

Application for Mammography Facility/Machine Certification

PLEASE PRINT OR TYPE ALL INFORMATION

SECTION 1—FACILITY STATUS

a. Application is for: (check one category box below and circle appropriate selection within category checked)

- | | | | |
|--|--|--------------------------------------|--|
| <input type="checkbox"/> Biopsy-only facility: | <input type="checkbox"/> New facility | <input type="checkbox"/> New machine | <input type="checkbox"/> Renewal |
| <input type="checkbox"/> ACR MQSA facility: | <input type="checkbox"/> New facility | <input type="checkbox"/> New machine | <input type="checkbox"/> State certificate renewal |
| <input type="checkbox"/> Change of address | <input type="checkbox"/> Transferring machine to different address | | |
- * Submit a Radiation Machine Registration Form RH 2261 with all above actions*
- Change of facility name or owner – Submit with legal documentation and RH 2261
- Changes to facility personnel: Technologists Radiologists Physicist

b. Current FDA facility identification number	FDA certificate expiration date	c. State registration number	State certificate expiration date
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SECTION 2—FACILITY ADDRESS INFORMATION

a. Facility name _____

b. D.B.A. (if applicable) _____

c. Contact name	Contact title
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d. Phone number	Fax number	e. Employer Identification number (Federal Tax ID number)
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f. Facility location address (line 1)	g. Facility mailing address (line 1)				
(address line 2)	(address line 2)				
City	State	ZIP code	City	State	ZIP code

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: (1) indicate the identity of specific machines that failed, (2) the dates of failure, (3) details of how you corrected CIR deficiencies (including any physician or technologist training and machine/processor repair) and, (4) if the machine subsequently passed CIR after corrective actions were taken.
 - If the failed CIR was performed under the direction of an Accrediting Body other than the State of California (for example ACR) and occurred within the last three years, submit full copies of failure reports with this application.
 - For suspensions or revocations, describe the circumstances that led to suspension or revocation.

SECTION 4—FACILITY PROCEDURE INFORMATION

- a. Do you currently accept self-referrals? Yes No
- b. Number of screening procedures performed per year: _____
- c. Number of diagnostic procedures performed per year: _____
- d. Total number of procedures performed per year in 4b and 4c above: _____
- e. Number of stereotactic procedures performed per year: _____
- f. Number of needle localizations performed per year: _____

SECTION 5—ASSOCIATED PROGRAM INFORMATION

- a. Do you now participate or intend to participate in the Every Woman Counts Program (formerly known as BCEDP/BCCCP)? Yes No
- b. Supply the nine-digit Medi-Cal number used to bill for mammographic examinations performed at this facility location address: _____

SECTION 6—PERSONNEL QUALIFICATIONS

- a. **Physician's qualifications** (list all physicians who interpret mammography exams for this facility):

NAME (CHECK BOX OF THE INTERPRETING PHYSICIAN)	CALIFORNIA MEDICAL BOARD LICENSE NUMBER	SUPERVISOR/ OPERATOR CERTIFICATE (RHL) NUMBER	SUPERVISOR/ OPERATOR EXPIRATION DATE	ABR, AOBR, OR RCPSC CERTIFIED IN DIAGNOSTIC RADIOLOGY?
1. <input type="checkbox"/>				<input type="checkbox"/> Yes <input type="checkbox"/> No*
2. <input type="checkbox"/>				<input type="checkbox"/> Yes <input type="checkbox"/> No*
3. <input type="checkbox"/>				<input type="checkbox"/> Yes <input type="checkbox"/> No*
4. <input type="checkbox"/>				<input type="checkbox"/> Yes <input type="checkbox"/> No*
5. <input type="checkbox"/>				<input type="checkbox"/> Yes <input type="checkbox"/> No*
6. <input type="checkbox"/>				<input type="checkbox"/> Yes <input type="checkbox"/> No*
7. <input type="checkbox"/>				<input type="checkbox"/> Yes <input type="checkbox"/> No*

(Use additional sheets if necessary.)

* If a physician is **non-ABR**, -AOBR or -RCPSC certified, supply attachments documenting their qualification 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 three 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.

- b. **Technologist's qualifications** (list all technologists performing mammography at this facility):

NAME (CHECK BOX OF THE LEAD QA/QC TECHNOLOGIST)	STATE MAMMOGRAPHY CERTIFICATE NUMBER	CERTIFICATE EXPIRATION DATE
1. <input type="checkbox"/>		
2. <input type="checkbox"/>		
3. <input type="checkbox"/>		
4. <input type="checkbox"/>		
5. <input type="checkbox"/>		
6. <input type="checkbox"/>		
7. <input type="checkbox"/>		
8. <input type="checkbox"/>		
9. <input type="checkbox"/>		
10. <input type="checkbox"/>		

(Use additional sheets if necessary.)

- c. **Physicist's qualifications** (identify the physicist that performs required annual mammography physicist surveys):

Mammography Medical Physicist	State Physicist registration number
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SECTION 7—MAMMOGRAPHY EQUIPMENT INFORMATION

a. Mammography Machine Listing (Complete one line for each machine at your facility.)

MAKE	MODEL	CONTROL SERIAL NUMBER OR THE FACILITY'S RADIATION MACHINE IDENTIFICATION NUMBER	FACILITY ROOM NUMBER	UNIT MAP ID NUMBER ON ACR CERT INCLUDING NUMBER AFTER HYPHEN	IS THIS MACHINE MOBILE? (see Section 7c below)	THIS MACHINE IS USED FOR THE FOLLOWING PROCEDURES: (Check all that apply)			IF STEREOTACTIC, CHECK: D = DEDICATED UNIT OR A = ADD-ON UNIT	MANUFACTURER AND TYPE OF FILM/SCREEN SYSTEM USED FOR THIS UNIT AND/OR ENTER "D" IF THIS MACHINE IS DIGITAL ONLY	FOR OFFICE USE ONLY
						SCREENING/DIAGNOSTIC	NEEDLE LOC	STEREO			XM NUMBER
1.					<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> D <input type="checkbox"/> A		
2.					<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> D <input type="checkbox"/> A		
3.					<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> D <input type="checkbox"/> A		
4.					<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> D <input type="checkbox"/> A		
5.					<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> D <input type="checkbox"/> A		

b. Film Processor Listing

MAKE	MODEL	EXTENDED PROCESSING? (Y/N)	THIS PROCESSOR IS USED FOR THE ABOVE MACHINE NUMBERS:
1.		<input type="checkbox"/> Yes <input type="checkbox"/> No	
2.		<input type="checkbox"/> Yes <input type="checkbox"/> No	

c. Additional Requirements for mobile machines:

Attach a separate sheet providing the following information. For each mobile machine, specify: (1) the 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 on-board or, if processed at different locations, the address of each location; (4) whether the machine is 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 number within the building at each use location; and (5) a description of the quality control tests that will be performed each time the radiation machine is relocated.

SECTION 8—PHYSICIST REPORTS

Attach the latest complete physicist report for each machine listed above. The report may not be over 12 months old. 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 physicist's 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, and 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, 830317.10, 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 Mammographic 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 statements or failure to report changes in 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 and Contact phone number if different than in Section 2d of this application

If the individual who signed above is not the Lead Interpreting Physician, the following must be completed:

As the Lead Interpreting Physician responsible for mammography operations at this facility, I concur with all representations in this application, signed,

Signature of Lead Interpreting Physician	Date
Type or print name	Contact phone number if different than that in Section 2d of this application

Mail completed form to:

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

For more information, go to www.cdph.ca.gov or phone (916) 327-5106.