State of California—Health and Human Services Agency
California Department of Public Health

TOMÁS J. ARAGÓN, MD, DrPH
Director and State Public Health Officer

GAVIN NEWSOM
Governor

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EXEMPTION TO CALIFORNIA CODE OF REGULATIONS (CCR), TITLE 17, Sections 30316.60(a), 30315.10(b)(21)(D), and 30315.60(a)(3)

1. The cited regulations unreasonably burden the completion of surveys per title 17, CCR, (17 CCR) § 30316.60(a) of the mammography diagnostic review workstation per 17 CCR § 30315.10(b)(21)(D), when the viewing device being evaluated is physically located in another State by requiring the direct supervision of the performance of the survey under a California Authorized Medical Physicist.

2. The cited regulations unreasonably burden the application to conduct mammography surveys per 17 CCR § 30315.60(a)(3) by requiring the direct supervision of the performance of the survey under a California Authorized Medical Physicist, when the applicant is deemed qualified by the FDA per title 21, Code of Federal Regulations (21 CFR), section 900.12(a)(3), or a certifying agency approved by the FDA pursuant to 21 CFR, section 900.21.

Therefore, the Radiologic Health Branch, pursuant to 17 CCR § 30104 grants an exemption from 17 CCR § 30316.60(a), § 30315.10(b)(21)(D), and § 30315.60(a)(3) in regards to the requirement of direct supervision in the below circumstances. Compliance with the conditions will be evaluated during inspections. This exemption remains in effect unless and until regulations are revised, provided the following conditions are met.

1. Review of offsite Diagnostic Review Workstations:
    a. When a Diagnostic Review Workstation (DRW) (17 CCR § 30315.10(b)(21)(D)) is located outside of California, an individual who performs the Quality Control (QC) tests on the DRW does not require direct supervision under a California Authorized Mammography Medical Physicist (CA MMP) as required in 17 CCR § 30316.60(a), provided the following conditions are met:
        i. The facility keeps, on record, documentation to provide evidence the individual meets 21 CFR section 900.12(a)(3)(i); or

ii. Facility obtains a letter, on record, issued to the individual by the FDA, stating that the individual met the requirements of title 21, Code of Federal Regulations, section 900.12(a)(3); or
iii. Facility obtains a letter, on record, issued to the individual by a certifying agency approved by the FDA pursuant to title 21, Code of Federal Regulations, section 900.21, stating that the individual met the requirements of title 21, Code of Federal Regulations, section 900.12(a)(3).

2. An applicant may submit a copy of the sample report required in 17 CCR § 30315.60(a)(3) without the need of direct supervision under a CA MMP for the purposes of applying for Authorization to Conduct Mammography Surveys in California per 17 CCR § 30315.60(a), provided that the following conditions are met:
    i. Applicant provides a copy of a letter issued to the applicant by the FDA, stating that the applicant met the requirements of title 21, Code of Federal Regulations, section 900.12(a)(3).
    ii. Applicant provides a copy of a letter issued to the applicant by 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).

For the Department of Public Health

Signature on file

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Sean Tierney, ICE X-ray Section Chief
Radiologic Health Branch