

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 notice (third 15-day public comment period) are indicated as follows:

- Deletions from the proposed text are indicated by a double strike-through *italicized* font (~~strike-through~~).
- Additions to the proposed text are indicated by a double underline *italicized* font (underline).

Regulation text not subject to this third 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~~).
- Additions to the regulation text as initially proposed is indicated by single underline (underline).
- Deletions from the proposed text presented during the first 15-day public comment period are indicated by double strike-through (~~strike-through~~).
- Additions to the proposed text presented during the first 15-day public comment period are indicated by double underline (underline).
- Deletions from the proposed text presented during the second 15-day public comment period are indicated by a shaded double strike-through (~~strike-through~~).
- Additions to the proposed text presented during the second 15-day public comment period are indicated by a shaded double underline (underline).

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).

~~(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 36 months of being authorized or renewed authorization by the Department pursuant to section 30315.60, 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 or attending an identical course a specific course can be counted only once, even if the course is taught multiple times during the 36 months36-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 conduct surveys inof 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 mammography systems using 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) and (b) *No change to initially proposed regulation text.*

~~(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~~ 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.

(d) through (i) *No change to initially proposed regulation text.*

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.

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