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Preparing for an MQSA Inspection at Your Mammography Practice

A Comprehensive Manual for the Breast Imaging Community

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IMPORTANT NOTICE AND DISCLAIMER

This manual is intended solely as an educational resource and practical guide to assist mammography facilities in preparing for inspections conducted under the Mammography Quality Standards Act (MQSA). It has been developed to help facility personnel understand the inspection process, organize required documentation, and foster a culture of regulatory compliance and quality improvement.

This publication is not intended to replace, supersede, or serve as a substitute for the official regulations, guidance documents, policy statements, or inspection protocols issued by the U.S. Food and Drug Administration (FDA), the Department of Health and Human Services (HHS), or any FDA-approved accreditation body. The information contained herein represents a synthesis and interpretation of publicly available regulatory materials and peer-reviewed literature current as of the date of publication and is provided for informational and preparatory purposes only.

Mammography facilities and their personnel bear sole responsibility for ensuring compliance with all applicable federal and state laws, including the most current version of 21 CFR Part 900 and any subsequent amendments, interim final rules, or guidance documents. Regulations are subject to change, and facilities should regularly consult the official FDA MQSA website (www.fda.gov/radiation-emitting-products/mammography-quality-standards-act-and-program) and the U.S. Federal Register for the most up-to-date requirements.

Intended Use of This Manual:

This manual is designed to serve as a companion resource for quality assurance personnel, lead interpreting physicians, facility managers, and mammography technologists who wish to gain a comprehensive understanding of the MQSA inspection framework. It may be used to conduct internal readiness assessments, train new staff members on compliance expectations, organize recordkeeping systems, and identify areas requiring attention prior to a scheduled inspection. The manual should be used in conjunction with—not in lieu of—official FDA publications, accreditation body requirements, and direct consultation with MQSA inspectors or regulatory specialists when questions arise.

Neither the authors nor the publisher assume any liability for actions taken or not taken based on the contents of this manual. When in doubt regarding any regulatory requirement, readers are strongly encouraged to contact the FDA Division of Mammography Quality Standards or their designated accreditation body directly for authoritative clarification.

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PREFACE

Historical foundation of the Mammography Quality Standards Act

The Mammography Quality Standards Act (MQSA) represents one of the most significant federal interventions in medical imaging quality ever enacted in the United States. Before Congress passed MQSA on **October 27, 1992** (Public Law 102-539, codified at 42 U.S.C. 263b), federalregister mammography quality in America was alarmingly inconsistent. GovInfo The Nationwide Evaluation of X-Ray Trends (NEXT) study in the mid-1980s revealed that image quality at up to one-third of mammography facilities was "less than desirable." PubMed Central By 1991, only half of all mammography facilities had even applied for voluntary accreditation—and only half of those earned it. American Medical Association

A pivotal moment came in June 1990 when NBC Nightly News aired a three-part investigation exposing widespread mammography quality problems across the nation. The Senate Committee on Labor and Human Resources subsequently documented four critical failures: **poor quality equipment** producing difficult-to-interpret images, **lack of quality assurance procedures**, **poorly trained technologists and interpreting physicians**, and **absence of facility inspections or consistent governmental oversight**. govinfo These findings demanded federal action because breast cancer was—and remains—the most common non-skin cancer in women and the second leading cause of cancer death after lung cancer.

MQSA established mandatory national quality standards for all mammography facilities federalregister and created the federal inspection program that continues today. RSNA +3 The original interim rules published on **December 21, 1993** (58 FR 67558 and 58 FR 67565) took effect on October 1, 1994, when certification became mandatory for all facilities. Wikipedia The comprehensive final regulations followed on **October 28, 1997** (62 FR 55852), establishing the detailed framework that governs mammography practice. GovInfo

Evidence of MQSA's impact on breast cancer detection quality

The inspection program has demonstrably improved mammography quality nationwide. During the first round of MQSA inspections in 1995-1996, **26% of facilities had significant violations**. By the second inspection round in 1997, that figure dropped to just **10%**. Wikipedia The most serious findings (Level 1 violations) declined from 2% to less than 1% of facilities. The proportion of facilities with no violations increased from approximately 30% in 1995 to 55% by 1997. National Academies Press

The American College of Radiology (ACR) Mammography Accreditation Program documented equally striking improvements: between 1987-1991, only 70% of mammography units passed accreditation on their first attempt; by 2003, **88.3% achieved first-attempt passage**. The Government Accountability Office concluded in

1998 that MQSA "had a positive effect on the quality of mammography" without inadvertently limiting access to mammography services. National Academies Press A 2005 Institute of Medicine report confirmed that MQSA "led to nationwide improvements in the technical quality of mammography." National Academies

Rationale for the inspection program

Annual inspections serve as the cornerstone of MQSA's quality assurance framework. Required by 42 U.S.C. 263b(g)(1)(E), these inspections FDA provide independent verification of facility compliance with quality standards, identify problems before patient harm occurs, ensure consistency of mammography quality nationwide, and maintain accountability in the accreditation-certification system. FDA Approximately 250 FDA-trained and certified federal and state inspectors conduct these annual reviews across all mammography facilities in the United States.

The 2023 MQSA Final Rule (88 FR 15126), which became fully effective on **September 10, 2024**, represents the most comprehensive update to MQSA regulations since 1997. Federal Register +2 This modernization addressed technological advances including digital mammography and tomosynthesis, enhanced enforcement mechanisms, and established the nation's first mandatory breast density notification requirements. Federal Register +3 The FDA estimates that these amendments will provide annualized benefits ranging from **$8.5 million to $266 million** through reduced mortality and breast cancer treatment costs. federalregister

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PART I: REGULATORY FRAMEWORK AND ORGANIZATIONAL STRUCTURE

Chapter 1: Understanding MQSA regulatory authority

The MQSA regulatory framework operates through a hierarchical structure beginning with the statutory authority in the Mammography Quality Standards Act itself, implemented through detailed regulations in **21 CFR Part 900**. eCFR The Code of Federal Regulations organizes MQSA requirements into three subparts: Subpart A (§900.1-§900.9) governs accreditation bodies, Subpart B (§900.10-§900.18) establishes quality standards and certification requirements, and Subpart C (§900.20-§900.25) addresses states as certifiers.

Key regulatory sections for inspection preparation

The primary quality standards reside in **21 CFR 900.12**, which encompasses personnel requirements (§900.12(a)), equipment standards (§900.12(b)), medical records and reports (§900.12(c)), quality assurance requirements (§900.12(d)), quality control testing (§900.12(e)), and medical outcomes audit (§900.12(f)). Federal Register Facilities should maintain current copies of these regulations and monitor the Federal Register for amendments.

The 2024 regulatory update (effective September 10, 2024) modified numerous sections including §900.12(a)(4) regarding personnel records retention, §900.12(c)(1) concerning mammography report contents and breast density classification, §900.12(c)(2) specifying patient communication requirements with standardized breast

density notification language, and §900.12(f) enhancing medical outcomes audit requirements to include specific performance metrics. federalregister

Federal Register citations for key MQSA rulemakings

Date	Federal Register Citation	Description
December 21, 1993	58 FR 67558-67572	Original interim rules
October 28, 1997	62 FR 55852-55994	Comprehensive final regulations
February 6, 2002	67 FR 5446	State certification agency rule
March 28, 2019	84 FR 11669	Proposed modernization rule
March 10, 2023	88 FR 15126-15171	2023 Final Rule (effective 9/10/2024)
August 26, 2024	FR Doc. 2024-19058/19059	Alternative standards amendments

Chapter 2: Roles and responsibilities during MQSA inspections

Understanding each team member's role during an inspection ensures efficient compliance verification and demonstrates organizational commitment to quality mammography. The inspection process typically requires approximately 20 minutes per mammography unit for phantom imaging assessment plus an exit interview of 15-20 minutes. FDA

Lead Interpreting Physician responsibilities

Every mammography facility must designate one interpreting physician as the **Lead Interpreting Physician (LIP)** pursuant to 21 CFR 900.2(x) and 900.12(d)(1)(i). For facilities with only one interpreting physician, that individual automatically assumes the LIP role. The LIP bears **general responsibility** for ensuring the quality assurance program meets all regulatory requirements. Legal Information Institute

The LIP must determine qualifications for all QA task assignments and evaluate performance adequacy of individuals assigned QA responsibilities. No individual may be assigned or retain QA responsibility without LIP approval. Oregon Public Law The LIP ensures that an effective QA program exists and is properly documented, reviews technologist QC monitoring data, and provides frequent feedback to mammography technologists regarding image quality.

For medical outcomes audit purposes, the LIP must review and discuss audit results with all interpreting physicians at least annually or designate an audit interpreting physician to perform this function. During inspections, the LIP should be available to discuss the QA program structure and demonstrate oversight of QC records and corrective actions.

Interpreting physician responsibilities

All interpreting physicians must maintain compliance with continuing education and experience requirements and be prepared to provide documentation during inspections. Each physician should have readily accessible records of **960 mammographic examinations** performed during the preceding 24-month period and **15 Category I CME credits** in mammography during the preceding 36 months. eCFR

Physicians must participate in the facility's medical outcomes audit program and review their individual performance metrics alongside facility aggregate data. For inspections, physicians should ensure their state medical license, board certification documentation, modality training certificates, and CME records are current and organized.

Radiologic technologist responsibilities

Mammography technologists serve as the primary operators of quality control programs and must maintain meticulous documentation of all QC testing. The **Quality Control (QC) Technologist** holds specific responsibility for ensuring completion of all QC tasks not assigned to the LIP or medical physicist.

Technologists must document **200 mammographic examinations** performed during the preceding 24-month period and **15 continuing education units** in mammography during the preceding 36 months, including at least 6 units in each mammographic modality used. eCFR Medical Professionals During inspections, technologists should be prepared to demonstrate daily and weekly QC procedures and provide access to all QC documentation.

Medical physicist responsibilities

The medical physicist ensures equipment performance meets MQSA standards through annual surveys and equipment evaluations. PubMed Central Physicists must maintain documentation of **surveys of at least 2 facilities and 6 mammography units** during the preceding 24-month period, with no more than one survey of the same facility within 10 months. eCFR

Survey reports must be sent to facilities within **30 days** of survey completion. PubMed Central Physicists should ensure all reports include complete documentation of tests performed, results obtained, recommendations for improvements, and the physicist's signature.

Facility management responsibilities

Facility management ensures organizational infrastructure supports MQSA compliance. This includes maintaining current FDA certification and accreditation, ensuring adequate staffing levels for QC activities, providing resources for personnel continuing education, and organizing documentation systems for efficient inspection access.

Management must also maintain consumer complaint procedures per 21 CFR 900.12(h) and ensure the facility has systems for patient communication that meet regulatory timeframes. Before any facility closure,

management must arrange continued patient and provider access to mammographic records and notify accreditation bodies and certification agencies in writing. Mintz +2

PART II: PERSONNEL QUALIFICATIONS AND DOCUMENTATION

Chapter 3: Interpreting physician requirements

Initial qualifications (21 CFR 900.12(a)(1)(i))

To qualify as an interpreting physician under MQSA, individuals must hold a state medical license and satisfy certification requirements through one of two pathways. **Option 1** requires board certification in an appropriate specialty by an FDA-approved body: the American Board of Radiology (ABR), American Osteopathic Board of Radiology (AOBR), or Royal College of Physicians and Surgeons of Canada (RCPSC). **Option 2** requires at least 3 months of documented formal training in mammography interpretation under direct supervision of a qualified interpreting physician, covering radiation physics, radiation effects, radiation protection, and mammography-specific topics. eCFR

All interpreting physicians must complete **60 hours of Category I CME** in mammography regardless of certification pathway. This training must include interpretation of mammograms, basic breast anatomy, pathology, and physiology, technical aspects of mammography, and quality assurance principles. At least 15 of these 60 hours must be acquired within 3 years preceding the qualification date. Hours devoted specifically to mammography during residency count as Category I CME if documented in writing by the training institution. eCFR

Initial experience requires interpreting or multi-reading **240 mammographic examinations** within a 6-month period FDA immediately preceding qualification. UCLA Health This experience must occur under direct supervision of a qualified interpreting physician. Modality-specific training of **8 hours** is required for each mammographic modality (FFDM, DBT) before beginning to use that modality independently.

Continuing requirements (21 CFR 900.12(a)(1)(ii))

Maintaining qualifications requires ongoing compliance with education and experience standards. Interpreting physicians must complete **15 Category I CME units** in mammography during each 36-month period preceding the facility's annual inspection, with at least **6 credits in each mammographic modality used**. eCFR U.S. Food and Drug Administra… CME hours earned through teaching count only once per 36-month period. eCFR

The continuing experience requirement mandates **960 mammographic examinations** during the 24-month period preceding the MQSA inspection. Effsystems eCFR These may be primary interpretations or multi-reads. Re-interpretation of previously interpreted mammograms counts only if the physician did not perform the initial interpretation. Effsystems Facilities may calculate this period using either the inspection date or the last day of the preceding calendar quarter.

Reestablishing qualifications (21 CFR 900.12(a)(1)(iv))

If continuing experience lapses, physicians must interpret or multi-read **240 examinations under direct supervision** within 6 months, or complete sufficient exams to bring the total to 960 for the prior 24 months, whichever is less. (Effsystems) If continuing education lapses, physicians must obtain sufficient Category I CME to bring the total to 15 credits in the previous 36 months.

Documentation checklist for inspections

- Current state medical license
- Board certification documentation OR residency letter documenting 3-month training
- Initial CME certificates totaling 60 hours
- Continuing CME certificates (15 hours per 36 months)
- 8-hour modality training certificates for each modality used
- Examination logs demonstrating initial 240 exams
- Examination logs demonstrating continuing 960 exams per 24 months

Chapter 4: Radiologic technologist requirements

Initial qualifications (21 CFR 900.12(a)(2)(i)-(ii))

Technologists must possess a state license to perform general radiographic procedures or hold certification from the American Registry of Radiologic Technologists (ARRT) or American Registry of Clinical Radiography Technologists. Mammography-specific training requires **40 contact hours** of documented training covering breast anatomy and physiology, positioning and compression techniques, QA/QC procedures, and imaging patients with breast implants. (MTMI) (ASRT)

Initial clinical experience requires completion of **25 supervised mammographic examinations** under direct supervision of an MQSA-qualified individual. (ASRT) Before independently performing mammograms using any specific modality, technologists must complete **8 hours of modality training** for that technology. (MTMI +2)

Continuing requirements (21 CFR 900.12(a)(2)(iii)-(iv))

Technologists must maintain **15 continuing education units** in mammography during each 36-month period, with at least **6 units related to each mammographic modality used**. (eCFR) (eCFR) The continuing experience requirement mandates **200 mammographic examinations** during each 24-month period preceding the inspection. (MTMI) (Medical Professionals)

Reestablishing qualifications

If CE lapses, technologists must obtain sufficient units to reach 15 in the previous 36 months before performing unsupervised mammography. If experience lapses, technologists must perform **25 mammographic**

examinations under direct supervision of a qualified technologist, then have 6 months to bring the total to 200 examinations.

Documentation checklist for inspections

- ARRT certification OR state radiography license
- Initial 40-hour mammography training certificates
- Documentation of 25 supervised initial examinations
- 8-hour modality training certificates
- Continuing education certificates (15 units per 36 months)
- Examination logs demonstrating 200 exams per 24 months

Chapter 5: Medical physicist requirements

Initial qualifications (21 CFR 900.12(a)(3)(i))

For physicists qualifying after April 28, 1999, requirements include a **master's degree or higher** in a physical science from an accredited institution with at least 20 semester hours (or 30 quarter hours) of college-level physics coursework. Training must include **20 contact hours** of documented specialized instruction in conducting surveys of mammography facilities. Iowa Department of Health and…

Initial survey experience requires conducting surveys of at least **1 mammography facility and 10 mammography units** under direct supervision of a qualified medical physicist. Iowa Department of Health and… Ncdhhs No more than one survey of a specific unit within 60 days counts toward this requirement.

Certification or licensure requires state licensing or approval as a medical physicist, or certification by the American Board of Radiology (ABR) in Diagnostic Radiological Physics, Diagnostic Medical Physics, Imaging Physics, or Radiological Physics, or certification by the American Board of Medical Physics. acr

Alternative qualifications for grandfathered physicists

Physicists who qualified before April 28, 1999 may have done so with a bachelor's degree in physical science (with at least 10 semester hours of physics), 40 contact hours of specialized mammography survey training, and experience surveying 1 facility and 20 mammography units. Iowa Department of Health and… acr

Continuing requirements (21 CFR 900.12(a)(3)(iii))

Physicists must complete **15 continuing education units** in mammography during each 36-month period, including training appropriate to each mammographic modality evaluated. Ncdhhs The continuing experience requirement mandates surveys of at least **2 mammography facilities and 6 mammography units** during the 24-month period preceding inspection. No more than one survey of the same facility within 10 months, and no more than one survey of the same unit within 60 days, may count toward these totals. eCFR

Documentation checklist for inspections

- Master's or bachelor's degree in physical science
- Transcript showing physics coursework hours
- Initial training certificates (20 or 40 hours)
- Documentation of initial survey experience
- ABR/ABMP certification OR state license
- 8-hour modality training certificates for each modality surveyed
- Continuing education certificates (15 units per 36 months)
- Survey logs demonstrating 2 facilities/6 units per 24 months
- All survey reports from preceding inspection period

Chapter 6: Personnel records retention requirements

The 2023 MQSA Final Rule significantly enhanced personnel records requirements effective September 10, 2024. Under 21 CFR 900.12(a)(4), facilities must maintain current personnel records available for inspection and retain former personnel records for **at least 24 months** from the date of departure. These records must be available for review during any annual inspection occurring within that 24-month period. (eCFR +2)

Facilities are now required to provide copies of MQSA personnel records to both current and former employees upon request. (FDA) Before closing or ceasing mammography services, facilities must make arrangements for current and former personnel to access their MQSA qualification records. (eCFR)

PART III: EQUIPMENT STANDARDS AND QUALITY CONTROL

Chapter 7: Mammography equipment requirements

General equipment standards (21 CFR 900.12(b))

All radiographic equipment used for mammography must be specifically designed for mammography purposes. Equipment must be certified pursuant to 21 CFR 1010.2 as meeting applicable requirements of 21 CFR 1020.30 and 1020.31. (Wisc) Under the 2024 updates, **all devices used in mammography must have met applicable FDA premarket authorization requirements** for medical devices of that type with intended use (21 CFR 900.12(b)(2)(i)). (FDA +3)

Radiographic equipment designed for general purpose or special non-mammography procedures is prohibited for mammography use. Systems modified or equipped with special attachments for mammography are likewise prohibited.

Compression device requirements

All mammography systems must incorporate a compression device with initial power-driven compression using hands-free controls operable from both sides of the patient. Fine adjustment compression controls must also be operable from both sides. Compression paddles must match all full-field image receptor sizes, be flat and parallel to the breast support table (with deflection not exceeding 1.0 cm), and have a chest wall edge that is straight and parallel to the image receptor edge.

Compression force testing requirements specify a minimum of **111 N (25 lbs)** achievable compression. For initial power-driven compression, the maximum force must fall within **111-200 N (25-45 lbs)**.

Image receptor requirements

Systems must provide capability for at least **18 × 24 cm and 24 × 30 cm** image receptors. Moving grids matched to all image receptor sizes are required. Systems for noninterventional problem-solving must have magnification capability with at least one magnification value within the range of 1.4 to 2.0.

Reading workstation requirements

Displays used to interpret mammograms must have met applicable FDA premarket authorization requirements per 21 CFR 892.2050. (federalregister) Quality management programs must be substantially the same as programs recommended by the image receptor manufacturer. (AAPM) This includes compliance with DICOM Grayscale Standard Display Function (GSDF) requirements and appropriate luminance and resolution standards for mammographic interpretation. (PubMed Central)

Remote and telemammography workstations require the same documentation as on-site workstations, including personnel qualifications, QA documentation, and QC records. New workstations must be tested by a medical physicist prior to use for mammography interpretation. Existing workstations joining facility groups must have documentation of medical physicist testing within the previous 14 months. (Mammographyeducation)

Chapter 8: Quality control testing program

Daily testing requirements (21 CFR 900.12(e)(1))

For screen-film systems, daily processor performance testing must be completed before any clinical films are processed. Base plus fog density must remain within ± **0.03** of established operating levels, mid-density within ± **0.15**, and density difference within ± **0.15**.

Weekly testing requirements (21 CFR 900.12(e)(2))

Phantom image quality testing using an FDA-approved phantom must be performed weekly. Optical density at the phantom center must achieve at least **1.20** under typical clinical conditions. Density variation must not exceed ± **0.20** from the established operating level. The phantom score must meet the minimum established by the accreditation body, and density difference (contrast) must not vary by more than ± **0.05** from the established operating level.

Quarterly testing requirements (21 CFR 900.12(e)(3))

Fixer retention in film must not exceed **5 micrograms per square centimeter**. Repeat/reject analysis must be performed quarterly, and if the rate changes by more than 2.0% from the previous quarter, the facility must determine reasons and document corrective actions.

Semiannual testing requirements (21 CFR 900.12(e)(4))

Darkroom fog testing requires density increase of no more than **0.05 OD** when film with mid-density of at least 1.2 OD is exposed to darkroom conditions for 2 minutes. Screen-film contact testing must be performed on all cassettes using a 40-mesh copper screen. Compression force testing must verify the minimum 111 N capability and maximum initial power drive range of 111-200 N.

Annual testing requirements (21 CFR 900.12(e)(5))

Annual quality control testing encompasses comprehensive equipment performance verification:

- **AEC performance**: Optical density must remain within ± 0.15 of the mean across 2-6 cm thickness range with density at center ≥ 1.20
- **kVp accuracy**: Within ± 5% at lowest, most common, and highest clinical kVp settings
- **kVp reproducibility**: Coefficient of variation ≤ 0.02
- **System resolution**: Minimum 11 lp/mm perpendicular to anode-cathode axis; 13 lp/mm parallel
- **Half-value layer (beam quality)**: Must meet specifications (e.g., ≥ 0.30 mm Al at 30 kVp)
- **Air kerma reproducibility**: Coefficient of variation ≤ 0.05
- **Dosimetry**: Average glandular dose must not exceed **3.0 mGy** (0.3 rad) per exposure
- **X-ray/light field alignment**: Total misalignment ≤ 2% of SID
- **Compression paddle alignment**: Chest wall edge not extending beyond image receptor by > 1% of SID
- **Radiation output**: ≥ 7.0 mGy air kerma/sec at 28 kVp in molybdenum/molybdenum mode

Digital mammography QC requirements

For digital mammography and DBT systems, facilities may follow the quality assurance program recommended by the image receptor manufacturer or use the **ACR Digital Mammography Quality Control Manual** under Alternative Standard #24 (approved July 13, 2018). (FDA +2) The ACR manual provides standardized QC tests, frequencies, and performance criteria applicable to all digital mammography manufacturers.

Technologist tests for digital systems include:

Test	Frequency
Flat field/detector calibration	Per manufacturer specification
Artifact evaluation	Weekly
Phantom image quality	Weekly
Compression thickness indicator	Monthly
Acquisition workstation monitor QC	Weekly
Reading workstation monitor QC	Weekly
Repeat analysis	Quarterly
Compression force	Semiannually

Chapter 9: Medical physicist survey requirements

Annual survey content (21 CFR 900.12(e)(9))

Medical physicist surveys must be performed at least **once per year** with intervals not exceeding 12-14 months. Surveys may be conducted by a qualified medical physicist or by an individual under the direct supervision of a qualified medical physicist. FDA FDA

Each annual survey must include all annual tests described in 21 CFR 900.12(e)(5), all applicable annual tests for other modalities per §900.12(e)(6), weekly phantom image quality testing per §900.12(e)(2), review of all facility QC test results from §900.12(e)(1)-(7), review of written documentation of corrective actions and results, and evaluation of the adequacy of the facility's QC program.

Survey report requirements (21 CFR 900.12(e)(9)(iii)-(v))

Survey reports must be sent to the facility **within 30 days** of the survey date. Reports must include a summary of the review of the facility's QC program, recommendations for necessary improvements, the survey date, and the medical physicist's signature. If portions of the survey were performed by another individual, the report must identify that individual and specify which portions they performed.

Equipment evaluations (21 CFR 900.12(e)(10))

Mammography equipment evaluations are required whenever a new unit or processor is installed, whenever equipment is disassembled and reassembled at the same or a new location, when major components are changed or repaired, and when software changes or upgrades are implemented (FDA considers these major repairs). All problems identified during equipment evaluations must be corrected **before the equipment is placed into clinical service**. FDA

Chapter 10: Phantom imaging requirements

Approved phantoms

FDA-approved phantoms for MQSA compliance include the ACR Mammography Accreditation Phantom (Model 156, 18-220), the ACR Digital Mammography Phantom (Model 086 for FFDM), and CIRS phantoms (Model 015 and Full-Field Digital Mammography Phantom).

Phantom construction and specifications

Standard mammography phantoms simulate **4.2 cm of compressed breast tissue** composed of 50% glandular and 50% adipose tissue. PubMed Central Test objects include nylon fibers, spherical glass specks, and low-contrast masses embedded within a 7 mm thick wax insert with appropriate compensation for matched attenuation. Cirsinc

Pass/fail criteria

Minimum visibility requirements per ACR guidelines:

Object Type	Minimum Visible	Scoring Method
Fibers	4 fibers (≥ 0.75 mm)	+1 per visible, +0.5 for 50% visible
Speck groups	3 groups (≥ 0.32 mm)	+1 per visible group
Masses	3 masses (≥ 0.75 mm)	+1 per visible mass

False structures such as dust artifacts incur a penalty of **-1 point** each. PubMed Central Phantom images must demonstrate optical density of at least 1.20 at center and density variation within ± 0.20 of the established operating level.

Chapter 11: Equipment service documentation

Required service records

Facilities must maintain service records for all repairs, installations, and modifications affecting the mammography unit or processor. Records must document any maintenance or modification affecting the useful beam. Service history should include dates of service, nature of repairs or modifications, and verification of proper function following service.

QC record retention requirements (21 CFR 900.12(d)(2))

Quality control records must be retained until the next annual inspection is completed and FDA determines compliance, **OR** until the test has been performed two additional times at the required frequency—whichever is

longer.

Active versus non-active equipment

Active equipment requires full QC testing at specified frequencies. Equipment that is temporarily out of service does not require routine QC testing while inactive but **requires a mammography equipment evaluation (MEE)** before returning to clinical service. The MEE must verify compliance with all applicable standards in 21 CFR 900.12(b) and (e), and all identified problems must be corrected before the equipment is used clinically. FDA

Mobile unit requirements (21 CFR 900.12(e)(7))

Mobile mammography units must meet all standard QC requirements. Additionally, at **each examination location** before any examinations are performed, the facility must verify satisfactory performance using a test method that establishes adequacy of image quality.

PART IV: EQUIP PROGRAM AND QUALITY ASSURANCE

Chapter 12: Understanding EQUIP requirements

Overview of the EQUIP program

The **Enhancing Quality Using the Inspection Program (EQUIP)** initiative, launched by FDA on October 27, 2016 (with inspections beginning January 1, 2017), emphasizes clinical image quality as one of the most important determinants of mammography accuracy. The program highlights Lead Interpreting Physician responsibilities for image quality and promotes ongoing facility review of clinical images.

EQUIP operates under the regulatory basis of **21 CFR 900.12(i)**, which requires clinical images to comply with standards established by the facility's accreditation body. The program focuses on ensuring that facilities maintain active processes for monitoring and improving clinical image quality.

The three EQUIP inspection questions

Question 1: Clinical image corrective action procedures (21 CFR 900.12(d)(1)(ii)(A))

Inspectors assess whether the facility has established procedures for corrective action when clinical images are of poor quality. These procedures must include a mechanism for ongoing interpreting physician feedback to radiologic technologists. Facilities must document corrective actions taken and their effectiveness. No written standard operating procedure is required—verbal explanation during inspection is acceptable. There is no specific timeframe or retention requirement for feedback documentation.

Question 2: Periodic clinical image quality review

Facilities must conduct clinical image quality reviews **at minimum annually** (completed before the next annual inspection). Reviews must include a sample of mammograms from **each active radiologic technologist and each active interpreting physician**. Written documentation is required and may include summary reports, signed LIP statements, or meeting records.

Reviews must evaluate eight image quality attributes: **positioning, compression, exposure level, contrast, sharpness, noise, artifacts, and examination identification**. Sample size is determined by the facility, but images must be selected from the past year and cannot predate the previous inspection.

Question 3: LIP oversight of QA/QC records

The Lead Interpreting Physician must demonstrate oversight of QA/QC records and corrective actions. Documentation may take the form of an attestation, signed SOP, or verbal answers during inspection. If the LIP is unavailable during inspection, an attestation signed prior to the inspection date is required. A new attestation must be prepared each year when the LIP cannot attend the inspection.

EQUIP citation progression

During Year 1 of EQUIP implementation, no citations were issued (educational period). In Year 2, Level 2 citations became possible, requiring facility response within 30 days. For Year 3 and beyond, repeat violations are cited as Level 2 repeat with a 15-day response window and referral to the accreditation body for clinical image evaluation.

Chapter 13: Quality assurance program structure

Lead Interpreting Physician oversight role (21 CFR 900.12(d)(1)(i))

The LIP holds **general responsibility** for ensuring the quality assurance program meets all requirements. This includes determining qualifications for QA task assignments, evaluating performance adequacy of individuals assigned QA tasks, and ensuring that no individual is assigned or retains QA responsibility without LIP approval.

The LIP must ensure proper maintenance of QA records, review technologist QC monitoring data, provide frequent feedback to mammography technologists, and ensure documentation of corrective actions. The LIP must be prepared to discuss these responsibilities during inspections.

Quality Control Technologist responsibilities (21 CFR 900.12(d)(1)(iv))

The QC Technologist holds assigned responsibility for all QC tasks not specifically assigned to the LIP or medical physicist. Tasks may be performed by the QC Technologist or other qualified personnel, but the QC Technologist ensures all tasks are completed properly and documented appropriately.

Required QA documentation

Facilities must maintain documentation of mammography technique and procedures, quality control monitoring data, problems detected by analysis of QC data, corrective actions taken, effectiveness of corrective actions,

safety and protection records, and employee qualifications for assigned QA tasks.

Corrective action requirements

Immediate corrective action (before further examinations or processing) is required for failures of daily processor QC, weekly phantom image quality, compression device performance, dosimetry (> 3.0 mGy), mobile unit pre-examination tests, or any test outside manufacturer action limits for digital systems.

Corrective action within 30 days is required for all other failed tests specified in 21 CFR 900.12(e).

The corrective action process requires identifying the source of the problem, implementing corrective action, documenting the action taken, re-testing to verify correction effectiveness, and documenting the results. Medical physicists evaluate the adequacy of corrective actions during annual surveys.

PART V: MEDICAL OUTCOMES AUDIT AND PEER REVIEW

Chapter 14: Medical outcomes audit requirements

Audit program structure (21 CFR 900.12(f))

Every mammography facility must establish a mammography medical outcomes audit program to collect and review outcome data for all mammograms performed, follow up on disposition of all positive mammograms, correlate pathology results with the interpreting physician's mammography report, and ensure reliability, clarity, and accuracy of interpretation.

The first audit must be initiated within **12 months of certification** and completed within an additional 12 months to permit adequate data collection. Subsequent analyses must be conducted at least every **12 months**.

Required audit metrics (effective September 10, 2024)

The 2023 MQSA Final Rule established three specific metrics that must be calculated:

Positive Predictive Value (PPV): The percentage of patients with positive mammograms who are diagnosed with breast cancer within one year of examination.

Cancer Detection Rate (CDR): The number of patients with "Incomplete," "Suspicious," or "Highly Suggestive of Malignancy" assessments who are diagnosed with breast cancer within one year, expressed as a ratio per 1,000 patients.

Recall Rate: The percentage of screening mammograms assigned an assessment of "Incomplete: Need additional imaging evaluation."

Analysis and reporting requirements

These metrics must be calculated for **each interpreting physician individually** and for the **facility as a whole**.

Each facility must designate at least one interpreting physician to review audit data at least every 12 months. This audit physician must record dates of audit periods, analyze results, document findings, notify other interpreting physicians of their individual results and facility aggregate results, and document the nature of any follow-up actions taken.

Outcome tracking procedures

Facilities must follow up on all positive mammograms. When breast cancer cases become known to the facility, staff must promptly initiate follow-up on surgical and pathology results. Review of prior mammograms taken before the malignancy diagnosis is required to correlate imaging findings with pathologic outcomes.

Audit record retention

Audit records must be retained until the next annual inspection has been completed and FDA determines compliance, or until the test has been performed two additional times at the required frequency—whichever is longer.

Chapter 15: Peer review documentation

Radiologist peer review

The EQUIP-required annual clinical image quality review functions as the primary peer review mechanism for interpreting physicians under MQSA. Reviews must include mammograms interpreted by each active interpreting physician and evaluate imaging quality attributes including positioning, compression, exposure, contrast, sharpness, noise, artifacts, and examination identification.

Documentation should include the review date, names of reviewing and reviewed physicians, number of cases reviewed, findings regarding image quality, and any recommended improvements. The Lead Interpreting Physician must sign off on review completion.

Technologist peer review

Clinical image quality reviews must also include samples from each active radiologic technologist. The LIP provides ongoing feedback to technologists regarding image quality and documents any corrective action recommendations.

Documentation should include the review date, names of technologists whose images were reviewed, number of cases reviewed per technologist, findings regarding positioning and technical quality, corrective action recommendations, and evidence of follow-up on previous recommendations.

Lead Interpreting Physician sign-off requirements

The LIP must sign off on all audit data reviews and peer review documentation. Attestations confirming LIP oversight must be dated and signed. If the LIP is unavailable during inspection, the attestation must be signed prior to the inspection date.

PART VI: COMMUNICATION AND REPORTING REQUIREMENTS

Chapter 16: Patient communication requirements

Lay summary requirements (21 CFR 900.12(c)(2))

Every patient must receive a lay summary of their mammography results containing the patient's name, facility name, address (city, state, ZIP code), and telephone number, the overall assessment in lay terminology, and the overall assessment of breast density with standardized notification language.

Breast density notification statements (effective September 10, 2024)

Federal law now requires specific standardized language in all patient lay summaries based on breast density category:

For Non-Dense Breast Tissue (Categories A or B): "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."

For Dense Breast Tissue (Categories C or D): "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."

Communication timeframes

Assessment Category	Deadline
Standard results (all other categories)	Within **30 calendar days** of examination
"Suspicious" or "Highly Suggestive of Malignancy"	Within **7 calendar days** of final interpretation
"Incomplete: Need prior mammograms for comparison"	Follow-up report with final assessment within **30 calendar days** (whether or not priors obtained)

Self-referred patient requirements (21 CFR 900.12(c)(2)(i)-(ii))

Patients without referring healthcare providers receive both the lay summary and the full mammography report. Facilities accepting self-referred patients must maintain a system for referring such patients to healthcare

providers when mammogram assessment is "Probably Benign," "Suspicious," or "Highly Suggestive of Malignancy."

Chapter 17: Healthcare provider reporting requirements

Mammography report contents (21 CFR 900.12(c)(1))

Written reports to healthcare providers must include the patient name and an additional patient identifier, date of examination, facility name and location (city, state, ZIP code, telephone number), name of the interpreting physician, overall final assessment of findings, overall assessment of breast density (four categories), and recommendations for additional actions.

Final assessment categories (21 CFR 900.12(c)(1)(iv))

Reports must use one of the following standardized final assessment categories:

1. **"Negative"** — Nothing to comment upon
2. **"Benign"** — Normal result with benign findings, no evidence of malignancy
3. **"Probably Benign"** — Finding has high probability of being benign
4. **"Suspicious"** — Findings indicating definite probability of malignancy
5. **"Highly Suggestive of Malignancy"** — High probability of malignancy
6. **"Known Biopsy-Proven Malignancy"** — Reserved for known malignancies being evaluated
7. **"Post-Procedure Mammogram for Marker Placement"** — New category added in 2024

Incomplete assessment categories (21 CFR 900.12(c)(1)(v))

Two incomplete categories are now codified:

- **"Incomplete: Need Additional Imaging Evaluation"**
- **"Incomplete: Need Prior Mammograms for Comparison"**

For the latter category, a follow-up report with a final assessment is required within 30 calendar days regardless of whether prior mammograms are obtained.

Breast density categories for provider reports (21 CFR 900.12(c)(1)(vi))

Provider reports must include one of four standardized breast density assessments:

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

Chapter 18: Sample letters and documentation

Required sample documentation for inspections

Facilities should prepare sample documentation demonstrating compliance with communication requirements:

- Sample patient lay summaries showing all required elements
- Sample provider reports with required assessment and density categories
- Sample 7-day notification letters for suspicious/highly suggestive findings
- Sample 30-day follow-up letters for incomplete assessments
- Documentation of self-referred patient referral system
- Sample letters demonstrating breast density notification language

Record transfer requirements (21 CFR 900.12(c)(4)(ii)-(iii))

Original mammographic images and copies must be transferred within **15 calendar days** of request. Digital images submitted for final interpretation must be provided electronically. Fees charged cannot exceed documented costs of transfer.

PART VII: ACCREDITATION, CERTIFICATION, AND RECORDKEEPING

Chapter 19: Accreditation requirements and processes

FDA-approved accreditation bodies

Currently approved accreditation bodies through April 28, 2027:

1. **American College of Radiology (ACR)** — National accreditor for all states
2. **State of Arkansas** — Facilities within Arkansas
3. **State of Texas** — Facilities within Texas
4. **State of Iowa** — Accreditation only for facilities within Iowa

Accreditation review components (21 CFR 900.4)

Accreditation bodies must review equipment performance, personnel qualifications (interpreting physicians, radiologic technologists, medical physicists), clinical image quality (eight attributes), and facility practices and procedures.

Accreditation cycle

Initial accreditation is required before FDA certification can be issued. Re-accreditation occurs every **3 years**. Facilities should allow at least 6 months for the re-accreditation process and should not allow accreditation to lapse.

Failed accreditation consequences (effective September 10, 2024)

Under the 2023 Final Rule, facilities that fail accreditation after **three consecutive attempts** must wait **1 year** before reapplying to any accreditation body. This provision prevents "accreditation body shopping" following failed attempts.

Chapter 20: Certification requirements

Provisional certificates (21 CFR 900.11(b)(2))

Provisional certificates are valid for up to **6 months** and are issued when a facility's accreditation application is accepted. During this period, the facility must collect clinical images and complete the accreditation process. A one-time 90-day extension may be available in certain circumstances.

Full certificates

Full certificates are valid for **3 years** and are issued upon achieving full accreditation. Certificates must be conspicuously displayed at the facility.

State as Certifier (SAC) programs

Four states are certified to issue MQSA certificates directly: Illinois, Iowa, South Carolina, and Texas. Facilities in these states work with their state programs rather than directly with FDA for certification purposes.

Inspection frequency

Annual inspections are required by statute (42 U.S.C. 263b(g)(1)(E)). Inspections are conducted by federally trained and certified inspectors who review equipment, personnel qualifications, clinical image quality, medical audit records, and the QA/QC program. Facilities typically receive at least **5 business days advance notice** of scheduled inspections.

Chapter 21: Recordkeeping requirements

Medical record retention (21 CFR 900.12(c)(4))

Original mammographic images and reports must be retained for the **longest** of:

- 5 years from date of examination if the patient continues having mammograms at the facility
- 10 years from date of examination if no additional mammograms are performed at the facility

- Period mandated by state or local law

Images must be retained in their **original mammographic modality**. Facilities cannot satisfy retention requirements by scanning, copying, or digitizing hardcopy originals.

Personnel records retention (21 CFR 900.12(a)(4))

Current personnel records must be maintained and available for inspection. Former personnel records must be retained for at least **24 months** from the departure date. Records must be available during inspections occurring within the 24-month period. Copies must be provided to current and former employees upon request.

Quality control records retention (21 CFR 900.12(d)(2))

QC records must be retained until the next annual inspection is completed and FDA determines compliance, **OR** until the test has been performed two additional times at the required frequency—whichever is **longer**.

Consumer complaint records (21 CFR 900.12(h)(2))

Serious complaints must be retained for at least **3 years** from the date received.

Facility closure requirements

Before closing or ceasing mammography services, facilities must arrange patient and provider access to mammographic records for the remainder of applicable retention periods, notify the accreditation body and certification agency in writing, and make reasonable efforts to notify all affected patients.

Chapter 22: Consumer complaint policies

Required complaint procedures (21 CFR 900.12(h))

Every facility must establish a written system for collecting and resolving consumer complaints. Serious complaint records must be maintained for at least 3 years. Facilities must provide consumers with directions for filing complaints with the accreditation body if complaints remain unresolved. Unresolved serious complaints must be reported to the accreditation body according to the body's requirements.

State radiation certificates and personnel monitoring

Facilities must maintain current state radiation control certificates as required by state law. Personnel monitoring programs should comply with state requirements for occupational radiation exposure monitoring. Records of personnel monitoring results should be maintained according to state requirements and made available during inspections if requested.

Radiation signage requirements

Facilities must post required radiation warning signs as mandated by state radiation control programs. Signs should be conspicuously displayed at entrances to mammography rooms and should meet state specifications

for content, size, and placement.

PART VIII: INSPECTION PREPARATION CHECKLIST

Chapter 23: Comprehensive documentation checklist

The following checklist organizes all documentation required for MQSA inspection review:

Personnel documentation

Interpreting Physicians (for each):

- [ ] State medical license (current)
- [ ] Board certification OR 3-month training documentation
- [ ] Initial 60-hour CME certificates
- [ ] Continuing CME certificates (15 hours/36 months)
- [ ] Modality training certificates (8 hours each)
- [ ] Examination logs (960 exams/24 months)

Lead Interpreting Physician:

- [ ] Written designation document
- [ ] QA program oversight attestation (current year)
- [ ] Medical audit review sign-off documentation

Radiologic Technologists (for each):

- [ ] ARRT certification OR state license
- [ ] Initial 40-hour mammography training
- [ ] Initial 25 supervised examination documentation
- [ ] Modality training certificates (8 hours each)
- [ ] Continuing education certificates (15 units/36 months)
- [ ] Examination logs (200 exams/24 months)

Medical Physicist:

- [ ] Graduate degree and physics coursework transcript
- [ ] Initial training certificates (20 or 40 hours)
- [ ] Initial survey experience documentation
- [ ] ABR/ABMP certification OR state license
- [ ] Modality training certificates (8 hours each)
- [ ] Continuing education certificates (15 units/36 months)

- [ ] Survey logs (2 facilities/6 units/24 months)
- [ ] All survey reports from inspection period

Former Personnel (departed within 24 months):

- [ ] Qualification records retained per requirements

Equipment and QC documentation

Active Equipment:

- [ ] Daily QC records (processor performance)
- [ ] Weekly phantom image records
- [ ] Quarterly fixer retention and repeat analysis
- [ ] Semiannual darkroom fog and compression tests
- [ ] Annual medical physicist survey reports
- [ ] Equipment evaluation records (new/modified equipment)
- [ ] Service history documentation
- [ ] State radiation certificate

Reading Workstations:

- [ ] Medical physicist testing documentation
- [ ] QC checklist records

Non-Active Equipment:

- [ ] Equipment evaluation before return to service

EQUIP documentation

- [ ] Clinical image corrective action procedures
- [ ] Annual clinical image quality review documentation
- [ ] LIP oversight attestation (current year)
- [ ] Feedback documentation to technologists

Medical outcomes audit

- [ ] Audit methodology documentation
- [ ] PPV, CDR, and Recall Rate calculations
- [ ] Individual physician results
- [ ] Facility aggregate results
- [ ] LIP/audit physician sign-off
- [ ] Physician notification documentation

Communication samples

- [ ] Sample patient lay summaries (all density categories)
- [ ] Sample provider reports
- [ ] Sample 7-day notification letters
- [ ] Sample 30-day follow-up letters
- [ ] Self-referral policy and referral system documentation

Policies and procedures

- [ ] Consumer complaint policy
- [ ] Personnel monitoring program
- [ ] Record retention and transfer procedures
- [ ] Self-referral policy (if applicable)
- [ ] Radiation signage compliance

Accreditation and certification

- [ ] Current FDA certificate (displayed)
- [ ] Accreditation documentation
- [ ] State radiation control certificate

CONCLUSION

Synthesizing MQSA compliance for inspection readiness

Preparing for an MQSA inspection requires systematic organization of documentation across personnel qualifications, equipment standards, quality control programs, medical outcomes audits, patient communications, and facility policies. The 2023 Final Rule effective September 10, 2024 introduced significant new requirements including mandatory breast density notification, enhanced audit metrics, strengthened personnel records retention, and new consequences for repeated accreditation failures.

The evidence accumulated since MQSA's enactment in 1992 demonstrates that systematic federal oversight has measurably improved mammography quality nationwide. Facilities that approach inspection preparation as an ongoing quality management process—rather than an annual compliance exercise—will find themselves best positioned to demonstrate the excellence in mammography that MQSA was designed to ensure.

Success in MQSA compliance ultimately serves the program's foundational purpose: ensuring that every woman in the United States has access to high-quality mammography capable of detecting breast cancer at its earliest, most treatable stages. The detailed requirements outlined in this manual reflect three decades of regulatory refinement aimed at optimizing this life-saving capability.

Facilities should maintain continuous communication with their accreditation bodies, medical physicists, and state radiation control programs to stay current with regulatory interpretations and guidance updates. The FDA MQSA hotline (1-800-838-7715) and email (MQSA@fda.hhs.gov) remain available resources for compliance questions.

KEY REGULATORY CITATIONS REFERENCE

Topic	Primary Citation
Quality Standards (Complete)	21 CFR 900.12
Personnel Requirements	21 CFR 900.12(a)
Equipment Standards	21 CFR 900.12(b)
Medical Records/Reports	21 CFR 900.12(c)
Quality Assurance - General	21 CFR 900.12(d)
Quality Assurance - Equipment	21 CFR 900.12(e)
Medical Outcomes Audit	21 CFR 900.12(f)
Consumer Complaints	21 CFR 900.12(h)
Clinical Image Quality	21 CFR 900.12(i)
Accreditation Bodies	21 CFR 900.4
Certification	21 CFR 900.11
Definitions	21 CFR 900.2
1997 Final Rule	62 FR 55852 (October 28, 1997)
2023 Final Rule	88 FR 15126 (March 10, 2023)
Enabling Statute	42 U.S.C. 263b

This manual synthesizes requirements from FDA regulatory documents (21 CFR Part 900), Federal Register publications (58 FR 67558, 62 FR 55852, 88 FR 15126), FDA guidance documents including the Small Entity Compliance Guide and EQUIP FAQ, peer-reviewed literature from journals including Radiology, AJR, and JACR, and ACR accreditation support materials. Facilities should consult primary regulatory sources and current FDA guidance for authoritative compliance information.

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