.~~

~~(c) The facility's lead interpreting physician shall verify that the provisions of this section and sections 30316.20, 30316.40, 30316.50, 30316.60, 30317.10, 30317.20, 30317.30, 30317.40, 30317.60, and 30319.20 are met.~~

~~(d) A facility shall ensure an interpreting physician is available by telephone or in person for consultation when mammographic examinations are performed.~~

~~(e) A facility shall ensure that mammographic examinations are performed under the supervision, as defined in Health and Safety Code section 114850(g), of an individual who meets the requirements of section 30315.50.~~

~~(f) Each facility shall provide and require that all operators of radiation machines used for mammography use a chart or manual that specifies technique factors to be utilized relative to the patient's body habitus.~~

~~(g) Each facility shall maintain an inventory of each mammography Radiation machine. The inventory shall identify each machine by a unique radiation machine identification number. That number shall be permanently affixed to the machine.~~

NOTE: Authority cited: Sections 115060, 131051 and 131200, Health and Safety Code.
Reference: Sections 115060, 115100 and 115115, Health and Safety Code.

Repeal and Adopt section 30317.10 to read as follows:

§ 30317.10. Mammography Quality Assurance Program.

(a) Each user possessing a radiation machine used for mammography is responsible for the acts and omissions of all individuals involved in the user's mammography quality assurance (QA) program.

(b) Each user possessing a radiation machine used for mammography shall designate a lead supervising physician, who is responsible for:

(1) Establishing and maintaining a mammography quality assurance program that meets the requirements in this section and in sections 30316.20 and 30318.10;

(2) Reviewing the QA program and documenting that review at intervals not to exceed six months;

(3) Ensuring that mammography is performed only by individuals who meet the requirements of section 30315.50(a)(2) and are acting under the supervision, as defined in section 30400, of a physician meeting the requirements in section 30315.50(a)(1). The physician shall be immediately available to the individual performing mammography by telephone or in person for consultation;

(4) Ensuring that both the evaluation specified in section 30316.10 and the annual survey required in section 30316.60 are conducted by a mammography medical physicist; and

(5) Designating the quality control technologist responsible for the tasks specified in subsection (d). No other individual shall be assigned or shall retain responsibility for those tasks unless the lead supervising physician has determined that that individual is qualified to perform those assignments. If other personnel are utilized to perform any of the tasks, the quality control technologist shall verify that those tasks are performed correctly and shall maintain documentation of the mammography quality control training received by those personnel.

(c) Each user shall provide and require that all operators of radiation machines used for mammography use a chart or manual that specifies technique factors to be utilized relative to the patient's body habitus.

(d) The quality control technologist shall be responsible for ensuring that:

(1) The tests specified in section 30316.20(a) through (d) and in section 30318.10(b) are performed;

(2) The tests established for mammography systems using image receptor modalities other than screen-film, as recommended by the image receptor manufacturer, are performed;

(3) The chart or manual required pursuant to subsection (c) is available to all individuals performing mammography in the facility; and

(4) All mammography equipment is disinfected prior to each mammographic examination in accordance with:

(A) Title 29, Code of Federal Regulations, section 1910.1030;

(B) Title 8, California Code of Regulations, section 5193; and

(C) The equipment manufacturer's recommended procedures.

~~(a) Each facility shall establish and maintain a mammography quality assurance (QA) program to ensure the safety, reliability, clarity and accuracy of mammography services performed at the facility. A review of the QA program shall be conducted and documented by the lead interpreting physician at intervals not to exceed six months. The QA program shall, at a minimum, include the following:~~

~~(1) Establishment of operating levels meeting manufacturer specifications by which the criteria specified in section 30316.20(a) is compared.~~

~~(2) Documentation of accreditation by an entity approved by the FDA pursuant to 42 United States Code Section 263b(e)(1)(A) and certification by FDA;~~

~~(3) Documentation that each interpreting physician who interprets mammograms for the facility meets the requirements of section 30315.50.~~

~~(4) Documentation that each mammographic radiologic technologist who performs mammography meets the requirements of section 30315.51;~~

~~(5) Documentation that each medical physicist who performs the tests specified in section 30316.20(e) meets the requirements of section 30315.52;~~

~~(6) The QA manual required by section 30317.20;~~

~~(7) The mammography procedures manual required by section 30317.30; and~~

~~(8) If the facility is a mobile service provider, a list identifying the physical location where radiation machines are used.~~

~~NOTE: Authority cited: Sections 100275 and 115060, Health and Safety Code.~~

~~Reference: Sections 115060, 115100 and 115115, Health and Safety Code.~~

NOTE: Authority cited: Sections 114975, 115000, 115060 and 131200, Health and Safety Code. Reference: Sections 115060, 115100, 115115, 131050 and 131051, Health and Safety Code.

Repeal and Adopt section 30317.20 to read as follows:

§ 30317.20.-~~Quality Assurance Manual~~ Records.

(a) Each user possessing a radiation machine used for mammography shall maintain and make available to the Department the following records:

(1) An inventory that identifies each radiation machine used for mammography by a unique identification number that is permanently affixed to the machine by the user;

(2) Reports of the evaluation of new, reassembled, replaced or repaired equipment required in section 30316.10;

(3) Reports of the annual surveys required in section 30316.60;

(4) Records of the results of each test specified in section 30316.20(a) through (e) and (g) and in section 30318.10(b), along with documentation of any corrective actions taken; and

(5) For each radiation machine used for mammography that is subject to 42 United States Code Section 263b (Mammography Quality Standards Act [Pub. L. 102-539], as amended), documentation that the machine has been accredited by an entity approved by the FDA pursuant to 42 United States Code Section 263b(e)(1)(A).

(b) The records specified in subsection (a) shall be maintained until the next inspection has been completed and the Department has determined that the user is in compliance with all quality assurance requirements specified in section 30317.10.

(c) Each user possessing a radiation machine used for mammography shall maintain and make available to the Department documents demonstrating compliance with the personnel requirements in section 30315.50. Records of personnel no longer performing mammography for the user and physicians no longer supervising personnel performing mammography for the user may not be discarded until the next inspection has been completed and the Department has determined that the user is in compliance with section 30315.50.

~~(a) Each facility that performs mammography shall establish and maintain a written quality assurance (QA) manual. The lead interpreting physician shall document a~~

~~review of the QA manual at intervals not to exceed six months. At a minimum, the QA manual shall contain:~~

- ~~(1) A list of names identifying the following:
 - ~~(A) The lead interpreting physician designated by the facility;~~
 - ~~(B) The quality assurance technologist;~~
 - ~~(C) The medical physicist who will perform the tests specified in subsection (e) of section 30316.20; and~~
 - ~~(D) The company providing processor and equipment services.~~~~
- ~~(2) The procedures to be used to ensure that the tests specified in section 30316.20(a) through (d) and (f) are performed and the criteria have been met;~~
- ~~(3) The procedure for correcting each finding that fails to meet the requirements of section 30316.20(a) through (f);~~
- ~~(4) Examples of the forms to be used for each test specified in section 30316.20(a) through (d) and (f);~~
- ~~(5) Documentation that equipment used during QA tests specified in section 30316.20 meet manufacturer specifications;~~
- ~~(6) The most recent survey report required to be obtained pursuant to section 30316.60 and evidence that instruments used by the medical physicist are calibrated pursuant to section 30316.61;~~
- ~~(7) Documentation of all QA tests required to be performed pursuant to section 30316.20(a) through (d) and (f);~~
- ~~(8) Documentation of compliance with section 30316.20(g) and (h);~~
- ~~(9) Documentation of compliance with section 30316.10 covering the previous two years;~~
- ~~(10) Documentation that each interpreting physician, mammographic radiologic technologist and medical physicist has reviewed the manual annually or, if any update has occurred, evidence that the manual has been reviewed by the said individuals; and~~
- ~~(11) Documentation of preventive and corrective maintenance, chemistry replacement and cleaning of each processor used to process mammograms. The documentation shall contain the signature of the individual who performed the maintenance.~~

~~NOTE: Authority cited: Sections 100275 and 115060 Health and Safety Code.
Reference: Sections 115060, 115100 and 115115, Health and Safety Code.~~

NOTE: Authority cited: Sections 114975, 115000, 115060 and 131200, Health and Safety Code. Reference: Sections 115060, 115100, 115115, 131050, 131051 and 131052, Health and Safety Code.

Repeal section 30317.30.

§ 30317.30. Mammography Procedures Manual.

~~(a) Each facility shall establish a written mammography procedures manual. The lead interpreting physician shall document a review of the manual at intervals not to exceed six months. The mammography procedures manual shall, at a minimum, contain the following:~~

~~(1) The procedure for corrective action when the images interpreting physicians are asked to interpret are of poor quality and documentation that the procedure is followed;~~

~~(2) A policy that requires each interpreting physician to participate in the mammography medical outcomes audit as specified in section 30317.60;~~

~~(3) Examples of mammographic examination reports in lay language for each assessment of findings category and the procedures used to ensure the patient, if the patient does not indicate a health care provider, is referred to a health care provider if the patient's mammogram is interpreted by an interpreting physician as a positive mammogram;~~

~~(4) The procedure used to inquire whether or not the patient has prosthetic devices implanted in the breast prior to the mammographic examination and evidence that the procedure is followed. The procedure shall specify that except where contraindicated, or unless modified by a physician's directions, patients with such implants shall have mammographic views to maximize the visualization of breast tissue;~~

~~(5) The procedure to be used by each mammographic radiologic technologist to ensure that prior to each mammographic examination the mammography equipment is disinfected. The procedure shall comply with title 29, Code of Federal Regulations section 1910.1030 as of July 1, 2001, title 8, California Code of Regulations section 5193 and with the manufacturer's recommended procedures for cleaning and disinfection of the mammography equipment used in the facility;~~

~~(6) The procedures used to comply with section 30317.70 pertaining to consumer complaints;~~

~~(7) The procedure used to ensure mammographic examination reports are sent as required by section 30317.40; and~~

~~(8) Documentation that the mammography medical outcomes audit is performed as specified in section 30317.60.~~

~~(b) Procedures and policies developed to comply with this section shall be followed by the facility.~~

NOTE: Authority cited: Sections 100275 and 115060, Health and Safety Code.
Reference: Sections 115060, 115100 and 115115, Health and Safety Code.

Repeal section 30317.40:

§ 30317.40. Mammographic Examination Reports.

~~(a) Each facility shall ensure that a written report of the results of each mammographic examination conducted at that facility is prepared and includes at least the following:~~

- ~~(1) Name of the patient and an additional patient identifier;~~
- ~~(2) Date of the examination;~~
- ~~(3) Name of the interpreting physician who interpreted the mammogram;~~
- ~~(4) Overall assessment of findings, classified in one of the following categories:
 - ~~(A) "Negative:" Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained);~~
 - ~~(B) "Benign:" Also a negative assessment;~~
 - ~~(C) "Probably Benign:" Finding(s) has a high probability of being benign;~~
 - ~~(D) "Suspicious:" Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant;~~
 - ~~(E) "Highly suggestive of malignancy:" Finding(s) has a high probability of being malignant;~~~~
- ~~(5) In cases where a final assessment category cannot be assigned due to incomplete work-up, "Incomplete: Need additional imaging evaluation" shall be assigned as an assessment and reasons why no assessment can be made shall be stated by the interpreting physician; and~~
 - ~~(6) Recommendations made to the patient's health care provider about what additional actions, if any, should be taken. All clinical questions raised by the referring physician shall be addressed in the report to the extent possible, even if the assessment of findings is negative or benign.
 - ~~(b) Each facility shall ensure that the report specified in subsection (a) is summarized in lay terms and sent no later than 30 calendar days from the date of the mammographic examination to the patient.~~
 - ~~(c) Each facility shall ensure that the report specified in subsection (a) is sent no later than 30 calendar days from the date of the mammographic examination to the referring physician(s), or if the patient is self-referred, to the physician indicated by the patient or the physician to whom the facility refers the patient.~~
 - ~~(d) Each facility shall verify that:
 - ~~(1) Patients with an overall assessment of findings of "suspicious" or "highly suggestive of malignancy" and patients needing repeat examinations have received notification; and~~
 - ~~(2) Physicians have received notification of patients with an overall assessment of findings of "suspicious" or "highly suggestive of malignancy" and needing repeat examinations.~~~~
 - ~~(e) If an interpreting physician has given a mammogram an assessment of findings as "suspicious" or "highly suggestive of malignancy," the facility shall attempt to communicate the results to the patient within five working days and the health care provider or if the health care provider is unavailable, to a responsible designee of the health care provider within three working days.~~~~

NOTE: Authority cited: Sections 100275 and 115060, Health and Safety Code.
Reference: Section 115060, Health and Safety Code.

Repeal section 30317.50:

§ 30317.50. Mammogram and Report Retention.

~~Unless otherwise required by law, each facility that performs mammography shall:~~

~~(a) Unless transferred in accordance with subsection (b), maintain mammograms and the reports specified in section 30317.40 for a minimum of seven years and if no additional mammograms of the patient are taken by the facility, mammograms and reports shall be maintained for a minimum of ten years.~~

~~(b) Upon request or on behalf of the patient, permanently or temporarily transfer the original mammograms and copies of the patient's mammographic examination reports to a medical institution, a physician or to the patient directly. Any fee charged for this service shall not exceed the documented cost of the service.~~

~~(c) If the facility will discontinue the performance of mammography, notify the Department prior to discontinuing mammography of how all records kept pursuant to subsection (a) will be maintained.~~

NOTE: Authority cited: Sections 100275 and 115060, Health and Safety Code.
Reference: Sections 115060 and 123145, Health and Safety Code.

Repeal section 30317.60.

§ 30317.60. Mammography Medical Outcomes Audit.

~~(a) Each facility possessing a facility accreditation certificate shall collect and review outcome data for all mammograms interpreted by the facility as a positive mammogram, including follow up on the disposition of all positive mammograms and correlation of pathology results with the interpreting physician's mammographic examination report. Each facility shall analyze these outcome data for all interpreting physicians, both individually and collectively. The lead interpreting physician or an interpreting physician designated by the lead interpreting physician shall perform the analysis.~~

~~(b) For any cases of an individual diagnosed with breast cancer who was imaged at the facility and whose identity became known to the facility, the facility shall initiate follow up on surgical and/or pathology results and conduct a review of any mammogram taken prior to the diagnosis of a malignancy. These cases shall be included in the analysis required pursuant to subsection (a).~~

~~(c) Each facility possessing a facility accreditation certificate shall ensure that the analysis required by subsection (a) is initiated no later than 12 months after the date of issuance of the facility accreditation certificate. The analysis shall be completed within 12 months of the date the analysis was initiated. Subsequent audit analyses shall be performed at least once every 12 months thereafter.~~

~~(d) The facility's lead interpreting physician or an interpreting physician designated by the lead interpreting physician, shall:~~

- ~~(1) Record the dates of the audit period(s);~~
 - ~~(2) Document the results;~~
 - ~~(3) Review the medical outcomes audit data;~~
 - ~~(4) Analyze the results of the audit;~~
 - ~~(5) Provide the results of the review of a specific interpreting physician to that interpreting physician and the overall results of the review for the facility review; and~~
 - ~~(6) Provide a written description of any follow-up actions and the nature of the follow-up actions taken.~~
- ~~(e) Each facility shall maintain reports, outcome data, analyses and documentation of actions taken specified in this section in accordance with section 30319.20.~~

NOTE: Authority cited: Sections 100275 and 115060, Health and Safety Code.
Reference: Sections 115060, 115100 and 115115, Health and Safety Code.

Repeal section 30317.70.

§ 30317.70. Consumer Complaints.

- ~~Each facility possessing a facility accreditation certificate shall:~~
- ~~(a) Establish a written procedure for collecting and resolving consumer complaints;~~
 - ~~(b) Maintain a record of each serious complaint received by the facility in accordance with section 30319.20;~~
 - ~~(c) Provide to the consumer, upon request, a copy of the facility's procedure required in subsection (a) and instructions for filing serious complaints to the entity approved by the FDA pursuant to 42 United States Code Section 263b(e)(1)(A) that accredited the facility;~~
 - ~~(d) Report unresolved serious complaints to the Department within 30 calendar days of receiving the complaint.~~

NOTE: Authority cited: Sections 100275 and 115060, Health and Safety Code.
Reference: Section 115060, Health and Safety Code.

Amend section 30318.10 to read as follows:

§ 30318.10. Additional Requirements for Mobile Service Providers Mammography.

- (a) Prior to the performance of performing mammography by in a mobile service provider setting at a location other than a location identified on the application submitted pursuant to section 30315.22 or 30315.23, the provider user shall notify the Department. The notification shall include of the following information in writing:

- (1) The name and physical and mailing address of the ~~mobile service provider~~user;
- (2) The ~~certificate number as shown on the facility accreditation certificate of the mobile service provider~~name and telephone number of a contact person for the user;
- (3) The physical location of the new location where mammography will be performed;
- (4) The ~~name and telephone number of the individual who is allowing the service to be provided at the new location~~ registration number issued to the user by the Department;
- (5) If the radiation machine is moved to where the mammographic examinations will be performed, the ~~designated room number within the physical building at the new location of use~~ The unique identification number assigned by the user to the radiation machine pursuant to section 30317.20(a)(1); and
- (6) The physical location where mammograms produced at the new location will be processed.
 - (b) ~~After each relocation of the radiation machine and before the performance of mammography on humans, the processor shall be tested to ensure that the criteria specified in section 30316.20(a) are met, and the radiation machine shall be tested to ensure that it meets the requirements of section 30316.20(b)(1) through (3). If a processor is not available at the location where mammography is performed, a phantom image shall be produced by using the procedure specified in section 30316.20(b). The selected kilovoltage peak and milliamperere seconds (mAs) shall be recorded and compared to the mAs value previously established as meeting the phantom image criteria specified in section 30316.20(b). If the two mAs values are within plus or minus 10 percent of each other, mammography may be performed. If the values exceed the limits, mammography shall not be performed and corrective actions shall be taken to bring the two values within the limit.~~
 - (c) ~~If a mobile service provider processes mammograms at a location other than where the mammograms are taken:~~

~~(1) The mammograms shall be transported in a container that protects the film from exposure to light, heat, humidity, radiation, and conditions that may damage the mammograms and processed within 48 hours from the time the mammogram is taken;~~

~~(2) A log shall be maintained that includes the name of each patient and unique identification number, date, and time of the first exam of each batch, and date and time of batch processing in accordance with section 30319.20; and~~

~~(3) The container used to transport the mammograms shall be cleaned at intervals not to exceed seven days or if mammography is performed at greater intervals, before the mammograms are transported.~~

~~(d) Prior to processing mammograms, the provider shall ensure that the test specified in section 30316.20(a) has been met and that the phantom image produced during the test specified in subsection (c) of this section meets the phantom image criteria specified in section 30316.20(b) and if the phantom image fails due to processing problems, the problems shall be corrected prior to processing the mammograms. If the phantom image fails due to a non-processor problem, the provider may process the mammograms, but the lead interpreting physician shall evaluate each mammogram to determine whether any patient must be recalled to have their mammograms repeated. Prior to further clinical use, the mammography system shall be evaluated and problems corrected to ensure that the mammography system is in compliance with all requirements of this article.~~

~~(e) Documentation demonstrating compliance with this section shall be maintained in accordance with section 30319.20.~~

(b) Prior to performing screen-film mammography at a new location, the individual operating the radiation machine shall determine that the standards specified in sections 30316.20(a) and (b) are met. If the processor is not located where mammography is performed:

(1) A phantom image shall be produced using the procedure specified in section 30316.20(b);

(2) The selected peak kilovoltage (kVp) and resulting milliampere-seconds (mAs) used to produce the phantom image shall be recorded and compared to the previously

established mAs value that produced a phantom image meeting the criteria specified in section 30316.20(b). If the resulting mAs value is greater than plus or minus 10 percent of the previously established mAs value, mammography may not be performed until corrective action has been taken to bring the resulting mAs value to within 10 percent of the previously established mAs value;

(3) The unprocessed phantom image shall be transported along with any subsequent clinical films in a container that protects the film from exposure to conditions that may damage the mammograms. The phantom image and mammograms shall be processed within 48 hours from the time the mammographic examinations were performed;

(4) Before processing the phantom image, the processor performance shall be tested to ensure that the criteria specified in section 30316.20(a) are met;

(5) Before processing the mammograms, the phantom image shall be processed and evaluated to determine that the phantom image quality meets the criteria specified in section 30316.20(b); and

(6) If the phantom image fails the criteria specified in section 30316.20(b), the mammograms may be processed, but the lead supervising physician shall evaluate each mammogram to determine whether any patients need to be recalled to have their mammographic examination repeated. Prior to further clinical use, the mammography system shall be evaluated and all problems corrected to ensure that the mammography system is in compliance with all requirements of this article.

(c) Each user shall maintain a log for each radiation machine that identifies every date and physical location where mobile mammography was performed, and includes the name of the operator and results of the tests and corrective actions taken pursuant to subsection (b).

~~NOTE: Authority cited: Sections 100275 and 115060, Health and Safety Code.
Reference: Sections 115060, 115100 and 115115, Health and Safety Code.~~

NOTE: Authority cited: Sections 114975, 115000 and 131200, Health and Safety Code.
Reference: Sections 115060, 115115, 131050 and 131051, Health and Safety Code.

Repeal and Adopt section 30318.11 to read as follows:

§ 30318.11. Posting Requirements for Mobile Service Providers Mammography.

(a) The following documents shall be posted so that patients receiving a mammographic examination in a mobile setting may view them:

(1) All items required to be posted pursuant to section 30255;

(2) If applicable, a copy of the certificate issued by FDA pursuant to title 21, Code of Federal Regulations, section 900.11(a);

(3) A copy of the current mammographic radiologic technology certificate issued by the Department pursuant to section 30455.1 to the individual performing the mammographic examination; and

(4) A copy of the current supervisor and operator certificate or permit issued to the lead supervising physician by the Department pursuant to section 30466.

~~(a) Each mobile service provider shall ensure the following are kept with each radiation machine used to perform mammography in a mobile setting:~~

~~(1) All items required to be posted pursuant to section 30255;~~

~~(2) The mammographic radiologic technologist's certificate issued pursuant to section 30455.1 to the individual performing the mammographic examination and posted so the patient can view it during the examination;~~

~~(3) For facilities performing mammography, the lead interpreting physician's radiology supervisor and operator certificate issued pursuant to section 30466(d) or 30467 and posted so the patient can view it during the examination;~~

~~(4) The document required to be posted on the radiation machine pursuant to Health and Safety Code section 115115(b) so the patient can view it during the examination;~~

~~(5) A copy of the certificate issued by FDA and posted so the patient can view it during the examination;~~

~~(6) The quality assurance records for on-board processors as specified in section 30316.20(a) for at least the last 30 calendar days.~~

~~(7) Documentation that, for each location of use visited in the last 30 calendar days, section 30318.10(b) has been met; and~~

~~(8) The quality assurance manual as specified in section 30317.10.~~

~~(b) Each provider shall maintain a log that identifies the date and physical location where each radiation machine is used.~~

~~NOTE: Authority cited: Sections 100275 and 115060, Health and Safety Code.~~

~~Reference: Sections 115060, 115100 and 115115, Health and Safety Code.~~

NOTE: Authority cited: Sections 114975, 115000, 115060 and 131200, Health and Safety Code. Reference: Sections 115060, 115115, 101050 and 131051, Health and Safety Code.

Amend section 30319 to read as follows:

§ 30319. Notification Requirements.

(a) Within 30 calendar days of the occurrence of any of the following events, each ~~facility that performs~~ user possessing a radiation machine used for mammography shall inform the Department of ~~the event~~:

(1) ~~Change~~ Any change in the information submitted in response to section 30315.22(a)(1) in an application accepted by the Department pursuant to sections 30315.22 or 30315.23;

(2) ~~Change in the identity of the entity approved by the FDA pursuant to 42 United States Code Section 263b(e)(1)(A) that accredited the facility;~~

(3) ~~Change~~ Any change in certification status with the FDA;

(4) ~~Change in facility personnel and, if adding an interpreting physician, mammographic radiologic technologist, or medical physicist;~~

(5) ~~Change in location of a radiation machine within the facility;~~

(6) ~~Change in facility name or owner;~~

(7) ~~Disassembly and reassembly of any radiation machine or processing equipment;~~

(8) ~~Change in the accreditation status;~~ The receipt of an unsatisfactory image quality report from an entity approved by the FDA pursuant to 42 United States Code Section 263b(e)(1)(A).

(9) ~~Change in the facility's contact person.~~

(b) Notifications made pursuant to this section shall be made in writing and contain the information and signatures required in section 30315.33(a)(1) through (a)(4) and (a)(9) ~~name, signature and date of signature of the facility administrator, owner or designee.~~

~~NOTE: Authority cited: Sections 100275 and 115060, Health and Safety Code.
Reference: Section 115060, Health and Safety Code.~~

NOTE: Authority cited: Sections 114975, 115000, 115060 and 131200, Health and Safety Code. Reference: Sections 115060, 131050 and 131051, Health and Safety Code.

Repeal section 30319.20:

§ 30319.20. Record Keeping Requirements.

~~(a) Each facility shall maintain and make available for inspection by the Department the records specified in Table 1 until Department inspection or the time interval specified which ever is greater:~~

Table 1
Record Keeping Requirements

Specific section	Type of Record	Time Interval for Record Keeping
30315.50	Personnel Qualifications for physicians	At least two years after the physician no longer worked at the facility
30455.1	Personnel Qualifications for mammographic radiologic technologists	At least two years after the technologist no longer worked at the facility
30315.52	Personnel Qualifications for medical physicists	At least two years after the medical physicist no longer worked at the facility
30316.20(a)	QA logs	3 years
30316.20(b)	Processor film strips	1 year
30316.20(b)	Phantom image score sheets	3 years
30316.20(b)	Phantom images	1 year
30316.20(c)(1)	Fixer retention log sheet	3 years
30316.20(c)(1)	Fixer retention test film	1 year
30316.20(c)(2)	Repeat Analysis	3 years
30316.20(d)(1)	Darkroom fog log sheets	3 years
30316.20(d)(1)	Darkroom test films	1 year
30316.20(d)(2)	Screen film contact log sheets	3 years
30316.20(d)(2)	Screen film contact test films	1 year
30316.20(d)(3)	Compression test log sheet	3 years

30316.20(f)	Darkroom cleaning logs Intensifying screen cleaning logs View box cleaning logs	3 years 3 years 3 years
30316.60	Medical Physicist Survey Report evaluations & instrument calibration reports	3 years
30316.10	Evaluations of new or repaired equipment	3 years
30317.60	Medical Outcomes Audit analysis	3 years
30317.70	Consumer complaints	3 years
30318.10	All mobile service provider documents	3 years

~~(b) Each facility shall maintain records for inspection by the Department showing calibrations, maintenance, and modifications performed on each radiation machine for three years. These records shall include the date of the calibration, maintenance, or modification performed, the name of the individual making the record, and the manufacturer's model and the facility's radiation machine identification number as specified in section 30317(g).~~

~~(c) Each facility shall maintain records showing the receipt, transfer, and disposal of radiation machines pursuant to section 30293. These records shall include the date of receipt, transfers, or disposal, the name and signature of the individual making the record, and the manufacturer's model and the facility's radiation machine identification number as specified in section 30317(g). Records shall be maintained for inspection by the Department until the facility ceases use and disposes of the radiation machine.~~

NOTE: Authority cited: Sections 115060, 131051 and 131200, Health and Safety Code.
Reference: Section 115060, Health and Safety Code.

Amend section 30320.90 to read as follows:

§ 30320.90. Grounds for Suspension, Revocation, Amendment or Restriction of a Facility Accreditation Mammography Machine Certificate.

(a) A ~~facility accreditation certificate~~ mammography machine certificate may be revoked, suspended, amended or restricted for any of the following:

(1) Violation of any provision of the Act, any regulation promulgated pursuant to the Act, any provision of the Radiologic Technology Act, as defined in Health and Safety Code section 27, any regulation promulgated pursuant to the Radiologic Technology Act, or any order of the Department;

(2) Failure to pay fees pursuant to sections 30145 or 30145.1;

- (3) Refusal to submit to ~~clinical image review or a~~ mammography review pursuant to section 30315.36 as directed by the Department;
- (4) Failure of clinical images to pass ~~clinical image review or a~~ mammography review;
- (5) Failure to take corrective action when directed by the Department;
- (6) Failure to report changes pursuant to section 30319;
- (7) Procuring a ~~facility accreditation~~ mammography machine certificate by fraud, or misrepresentation, or because of mistake;
- ~~(8) Failure to maintain mammograms and reports pursuant to section 30317.50;~~
- ~~(9)~~(8) Failure to ensure the average glandular dose criteria specified in section 30316.20(e)~~(10)~~(8) is not exceeded;
- ~~(10)~~(9) Failure during a Department inspection to obtain the phantom image score specified in section ~~30316.20(b)(3); 30316.30; or~~
- ~~(11) Failure to comply with policies or procedures required to be developed pursuant to section 30317.30; and~~
- ~~(12)~~(10) Suspension or revocation of the facility's certificate issued by the FDA pursuant to title 21, Code of Federal Regulations, section 900.11(a).

~~NOTE: Authority cited: Sections 100275 and 115060, Health and Safety Code.
Reference: Sections 115060, 115100, 115115, 115145, 115165 and 115215, Health and Safety Code.~~

NOTE: Authority cited: Sections 114975, 115000 and 131200, Health and Safety Code.
Reference: Sections 115060, 115100, 115115, 115145, 115165, 115215, 151050 and 131051, Health and Safety Code.