

## **Fact Sheet for Mammography Facilities Operating in the State of California**

The following guidelines should help you in clarifying the process of satisfying State and Federal requirements.

In California, performance of mammography is regulated by State and Federal laws and regulations, promulgated in the California Health and Safety Code; Title 17, California Code of Regulations, sections 30315.10 through 30320.90; and Title 21 Code of Federal Regulations, part 900.

Mammography facilities must comply with all applicable laws and regulations. Mammography can be legally performed in California only after a facility has received and posted a certificate (or interim notice) issued directly from the Federal Food and Drug Administration (FDA) and individual mammography machine certificate(s) issued by the California Department of Public Health, Radiologic Health Branch (RHB).

**Mammography examinations shall not be performed until the user has the appropriate authorization and is in possession of all the appropriate certificates. This means that an applications specialist may not conduct training on a new machine, if imaging human breasts, until the user has a current FDA certificate and a valid State of California mammography machine certificate for that specific machine. As a result, please be aware that the user must make the appropriate agency notifications in advance in order to fulfill the necessary requirements to receive a certificate and begin performing mammography.**

**State Certification** is machine-based and an individual certificate is issued for each machine used to perform mammography. This includes screening, diagnostic, interventional, and research mammography machines. State mammography machine certificates are issued only by the RHB. Please allow 30 days for application processing. State mammography machine certificates are valid for three years.

**FDA Certification** is facility-based. The FDA must certify a facility before the user may begin performing screening/diagnostic mammography. For a facility to be certified by the FDA, an accrediting body (AB) approved by the FDA must accredit the facility.

The only AB approved by the FDA for mammography facilities in California is the American College of Radiology (ACR). Upon completion of accreditation requirements, ACR will inform the FDA of accreditation, and an FDA certificate will be issued.

Refer to the following instructions when applying for a state Mammography Machine Certificate:

**A. As a new mammography facility**

1. RHB requirements:
  - a. Have a mammography medical physicist who has been authorized by RHB perform a complete evaluation of each mammography machine. Deficiencies reported must be corrected.
  - b. Submit the Application for Mammography Machine Certification, the physicist's evaluation report(s) including documentation of corrective action of deficiencies, and a Radiation Machine Registration Form to RHB via mail, fax or email.
  - c. Upon approval of the Application for Mammography Machine Certification and all the attached documentation, a state mammography machine certificate will be issued valid for the duration of the ACR accreditation review.
  - d. Upon passing the ACR accreditation review, submit a copy of the ACR certificate to the RHB and a mammography machine state certificate valid for the duration of the FDA certification will be issued.
2. FDA requirements: contact the ACR or the FDA.

**B. As an existing mammography facility adding a mammography machine**

1. RHB requirements:
  - a. Have a mammography medical physicist who has been authorized by RHB perform a complete evaluation of each mammography machine. Deficiencies reported must be corrected.
  - b. Submit the Application for Mammography Machine Certification, the physicist's evaluation report(s) including documentation of corrective action of deficiencies, and a Radiation Machine Registration Form to RHB via mail, fax or email.
  - c. Upon approval of the Application for Mammography Machine Certification and all the attached documentation, a state mammography machine certificate will be issued valid for the duration of the ACR accreditation review.
  - d. Upon passing the ACR accreditation review, submit a copy of the ACR certificate to the RHB and a mammography machine state certificate valid for the duration of the FDA certification will be issued.
2. FDA requirements: contact the ACR or the FDA.

**C. As an existing mammography facility renewing a state mammography machine certificate**

1. RHB requirements:
  - a. State mammography machine certificates are valid for three years. You must renew a state mammography machine certificate to be able to continue performing mammography using that machine.
  - b. Have a mammography medical physicist who has been authorized by RHB perform a complete evaluation of each mammography machine. Deficiencies reported must be corrected.
  - c. At least 60 days before the expiration date of the state mammography machine certificate, submit the Application for Mammography Machine Certification and the physicist's evaluation report(s) including documentation of corrective action of deficiencies to RHB via mail, fax or email.
  - d. Upon approval of the Application for Mammography Machine Certification and all the attached documentation, a state mammography machine certificate will be issued valid for the duration of the FDA certification.
2. FDA requirements: contact the ACR or the FDA.

**D. As an existing mammography facility with a machine that will no longer be used for mammography**

1. RHB requirements: mail the original state mammography machine certificate along with a Radiation Machine Registration Form to RHB.
2. FDA requirements: contact the ACR or the FDA.

**E. As an existing mammography facility that moved to a different location**

1. RHB requirements:
  - a. Have a mammography medical physicist who has been authorized by RHB perform a complete evaluation of each mammography machine. Deficiencies reported must be corrected.
  - b. Within 30 days of the move, submit the Application for Mammography Machine Certification, the physicist's evaluation report(s) including documentation of corrective action of deficiencies, and a Radiation Machine Registration Form to RHB via mail, fax or email.
  - c. Upon approval of the Application for Mammography Machine Certification and all the attached documentation, a state mammography machine certificate will be issued valid for the duration of the FDA certification.
2. FDA requirements: contact the ACR or the FDA.

**F. As an existing mammography facility that closes or will no longer be performing mammography**

1. RHB requirements: within 30 days of closing, submit the following to RHB:
  - A letter stating that you will no longer be performing mammography, where all patient records and images will be maintained, and how patients may obtain images and records.
  - The original state mammography machine certificate(s).
  - A Radiation Machine Registration Form.
2. FDA requirements: contact the ACR or the FDA.

**More information:**

**Inspections** – Both Federal and State law mandate inspections. The State of California has been contracted by the FDA to perform MQSA inspections within the state. State inspectors have been trained by the FDA to proficiently conduct MQSA inspections. Mammography programs are inspected annually. The state inspector will perform both the state and federal inspection simultaneously.

**Monitor Certificate Expiration Dates** – State mammography machine certificates are issued with expiration dates. It is the user's responsibility to ensure that all mammography machines have a valid certificate. If any state certificates have expired or are about to expire notify RHB immediately. **Performing mammography with expired or without State mammography machine certificates is illegal!**

If you have any further questions, you may reach the California Department of Public Health, Radiologic Health Branch at (916) 327-5106, fax (916) 440-7999, or visit our website at <https://cdph.ca.gov/rhb>.

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