



AMENDMENT APPLICATION FOR MAMMOGRAPHY CERTIFICATION

ZZ113-181

TEXAS DEPARTMENT OF STATE HEALTH SERVICES (DSHS)
RADIATION SAFETY LICENSING BRANCH (RSLB)
Mail Code 2835
P.O. Box 149347
Austin, Texas 78714-9347

For questions regarding the application process, contact the Mammography Program at (512) 834-6688. Submit the completed application and required documentation to the address above.

Retain a copy for your records. This amendment application is for mammography units only. If you have an interventional breast unit used only for interventional studies (breast biopsy or needle localizations), complete RC Form 230-4 – Amendment Application for Interventional Breast Radiography.

Note: If the facility is accredited with the State of Texas, request a combination application.

AMENDMENT APPLICATION TYPE: For each amendment selected, complete and submit the required application sections, along with the required documentation.

Note: A Name change requires that you submit the Business Information Form RC 226-1. An Ownership change requires a New Facility application.

- Name Change (Sec 1, 4)
- Address Change (Sec 1, 4)
- Add Mammography Unit(s) (Sec 1, 3, 4)
- Add Self-Referral Authorization (Sec 1, 2, 4)
- Add Mobile Services (Sec 1, 2, 4)
- Add Digital Breast Tomosynthesis (Sec 1, 3, 4)
- Radiation Safety Officer Change (Sec 1, 4)
- Lead Interpreting Physician Change (Sec 1, 4)
- Other

SECTION 1: FACILITY INFORMATION

MAMMOGRAPHY CERTIFICATION NUMBER: M _____

MQSA FACILITY IDENTIFICATION NUMBER: (6 digits) _____

LEGAL NAME OF FACILITY: The legal name of the facility filed with the Texas Secretary of State Office. If the facility name does not match with the Texas Secretary of State Office, the application will be delayed.

DOING BUSINESS AS (DBA) name (if applicable): The 'dba' name must be filed with the Texas Secretary of State Office and / or county clerk office.

FACILITY ADDRESSES / PHONE NUMBERS /CONTACTS

MAILING ADDRESS		PHYSICAL USE LOCATION
Street / PO Box		
City / State / Zip		
County		
Phone No. & Ext.		
Fax Number		

LEAD INTERPRETING PHYSICIAN	RADIATION SAFETY OFFICER	FACILITY CONTACT
Name		
Phone No. & Ext.		
Email		

SECTION 2: FACILITY PRACTICE INFORMATION and PROCEDURES

MEDICAL RECORDS AND MAMMOGRAPHY FILM RETENTION POLICIES

Refer to 25 TAC §289.230 for specific details.

Submit procedures for each of the following:

- Mammography film retention under normal circumstances.
- The disposition/retention of medical records, including films, in the event of termination, failure to renew or bankruptcy.

SELF REFERRAL AUTHORIZATION

Self-referral authorization must be obtained prior to providing self-referral mammography services.

Refer to 25 TAC §289.230 for specific details.

Will the facility be providing self-referral mammography services? No
 Yes, *answer questions and submit required information*

Number of views for a typical mammogram:

Type of views for typical mammogram:

Age range of the population that will be examined:

Frequency of the exam:

Submit procedures for the following:

- Recommending a physician to patients who do not have a physician.
- Advising patients and private physicians of the mammography results within the required time frame.
- Description of the methods for educating patients in breast self-examination techniques and on the necessity for follow-up by a physician.
- Follow-up with patients and physicians of the mammography results for patients with positive findings and needing repeat exams.

MOBILE SERVICE AUTHORIZATION

Mobile service authorization must be obtained prior to providing mobile mammography services.

Refer to 25 TAC §289.226 for specific details.

Will the facility be providing mobile mammography services? No
 Yes, *submit the required information*

Street address where the mammography van and records will be maintained for inspection:

Submit documentation for the following:

- Attach a sketch or description of the normal configuration of the mammography unit's use including the operator's position and any ancillary personnel's location during exposures. If a mobile van is used with a fixed unit inside, furnish the floor plan indicating protective shielding and the operator's location.
- Submit a current copy of the facility's Operating and Safety Procedures regarding radiological practices for protection of patients, operators, employees, and the general public.

SECTION 3: MAMMOGRAPHY UNIT INFORMATION

- Make copies of this page, if needed.
- Complete applicable sections and check all appropriate boxes.
- Include a copy of a current complete medical physicist's survey report for each mammography unit:
 - Medical physicist surveys for new facilities or new mammography units must be dated within 6 months of application.

Note – if there are any failures and/or deficiencies on the report include copies of service/work invoices with the description of corrective actions.

MAMMOGRAPHY UNIT(S) INFORMATION

Location		Manufacturer	Model Name	Serial #	Type of Imaging System				Additional Services	
Onsite	Mobile Van				FSM	CRm	FFDM	FFDM / DBT *	BX Attach	NL

* **If you indicated FFDM / DBT (Full Field Digital / Breast Tomosynthesis), check the box that pertains to this unit.**

- The Breast Tomosynthesis component will be used in conjunction with the digital mammography unit and the FDA has been notified. A copy of the FDA Certification extension letter will be provided upon approval.
- The Breast Tomosynthesis component will not be utilized at this time. Prior to utilizing the breast tomosynthesis component, the medical physicist will survey that component and an application for use will be submitted to the STX and FDA.

SECTION 4: SIGNATURES

This certification is to be signed by the Authorized Representative of the Applicant, an individual with the capacity and authority to legally bind the Applicant.

Certification must be made by the person completing the application

I certify that all information submitted with this application is true and correct to the best of my knowledge.

Name	Title	Date	Signature

Certification must be made by the Administrator, President, Chief Executive Officer, Owner or Partner of the facility

I certify that all of the information provided herein is true, correct, and complete. I certify that the Applicant has read, understands, and will comply with applicable provisions of the Chapter 401 of the Texas Health and Safety Code, titled *Texas Radiation Control Act*, and with all applicable provisions or Title 25, Texas Administrative Code, Chapter 289, titled *Radiation Control*.

Name	Title	Date	Signature

Certification must be made by the Lead Interpreting Physician

I certify that I have read and understand Title 25, Texas Administrative Code, Section 289.230, titled *Certification of Mammography Systems and Mammography Machines Used for Interventional Breast Radiography*. I certify that I am qualified to serve, agree to serve, and will carry out those duties and responsibilities of the Lead Interpreting Physician of the Applicant, pursuant to 25 TAC §289.230.

Name	Date	Signature

Certification must be made by the Radiation Safety Officer

I certify that I have read and understand and will comply with applicable provisions of the Chapter 401 of the Texas Health and Safety Code, titled *Texas Radiation Control Act*, and with all applicable provisions or Title 25, Texas Administrative Code, Section 289, titled *Radiation Control*. I certify that I am qualified to serve, agree to serve, and will carry out those duties and responsibilities of the Radiation Safety Officer of the Applicant, as set forth in the Radiation Control rules, 25 TAC §289.226.

Name	Date	Signature

PRIVACY NOTIFICATION: If you are applying as an individual, with few exceptions, you have the right to request and be informed about information that the State of Texas collects about you. You are entitled to receive and review the information upon request. You also have the right to ask the state agency to correct any information that is determined to be incorrect. See <http://www.dshs.state.tx.us> for more information on Privacy Notification. (Reference: Government Code, Section 552.021, 552.023, 559.003 and 559.004)