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Mammography Quality Standards Act and Regulation Amendments: Small Entity Compliance Guide

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Guidance for Industry and Food and Drug Administration Staff

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For questions about this document, contact the MQSA Hotline at 1-800-838-7715, or by e-mail at MQSAhotline@versatechinc.com.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

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Preface

Public Comment

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Mammography Quality Standards Act and Regulation Amendments: Small Entity Compliance Guide

Guidance for Industry and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

On March 10, 2023, the Food and Drug Administration (FDA) issued a final rule[1] ("2023 MQSA Rule") to update the mammography regulations in part 900 of subchapter I of title 21 of the Code of Regulations ("MQSA regulations" or "implementing regulations") that were issued under the Mammography Quality Standards Act of 1992 (MQSA) and the Federal Food, Drug, and Cosmetic Act (FD&C Act). FDA has prepared this Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121, as amended by Public Law 110-28) to assist small entities to comply with these changes in the MQSA regulations, which become effective September 10, 2024.

Mammography is an x-ray imaging examination used to identify signs of breast cancer. For patients to receive the full benefit of mammography, the service must be of high quality, including performance of the examination by qualified technologists, using equipment that is tested and properly functioning; interpretation by qualified physicians; and clear and prompt communication of results to patients and their referring healthcare providers. The MQSA establishes uniform baseline Federal standards designed to ensure, among other things, that all patients nationwide have access to quality mammography services. The MQSA implementing regulations address, among other things, standards for accreditation bodies and certifying agencies, as well as mammography quality standards for facilities, such as qualifications of personnel at mammography facilities, standards for mammography equipment, the content and terminology for mammography reports, the requirement to establish a quality assurance program, standards and timing for quality assurance testing, standards for clinical image quality,

[1] 88 FR 15126 (March 10, 2023).

recordkeeping, communication of results, and clinical image review by the facility's accrediting body (AB). Based on technology changes in mammography and our experience with the administration of the MQSA program, FDA has modernized and updated the regulations as well as improved the information, including breast density information, required to be provided by mammography facilities to patients and their healthcare providers. The 2023 MQSA Rule requires that the summary of the mammography report written in lay terms ("lay summary") that is provided to patients identifies whether the patient has dense or non-dense breast tissue and includes a prescribed paragraph on the significance of breast density. The 2023 MQSA Rule also establishes four categories for reporting breast tissue density in the mammography report that is provided to the patient's referring healthcare provider.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Questions and Answers on the MQSA and Implementing Regulations

The 2023 MQSA Rule updating the MQSA regulations renumbered and added certain provisions to the regulations. Throughout this guidance document, where FDA intends to cite a portion of the MQSA regulations that has been renumbered or added to the regulations by the 2023 MQSA Rule, that citation is in italics. Where the citation is in plain text, the citation remains unchanged in the 2023 MQSA Rule.

A. GENERAL BACKGROUND

1. What is a mammography facility?

A mammography facility is a hospital, outpatient department, clinic, radiology practice, mobile unit, office of a physician, or other facility that conducts mammography activities, including the following: Operation of equipment to produce a mammogram, processing of the mammogram, initial interpretation of the mammogram, and maintaining viewing conditions for that interpretation. This term does not include a facility of the Department of Veterans Affairs. (42 U.S.C. 263b(a)(3), 21 CFR 900.2(q)).

2. What do the MQSA and its implementing regulations address?

The MQSA and its implementing regulations address, among other things, standards for ABs and certifying agencies, as well as mammography quality standards for facilities, such as qualifications of personnel at mammography facilities, standards for mammography equipment, the content and terminology for mammography reports, the requirement to establish a quality assurance program, standards and timing for quality assurance testing, standards for clinical image quality,

recordkeeping, communication of results, and clinical image review by the facility's AB.

3. What specific areas do the MQSA and its implementing regulations NOT address?

The MQSA and its implementing regulations do not contain clinical practice guidelines, including on topics such as the age range or time interval for screening mammography. The interpretation of the imaging findings is the responsibility of the qualified interpreting physician. The MQSA and its implementing regulations do not take a position on any other clinical standards of care, which are more appropriately considered during the clinical decision-making by the interpreting physician, the referring healthcare provider, and the patient. Computed tomography of the breast is not regulated under the MQSA regulations. (*21 CFR 900.2(aa)(3)*). Additionally, the regulations generally do not apply to radiography of the breast performed during invasive interventions for localization or biopsy procedures or performed with an investigational mammography device as part of a study conducted in accordance with FDA's Investigational Device Exemption regulations found in 21 CFR part 812. (See 21 CFR 900.2(aa)(1)-(2)). FDA does not typically review clinical images for quality, as this is generally performed by the ABs. (See 21 CFR 900.4(c), 900.12(i), and 900.12(j)).

B. CERTIFICATION

1. What does certification mean?

Certification means the process of approval of a facility by FDA or by a State that has received FDA approval as a certifier ("State Certification Agency," "State as Certifier" or "SAC") to provide mammography services. (21 CFR 900.2(i)). In other words, a mammography facility that receives MQSA certification has shown it is capable of providing quality mammography. Certification is issued by the FDA or, for facilities located in the States in which the State is an SAC (found here: https://www.fda.gov/radiation-emitting-products/facility-certification-and-inspection-mqsa/mqsa-accreditation-bodies https://www.fda.gov/radiation-emitting-products/mammography-quality-standards-act-and-program/facility-accreditation-and-certification), by that SAC. A facility that is certified has completed a rigorous review of its practices by an FDA-approved AB, and FDA or the SAC has determined that the facility has satisfied the requirements for certification (21 CFR 900.11(a) and (b)(1); 900.20). A facility that has been provisionally certified is undergoing the process of accreditation with an FDA-approved AB, and FDA or the SAC has determined the facility has submitted the required information to the AB. (21 CFR 900.11(b)(2); 900.20).

2. What is the difference between full certification vs. provisional certification?

Full Certification: A fully certified facility has completed the accreditation review

process and has been issued an MQSA certificate that is valid for three years. (42 U.S.C. 263b(c)(1); 21 CFR 900.11(b)(1)).

Provisional Certification: A provisionally certified facility has had its application accepted by an FDA-approved AB, the AB has decided that the facility has submitted the required information, and FDA or an SAC has issued a provisional certificate to enable the facility to perform mammography and to obtain the clinical images needed to complete the accreditation process (see 21 CFR 900.11(b)(2)). A provisional certificate is valid for up to six months. During the six-month provisional period, the facility must collect clinical images and other data needed for completion of the accreditation process (within the AB required timeframes) and adhere to all requirements of the AB (21 CFR 900.11(b)(2)(ii)). If the facility has not completed the accreditation process prior to the expiration of the provisional MQSA certificate, it must cease performing mammography (see 21 CFR 900.11(a)). A facility may apply for and receive reinstatement of the facility's MQSA certificate (21 CFR 900.11(c)). Alternatively, a facility that meets certain criteria[2] may qualify for a one-time 90-day extension of the provisional MQSA certificate. (21 CFR 900.11(b)(3)).

3. Can a facility get certification from the State?

Yes. FDA may delegate certain aspects of the MQSA certification program to qualified States that have applied for and that have received FDA approval as a certifying agency. (42 U.S.C. 263b(q); 21 CFR 900.21(d)). A State as Certifier, or SAC, may perform several functions, including:

- Issuance, renewal, denial, suspension, and revocation of certificates to mammography facilities within the State.[3]
- Annual facility inspections of facilities.[4]

The current list of approved SACs is available at: https://www.fda.gov/radiation-emitting-products/mammography-quality-standards-act-and-program/facility-accreditation-and-certification.

FDA generally does not certify facilities located in States that have an FDA-approved SAC. (See 21 CFR 900.20).

4. Are all facilities practicing mammography required to be certified?

To perform mammography, all "facilities" that are subject to the MQSA[5] must be either provisionally certified while they undergo accreditation review or certified. If a facility is not certified or provisionally certified, it must stop providing

[2] 42 U.S.C. 263b(c)(4) describes the criteria for FDA to issue a 90-day extension.
[3] Under 21 CFR 900.21(d), FDA may limit the scope of certification authority delegated to the State in accordance with MQSA. To date, FDA has not granted certification authority to a State for Federal facilities.
[4] 42 U.S.C. 263b(g)(1); 21 CFR 900.22(b).
[5] As defined in the MQSA, "facility" does not include a facility of the Department of Veterans Affairs (42 U.S.C. 263b(a)(3)(A).)

mammography services. (21 CFR 900.11).

5. What is a 90-day extension?

If the accreditation process is not completed within the six-month provisional period, a facility may apply to FDA or the SAC, through its AB, for a 90-day extension. To be eligible for a 90-day extension, a facility must describe the steps being taken to qualify the facility for certification and provide evidence that there would be a significant adverse impact on access to mammography in the geographic area served if such facility did not obtain an extension. (21 CFR 900.11(b)(3)).

To apply for a 90-day extension, a facility must contact its AB or other entity designated by FDA. (21 CFR 900.11(b)(3)(i)).

6. Is there a list of MQSA-Certified Facilities?

FDA's publicly available database can be checked to confirm the certification status of all mammography facilities.

7. Does Medicaid or Medicare pay for mammography services performed at facilities that are not MQSA-certified?

No facility subject to the MQSA may conduct a mammography examination or procedure unless the facility obtains a certificate, or a temporary renewal certificate, or provisional certificate. (42 U.S.C. 263b(b)(1)). The Centers for Medicare and Medicaid Services (CMS) regulations govern the amount and frequency of Medicaid or Medicare reimbursement. (See 42 CFR subchapters B and C of chapter IV). For information or questions regarding Medicare or Medicaid contact CMS.

C. ACCREDITATION

1. What is accreditation?

Accreditation is the process by which an FDA-approved AB accredits mammography facilities to be eligible to obtain certification to perform mammography services. For a facility to obtain accreditation and qualify for a certificate, a facility must apply to an FDA-approved AB, and the AB must decide to accredit the facility. The facility must submit to the AB the information required by 21 CFR 900.11(b)(1), (2), or (3), as applicable. (See 42 U.S.C. 263b(d)(1)(A)(iv) and 21 CFR 900.11(a)). The AB reviews the facility's accreditation application materials in accordance with established requirements and standards for accreditation in the MQSA regulations and FDA-approved AB policies and evaluates the facility for compliance with national quality standards. (See 21 CFR 900.1, 900.3, 900.4, and 900.12).

2. Where can a facility apply for accreditation?

FDA has approved a private non-profit organization, the American College of Radiology (ACR), which serves as a nationwide AB, and some State agencies to serve as ABs for facilities in their respective States, for 7-year terms. (See 21 CFR 900.3(g)). The list of current ABs can be found here: https://www.fda.gov/radiation-emitting-products/mammography-quality-standards-act-and-program/facility-accreditation-and-certification.

3. Do all FDA-approved ABs have the same requirements for mammography quality?

Yes. All mammography facilities accredited by any FDA-approved AB are held to the same federal quality standards. The MQSA regulations require the AB to review a mammography facility's equipment, personnel (interpreting physicians, radiologic technologists, and medical physicists), clinical image quality, and practices. The AB will accredit the facility if its review establishes that the mammography facility meets the federal quality standards established under the MQSA and its implementing regulations. (21 CFR 900.4). There may be specific State requirements independent of the MQSA requirements that are applicable to a facility.

4. How does a facility know which accreditation body it should apply to?

To be accredited by a State, a facility must be located in that AB's State. Under the MQSA, a facility located in a State with an FDA-approved AB may be accredited either by the State or by the ACR. (See 42 U.S.C. 263b(e) and 21 CFR 900.3(a)). Currently, the ACR can accredit any facility in the United States.

5. What is the cost for accreditation?

Each AB has its own fee schedule. You should contact your AB for more information related to the cost of accreditation. (21 CFR 900.4(i)).

6. How long is accreditation valid?

Accreditation is valid for up to three years. (See 42 U.S.C. 263b(c)(1); 21 CFR 900.4(c)(1) & (d)(1)). Facilities with a lapse in accreditation or that have not been reaccredited will not be able to obtain new or renewed MQSA certificates until accreditation or reaccreditation occurs. (21 CFR 900.11(b)(1)). Further, without an MQSA certificate that is in effect, the facility cannot lawfully operate. (21 CFR 900.11(a)). Accordingly, facilities should ensure they allow sufficient time to complete the reaccreditation process before their MQSA certificate expires.

7. When a certified facility purchases a new mammography unit, what steps must the facility take before the unit can be used for mammography?

In an already-certified facility, a newly-installed mammography unit can be used only after:

- A mammography equipment evaluation (MEE) has been conducted by a qualified medical physicist within the six months prior to submitting a unit accreditation application; and
- Each mammography equipment unit undergoes accreditation by the facility's AB.

See 21 CFR 900.4(e) and 900.12(e)(10). Please note that after the initial MEE is conducted by a medical physicist, subsequent MEEs may be performed by a medical physicist or under the direct supervision of a medical physicist. (21 CFR 900.4(e) and 900.12(e)(10)).

As part of the facility's record-keeping requirement, a facility must have documentation showing that it has passed an MEE *before a new unit may be used on patients*. (See 21 CFR 900.12(d)(2) and 900.12(e)(10)). Before using a new unit, a facility should also have documentation showing that it has received confirmation that the accreditation application for the new unit has been accepted and is under review by its AB. FDA generally considers a new unit to be undergoing accreditation when the facility has submitted the initial part of the application for accreditation to its AB and has received confirmation that the application is under review. A facility should then follow its AB's guidelines for newly installed mammography units. (21 CFR 900.4(e) and 900.12(e)(10)).

8. As of September 10, 2024, what are the facility's updated responsibilities when a mammography unit is converted from one modality to another?

An MEE is required prior to clinical use when a mammography unit is converted from one modality to another modality. The MEE must demonstrate compliance with applicable requirements. In addition, the AB's procedures must be followed for applying for accreditation of that unit. (*21 CFR 900.12(b)(2)(ii)*, 21 CFR 21 CFR 900.4(e), 900.12(e)(10)).

9. If a facility failed the 2D portion of unit accreditation but passed the 3D portion, can the unit be used for acquiring 3D images only?

A facility may perform mammography using the 3D mode only if it is a separately accredited modality. However, a unit that takes both 2D and 3D images during one exposure (i.e., combination mode) and the 2D portion of the unit is unaccredited, it would not comply with applicable MQSA requirements. (21 CFR 900.4(e), *21 CFR 900.12(b)(2)(ii)*, 21 CFR 900.12(e)(10)).

10. Are mobile mammography facilities required to meet the same standards as stationary facilities?

Yes. The MQSA regulations apply to all mammography facilities as defined in 21

CFR 900.2(q), including mobile units. The same standards for image quality apply to all facilities, whether stationary or mobile. Mobile facilities, similar to other facilities, must prominently display an MQSA certificate issued by FDA or the SAC for that facility. (See 42 U.S.C. 263b(b)(1)(A)(iii)).

11. Beginning September 10, 2024, what are the consequences if a facility fails to become accredited after three consecutive attempts?

A facility that fails to become accredited after three consecutive attempts must wait 1 year from the date of the most recent accreditation failure before applying to any AB. (*21 CFR 900.4(a)(6)(ii)*).

D. INSPECTIONS

1. During an annual inspection, what will inspectors review?

Each facility location must be inspected at least annually by a certified MQSA inspector for the following:

- Equipment performance
- Quality Assurance (QA) records
- Quality Control (QC) records to include:
  - Technologist tests
  - Medical physicist's annual survey report
  - Mammography equipment evaluations, if any
- Personnel qualification records
- Medical records (mammography reports) and lay summaries
- Medical audit and outcome analysis records

See 42 U.S.C. 263b(g)(1)(E); *21 CFR 900.12(a)(4), 900.12(c)(4),* 900.12(d)(2), and *900.12(f)(4)*.

Annual inspections are generally conducted by FDA, or a State or local agency acting on behalf of FDA, and typically do not include a review of clinical image interpretations or quality, which the AB reviews separately according to its FDA-approved timeframe, or as specified by FDA (see 42 U.S.C. 263b(g)(1), 21 CFR 900.4(c)(1), and 900.12(j)). This means that even if the annual inspection does not identify any adverse observations, a facility could have mammography image quality issues.

Concurrent with the MQSA annual inspection, States may also inspect for some items that are required by their laws and regulations but are independent of MQSA requirements. However, these items generally do not affect the facility's compliance with MQSA or the associated MQSA inspection fee. (See 42 U.S.C. 263b(g)).

2. What documentation will the inspector review during each annual MQSA

inspection?

During the annual MQSA inspection, inspectors will review documentation that relates to whether the facility is meeting the requirements of the MQSA. This may include, but is not limited to:

- accreditation and certification documentation;
- licensure, board certification, training letters and certificates, and experience records of mammography personnel;
- the medical physicist survey, or MEE reports, the quality control records and images documenting the results of periodic quality control tests recommended by the manufacturer of the equipment or under an alternative standard;
- to assess equipment performance, an inspector typically requests the facility perform a phantom image from each mammography unit during the inspection;
- a sample of medical reports issued for mammographic examinations performed at the facility;
- a sample of the lay summary letters issued to mammography patients whose mammograms were performed at the facility;
- and any other documentation required of the facility under the MQSA. (42 U.S.C. 263b(g), 21 CFR 900.12(d)(2)).

3. How is the scheduling of the inspection coordinated? Is it an unannounced inspection?

Normally, the inspector will provide the facility with advance notice of at least five business days before an inspection. The inspector will generally work with the facility in scheduling the inspection to minimize any inconvenience to the facility. (See 42 U.S.C. 263b(g)(4)).

4. How long do inspections last?

Based on national data, the average on-site inspection of a facility with a single mammography unit could take between five and six hours. During a typical inspection, the inspector ordinarily observes the technologist take a phantom image and will score the phantom image either at the acquisition workstation or at the radiologist review workstation. To help minimize disruption to the facility's activities, as well as to reduce the inspection time, FDA recommends that the facility organize and consolidate all records the inspector will need and have them readily available on the day of the inspection. While not intended to disrupt facility personnel from conducting their usual duties during the inspection, such personnel should be available if the inspector has questions or needs assistance.

5. How are inspection results communicated to the facility?

After the MQSA inspection, inspectors will generally meet with representatives of the facility to discuss the inspection and any noncompliance(s) that was observed, as

well as timeframes to submit any pending documentation and/or corrective action. FDA recommends that the lead interpreting physician, inspection contact, quality control technologist, radiology manager, and if possible, the facility's designated most responsible individual attend the closeout discussion, which could take approximately 15-20 minutes. Typically, the inspector will provide the facility with a copy of an inspection closeout document, "Important Information About Your MQSA Inspection," and discuss how the facility would like to receive the Post-Inspection Report (e.g., e-mail, postal mail).

6. What information is contained in the Post-Inspection Report?

The Post-Inspection Report (PIR) identifies the key facility contacts for the facility's mammography program, identifies the mammography units in use at the facility, documents the phantom image score obtained by the inspector for each mammography unit, provides the inspector's inspection observations identified by the level of noncompliance and any relevant inspector remarks intended to assist the facility in addressing corrective actions for adverse inspection observations. Adverse inspection observations are generally placed into a category level based on the FDA's assessment of how the observation may affect the quality of mammography. The category level is also used to determine how the facility should respond to the observation. Identical observations found during two consecutive inspections are identified as repeats.

The two[6] possible levels of noncompliance resulting from an MQSA inspection are:

- Level 1: Indicates that the inspector found one or more deviations from key MQSA requirements that may compromise the quality of mammography performed at the facility. Level 1 noncompliances are the most severe findings.
- Level 2: Indicates that the facility meets key MQSA requirements, however the inspector found that the facility failed to meet one or more significant mammography quality items. The PIR is provided to the facility. The inspector will generally aim to send the final inspection report within five business days of the date of the on-site inspection (or within five business days of receipt of any pending documentation submitted by the facility to the inspector to resolve pending inspection items).

7. How should a facility address inspectional observations?

Facilities should address any noncompliance noted on the PIR, including any inspectional observations noted in printable remarks, in its written response to the FDA compliance officer. If the facility's response to the inspection's observations appears adequate, FDA may decide that no further action is needed and will notify the facility that the matter is closed.

[6] FDA has previously described three possible levels of noncompliance (see, e.g., "MQSA Inspection Procedures"); however, FDA generally classifies observations into one of two levels (see, e.g., FDA website, "Follow Up for Inspection Violations").

If the facility's written response to the inspection observations is not sufficient or the facility fails to respond, FDA may need to re-inspect the facility to verify that it has corrected all of the problems. The current cost of this inspection may be found on FDA's website. FDA may also decide to issue a Warning Letter, and/or take other regulatory action, such as requiring an Additional Mammography Review (AMR), imposing sanctions such as a Directed Plan of Correction or Civil Money Penalties, or ordering Suspension or Revocation of an MQSA certificate. (42 U.S.C. 263b(h) and (i)).

Repeat Level 2 observations associated with the Enhancing Quality Using the Inspection Program (EQUIP) initiative may result in the facility undergoing an AMR performed by the facility's AB. Additionally, based on observations identified during an inspection, a facility may undergo an AMR when FDA or SAC has reason to believe that mammography quality has been compromised and may present a serious/significant risk to human health, regardless of whether a facility has taken corrective action(s) and submitted its response to FDA. (42 U.S.C. 263b(g)(4)).

8. Will the State regulatory agency or the FDA inspect the facility?

FDA contracts with State regulatory agencies and trains their personnel to conduct MQSA inspections. (42 U.S.C. 263b(g)(1)(D)). If a State is not under contract to conduct MQSA inspections on behalf of FDA, then FDA inspectors perform the inspections. Veterans Affairs facilities are outside the scope of the MQSA but are inspected by FDA employees through an Inter-Agency Agreement (IAA) with FDA.[7] Mammography facilities located on U.S. military facilities or within federal agencies are inspected by FDA employees.[8]

9. Will a new MQSA certificate be issued to a facility after its annual inspection?

No. Following the initial MQSA certification, the issued certificate is effective for up to three years. The effective dates start from the time of initial issuance of the certificate as opposed to the time of inspection. Facilities that wish to continue to lawfully provide mammography services must be reaccredited and obtain renewed MQSA certification before the current MQSA certificate expires. (42 U.S.C. 263b(c)(1); 21 CFR 900.11).

10. What are the fees for annual inspections?

The current FDA MQSA inspection fees can be found at https://www.fda.gov/radiation-emitting-products/inspection-resources/mammography-facility-inspection-fees. Facilities in certifying States should contact their SAC to determine the fees that apply to them. The current FDA portion of the fee for facilities within States that have an SAC can be found at https://www.fda.gov/radiation-emitting-products/inspection-resources/mammography-facility-inspection-fees. (See 42 U.S.C. 263b(r)(1)(A)).

[7] See FDA Compliance Program Guidance Manual, Program 7385.014, p. 8.
[8] *Id*. at p. 17; see also 42 U.S.C. 263b(a)(3)(A) and (g)(1)(A).

11. How will we receive our bill for the inspection?

The MQSA User Fee Program sends inspection fee invoices via email to mammography facilities after their annual inspection. MQSA inspectors will generally collect each facility's billing contact information, which includes the billing contact's name and email address, during each annual inspection. Facilities with inspection fee or billing questions can e-mail the MQSA User Fee program at MQSAUserFeeSupport@fda.hhs.gov.

12. Can the inspection fee be waived?

Yes, if your facility is deemed a governmental entity (GE). A governmental entity is a mammography facility subject to inspection under section 354(g)(1) of the PHS Act, 42 U.S.C. 263b(g)(1) when it meets either of the following criteria, as identified by FDA in the Federal Register Notice of July 6, 2007 (72 FR 37027), consistent with 42 U.S.C. 263b(r)(1)(A):

(1) The facility is operated by any federal department, State, district, territory, possession, federally recognized Indian tribe, city, county, town, village, municipal corporation or similar political organization or subpart thereof. The entire salary of all on-site personnel of the mammography facility must be directly paid by a particular form of government as listed above. All the facility's mammography equipment must be owned, rented by, or leased by a particular form of government as listed above. The facility's ultimate authority to make day-to-day decisions concerning the management and operation of the mammography facility must come from a particular form of government as listed above. All these requirements must be met in order for a facility to be considered a governmental entity. The particular form of government also must be listed on the Governmental Entity Declaration form (FDA Form 3422) in the space provided. FDA does not recognize a facility providing Medicare/Medicaid services without meeting the governmental entity criteria described above; or

(2) The facility provides services under the Centers for Disease Control and Prevention (CDC) grant supporting the Breast and Cervical Cancer Mortality Prevention Act of 1990 and at least 50% of the mammography screening examinations provided during the preceding 12 months were funded under that statute. The FDA does not recognize other breast cancer or mammography programs/grants under the governmental entity exemption.

Following the closure of the FDA MQSA inspection, the FDA issues an invoice and includes the GE Declaration form mentioned above (FDA Form 3422). If your facility fulfills the GE criteria, you can complete the form and should return within 30 days of receipt of your MQSA inspectional invoice to the following email address: **MQSAUserFeeSupport@fda.hhs.gov.**

If the FDA determines your facility is a governmental entity, additional fee statements concerning the inspection will not be sent. If you continue to receive fee statements, however, you should contact the MQSA Hotline to discuss the status of your claim.

Facilities claiming governmental entity status should submit a governmental entity form each year. The FDA conducts a Governmental Entity Audit periodically. Your facility could be selected as part of an audit sample. If your facility is selected to participate in the audit, your facility could be notified and asked to provide additional information substantiating your GE claim. Additional information can be found on FDA's website at page titled Mammography Facility Inspection Fees.

E. GENERAL RESPONSIBILITIES OF A FACILITY TO PATIENTS

1. What mammogram results will a facility be required to communicate to patients as of September 10, 2024? When must this be done?

A mammography facility must provide each patient with a written summary of the results of the exam. The summary must be in lay terms or words a patient can easily understand. (21 CFR 900.12(c)(2)). As of September 10, 2024, the summary must include, at a minimum, the name of the patient, the name, address, and telephone number of the facility performing the mammographic exam, an overall final assessment of the findings, an overall assessment of the patient's breast tissue density, additional information regarding breast density based on the assessment, and any recommendations made to the healthcare provider (if needed). (*21 CFR 900.12(c)(2))*. This summary can be handed to the patient at the time of the exam, mailed, or be provided by electronic means (e.g., patient portal, e-mail), and must be sent to the patient within 30 calendar days after the exam. (*21 CFR 900.12(c)(2))*. However, if the assessment of the mammography report is "Suspicious" or "Highly Suggestive of Malignancy," the summary must be provided within 7 calendar days of the final interpretation of the exam. (*21 CFR 900.12(c)(2) & (c)(2)(i)*). The patient's doctor or healthcare provider must be sent the more technical report of the exam results (see *21 CFR 900.12(c)(1)* and 900.12(c)(3)) unless the patient does not name a healthcare provider to receive the report. In that case, the report must be sent to the patient. (21 CFR 900.12(c)(2)(i)).

2. Are facilities required to send reminder notices to patients to schedule their routine screening or diagnostic/follow-up imaging?

No. Facilities are required to provide each patient with a written summary of the mammography report written in lay terms for every mammography exam performed. (21 CFR 900.12(c)(2)). There is no MQSA requirement that reminder notices be provided to patients for routine screening or diagnostic/follow-up imaging.

3. What are the facility's updated responsibilities to patients who do not have a healthcare provider as of September 10, 2024?

A mammography facility must provide a patient with a summary of the results written in lay language regardless of whether the patient names a healthcare provider to receive the more technical mammography report. For patients who do not name a healthcare provider to receive the mammography report, the patient must be sent the more technical mammography report within 30 days of the exam. If the assessment of the mammography report is "Suspicious" or "Highly Suggestive of Malignancy," the facility must send the mammography report and lay summary to the patient within 7 calendar days of the final interpretation of the exam. Facilities must have a system for referring such patients to a healthcare provider when clinically indicated, including when the assessment is either "Probably Benign," "Suspicious," or "Highly Suggestive of Malignancy." (*21 CFR 900.12(c)(2)(i) and (c)(2)(ii)*).

4. Must a facility provide the patient with a written lay summary even if the results are incomplete and additional imaging is needed?

Yes. Even if the facility verbally transmits the results to the patient, and those results are incomplete and additional imaging is needed, the facility must provide, within 30 calendar days of the examination, a written lay summary of the mammography report, which should indicate that additional imaging is needed.

If the results of the follow-up examination are available within 30 calendar days of the initial examination, the facility might combine the results into one lay summary (rather than providing two lay summaries). If one combined lay summary is provided, it should indicate that it refers to both the initial and the follow-up examinations. If the results of the follow-up examination are not available within 30 calendar days of the initial examination, the facility must provide two lay summaries, one for the initial examination and one for the follow-up. Each must be provided within 30 calendar days of the examination it covers. (21 CFR 900.12(c)(2)).

5. Are there updated special considerations for reporting results to patients when the assessment of the mammography report is "Suspicious" or "Highly Suggestive of Malignancy"?

Yes. As of September 10, 2024, in these cases, the facility must provide the written lay summary to the patient within seven calendar days after the mammogram is interpreted. If the patient does not have a referring provider, the facility must also provide the patient with the more technical report to the patient within seven calendar days after the mammogram is interpreted. Even if the results are given to the patient verbally, where the assessment is "Suspicious" or "Highly Suggestive of Malignancy," the facility must send the patient the written lay summary within seven calendar days of the interpretation. (*21 CFR 900.12(c)(2)*).

6. What is the difference between self-referred and self-requesting patients, and

how will this affect what types of reports these patients receive?

For purposes of this document, self-referred patients are those who come for mammography, but have no healthcare provider, or who decline a healthcare provider, or for whom the provider declines responsibility. Facilities must provide such patients with the written mammography report, in addition to a summary of the report written in lay terms. This would enable self-referred patients to give their new provider their latest mammogram results when they acquire a healthcare provider. Effective September 10, 2024, facilities must have a system for referring such patients to a healthcare provider when clinically indicated, including when the assessment is either "Probably Benign," "Suspicious," or "Highly Suggestive of Malignancy." (*21 CFR 900.12(c)(2)(i)*).

For purposes of this document, self-requesting patients are those who come for mammography on their own initiative but can name a healthcare provider (or accept a healthcare provider offered by the facility) who accepts responsibility for that patient's clinical breast care. Such patients must be provided the same communication of results as referred patients. (*21 CFR 900.12(c)(2)(i) & (ii)*).

7. What are a facility's responsibilities to patients who request their "original" mammographic images as of the effective date of the 2023 MQSA Rule?

Effective September 10, 2024, facilities are required to maintain the original mammograms and mammography reports in a permanent medical record of the patient for the longest of the following: a period of not less than 5 years, a period of not less than 10 years if no additional mammograms of the patient are performed at the facility, or a period, if any, mandated by State or local law. The originals must be able to be retrieved in the same form of mammographic modality in which they were initially produced. (*21 CFR 900.12(c)(4)(i)*).

Original mammograms were especially important when the mammogram was performed using screen-film technology. Today, however, almost all mammograms are performed using digital technologies (Full-Field Digital Mammography (FFDM) and Digital Breast Tomosynthesis (DBT)), not screen-film. For these digital technologies, identical copies can be provided, while the original images are kept by the performing facility, so digital originals are usually not transferred.

If patients request original screen-film mammograms, they can ask -- or have someone else ask -- the facility for their original mammograms and a copy of the medical report. Upon such request, the facility must transfer the mammograms and mammogram reports within 15 calendar days of receiving the request. They can ask the facility to send the original mammograms either temporarily or permanently to another medical facility, to their doctor, or to the patient. The facility may ask the patient to fill out a form to release the medical records. If the facility charges a fee for this service, the fee must not be more than it costs them (i.e., the documented costs) to provide this service. (See *21 CFR 900.12(c)(4)(ii), (iii), & (iv)*).

For example, patients who had a screen-film mammogram may request their original

mammogram if they:

- change mammography facilities,
- make an appointment for a second mammographic opinion,
- make an appointment for a stereotactic breast biopsy,
- make an appointment with a surgeon, oncologist, or radiation therapist, or
- need earlier mammograms to compare with current ones.

8. What are appropriate charges for the transfer of mammography records, and can the facility charge the cost of making copies of the images to the patient?

Appropriate charges for the transfer of mammography records could include: 1) administrative costs incurred in logging in the request, 2) retrieving the appropriate images and reports, 3) having the patient sign a release (if not already done), 4) packaging and mailing charges for the materials, 5) and photocopying costs incurred in making copies of the report(s).

When transferring original screen-film mammograms, facilities may, but are not required to, make copies of the mammography films. If these copies are requested by the patient or are mandated by State or local law, then the cost of making the copies can be charged to the patient. If the facility elects to keep copies for other reasons, the cost should not be charged to the patient.

Facilities must not charge patients a fee exceeding the documented costs associated with this service. (*21 CFR 900.12(c)(4)(iv)*).

9. What is a facility's responsibility to address patient complaints?

Under the MQSA regulations, all facilities are required to establish a written and documented system for collecting and resolving consumer complaints. (21 CFR 900.12(h)(1)). The regulations also require the facility to give consumers with serious unresolved complaints directions for filing such complaints with the facility's AB. (21 CFR 900.12(h)(3)). Examples of serious complaints that fall under MQSA regulations include the following: the use of unqualified personnel, and failure to send mammography reports or patient lay summaries within 30 days. (See 21 CFR 900.2(c)(2) & (3)). Facilities must report unresolved serious complaints to the AB in a manner and timeframe specified by the AB. (21 CFR 900.12(h)(4)).

F. BREAST DENSITY REPORTING REQUIREMENTS

1. What are the requirements for mammography reports and lay summaries?

In addition to the information required to be included in mammography reports to referring healthcare providers and lay summaries to patients under the MQSA regulations prior to September 10, 2024, the 2023 MQSA Rule (effective September 10, 2024) requires facilities to include the facility name and location (at a minimum,

the city, State, ZIP code, and telephone number) on mammography reports (*21 CFR 900.12(c)(1)(ii)*); and the facility name, address, and telephone number on patient lay summaries. (*21 CFR 900.12(c)(2)*).

There is a new Federal breast density notification requirement as of September 10, 2024, independent of any applicable State or local requirements. The FDA requires that the specific breast density assessments and notification statements below be included in every report to the referring healthcare provider and every lay summary to the patient, respectively. (*21 CFR 900.12(c)(1)(vi), (2)(iii), and (2)(iv)*).

Mammography Report to Referring Healthcare Providers or Patients Without a Named Healthcare Provider

The mammography report must include an overall assessment of breast density, classified in one of the following categories:

- "The breasts are almost entirely fatty."
- "There are scattered areas of fibroglandular density."
- "The breasts are heterogeneously dense, which may obscure small masses."
- "The breasts are extremely dense, which lowers the sensitivity of mammography."

(*21 CFR 900.12(c)(1)(vi)*).

Lay Summary to Patients

If the mammography report identifies the patient's breast density as "The breasts are almost entirely fatty" or "There are scattered areas of fibroglandular density," the lay summary must include the statement, "Breast tissue can be either dense or not dense. Dense tissue makes it harder to find breast cancer on a mammogram and also raises the risk of developing breast cancer. Your breast tissue is not dense. Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation." (*21 CFR 900.12(c)(2)(iii)*).

If the mammography report identifies the breast density as "The breasts are heterogeneously dense, which may obscure small masses" or "The breasts are extremely dense, which lowers the sensitivity of mammography," the lay summary must include the statement, "Breast tissue can be either dense or not dense. Dense tissue makes it harder to find breast cancer on a mammogram and also raises the risk of developing breast cancer. Your breast tissue is dense. In some people with dense tissue, other imaging tests in addition to a mammogram may help find cancers. Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation." (*21 CFR 900.12(c)(2)(iv)*).

The required breast density notification language in the 2023 MQSA Rule (effective September 10, 2024) is intended to provide a uniform density notification for all patients nationwide to receive a baseline, consistent set of key density information. The 2023 MQSA Rule does not prohibit facilities from providing patients with additional information, including information that may be required by any applicable State breast density reporting requirements. However, any additional information given to patients should be separate and distinct from the required

Federal breast density notification statements.

2. Do the mammography reports need to include the ACR BI-RADS breast density letter category along with the overall breast density assessment?

No. The breast density letter categories used by ACR are not required to be included in the mammography report. (See *21 CFR 900.12(c)(1)*). The MQSA regulations do not prohibit facilities from adding a letter category for breast tissue density, although the letter category alone will not satisfy the FDA reporting or notification requirements. One of the specific Federal breast density assessments must be included in the mammography report to the referring healthcare provider.

3. Can additional information be added to the patient lay summary, such as the patient's specific breast density category? For example, can we edit the Federal language from "*Your breast tissue is dense" to "Your breast tissue is extremely dense"?*

One of the Federal breast density notification statements must be included in the lay summary as described in 21 CFR 900.12(c)(iii) and (iv). The MQSA regulations do not prohibit facilities and practitioners from providing additional information to patients. However, any additional information given to patients should generally be separate and distinct from the required Federal breast density notification statement to help to ensure that patients receive consistent baseline breast density information in easily understandable language.

4. Must the breast density assessment appear on the mammography report, and the breast density notification statement appear on the lay summary, for both screening and diagnostic mammograms?

Yes, as of the effective date of September 10, 2024. The current (and amended) MQSA regulations require that facilities send a medical report and patient lay summary for each mammographic examination performed under its certificate; there is no differentiation between screening and diagnostic mammograms. (See *21 CFR 900.2(aa) and 900.12(c)*).

5. Must the breast density assessment appear on mammography reports, and the breast density notification statement appear on lay summaries, for both male and female patients?

Yes. Prior to and following the updated MQSA regulations, a patient continues to be defined as "any individual who undergoes a mammography evaluation in a facility…", and therefore the breast density assessment and notification statement requirements apply to mammograms performed on patients of any sex. (21 CFR 900.2(ii); *21 CFR 900.2(ii); 21 CFR 900.12(c)(1)(vi) and (2)(iii)-(iv)*).

6. Must the breast density assessment appear on mammography reports, and the

breast density notification statement appear on lay summaries, for both unilateral and bilateral mammograms?

Yes. As of the effective date of September 10, 2024, the amended MQSA regulations require that facilities include a breast density assessment in the mammography report, and a breast density notification statement in the patient lay summary, for each mammographic examination performed under its certificate; there is no differentiation between unilateral and bilateral mammograms. (*21 CFR 900.12(c)(1)(vi) and (c)(2)(iii)-(iv)*).

7. Can the breast density assessment be edited for unilateral mammograms? For example, can we edit the Federal language from *"The breasts are almost entirely fatty"* to *"The breast is almost entirely fatty"*?

One of the breast density assessments in 21 CFR 900.12(c)(1)(vi) must be included in the mammography report. The required density notification language is aimed at providing patients nationwide consistent baseline breast density information in easily understandable language.

8. Can facilities send the breast density notification to patients as an attachment to the lay summary?

While there is no specific format requirement for patient lay summaries, they are required to include certain elements, including the name of the patient; the name, address, and telephone number of the facility performing the mammographic examination; and one of the two FDA required breast density notification statements. All these required elements must appear within the same lay summary. (*21 CFR 900.12(c)(2)*).

9. Can a facility use software to assign a density category?

FDA acknowledges that there are various methods for the assessment of breast density, which may include automated processes such as FDA-cleared density assessment software devices used as an aid to physician interpretation. However, the assessment of breast density is part of the interpretation of the mammogram, which must be performed by a physician who meets the qualifications set forth in 21 CFR 900.12(a)(1).

G. MAMMOGRAPHY REPORT REQUIREMENTS

1. What information must be included in the mammography report?

As of September 10, 2024, the mammography report must include the following information: the name of the patient and an additional patient identifier; date of examination; facility name, and location (at a minimum, the city, State, ZIP code, and telephone number of the facility where the mammogram was performed); the

name of the interpreting physician who interpreted the mammogram; overall final assessment of findings, an overall assessment of breast density; and recommendations to the healthcare provider about what additional actions, if any, should be taken (all clinical questions raised by the referring healthcare provider shall be addressed in the report to the extent possible, even if the assessment is negative or benign). (*21 CFR 900.12(c)(1)*).

2. What are the categories that must be included in mammography reports for final assessment of findings, once the amended regulations are effective?

As of September 10, 2024, an overall final assessment of findings must be classified in one of the following categories: "Negative," "Benign," "Probably Benign," "Suspicious," "Highly Suggestive of Malignancy," "Known-Biopsy-Proven Malignancy," or "Post-Procedure Mammogram for Marker Placement." (*21 CFR 900.12(c)(1)(iv)*).

In cases where no final assessment category can be assigned due to incomplete work-up, one of the following classification statements shall be assigned as an assessment and reasons why no final assessment can be made shall be stated by the interpreting physician: "Incomplete: Need additional imaging evaluation" (reserved for exams where additional imaging needs to be performed before an assessment category can be given); or "Incomplete: Need prior mammograms for comparison" (reserved for examinations where comparison with prior mammograms should be performed before an assessment category can be given). (*21 CFR 900.12(c)(1)(v)*). If this latter assessment category is used, a follow up report with a final overall assessment category must be issued within 30 calendar days of the initial report whether or not comparison views can be obtained. (*21 CFR 900.12(c)(1)(v)(B)*).

3. Are facilities required to include the explanatory language on mammography reports?

For each assessment category, the required assessment statement is only the word or phrase in quotation marks *(21 CFR 900.12(c)(1)(iv)*). As in the regulations prior to September 10, 2024, each assessment statement, identified in quotation marks, is followed by explanatory language, which is not in quotation marks; this explanatory language not in quotation marks is intended to provide an explanation of the assessment category in order to promote its consistent use, but it is not part of the assessment statement, and is not required to be included in the mammography report to the referring healthcare provider.

4. What changes were made in the explanatory language for the "Negative" and "Benign" assessment categories under the amended regulations?

Prior to September 10, 2024, the explanatory language for the negative assessment stated, "Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained);"

and for the benign assessment it stated, "Also a negative assessment." (21 CFR 900.12(c)(1)(iv)(A) & (B)).

As of September 10, 2024, the explanatory language for the negative assessment states, "Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be documented and addressed)." As of September 10, 2024, the explanatory language for the benign assessment category states, "Also a normal result, with benign findings present, but no evidence of malignancy (If the interpreting physician is aware of clinical findings or symptoms, despite the benign assessment, these shall be documented and addressed)." (*21 CFR 900.12(c)(1)(iv)(A) and (B)*).

5. What are FDA's policies if a facility uses certain variations to the final assessment category wording?

FDA has generally exercised enforcement discretion regarding the final assessment category wording where the variation in wording does not change the meaning of the assessment category, and FDA intends to continue such a practice. For example, FDA has considered the following statements to be close variants to the wording listed in the regulations and has generally not objected to their use:

Negative
Negative Mammogram

Benign
Benign Finding, Benign Findings, Benign Abnormality, Benign Abnormalities, Benign Mammogram

Probably Benign
Probably Benign Finding, Probably Benign Findings, Probably Benign Abnormality, Probably Benign Abnormalities, Probably Benign - Short Interval Followup Suggested, Probably Benign Finding - Short Interval Follow-up Suggested, Probably Benign Mammogram

Suspicious
Suspicious Finding, Suspicious Findings, Suspicious Abnormality, Suspicious Abnormalities, Suspicious for Malignancy, Suspicious of Malignancy, Suspicious Abnormality - Biopsy Should Be Considered, Suspicious Finding - Biopsy Should Be Considered, Suspicious Mammogram

Highly Suggestive of Malignancy
Highly Suggestive for Malignancy, Highly Suggestive of Malignancy - Appropriate Action Should Be Taken

Incomplete: Need Additional Imaging Evaluation
Incomplete: Needs Additional Imaging Evaluation, Incomplete: Additional Imaging Evaluation Needed, Need Additional Imaging Evaluation (the term "Incomplete"

can be inferred in this example), Incomplete Mammogram: Need Additional Imaging Evaluation

Incomplete: Need prior mammograms for comparison
Incomplete: Needs Prior Mammograms for Comparison, Incomplete: Comparison with Prior Mammograms Needed, Need Prior Mammograms for Comparison (the term "Incomplete" can be inferred in this example), Incomplete Mammogram: Need Prior Mammogram for Comparison

Known Biopsy Proven Malignancy
Known Biopsy Proven Cancer, Known Malignancy, Known Cancer

6. As of September 10, 2024, are there any special considerations for sending mammography reports when examinations are assessed as "Incomplete: Need prior mammograms for comparison"?

When the assessment category "Incomplete: Need prior mammograms for comparison" is used, a follow-up report with an assessment category identified in *21 CFR 900.12(c)(1)(iv)(A) through (E)* must be issued within 30 calendar days of the initial report, whether or not comparison views can be obtained. (*21 CFR 900.12(c)(1)(v)(B)*).

7. Is there a new specific report format required?

There is no explicit requirement for the formatting of the mammography report. There are multiple elements that must be included in the contents of the report (see 21 CFR 900.12(c)). As of September 10, 2024, these required elements include two overall assessments – the overall assessment of the findings and the overall assessment of breast density. Since these two elements refer to the examination overall, and since they should also be readily verifiable by an MQSA inspector, these assessments should each be placed in a way that is distinct and identifiable.

8. What is the difference between the updated assessments "Incomplete: Need additional imaging evaluation" and "Incomplete: Need prior mammograms for comparison"?

Additional imaging may be necessary to evaluate an area of abnormality on the mammogram, or an area of the breast that was not adequately or optimally visualized, or an area where the patient has physical signs or symptoms concerning breast cancer. In such circumstances, an assessment of "Incomplete: Need additional imaging evaluation" may be appropriate. (21 CFR 900.12(c)(1)(v)). As of September 10, 2024, the amended regulations include the same assessment "Incomplete: Need additional imaging evaluation." (*21 CFR 900.12(c)(1)(v)(A)*). If an area of possible abnormality is visualized on the mammogram, but it is important to determine whether this area is stable or has changed, then it may be necessary to request prior mammograms for comparison, using the added assessment "Incomplete: Need prior mammograms for comparison." (*21 CFR*

900.12(c)(1)(v)(B)).

9. May our facility continue to use the combined assessment, "Incomplete: Need additional imaging evaluation and/or prior mammograms for comparison" after September 10, 2024?

The assessment statement "Incomplete: Need additional imaging evaluation and/or prior mammograms for comparison" does not appear in either the existing or the amended MQSA regulations, but was approved on August 29, 2003, as part of MQSA Alternative Standard #11, "Modifications in the Assessment Categories Used in Medical Reports." However, as provided in the Federal Register, FDA is withdrawing Alternative Standard #11 upon the effective date of the final rule, after which the assessment statement found in that standard may no longer be used.

Under the amended regulations, there are two Incomplete assessment statements, "Incomplete: Need additional imaging evaluation" and "Incomplete: Need prior mammograms for comparison." These statements reflect FDA's recognition that some mammograms require comparison for interpretation, while some mammograms require additional imaging to reach a final interpretation. Additionally, the two Incomplete assessment categories have different reporting requirements. When the assessment category "Incomplete: Need prior mammograms for comparison" is used, a follow-up report to the mammographic examination with an assessment category identified in 21 CFR 900.12(c)(1)(iv)(A) through (E) ["Negative," "Benign," "Probably Benign," "Suspicious," or "Highly Suggestive of Malignancy,"] must be issued within 30 calendar days of the initial report whether or not comparison views can be obtained. Whereas the assessment category "Incomplete: Need additional imaging evaluation" does not require a follow-up report to the mammographic examination be issued within a specified time frame. Therefore, facilities must use the two separate Incomplete assessment categories, as applicable, after the September 10, 2024, effective date of the 2023 MQSA Rule. (*21 CFR 900.12(c)(1)(v)*).

10. What are the new deadlines for sending mammography reports to referring healthcare providers?

Prior to and after September 10, 2024, the effective date of the 2023 MQSA Rule, facilities must provide a written mammography report of the mammography examination to the patient's referring healthcare provider as soon as possible, but no later than 30 days from the date of the mammography examination. (21 CFR 900.12(c)(3)(i)).

As of September 10, 2024, if the assessment is "Suspicious" or "Highly Suggestive of Malignancy," the facility must provide a written mammography report of the mammographic examination to the referring healthcare provider, or if the referring healthcare provider is unavailable, to a responsible designee of the referring healthcare provider, within 7 calendar days of the final interpretation of the

mammograms. (*21 CFR 900.12(c)(3)(ii)*).

11. Is it necessary to include an assessment number or letter code, in addition to the overall final assessment category, on mammography reports?

No. There is no requirement that any assessment number or letter code be included on the mammography report, nor is it prohibited.

12. What facility name/location must appear on the mammography report to the healthcare provider and lay summary to the patient for large healthcare networks with multiple certified MQSA facilities? What about mobile units that travel to different locations?

The facility identification information in the mammography report to the healthcare provider and the lay summary sent to the patient must be unique to the actual facility where the mammogram was performed and must include the name under which the facility is accredited and certified. The FDA distinguishes each mammography facility based on its physical location. Healthcare networks that offer mammography services at several locations are required to apply for accreditation and certification of each of those locations as a separate facility. The name recognized by FDA for a facility is the name under which the facility is accredited by its AB. Similarly, for mammograms performed on a mobile unit that travels to different locations, the facility identification information in the mammography report to the referring healthcare provider and the lay summary sent to the patient must include the name under which the facility is accredited and certified. (See 21 CFR 900.2(q), 900.11(b), *900.12(c)(1)(ii) and (c)(2)*).

The mammography report to the healthcare provider must include the facility name and location. At a minimum, the location shall include the city, State, ZIP code, and telephone number of the facility (see *21 CFR 900.12(c)(1)(ii)*). The lay summary to the patient must include the name, address, and telephone number of the facility performing the mammographic examination (see *21 CFR 900.12(c)(2)*). Sometimes, a facility chooses to include additional information about a healthcare network or affiliated site on its medical reports and lay summaries.

13. If a facility performs a mammogram following a biopsy to confirm the deployment and position of a breast tissue marker, is the facility required to issue a mammography report to the referring healthcare provider, or lay summary to the patient?

Yes, where the post-procedure mammogram is a separately logged examination (rather than part of the interventional procedure), the mammogram is subject to all MQSA quality standard requirements, including a report to the referring healthcare provider and a summary of the report in lay language to the patient. (See *21 CFR 900.12(c)(1)(iv)(G)*). The lay summary must be specific to the examination and report. For example, if the assessment statement in the report states that an examination was a post-procedure mammogram for marker placement, then the lay

summary of that report should likewise mention the procedure or the marker placement; however, it would not be appropriate to state that the mammogram results were abnormal, worrisome, suspicious for cancer, etc., so as not to misconstrue the assessment as a new or additional abnormality. If a facility makes the post-procedure examination part of the interventional procedure instead of a separately logged examination, then the examination is not subject to the MQSA quality standard requirement and need not receive an assessment or any report separate from the report of the interventional procedure.

14. Can facilities use one of the following three subcategories (derived from ACR's Breast Imaging—Reporting and Data System (BI–RADS)) for a category 4 "Suspicious" assessment as the overall assessment in its mammography reports: 4A – Low Suspicion for Malignancy, 4B- Intermediate Suspicious for Malignancy, or 4C- Moderate Concern but not Classic for Malignancy?

While the facility has the option of using one of the three BI-RADS subcategories of category 4, "Suspicious", in addition to a final assessment category, as identified in *21 CFR 900.12(c)(1)(iv)*, the BI-RADS subcategories are not a replacement for a required final assessment category, such as "Suspicious," in the mammography report.

H. MEDICAL OUTCOMES AUDIT

1. Under the amended regulations, what items need to be included in the medical outcomes audit?

Facilities are required to establish a system to collect and review outcome data for all mammographic examinations performed, including followup on the disposition of all positive mammograms (those with an assessment of Suspicious or Highly Suggestive of Malignancy[9]), as well as any cases of breast cancer among patients imaged at the facility that subsequently become known to the facility. In this audit, facilities must correlate the pathology results with the mammography report, and as of September 10, 2024, at a minimum, three metrics must be included in the medical outcomes audit: the positive predictive value, cancer detection rate, and recall rate. (*21 CFR 900.12(f)(1)*).

2. Will facilities be required to include both screening and diagnostic mammograms in the medical outcomes audit under the amended regulations?

Yes. For the purposes of the audit requirements, a mammographic examination consisting of routine views of an asymptomatic patient is termed a screening mammogram, while a mammographic examination consisting of individualized

[9] See 21 CFR 900.2(mm) (*Positive mammogram* means a mammogram that has an overall assessment of findings that are either "suspicious" or "highly suggestive of malignancy").

views of a patient with breast symptoms, physical signs of breast disease, or abnormal findings on a screening mammogram is termed a diagnostic mammogram. The medical outcomes audit requires facilities to collect and review outcome data for all mammographic examinations performed. (*21 CFR 900.12(f)(1)*).

3. Will facilities be required to include mammograms with the assessment category, "Incomplete: Need additional imaging evaluation" in the medical outcomes audit under the amended regulations?

Yes. As of September 10, 2024, the calculation of two of the three metrics required to be included in the medical outcomes audit – cancer detection rate and recall rate – incorporates mammograms that received an assessment of "Incomplete: Need additional imaging evaluation." (*21 CFR 900.12(f)(1)(ii-iii)*).

4. Will facilities that do not have any positive mammography examinations (e.g., screening-only facilities) be required to perform a medical outcomes audit under the amended regulations?

Yes. As of September 10, 2024, the outcomes audit must include, at a minimum, the calculation of the following three metrics: positive predictive value, cancer detection rate, and recall rate. (*21 CFR 900.12(f)(1)*). One of these metrics, the recall rate, is calculated as the percentage of screening mammograms given an assessment of "Incomplete: Need additional imaging evaluation," and can be calculated even in the absence of any positive mammograms. (*21 CFR 900.12(f)(1)(iii)*). Since the cancer detection rate depends in part on the subsequent diagnoses of cancer in patients whose mammograms were initially classified as "Incomplete: Need additional imaging evaluation" (see *21 CFR 900.12(f)(1)(ii)*), a facility that classifies some mammograms as "Incomplete: Need additional imaging evaluation" should have a system in place to obtain, or attempt to obtain, the subsequent pathology results for those patients who received that assessment and subsequently underwent biopsy. Facilities that have not had any positive examinations and have been unable to obtain any pathology results should calculate the recall rate and provide written documentation describing how the facility's medical audit system would: (1) follow-up on positive cases (and any cases of breast cancer among patients imaged at the facility that subsequently became known to the facility), (2) correlate pathology results with the interpreting physician's findings, and (3) perform the appropriate analyses annually.

5. Under the new requirements found in the amended regulations, how should the minimum required metrics be calculated?

For positive predictive value (PPV), the minimum requirement is to calculate this metric as the percent of patients with positive mammograms (those with an

assessment of either "Suspicious" or "Highly Suggestive of Malignancy"[10]) who are diagnosed with breast cancer within 1 year of the date of the mammographic examination. (*21 CFR 900.12(f)(1)(i)*). In addition to performing the calculation in this required manner, some facilities also choose to use other methods for calculating PPV.

For cancer detection rate (CDR), the minimum required calculation is a single calculation for CDR for screening mammograms, which must be calculated as follows: out of the patients initially examined with screening mammograms who receive an assessment of "Incomplete: Need additional imaging evaluation," "Suspicious," or "Highly suggestive of malignancy" on the screening mammogram or on a subsequent diagnostic mammogram, the number of patients who are diagnosed with breast cancer within 1 year of the date of the initial screening mammogram, expressed arithmetically as a ratio per 1,000 patients. (*21 CFR 900.12(f)(1)(ii)*). It can be noted that the PPV calculation requirement is essentially equivalent to a CDR calculation for diagnostic mammograms.

For recall rate, this must be calculated as the percentage of screening mammograms given an assessment of "Incomplete: Need additional imaging evaluation." (*21 CFR 900.12(f)(1)(iii)*).

6. Will the minimum required metrics for the medical outcomes audit need to be calculated for each interpreting physician or collectively for all interpreting physicians at a facility under the amended regulations?

The medical outcomes audit must include calculations of the minimum required metrics for each individual interpreting physician and also collectively for all interpreting physicians at a facility. *(21 CFR 900.12(f)(1)*).

7. Will the specific results of the medical outcomes audit be recorded during the annual MQSA inspection after the effective date of September 10, 2024?

During the annual MQSA inspection, the inspector will generally assess whether the minimum required metrics have been performed for each interpreting physician and collectively for all interpreting physicians at the facility during the time period for which the inspector is evaluating the facility. It is not anticipated that the inspector will document the specific numerical values for the metrics. If the inspection occurs during the first 2 years of a facility's operation, the inspector will generally verify that the facility has established the required audit procedures and designated an audit interpreting physician (i.e., an "audit IP"). (21 CFR 900.12(f)).

8. Is a facility required to have a designated audit interpreting physician (IP)?

[10] See 21 CFR 900.2(mm).

Yes, a facility is required to have a designated audit interpreting physician ("audit IP"), who is responsible for notifying each IP at the facility of their respective individual audit results and of the facility's aggregate audit results. The audit IP is also responsible for documenting any follow-up actions taken. (21 CFR 900.12(f)(3)).

9. Should mammograms that receive an overall assessment of "Post-Procedure Mammogram for Marker Placement" or "Known Biopsy-Proven Malignancy" be included in the medical outcomes audit calculations required by the amended regulations?

No, those mammograms should not be included in the calculations for the minimum required metrics for the medical outcomes audit so as not to count the finding as a new or additional abnormality. Only a mammogram that receives an overall assessment of either "suspicious" or "highly suggestive of malignancy" is defined as a positive mammogram subject to followup and correlation of pathology results. As of September 10, 2024, the calculation of two of the three metrics required to be included in the medical outcomes audit – cancer detection rate and recall rate – also incorporates mammograms that received an assessment of "Incomplete: Need additional imaging evaluation." (*21 CFR 900.12(f)(1)(ii) and (iii)*; 900.2(mm)). However, the calculation of the required metrics does not involve mammograms that receive an assessment of "post-procedure mammogram for marker placement" or "known biopsy-proven malignancy."

10. How long should my facility keep the results of the medical outcomes audit required by the amended regulations?

As of September 10, 2024, at a minimum, a facility is required to retain its medical outcomes audit data until the MQSA annual inspection following the facility's analysis of that information, although the facility and the audit IP can choose a longer retention period if preferred. (*21 CFR 900.12(f)(4)*).

11. Does a medical outcomes audit that includes mammograms performed before September 10, 2024, have to include the three metrics of positive predictive value, cancer detection rate, and recall rate?

As of September 10, 2024, a facility must have designated an audit interpreting physician (or "audit IP"), and must have established the required audit procedures, including the procedures for calculating the three required metrics (i.e., PPV, CDR, and recall rate). For an audit that includes some mammograms performed before the effective date, the facility might choose to perform the calculations where the necessary outcomes data are available. Alternatively, the facility might report one or more of the three metrics (i.e., PPV, CDR, and recall rate) as "Not Applicable." For an audit that covers only mammograms performed on or after September 10, 2024, all three metrics (i.e., PPV, CDR, and recall rate) must be calculated, as applicable

(e.g., screening-only facilities or facilities with no positive exams might report some metrics as "Not Applicable"). (*21 CFR 900.12(f)*).

I. RECORDKEEPING/TRANSFER OF RECORDS

1. As of September 10, 2024, how long must a facility maintain the original mammograms and mammography reports?

Facilities must maintain the original mammograms and mammography reports in a permanent medical record of the patient for the longest of the following: a period of not less than 5 years, a period of not less than 10 years if no additional mammograms of the patient are performed at the facility, or a period, if any, mandated by State or local law. Effective September 10, 2024, facilities shall implement policies and procedures to minimize the possibility of loss of these records. FFDM and DBT mammographic images must be retained in their original mammographic modality. (*21 CFR 900.12(c)(4)(i)*).

2. What are the facility's updated responsibilities for providing patient records?

Upon request by, or on behalf of, the patient, the facility must provide copies of mammograms and copies of mammography reports to a medical institution, a physician or healthcare provider of the patient, or to the patient directly within 15 calendar days of the facility receiving such request. For digital mammograms or DBT, if the copies are being released for final interpretation purposes, the facility must be able to provide the recipient with digital images electronically. (*21 CFR 900.12(c)(4)(iii)*).

3. Can facilities store or transfer digital mammographic images using lossy compression as of the effective date of the regulations?

No. Images that *have* undergone lossy compression, which does not maintain all the data related to the mammogram image files, would not be considered as being in their "original mammographic modality." (*21 CFR 900.12(c)(4)*).

4. Can digital images be stored with computer-aided detection (CAD) markings as of the effective date of the regulations?

A facility can choose to retain a set of the images with permanent CAD marks, but this set of images alone would not meet the retention requirement. The facility must retain images that are capable of being displayed without the CAD marks as any CAD markings placed by computer software after the mammographic images are obtained typically overlie and obscure portions of the image. (See *21 900.12(c)(4)(i)*).

5. What is a facility's responsibility as of September 10, 2024, when another facility requests copies of mammograms on behalf of the patient for comparison?

Facilities must provide a copy of the mammograms and mammography reports within 15 calendar days of receiving the request. (*21 CFR 900.12(c)(4)(iii)*).

6. What methods can facilities use to transfer or release digital mammographic images to another facility?

The technical methods of either transfer or release of digital images are not prescribed by the 2023 MQSA Rule, and could include, but are not limited to, the following: direct electronic transmission of digital mammogram files that is arranged between two facilities utilizing Health Insurance Portability and Accountability Act of 1996 (HIPAA)-compliant and appropriate practices for privacy and data security; providing the requesting facility with HIPAA-compliant remote electronic access to the images in the picture archiving and communication system (PACS) of the originating facility; the viewing of digital mammogram images located on a physical storage medium such as a CD; or the uploading of such images from a digital storage medium to a receiving facility's PACS.

7. What are a facility's responsibilities as of September 10, 2024, for patient records and images when it closes or ceases to provide mammography services?

Effective September 10, 2024, before a facility closes or ceases to provide mammography services, it must make arrangements for access by patients and healthcare providers to their mammographic records. This access may be provided by the permanent transfer of mammographic records to the patient or the patient's healthcare provider or the transfer of the mammographic records to a facility or other entity that will provide access to patients and healthcare providers. Access to the records must be provided by such other facility or entity for the remainder of the required recordkeeping time periods. If a facility ceases to perform mammography but continues to operate as a medical entity and is able to satisfy the recordkeeping requirements, it may choose to continue to retain the medical records rather than transfer them to another facility, unless such a transfer is requested by, or on behalf of, the patient. The facility must notify its AB and certification agency in writing of the arrangements it has made and must make reasonable efforts to notify all affected patients. (*21 CFR 900.12(c)(4)(v)*).

J. GENERAL PERSONNEL RECORD REQUIREMENTS

1. What specific records must be maintained for personnel?

Facilities must maintain records of training and experience relevant to their qualification under MQSA for personnel who work or have worked at the facility as

interpreting physicians, radiologic technologists, or medical physicists. (21 CFR 900.12(a)(4)).

2. How long must a facility maintain personnel records for interpreting physicians, radiologic technologists, and medical physicists that are no longer employed by the facility?

A facility must maintain records of personnel no longer employed by the facility. As of September 10, 2024, the facility must also make these records available for inspection for no less than 24 months from the date an employee departs the facility. If current interpreting physicians, radiologic technologists, and medical physicists request such records, the facility must provide copies. Facilities must also provide personnel records to former employees if the former employees request their records within 24 months of the date of their departure. If it has been more than 24 months since the employee departed the facility, and the facility has maintained those records, the facility must provide those records to former employees upon request. Before a facility closes or ceases to provide mammography services, it must make arrangements to give current and former personnel access to their MQSA personnel records. *(21 CFR 900.12(a)(4)*).

3. What is a facility's responsibility to interpreting physicians, radiologic technologists, and medical physicists who request their personnel records?

Facilities must provide copies of personnel records to current interpreting physicians, radiologic technologists, and medical physicists upon their request. Facilities must provide personnel records to former employees if the former employees communicate their request within 24 months of the date of their departure or if it has been more than 24 months and the facility has maintained those records. Additionally, before a facility closes or ceases to provide mammography services, it must make arrangements for access by current and former personnel to their MQSA personnel records. This access may be provided by the permanent transfer of these records to the personnel or to a facility or other entity that will provide access to these records for no less than 24 months from the date of facility closure or cessation of mammography services. (*21 CFR 900.12(a)(4*)).

4. Are there consequences if a facility refuses to provide copies of personnel records upon request of a current or former employee?

FDA (or the SAC for that facility) may take action as appropriate, including but not limited to, suspension or revocation of the facility's mammography certificate when a facility fails to comply with requests of current or former facility personnel for records of their training or experience relevant to their qualification under the MQSA. (*21 CFR 900.14(a)(7)*).

K. INTERPRETING PHYSICIAN REQUIREMENTS

1. What are the qualifications an interpreting physician must meet under the MQSA regulations in order to independently interpret mammograms?

Prior to independently interpreting mammograms, an interpreting physician must complete all of the following requirements:

- Have a valid State license to practice medicine (21 CFR 900.12(a)(1)(i)(A));
- Be Board Certified in an appropriate specialty area by a body[11] determined by FDA to have adequate procedures and requirements for interpreting radiological procedures, or have 3 months of documented formal training in the interpretation of mammograms, which must be under the direct supervision of a physician who already meets the MQSA requirements to be an interpreting physician, and in topics related to mammography to include instruction in radiation physics specific to mammography, radiation effects, and radiation protection (21 CFR 900.12(a)(1)(i)(B));
- Complete a minimum of 60 hours of documented medical education in mammography, which shall include instruction in the interpretation of mammograms and education in basic breast anatomy, pathology, physiology, technical aspects of mammography, and quality assurance and quality control in mammography. All 60 of these hours shall be category I with at least 15 obtained in the 3 years immediately prior to qualifying as an interpreting physician. Hours that are specifically devoted to mammography spent in a residency program accredited by a body[12] determined by FDA to have adequate procedures and requirements to accredit graduate medical education programs are generally considered as equivalent to category I continuing medical education credits and will generally be accepted where documented in writing by the appropriate representative of the training institution (21 CFR 900.12(a)(1)(i)(C)); and
- Have interpreted or multi-read 240 mammographic examinations under direct supervision of an interpreting physician in the 6 months immediately prior to qualifying as an interpreting physician OR if the physician becomes appropriately board certified in diagnostic radiology at the first allowable time (as defined by an eligible certifying body), the 6-month period could have been anytime in the last two years of the diagnostic radiology residency program (21 CFR 900.12(a)(1)(i)(D), 21 CFR 900.12(a)(1)(iii)(B)).

Before an interpreting physician may begin independently interpreting mammograms produced by a new mammographic modality, interpreting physicians must also have 8 hours of training in the mammographic modality in which the physician has not previously been trained. (21 CFR 900.12(a)(1)(ii)(C)). Mammographic modality means a technology, within the scope of 42 U.S.C. 263b, for radiography of the breast. Examples are screen-film mammography, FFDM, and

[11] The FDA has determined that the following organizations are bodies with adequate procedures and requirements to ensure that the interpreting physicians they certify with specialties in radiology and diagnostic radiology are competent to interpret radiological procedure, including mammography: American Board of Radiology (ABR), American Osteopathic Board of Radiology (AOBR), Royal College of Physicians and Surgeons of Canada (RCPSC).

[12] The FDA has determined that the following organizations are bodies with adequate procedures and requirements to accredit graduate medical education programs: Accreditation Council for Graduate Medical Education (ACGME) American Osteopathic Association (AOA), and Canadian Residency Accreditation Consortium (CanRAC).

DBT.[13] Interpreting physicians who completed their initial training on a certain modality are not required to complete or document an additional 8 hours of training on that modality.

After meeting all the initial requirements, interpreting physicians must:

- Maintain continuing education (15 category I continuing medical education (CME) hours/36 months[14]) (21 CFR 900.12(a)(1)(ii)(B)); and
- Maintain continuing experience (interpreted or multi-read at least 960 examinations/24months) (21 CFR 900.12(a)(1)(ii)(A)).

2. Where can I find a template of a residency letter?

A template of a residency letter can be found at the following link: https://www.fda.gov/radiation-emitting-products/inspection-resources/preparing-inspection.

3. Can category 1 CME hours/credits in breast ultrasound or breast MRI be used to meet the continuing education requirement for interpreting physicians?

Yes. All Category 1 CME hours/credits related to the diagnosis or treatment of breast disease, or to other areas that aid facility personnel in improving the quality of mammography, should qualify for credit toward the continuing education requirement (see 21 CFR 900.2(l), (m), and (n); 900.12(a)(1)(ii)(B)).

4. Can the American Board of Radiology (ABR) examination be used to meet the continuing education requirement for interpreting physicians?

No. The ABR does not award Category I continuing medical education units for passing the ABR initial certification or recertification exam. To find out about receiving continuing medical education, the physician can contact an organization that grants Category 1 CME units to inquire whether the organization will grant Category 1 CME units specific to mammography. Mammography personnel might get a letter, certificate, or other documentation from the authorized organization stating how many and what type of CME units were awarded and the date the credit

[13] See *21 CFR 900.2(z)*.

[14] In light of recommendations from the National Mammography Quality Assurance Advisory Committee and the Institute of Medicine stating that the general requirement of obtaining 15 hours of continuing education in mammography every three years provides adequate assurance that personnel receive appropriate updated information about all mammographic modalities in a timely fashion, FDA has generally exercised enforcement discretion regarding the CME credits required for each specific modality used by the interpreting physician in his or her practice, and intends to continue such a practice (see 21 CFR 900.12(a)(1)(ii)(B) ("This training shall include at least six category I continuing medical education credits in each mammographic modality used by the interpreting physician in his or her practice")). For example, FDA generally still intends to not object to an interpreting physician who does not document six category I CME credits in screen-film mammography as part of the 15 general mammography CME credits where the facility uses only that one type of mammographic modality.

was given.

5. What are the consequences of an interpreting physician failing to meet the continuing experience requirement?

If during an inspection, the inspector determines that an interpreting physician has failed to meet the continuing experience requirement (e.g., interpreting at least 960 mammography exams in the previous 24 months), including that the physician has not started reestablishing the qualification process before the inspection, the inspector could make that observation in the inspection report (see 42 U.S.C. 263b(g)(1)(A) & (C); 21 CFR 900.12(a)(1)(iv)).

The interpreting physician may not interpret mammograms independently until the interpreting physician re-qualifies to do so. The interpreting physician can re-qualify by interpreting under direct supervision, within a 6-month period, either 240 mammograms or the balance needed to bring the total to 960, whichever is less (see 21 CFR 900.12(a)(1)(iv)(A)).

When a facility is inspected within the 6-month period following the date the interpreting physician last re-qualified, FDA generally does not intend to object if the re-qualified interpreting physician has not interpreted 960 mammogram exams in the previous 24 months. This may help facilitate the interpreting physician having sufficient time to complete the required continuing experience by the end of this 6-month timeframe. (See 21 CFR 900.12(a)(1)(iv)(A)).

Note that FDA or an SAC can take action against a facility where the training and qualification requirements under 21 CFR 900.12(a) have not been met, including seeking civil money penalties, or suspension or revocation of the facility's MQSA certificate. (42 U.S.C. 263b(h)(3); 21 CFR 900.14(a)(2)).

6. What is required for an interpreting physician who completed the initial qualification requirements in the past, has not worked in the field of mammography for an extended period, but would now like to independently interpret mammography exams?

The interpreting physician must:

- Document that the physician has met the initial training and experience requirements to be an interpreting physician (21 CFR 900.12(a)(1)(i)(B), (C), and (D)),
- Document that the physician holds a valid State license to practice medicine (21 CFR 900.12(a)(1)(i)(A)), and
- Complete 15 continuing medical education units in mammography in the previous 36 months (21 CFR 900.12(a)(1)(ii)(B) and (a)(1)(iv)(B)).

If the interpreting physician has not interpreted at least 960 mammographic exams in the previous 24 months (see 21 CFR 900.12(a)(1)(ii)(A)), the interpreting physician

must re-qualify, under direct supervision, by:

- interpreting or multi-reading at least 240 mammographic exams (21 CFR 900.12(a)(1)(iv)(A)(*1*)), or
- A sufficient number of mammographic exams to bring the total up to 960 for the prior 24 months, whichever is less (21 CFR 900.12(a)(1)(iv)(A)(*2*)).

Additionally, if the interpreting physician will be using a mammographic modality other than one for which the physician was initially trained, the interpreting physician must complete at least 8 hours of training in the new modality. (21 CFR 900.12(a)(1)(ii)(C)).

7. What does direct supervision of an interpreting physician mean?

Direct supervision of an interpreting physician means that during joint interpretation of mammograms, the supervising interpreting physician reviews, discusses, and confirms the diagnosis of the physician being supervised and signs the resulting report before it is entered into the patient's records. (21 CFR 900.2(o)(1)). This means that, if the supervising interpreting physician is not present when the physician being supervised makes his or her initial interpretation, the supervising physician must be present to review and, if necessary, correct the final interpretation before it is given to the patient or the patient's healthcare provider.

When the physician being supervised reads previously interpreted mammographic examinations, these interpretations should still be reviewed, discussed, and confirmed or corrected by a supervising interpreting physician. This should be done even if the supervised physician's interpretation agrees with the previous interpretation and/or the interpretation of the supervising interpreting physician. Where mammographic examinations are being read retrospectively under direct supervision, FDA generally has not enforced and does not intend to enforce the requirement that the multi-reading be done before the patient receives their results.

8. Can an interpreting physician count multi-reads toward meeting the initial, continuing, or requalification requirements?

Yes. Multi-reading means two or more physicians, at least one of whom is an interpreting physician, interpreting the same mammogram. (21 CFR 900.2(hh)). This applies when reading and interpreting current examinations or previously interpreted examinations. FDA generally considers re-interpretation of a previously interpreted mammographic examination to count towards meeting the applicable MQSA requirements, where the interpreting physician did not do the initial interpretation. In other words, multi-reading of mammograms by interpreting physicians could be used to meet the initial qualifications (21 CFR 900.12(a)(1)(i)(D)), continuing experience and education (21 CFR 900.12(a)(ii)(A)), or reestablishing qualifications (21 CFR 900.12(a)(iv)(A)) requirements.

Multi-readings should be documented by the same method(s) as are used for original

interpretations, including letters and logs/charts maintained by the facility or interpreting physician (which should be confirmed by the facility). The documentation should be either computerized or handwritten.

L. RADIOLOGIC TECHNOLOGIST REQUIREMENTS

1. What are the initial training requirements for radiologic technologists under the MQSA regulations?

Prior to independently performing mammographic examinations, a radiologic technologist must complete all the following requirements:

- Be State licensed to perform general radiographic procedures, or have certification as a radiographer from one of the bodies[15] determined by FDA to have adequate procedures and requirements to perform radiologic examinations (21 CFR 900.12(a)(2)(i));
- Have, prior to April 28, 1999, qualified as a radiologic technologist under the interim regulations of December 21, 1993; or completed 40 contact hours of documented training specific to mammography under the supervision of a qualified instructor. The 40 hours of documented training shall include, but not necessarily be limited to:
    - Training in breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, and imaging of patients with breast implants;
    - The performance of a minimum of 25 mammography examinations under the direct supervision of a radiologic technologist qualified under 21 CFR 900.12(a)(2) (*generally, time spent performing the 25 exams under direct supervision should be no more than 12.5 hours[16] of the 40 contact hours of training requirement*); and
    - At least 8 hours of training in each mammographic modality to be used by the technologist. (21 CFR 900.12(a)(2)(ii)).

After meeting all the initial requirements, radiologic technologists must:

- Maintain continuing education (15 continuing education units (CEU)/36 months) (21 CFR 900.12(a)(2)(iii)(A)).[17]

[15] The FDA has determined that the American Registry of Radiologic Technologists (ARRT) and the American Registry of Clinical Radiography Technologists (ARCRT) are bodies with adequate procedures and requirements to ensure that the radiologic technologists they certify are competent to perform radiologic examinations.

[16]This is the amount of time credited by ARRT for 25 exams, a standard which is based on ARRT's experience in issuing certifications.

[17] In light of recommendations from the National Mammography Quality Assurance Advisory Committee and the Institute of Medicine stating that the general requirement of obtaining 15 hours of continuing education in mammography every three years provides adequate assurance that personnel receive appropriate updated information about all mammographic modalities in a timely fashion, FDA has generally exercised enforcement discretion regarding the CE units required for each specified modality used by the radiologic technologist in his or her practice, and intends to continue such a practice (see 21 CFR 900.12(a)(2)(iii)(C) ("at least 6 of the continuing education units required . . . shall be related to each mammographic modality used by the technologist")). For example, FDA generally still intends to not object to a radiologic technologist who does not document six continuing education units in screen-film mammography as part of the 15 CEUs in mammography where the radiologic technologist uses only that one type of mammographic modality.

- Maintain continuing experience (200 examinations/24months) (21 CFR 900.12(a)(2)(iv)(A)).

2. Can the American Registry of Radiologic Technologists (ARRT) advanced certificate in mammography (ARRT)(M) be used to meet the initial training in mammography requirement?

Yes, but it depends on when the ARRT(M) certificate was issued. Documentation of passing the ARRT(M) prior to 04/28/1999 or after 01/01/2001 may be used to meet the initial training requirement. If the ARRT(M) was awarded between 04/29/1999 and 12/31/2000, documentation of passing it counts as 24 hours of the 40-hour initial training requirement (includes necessary subject areas), but the technologist would also need to show documentation of completing 25 mammography exams under the direct supervision of a qualified radiologic technologist, as required by 21 CFR 900.12(a)(2)(ii)(B).

3. Can a technologist count the performance of 25 mammography examinations under direct supervision toward the 8-hour new modality training requirement?

No. The performance of a mammography examination under direct supervision does not qualify as continuing education units for new modality training. New mammographic modality training requires 8 hours of continuing education units, as described in 21 CFR 900.12(a)(2)(iii)(E), and can be in many forms, including, but not limited to, professional training, special training courses, continuing medical education, and training provided by the manufacturer.

4. What is required for a radiologic technologist who completed the initial qualification requirements in the past, has not worked in the field of mammography for an extended period, but would like to independently perform mammography?

As an initial matter, the radiologic technologist seeking requalification after not working in the field for an extended period must have originally met the qualification requirements outlined in 21 CFR 900.12(a)(2)(i) and (ii). The radiologic technologist must also still hold a current State license to perform general radiographic procedures or a general certification from a body determined by FDA to have adequate procedures and requirements for performing radiologic examinations.[18] (21 CFR 900.12(a)(2)(i)). The radiologic technologist must also complete the requalification requirements for both continuing education and continuing experience, which are found in 21 CFR 900.12(a)(2)(iii)(D) and (iv)(B), respectively, before the radiologic technologist can resume performing unsupervised

[18] The FDA has determined that the American Registry of Radiologic Technologists (ARRT) and the American Registry of Clinical Radiography Technologists (ARCRT) are bodies with adequate procedures and requirements to ensure that the radiologic technologists they certify are competent to perform radiologic examinations.

mammography examinations.

To meet the requalification requirements for continuing education, the radiologic technologist must obtain a sufficient number of continuing education units to bring their total up to at least 15 in the previous 36 months. (21 CFR 900.12(a)(2)(iii)(D)).[19] For requalification of continuing experience, if the radiologic technologist has not performed at least 200 mammograms in the previous 24 months, the technologist must re-qualify by performing 25 mammograms under the direct supervision of a qualified radiologic technologist. (21 CFR 900.12(a)(2)(iv)(B)). Additionally, if the radiologic technologist will be using a mammographic modality other than one for which the technologist was initially trained, the radiologic technologist must complete at least 8 hours of continuing education units in the new modality. (21 CFR 900.12(a)(2)(iii)(E)).

5. Can passing either the ARRT(M) or ARRT Breast Sonography (BS) exam be used to meet the MQSA continuing education requirement?

Yes. Passing the ARRT(M) and/or the ARRT(BS) examination would count as meeting the entire continuing education requirement for 36 months from the date of obtaining the ARRT(M) or ARRT(BS) certification. FDA generally accepts CEUs related to the diagnosis or treatment of breast disease, and both the ARRT(M) and ARRT(BS) examinations require the technologist to complete greater than 15 hours of structured education in mammography or breast sonography. Inspectors therefore can accept the passing of the ARRT(M) and ARRT(BS) as meeting the CEU requirement for 36 months from the date of obtaining the certification.

6. What are the consequences of a radiologic technologist failing to meet the continuing experience requirement at the time of the annual MQSA inspection?

An observation could be cited in the inspection report to the facility when an inspection reveals that a radiologic technologist has failed to meet the continuing experience requirement (i.e., performing 200 mammograms in the previous 24 months) including when the radiologic technologist has not started the requalification process before the inspection. (See 42 U.S.C. 263b(g)(1)(A) & (C); 21 CFR 900.12(a)(2)(iv)). The technologist must not perform mammograms independently until the technologist re-qualifies by performing 25 mammograms under direct supervision of a MQSA-qualified radiologic technologist. (21 CFR 900.12(a)(2)(iv)(B)).

[19] In light of recommendations from the National Mammography Quality Assurance Advisory Committee and the Institute of Medicine stating that the general requirement of obtaining 15 hours of continuing education in mammography every three years provides adequate assurance that personnel receive appropriate updated information about all mammographic modalities in a timely fashion, FDA has generally exercised enforcement discretion regarding the CE units required for each specified modality used by the radiologic technologist in his or her practice, and intends to continue such a practice (see 21 CFR 900.12(a)(2)(iii)(C) ("at least 6 of the continuing education units required . . . shall be related to each mammographic modality used by the technologist")). For example, FDA generally still intends to not object to a radiologic technologist who does not document six continuing education units in screen-film mammography as part of the 15 CEUs in mammography where the radiologic technologist uses only that one type of mammographic modality.

Consistent with existing practice, when a facility is inspected within the 6-month period following the documented requalification date, FDA generally does not intend to object to the radiologic technologist not complying with the continuing experience requirements under 21 CFR 900.12(a)(2)(iv)(A) or (B). This may help facilitate the radiologic technologist having sufficient time to complete the required continuing experience by the end of this 6-month timeframe or to restart the requalification process by performing 25 mammographic examinations under direct supervision.

Facilities must maintain written documentation of all radiologic technologist qualifications. (See 21 CFR 900.12(d)(2)). This should include documentation of each requalification cycle, including the dates the radiologic technologist performed mammography under direct supervision to meet the requalification requirement and the qualification documentation for the radiologic technologist who provided direct supervision. The requalification documentation should be made available during inspection. (See 42 U.S.C. 263b(g)(1)(A) & (C)).

Note that FDA or an SAC can take action against a facility where the training and qualification requirements under 21 CFR 900.12(a) have not been met, including seeking civil money penalties, or suspension or revocation of the facility's MQSA certificate. (42 U.S.C. 263b(h)(3); 21 CFR 900.14(a)(2)).

M. MEDICAL PHYSICIST REQUIREMENTS

1. What are the initial training requirements for medical physicists under the MQSA regulations?

Prior to independently conducting surveys of mammography facilities and providing oversight of a facility's equipment-related quality assurance program, a medical physicist must complete all of the following requirements:

- Be State licensed or approved, or have certification with a specialty in diagnostic radiological physics, radiological physics, or diagnostic imaging physics by a body[20] determined by FDA to have adequate procedures and requirements to perform physics survey; (21 CFR 900.12(a)(3)(i)(A));
- Have a master's degree or higher in a physical science[21] from an accredited institution, with no less than 20 semester hours or equivalent (e.g., 30 quarter hours) in college undergraduate or graduate level physics; (21 CFR 900.12(a)(3)(i)(B)(*1*));
- Have 20 contact hours of documented specialized training in conducting mammography facility surveys; (21 CFR 900.12(a)(3)(i)(B)(*2*)); and

[20] The FDA has determined that the American Board of Radiology (ABR) or the American Board of Medical Physics (ABMP) are bodies with adequate procedures and requirements to ensure that the medical physicists they certify are competent to perform physics surveys.

[21] See 21 CFR 900.2(ll) (*Physical science* means physics, chemistry, radiation science (including medical physics and health physics), and engineering).

- Have experience of conducting surveys of at least 1 mammography facility and a total of at least 10 mammography units. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement. After April 28, 1999, experience conducting surveys must be acquired under the direct supervision of a medical physicist who meets all the requirements of 21 CFR 900.12(a)(3)(i) and (iii). (21 CFR 900.12(a)(3)(i)(B)(*3*)).

Medical physicists must document 8 hours of training in each mammographic modality in which the medical physicist has not previously been trained prior to independently performing surveys units of that mammographic modality. Examples of mammographic modalities include FFDM and DBT. Medical physicists who completed their initial training on a certain modality are not required to complete or document an additional 8 hours of training on that modality. (21 CFR 900.12(a)(3)(iii)(C)).

After meeting all the initial requirements, interpreting physicians must:

- Maintain continuing education (15 continuing education units[22] (CEUs)/36 months) (21 CFR 900.12(a)(3)(iii)(A)); and
- Maintain continuing experience (2 mammography facilities and 6 mammography units/24months) (21 CFR 900.12(a)(3)(iii)(B)).

2. What does it mean to be under "direct supervision" of a Medical Physicist?

"Direct Supervision" means that during the performance of a mammography examination or survey of the facility's equipment and quality assurance program, the supervisor is present to observe and correct, as needed, the performance of the individual being supervised. (21 CFR 900.2(o)(2)). For the physics survey and/or mammography equipment evaluation, direct supervision means that the supervising medical physicist must have qualified under the Master's or higher pathway and meet all continuing qualifications (21 CFR 900.12(a)(3)(i)(B)(*1*) and (*3*)) and be present to observe and correct, as needed, the performance of the supervisee. FDA has generally considered the supervisor's physical presence in the room with the supervisee during the performance of the individual equipment tests to satisfy this requirement. The supervisor should review any calculations made from, and any conclusions drawn from the test results, before those results are provided to the facility.

Furthermore, when conducting a physics survey, the supervisor and supervisee

[22] In light of recommendations from the National Mammography Quality Assurance Advisory Committee and the Institute of Medicine stating that the general requirement of obtaining 15 hours of continuing education in mammography every three years provides adequate assurance that personnel receive appropriate updated information about all mammographic modalities in a timely fashion, FDA has generally exercised enforcement discretion regarding the CEU credits required for each specific modality used by the medical physicist in his or her practice, and intends to continue such a practice (see 21 CFR 900.12(a)(3)(iii)(A) ("This continuing education shall include hours of training appropriate to each mammographic modality evaluated by the medical physicist during his or her surveys or oversight of quality assurance programs"). For example, FDA generally still intends to not object to a medical physicist who does not document CEU credits in screen-film mammography as part of the 15 general mammography CEU credits where the facility uses only that one type of mammographic modality.

should generally jointly review the QC program records to ensure the supervisor can correct any potential mistakes made by the supervisee. (See 21 CFR 900.12(a)(3)(i)). Consistent with past practice, FDA generally does not intend to enforce the requirement that the supervisor be present when the supervisee initially reviews the QC program records where the supervisor reviews, discusses, confirms, and if necessary, corrects the findings made by the supervisee prior to either the initial or final survey report being issued. (See 21 CFR 900.12(e)(9)).

The goal of direct supervision is to provide reasonable assurance that any mistakes made by the supervisee are corrected before the QC program review or tests are completed.

3. Can a letter issued by the FDA or a State confirming the initial qualification requirements were met under the MQSA be used to document that a medical physicist has met all the initial qualification requirements?

In 2016, the FDA stopped issuing letters to medical physicists confirming initial qualification requirements were met under the MQSA; however, these letters can still be used to document the medical physicist's initial qualification requirements under 21 CFR 900.12(a)(3)(i). The medical physicist must maintain a valid State license, State approval, or certification as well as meet the continuing education and experience qualifications stated in 21 CFR 900.12(a)(3)(iii)(A) and (B). FDA has reviewed information in State issued letters that indicate a physicist met State licensure/approval, as required under 900.12(a)(3)(i)(A), to determine whether part of the initial qualification requirements are met; specifically, that the medical physicist be State licensed or approved.

4. Does a degree in a physical science obtained at a non-US institution qualify for meeting the degree requirement?

A degree from a non-US institution can be used to meet the degree requirement where the physicist can provide information showing that his or her foreign degree is accepted by an accredited institution. (21 CFR 900.12(a)(3)(i)(B)). FDA has recognized accredited institutions as including accredited US institutions, the Committee on Accreditation of Medical Physicists Education Programs (CAMPEP), World Education Testing, or by the ABR or ABMP.

5. Can the performance of facility and unit surveys under direct supervision of a qualified instructor count toward the 20 contact hours of specialized training in conducting mammography surveys?

Yes. However, it is recommended that no more than four hours for each facility survey and two hours for each unit survey should be counted toward the required total hours of training. (21 CFR 900.12(a)(3)(i)(B)(*2*)).

6. If a medical physicist performed their initial experience under direct

supervision on full field digital mammography (FFDM) units is any additional documentation needed for modality training?

Medical physicists who completed their initial training (10 mammography unit surveys under direct supervision, see 21 CFR 900.12(a)(3)(i)(B)(*3*)) on FFDM units are initially trained in FFDM. They therefore would not need to provide any additional statement or documentation that they have completed at least 8 hours of additional FFDM training where the initial training documentation identifies FFDM as the modality used during the training, or the coversheets for each survey performed during the training is included in the initial training documentation such that it demonstrates the training was completed on FFDM units.

However, the medical physicist would be required to complete 8 hours of new modality training in digital breast tomosynthesis (DBT) prior to independently performing DBT unit surveys. (21 CFR 900.12(a)(3)(iii)(C)). This must be accomplished by performing at least 8 FFDM/DBT unit surveys (each of which provides1 hour of FFDM training and 1 hour of DBT training) under direct supervision of an MQSA-qualified medical physicist or by completing at least 8 hours of training or continuing education courses in conducting DBT unit surveys.

7. What are recommended methods for documenting medical physicist initial and/or continuing experience?

Although the survey reports themselves (original, copy or coversheet from the report) can be used as documentation, in general, a summary document, such as a letter or memorandum from the facility where the survey was performed or from the physics company providing the service, should be sufficient. The letter should be on official facility or company letterhead and should indicate the number of facility and/or unit surveys performed, the dates on which they were performed, and be signed by either a responsible official of the facility or physics company providing the service, or by the person providing the direct supervision.

This assumes that the summary documentation is based upon the survey reports and that these could be examined if needed.

8. What are recommended continuing education topics for medical physicists?

All continuing education units related to the diagnosis or treatment of breast disease or to other areas that aid facility personnel in improving the quality of mammography should qualify for credit toward meeting the continuing education requirement, which can be found at 21 CFR 900.12(a)(3)(iii). (See also 21 CFR 900.2(l), (m), and (n)).

Additionally, some general diagnostic medical physics courses not directly related to mammography could qualify for meeting the continuing education requirement where those credits are anticipated to help the individual in their role as a medical physicist for a mammography facility.

N. MAMMOGRAPHY EQUIPMENT REQUIREMENTS

1. What does the regulation found at *21 CFR Part 900.12(b)(2)(i)* mean by "all devices used in mammography must have met the applicable FDA premarket authorization requirements for medical devices of that type with that intended use"?

The FDA classifies a device based on its intended use (IU), including indications for use (IFU), technological characteristics, and the level of risk that the device poses to the patient and/or the user. Before a medical device, such as a mammography unit or a display monitor for primary image interpretation, can be marketed in the United States, it must meet any applicable FDA premarket authorization requirements. If a display device for primary image interpretation or mammography unit is cleared, granted, or approved by the FDA for use in mammography, this will be stated in the IFU of the cleared/granted/approved device.

2. How does a facility know if its display device for primary image interpretation is approved, granted, or cleared for mammography use?

For a 510(k)-cleared device, if it is unclear whether a facility's display device for primary image interpretation is intended for mammography, it is recommended that the facility request a copy of the 510(k) Summary with the Indications for Use (IFU) statement from the manufacturer of the display device to verify/ensure it is intended for use in displaying mammographic images for primary image interpretation. Facilities can also look up its display device's 510(k) status at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm. For granted or approved devices, the marketing status can be searched at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm and https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm, respectively.

O. QUALITY CONTROL

1. If a facility recently had a software upgrade and now the facility's full field digital mammography (FFDM) unit can be used in the digital breast tomosynthesis mode (DBT), can the facility immediately begin imaging patients in the DBT mode?

No. Due to the differences in technology between FFDM and DBT, FDA currently considers each imaging modality to be a separate unit. (*21 CFR 900.12(b)(2)(ii)*). A single mammography system designed to provide imaging in two modalities must be accredited as two separate units. Each mammography equipment unit must be accredited by the facility's AB, which in turn requires completing a mammography equipment evaluation (MEE) within the six months prior to submitting a unit accreditation application. (21 CFR 900.4(e)(1)(i) and *900.12(b)(2)(ii)*). As part of

the facility's record-keeping requirement, a facility must have documentation showing that it has passed an MEE prior to use on patients. (21 CFR 900.12(d)(2)). Before using a new unit, a facility should also have documentation showing that it has received confirmation that the accreditation application for the new unit has been accepted and is under review by its AB. FDA generally considers a new unit to be undergoing accreditation when the facility has submitted the initial part of the application for accreditation submission to its AB and has received confirmation that the application submission is under review. (21 CFR 900.4(e)(1) and 21 CFR 900.12(e)(10)).

After the AB confirms that the new mammography unit meets all the requirements and, if applicable, all problems are corrected, it may be used on patients and to obtain the clinical images needed for review by the AB to complete its accreditation evaluation. (21 CFR 900.4(e) and 900.12(e)(10)).

2. Who is responsible for the quality control of remote review workstations?

Where procedures such as the interpretation of the mammogram are performed in a location different from where the mammogram is performed, the facility performing the mammogram is responsible for meeting the quality standards, including the establishment and maintenance of a quality assurance and quality control program. (42 U.S.C. 263b(a)(3)(B)).

3. What are the Mammography Equipment Evaluation (MEE), annual survey, and routine quality control requirements for remote review workstations?

For systems with image receptor modalities other than screen-film, the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer (21 CFR 900.12(e)(6)). Therefore, all review workstations, whether located on-site or at a remote location, are required to be evaluated by a quality assurance program that is substantially the same as the quality assurance program recommended by the image receptor manufacturer, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems which is defined in 21 CFR 900.12(e)(5)(vi). That provision indicates that the average glandular dose delivered during a single cranio-caudal view of an FDA-accepted phantom simulating a standard breast shall not exceed 3.0 milligray (mGy) (0.3 rad) per exposure.

Remote review workstations, just like on-site workstations, shall also undergo an annual survey performed by an MQSA-qualified medical physicist or by an individual under the direct supervision of an MQSA-qualified medical physicist. (21 CFR 900.12(e)(9)). Additionally, remote review workstations, just like on-site workstations, shall conduct an MEE when it is installed, when it is disassembled and reassembled at the same or a different location, and when there is a change or repair of a major component. (See 21 CFR 900.12(e)(10)). When the image receptor manufacturer does not identify specific quality control tests for the review workstations, you should refer to the manufacturer of the review workstation for

quality control testing. These evaluations are used to determine whether the new or repaired review workstation is performing properly before it is placed into service for the final interpretation of mammograms.

If the image receptor manufacturer and the review workstation manufacturer have not identified quality control tests, we recommend the facility, in conjunction with the medical physicist, seek information and guidance from a standards body or organization with experience in the evaluation of display devices used in the interpretation of mammograms.

4. Can facilities use the ACR Digital Mammography Quality Control Manual for Full-Field Digital Mammography Systems and Supplement for Digital Breast Tomosynthesis Mammography Systems instead of the mammography unit's quality control manual from the manufacturer?

Yes. The ACR Digital Mammography Quality Control Manual for Full-Field Digital Mammography Systems and Supplement for Digital Breast Tomosynthesis Mammography Systems was approved by the FDA as Alternative Standard #24[23] on July 13, 2018. It was approved as an alternative to the quality assurance program recommended by the image receptor manufacturer as defined in the original standard at 21 CFR 900.12(e)(6). Alternative Standard #24 has no time limit. Any facility may avail itself of the approved alternative standard. You may visit the ACR Mammography Accreditation website at https://www.acraccreditation.org/-/media/ACRAccreditation/Documents/Resources/DMQC/DMQCFAQs.pdf for the latest information and instructions for implementation of the ACR manual.

5. Are facilities required to print quality control (QC) logs from the mammography unit or review workstation software in addition to completing the QC forms provided by the manufacturer?

If it is possible for the inspector to review test data or documentation electronically at your facility, then it is generally not necessary to print QC logs. However, inspectors will generally request a copy of documentation that could support any noncompliance(s) found during the inspection process. Although QC forms provided by the manufacturer can be used to handwrite QC test results, inspectors might use any additional tools available such as internal review workstation (RWS) display reports or test data stored in the mammography unit (or PACS) to verify the accuracy and results of any QC test performed.

6. Should facilities record the actual numerical result of the QC test (e.g., compression, signal-to-noise ratio) or just whether it passes or fails?

[23] See "#24: Approval of an Alternative Standard for Using the Quality Assurance Program Recommended by the ACR Digital Mammography Quality Control Manual for Full-Field Digital Mammography Systems and Supplement for Digital Breast Tomosynthesis Mammography Systems", available at https://www.fda.gov/radiation-emitting-products/regulations-mqsa/24-approval-alternative-standard-using-quality-assurance-program-recommended-acr-digital-mammography

The lead interpreting physician, quality control technologist, and medical physicist shall ensure that records concerning mammography quality control (including monitoring data, problems detected by analysis of that data, corrective actions, and the effectiveness of the correction actions) are properly maintained and updated. Quality control records shall be kept for each test specified in 21 CFR 900.12(e) and (f) until the next annual inspection has been completed and FDA has determined that the facility is in compliance with the quality assurance requirements or until the test has been performed two additional times at the required frequency, whichever is longer. (21 CFR 900.12(d)(2)).

Accordingly, QC records should show the numerical results of those QC tests for which numbers are a natural by-product of the test. These numerical results will indicate whether the QC tests are within the required action or control limits. However, for tests such as artifact evaluation, where no meaningful quantitative test results are produced, FDA generally considers a pass/fail indication to be appropriate and sufficient.

7. When a facility uses a hardcopy print of digital images, are there any new requirements for the type of film the facility can use to create those hardcopy images?

Effective September 10, 2024, for facilities using hardcopy prints of digital images for transfer, retention, or final interpretation purposes, the facility shall use a type of film designated by the film manufacturer as appropriate for these purposes and compatible with the printer being used. (*21 CFR 900.12(b)(11)*).

8. Which quality standards will now be required for systems with image receptor modalities other than screen-film?

Systems with image receptor modalities other than screen-film shall demonstrate compliance with quality standards by successful results of quality assurance testing as specified under 21 CFR 900.12(e)(6). (*21 CFR 900.12(b)(16)*).

9. A facility recently had a part repaired/replaced on their mammography unit (and/or display device) and is not sure if it's a major component that would require an MEE. What does FDA recommend in this situation?

Facilities with digital mammography units must follow a quality assurance program that is substantially the same as the quality assurance program recommended by the image receptor manufacturer (mammography unit), except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems in 21 CFR 900.12(e)(5)(vi). (21 CFR 900.12(e)(6)). If it is unclear whether an MEE is indicated under the image receptor manufacturer's recommended quality assurance program for an adjustment, change, or repair of a digital mammography unit (or display device), the FDA recommends that the facility or its medical

physicist contact the mammography unit (or display device) manufacturer for clarification. If an MEE is not indicated, FDA recommends that the mammography unit (or display device) manufacturer provide the facility with a written statement of such for its records. These recommendations also apply to software upgrades to mammography units and/or display devices.

P. COMPLIANCE AND ENFORCEMENT

1. What is an Additional Mammography Review (AMR)?

Under an AMR, a facility shall provide clinical images and other relevant information, as specified by FDA or the SAC, for review by the AB or the SAC if FDA or the SAC believes that mammographic quality at a facility has been compromised and, before September 10, 2024, may present a serious risk to human health, and, on or after September 10, 2024, may present a significant risk to human health. The AMR review will help FDA or the SAC determine whether the facility is in compliance with the quality standards,[24] including the standards for clinical image quality established by the facility's AB (see 21 CFR 900.12(i)), and if not, whether there is a need to notify affected patients, their referring physicians or other healthcare providers, and/or the public, that there is a serious/significant risk to human health. (21 CFR 900.12(j) and *21 CFR 900.12(j)*).

2. How are AMRs different from the reviews that are performed for accreditation, reaccreditation, or a random clinical image review?

AMRs are performed in cases where FDA or the SAC believes that mammographic quality at a facility has been compromised and, before September 10, 2024, may present a serious risk to human health, and, on or after September 10, 2024, may present a significant risk to human health. (21 CFR 900.12(j) and *21 CFR 900.12(j)*). An example of such a circumstance might be the observation of a Level 1 phantom image failure during an inspection. Accreditation bodies do not use the clinical image reviews (CIRs) performed during accreditation, re-accreditation, and random clinical image review to investigate possible problems at facilities. Accreditation bodies use these types of CIRs to evaluate the ongoing quality of mammography at all facilities.

3. Are there any options available to facilities that disagree with an accreditation body's adverse accreditation or reaccreditation decision?

When an AB denies accreditation or reaccreditation (i.e., revocation of accreditation) to a facility, the AB will notify the facility in writing and explain the bases for its decision. The notification will also describe the appeals process

[24] As described in 21 CFR 900.12, as amended on September 10, 2024.

available from the AB for the facility to contest the decision. (*21 CFR 900.4(a)(6)(i)*).

If a facility appeals an adverse decision through the appeals process provided by the AB and still cannot achieve a satisfactory resolution, the facility may request reconsideration, or further appeal, of the adverse decision from the Director of FDA's Division of Mammography Quality Standards. (See 21 CFR 900.7(b) and (c)). It is important to note that a facility cannot appeal the adverse accreditation decision to FDA without first availing themselves of the accreditation body's appeals process. (21 CFR 900.15(c)). Facilities should refer to FDA's guidance, "Appeal Options Available to Mammography Facilities Concerning Adverse Accreditation Decisions, Suspension/Revocation of Certificates, or Patient and Physician Orders" for more information.

4. What is a Patient and Provider Notification (PPN)?

FDA or the SAC may require a facility to perform a PPN. This means, among other things, that the facility must send notification letters to patients and providers to notify them that the quality of mammography did not meet the Federal standards and it posed a significant risk to human health. (See 42 U.S.C. 263b(h)(2)); *21 CFR 900.12(j)(2)*). Based on the results of an AMR, the facility's failure to comply with terms of an AMR, or other information, FDA or the SAC may determine that the quality of mammography performed by a facility, whether or not certified under § 900.11, was so inconsistent with the quality standards established in 21 CFR 900.12, as to present a significant risk to human health. FDA or the SAC may require such a facility to notify all patients who received mammograms at the facility or those patients who are determined to be at risk due to the quality of their mammography, and their referring physicians or other healthcare providers, of the deficiencies and resulting potential harm, appropriate remedial measures, and such other relevant information as FDA or the SAC may require. Such notification shall occur within a timeframe and in a manner specified by FDA or the SAC. (*21 CFR 900.12(j)(2)*).

5. Are there any options available to facilities to appeal the order to perform a PPN?

In accordance with 21 CFR 10.75, a facility receiving a PPN order can appeal the order to the next level supervisor of the official who signed the PPN order. Facilities should refer to FDA's guidance, "Appeal Options Available to Mammography Facilities Concerning Adverse Accreditation Decisions, Suspension/Revocation of Certificates, or Patient and Physician Orders" for more information.

6. What are the consequences if a facility is unable or unwilling to perform a PPN once the amended regulations take effect?

If a facility is unable or unwilling to perform a PPN, the FDA or the SAC may notify patients and their referring physicians or other healthcare providers

individually or through the mass media. (*21 CFR 900.12(j)(2)*).

The FDA generally intends to post a Public Safety Notice of the facility's noncompliance and image quality issues as indicated by the AB.[25] (See *21 CFR 900.12(j)(2)*). An AB is not likely to accept any future re-accreditation application until, at the least, pending compliance actions are resolved. (See 21 CFR 900.4(a)(1), 900.4(b), and *900.4(a)(6)(ii)*). In addition, civil money penalties may be assessed, including for each failure to notify a patient of risk. (42 U.S.C. 263b(h)(3)).

7. Under what circumstances can FDA suspend or revoke a facility's MQSA certificate?

FDA may suspend or revoke a certificate after providing the owner or operator of the facility with notice and opportunity for an informal hearing when the facility, owner, operator, or any employee of the facility:

- Has been guilty of misrepresentation in obtaining the certificate;
- Has failed to comply with the quality standards of 21 CFR 900.12;
- Has failed to comply with reasonable requests of FDA, SAC or the AB for records, information, reports, or materials, including clinical images for an AMR, that are necessary to determine continued eligibility of the facility for a certificate or continued compliance with the quality standards of 21 CFR 900.12;
- Has refused a reasonable request of a FDA or State inspector, or AB representative for permission to inspect the facility or the operations and pertinent records of the facility;
- Has violated or aided and abetted in the violation of any provision of the MQSA or its implementing regulations;
- On or after September 10, 2024, has failed to comply with prior sanctions imposed by FDA or the SAC under 42 U.S.C. 263b(h), including a directed plan of correction or a PPN; or
- On or after September 10, 2024, has failed to comply with requests of current or former facility personnel for records of their training or experience relevant to their qualification under MQSA. (42 U.S.C. 263b(i)(1); 21 CFR 900.14(a)(1)-(6) and *21 CFR 900.14(a)(1)-(7)*).

FDA may suspend the MQSA certificate of a facility before holding a hearing if FDA makes a finding described above and also determines that the failure to comply with required standards presents a serious risk to human health, the refusal to permit inspection makes immediate suspension necessary, or there is reason to believe that the violation or aiding and abetting of the violation was intentional or associated with fraud. (42 U.S.C. 263b(i)(2); 21 CFR 900.14(b)(1)-(3)). If the FDA suspends a certificate before holding a hearing, the FDA shall provide the facility with an

[25] Available at MQSA Reports and Safety Notifications.

opportunity for an informal hearing not later than 60 days from the effective date of the suspension. (21 CFR 900.14(c)).

Q. MISCELLANEOUS

1. How can a facility stay up to date with MQSA requirements and news?

Facilities can visit the following website and subscribe to the MQSA listserv to receive email updates when new information is posted: https://www.fda.gov/radiation-emitting-products/mammography-quality-standards-act-and-program.

2. Who can the facility contact for further information on the 2023 MQSA Rule?

Facilities can contact the MQSA Hotline at 1-800-838-7715, or by e-mail at MQSAhotline@versatechinc.com.

3. What is The National Mammography Quality Assurance Advisory Committee (NMQAAC)?

The NMQAAC, mandated by Congress, consists of between 13 and 19 members. (42 U.S.C. 263b(n)). These include physicians, practitioners, other health professionals, consumer, and industry representatives – all whose clinical practice, research specialization, or professional expertise include a significant focus on mammography.

The functions of this committee are to advise FDA on:

A. Developing appropriate quality standards and regulations for mammography facilities;
B. Developing appropriate standards and regulations for bodies accrediting mammography facilities under this program;
C. Developing regulations with respect to sanctions;
D. Developing procedures for monitoring compliance with quality standards under 42 U.S.C. 263b(f) (as promulgated under 21 CFR 900.12);
E. Establishing a mechanism to investigate consumer complaints;
F. Reporting new developments concerning breast imaging that should be considered in the oversight of mammography facilities;
G. Determining whether there exists a shortage of mammography facilities in rural and health professional shortage areas and determining the effects of personnel or other quality requirements under 42 U.S.C. 263b(f) on access to the services of such facilities in such areas;
H. Determining whether there will exist a sufficient number of medical physicists after October 1, 1999, to assure compliance with 42 U.S.C. 263b(f)(1)(E); and
I. Determining the costs and benefits of compliance with these requirements.

(42 U.S.C. 263b(n)).