

U.S Department of Health and Human Services
Food and Drug Administration (FDA)

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.

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.

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 active 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) Does the procedure 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.*

Facilities will not be cited for violations related to the new questions 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 the 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.

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 or the MQSA Facility Hotline at 800-838-7715 or by e-mail at MQSAhotline@versatechinc.com.