

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, including informational videos, documents, and MQSA Insights articles, may be found on the MQSA website under [‘Inspection News’](#).

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?

Q1.1. 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.

Q1.2. Who determines whether images are of poor quality on an ongoing basis?

For the purpose of this inspection question, the IP is responsible for determining if images are of poor quality and providing feedback. The IP may use available tools, such as software programs, to help determine if images are of poor quality.

Q1.3. Does the FDA have examples of acceptable mechanisms for the IP to provide ongoing feedback on poor image quality?

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

Q1.4. 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.

Q1.5. 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.

Q1.6. 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 corrective action taken.

Q1.7. 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.

Q1.8. 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.

Q1.9. 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.

New! Added 06/2018:

Q1.10. How many cases of corrective action are too many?

It is up to your facility to determine the effectiveness of any corrective action taken. The goal of the daily review is to produce a high quality individual mammogram that can be interpreted. Inspectors will be asking about your process; they will not be reviewing documentation of corrective action or the effectiveness of 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?

Q2.1. Is a periodic clinical image quality review required and how often?

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

Q2.2. Is written documentation of the periodic clinical image quality review required?

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

Q2.3. Does repeat analysis QC count as a periodic clinical image quality review?

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

Q2.4. Does the periodic clinical image quality review have to be performed by the Accreditation contact or the LIP?

No. For the purpose of this inspection question, the IP or any designated person, group of individuals, or organization, **working in conjunction with an IP**, can be responsible for performing the periodic clinical image quality review.

Q2.5. Does the periodic clinical image quality review need to be signed?

No.

Q2.6. Does the periodic clinical image quality review need to be dated?

Yes.

Q2.7. Does daily review of every mammogram at the time of interpretation count as a periodic review of a sample of images?

No.

Q2.8. 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.

Q2.9. 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.

Q2.10. Do employees who have left the facility have to be included in the periodic clinical image quality review?

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

Q2.11. If there is only one IP in facility, is someone else responsible for reviewing his or her images?

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

Q2.12. 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.

Q2.13. 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 three mammographic modalities (DBT, FFDM, and screen/film).

Q2.14. 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.

Q2.15. We have a multi-site network of certified facilities. Mammograms are performed and interpreted by a large number of RTs and IPs across our network. When evaluating clinical images, can the periodic clinical image quality review include a sample of clinical images selected from across our entire network system for each RT and each IP?

No. Because MQSA regulates facilities, the periodic clinical image quality reviews are to be conducted for each facility, to include clinical images performed by each RT and interpreted by each IP at that specific facility. It is up to the facility to decide the sample size of clinical images pulled for review for each IP and each RT at each facility and it is up to the facility to determine how the reviews are conducted and with what frequency; the minimum frequency for the review is annually.

Q2.16. Is the periodic clinical image quality review intended to evaluate linkages between the images taken by each RT and read by each IP? For example, does every IP at the facility have to review images by technologist A, technologist B, technologist C, etc?

No. The periodic clinical image quality review is not intended to evaluate linkages between RTs and IPs. A sample of images performed by each RT and a sample of images interpreted by each IP must be included in the periodic clinical image quality review. It is intended to evaluate the quality of mammography by the personnel who perform and interpret mammograms.

Q2.17. Our facility chooses one mammogram from each RT and critiques it as a group. Is this acceptable?

Yes. The sample size of images to review is left up to the facility to determine. The results of the periodic clinical image quality review need to be documented.

Q2.18. Does the periodic clinical image quality review need to include IP interpretation accuracy?

No. The periodic clinical image quality review is not intended to assess the IP's interpretation accuracy, but to assess whether the IP accepted images which meet the image quality standards of the AB. On the other hand, the medical outcomes audit and analysis is designed to ensure the reliability, clarity, and accuracy of the interpretation of mammograms by each IP.

Q2.19. Can our facility use IP peer reviews to meet the periodic clinical image quality review requirement?

Yes. If such peer review, in addition to whatever else it is designed to assess, also includes assessing the quality of the images accepted for interpretation, then the facility may use IP peer reviews to meet the periodic clinical image quality review requirement.

Q2.20. Can our facility select images that are more than a year old for the periodic clinical image quality review?

No. Because the periodic clinical image quality review is intended to ensure that clinical images continue to comply with the clinical image quality standards established by the facility's

AB, images that are more than a year old and predate the previous inspection should not be selected for the periodic clinical image quality review.

Q2.21. Our facility plans to have a mammography technologist perform the periodic clinical image quality reviews. Is this acceptable?

Yes. For the purpose of this inspection question, any designated person, group of individuals, or organization, **working in conjunction with an IP**, can be designated for performing the periodic clinical image quality review. However, the LIP is ultimately responsible for ensuring that clinical images continue to comply with the clinical image quality standards established by the facility's accreditation body.

Q2.22. Can a mammography technologist perform the periodic clinical image quality review on her own images?

No.

New! Added 06/2018:

Q2.23. Does the LIP need to be included in the periodic clinical image review?

Yes. The LIP is an IP and therefore needs to have a sample of images he or she accepted for interpretation included in the periodic clinical image review.

New! Added 06/2018:

Q2.24. What is the role of the LIP in the EQUIP initiative?

The LIP is viewed as the individual most responsible for ensuring image quality is continuously maintained by the facility. The LIP is also an IP and therefore subject to the same requirement of having images they accepted for interpretation included in the overall facility image review process. The Lead Interpreting Physician is an MQSA designation only, and does not confer any supervisory responsibility over other IPs.

New! Added 06/2018:

Q2.25. Can an LIP perform the periodic clinical image quality review on his or her own images, even if there are other IPs at the facility?

Yes. However, if other IPs are available, it could benefit the LIP to have another IP review the images for interpretive quality. Any IP or any designated person, group of individuals, or organization, working in conjunction with an IP, can be responsible for performing the periodic clinical image quality review.

New! Added 06/2018:

Q2.26. If an IP or RT only performs diagnostic studies, must they be included in the periodic clinical image review?

All IPs and RTs must be included in the review, even if they only perform diagnostic studies. The MQSA does not distinguish between diagnostic and screening mammography.

New! Added 06/2018:

Q2.27. Should our facility only choose screening studies to be included in the periodic clinical image review?

No. Any screening exam views or standard CC or MLO view performed as a diagnostic mammography exam is able to be evaluated on the eight (8) image quality attributes.

New! Added 06/2018:

Q2.28. Does our documentation for the periodic clinical image quality review need to list or include a statement that the review included the eight (8) image quality attributes?

No.

New: Added 06/2018:

Q2.29. We have a multi-site network of certified facilities. We know we have to conduct the periodic clinical image quality review for each certified facility. Can we include all the reviews on one report if we clearly differentiate each facility on the report?

Yes. It is up to your facility how to document the performance of the periodic clinical image quality review. The reviews for multi-site networks may be included in one report if the facilities are clearly differentiated on the report.

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?

Q3.1. 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.

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Q3.2. 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.

Q3.3. 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.

Q3.4. 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.

Q3.5. 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 is subject to the MQSA regulations which state that oversight of QA/QC records and corrective actions are the LIP's responsibility.

Q3.6. 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 corrective action is taken.

Q3.7. Do LIPs need specific training in QA/QC?

No.

Q3.8. 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 corrective action during the inspection.

New! Added 06/2018:

Q3.9. Our LIP will not be available on the day of the inspection to answer questions regarding the oversight of QA/QC records. When should our LIP sign the attestation?

The LIP should sign the attestation at any time prior to the date of the inspection.

New! Added 06/2018:

Q3.10. Does our LIP have to sign a new attestation every year he or she is unavailable to discuss the oversight of QA/QC records?

Yes. Each year the LIP cannot be available at the time of inspection, a new attestation is required. However, we strongly encourage the LIP to be available for discussion of the oversight of QA/QC records and corrective actions during the inspection.

New! Added 06/2018:

Q3.11. Our facility has an SOP which describes the LIP oversight of the QA/QC records and corrective actions. Does our LIP have to sign the SOP every year?

Yes. If the facility chooses to provide a signed SOP in lieu of the LIP signing an attestation or attending the inspection by phone or in person, the SOP should be signed each year at any time prior to the inspection date.

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. 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.

Q2. 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.

Q3. 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.

Q4. 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.

Q5. When will the educational or first introduction year of EQUIP begin?

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

Q6. Who should a facility contact if it needs further clarification about the clinical image quality inspection questions?

A facility should first contact its inspector with questions related to the clinical image quality inspection questions. 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.