

U.S. Department of Health and Human Services  
**Food and Drug Administration (FDA)**  
and  
**Texas Department of State Health Services (DSHS)**

*Mammography Quality Standards Act (MQSA)*

*Important Information about the*

*Enhancing Quality Using the Inspection Program (EQUIP) Initiative*

Since the quality of mammograms is one of the most important determinants of the accuracy of mammography, the production of high quality clinical images by certified mammography facilities is one of the primary goals of the MQSA. In fact, there are MQSA regulations which specifically address clinical image quality. Inspection questions related to these clinical image quality regulations have previously not been part of the annual inspection. As part of its EQUIP initiative, FDA's Division of Mammography Quality Standards developed inspection questions related to the image quality regulations and added them to the inspection program, thereby emphasizing the significance of continuous clinical image quality. EQUIP also highlights the responsibilities of the Lead Interpreting Physician (LIP) and other Interpreting Physicians (IP) in the clinical image quality process. These enhancements to the inspection process will EQUIP facilities to continue to provide quality mammography. Your facility is certified by the Texas State Certification Agency (CA). A CA's standard for mammography facilities must be as stringent as the MQSA. In some cases, the Texas regulations for the Certification of Mammography Systems are more stringent than the MQSA and some aspects of LIP oversight are already inspected for during Texas DSHS mammography inspections. However, the MQSA inspection still requires a facility to answer the three questions presented here.

**MQSA Clinical Image Quality-Related Regulations**

§ 900.12(i) *Clinical image quality*. Clinical images produced by any certified facility must continue to comply with the standards for clinical image quality established by that facility's accreditation body.

§ 900.12(d)(1)(ii)(A) All interpreting physicians shall follow the facility procedures for corrective action when the images they are asked to interpret are of poor quality.

§ 900.12(d)(2) *Quality assurance records*. The lead interpreting physician ... shall ensure that records concerning mammography technique and procedures, quality control (including monitoring data, problems detected by analysis of that data, corrective actions, and the effectiveness of the corrective actions), safety, protection and employee qualifications to meet assigned quality assurance tasks are properly maintained and updated.

**Texas Administrative Code (TAC) Clinical Image Quality-Related Regulations**

Texas mammography regulations include virtually the same requirements as the MQSA. TAC references for the Texas regulations are: 25 TAC §289.230 (z) Clinical image quality, 25 TAC §289.230 (u) Quality Assurance, 25 TAC §289.230 (u)(1)(B)(i) Interpreting Physicians, and 25 TAC §289.230 (u)(2) Lead Interpreting Physician.

Listed below are the three new main questions, and their sub-questions, that inspectors will answer during the annual MQSA inspection.

**Quality Assurance –Clinical Image Corrective Action**

**1. Does the facility have procedures for corrective action (CA) when clinical images are of poor quality?**

- (a) Do the procedures include a mechanism for providing ongoing IP feedback on image quality to RT's or other designated facility personnel?
- (b) Do the procedures require documenting any corrective actions taken and documenting the effectiveness of any corrective actions taken?

*Discussion: Interpreting physicians (IP) are required to follow facility procedures for corrective action when the images they are asked to interpret are of poor quality. The facility must have a mechanism for the IP to provide feedback to RT's or other designated facility personnel when images are of poor quality. The facility must have a mechanism to document corrective action taken and the effectiveness of the corrective action.*

**Clinical Image Quality**

**2. Does the facility have procedures to ensure that clinical images continue to comply with the clinical image quality standards established by the facility's accreditation body?**

- (a) Do the procedures include a mechanism for regular reviews of image quality attributes of a sample of mammograms performed by each active RT and a sample of mammograms accepted for interpretation by each active IP?
- (b) Is there documentation of such review since the last inspection?

*Discussion: Facilities must have a system in place to ensure that images continue to comply with the clinical image quality standards established by the facility's accreditation body. The facility must perform regular reviews of image quality attributes of a sample of mammograms performed by each RT and of mammograms accepted for interpretation by each active IP. During each annual inspection, inspectors will ask for documentation that the facility performed a clinical image review at least once since the last inspection.*

**Quality Control**

**3. Does the facility have a procedure for LIP oversight of QA/QC records and corrective actions?**

- (a) Do the procedures include requirements for LIP oversight of QA/QC records, including review of the frequency of performance of all required tests?
- (b) Does the procedure include requirements for LIP review to determine whether appropriate corrective actions were performed when needed?

***Discussion:** The LIP is responsible for providing oversight of the QA and QC records, including a review of the frequency of performance of all required tests, and review of any corrective actions when needed. The LIP must be either available to answer questions on the day of the inspection, sign an attestation provided to the facility, or sign a written facility procedure regarding QA/QC oversight which includes the elements above and is presented during the inspection.*

***Under the State of Texas mammography regulations,** all policy and procedures must be in writing, thus a verbal discussion or the use of the attestation mentioned above will not meet Texas mammography requirements. Texas mammography regulations require the LIP to review the mammography technologist's QC test results at least every three months, or more frequently if the tests are not performed at the required interval or the results exceed the control limits. The LIP must also review the physicist's tests results within 60 days of receipt of the survey report or more frequently when needed. In order to meet the Texas LIP requirements, the annual LIP review of policies and procedures, LIP evaluation of corrective actions taken, and the recording of these LIP reviews must be added to the written policies and procedures.*

#### **MQSA Facility Inspection Report**

Facilities will not be cited for violations related to the new questions on the MQSA Facility Inspection Report during the first inspection after EQUIP goes into effect. Any deficiencies will be noted on the post inspection report; however, no citations will be generated. Inspectors will discuss the questions with facility's representatives, giving facilities time to become familiar with the inspection questions and the documentation needed. Citations will begin in year two of inspections including EQUIP.

#### **Texas DSHS Mammography Inspection Report**

Violations observed regarding questions 1 and 2 will be treated as described above in Texas DSHS mammography inspection results. Question number 3 regards a Texas mammography regulation that has been enforced since the creation of the Texas mammography regulations. Therefore, although no MQSA citation will be generated, failure to comply with the requirement for LIP quarterly review of the mammography technologist's QC test results will be cited as usual in the State of Texas mammography inspection results.

The FDA EQUIP video can be viewed by facilities [here](#).

The Facility EQUIP FAQ's can be found on the [MQSA web site](#).

Facilities may also contact their MQSA inspector, the MQSA Facility Hotline at 800-838-7715 or by email at [MQSAhotline@versatechine.com](mailto:MQSAhotline@versatechine.com), or any one listed below from the Texas CA for more information.

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