

MAMMOGRAPHY QUALITY STANDARDS ACT
EXPIRATION OF CERTIFICATE (Provisional) FACT SHEET
(October 2001)

MQSA Requirements

Under the Mammography Quality Standards Act (MQSA) of 1992, the Food and Drug Administration (FDA) may not issue a three-year certificate to a facility whose provisional certificate has expired before a facility has become fully accredited by an FDA-approved Accreditation Body.

As the cover letter states, as of the date of expiration of your FDA Mammography Facility Certificate, your facility is no longer certified. Once your certificate expires, you:

1. **may no longer perform** mammography,
2. **may no longer display** your certificate,

NOTE: If your facility does not remove your certificate from display, a representative of FDA may visit you to confirm that you have discontinued performing mammography. If FDA establishes that your facility continues to perform mammography without a valid certificate after receiving this notice, you could be subject to sanctions under MQSA. These sanctions include civil money penalties of up to \$10,000 per violation per day for performing mammography without a valid certificate (42 U.S.C. 263b(h)(2)(A)) and injunction proceedings by FDA against your facility (42 U.S.C. 263b(j)).

3. you are no longer eligible to receive payment for diagnostic or screening mammography services under the Centers for Medicare and Medicaid Services (CMS).

Appeal for Reconsideration

The MQSA provides your facility with the right to appeal FDA's decision to deny your facility full certification. If your facility chooses to appeal, FDA recommends that you first submit a request for reconsideration to your Accreditation Body within 30 days from receipt of the accompanying letter. Your Accreditation Body will inform your facility of the Accreditation Body's own appeals procedure for reconsideration.

If your facility cannot achieve satisfactory resolution at the Accreditation Body level, you may submit a request for reconsideration directly to FDA.

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You must submit this request within 60 days of Accreditation Body's denial of accreditation, or within 60 days of the Accreditation Body's notice of denial of the appeal for reconsideration, whichever is later. Your appeal to FDA must include copies of all of the following records that are applicable;

1. the Accreditation Body's original denial of accreditation;
2. all information your facility submitted to the Accreditation Body as part of the appeal for reconsideration process;
3. the Accreditation Body's denial of the appeal for reconsideration; and
4. a statement of your facility's reasons for disagreement with the denial of accreditation or denial of reconsideration decision;
5. if the appeal is for Clinical Image Review (CIR), the original films submitted to the AB are required.

When the FDA receives your appeals request, you will be notified of any further procedures that you must follow to receive formal FDA reconsideration and review of the Accreditation Body's decision. Address your appeal to: Food and Drug Administration, Center for Devices and Radiological Health, Division of Mammography Quality and Radiation Programs (HFZ-240), 1350 Piccard Drive, Rockville, MD 20850, Attn: Director.

NOTE: While an adverse accreditation decision is being reviewed, whether by an Accreditation Body or by FDA, a facility **cannot lawfully perform** mammography. A facility that continues to provide diagnostic or screening mammography services during that time is not eligible to receive payment under the Centers for Medicare and Medicaid Services (CMS). In addition, a facility that performs mammography without a valid certificate is subject to sanctions under MQSA, including civil money penalties of up to \$10,000 per violation per day and injunction proceedings by FDA against that facility (42 U.S.C. 263b(h) and (j)).

Centers for Medicare and Medicaid Services (CMS) Payment

Upon expiration of your FDA certificate, the FDA will notify CMS (formerly known as HCFA) that your mammography facility is no longer certified, and may not continue to legally offer mammography services. Therefore, your facility will no longer be eligible to receive payment for diagnostic or screening mammography services under CMS.

Responsibilities to Patients

If for any reason, your facility status changes, and you are no longer performing mammography, you have an obligation to the patients previously served by your facility. It is important that you establish a procedure to provide your former patients their mammography and attendant medical records OR transfer the records to their designated health care practitioner upon request. Your

responsibility to former patients does not end upon expiration of your FDA Mammography Facility Provisional Certificate.

Procedures to Follow to Become Reinstated as a New Facility

To become eligible for a new provisional certificate and be allowed to resume mammography services, a facility must undergo reinstatement as a new facility. To achieve reinstatement, a facility must:

1. contact an approved Accreditation Body to determine the requirements for re-application and accreditation;
2. fully document your facility's history as a provisionally or fully certified mammography facility, including a new submission of the following information as part of the re-application;
 - a) name and address of the facility under which it was provisionally or fully certified,
 - b) name of owner/lessor,
 - c) employer tax identification number (EIN),
 - d) FDA facility identification number (located on the lower right-hand corner of your certificate), and
 - e) expiration date of the FDA provisional or full certificate; and
3. submit to the Accreditation Body a corrective action plan that details how the facility has corrected deficiencies or how the facility intends to implement corrections that justify re-application for accreditation as a new facility (e.g., hire or train personnel, purchase new equipment) and obtain the Accreditation Body's approval of the correction or plan for correction.

Note: If a facility that has failed the accreditation process changes its name, the change in name alone does not qualify that facility to be eligible for reinstatement as a new facility and receive a new provisional certificate. A facility must make substantive changes related to quality of services to qualify for reinstatement.

If the Accreditation Body determines that your facility has adequately corrected pertinent deficiencies, the Accreditation Body will notify FDA. If FDA agrees that your facility has taken sufficient corrective action since your prior accreditation failure, your facility then becomes eligible for a new provisional certificate. In that instance, FDA will notify your facility that you may resume performing mammography services lawfully while the new provisional certificate is being mailed to your facility. A facility may not resume mammography until correction of deficiencies that could result in failure of accreditation have been implemented and verified by the Accreditation Body.

Application Procedures for a 90-Day Extension

Only provisionally accredited and provisionally reinstated facilities are eligible for a one-time 90-Day Extension of their certificate. To apply for a 90-Day Extension, a facility must prepare a letter that includes the following required information:

1. Facility name as it appears on your certificate,
2. FDA MQSA Facility ID #,
3. Contact person's name including phone number and fax number,
4. Request for a 90-Day Extension,
 - Description of circumstances that make the extension necessary,
 - A specific description of the services your facility provides which, if your facility cannot offer mammography services, will negatively impact the community due to reduced access to mammography, **and**
 - List of steps that will be taken to pass accreditation, i.e., to qualify for certification.

Determination will be coordinated with the Accreditation Bodies (ABs). Facilities should keep in contact with their AB throughout the accreditation process.

Facilities accredited by the American College of Radiology (ACR), should submit applications directly to ACR.

Facilities accredited by the States of Arkansas, California, Iowa or Texas should submit applications directly to their State AB.