

## EQUIP: Enhancing Quality Using the Inspection Program

The promotion of clinical image quality is a primary goal of the Mammography Quality Standards Act (MQSA). In fact, there is a requirement in the MQSA regulations that “[c]linical images produced by any certified facility must continue to comply with the standards for clinical image quality established by that facility’s accreditation body” (21 CFR 900.12(i)). When performing clinical image reviews, FDA-approved accreditation bodies (AB) must include in the review the eight image quality attributes listed at 21 CFR 900.4(c)(2) .

As we have noted in a [previous MQSA Insights article](#), one of the most consequential of these attributes is patient positioning; poor positioning is a factor in most deficiencies and failures of clinical images. The regulations also require that all interpreting physicians interpreting mammograms for the facility shall “[f]ollow the facility procedures for corrective action when the images they are asked to interpret are of poor quality” (21 CFR 900.12(d)(1)(ii)(A)).

Furthermore, “[t]he lead interpreting physician [. . .] shall ensure that records concerning [. . .] quality control (including [. . .] corrective actions [. . .] ) [. . .] are properly maintained and updated” (21 CFR 900.12(d)(2)). This is among the important responsibilities of the Lead Interpreting Physician (LIP) under MQSA. Additionally, 21 CFR 900.2(x) states that the LIP has the general responsibility for ensuring that a facility’s quality assurance (QA) program meets all of the requirements of 21 CFR 900.12(d)-(f). These subsections address the establishment and maintenance of a QA program and maintenance of associated records; quality control (QC) testing of equipment and corrective action as needed; performance of physicist surveys and mammography equipment evaluations; and a mammography medical outcomes audit. Some of the responsibilities for parts of this QA program are assigned to other qualified individuals, such as the QC technologist and the medical physicist, but the LIP is the operator responsible, on behalf of the facility, to make sure that all quality assurance requirements found in 21 CFR 900.12(d) through (f) are met, including that tests and surveys are performed at the required frequencies, corrective actions are taken when warranted by test results, and records are kept.

Some of these existing MQSA requirements related to QA and image quality have generally not been verified or highlighted by inspectors during annual facility inspections. Conversely, some items which have been inspected annually have very rarely identified violations. Therefore, the Division of Mammography Quality Standards is introducing the Enhancing Quality Using the Inspection Program or EQUIP initiative. The EQUIP initiative will begin to be introduced on October 27, 2016, to mark the beginning of the 25th year since the passage of MQSA. As part of EQUIP, in order to emphasize the need for ongoing facility review of clinical image quality, FDA is adding three inspection questions and removing two. Remember, even if questions are removed from the inspection process, the regulations that create the requirements for inspection questions intended to assess compliance still have the force of law and facilities must continue to comply with all the MQSA regulations even if compliance is not generally checked via questions at the time of inspection.

The three new inspection questions will focus on the three regulations quoted above. The first new inspection question assesses for facility procedures to ensure that clinical images continue to comply with AB standards (including image quality attributes such as positioning), and include regular reviews of sample images from each technologist and each interpreting physician (IP). The second new inspection question assesses for corrective procedures when clinical images are of poor quality, including a mechanism for providing ongoing IP feedback to technologists or other designated personnel. The third new inspection question assesses for the procedure for LIP oversight of QA/QC records—including overseeing the frequency of performance of all required tests—and determining whether corrective actions were taken when needed. In addition to satisfying MQSA requirements, FDA anticipates that the clinical image review and the LIP oversight of QA/QC will also meet Practice Quality Improvement (PQI) requirements for American Board of Radiology (ABR) -certified IPs who are subject to PQI requirements, and will post an addendum to this article upon confirmation by the ABR.

During year one of inspections containing the new EQUIP questions, which will begin January 1, 2017, deficiencies identified by the three new questions will be noted on MQSA inspection reports, but no citations will be generated by the inspection software during the year following the January 1, 2017, start date. Inspectors will discuss the three new questions introduced in the EQUIP initiative with facility personnel and point out to the facility that, should procedures assessed by the inspection questions still not be in place by the time of the next annual MQSA inspection and beyond, Level 2 violation citations will be issued. This stepwise introduction will give facilities and inspectors time to become familiar with the three new inspection questions and refresh facilities' understanding of the underlying requirements the questions are intended to aid in assessing. FDA has posted [Frequently Asked Questions for Facilities](#) about the EQUIP initiative and intends to update those FAQs after approximately 3-6 months of inspector experience and facility feedback.

The addition of the three new questions to the inspection process under the EQUIP initiative is intended to continue MQSA's emphasis on the significance of clinical image quality, which is one of the most important determinants of the accuracy of mammography. The changes will help "EQUIP" facilities to continue to provide quality mammography.

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.

For a short informational video about EQUIP visit

<http://fda.yorkcast.com/webcast/Play/8f6e09f304f446479cd70acb025b0bed1d>.

For Facility EQUIP FAQs visit <http://www.fda.gov/downloads/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityCertificationandInspection/UCM526239.pdf>. Facilities may also contact their MQSA inspector or the MQSA Facility Hotline at 800-838-7715 or by e-mail at [MQSAhotline@versatechinc.com](mailto:MQSAhotline@versatechinc.com).

**Mammography Quality Standards Act (MQSA)**  
**Enhancing Quality Using the Inspection Program (EQUIP)**  
**Frequently Asked Questions - Facilities**

The purpose of this document is answer questions facilities may have about the EQUIP inspection questions. The three questions, and their sub-questions, that the inspector will be answering during the annual inspection, as well as the compliance pathway, are outlined below and followed by FAQs. More information about the EQUIP initiative may be found in the [MQSA Insights article](#), and the “Important Information about the EQUIP Initiative” that inspectors will provide to facilities at their MQSA inspections.

***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?*

**Q1. Does the facility's system for corrective action when clinical images are of poor quality need to be in the form of a written SOP?**

No. Facilities are not required to create a written procedure. A facility may verbally explain its system to the inspector. Whether written or verbal, the system must include mechanisms for ongoing IP feedback and for documenting and assessing corrective actions. The details of those mechanisms will not be assessed by the inspector. He/she will assess that a system is in place and contains those two elements.

**Q2. Who determines whether images are of poor quality?**

For the purpose of this inspection question, the IP is responsible for determining if images are of poor quality and providing feedback.

**Q3. Does the FDA have examples of acceptable mechanisms for the IP to provide feedback on poor image quality?**

No. The mechanism for the IP to provide feedback on poor image quality is left up to the facility.

**Q4. How should a facility document any corrective actions taken or the effectiveness of any corrective action taken?**

It is up to the facility to determine how to document any corrective action taken or the effectiveness of any corrective actions taken.

**Q5. If there were no images of poor quality, does there have to be any documentation of the fact that there was no corrective action?**

No.

**Q6. Is there a specific way a facility should determine the effectiveness of corrective actions?**

No. It is up to the facility how it determines the effectiveness of any C/A taken.

**Q7. Is there a timeframe for corrective action to be taken when the IP determines images are poor quality?**

No. The facility determines its timeframe for completing any needed corrective action.

**Q8. Is there a requirement for how long a facility should retain feedback from the IP to personnel when there are images of poor quality?**

No. There is no requirement on how long the facility should retain clinical image quality feedback from the IP.

**Q9. If a facility is cited under this question and a written response is required, can the facility respond with a written explanation of how it has set up its system rather than submit a written procedure?**

Yes.

### ***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?*

**Q1. Is a regular review required and how often?**

Yes. Since the reviews are discussed at the time of the inspection and need to have been done since the last inspection, by default the review needs to be done at least annually. More frequent review (i.e., monthly, quarterly) is encouraged.

**Q2. Is written documentation of the review required?**

Yes. A verbal demonstration or discussion will not be accepted. Documentation can include such things as a summary report, signed statement by LIP that a review was performed, clinical image review meeting records, memos of review results to RTs and IPs, etc.

**Q3. Does repeat analysis QC count as a review?**

No. Repeat/reject rates are not necessarily directly linked to poor quality images presented for interpretation to the IP.

**Q4. Does the review have to be performed by the Accreditation contact?**

No. It is the responsibility of the facility to ensure the review is performed. Anyone may gather and compile data in order to report on the clinical image quality for the facility.

**Q6. Does the review need to be signed?**

No.

**Q7. Does the review need to be dated?**

Yes.

**Q8. Does daily review of every mammogram at the time of interpretation count as "regular review of a sample of images"?**

No.

**Q9. Is there a requirement of an acceptable sample size of images to review for each active RT and IP?**

No. The sample size of images to review is left up to the facility to determine.

**Q10. Are there any exceptions for facilities with a large number of RTs and IPs?**

No. The review must include all RT's and IP's.

**Q11. Do employees who have left the facility have to be included in the review?**

No. Only employees that are actively performing/interpreting mammograms at the time of the review need to be included in the review.

**Q12. If there is only one IP in facility, is someone else responsible for reviewing him or her?**

No. The sole IP at the facility would also be the LIP and would need to assess his/her own images for quality.

**Q13. What are the AB standards for image quality attributes?**

There are eight image quality attributes listed in 900.4(c)(2)(i-viii). They are: positioning, compression, exposure level, contrast, sharpness, noise, artifacts, and examination identification.

**Q14. For the 3D portion of DBT units are there any FDA clinical image quality standards?**

Yes. Clinical image quality is not specific to any particular technology. The image quality attributes can be used to evaluate images of all 3 mammographic modalities (DBT, FFDM, and screen/film).

**Q15. Does the system to ensure that clinical images continue to comply with clinical image quality standards established by a facility's accreditation body have to include a written SOP?**

No.

### ***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?*

**Q1. Does the system for LIP oversight have to be a written SOP?**

No. The LIP may provide an attestation or can verbally answer questions regarding oversight of QA/QC records.

**Q2. If the LIP is located off site, can he or she be contacted via phone on the day of the inspection to discuss the oversight of QA/QC records?**

Yes.



**Q3. What documentation is needed to effectively demonstrate a system is in place for LIP oversight of QA/QC records and corrective actions?**

The facility may provide LIP attestation or the LIP may verbally answer questions regarding C/A during the inspection, or an SOP signed by the LIP may be presented to the inspector.

**Q4. Can the facility designate another individual to perform the oversight LIP responsibilities of the QA/QC records?**

Yes. The LIP may designate someone other than the LIP to perform the oversight, but the LIP is the one responsible and will be the one attesting, in writing or verbally, or signing an SOP.

**Q5. If the LIP is offsite or part of a tele-radiology company, is oversight of QA/QC part of his or her responsibility?**

Yes. If that person is designated as the LIP for MQSA purposes, then he/she must comply with the MQSA regulations which state that oversight of QA/QC records and corrective actions are the LIP's responsibility.

**Q6. Is there a required frequency for "LIP review" of QA/QC records?**

No. The LIP review should be appropriate to ensure the QC tests are performed at the required frequency and any needed C/A is taken.

**Q7. Do LIPs need training in QA/QC?**

No.

**Q8. If there were no actionable QA/QC test results, does there have to be any documentation of the fact that no C/A was performed?**

No. The facility still needs to provide the LIP attestation or an SOP signed by the LIP, or the LIP may verbally answer questions regarding C/A during the inspection.

***Compliance Pathway***

- *During the initial year of implementation facilities will not be cited for violations of the Clinical Image Quality Review (CIQR) requirements*
- *MQSA Inspection Year Two: Facilities will receive Level 2 citations for deficiencies noted by MQSA inspectors in the area of CIQRs. The facility will be required to provide a written response to the FDA district office within 30 days*
- *MQSA Inspection Year Three: A repeat violation of the CIQRs will be cited as a Level 2 repeat violation. The facility will be required to provide a written response to the FDA district office within 15 days and will be referred to its accreditation body for an evaluation of clinical images.*

**Q1. Will facilities be cited for any noncompliances related to clinical image quality in year one?**

No. Citations related to clinical image quality will not be issued during the first year. The first year of the EQUIP initiative allows the facility to become familiar with the requirements.

**Q2. What are the reasons for the EQUIP initiative?**

The EQUIP initiative places emphasis on the significance of clinical image quality, one of the most important determinants of the accuracy of mammography. It also highlights the LIP's responsibilities for image quality.

**Q3. Do you have any sample clinical image quality programs or procedures that will be acceptable to FDA?**

No. Each facility is responsible for implementing a program that is appropriate for its site.

**Q4. How soon after the first year must documentation of a review being performed be provided to the inspector?**

At least one review needs to be completed by the annual inspection that follows the inspection where EQUIP is introduced.

**Q5. If during the first year, a facility's system/procedure was deemed inadequate and this continues into the second year, will the initial citation be treated as a repeat?**

No. Citations related to clinical image quality will not be issued during the first year. The first year of the EQUIP initiative allows the facility to become familiar with the requirements. If a facility is issued a citation in year two, and the same noncompliance is found in year three, then the citation will be treated as a repeat. Please see compliance pathway above.

**Q6. When will the educational or first introduction year of EQUIP begin?**

The effective date of the educational year will begin January 1, 2017.

**Q7. Who should a facility contact if it needs further clarification about the new inspection questions?**

A facility should contact its inspector first with questions related to the clinical image quality requirements. Inspector contact information can be found on the "MQSA Inspection Confirmation". Facilities may also contact the MQSA Facility Hotline at 800-838-7715 or by e-mail at [MQSAhotline@versatechinc.com](mailto:MQSAhotline@versatechinc.com).

**Mammography Quality Standards Act  
Enhancing Quality using the Inspection Process (EQUIP)  
Quality Assurance / Quality Control Attestation by the  
Lead Interpreting Physician (LIP)**

On the day of your MQSA inspection one of the following needs to occur at inspection in order to avoid a citation related to the following inspection questions:

**Does the facility have a procedure for LIP oversight of QA/QC records and corrective actions that includes:**

(a) Requirements for LIP oversight of QA/QC records, including review of the frequency of performance of all required tests? **Yes or No**

[Note: This includes tests performed by the QC technologist, medical physicist, and any other designated personnel.]

(b) Requirements for LIP review to determine whether appropriate corrective actions were performed when needed? **Yes or No**

- 1) the attestation below signed by the LIP is presented to the inspector or;
- 2) the LIP verbally describes the procedure to the inspector or;
- 3) a written facility procedure that contains the required elements and is signed by the LIP is presented to the inspector

If one of these three scenarios does not occur on the day of the inspection, the inspection questions will be answered “No” by the inspector and a level 2 citation will be generated. If you have questions, contact the inspector at the telephone number provided on the Inspection Confirmation Notice.

## Lead Interpreting Physician (LIP) QA/QC Attestation :

**I attest that this facility has a procedure for:**

(a) my oversight of QA/QC records, including review of the frequency of performance of all required tests;

[Note: This includes tests performed by the QC technologist, medical physicist, and any other designated personnel.]

(b) my review of corrective actions to determine that appropriate corrective actions were performed when needed.

Facility Name: \_\_\_\_\_ MQSA ID# \_\_\_\_\_

LIP Name: \_\_\_\_\_

LIP Signature: \_\_\_\_\_ Date Signed: \_\_\_\_\_

Please maintain the completed LIP attestation statement with the QA/QC records that will be presented to the inspector on the day of the MQSA inspection.