Application for Mammography Machine Certification

Section 1 – Facility Status

- Type of mammography facility (check one):

  ☐Screening/Diagnostic

  ☐Interventional Only

  ☐Other (specify) ______________________________

- Reason for this application (check all that apply):

  ☐New Facility ☐Renewal ☐Ownership Change ☐Name Change

  ☐New Machine ☐Reinstatement ☐Address Change ☐Personnel Change

  ☐Other (specify) ______________________________

- **Note**: For a New Facility, Ownership Change, Name Change, or Address Change, submit with a radiation machine registration form, RH 2261.
- State Registration Number: FAC ____________________
- State Registration Expiration Date: ____________________
- FDA Facility Identification Number: ____________________
- FDA Certificate Expiration Date: ____________________

Section 2 – Facility Information

- Facility Name: ______________________________
- Doing Business as (DBA) Name (if applicable): ______________________________
- Contact Name: ______________________________
- Phone Number: ____________________
- E-mail Address: ____________________

  Facility Location Address

  Street ____________________ City ______________ State _______ Zip _______
- Facility Mailing Address (if different from above)

  Street ____________________ City ______________ State _______ Zip _______

Section 3 – Mammography Personnel

Physicians. List all physicians who interpret mammography exams for this facility. Use additional sheets if necessary.

- Name (First, MI, Last): ______________________ ☐Lead Supervising Physician
  Supervisor/Operator Certificate/Permit Number: ______________________
  Certificate/Permit Expiration Date: ______________________
- Name (First, MI, Last): ______________________ ☐Lead Supervising Physician
  Supervisor/Operator Certificate/Permit Number: ______________________
  Certificate/Permit Expiration Date: ______________________
- Name (First, MI, Last): ______________________ ☐Lead Supervising Physician
  Supervisor/Operator Certificate/Permit Number: ______________________
  Certificate/Permit Expiration Date: ______________________
- Name (First, MI, Last): ______________________ ☐Lead Supervising Physician
  Supervisor/Operator Certificate/Permit Number: ______________________
  Certificate/Permit Expiration Date: ______________________

Technologists. List all mammography technologists for this facility. Use additional sheets if necessary.

- Name (First, MI, Last): ______________________ ☐QC Technologist
  State Mammography Technologist Certificate Number: RHM ______________________
  Certificate Expiration Date: ______________________
- Name (First, MI, Last): ______________________ ☐QC Technologist
  State Mammography Technologist Certificate Number: RHM ______________________
  Certificate Expiration Date: ______________________
- Name (First, MI, Last): ______________________ ☐QC Technologist
  State Mammography Technologist Certificate Number: RHM ______________________
  Certificate Expiration Date: ______________________

Section 4 – Mammography System Information

Mammography Machines. List all mammography machines at this location. Use additional sheets if necessary.

- Manufacturer: ____________________ Model: ____________________
  Serial Number: ________________ Unique Identification Number: ______________
  Room Name or Number: ______________ MAP-ID Number: ________________
  Manufacturer and Model of Image Receptor or Add-on DBT: ____________________
  Check if: ☐Mobile ☐Screening/Diagnostic ☐Interventional ☐Research
  Choose the modality: ☐Screen-Film ☐CR ☐FFDM ☐DBT ☐Other
- Manufacturer: ____________________ Model: ____________________
  Serial Number: ________________ Unique Identification Number: ______________
  Room Name or Number: ______________ MAP-ID Number: ________________
  Manufacturer and Model of Image Receptor or Add-on DBT: ____________________
  Check if: ☐Mobile ☐Screening/Diagnostic ☐Interventional ☐Research
  Choose the modality: ☐Screen-Film ☐CR ☐FFDM ☐DBT ☐Other
- Manufacturer: ____________________ Model: ____________________
  Serial Number: ________________ Unique Identification Number: ______________
  Room Name or Number: ______________ MAP-ID Number: ________________
  Manufacturer and Model of Image Receptor or Add-on DBT: ____________________
  Check if: ☐Mobile ☐Screening/Diagnostic ☐Interventional ☐Research
  Choose the modality: ☐Screen-Film ☐CR ☐FFDM ☐DBT ☐Other

Film Processor. List if any. Use additional sheets if necessary.

- Manufacturer: ________________________ Model: __________________
  Location: ____________________ For which machine named above: ____________

Additional Requirements for Mobile Machines.

Attach a separate sheet specifying the following for each 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.

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 and the date corrections were achieved. 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 6 – Acknowledgement and Certification

I certify to the best of my knowledge that:

- 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.
- The physicians, technologists, and physicists meet the requirements of the California Health and Safety Code, Sections 106965 through 115115 and California Code of Regulations, Title 17, Sections 30315.50 and 30315.52;
- The x-ray machine(s) is/are specifically designed to perform mammography and comply with California Code of Regulations, Title 17, Section 30316;
- The facility will adhere to medical records and mammography reports requirements set forth in California Code of Regulations, Title 17, Section 30315.36;
- The facility has a quality assurance program that complies with California Code of Regulations, Title 17, Sections 30316.20, 30316.30, 30317.10, and 30317.20;
- The California Department of Public Health – 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,
- 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.

  User Signature: ________________________ **Name**: __________________________

  Date: _______________ **Phone Number (if different from Section 2)**: _________________
- If the individual who signed above is not the Lead Supervising Physician, the following information must be completed: As the Lead Supervising Physician responsible for mammography operations at this facility, I concur with all representations in this application.

  Lead Supervising Physician Signature: _______________ **Name**: ___________________

  Date: _______________ **Phone Number (if different from Section 2)**: _________________

Section 7 – Mail and Submit

Mail completed application and supporting documents to:

California Department of Public Health, Radiologic Health Branch

ATTN: Registration Unit

MS 7610

P.O. Box 9971414

Sacramento, CA 95899-7414