INSTRUCTIONS FOR COMPLETING THE APPLICATION FOR MAMMOGRAPHY MACHINE CERTIFICATION

I. USE OF CDPH 8624.

Use this form when all of the following conditions are met:

- You facility, business, or practice possesses one or more radiation machines used for mammography, as defined below.
- You wish to notify the California Department of Public Health, Radiologic Health Branch (CDPH-RHB) of your new mammography facility, renew/reinstate a mammography machine certificate, change your existing facility information, add a new machine, or other reasons pertaining to mammography machine certification.

II. REGULATORY AUTHORITY

Title 17 California Code of Regulations, Division 1, Chapter 5, Subchapter 4, Group 3, Article 4.5, Requirements for the Use of X-Ray in Mammography.

III. DEFINITIONS

- “Diagnostic mammography” means the mammographic examination of patients who, by virtue of symptoms, physical findings, or screening mammography, are considered to have a substantial likelihood of having breast disease.
- “Facility” means a hospital, outpatient department, clinic, radiology practice, an office of a physician, mobile setting, or other place or building in which a person conducts mammography.
- “Interventional mammography” means the creation of a mammogram during invasive interventions for localization or biopsy procedures.
- “Lead supervising physician” means the physician designated by the user to establish and maintain the user's mammography quality assurance program and who meets the requirements of section 30315.50(a)(1).
- “Mammographic Modality” means a technology for radiography of the breast such as screen-film mammography, digital mammography, full field digital mammography, and digital breast tomosynthesis.
- “Mammography” means the procedure for creating a mammogram for the purposes of screening, diagnostic, interventional or research mammography.
- “Mammography system evaluation” means an evaluation of a mammography system conducted by a mammography medical physicist for the purpose of making a preliminary determination as to whether the system is in compliance with the regulatory requirements.
- “Mobile mammography” means mammography performed in a mobile setting.
- “Quality control technologist” means an individual who is responsible for quality assurance tasks.
- “Research mammography” means the creation of a mammogram with an investigational mammography device as part of a scientific study.

- "Screening mammography" means a mammographic examination of asymptomatic persons in an attempt to detect breast cancer when it is small, non-palpable and confined to the breast.
- "Unique Identification Number" means an identification number permanently affixed to the machine by the user for the purpose of identifying each radiation machine used for mammography.
- "User" means any person or who has registered as possessing a reportable source of radiation or who otherwise possesses a source of radiation which is subject to such licensure or registration.

IV. INSTRUCTIONS

A. Section 1 – Facility Status

- **Type of Facility.** Check one of the boxes if you are an Screening/Diagnostic Facility, Interventional-Only Facility, or other type of mammography facility. If you checked other, specify the type of mammography facility.
- **Reason for Submittal.** Check all boxes that apply. If you're submitting for a new facility, ownership change, name change, new machine, or address change, submit CDPH 8624 with a radiation machine registration form, RH 2261.
- **State Registration Number and Expiration Date.** Enter the registration number and expiration date issued by the CDPH-RHB for this facility. Submit a radiation machine registration form if you do not have a registration number (in case of new facility or ownership change).
- **FDA Facility Identification Number and Certification Expiration Date.** Enter the facility identification number and certificate expiration date issued by the FDA for this facility, business, or practice. Contact the accrediting body, American College of Radiology (ACR), if you do not have a facility identification number.

B. Section 2 – Facility Information

- **Facility Name and Doing Business As (DBA) Name.** Enter the registered name of the facility. If applicable, include the "doing business as" name (DBA).
- **Contact Name, Phone Number, and E-mail Address.** Provide the name and contact information of the individual that a CDPH-RHB representative may contact regarding any information provided on this form. This individual may be different from the user or lead supervising physician. Enter the name, phone number, and e-mail address of the individual.
- **Facility Location Address.** Enter the location/physical address of the facility.
- **Facility Mailing Address.** Enter the mailing address of the facility if different from the facility location address.

C. Section 3 – Personnel Qualifications

- **Physicians.** List all the physicians who interpret mammography exams for this facility. Enter name and check the appropriate box if lead supervising physician. Enter supervisor/operator certificate/permit number and expiration date issued by the CDPH-RHB for each physician. Use additional sheets if necessary.
- **Technologists.** List all the mammography technologists at this facility. Enter name and check the appropriate box if QC technologist. Enter state mammography technologist certificate number and expiration date issued by the CDPH-RHB for each technologist. Use additional sheets if necessary.

CI. Section 4 - Mammography System Information

1. **Mammography Machine Listing.** List all the machines at this facility.
   - **Manufacturer.** Enter the name of the manufacturer.
   - **Model.** Enter the manufacturer's model name and/or number.
   - **Machine ID Number.** Enter the serial number and unique identification number.
   - **Room Number.** Enter the room number where the machine is installed.
   - **Unit MAP-ID.** If accredited by the ACR, enter the Unit MAP-ID.
   - **Mobile.** Check the box if this is a mobile mammography machine. See Section 4 of the Application for Mammography Machine Certification (CDPH 8624) for additional requirements.
   - **Procedures.** Check all procedures that the machine is used for: Screening/Diagnostic, Interventional Mammography, and/or Research Mammography.
   - **Mammographic Modality.** Check all modalities that apply: Screen-Film (SF), Computed Radiography (CR), Full-field Digital Mammography (FFDM), Digital Breast Tomosynthesis (DBT), and/or Other: please specify.
   - **Manufacturer and Model of SF, CR, or Add-on DBT Unit**. Enter the name of the manufacturer and manufacturer's model name and/or number of the screen-film (SF), computed radiography (CR), or add-on digital breast tomosynthesis (DBT) unit.

2. **Film Processor.** List all the mammography film processors used at this facility.
   - **Manufacturer.** Enter the name of the manufacturer.
   - **Model.** Enter the manufacturer's model name and/or number.
   - **Location.** Enter the location where the processor is installed.
   - **Used for the above machine numbers.** Enter machine ID number, serial number or unique identification number, of the mammography machine designated with film processor.

3. **Additional Requirements for Mobile Machine.** Attach a separate sheet providing the following information for each mobile mammography machine:
    - The physical address of each location where mammography will be performed;
    - The name and telephone number of the responsible person who is allowing the service to be provided at the location;
    - Whether mammograms will be processed with an on-board processor or, if processed at different locations, the address of each location;
    - 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
    - A description of the quality assurance tests that will be performed each time the machine is relocated.

E. Section 5 - 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.

F. Section 6 - Acknowledgement and Certification

a. Read, acknowledge, and certify the provisions listed.
    - **User Signature.** Enter the signature of the user or authorized representative.
    - **Name.** Enter the name of the user or authorized representative.
    - **Date.** Enter the date the form is signed.
    - **Phone Number.** Enter the phone number if different from Section 2 of the CDPH 8624 form.

b. If the individual who signed as the User is not the Lead Supervising Physician, enter the following information:
    - **Lead Supervising Physician Signature.** Enter the signature of the Lead Supervising Physician.
    - **Name.** Enter the name of the Lead Supervising Physician.
    - **Date.** Enter the date the form is signed.
    - **Phone Number.** Enter the phone number if different from Section 2 of the CDPH 8624 form.

G. Section 7 – Mailing. Mail completed form and supporting documents to:

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