

# Mammography Fact Sheet

## for Facilities Operating in the State of California

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

In California, screening/diagnostic mammography is regulated by State and Federal laws and regulations, promulgated in the California Health and Safety Code, Mammography Quality Assurance Act (MQAA) of 1992; California Code of Regulations (CCR), Title 17, Article 4.5; Mammography Quality Standards Act (MQSA) of 1992, amended by the Mammography Quality Standards Reauthorization Act (MQSRA) of 1998; and 21 Code of Federal Regulations (CFR), Part 900. Interventional mammography is controlled by State law and the Rules of Good Practice. Federal laws and regulations are augmented by State laws and regulations. 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 facility 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 (CDPH), Radiologic Health Branch (RHB).

**No mammography examinations shall be performed until you have the appropriate authorization and re in possession of *all* certificates. This means that an applications specialist may not conduct training on a new machine if imaging human breasts until you have current FDA certification *and* a new state certificate for that specific machine. As a result, please be aware that you must make the appropriate agency notifications *in advance* in order to fulfill the necessary requirements to receive your certificates and begin performing mammography.**

**FDA Certification** is facility-based and results in one certificate issued for each facility. The FDA must certify your facility before you perform screening/diagnostic mammography. For your facility to be certified by the FDA, an accrediting body (AB) approved by the FDA must accredit your facility. The only AB approved by the FDA for mammography facilities in California is the American College of Radiology (ACR) - (800) 227-6440. After you have completed accreditation requirements, ACR will inform the FDA of your accreditation, and you will receive your FDA certificate. MQSA applies only to screening and diagnostic mammography machines.

**State Certification** is machine-based and results in individual certificates for each machine used to perform mammography. This includes biopsy and stereotactic units *in addition to* screening and diagnostic units. State certificates are issued only by CDPH RHB. Please allow 30 days for application processing.

**New Facility – After receiving state mammography machine certificates and federal interim notice or certificate, you may perform mammography exams.**

<b>State</b>	<b>Federal</b>
<p><b>1.</b> Notify CDPH, Radiologic Health Branch (RHB) of your intention to perform mammography.</p>	<p><b>1.</b> Contact ACR to be your AB.</p>
<p><b>2.</b> Have a medical physicist who has been authorized by RHB perform a complete evaluation of the facility and each mammographic machine(s). Deficiencies found must be corrected.</p>	<p><b>2.</b> Complete the ACR application, and submit it along with requested attachments to the ACR.</p>
<p><b>3.</b> Fax or mail application for State certificates, physicist report(s), including corrective action documentation of deficiencies, and machine registration forms to the RHB.</p>	<p><b>3.</b> ACR will inform FDA of your accreditation status FDA will then send you a provisional certificate valid for a period of six months.</p>
<p><b>4.</b> Arrange for an onsite inspection by an RHB inspector.</p>	<p><b>4.</b> ACR will send you labels to complete the accreditation review portion of the accreditation process. Accreditation review results <b>must</b> be received before your certificates expire.</p>
<p><b>5.</b> When the inspection and all submissions are approved, you will receive a State certificate for each approved machine valid for up to six months, the time allotted for accreditation review.</p>	<p><b>5.</b> If you pass the accreditation review, ACR will inform FDA of your accreditation approval, and your facility will receive a new FDA certificate valid for up to three years.</p>
<p><b>6.</b> After passing accreditation review, send/fax RHB a copy of the ACR certificate for each machine. You will receive a new State certificate for each machine issued an ACR certificate, valid until the FDA certificate expiration date.</p>	

**Accredited Facility Adding New Machine – *Only after you receive a state certificate for the new machine can you begin performing mammography exams with new machine.***

<b>State</b>	<b>Federal</b>
<p><b>1.</b> Notify RHB that you will be purchasing a new machine by submission of the information requested below.</p>	<p><b>1.</b> Notify ACR that you have a new machine.</p>
<p><b>2.</b> Have a medical physicist who has been authorized by RHB perform a complete evaluation of new machine(s). Deficiencies found by the physicist must be corrected.</p>	<p><b>2.</b> ACR will send information regarding the accreditation review process.</p>
<p><b>3.</b> Fax or mail physicist report, including corrective action documentation of deficiencies; application, and machine registration forms to RHB.</p>	<p><b>3.</b> If you pass the accreditation review the ACR will inform FDA of your accreditation, and your facility will receive a new FDA certificate valid for up to three years.</p>
<p><b>4.</b> No onsite inspection is required; however your machine registration fee status will be reviewed. If you are delinquent, RHB will not issue a State certificate until all fees are paid.</p>	
<p><b>5.</b> When all submittals are approved, and after verification that your fees are current, you will receive a State certificate for the new machine valid for up to six months, the time allotted for the accreditation review process.</p>	
<p><b>6.</b> After passing accreditation review, send/fax RHB a copy of the ACR certificate for each machine. You will receive a new State certificate for each machine issued a ACR certificate, valid until the FDA certificate expiration date.</p>	

***Federal and State Certificate Renewal – You may not perform mammography if either your federal or State certificate has expired.***

<b><i>State</i></b>	<b><i>Federal</i></b>
<p><b>1.</b> Your State certificate(s) will expire on the same day as your FDA certificate. To renew your State certificate(s), you must: complete the renewal CIR with the ACR; mail/fax the most current physicist report(s) (including documentation of correcting deficiencies), State application, and ACR certificates to the RHB; have had satisfactory annual inspections by the State of California; and be current with all California registration fees.</p>	<p><b>1.</b> If you were not contacted by ACR at least 9 months prior to your FDA certificate expiration date, call them and ask for a renewal application.</p>
<p><b>2.</b> When all submittals are approved and after verification that your fees are current, you will receive a new State certificate for each machine issued an ACR certificate, valid until the FDA certificate expiration date.</p>	<p><b>2.</b> Submit the completed ACR application and required attachments to ACR.</p>
	<p><b>3.</b> Submit images as directed by ACR.</p>
	<p><b>4.</b> When your machines pass accreditation review, ACR will inform the FDA of your successful renewal of accreditation and your facility will receive a new FDA certificate valid for up to three years.</p>

## ***Mammography Facility Closes or Merges with Other Facility***

<b><i>State</i></b>	<b><i>Federal</i></b>
<b>1.</b> Notify RHB in writing that you will be terminating your mammographic services. If merging, notify RHB in writing that you are adding machines to the combined facility.	<b>1.</b> Notify ACR in writing that you wish to withdraw from the MQSA program.
<b>2.</b> Send a letter informing RHB where all patient mammography records and mammograms will be maintained and information about how patients may obtain their records.	<b>2.</b> ACR will notify FDA of your request. <b>Or</b>
<b>3.</b> Send RHB machine registration forms showing the disposition of X-ray equipment after any X-ray machine(s), including mammography machines, have been transferred to a third party or disabled.	<b>3.</b> If merging, tell ACR that you are adding machines to the combined facility, and terminating another facility.
<b>4.</b> Return all previously issued State certificates to RHB.	

<b>Accredited Facility Removing Old Machine</b>	
<b>State</b>	<b>Federal</b>
1. Notify RHB that you will be removing a machine by submission, via fax or mail, of machine registration forms indicating the disposition of the mammography machine within 30 days.	1. Notify ACR that you no longer have the machine.

**More information:**

**-Inspections-** Both Federal law and State law mandate inspections. The State of California has a contract with FDA to perform MQSA inspections within the state. State inspectors have been specifically trained by FDA to be proficient in MQSA inspections. Your mammography program will be inspected annually. One inspector will perform both the state and federal inspections at the same time.

**-Monitor The Expiration Date On Your State Certificates -** *State certificates are tied to your federal certification renewal and facilities are responsible for renewal of their own State certificates. If any of your State certificates are about to expire, notify the RHB immediately.*

**Performing mammography with expired State certificates is illegal!**

If you have any further questions about this material, you may reach the California Radiologic Health Branch at (916) 327-5106, fax (916) 440-7999, or visit our website at [www.dhs.ca.gov/rhb](http://www.dhs.ca.gov/rhb).

**Mailing Address:**

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