Application for Mammography Facility/Machine Certification

Section 1 – Facility Status

a. Type of Facility (check one): ☐ Biopsy-Only Facility ☐ ACR/MQSA Facility ☐ Other (specify):	
b. Reason for Submittal (check all that apply)	
☐ New Facility* ☐ Renewal ☐ Ownership Change* ☐ Name Change* ☐ New Machine* ☐ Reinstatement ☐ Address Change* ☐ Personnel Change ☐ Other (specify) *Submit with a radiation machine registration form, RH 2261.	
c. State Registration Number: FAC State Registration Expiration Date:	d. FDA Facility Identification Number: FDA Certificate Expiration Date:

Section 2 – Facility Information

a. Facility Name:			
b. Doing Business As (DBA) Name (if applicable):			
c. Contact Name:		d. Contact Title:	
e. Phone Number:		f. Fax Number:	
g. E-mail address:		h. Mobile Phone Number:	
i. Federal Employer ID:		j. California Taxpayer ID:	
k. Facility Location Address Street:	City:	State:	Zip:
l. Facility Mailing Address (if different from the Facility Location Address) Street:	City:	State:	Zip:

Section 3 – Facility Mammography Accreditation History

a. For this physical location address, have you previously applied for FDA MQSA certification?	☐ Yes	☐ No
b. Has the accreditation status of this facility ever been denied (including failure to pass provisional, reinstatement, or renewal periods), revoked, or suspended?	☐ Yes	☐ No

- If yes, provide a detailed written explanation and attach to this application. The following information must be included:
  - The identity of any specific radiation machine(s) that failed clinical image review (CIR);
  - The dates of failure;
  - The actions taken to correct any CIR deficiencies including physician or technologist training, radiation machine or processor repair and acquisition of replacement equipment or image receptors;
  - Whether the radiation machine passed the CIR subsequent to actions taken as identified above and when;
- Submit full copies of failure reports with this application, if the failed CIR was performed under the direction of an accrediting body other than the State of California (ACR, for example) and occurred within the last three years.
- For suspensions or revocations, describe the circumstances that led to suspension or revocation.

Section 4 – Facility Procedure Information

a. ☐ Self-referral (check this box if you accept self-referrals).	
For Renewals Only	
b. Number of Screening Procedures: Number of Diagnostic Procedures: Total:	c. Number of Stereotactic Procedures: d. Number of Needle Localizations: e. Number of Therapeutic Procedures:

Section 5 – Associated Program Information

a. ☐ BCEDP/BCCP (check this box if you intend to or now participate in the Every Woman Counts Program.
b. Medi-Cal Number (if applicable):
c. Medicare Number (if applicable):

Section 6 – Personnel Qualifications

a. **Physician's Qualifications**. List all the physicians who interpret mammography exams for this facility. Use additional sheets if necessary.

Name (First, MI, Last)	Check if Lead Interpreting Physician	California Medical Board License Number	Supervisor/ Operator Certificate/ Permit Number	Supervisor/ Operator Certificate/ Permit Expiration Date	ABR, AOBR, or RCPSC Certified in Diagnostic Radiology?	
					Yes	No*
	☐				☐	☐
	☐				☐	☐
	☐				☐	☐
	☐				☐	☐
	☐				☐	☐
	☐				☐	☐
	☐				☐	☐
	☐				☐	☐
	☐				☐	☐
	☐				☐	☐
	☐				☐	☐
	☐				☐	☐

*If a physician is non-ABR, non-AOBR or non-RCPSC certified, supply attachments documenting their qualifications as an interpreting physician under Section 900.12 (a)(1) of 21 Code of Federal Regulations, Part 900. These must include the following initial qualifications: (1) attending 3 months full time training in the interpretation of mammograms (provide a signed statement by the physician-preceptor who administered this training); (2) copies of certificates demonstrating 60 hours of continuing medical education in mammography (time spent in a radiology residency program will be accepted if documented in writing); and (3) documentation that they have read and interpreted 240 mammograms in the six months preceding this application.

If any interpreting physician you seek to allow to interpret mammograms is under a Department-directed plan of corrective action for interpretation done at some other facility, then provide the following details for that physician. Use additional sheets if necessary.	
Name of Interpreting Physician:	Medical License Number:
Facility name where the interpreting physician was required to complete a directed plan of corrective action:	Facility Registration Number: FAC

b. **Technologist's Qualifications**. List all the mammography technologists at this facility. Use additional sheets if necessary.

Name (First, MI, Last)	Check this box if lead QC/QA Technologist	State Mammography Technologist Certificate Number	Certificate Expiration Date
	☐	RHM	
	☐	RHM	
	☐	RHM	
	☐	RHM	
	☐	RHM	
	☐	RHM	
	☐	RHM	
	☐	RHM	

c. **Physicist's Qualification**. List all physicists that perform the required annual mammography physicist surveys at this facility. Use additional sheets if necessary.

Name (First, MI, Last)	State Mammography Physicist Registration Number
	MQA
	MQA

Section 7 – Mammography Equipment Information

a. Mammography Machine Listing. Use additional sheets if necessary.

Manufacturer	Model	Manufacturer and Model of FS, CR, or Add-on DBT Unit	Machine Identification Number	Room Number	If Accredited by the ACR, the Unit MAP-ID	Mobile (see 7c below)	Used for Procedures: (Check all that apply)			Modality+ (Check all that apply)			
							Screening/ Diagnostic	Needle Localization	Stereo (D=Dedicated or A = Add-on Unit)	FS	CR	FFDM	DBT
1.						☐	☐	☐	☐	☐	☐	☐	☐
2.						☐	☐	☐	☐	☐	☐	☐	☐
3.						☐	☐	☐	☐	☐	☐	☐	☐
4.						☐	☐	☐	☐	☐	☐	☐	☐
5.						☐	☐	☐	☐	☐	☐	☐	☐
6.						☐	☐	☐	☐	☐	☐	☐	☐
7.						☐	☐	☐	☐	☐	☐	☐	☐
8.						☐	☐	☐	☐	☐	☐	☐	☐

+Modality: FS = Film Screen; CR = Computed Radiography; FFDM = Full-field Digital Mammography; DBT = Digital Breast Tomosynthesis

b. Film Processor

Manufacturer	Model	Standard Processing	Extended Processing	Used for the above machine numbers
		☐	☐	
		☐	☐	

c. Additional Requirements for mobile machines. Attach a separate sheet providing the following information:
For each machine, specify:
(1) The physical address of each location where mammography will be performed;
(2) The name and telephone number of the responsible person who is allowing the service to be provided at the location;
(3) Whether mammograms will be processed with an on-board processor or, if processed at different locations, the address of each location;
(4) Whether the machine is fixed or used, exclusively, in a mobile vehicle or if transported to the use location and moved to the area examinations are to be performed, the designated room within the building at each use location; and
(5) A description of the quality assurance tests that will be performed each time the machine is relocated.

Section 8 – Medical Physicist Report

Attach the latest complete report of a mammography system evaluation performed less than 6 months prior to the date of the application for a new machine or a report of a survey performed less than 12 months prior to the date of the renewal application. If any failures and/or recommendations are referenced in a report, attach a list of corrective actions taken to mitigate all deficiencies. Include copies of work invoices with the description of corrective actions taken. Incomplete physicist's reports or reports with deficiencies that are not addressed will not be accepted.

Section 9 – Acknowledgment and Certification

I certify to the best of my knowledge that:

a. I declare under penalty of perjury under the state law of California that the information submitted on this form with its attachments to be true and correct, and I agree to abide by all laws and regulations that pertain to the operation and registration of the radiation source(s) for which I am applying.
b. The physicians, physicists and technologists meet the requirements of the California Health and Safety Code, Sections 106965 through 115115. Also, those physicians, technologists, and physicists who are associated with screening/diagnostic mammography operations meet the requirements of California Code of Regulations, Title 17, Sections 30315.50, 30315.51, and 30315.52;
c. The x-ray machine(s) is/are specifically designed to perform mammography. Also, x-ray machines used for screening/diagnostic mammography comply with California Code of Regulations, Title 17, Section 30316;
d. For screening/diagnostic operations, the facility will adhere to medical records and mammography reports requirements set forth in California Code of Regulations, Title 17, Sections 30316.50, 30317.40, 30317.50, 30319.20;
e. That, if the above mentioned facility performs screening/diagnostic mammography, the facility has a quality assurance program that complies with California Code of Regulations, Title 17, Sections 30316.20, 30316.22, 30316.30, 30316.40, 30317.10, 30317.20, 30317.60.

f. That, if the above-mentioned facility performs interventional mammography, the facility has a quality assurance program that complies with “Rules of Good Practice for Supervision and Operation of X-ray Equipment.”
g. The Mammography Program of the Radiologic Health Branch will be notified in writing of any changes in our status to comply with California Code of Regulations, Title 17, Section 30319; and,
h. False statement or failure to report changes on our status may result in revocation of authorization to perform mammography in California as set forth in California Code of Regulations, Title 17, Section 30320.90.

Signature of Facility Owner or Administrator	Date
Type or Print Name	Title & Contact Phone Number (if different from Section 2e)

If the individual who signed above is not the Lead Interpreting Physician, the following information must be completed:
As the Lead Interpreting Physician responsible for mammography operations at this facility, I concur with all representations in this application.

Signature of Lead Interpreting Physician	Date
Type or Print Name	Contact Phone Number (if different from Section 2e)

Mail completed form and supporting documents to:

California Department of Public Health, Radiologic Health Branch
ATTN: Registration Unit, Mammography Certification Program
MS 7610
P.O. Box 997414
Sacramento, CA 95899-7414