

Methodology to Indicate Changes to
DPH-10-005 – Requirements for the Use of X-ray in Mammography

The proposed changes for comment that are the subject of this 15-day public comment period are indicated as follows:

- Deleted text is indicated by double strike-through (~~strike-through~~).
- Additions to the regulation text are indicated by double underline (underline).

Regulation text not subject to this 15-day public comment period are presented for the reader's convenience and are indicated as follows:

- Deleted text as initially proposed is indicated by single strike-through (~~strike-through~~).
- Added text as initially proposed is indicated by single underline (underline).

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

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 e 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(b)(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 30315.22 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) ~~Applicant has submitted to the Department all the information~~ 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 30315.33 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. ~~The name and street address of each location where the radiation machine will be used for mammography;~~

(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, and/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 6 months prior to the date of the application ~~by a mammography 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, by a mammography medical physicist, prior to the date of the renewal application ~~by a mammography medical physicist~~. 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.

(9)(10) The signature, title, and date of signature, of the applicant user and the applicant's 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 ~~of its mailing~~, 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 notification by the Department to applicants shall be deemed to occur on the date the notification is postmarked, or if electronically received, 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 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;
- (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).
- (5) In lieu of being qualified under subsections (a)(2) through (4), be qualified under title 21, Code of Federal Regulations, section 900.12(a)(3).

(b) Until [one year from effective date to be entered by Office of Administrative Law], a mammography medical physicist shall meet the requirements specified in title 21, Code of Federal Regulations, section 900.12(a)(3)(iii)(A) and (B) and (iv). On and after [effective date to be entered by Office of Administrative Law], within ~~Within~~ 36 months of being authorized or renewed authorization by the Department pursuant to section 30315.60, the mammography medical physicist shall:

(1) Have taught or completed at least 15 continuing education units in mammography. This continuing education shall include training appropriate to each mammographic modality evaluated by the medical physicist. Units earned through teaching or attending an identical course ~~a specific course~~ can be counted only once, ~~even if the course is taught multiple times~~ during the 36 months 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 conduct surveys in 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 8 hours of training in surveying mammography systems using the new modality.

(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 number (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 the 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 sections 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 physicists 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 30316.20 to read as follows:

§ 30316.20. Quality Assurance Testing.

- (a) *No Change to Text.*
- (b) *No Changes to Initially Proposed Text.*
- (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) T~~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 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, the The 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, the~~The uniformity of screen speed of all cassettes in the facility are tested, and that the difference between the maximum and minimum optical densities do not exceed 0.30. The optical density of the test films shall be no less than 1.4;

~~(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, the The 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) *No Change to Text.*~~

~~(j) 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 30349.2030317.20.~~

~~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.

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

~~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 and Adopt section 30317.10 to read as follows:

§ 30317.10. Mammography Quality Assurance Program.

(a) through (c) *No change to initially proposed text.*

(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 ~~the machine's manufacturer, model, serial number and~~ 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; ~~and~~

(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.

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):

~~(2)~~(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

~~(3)~~(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.