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2018
Digital Mammography

QUALITY CONTROL MANUAL
Revised 2nd Edition — May 2020

Radiologist's Section

Radiologic Technologist's Section

Medical Physicist's Section

2018
Digital Mammography

QUALITY CONTROL MANUAL
2D and Digital Breast Tomosynthesis
Radiologist's Section
Radiologic Technologist's Section
Medical Physicist's Section

American College of Radiology
Subcommittee on Quality Assurance in Mammography
of the
Committee on Mammography Accreditation

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ACR 2018 Digital Mammography Quality Control Manual
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CITATION

PREFACE, 2ND EDITION

In February 2016, the FDA approved the ACR's new Digital Mammography Quality Control (QC) Manual and Digital Mammography QC Phantom as an alternative standard for use in routine QC of digital mammography equipment. This approval, as an alternative standard, allowed mammography facilities, including QC technologists and medical physicists, to use the new ACR manual in lieu of manufacturers' quality control manuals. However, the approval specified that the new manual could not be used on full-field digital mammography systems with advanced imaging capabilities (e.g., tomosynthesis and contrast enhancement). In July 2018, the FDA approved the ACR's QC procedures for digital breast tomosynthesis (DBT) through an amendment to the 2016 alternative standard. This updated 2018 Digital Mammography Quality Control Manual integrates the new DBT QC procedures so that the entire manual may be used for both full-field digital mammography and DBT systems. [Author's Note: Regarding digital mammography units with contrast enhancement capability, the FDA has determined that facilities may use this manual for QC of the 2D and DBT applications of these units, and recommends that facilities follow manufacturer QC procedures for contrast enhancement applications.]

I would again like to extend a sincere thank you to all who collaborated on this 2nd Edition including the entire committee and ACR Staff. In particular Doug Pfeiffer and Penny Butler dedicated countless hours to bring this manual to fruition. Their efforts were invaluable.

Eric A. Berns, PhD, FACR

Chair, Subcommittee on Quality Assurance in Mammography of the Committee on Mammography Accreditation

September 2018

PREFACE, 1ST EDITION

The American College of Radiology's original ACR Committee on Mammography Quality Assurance, chaired by Gerald Dodd, MD, first published its Mammography Quality Control Manual in 1990 to provide quality control procedures for screen-film mammography. Three more versions were published, the latest in 1999 under the chairmanship of R. Edward Hendrick, PhD. In 2000 the first full-field digital mammography unit was approved by the US Food and Drug Administration (FDA) for clinical use. Since then, the FDA has required that facilities perform quality control for approved digital mammography systems according to their respective manufacturer's quality control manual.

In February 2016, the FDA approved the ACR's new Digital Mammography Quality Control (QC) Manual and Digital Mammography QC Phantom as an alternative standard for use in routine QC of digital mammography equipment. Currently, the FDA requires digital mammography facilities to perform QC for approved imaging systems, according to their respective manufacturers' quality control manuals. This approval, as an alternative standard, allows mammography facilities, including QC technologists and medical physicists, to use the new ACR manual in lieu of manufacturers' quality control manuals. ***The FDA alternative standard specifies that the new manual may be used only for full-field digital mammography systems without advanced imaging capabilities (e.g., tomosynthesis and contrast enhancement).***

The manual consists of 3 sections: Radiologist's Section, Radiologic Technologist's Section, and Medical Physicist's Section. The latter two sections contain detailed instructions and procedures for quality control tests without being too rigid, allowing for differences between digital manufacturers. Action limits are given for each test.

The objective of this manual is to ensure high quality digital mammograms while keeping radiation doses low. New to this release are tests, and ways to run a QC program, that have resulted from the evolution of modern digital mammography. Today, facilities have grown to include networks that have multiple digital manufacturers, different monitor manufacturers, different PACS systems, and, most significantly, multiple locations. Every QC test in the manual has been adapted for digital mammography. Additionally, we have introduced a new phantom that resembles the previous ACR accreditation mammography phantom but has changed in size to optimize for artifact evaluation while maintaining the ability to measure dose according to FDA requirements and similar test object scoring. The move from film display to softcopy display has presented a new challenge for quality control and documentation. The concept of a quality control team with the radiologist included in a formal quality control review test is new to this manual.

The members of the ACR Subcommittee on Quality Assurance in Mammography who participated in the publication of this manual deserve our heartfelt thanks. This was truly a team effort. Our radiologists consisting of Drs. Jay Baker, Lora Barke, Lawrence Bassett,

2018
Digital Mammography

QUALITY CONTROL MANUAL

Radiologist's Section

Contents

Revisions

Date	Page(s)	Section	Description of Revisions
November 2018			2nd edition with digital breast tomosynthesis QC

RADIOLOGIST'S SECTION

Introduction

Regular mammographic screening significantly reduces mortality from breast cancer. The effectiveness and success of screening and diagnostic mammography, however, depends on consistent production of high-quality mammographic images. It is widely known that improving image quality in mammography can improve breast cancer detection [1]. Achieving high image quality requires vigilant attention to every step of quality control (QC). High standards must be maintained.

The American College of Radiology (ACR) established a voluntary mammography accreditation program in 1987 to direct attention to the need for reproducibly high-quality mammography [2, 3]. Calls for quality assurance in mammography had come from breast imaging radiologists, medical physicists, and other professional organizations and regulatory groups. The ACR Subcommittee on Quality Assurance in Mammography, under the Committee on Mammography Accreditation, establishes practices and standards for QC in mammography. Since the original publication of the screen-film manual in 1990, it has been updated and revised several times to reflect improvements in mammographic technology, improved QC procedures, and requirements of the Food and Drug Administration's (FDA) Final Rule for the Mammography Quality Standards Act (MQSA) [4]. Pertinent FDA regulations are provided in the boxes below. This version of the ACR Mammography QC Manual provides guidance for image quality and QC of 2D and digital breast tomosynthesis (DBT) full-field digital mammography (DM) systems across all manufacturers.

> **Important:** Although the FDA uses the term "interpreting physician" throughout their regulations and guidance, since the overwhelming majority of interpreting physicians are radiologists, the ACR Digital Mammography Quality Control Manual uses the term "radiologists" to refer to "interpreting physicians."

The "Radiologist's Section" details the mammography staff's responsibilities in an ongoing mammography QC program.

- The *lead mammography radiologist* (lead interpreting physician) has the responsibility for ensuring that all quality assurance requirements are met. This is good practice and is mandated by MQSA.

- *Mammography radiologists* (interpreting physicians) must follow the facility procedures for corrective action when the images they are asked to interpret are of poor quality.

- The *medical physicist* is responsible for overseeing all equipment-related quality assurance practices.

- A primary *quality control technologist* must be identified by the mammography facility to conduct all quality assurance activities not assigned to the lead mammography radiologist or the medical physicist.

The section on "*Clinical Image Quality Evaluation*" that was present in the 1999 version of the screen-film quality control manual has been removed from this manual. The ACR Mammography Quality Control Manual for screen-film was the only ACR quality control manual with a clinical image quality section; this change in the ACR Digital Mammography Quality Control Manual makes it more consistent with other ACR manuals and accreditation programs. *The "Clinical Image Quality Evaluation" section will be updated and made available on the ACR website.* Until a new document is provided, technologists and radiologists can refer to the 1999 ACR Mammography Quality Control Manual as well as training resources provided by the American Society of Radiologic Technologists [5] for guidance on positioning and clinical image quality.

Details of the mammography technologist's and medical physicist's tests are given in the Radiologic Technologist's Section and the Medical Physicist's Section, respectively.

The radiologist and mammography technologist must look at every image with QC in mind. Deviations from high-quality performance may occur quickly or gradually. Abrupt changes in quality may be detected during routine clinical work. More gradual or subtle changes require regular quality assurance testing for detection. The QC program provides a framework within which even gradual or subtle problems can be identified, isolated, and resolved before they significantly impact the quality of patient images.

RADIOLOGIST'S SECTION

Definitions

A. Quality Assurance

Quality assurance (QA) is a comprehensive concept that comprises all management practices instituted by the lead mammography radiologist to ensure that

- Every imaging procedure is necessary and appropriate to the clinical problem at hand

- The images generated contain information critical to the solution of that problem

- The recorded information is correctly interpreted and results made available in a timely fashion to the patient and her physician

- The examination results in the lowest possible radiation exposure, cost, and inconvenience to the patient consistent with imaging objectives

The QA program comprises many facets, including efficacy studies, continuing education, QC, and preventive maintenance and calibration of equipment.

A critical aspect of the QA program is the FDA-required ongoing assessment of mammography interpretation quality through an annual mammography medical outcomes audit [4]. All interpreting physicians must participate in this process. Detailed guidance for conducting a medical outcomes audit program is not addressed in this manual but can be found in the Follow-up and Outcomes Monitoring Section [6] of the 2013 Breast Imaging Reporting and Data System Atlas [7].

900.12(f) Quality assurance—mammography medical outcomes audit. Each facility shall establish and maintain a mammography medical outcomes audit program to followup positive mammographic assessments and to correlate pathology results with the interpreting physician's findings. This program shall be designed to ensure the reliability, clarity, and accuracy of the interpretation of mammograms.

(1) General requirements. Each facility shall establish a system to collect and review outcome data for all mammograms performed, including followup on the disposition of all positive mammograms and correlation of pathology results with the interpreting physician's mammography report. Analysis of these outcome data shall be made individually and collectively for all interpreting physicians at the facility. In addition, any cases of breast cancer among women imaged at the facility that subsequently become known to the facility shall prompt the facility to initiate followup on surgical and/or pathology results and review of the mammograms taken prior to the diagnosis of a malignancy.

(2) Frequency of audit analysis. The facility's first audit analysis shall be initiated no later than 12 months after the date the facility becomes certified, or 12 months after April 28, 1999, whichever date is the latest. This audit analysis shall be completed within an additional 12 months to permit completion of diagnostic procedures and data collection. Subsequent audit analyses will be conducted at least once every 12 months.

Digital Mammography Quality Control Manual

(3) Audit interpreting physician. Each facility shall designate at least one interpreting physician to review the medical outcomes audit data at least once every 12 months. This individual shall record the dates of the audit period(s) and shall be responsible for analyzing results based on this audit. This individual shall also be responsible for documenting the results and for notifying other interpreting physicians of their results and the facility aggregate results. If followup actions are taken, the audit interpreting physician shall also be responsible for documenting the nature of the followup.

B. Quality Assurance Committee

A Quality Assurance Committee (QAC) can be useful to provide oversight of the QA program, setting the goals and direction, determining policies, and assessing the effectiveness of QA activities.

A QAC should consist of the following:

- One or more radiologists, including the lead mammography radiologist

- A medical physicist

- A facility manager

- A supervisory mammography technologist

- The quality control technologist

- Other radiology department personnel involved in caring for mammography patients (this may include a nurse, desk attendant, medical secretary, or others)

The QAC also may include medical and paramedical staff from outside the radiology department, such as a surgeon, referring physician, nurse educator, nurse from a comprehensive breast clinic, etc. Anyone who helps provide care to the patient seeking breast cancer screening or diagnosis should be considered as a member of the QAC since his or her efforts affect the quality of care and the satisfaction of the patient.

Routine evaluation and communication via the QAC are particularly effective in larger mammography facilities. Some mammography facilities may not need a formal QAC as long as communication among the staff is routine and effective.

One of the major changes to the ACR Digital Mammography Quality Control Manual is the addition of the Facility QC Review. The lead mammography radiologist, along with the facility manager, must review

the QC test results at least quarterly, or more frequently if problems are noted. (See Facility QC Review in the Radiologic Technologist's Section for more information.) This may become a responsibility of the QAC.

C. Quality Control

QC is an integral part of QA and consists of a series of distinct technical procedures that ensure the production of a satisfactory product, i.e., high-quality screening or diagnostic images. Four steps are involved:

- Acceptance testing to detect defects in equipment that is newly installed or has undergone major repair

- Establishment of baseline performance of the equipment

- Detection and diagnosis of changes in equipment performance before they become radiologically apparent

- Verification of equipment performance after service has been performed

Specifics of the QC program for full-field digital mammography are provided by the American College of Radiology in this manual.

Important: The QC program provides a frame of reference within which even gradual or subtle problems can be identified, isolated, and resolved *before* they significantly impact the quality of patient images.

D. QA/QC Procedures Manual

Working as a team, the mammography radiologist, QC technologist, and medical physicist should develop and follow a mammography QA/QC program that is available to all members of the staff. Proper documentation of procedures and test results is an essential part of maintaining quality and meeting FDA MQSA regulations. This information may be maintained as hardcopy or electronically and must be available at the mammography facility for review by the MQSA inspector and accreditation body.

The QC testing described in this ACR Quality Control Manual should be a central part of the site's QA/QC documentation. The facility's QA/QC program should contain

- Clearly assigned responsibilities for QA/QC testing

- Clearly developed procedures for QA/QC testing

- Records of the QC tests performed by the QC technologist and medical physicist

- Records of any corrective action as a result of the QA/QC testing

- Records of routine and non-routine equipment service and maintenance

- Records of QAC meetings

- A description of the orientation program for operators of mammography equipment, including its duration and content

- Procedures for proper use and maintenance of equipment

- Mammographic techniques to be used, including pertinent information on positioning, compression, appropriate image receptors, imaging modes, and kVp-target-filter combinations if applicable

- Precautions to protect the operator of the equipment, the patient, and individuals in surrounding areas from unnecessary radiation exposure

- Policies and employee responsibilities concerning personnel radiation monitoring

- Procedures for cleaning and disinfection of mammography equipment

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900.12(e) Quality assurance—equipment. (13) Infection control. Facilities shall establish and comply with a system specifying procedures to be followed by the facility for cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials. This system shall specify the methods for documenting facility compliance with the infection control procedures established and shall (i) comply with all applicable Federal, State, and local regulations pertaining to infection control; and (ii) comply with the manufacturer's recommended procedures for the cleaning and disinfection of the mammography equipment used in the facility; or (iii) if adequate manufacturer's recommendations are not available, comply with generally accepted guidance on infection control, until such recommendations become available.

Responsibilities

The radiologist, medical physicist, and QC technologist, working together as a team, are the keys to providing optimum quality mammography images, which will ultimately provide the best medical care possible to the patient. Mammography team members are strongly encouraged to review other sections of the ACR Digital Mammography QC Manual that are not directed towards them. For example, the radiologist should be familiar with Technologist's Test Facility QC Review and the Technologist's Optional Tests System QC for Radiologist and Radiologist Image Quality Feedback. The radiologic technologist should review the Medical Physicist's Test Evaluation of Site's Technologist QC Program and Evaluation of Display Device Technologist QC Program. The medical physicist should be familiar with all of the radiologic technologist's tests.

A. Radiologist's Responsibilities

1. Lead Interpreting Physician

The FDA's MQSA regulations [4] specify that a lead interpreting physician (typically a radiologist) must be identified by the mammography facility to have the general responsibilities of ensuring that all MQSA-required activities are met. This individual will most likely be the lead mammography radiologist. Radiologists interpreting mammography must assume the primary responsibility for the quality of mammography and for the implementation of an effective QA program at their site. The staff's commitment to high quality will often mirror that of the lead mammography radiologist. The individuals performing QC tests need to know that the lead radiologist understands the program and is interested in the results. The radiologist needs to review the test results and trends periodically and provide direction when problems are detected.

> *900.12(d) Quality assurance—general. (1) Responsible individuals. (i) Lead interpreting physician. The facility shall identify a lead interpreting physician who shall have the general responsibility of ensuring that the quality assurance program meets all MQSA QA requirements. No other individual shall be assigned or shall retain responsibility for quality assurance tasks unless the lead interpreting physician has determined that the individual's qualifications for, and performance of, the assignment are adequate.*

The lead mammography radiologist's (lead interpreting physician's) specific responsibilities in mammography QC are to

1. Ensure that technologists have adequate training and continuing education in mammography.

2. Provide an orientation program for technologists based on a carefully established procedures manual.

3. Ensure that an effective QC program exists for all mammography performed at the site. (The radiologist should provide motivation, oversight, and direction to all aspects of the QC program. One mechanism the radiologist can use to demonstrate commitment to QC is routine use of the new Optional System QC for Radiologist procedure and form in the Radiologic Technologist's Section to quickly evaluate the entire mammographic imaging chain from the radiologist workstation.)

4. Select a single technologist to be the primary QC technologist to perform the prescribed QC tests (in order to ensure consistency in QC test performance) and to oversee tests that have been delegated to other individuals. (It is not desirable, for example, to rotate this assignment among a group of technologists. Such a practice would introduce into the test results variability extraneous to the items being tested. However, properly trained backup QC technologists are essential to provide continuity when the primary QC technologist is unavailable.)

> *900.12(d) Quality assurance—general. (1) Responsible individuals. (iv) Quality control technologist. Responsibility for all individual tasks within the quality assurance program not assigned to the lead interpreting physician or the medical physicist shall be assigned to a quality control technologist(s). The tasks are to be performed by the quality control technologist or by other personnel qualified to perform the tasks. When other personnel are utilized for these tasks, the quality control technologist shall ensure that the tasks are completed in such a way as to meet the requirements of paragraph (e) of this section.*

5. Ensure that appropriate test equipment and materials are available to perform the technologist's QC tests.

6. Arrange staffing and scheduling so that adequate time is available to carry out the QC tests and to record and interpret the results. (Most tests take little time; however, the necessary time must be incorporated into the daily schedule.)

7. Provide frequent and consistent positive and negative feedback to technologists about clinical image quality and QC procedures. (The new Optional Radiologist Image Quality Feedback procedure and form in the Radiologic Technologist's Section was designed to assist radiologists with this responsibility.)

8. Select a medical physicist who will oversee the equipment-related QC program and perform the medical physicist's tests.

9. Review the technologist's test results at least quarterly or more frequently if consistency has not yet been achieved. (See Facility QC Review in the Radiologic Technologist's Section.)

10. Review the medical physicist's test results annually, or more frequently when needed.

11. Oversee or designate a qualified individual to oversee the radiation protection program for employees, patients, and other individuals in the surrounding area.

12. Ensure that records concerning employee qualifications, mammography technique and procedures, infection control procedures, QC, safety, and protection are properly maintained and updated in the mammography QA/QC procedures manual.

> **Important:** The lead interpreting physician must review the mammography facility's QC at least quarterly.

The lead interpreting physician is ultimately responsible for image quality produced under his or her direction and bears ultimate responsibility for both proper QC testing and QA procedures in mammography.

2. Interpreting Physician

Responsibilities of all mammography radiologists (interpreting physicians) in mammography QC are to

1. Follow the facility procedures for corrective action when asked to interpret images of poor quality. Radiologists should notice and call the radiologic technologist's attention to image quality problems, including artifacts, whenever they occur.

2. Participate in the facility's medical outcomes audit program.

3. Provide documentation of his or her current qualifications to each mammography facility where they practice, according to MQSA and local rules.

> *900.12(d) Quality assurance—general. (1) Responsible individuals. (i) Interpreting physicians. All interpreting physicians interpreting mammograms for the facility shall (A) follow the facility procedures for corrective action when the images they are asked to interpret are of poor quality, and (B) participate in the facility's medical outcomes audit program.*

Digital Mammography Quality Control Manual

B. Medical Physicist's Responsibilities

The medical physicist's responsibilities relate to equipment performance and include

1. Image quality assessment

2. Patient dose evaluation

3. Operator safety concerns

Specific tests are listed in Table 1.

900.12(e) Quality assurance—equipment. (9) Surveys.

(iii) The medical physicist shall prepare a survey report that includes a summary of this review and recommendations for necessary improvements.

(iv) The survey report shall be sent to the facility within 30 days of the date of the survey.

The medical physicist must conduct appropriate tests after installation of new equipment, reassembling existing equipment, replacement of the x-ray tube, or other major service to the mammography unit. (See Table 1.)

900.12(e) Quality assurance—equipment. (10) Mammography equipment evaluations. Additional evaluations of mammography units or image processors shall be conducted whenever a new unit or processor is installed, a unit or processor is disassembled and reassembled at the same or a new location, or major components of a mammography unit or processor equipment are changed or repaired. All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing. The mammography equipment evaluation shall be performed by a medical physicist or by an individual under the direct supervision of a medical physicist.

Facilities should purchase mammography units with features and accessories appropriate to their practice and workflow needs. Assuring the suitability of new equipment to a particular practice's needs can be facilitated by the thoughtful development and use of purchase specifications. Purchase specifications describe to vendors the type of equipment that is desired by the purchaser. The help of the facility's medical physicist is essential in developing effective purchase specifications. The use of detailed purchase specifications with vendors usually results in the vendors responding with detailed technical and performance specifications for the purchaser's use in the final selection of equipment and as a basis for quantitative performance specifications to be compared with measurements on the mammography equipment

during acceptance testing. The purchase should be made contingent on satisfactory performance during acceptance testing.

Acceptance testing is typically more rigorous than the QC program detailed here and must be conducted by a qualified medical physicist. This QC program is intended to document consistency of performance after the unit has been accepted and put into service.

C. Radiologic Technologist's Responsibilities

The radiologic technologist's general responsibilities center on patient care and image quality. More specifically, these include

1. Patient positioning

2. Compression

3. Image production

4. Image processing

5. Infection control

The specific QC procedures to be conducted by the QC technologist are listed in Table 1. Radiologists should notice and call the radiologic technologist's attention to image quality problems, including artifacts, whenever they occur.

900.12(d) Quality assurance—general. (1) Responsible individuals. (iv) Quality control technologist. Responsibility for all individual tasks within the quality assurance program not assigned to the lead interpreting physician or the medical physicist shall be assigned to a quality control technologist(s). The tasks are to be performed by the quality control technologist or by other personnel qualified to perform the tasks. When other personnel are utilized for these tasks, the quality control technologist shall ensure that the tasks are completed in such a way as to meet the MQSA QA requirements.

QC Tests, Frequencies, and Timeframes for Corrective Action

Before a facility QC technologist may start using the procedures in the ACR Digital Mammography QC Manual for the first time on a unit, the medical physicist must first conduct an annual survey of the digital mammography unit and display devices using the manual and the ACR Digital Mammography Phantom. This is important to provide testing techniques and procedures for the QC technologist to use during routine QC. After this is done, the QC technologist may start performing routine QC using the ACR Digital Mammography QC Manual. For current information and more details on transitioning to the ACR Digital Mammography QC Manual, visit the Digital Mammography QC Manual: Frequently Asked Questions on the ACR Digital Mammography QC Manual Resources website.

> **Important:** Before a facility may start using the procedures in the ACR Digital Mammography QC Manual for the first time on a unit, the medical physicist must first conduct an annual survey of the digital mammography unit and display devices using the manual and the ACR Digital Mammography Phantom.

The minimum frequencies for both the technologist and medical physicist tests are listed in Table 1. The tests designated for DBT must be conducted in addition to the applicable tests for the 2D full-field digital mammography system. *Applicable 2D tests must be performed whether or not the system is used for 2D imaging since they test system components which may impact DBT performance.*

> **Important:** All applicable 2D tests must be performed in additional to the DBT tests for each system.

If the DBT system employs an "add-on" device, applicable 2D tests must be repeated with the "add-on" device in place.

The technologist and medical physicist will use the same forms they use for most of the digital mammography tests to record the data and results of the DBT tests. The previous digital mammography forms have been revised to allow for this. New forms have been added for DBT-unique tests (e.g., DBT Volume Coverage).

If problems are occurring or if equipment is unstable, it may be necessary to carry out some or all tests more frequently to identify problems before they affect clinical image quality or patient safety. If the QC program is just being initiated, it may be valuable to carry out QC tests more frequently for the first few months. This will provide the QC technologist with more experience in a shorter period of time and also will provide better baseline data regarding the reliability of imaging equipment. The necessity of performing tests designated as "Optional" or "If applicable" is left to discretion of the QAC, especially the lead interpreting radiologist,

QC technologist, and medical physicist team, who are most familiar with the facility's equipment and the quality needs of the mammography practice.

In addition to performing the mammography QC tests at the minimum frequencies indicated, tests also should be carried out for new equipment, both when problems are suspected and after any service or preventive maintenance. For example, the compression test should be carried out both when a new x-ray system is installed and after any service adjustment of compression force.

If any test fails, it is critical that the set up and techniques employed in the test be checked and the test repeated to verify performance before initiating corrective action. Upon confirmation of test failure, the MQSA Final Rule requires that the source of the problem be identified and corrective action be taken. In some cases, if test results fall outside of action limits, MQSA requires that the source of the problem be identified and corrective action taken *before* any further examinations are performed or any films are processed using the component of the mammography system that failed the test. Other test failures must be corrected within 30 days of the test date (Table 1).

Table 1. Digital Mammography (2D and DBT) Quality Control Tests

Test	Minimum Frequency	Corrective Action Timeframe
Technologist Tests		
1. ACR DM Phantom Image Quality	Weekly	Before clinical use
2. Computed Radiography Cassette Erasure (if applicable)	Weekly	Before clinical use
3. Compression Thickness Indicator	Monthly	Within 30 days
4. Visual Checklist	Monthly	Critical items: before clinical use; less critical items: within 30 days
5. Acquisition Workstation Monitor QC	Monthly	Within 30 days; before clinical use for severe defects
6. Radiologist Workstation Monitor QC	Monthly	Within 30 days; before clinical use for severe defects
7. Film Printer QC (if applicable)	Monthly	Before clinical use
8. Viewbox Cleanliness (if applicable)	Monthly	Before clinical use
9. Facility QC Review	Quarterly	Not applicable
10. Compression Force	Semiannual	Before clinical use
11. Manufacturer Calibrations (if applicable)	Mfr. Recommendation	Before clinical use
Optional - Repeat Analysis	As Needed	Within 30 days after analysis
Optional - System QC for Radiologist	As Needed	Within 30 days; before clinical use for severe artifacts
Optional - Radiologist Image Quality Feedback	As Needed	Not applicable
Medical Physicist Tests		
1. Mammography Equipment Evaluation (MEE) - MQSA Requirements	MEE	Before clinical use
2. ACR DM Phantom Image Quality	MEE and Annual	Before clinical use
3. DBT Z Resolution	MEE and Annual	Within 30 days
4. Spatial Resolution	MEE and Annual	Within 30 days
5. DBT Volume Coverage	MEE and Annual	Before clinical use
6. Automatic Exposure Control System Performance	MEE and Annual	Within 30 days
7. Average Glandular Dose	MEE and Annual	Before clinical use
8. Unit Checklist	MEE and Annual	Critical items: before clinical use; less critical items: within 30 days
9. Computed Radiography (if applicable)	MEE and Annual	Before clinical use
10. Acquisition Workstation Monitor QC	MEE and Annual	Within 30 days; before clinical use for severe defects
11. Radiologist Workstation Monitor QC	MEE and Annual	Within 30 days; before clinical use for severe defects
12. Film Printer QC (if applicable)	MEE and Annual	Before clinical use
13. Evaluation of Site's Technologist QC Program	Annual	Within 30 days
14. Evaluation of Display Device Technologist QC Program	Annual	Within 30 days
15. Manufacturer Calibrations (if applicable)	Mfr. Recommendation	Before clinical use
16. Collimation Assessment	MEE or Troubleshooting Annual (DBT only)	Within 30 days
MEE or Troubleshooting - Beam Quality (Half-Value Layer) Assessment	MEE or Troubleshooting	Before clinical use
MEE or Troubleshooting - kVp Accuracy and Reproducibility	MEE or Troubleshooting	MEE: before clinical use; troubleshooting: within 30 days
Troubleshooting - Ghost Image Evaluation	Troubleshooting	Before clinical use
Troubleshooting - Viewbox Luminance	Troubleshooting	Not applicable

V. QC Tests, Frequencies, and Timeframes for Corrective Action

> **Important:** Corrective action for any test performed for MEEs must be made before clinical use.

Documentation of QC and corrective action is essential. Data forms are provided in this manual and may be copied or downloaded from the ACR Digital Mammography QC Manual Resources website for use in performing and documenting the digital mammography QC program. QC data forms may be stored as either hardcopy (for example, in a notebook) or as a file on the computer. For some tests, it may be preferable to use software provided by equipment manufacturers or third-party vendors that can accumulate, trend, and print out QC data. However, the QC technologist and medical physicist must verify that all required information is available from such software before use. If QC records are stored electronically, all records should be periodically backed up to prevent loss.

> **Note:** If QC records are stored electronically, all records should be periodically backed up to prevent loss.

For detailed guidance on the FDA's requirements for record retention, see Quality Assurance Records and Retention of Personnel Records in the FDA Policy Guidance Help System. All documentation must be made available to MQSA inspectors during the annual inspection and the facility's accreditation body upon application and request.

> *900.12(d) Quality assurance—general. (2) Quality assurance records. The lead interpreting physician, quality control technologist, and medical physicist shall ensure that records concerning mammography technique and procedures, quality control (including monitoring data, problems detected by analysis of that data, corrective actions, and the effectiveness of the corrective actions), safety, protection and employee qualifications to meet assigned quality assurance tasks are properly maintained and updated. These quality control records shall be kept for each test specified in paragraphs (e) and (f) of this section 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.*

Table 2 provides a complete list of all the digital mammography tests and summarizes those tests that must be performed (as applicable) for the ***modes that the facility uses clinically on its 2D and DBT systems.***

Digital Mammography Quality Control Manual

Table 2. Required Tests for Imaging Modes Used on 2D and DBT Systems

Test	System Used for Both 2D and DBT Acquisition			System Used for DBT Acquisition Only
	2D	2D w/Add-on DBT Device	DBT	DBT
Technologist Tests				
1. ACR DM Phantom Image Quality	✓*	✓	✓	✓ & 2D*
2. Computed Radiography Cassette Erasure (*if applicable*)	✓*			
3. Compression Thickness Indicator	✓*	✓*		✓*
4. Visual Checklist	✓*	✓	✓	✓
5. Acquisition Workstation Monitor QC	✓*			✓*
6. Radiologist Workstation Monitor QC	✓*			✓*
7. Film Printer QC (*if applicable*)	✓*			✓*
8. Viewbox Cleanliness (*if applicable*)	✓*			✓*
9. Facility QC Review	✓*	✓	✓	✓
10. Compression Force	✓*	✓*		✓*
11. Manufacturer Calibrations (*if applicable*)	✓*	✓	✓	✓
Medical Physicist Tests				
1. Mammography Equipment Evaluation (MEE)	✓*			✓*
2. ACR DM Phantom Image Quality	✓*	✓	✓	✓ & 2D*
3. DBT Z Resolution			✓	✓
4. Spatial Resolution	✓*	✓	✓	✓
5. DBT Volume Coverage			✓	✓
6. Automatic Exposure Control System Performance	✓*	✓	✓	✓
7. Average Glandular Dose	✓*	✓	✓	✓
8. Unit Checklist	✓*	✓	✓	✓
9. Computed Radiography (*if applicable*)	✓*			
10. Acquisition Workstation Monitor QC	✓*			✓*
11. Radiologist Workstation Monitor QC	✓*			✓*
12. Film Printer QC (*if applicable*)	✓*			✓*
13. Evaluation of Site's Technologist QC Program	✓*	✓	✓	✓
14. Evaluation of Display Device Technologist QC Program	✓*			✓*
15. Manufacturer Calibrations (*if applicable*)	✓*	✓	✓	✓
16. Collimation Assessment	✓*	✓*	✓	✓
MEE or Troubleshooting - Beam Quality (Half-Value Layer [HVL]) Assessment	✓*TF			✓*TF
MEE or Troubleshooting - kVp Accuracy and Reproducibility	✓*TF			✓*TF
Follow the procedures and frequency outlined for 2D QC				
TFHVL and kVp tests must include kVp, target, and filter combinations used for DBT				

As an example, if a facility has a system that performs 2D, 2D with an add-on DBT device, and DBT, both the technologist and the medical physicist must evaluate phantom images for the 2D, 2D with an add-on DBT device, and DBT imaging modes. However, the Acquisition Workstation Monitor QC and Radiologist Workstation Monitor QC tests are only required to be evaluated using the 2D procedure and images.

If a system is not used for 2D mammography and is only used for DBT imaging, the technologist and the medical physicist are required to evaluate phantom images for the DBT *and 2D* imaging modes. For the Acquisition Workstation and Radiologist Workstation QC Tests, the 2D procedures should be used to evaluate the 2D image.

Conclusion

The public expects our profession to provide accurately interpreted mammograms of the highest quality. Only a strong, consistent commitment to QA by all parties involved in performing mammography will validate that trust.

RADIOLOGIST'S SECTION

References

A. Downloadable from the ACR Website (**www.acr.org**)

- [ACR Mammography Accreditation Program](#)

- [ACR Digital Mammography QC Manual Resources](#)

- Destouet JM, Bassett LW, Yaffe MJ, Butler PF, Wilcox PA: [The ACR's mammography accreditation program: ten years of experience since MQSA](#) JACR 2:7, 585-594, 2005.

- [ACR Appropriateness® Criteria - Breast Imaging](#)

- [ACR BI-RADS® Atlas](#)

- [ACR Practice Parameter for the Performance of Screening and Diagnostic Mammography](#)

- [ACR–AAPM–SIIM Practice Parameter for Determinants of Image Quality in Digital Mammography](#)

B. References

1. Taplin SH, Rutter CM, Finder C, Mandelson MT, Houn F, White E. Screening mammography: clinical image quality and the risk of interval breast cancer. *AJR Am J Roentgenol.* 2002;178:797-803.

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4. Department of Health and Human Services. [FDA Mammography Quality Standards, Final Rule.](#) *Fed Regist.* 1997;62(208):55852-55994.

5. American Society of Radiologic Technologists. [ASRT Continuing Education Designed for Mammographers.](#)

6. Sickles EA, D'Orsi CJ. [ACR BI-RADS® Follow-up and Outcome Monitoring.](#) In: ACR BI-RADS® Atlas, Breast Imaging Reporting and Data System. Reston, VA: American College of Radiology; 2013.

7. D'Orsi CJ, Sickles EA, Mendelson EB, et al. [ACR BI-RADS® Atlas, Breast Imaging Reporting and Data System.](#) Reston, VA: American College of Radiology; 2013.

2018
Digital Mammography

QUALITY CONTROL MANUAL

Radiologic Technologist's Section

Contents

**RADIOLOGIC
TECHNOLOGIST'S SECTION**

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Revisions

Date	Page(s)	Section	Description of Revisions
November 2018			2nd edition with digital breast tomosynthesis QC
May 2020	29	Introduction	Clarified FDA position regarding QC for contrast enhancement mammography systems
May 2020	39-44	1. ACR Digital Mammography (DM) Phantom Image Quality	Clarified that phantom QC needs to be performed using clinical system settings
May 2020	74	11. Manufacturer Calibrations	Clarified Objectives

RADIOLOGIC TECHNOLOGIST'S SECTION

INTRODUCTION

A. MQSA and Quality Control

For the purposes of this manual, quality control (QC) is defined as the routine performance and interpretation of equipment function tests and of the corrective actions taken. The objective of QC is to detect, identify, and correct equipment-related problems before they have a deleterious effect on clinical images. Due to their day-to-day contact and familiarity with their particular mammography equipment, radiologic technologists are the front line of defense against potential imaging problems. The purpose of this section of the manual is to provide effective and consistent methods of detecting and identifying image quality problems. Together with the radiologist, the medical physicist, and equipment service personnel, radiologic technologists can eliminate these problems before patient care is affected.

The 1999 American College of Radiology (ACR) Mammography Quality Control Manual was developed specifically for screen-film mammography to assist facility staff in complying with the Mammography Quality Standards Act (MQSA) Final Rule, which went into effect on April 28, 1999 [1]. Since that time, screen-film has been almost entirely replaced by digital mammography. Furthermore, a growing number of digital mammography systems include digital breast tomosynthesis (DBT) capability. The 1998 MQSA Final Rule specifies that "For systems with image receptor modalities other than screen-film [i.e., digital or DBT], the quality assurance program shall be 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." See the MQSA Policy Guidance Help System by the Food and Drug Administration (FDA) for more information [2].

> *900.12(e) Quality assurance—equipment. (6) Quality control tests—other modalities. 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, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems in paragraph (e)(5)(vi) of this section.*

As of the publication date, five models and manufacturers of DBT systems have been cleared by the Food and Drug Administration for sale in the U.S. [3], each with its own QC manual. (Over 30 models and manufacturers of digital mammography systems have been cleared.) These manuals all have different manufacturer- and model-specific tests, procedures, frequencies, and performance criteria. This variation is necessary in most cases to accommodate the design differences inherent to each device. Many of the tests, however, could be made more consistent across platforms. The ACR Digital Mammography Quality Control Manual has been designed to create a generic digital mammography QC

program by providing uniform test procedures, performance criteria, and minimum test frequencies that can be used for all manufacturers and models. Due to the unique manufacturer-specific design of certain equipment features, a few tests and criteria in the manual refer to the instructions and performance levels established by the manufacturer. For example, the Manufacturer Calibrations test/procedure (if available) is software-dependent and thus unique to each manufacturer.

Some digital mammography systems include contrast enhancement. The FDA has approved the use of the new ACR Digital Mammography QC Manual for digital mammography systems with contrast enhancement. *Facilities with contrast enhancement systems may follow this manual for QC of the 2D and DBT applications of these units, but should follow manufacturer QC procedures for contrast enhancement applications.*

> **Note:** Facilities *may* use the new ACR Digital Mammography QC Manual for digital mammography systems with contrast enhancement, but only for the 2D and DBT applications. Facilities should follow manufacturer QC procedures for contrast enhancement applications.

To legally allow facilities to use these new procedures instead of the procedures required by their system's QC manual, the ACR applied to the FDA and was granted an amendment to the existing Alternative Standard for Using the Quality Assurance Program Recommended by the ACR Digital Mammography Quality Control Manual for Full-Field Digital Mammography Systems, for Systems without Advanced Imaging. The amended alternative standard specifies that facilities must use the approved ACR Digital Mammography (DM) Phantom in concert with all of the applicable manual's procedures, performance criteria, and minimum test frequencies for both 2D and DBT QC. This phantom has been designed to cover most of the detector area and provide the same attenuation as the small ACR mammography phantom used in the 1999 Mammography Quality Control Manual, which approximates a 4.2 cm thick compressed breast consisting of 50% glandular and 50% adipose tissue. If you have multiple phantoms, use the same phantom each time on a given unit (Figure 1).

Figure 1. ACR DM Phantom. (*Different manufacturers' phantoms may appear slightly different. Use of one manufacturer's phantom photo does not imply ACR endorsement of one phantom manufacturer over another.*)

If a facility chooses to follow the ACR manual for its QC program, it is no longer required to follow its manufacturer's QC manual (for 2D or DBT). However, facilities should maintain their manufacturer's QC manual to refer to when performing ACR-required calibration or troubleshooting tests.

Facilities *may not* use the new procedures with the small ACR mammography phantom or use the newly developed ACR DM Phantom with the old test procedures. *The ACR DM Phantom was explicitly designed as a tool for the ACR Digital Mammography Quality Control Manual (for both 2D and DBT QC) and for the ACR Mammography Accreditation Program to meet FDA MQSA phantom image quality and dose requirements.*

> **Note:** The ACR Digital Mammography Phantom is required for the majority of the QC tests in this manual. ACR-approved manufacturers of the ACR Digital Mammography Phantom are listed on the ACR website. (For more information, visit https://www.acraccreditation.org/Resources/Digital-Mammography-QC-Manual-Resources.)

Although the ACR DM Phantom is the primary phantom used with this manual, facilities should not discard any manufacturer-provided phantoms since they may be needed for manufacturer-specified calibrations or service personnel testing.

The digital mammography test procedures and forms were designed to simplify the conduct, recording, and evaluation of digital mammography QC for technologists. Commonly performed tests that seldom, if

ever, identified deficiencies were eliminated; low-yield tests had their frequencies reduced. Forms were developed to aid technologists in documenting their results.

One of the major and most important aspects of the manual is a quarterly, documented review of the QC program performed by the lead interpreting radiologist, the facility manager, and the QC technologist. (See Facility QC Review) Although many high-quality facilities have such a review in place already, experience from the ACR Mammography Accreditation Program has demonstrated that lack of communication among the radiologists, managers, technologists, and medical physicists is a frequent underlying cause of poor-quality mammography. A structured review process can be beneficial to all facilities. These reviews may be done in person or via teleconference or video conference.

In addition, several optional procedures and forms are provided to aid in quality improvement. The System QC for Radiologist test is a structured tool allowing the radiologist to work with the technologist in evaluating the entire system performance at the radiologist workstation using a standard clinical image selected by the radiologist. The Radiologist Image Quality Feedback procedure and form enables the interpreting radiologist to notify the technical staff when asked to interpret sub-optimal cases (and also provides a way to commend the technical staff for exceptional quality). Using this procedure also helps facilities comply with the MQSA Final Rule that "All interpreting physicians interpreting mammograms for the facility shall follow the facility procedures for corrective action when the images they are asked to interpret are of poor quality."

The manual also includes several management forms to help organize and reference important information. The ACR Techniques and Summaries form provides a location to record techniques used for routine QC testing. The manual also provides a central location to record all corrective action for the digital mammography systems in the Corrective Action Log. (This makes it easier to document these important actions and have it available for review by the management, the lead interpreting radiologist, the medical physicist, and MQSA inspectors.) A Facility Offsite Display Locations form creates a convenient list of all locations of radiologist workstations and film printers (*if applicable*) to help with the management of all offsite QC.

For each of the required technologist QC tests included in this manual, the purpose and frequency of each test is clearly stated. The equipment and materials required to carry out each test are listed, and a step-by-step procedure is provided. Note that other methodologies for these tests may be used, provided that they yield the same results as the methodologies provided in this manual and have been ***reviewed and approved*** by the facility's medical physicist. Following each procedure is a discussion of precautions and caveats. Performance criteria are provided along with suggestions for the types of corrective actions that may be needed to resolve problems.

RADIOLOGIC TECHNOLOGIST'S SECTION

Relevant MQSA regulations are provided to supplement responsibilities and tests in this ACR Digital Mammography Quality Control Manual if they apply.

B. Responsibilities

The MQSA Final Rule requires that the facility's lead interpreting physician (typically a radiologist) has the general responsibility of ensuring that the quality assurance program meets all requirements.

In a facility where more than one technologist does mammography, one technologist must be assigned the responsibilities of QC (the QC technologist). Other qualified individuals may perform specific QC tests, but they must be reviewed and evaluated by the primary QC technologist. The primary QC technologist is responsible for ensuring that QC tasks are done properly by standardizing test methodology, reviewing all data, overseeing repeat testing before calling the medical physicist or service personnel, and conferring with the radiologist and medical physicist.

> *900.12(d) Quality assurance—general. (1) Responsible individuals. (iv) Quality control technologist. Responsibility for all individual tasks within the quality assurance program not assigned to the lead interpreting physician or the medical physicist shall be assigned to a quality control technologist(s). The tasks are to be performed by the quality control technologist or by other personnel qualified to perform the tasks. When other personnel are utilized for these tasks, the quality control technologist shall ensure that the tasks are completed in such a way as to meet the MQSA quality assurance requirements.*

The medical physicist is required to conduct a mammography equipment evaluation (MEE) of new equipment and after major repairs. This survey must be done and all relevant tests must pass prior to use of digital mammography equipment on patients. The medical physicist is also required to perform an annual survey on each unit. (An occasional period of up to 14 months between surveys is acceptable.) During this annual survey, the medical physicist must at least review the technologist's QC test results and provide written recommendations if there are problems or suggestions for improvement. The facility should provide this detailed information to the equipment service engineer to facilitate repair. Review of the technologist's QC program by the radiologist and medical physicist ensures that the QC program is carried out consistently and provides oversight to make sure that changes in image quality are not inadvertently overlooked.

> **Note:** If the medical physicist determines that there is need for corrective action, the facility should provide a copy of its medical physicist's full report to its equipment service engineer.

Mammography team members are strongly encouraged to review other sections of the ACR Digital Mammography QC Manual that are not directed towards them. For example, the radiologist should be familiar with Technologist's Test Facility QC Review and the Technologist's Optional Tests System QC for Radiologist and Radiologist Image Quality Feedback. The radiologic technologist should review the Medical Physicist's Test Evaluation of Site's Technologist QC Program and Evaluation of Display Device Technologist QC Program. The medical physicist should be familiar with all of the radiologic technologist's tests. The radiologist, medical physicist, and QC technologist, working together as a team, are the keys to providing optimum quality mammography images, which will ultimately provide the best medical care possible to the patient.

> **Note:** Facility management, along with the QC technologist and medical physicist, should work together to ensure that all "display devices" are QC'd and reviewed properly.

C. QC Tests, Frequencies, and Timeframes for Corrective Action

Before a facility QC technologist may start using the procedures in the ACR Digital Mammography QC Manual for the first time on a unit, the medical physicist must first conduct an annual survey of the digital mammography unit and display devices using the manual and the ACR Digital Mammography Phantom. This is important to provide testing techniques and procedures for the QC technologist to use during routine QC. After this is done, the QC technologist may start performing routine QC using the ACR Digital Mammography QC Manual. For current information and more details on transitioning to the ACR Digital Mammography QC Manual, visit the Digital Mammography QC Manual: Frequently Asked Questions on the ACR Digital Mammography QC Manual Resources website.

> **Important:** Before a facility may start using the procedures in the ACR Digital Mammography QC Manual for the first time on a unit, the medical physicist must first conduct an annual survey of the digital mammography unit and display devices using the manual and the ACR Digital Mammography Phantom.

The minimum frequencies for both the technologist and medical physicist tests are listed in Table 1. The tests designated for DBT must be conducted in addition to the applicable tests for the 2D full-field digital mammography system. *Applicable 2D tests must be performed whether or not the system is used for 2D imaging since they test system components that may impact DBT performance.*

> **Important:** All applicable 2D tests must be performed in additional to the DBT tests for each system.

If the DBT system employs an "add-on" device, applicable 2D tests must be repeated with the "add-on" device in place.

The technologist and medical physicist will use the same forms they use for most of the digital mammography tests to record the data and results of the DBT tests. The previous digital mammography forms have been revised to allow for this. New forms have been added for DBT-unique tests (e.g., DBT Volume Coverage).

If problems are occurring or if equipment is unstable, it may be necessary to carry out some or all tests more frequently to identify problems before they affect clinical image quality or patient safety. If the QC program is just being initiated, it may be valuable to carry out QC tests more frequently for the first few months. This will provide the QC technologist with more experience in a shorter period of time and also will provide better baseline data regarding the reliability of imaging equipment. The necessity of performing tests designated as "Optional" or "If applicable" is left to discretion of the Quality Assurance Committee, especially the lead interpreting radiologist, QC technologist, and medical physicist team, who are most familiar with the facility's equipment and the quality needs of the mammography practice.

In addition to performing the mammography QC tests at the minimum frequencies indicated, tests also should be carried out for new equipment, both when problems are suspected and after any service or preventive maintenance. For example, the compression test should be carried out both when a new x-ray system is installed and after any service adjustment of compression force.

If any test fails, it is critical that the set up and techniques employed in the test be checked and the test repeated to verify performance before initiating corrective action. Upon confirmation of test failure, the MQSA Final Rule requires that the source of the problem be identified and corrective action be taken. In some cases, if test results fall outside of action limits, MQSA requires that the source of the problem be identified and corrective action taken *before* any further examinations are performed or any films are processed using the component of the mammography system that failed the test. Other test failures must be corrected within 30 days of the test date (Table 1).

Digital Mammography Quality Control Manual

Table 1. Digital Mammography (2D and DBT) Quality Control Tests

Test	Minimum Frequency	Corrective Action Timeframe
Technologist Tests		
1. ACR DM Phantom Image Quality	Weekly	Before clinical use
2. Computed Radiography Cassette Erasure (*if applicable*)	Weekly	Before clinical use
3. Compression Thickness Indicator	Monthly	Within 30 days
4. Visual Checklist	Monthly	Critical items: before clinical use; less critical items: within 30 days
5. Acquisition Workstation Monitor QC	Monthly	Within 30 days; before clinical use for severe defects
6. Radiologist Workstation Monitor QC	Monthly	Within 30 days; before clinical use for severe defects
7. Film Printer QC (*if applicable*)	Monthly	Before clinical use
8. Viewbox Cleanliness (*if applicable*)	Monthly	Before clinical use
9. Facility QC Review	Quarterly	Not applicable
10. Compression Force	Semiannual	Before clinical use
11. Manufacturer Calibrations (*if applicable*)	Mfr. Recommendation	Before clinical use
Optional - Repeat Analysis	As Needed	Within 30 days after analysis
Optional - System QC for Radiologist	As Needed	Within 30 days; before clinical use for severe artifacts
Optional - Radiologist Image Quality Feedback	As Needed	Not applicable
Medical Physicist Tests		
1. Mammography Equipment Evaluation (MEE) - MQSA Requirements	MEE	Before clinical use
2. ACR DM Phantom Image Quality	MEE and Annual	Before clinical use
3. DBT Z Resolution	MEE and Annual	Within 30 days
4. Spatial Resolution	MEE and Annual	Within 30 days
5. DBT Volume Coverage	MEE and Annual	Before clinical use
6. Automatic Exposure Control System Performance	MEE and Annual	Within 30 days
7. Average Glandular Dose	MEE and Annual	Before clinical use
8. Unit Checklist	MEE and Annual	Critical items: before clinical use; less critical items: within 30 days
9. Computed Radiography (*if applicable*)	MEE and Annual	Before clinical use
10. Acquisition Workstation Monitor QC	MEE and Annual	Within 30 days; before clinical use for severe defects
11 Radiologist Workstation Monitor QC	MEE and Annual	Within 30 days; before clinical use for severe defects
12. Film Printer QC (*if applicable*)	MEE and Annual	Before clinical use
13. Evaluation of Site's Technologist QC Program	Annual	Within 30 days
14. Evaluation of Display Device Technologist QC Program	Annual	Within 30 days
15. Manufacturer Calibrations (*if applicable*)	Mfr. Recommendation	Before clinical use
16. Collimation Assessment	MEE or Troubleshooting Annual (DBT only)	Within 30 days
MEE or Troubleshooting - Beam Quality (Half-Value Layer) Assessment	MEE or Troubleshooting	Before clinical use
MEE or Troubleshooting - kVp Accuracy and Reproducibility	MEE or Troubleshooting	MEE: before clinical use; troubleshooting: within 30 days
Troubleshooting - Ghost Image Evaluation	Troubleshooting	Before clinical use
Troubleshooting - Viewbox Luminance	Troubleshooting	Not applicable

II. Introduction

> **Important:** Corrective action for any test performed for MEEs must be made before clinical use.

Documentation of QC and corrective action is essential. Data forms are provided in this manual and may be copied or downloaded from the ACR Digital Mammography QC Manual Resources website for use in performing and documenting the digital mammography QC program. QC data forms may be stored as either hardcopy (for example, in a notebook) or as a file on the computer. For some tests, it may be preferable to use software provided by equipment manufacturers or third-party vendors that can accumulate, trend, and print out QC data. However, the QC technologist and medical physicist must verify that all required information is available from such software before use. If QC records are stored electronically, all records should be periodically backed up to prevent loss.

> **Note:** If QC records are stored electronically, all records should be periodically backed up to prevent loss.

For detailed guidance on the FDA's requirements for record retention, see Quality Assurance Records and Retention of Personnel Records in the FDA's MQSA Policy Guidance Help System. All documentation must be made available to MQSA inspectors during the annual inspection and the facility's accreditation body upon application and request.

> *900.12(d) Quality assurance—general. (2) Quality assurance records. The lead interpreting physician, quality control technologist, and medical physicist shall ensure that records concerning mammography technique and procedures, quality control (including monitoring data, problems detected by analysis of that data, corrective actions, and the effectiveness of the corrective actions), safety, protection and employee qualifications to meet assigned quality assurance tasks are properly maintained and updated. These quality control records shall be kept for each test specified in paragraphs (e) and (f) of this section 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.*

Table 2 provides a complete list of all the digital mammography tests and summarizes those tests that must be performed (as applicable) for the ***modes that the facility uses clinically on its 2D and DBT systems.***

Digital Mammography Quality Control Manual

Table 2. Required Tests for Imaging Modes Used on 2D and DBT Systems

	Imaging Modes to Test			
	System Used for Both 2D and DBT Acquisition			System Used for DBT Acquisition Only
Test	2D	2D w/Add-On DBT Device	DBT	DBT
Technologist Tests				
1. ACR DM Phantom Image Quality	✓*	✓	✓	✓ & 2D*
2. Computed Radiography Cassette Erasure (*if applicable*)	✓*			
3. Compression Thickness Indicator	✓*	✓*		✓*
4. Visual Checklist	✓*	✓	✓	✓
5. Acquisition Workstation Monitor QC	✓*			✓*
6. Radiologist Workstation Monitor QC	✓*			✓*
7. Film Printer QC (*if applicable*)	✓*			✓*
8. Viewbox Cleanliness (*if applicable*)	✓*			✓*
9. Facility QC Review	✓*	✓	✓	✓
10. Compression Force	✓*	✓*		✓*
11. Manufacturer Calibrations (*if applicable*)	✓*	✓	✓	✓
Medical Physicist Tests				
1. Mammography Equipment Evaluation (MEE)	✓*			✓*
2. ACR DM Phantom Image Quality	✓*	✓	✓	✓ & 2D*
3. DBT Z Resolution			✓	✓
4. Spatial Resolution	✓*	✓	✓	✓
5. DBT Volume Coverage			✓	✓
6. Automatic Exposure Control System Performance	✓*	✓	✓	✓
7. Average Glandular Dose	✓*	✓	✓	✓
8. Unit Checklist	✓*	✓	✓	✓
9. Computed Radiography (*if applicable*)	✓*			
10. Acquisition Workstation Monitor QC	✓*			✓*
11. Radiologist Workstation Monitor QC	✓*			✓*
12. Film Printer QC (*if applicable*)	✓*			✓*
13. Evaluation of Site's Technologist QC Program	✓*	✓	✓	✓
14. Evaluation of Display Device Technologist QC Program	✓*			✓*
15. Manufacturer Calibrations (*if applicable*)	✓*	✓	✓	✓
16. Collimation Assessment	✓*	✓*	✓	✓
MEE or Troubleshooting - Beam Quality (Half-Value Layer [HVL]) Assessment	✓*TF			✓*TF
MEE or Troubleshooting - kVp Accuracy and Reproducibility	✓*TF			✓*TF
*Follow the procedures and frequency outlined for 2D QC				
TFHVL and kVp tests must include kVp, target, and filter combinations used for DBT				

RADIOLOGIC TECHNOLOGIST'S SECTION

As an example, if a facility has a system that performs 2D, 2D with an add-on DBT device, and DBT, both the technologist and the medical physicist must evaluate phantom images for the 2D, 2D with an add-on DBT device, and DBT imaging modes. However, the Acquisition Workstation Monitor QC and Radiologist Workstation Monitor QC tests are only required to be evaluated using the 2D procedure and images.

If a system is not used for 2D mammography and is only used for DBT imaging, the technologist and the medical physicist are required to evaluate phantom images for the DBT *and 2D* imaging modes. For the Acquisition Workstation and Radiologist Workstation QC Tests, the 2D procedures should be used to evaluate the 2D image.

Technologist Quality Control

A. Test Procedures

1. ACR Digital Mammography (DM) Phantom Image Quality

OBJECTIVES

To ensure that the image acquisition chain is consistently producing adequate image quality and that artifacts are not clinically significant.

FREQUENCY

Weekly, after relevant service, and upon installation of new equipment (before clinical use).

TEST EQUIPMENT

- ACR DM Phantom (required). This phantom has been designed to cover the majority of the DM detector area and provide the same attenuation as the small ACR mammography phantom used in the 1999 Mammography Quality Control Manual, which approximates a 4.2 cm thick compressed breast consisting of 50% glandular and 50% adipose tissue. If you have multiple phantoms, use the same phantom each time on a given unit (Figure 1).

- ACR DM Phantom Image Quality form.

TEST PROCEDURE

> **Important:** Do **not** follow the phantom imaging instructions or technical factors provided in the manufacturer's QC manual. Be sure to follow the instructions below. This technique must be the same as that used clinically for a 4.2 cm thick compressed breast consisting of 50% glandular and 50% adipose tissue, as defined by the FDA.

> **Important:** If clinical images are acquired using a combination mode (i.e. 2D plus DBT), then acquire the phantom using the clinical combination mode and evaluate the combination image set (2D and DBT). If clinical 2D and DBT images are acquired using separate acquisition modes, then acquire the 2D and DBT phantom images independently using their respective clinical modes.

> *900.2 Definitions. (uu) Standard breast means a 4.2 centimeter (cm) thick compressed breast consisting of 50 percent glandular and 50 percent adipose tissue.*

ACR DM Phantom Image Acquisition - 2D

1. Initiate an exam at the acquisition workstation as you would for a patient.

2. Use a name and image designation system that allows tracking of QC images. It is important to be able to match and identify the DM unit to the printed image from that same unit. See example below:

   a. Last Name: ACR DM Phantom

   b. First Name: Room 1

   c. Patient ID: "Date of Phantom Acquisition"

   d. Date of Birth: "Date of Phantom Acquisition"

3. Use the largest available image receptor size and corresponding paddle for the ACR DM Phantom image acquisition. Ensure that the type of paddle chosen (e.g., flex or fixed) is the one used for the majority of clinical imaging.

Important: For computed radiography (CR), completely erase the CR cassette prior to obtaining the phantom image.

---

4. Place the ACR DM phantom on the breast support surface as shown in Figure 2. Be sure to position the phantom in the same location each time you do the test to limit exposure variability. Check that

   a. The pink wax insert is on the top side of the phantom and nearer the chest wall

   b. The phantom is centered left-to-right

   c. The edge of the phantom is aligned with the chest wall edge of the digital image receptor

Figure 2. ACR DM Phantom positioned for image acquisition on a 2D system.

5. Manually compress the paddle to approximately 5 decanewtons (daN) or 12 pounds of compression force. It is important to use the same compression force each time for this test. Note that at this compression force, the compressed breast thickness indicator may not read 4.2 cm.

6. At the acquisition workstation, select the imaging mode from the ACR Technique and Procedure Summaries form. This is the imaging mode and technique that would be used for a clinical screening exam acquisition of a 4.2 cm thick compressed breast consisting of 50% glandular and 50% adipose tissue. *If a combination exposure mode (i.e. 2D plus DBT) is most commonly used clinically, use the combination mode for this test, record the data from the 2D and DBT*

acquisitions, and use those images for analysis. If a 2D-only mode is most commonly used clinically for screening, use the 2D-only mode for this procedure step. (If the system uses selectable AEC sensor positions, be sure to use the same position each time the phantom is acquired.)

7. Record or verify the following demographic information at the top of the form:

    a. Facility

    b. Mammography Accreditation Program (MAP) ID number

    c. Room ID

    d. X-ray unit manufacturer and model

8. For each weekly image acquisition, verify and use the following technique parameters in the [ACR Technique and Procedure Summaries](#) form:

    a. AEC mode

    b. Paddle and image receptor size

    c. Paddle type (regular or flex)

    d. Compression force

    e. AEC cell position (if applicable)

    f. Target/filter (if applicable)

    g. kVp (if applicable)

    h. Density setting (if applicable)

> **Note:** These parameters must be used for all subsequent phantom exposures. Consistent exposure parameters will help in troubleshooting problems.

9. Acquire an image of the phantom.

10. Record the following parameters that appear after the exposure on the form:

    a. Target/filter material (e.g., Mo/Mo, W/Ag, etc.)

    b. kVp (e.g., 28)

    c. mAs (e.g., 78.5)

ACR DM Phantom Image Acquisition - DBT

1. Initiate an exam at the acquisition workstation as you would for a patient.

2. Use a name and image designation system that allows tracking of QC images. It is important to be able to match and identify the mammography unit to the printed image from that same unit. See example below:

   a. Last Name: ACR DM Phantom

   b. First Name: Room 1

   c. Patient ID: "Date of Phantom Acquisition"

   d. Date of Birth: "Date of Phantom Acquisition"

3. Use the largest available image receptor size and corresponding paddle for the ACR DM Phantom image acquisition. Ensure that the type of paddle chosen (e.g., flex or fixed) is the one used for the majority of clinical imaging.

4. Place the ACR DM Phantom on the breast support surface as shown in Figure 3. Be sure to position the phantom in the same location each time you do the test to limit exposure variability. Check that

   a. The pink wax insert is on the top side of the phantom and nearer the chest wall

   b. The phantom is centered left-to-right

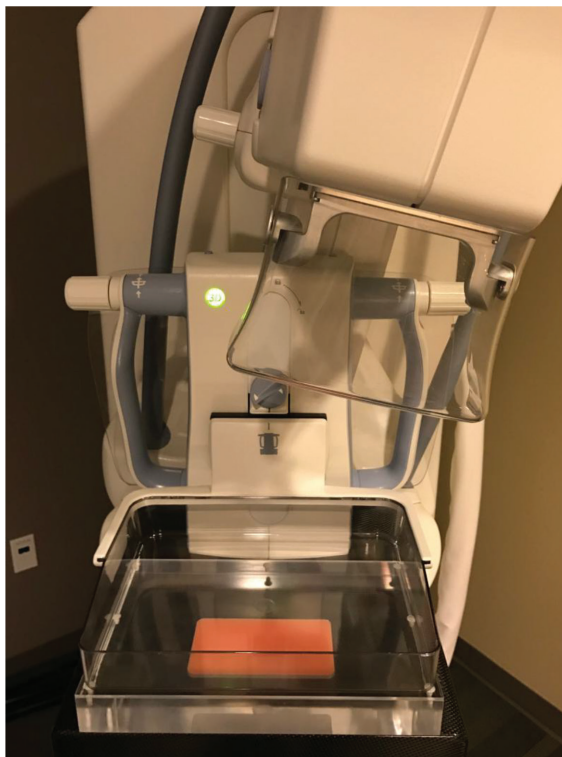   c. The edge of the phantom is aligned with the chest wall edge of the digital image receptor

Figure 3. ACR DM Phantom positioned for image acquisition on a DBT system.

5. Manually compress the paddle to approximately 5 daN or 12 pounds of compression force. It is important to use the same compression force each time for this test. Note that at this compression force, the compressed breast thickness indicator may not read 4.2 cm.

6. At the acquisition workstation, select the DBT imaging mode and technique that would be used for a clinical exam acquisition of a 4.2 cm thick compressed breast consisting of 50% glandular and 50% adipose tissue. *If a combination exposure mode (i.e. 2D plus DBT) is most commonly used clinically, use the combination mode for this test, record the data from the 2D and DBT acquisitions, and use those images for analysis. If a DBT-only mode is most commonly used clinically for screening, use the DBT-only mode for this procedure step.* (If the system uses selectable AEC sensor positions, be sure to use the same position each time the phantom is acquired.)

7. Record or verify the following demographic information at the top of the form:

   a. Facility

   b. MAP ID number

   c. Room ID

   d. X-ray unit manufacturer and model

8. For each weekly image acquisition, verify and use the following technique parameters in the [ACR Technique and Procedure Summaries](#) form:

   a. AEC mode

   b. Paddle and image receptor size

   c. Paddle type (regular or flex)

   d. View or selected image

   e. Compression force

   f. AEC cell position (if applicable)

   g. Target/filter (if applicable)

   h. kVp (if applicable)

   i. Density setting (if applicable)

> **Note:** These parameters must be used for all subsequent phantom exposures. Consistent exposure parameters will help in troubleshooting problems.

9. Acquire an image of the phantom.

10. Record the following parameters that appear after the exposure on the form:

    a. Target/filter material (e.g., Rh/Rh, W/Ag, etc.)

    b. kVp (e.g., 32)

    c. mAs (e.g., 78.5)

11. If the system uses an add-on device for DBT, repeat steps 3 through 11 in 2D mode with the DBT fixture in place.

**DATA ANALYSIS AND INTERPRETATION**

ACR DM Phantom – 2D and DBT

1. If possible, reduce the lighting in the acquisition room to be similar to that in the radiologist's reading room before image evaluation.

2. View the phantom image on the acquisition workstation display monitor. If review is not possible on the acquisition workstation, then review on a radiologist workstation.

> **Note:** Digital mammography phantom images must be "for presentation" (i.e., "processed," not "for processing" or "raw") for viewing and scoring (if applicable).

3. *For DBT images*, scroll to the one slice in which the test objects are best visualized. If "slices" are not available, then proceed to use the slab in which the objects are best visualized. (See the ACR Technique and Procedure Summaries form for guidance.) Record the best visualized slice or slab.

4. Adjust the window width (WW) and window level (WL) settings to optimize visualization of test objects (the test objects will be scored in the next section). It is important not to use unreasonably narrow WWs, which may enhance the appearance of artifacts. For guidance on approximate values, refer to those used by your medical physicist and recorded on the technologist's ACR Technique and Procedure Summaries form.

5. Using approximately the same WW and WL settings used to evaluate the test objects, examine the entire phantom for both broad area artifacts and detailed artifacts. (See Figure 4 for examples of properly windowed ACR digital phantom images without artifacts.)

    a. Broad area artifacts (e.g., non-uniformities, blotches, and streaks) usually are best seen while observing the phantom image as a whole and not in pieces (i.e., not magnified or at full resolution).

      b. Detailed artifacts (e.g., black or white pixels, clusters of pixels, lines, or dust particles) usually are best seen while observing the phantom image at full spatial resolution, where one pixel on the display matches one pixel in the image, or with magnification, using a zoom factor greater than 1.0.

6. See the Artifact Evaluation Guide in Appendix III for examples of "good" or "artifact free" images and some common digital artifacts.

7. Record the absence or presence of artifacts on the form as a pass or fail (P or F).
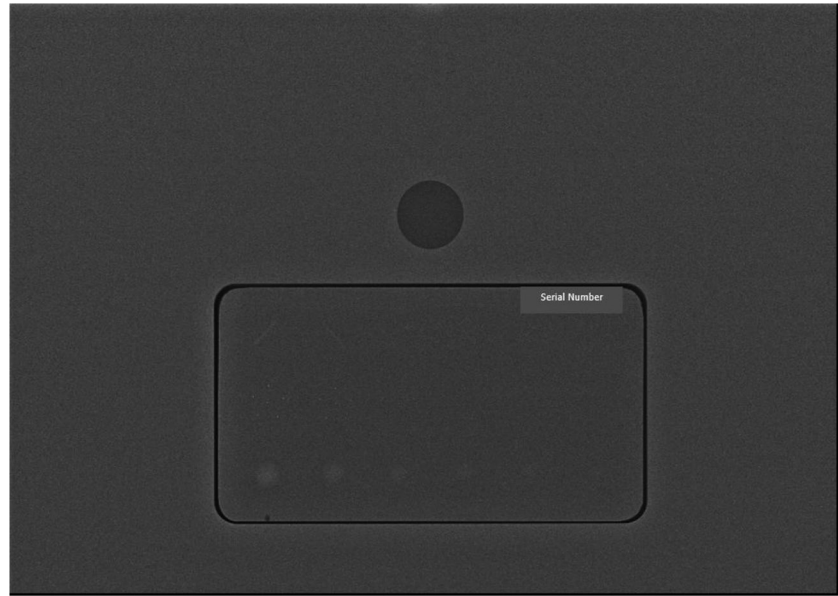
A

B

Figure 4. Images of a properly windowed ACR DM Phantom with no artifacts. A. 2D. B. DBT.

8. To score the phantom image, adjust the WW and WL settings to optimize visualization of test objects. You may need to slightly adjust the WW and WL to obtain optimum visualization of each test object. The zoom or magnification tool should also be used. Use a WW and WL that permit the best visualization of fibers, speck groups, and masses. Using the scoring methods described below, score the number of fibers, speck groups, and masses seen in the phantom and record on the form.

9. Do not deduct for artifacts. (Deducting for artifacts is *no longer part of* the ACR DM Phantom scoring procedure.)

10. Scoring method (see Figure 5 and Table 3):

    a. Count the number of visible objects from the largest object of a given type (fiber, speck group, or mass) downward, until a score of 0 or ½ is reached, then stop counting for that object type. (This step is the same as used in the 1999 Mammography Quality Control Manual [4].) For each test object type, the minimum possible score is 0 objects and the maximum possible score is 6 objects.
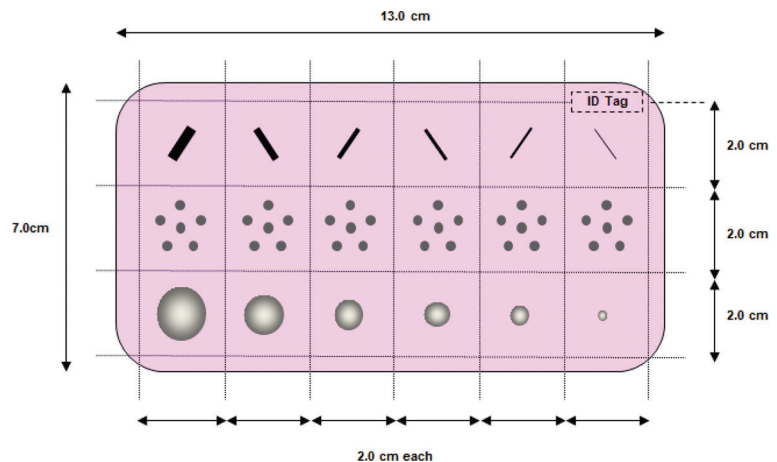

Figure 5. ACR DM Phantom wax insert map (test object sizes are not to scale).

    b. Fibers

        i. The fibers are manufactured to be 10 mm in length. If the entire length of the fiber is not visible, measure it using the display device's electronic calipers.

        ii. Count each fiber as 1 point if 8 mm or more of the fiber is visible in the correct location and orientation.

        iii. Count a fiber as ½ point if the fiber appears to be equal to or greater than 5 mm and less than 8 mm in length and is in the correct location and orientation.

        iv. If a small gap in the fiber is visible, and it is less than the width of the fiber, count the fiber as a full or half point depending on the total visible length.

c. Speck groups

   i. Count each speck group as 1 point if 4 to 6 specks are visible in the proper locations in the group.

   ii. Count a speck group as ½ point if 2 or 3 specks are visible in the proper locations in the group.

d. Masses

   i. Count each mass as 1 point if an object is visible in the correct location and the mass appears to be generally circular against the background (at least ¾ of the border is continuous and generally round).

   ii. Count a mass as ½ point if a mass-like object is visible in the correct location but does not have a generally circular appearance (greater than ½ but less than ¾ of a circle).

e. Enter the final scoring result in each category (fibers, speck groups, and masses) on the form.

11. If 2D add-on devices are used clinically with DBT, repeat the above steps to score the resulting 2D image.

12. See the ACR Digital Mammography Phantom Scoring Guide in Appendix II for examples on scoring.

Table 3. ACR DM Phantom Image Scoring Key

Test Object	Full Point	Half Point
Fibers (6)	• Full length visible (≥8 mm long) • Correct location • Correct orientation • 1 break allowed (must be ≤ width of fiber)	• At least half of length visible (≥5 and <8 mm long) • Correct location • Correct orientation • 1 break allowed (must be ≤ width of fiber)
Speck Groups (6)	• 4 to 6 specks visible • Correct locations	• 2 to 3 specks visible • Correct locations
Masses (6)	• Density difference visible • Border is continuous and generally circular (≥ ¾ border visible) • Correct location	• Density difference visible • Border is not continuous or generally circular (≥ ½ and < ¾ border visible) • Correct location

PRECAUTIONS AND CAVEATS

If any of these quantities are outside of the action limits stated below, the test should be repeated. Make sure the correct exposure mode has been used.

If one or two new computed radiography photostimulable phosphor (PSP) plates are acquired between the medical physicist's annual surveys, the QC technologist **must** first check the plate before putting it into clinical service. This **must** be done by following this ACR Digital Mammography Phantom Image Quality procedure and sending the completed form to the medical physicist for review.

> **Note:** If the facility replaces all of its PSP plates with new ones, the medical physicist **must** perform a Mammography Equipment Evaluation consisting of applicable tests.

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

ACR DM Phantom – 2D and DBT

1. Artifacts **must not** be clinically significant. This aspect of the test fails if artifacts are in a location that could impact clinical interpretation and

    a. Artifacts are as prominent as (or more prominent than) the visible test objects in the phantom image, or

    b. Artifacts obscure test objects in the phantom, or

    c. Artifacts could affect clinical interpretation.

    The cause of the artifact should be identified and isolated to determine if it originates from the x-ray system, the detector, or the monitor. If the artifact is confirmed to originate from the detector, then a recalibration or flat-fielding of the detector may be needed. Artifacts isolated to other components of the imaging chain should be investigated.

    After the artifact is resolved, repeat the phantom artifact test. If a clinically significant artifact persists, contact your authorized service representative. If the clinically significant artifact originated from the x-ray/detector system, do not image patients until it is corrected. If the clinically significant artifact originated from the monitor, do not use the monitor until it is corrected.

2. The fiber score **must be** ≥2.0.

3. The speck group score **must be** ≥3.0.

4. The mass score **must be** ≥2.0.

TIMEFRAME FOR CORRECTIVE ACTION

All failures of required items **must** be corrected before clinical use.

2. Computed Radiography (CR) Cassette Erasure
(if applicable)

OBJECTIVES

To ensure the cassette is free from signal information that could impact image quality.

FREQUENCY

Weekly.

> **Important:** This test is only applicable to computed radiography systems.

TEST EQUIPMENT

- All CR cassettes and CR readers.

- Computed Radiography Cassette Erasure form.

TEST PROCEDURE

1. Using the menu on the CR reader, select the option for CR cassette erasure.

2. Place the CR cassette into the CR reader and initiate the erasure process.

3. Repeat for all CR cassettes.

4. If a cassette fails the erasure test, repeat it.

5. If the CR cassette fails again, enter the date, cassette number, reason for failure, and action taken under "Action Taken on Cassette" at the bottom of the form.

6. Date and initial the form to indicate the test was completed.

7. If failing cassette(s) are put back into service at any time, document this on the form along with the date and description of service performed.

PRECAUTIONS AND CAVEATS

None

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

1. Each cassette should successfully pass the CR cassette erasure process.

2. If an error messages occurs, repeat the test on the cassette.

3. If an error message occurs again, pull the cassette from service and investigate the error message.

4. If the cassette cannot go through this procedure, or is rejected, the cassette should be pulled from service until the problem is investigated by a service engineer.

TIMEFRAME FOR CORRECTIVE ACTION

Cassettes that do not successfully pass the erasure process *must* be taken out of service immediately. After service or repair, the cassette should undergo the erasure process before being put back in to service.

3. Compression Thickness Indicator

OBJECTIVES To ensure that the indicated compression thickness is within tolerance.

FREQUENCY Monthly, whenever inaccurate indicator performance is suspected, and upon installation of new equipment (before clinical use).

TEST EQUIPMENT
- An object to use as a compression thickness indicator phantom.

    – This can be any commonly available object that is 10 cm long by 10 cm wide (or less) and 4 to 6 cm in thickness. For example, 1 2-inch roll of medical tape or 2 1-inch rolls stacked on top of each other would work.

    – Do not use an object with sharp edges that would scratch the compression paddle or bucky.

    – If tape is used, cover the sides of the roll (by using a thin plastic bag or paper) to prevent adhesive from sticking to the equipment.

    – Be sure to set aside the compression thickness indicator phantom and label the object for use only for this test.

- A ruler with a mm/cm scale.

- Compression Thickness Indicator form.

TEST PROCEDURE
1. Record a description of the compression thickness indicator phantom (e.g., "2 rolls of 1-inch tape") on the form.

2. Measure the thickness of the phantom using the same units provided on the indicator (cm or mm) and record this value on the form (Figure 6).

Figure 6. Measuring the width of the compression thickness indicator phantom.

3. In contact mode, place the phantom on the breast support so that it is centered laterally and aligned flush with the chest wall edge of the support (Figure 6).

4. Install the spot compression paddle (in contact mode).

   a. If a spot compression paddle is not available, use the smallest, non-flex compression paddle available.

   b. Be sure to turn off the flex function of the paddle if possible.

5. Apply a compression force of approximately 10 to 15 pounds (4.4 to 6.7 decanewtons) to the phantom (Figure 7).
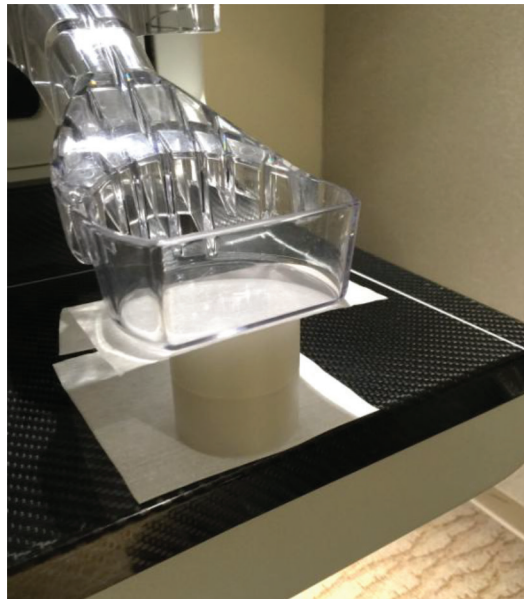

Figure 7. Position and compression of compression thickness indicator phantom using spot compression paddle.

6. Record the indicated thickness on the form (in cm or mm).

7. Release the compression device.

DATA ANALYSIS AND INTERPRETATION

1. Subtract the actual, measured thickness of the phantom from the indicated thickness.

2. Record the result on the form.

PRECAUTIONS AND CAVEATS

Many systems use the indicated compression thickness to drive the selection of initial kVp and filter under automatic exposure control. Omitting such a test may have an impact on image quality and patient dose, as suboptimal imaging techniques may be selected during imaging if the compression thickness is not accurate.

If your compression thickness indicator phantom is lost or damaged, obtain another object as identical to the previous object as possible. Measure and record the thickness as before and start a new chart.

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

1. The compression thickness indicator must be accurate to within ±0.5 cm (±5 mm) of the actual thickness. For example, if the compression thickness indicator phantom is 4.8 cm thick, the indicator may not show that it is less than 4.3 cm thick nor greater than 5.3 cm thick.

2. If the test fails, recheck the measurement of the phantom with the ruler and the setup of the equipment. Repeat the test.

3. If the test fails again, contact your authorized service representative.

TIMEFRAME FOR CORRECTIVE ACTION

The source of the problem *must* be identified and corrective action taken within 30 days.

4. Visual Checklist

OBJECTIVES

To ensure that digital mammographic x-ray system indicator lights, displays, mechanical locks and detents are working properly and that the mechanical rigidity and stability of the equipment is optimum.

FREQUENCY

Monthly, after relevant service, and upon installation of new equipment (before clinical use).

TEST EQUIPMENT

Visual Checklist form.

TEST PROCEDURE

1. Review all items listed on the visual checklist and indicate their status. Be sure to rotate the C-arm the way you would for patient imaging.

2. If specific checks that are not on the form are recommended by your medical physicist, add them to the checklist.

3. Date and initial the checklist where indicated.

DATA ANALYSIS AND INTERPRETATION

None

PRECAUTIONS AND CAVEATS

When checking for cracks in paddles, face shields, and breast supports, only indicate issues that impact patient safety and image quality. Tiny cracks may not be a safety or image quality issue. If unsure of the potential impact on image quality or safety, consult with the lead interpreting radiologist or the medical physicist.

Some of the items on the visual checklist are operator convenience features. Many of the items, however, are essential for patient safety and high-quality diagnostic images. It may be necessary to add additional items to the checklist that are specific to your particular equipment or procedures. For example, various systems will have unique items that should be checked. Consult with your medical physicist regarding the manufacturer's recommendations.

Items on the list that are not applicable to your system (e.g., "condition of imaging plates and cassettes" if computed radiography [CR] is not used) should be marked "not applicable" (NA).

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

The following tests listed in the Visual Checklist are critical, and failures *must* be repaired or replaced before clinical use, as applicable:

- Cleaning solution must be available.

- All locks must work correctly.

- Paddles/face shields must not be cracked.

- The breast support must not be cracked.

- The cassette holder for CR must hold and lock the cassette properly (small and large).

- The CR imaging plates and cassettes must be in acceptable condition. Cassettes should be free of cracks and dents, latches should function properly, and cassettes should run smoothly with the CR reader.

- The DBT assembly must move as designed through its range of motion.

The following tests listed in the Visual Checklist are less critical, and failures *must* be corrected within 30 days, as applicable:

- Magnification stands and paddles must be free from dust.

- The mammography room and countertops must be free from dust.

- Indicators must be working.

- The collimator light must be working.

- Cables must be safely positioned.

- The C-arm motion must be smooth.

- The compression paddle motion must be smooth.

Items missing from the room should be replaced. Malfunctioning equipment should be reported to the authorized service representative for repair or replacement as soon as possible.

TIMEFRAME FOR CORRECTIVE ACTION

Failures of critical tests *must* be corrected before clinical use; failures of less critical tests *must* be corrected within 30 days.

RADIOLOGIC TECHNOLOGIST'S SECTION

5. Acquisition Workstation (AW) Monitor QC

OBJECTIVES

- To ensure that AW monitors are clean and free from dust, fingerprints, and other marks that may interfere with clinical information.

- To ensure that monitors are calibrated correctly and the brightness and contrast settings are appropriate.

- To ensure that monitors meet manufacturer specifications via the conduct of Monitor Manufacturer Automated Tests (if available).

> **Important:** Monitor Manufacturer Automated Tests are required if such a tests are available in the manufacturer's documentation.

FREQUENCY

Monthly, after relevant service, and upon installation of new equipment (before clinical use).

TEST EQUIPMENT

- Dry, soft, lint-free cloth or cleaning tissue recommended by your AW manufacturer.

> **Note:** Any other cleaning methods may lead to damage of the anti-reflective screen coating. Please follow your AW manufacturer's recommendations for proper cleaning and cleaning material. If you don't have them, ask the AW manufacturer.

- The American Association of Physicists in Medicine (AAPM) TG18-QC test pattern [5] is strongly preferred. If one is not available on the monitor, ask the authorized service representative to install one. If this is not possible, a SMPTE test pattern [6] or another pattern that allows relevant measurements may be used (Figure 8). If it is not possible to install a relevant test pattern on the monitor, this part of the test is not applicable.
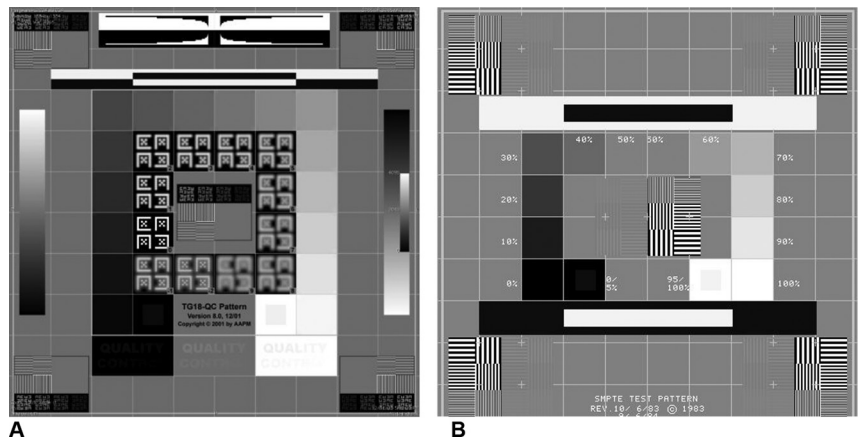

Figure 8. Test patterns: A. AAPM TG18-QC test pattern. B. SMPTE test pattern.

- Acquisition Workstation Monitor QC form.

Digital Mammography Quality Control Manual

TEST PROCEDURE

Monitor Condition

1. Visually inspect the surface of the monitor for the presence of dust, scratches, defects, fingerprints, shiny patches (from grease or gel), and other foreign material (e.g., pen marks, etc.).

2. If dirt, fingerprints, or other foreign material is present, wipe the monitor screen gently using a soft lint-free cloth dampened with water, paying particular attention to the items listed above. Then wipe with a dry, soft, lint-free cloth. A special-purpose screen cleaning tissue or cloth recommended by the monitor manufacturer may also be used.

3. After drying, recheck the monitor surface to be sure the items noted in step 1 have been eliminated. If they were not, clean the monitor again.

4. Record significant findings on the form (see Performance Criteria and Corrective Actions).

Test Pattern Image Quality (if available)

1. Reduce the lighting in the acquisition room to be similar to that in the radiologist's reading room before image evaluation.

2. Display the test pattern on the monitor. (If an appropriate test pattern is not available on the AW, skip this test.)

3. Evaluate the test pattern for the following visible targets and record pass or fail on the form (see the ACR Technique and Procedure Summaries form for further guidance on monitor test pattern evaluation):

   a. Are the 0%-5% contrast boxes visible?

   b. Are the 95%-100% contrast boxes visible?

   c. Are the line-pair images at the center and four corners visible and clearly distinguishable?

Monitor Manufacturer Automated Test (if available)

1. Open the monitor manufacturer automated test program.

2. Review the results and verify that all tests have passed.

3. Record an overall pass or fail on the form at the designated frequency.

DATA ANALYSIS AND INTERPRETATION

None

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PRECAUTIONS AND CAVEATS

</td><td>

Ideally, monitor screens should be free of dust, fingerprints, and other marks. Similarly, there should be no "shiny" patches or obvious non-uniformities on the surface. As described below, significant blemishes that interfere with the interpretation or QC of images *must* be corrected.

Most problems can be corrected by cleaning according to the manufacturer's instructions. However, if cleaning does not correct the problem, the manufacturer should be contacted to evaluate and correct the problem.

Do not use cleaning products, abrasive materials, or alcohols that will damage the anti-reflective coating on the screen.

Although this thorough check must be done and documented by the technologist monthly, technologists should clean significant dirt from their AW as it occurs if it is noted during daily use.

In most cases, Monitor Manufacturer Automated Tests and action limits are available in manufacturer manuals or documents published by the manufacturer. These tests are extremely valuable in maintaining quality and are specific to each manufacturer. If a Monitor Manufacturer Automated Test is available, the medical physicist should assist the facility in verifying that the automated system is set up and functioning properly.

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PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

Monitor Condition

Any large, significant blemish that interferes with the visualization or QC of images is a failure. (If there are questions regarding the significance of a monitor blemish, the lead interpreting radiologist should be consulted.)

Test Pattern Image Quality (if available)

1. The 0%-5% and 95%-100% contrast boxes *must* be visible.

2. The high-contrast line-pair patterns *must* be distinguishable at the center and corners.

Monitor Manufacturer Automated Test (if available)

Monitors *must* pass all manufacturer tests.

TIMEFRAME FOR CORRECTIVE ACTION

Monitor Condition

All failures *must* be corrected before clinical use.

Test Pattern Image Quality (if available) and Monitor Manufacturer Automated Test (if available)

All failures *must* be corrected within 30 days.

6. Radiologist Workstation (RW) Monitor QC

OBJECTIVES

- To ensure that radiologist workstation monitors are clean and free from dust, fingerprints, and other marks that may interfere with clinical information.

- To ensure monitors are calibrated correctly and the brightness and contrast settings are set correctly.

- To ensure that the image acquisition chain is producing adequate image quality and working consistently and that there are no obvious artifacts.

- To ensure that monitors meet manufacturer specifications via the conduct of Monitor Manufacturer Automated Tests (if available).

> **Important:** Monitor Manufacturer Automated Tests are required if such tests are available in the manufacturer's documentation.

FREQUENCY

Monthly, after relevant service, and upon installation of new workstations (before clinical use).

TEST EQUIPMENT

- Dry, soft, lint-free cloth or cleaning tissue recommended by your RW manufacturer.

> **Note::** Any other cleaning methods may lead to damage of the anti-reflective screen coating. Please follow your RW manufacturer's recommendations for instructions on proper cleaning and cleaning material. If you don't have them, ask the RW manufacturer.

- Acquired ACR Digital Mammography (DM) Phantom image.

- The American Association of Physicists in Medicine (AAPM) TG18-QC test pattern is strongly preferred. If one is not available on the monitor, ask the authorized service representative to install one. If this is not possible, a SMPTE test pattern or another pattern that allows relevant measurements may be used (Figure 8).

- Radiologist Workstation Monitor QC form.

TEST PROCEDURE

Monitor Condition

1. Check the surface of the monitors for the presence of dust, scratches, defects, fingerprints, shiny patches (from grease or gel), and other foreign material (e.g., pen marks, etc.).

RADIOLOGIC TECHNOLOGIST'S SECTION

2. If dirt, fingerprints, or other foreign material is present, wipe the monitor screen gently using a soft lint-free cloth, dampened with water, paying particular attention to the items noted above. Then wipe with a dry, soft, lint-free cloth. A special-purpose screen cleaning tissue or cloth recommended by the monitor manufacturer may also be used.

3. After drying, recheck the monitor surface to be sure the items noted in step 1 were eliminated. If they were not, clean the monitor again.

4. Record significant findings on the form (see Performance Criteria and Corrective Actions).

ACR DM Phantom

1. Display a phantom image that was acquired on one of the digital mammography units per instructions in Test #1 ACR Digital Mammography Phantom Image Quality.

2. Evaluate for artifacts and score the phantom test objects as in Test #1 ACR Digital Mammography Phantom Image Quality.

Test Pattern Image Quality

1. Display the test pattern on the monitor.

2. Evaluate the test pattern for the following visible targets and record pass or fail on the form (see the ACR Technique and Procedure Summaries form for further guidance on monitor test pattern evaluation):

   a. Are the 0%-5% contrast boxes visible?

   b. Are 95%-100% contrast boxes visible?

   c. Are the line-pair images at the center and four corners visible and clearly distinguishable?

Monitor Manufacturer Automated Test (if available)

1. Open monitor manufacturer automated test program.

2. Review the results and verify that all tests have passed.

3. Record an overall pass or fail on the form.

DATA ANALYSIS AND INTERPRETATION

ACR DM Phantom

1. Evaluate the phantom image for artifacts following the instructions under Data Analysis and Interpretation in Test #1 ACR Digital Mammography Phantom Image Quality.

2. Score the phantom image following the instructions under Data Analysis and Interpretation in Test #1 ACR Digital Mammography Phantom Image Quality.

3. Record results on the form.

PRECAUTIONS AND CAVEATS

Ideally, monitor screens should be free of dust, fingerprints, and other marks. Similarly, there should be no "shiny" patches or obvious non-uniformities on the surface. As described below, significant blemishes that interfere with the interpretation or QC of images must be corrected. If there are questions regarding the significance of a monitor blemish, the lead interpreting radiologist should be consulted.

Most problems can be corrected by cleaning according to the manufacturer's instructions. However, if cleaning does not correct the problem, the manufacturer should be contacted to evaluate and correct the problem.

Abrasive materials or alcohols should not be used on monitor faces, since the anti-glare surface on the display might be destroyed. Do not use cleaning products, abrasive materials, or alcohols that will damage the anti-reflective coating on the screen.

Although a thorough Monitor Condition check must be done and documented by the technologist monthly, radiologists should clean significant dirt from their RW as it occurs if it is noted during daily use.

In most cases, Monitor Manufacturer Automated Tests and action limits are available in manufacturer manuals or documents published by the manufacturer. These tests are extremely valuable in maintaining quality and are specific to each manufacturer. If a Monitor Manufacturer Automated Test is available, the medical physicist should assist the facility in verifying that the automated system is set up and functioning properly.

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

Monitor Condition

Any large, significant blemish that interferes with the interpretation or QC of images is a failure. (If there are questions regarding the significance of a monitor blemish, the lead interpreting radiologist should be consulted.)

ACR DM Phantom

1. Artifacts *must not* be clinically significant. This aspect of the test fails if any artifacts are in a location that could impact clinical interpretation and

   a. They are as prominent as (or more prominent than) the visible test objects in the phantom image, or

   b. They obscure test objects in the phantom, or

   c. They could affect clinical interpretation.

   The cause of the artifact should be identified and isolated to determine if it originates from the x-ray system, the detector, or the RW monitor. If the artifact is confirmed to originate from the detector, then a recalibration or flat-fielding of the detector may be needed. Artifacts isolated to other components of the imaging chain should be investigated.

   After the artifact is resolved, repeat the phantom artifact test. If a clinically significant artifact persists, contact your authorized service representative. If the clinically significant artifact originated from the x-ray/detector system, do not image patients until it is corrected. If the clinically significant artifact originated from the RW monitor, do not use the monitor to interpret patient images until it is corrected.

2. The fiber score *must* be ≥2.0.

3. The speck group score *must* be ≥3.0.

4. The mass score *must* be ≥2.0.

Test Pattern Image Quality

1. The 0%-5% and 95%-100% contrast boxes *must* be visible.

2. The high-contrast line-pair patterns *must* be distinguishable at the center and corners.

Monitor Manufacturer Automated Test (if available)

Monitors *must* pass all manufacturer tests.

TIMEFRAME FOR CORRECTIVE ACTION

Monitor Condition and ACR DM Phantom

All failures *must* be corrected before clinical use.

Test Pattern Image Quality and Monitor Manufacturer Automated Test (if available)

All failures *must* be corrected within 30 days.

7. Film Printer QC *(if applicable)*

OBJECTIVES

To ensure adequate and consistent image quality on printed images provided to referring physicians, patients, and other radiologists.

FREQUENCY

- Monthly (if printer is used less than monthly, before clinical films are printed).

- After relevant service (and before clinical use).

- Upon installation of new equipment (and before clinical use).

> **Note:** Film printer QC is only required if they are used clinically for mammography (i.e., for interpretation and to provide images to referring physicians and patients). If such is the case, it is important that the facility documents in its QC logs that that the film printer is not used clinically.

TEST EQUIPMENT

- ACR Digital Mammography (DM) Phantom image *(required).*

- Densitometer.

- Film Printer QC form.

TEST PROCEDURE

1. Print the ACR DM Phantom image (acquired in Test #1 ACR Digital Mammography Phantom Image Quality) without adjusting any parameters (window width/window level, sizing, etc.) using the film size used for the majority of clinical printing. (Refer to the ACR Technique and Procedure Summaries form.) Print the digital images without magnification or minification and as close to "true size" as possible. The ACR recommends printing the phantom images so that it is within 25% of the actual phantom size.

2. On the form, note the workstation used to print the image.

3. View the image.

DATA ANALYSIS AND INTERPRETATION

ACR DM Phantom

1. Evaluate the phantom image on the film for artifacts following the instructions under Data Analysis and Interpretation in Test #1 ACR Digital Mammography Phantom Image Quality.

2. Score the phantom image on the film following the instructions under Data Analysis and Interpretation in Test #1 ACR Digital Mammography Phantom Image Quality.

3. Record results on the form.

Background Optical Density

1. Measure the background optical density (OD) outside of the cavity on the printed phantom image.

2. Record on the form.

Contrast

1. Record the background OD from above in the "Contrast" section of the form.

2. Measure the OD inside the cavity and record on the form.

3. Subtract the background OD from outside of the cavity from the OD inside the cavity and record this on the form. This is the film contrast.

$$Contrast = Cavity\ OD - Background\ OD$$

Maximum Optical Density (D$_{max}$)

1. Measure the OD near the outside edge of the film at a location where the phantom image (including the detector area) is not located. If the phantom image covers the entire film and there is insufficient room, print a breast image and make this measurement in the non-breast area.

2. See the ACR Technique and Procedure Summaries form for a detailed schematic of where to measure the ODs.

PRECAUTIONS AND CAVEATS

Many facilities never actually provide a final interpretation report based on the hard copy images. However, even if a facility is using the printer only to provide final interpretation-quality hardcopy images to representatives, health-care providers, patients, or for retention purposes, it still needs to perform all the required printer QC tests at appropriate frequencies or prior to printing clinical images for patients and health-care providers or for retention, whichever is less frequent. See the FDA MQSA website for the most current requirements.

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

ACR DM Phantom

1. Artifacts ***must not*** be clinically significant. This aspect of the test fails if any artifacts are in a location that could impact clinical interpretation and

   a. They are as prominent as (or more prominent than) the visible test objects in the phantom image, or

RADIOLOGIC TECHNOLOGIST'S SECTION

b. They obscure test objects in the phantom, or

c. They could affect clinical interpretation.

If the artifact evaluation fails, check the softcopy images to determine if the same artifact appears. If the same artifact appears on the workstation, the problem should be addressed as described in the workstation test. If the artifact does not appear on the workstation, retest and seek service for the printer if the problem persists. Do not print patient images until clinically significant artifacts are corrected.

2. The fiber score **must** be ≥2.0.

3. The speck group score **must** be ≥3.0.

4. The mass score **must** be ≥2.0.

Background Optical Density

Background OD **must** be ≥1.6. (Background optical densities between 1.7 and 2.2 are recommended; approximately 2.0 is optimal.)

Contrast

Contrast (cavity OD – background OD) **must** be ≥0.1.

D$_{max}$

The D$_{max}$ **must** be ≥3.1 (≥3.5 is recommended).

TIMEFRAME FOR CORRECTIVE ACTION

All failures of required items **must** be corrected before clinical use.

8. Viewbox Cleanliness *(if applicable)*

OBJECTIVES

To ensure that the viewboxes and viewing conditions are optimized and maintained at an optimum level. If prior or outside clinical films are not viewed on viewboxes, this test is not applicable.

FREQUENCY

Monthly, after relevant service, and upon installation of new equipment (before clinical use)

TEST EQUIPMENT

- Cleaner recommended by viewbox manufacturer.

- Soft paper or cotton towels.

- Viewbox Cleanliness form.

TEST PROCEDURE

1. Clean viewbox surfaces using cleaner recommended by viewbox manufacturer and soft paper or cotton towels.

2. Ensure that all marks have been removed.

3. Visually inspect the viewboxes for uniformity of luminance.

4 Ensure that all viewbox masking equipment is functioning properly and easily.

DATA ANALYSIS AND INTERPRETATION

None.

PRECAUTIONS AND CAVEATS

High-quality viewboxes are still important in digital imaging because comparison images may only be available on film. The accuracy of the diagnosis and the efficiency of the radiologist are influenced by the conditions under which the mammograms are viewed. Viewing conditions may affect the diagnostic potential of even the best quality mammograms. These conditions are determined by the luminance of the viewboxes, the ambient room illumination or the amount of light falling on the viewbox surface, and good masking of films on the viewbox.

Contrast is extremely important in the mammography image and is degraded by extraneous light. Consequently, viewboxes should be positioned to avoid light from windows, other viewboxes, and other sources of bright light, either direct or reflected. General lighting in the room should be at a low level and diffuse.

Viewboxes used in mammography should provide a relatively high luminance level, generally higher than for viewing conventional radiographs. Consequently, it is essential to mask the area around the mammograms to exclude extraneous light that reduces image contrast and limits the maximum densities that can be seen without "bright-lighting" each film.

RADIOLOGIC TECHNOLOGIST'S SECTION

If a separate viewbox is used by the QC technologist to check the density of film images, this viewbox should be similar to the reading viewbox in luminance and color of the light and should be used with ambient lighting conditions similar to those in the room where the mammograms are interpreted.

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

Any marks that are not easily removed with window cleaner **must** be removed with a safe and appropriate cleaner. If viewboxes appear non-uniform, all of the fluorescent lamps **must** be replaced as soon as possible. If viewbox masks are difficult to use, appropriate service or modifications should be requested.

TIMEFRAME FOR CORRECTIVE ACTION

Failures must be corrected before clinical images are viewed on the viewbox.

9. Facility QC Review

OBJECTIVES

To ensure the lead interpreting radiologist and facility manager are aware that all QC tests are performed at the required frequencies, that data are collected appropriately, that results are adequately documented, that corrective action is taken, and that no patient exams are conducted when tests requiring correction before clinical use failed.

FREQUENCY

Quarterly.

TEST EQUIPMENT

- Facility QC forms and data.

- Facility QC Review form.

TEST PROCEDURE

QC data/notebooks must be reviewed by both the lead interpreting radiologist and facility manager. These reviews may be done in person or remotely (e.g., via teleconference or video conference).

1. Enter QC results from the most recent Medical Physicist's ACR Digital Mammography (DM) QC Test Summary form into the Facility QC Review form prior to the meeting.

2. Enter QC results from the most recent week of technologist QC into the form prior to the meeting.

3. Review the most recent quarter of QC data with both the lead interpreting radiologist and facility manager.

4. Review each QC test and its results.

5. If any tests fail, note that corrective action was documented.

6. Discuss reasons for failure and documented corrective action.

7. Review the Medical Physicist's ACR DM QC Test Summary and report for each mammography unit.

8. Record performance of this quarterly review and annual review with initials and date on the form.

DATA ANALYSIS AND INTERPRETATION

None

PRECAUTIONS AND CAVEATS

The MQSA Final Rule specifies that the lead interpreting physician has "the general responsibility of ensuring that the quality assurance program meets all MQSA QA [quality assurance] requirements." This responsibility *cannot be delegated* to individuals such as the medical physicist or the QC technologist. Routine and appropriate conduct of the Facility QC Review demonstrates that this responsibility is being properly exercised.

RADIOLOGIC TECHNOLOGIST'S SECTION

The lead interpreting radiologist, along with the facility manager, must review the QC test results at least quarterly or more frequently if problems are noted. It is particularly important for the lead interpreting radiologist and the facility manager to note that all tests and necessary corrective action are properly documented. Too often, investigations performed by MQSA inspectors, MQSA certifying bodies, and mammography accreditation bodies for non-compliance and quality issues demonstrate that neither facility management nor lead interpreting radiologists were aware that QC was not being performed at the required intervals or documented at their facilities.

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

1. If tests are not being done at an appropriate level or frequency, or if corrective action for failures are not implemented and/or documented, the facility needs to determine the reasons and allocate appropriate training and/or time so the work is done properly.

2. If there are questions regarding the conduct of the test or data interpretation, the medical physicist should be consulted for assistance and additional training.

TIMEFRAME FOR CORRECTIVE ACTION

Not applicable.

10. Compression Force

OBJECTIVES

To ensure that the mammography system can provide adequate compression in both manual fine-adjustment and hands-free, initial power-drive modes, that the equipment does not allow too much compression to be applied when used in initial power-drive mode, and that adequate compression can be maintained throughout image acquisition.

FREQUENCY

Every 6 months (semiannual), whenever reduced, excessive, or unstable compression is suspected, and upon installation of new equipment (before clinical use).

TEST EQUIPMENT

- Calibrated bathroom scale (The scale should be a flat, conventional, analog type. Digital scales sample the data and may not respond properly as additional pressure is applied slowly to the scale. Digital scales designed specifically to measure compression force may be used.)

- Several towels.

- Other calibrated tools specifically designed to measure compression force (such as digital gauges or compression force tools) may also be used.

- Compression Force form.

TEST PROCEDURE

1. Place a towel on the breast support surface (to protect the image receptor), then place the bathroom scale on the towel with the dial or read-out positioned for easy reading. Locate the center of the scale directly under the compression device (Figure 9).

2. Place one or more towels on top of the scale to prevent damage to the compression paddle.

3. Check that the force available during manual fine-adjustment mode meets minimum requirements.

   a. Using the manual fine-adjustment mode, compress the scale until a force of at least 25 pounds is noted.

   b. Note if 25 pounds was achieved on the form.

   c. Release the compression device.

4. Check that the maximum force available during initial power-drive mode is within the required range of 25 to 45 pounds.

   a. Using the hands-free, initial power-drive mode (e.g., foot pedal), activate the compression device and allow it to operate until it stops automatically. Do not tap the foot pedal (see Precautions and Caveats for exceptions.)

   b. Read and record the compression force on the form.

RADIOLOGIC
TECHNOLOGIST'S SECTION

5. Check that adequate force is maintained.

    a. Hold compression for the length of time it usually takes to either complete an average exposure or engage the manual fine-adjustment control. Check that at least 25 pounds is maintained.

    b. If the manual fine-adjustment control is engaged, then it must maintain a compression force of at least 25 pounds for the length of time it usually takes to complete an average exposure.

    c. Note on the form if adequate force was maintained.

6. Release the compression device.

Figure 9. Setup for the compression force test. Note the towel covering the image receptor under the scale and the towel on top of the scale to protect the paddle.

DATA ANALYSIS AND INTERPRETATION

None

PRECAUTIONS AND CAVEATS

Adequate compression is essential for high-quality mammography. Compression reduces the thickness of tissue that must be penetrated by radiation, thereby reducing scattered radiation and increasing contrast, while reducing radiation exposure to the breast. Compression improves image sharpness by reducing the breast thickness, thereby minimizing focal spot blurring of structures in the image, and by minimizing patient motion. In addition, compression makes the thickness of the breast more uniform, resulting in image signal values representing tissue-density differences rather than thickness differences, making images easier to interpret.

If the safety mechanism is not properly adjusted, it may be possible to damage the compression device and associated components. If the compression exceeds 200 newtons (20 decanewtons or 45 pounds) in the

initial power drive mode, immediately release the compression device and ask a service engineer to make the appropriate adjustments.

The initial power drive on some mammography units (e.g., Siemens Mammomat) is designed with a built-in sensor that terminates the pressure applied to the paddle once the system's software algorithm determines that additional force will not achieve further thickness reduction. This design is intended to maximize patient comfort while achieving optimum compression. When such a device is pressed against a hard surface (such as a bathroom scale), the sensor, recognizing that very little or no compression has been achieved by the applied force up to that point, terminates the pressure before the maximum force can be achieved. When performing the compression test with such a device, the person conducting the test (i.e., radiologic technologist or medical physicist) may have to press the foot pedal more than once to accurately measure the maximum force. Failure to do so may lead the person conducting the test to report an artificially low maximum compression force. This could lead to an inappropriate failure of the initial power drive compression device quality control test. See FDA Guidance.

If tools specifically designed to measure compression force are used, the above procedures should be modified.

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

1. A compression force of at least 25 pounds (111 newtons or 11.1 decanewtons) *must* be provided in both the initial power-drive and manual fine-adjustment modes.

> **Note:** This is the minimum compression force that is available to use on the unit. It is *not* the minimum force that must be used to compress the patient.

2. For the initial power-drive mode, the maximum compression force *must* be at least 25 pounds (111 newtons or 11.1 decanewtons) but no more than 45 pounds (200 newtons or 20.0 decanewtons).

3. The initial power-drive mode must maintain a compression force of at least 25 pounds (111 newtons or 11.1 decanewtons) for the length of time it usually takes to engage the fine-adjustment control. The fine-adjustment control must then maintain a compression force of at least 25 pounds for the length of time it usually takes to complete an average exposure.

TIMEFRAME FOR CORRECTIVE ACTION

The source of the problem *must* be identified and corrective action taken before any examinations are performed.

11. Manufacturer Calibrations *(if applicable)*

OBJECTIVES

To detect and automatically correct equipment problems, especially related to digital detector performance. This may include compensating for dead or over-responding pixels, structured or other noise, nonlinear response, and other technical performance parameters.

FREQUENCY

- *Must* be performed at the frequency specified by the manufacturer.

- Upon installation of new equipment (before clinical use).

> **Important:** This test is applicable if the manufacturer's documentation includes routine detector calibration.

TEST EQUIPMENT

- Manufacturer Calibrations form.

- Other forms per manufacturer's recommendations.

TEST PROCEDURE

1. See manufacturer's documentation for exact procedure steps. The medical physicist should help the facility in locating and implementing these procedures.

2. Enter the results on the form.

DATA ANALYSIS AND INTERPRETATION

Follow manufacturer's recommendations.

PRECAUTIONS AND CAVEATS

Most manufacturers provide specific instructions for system calibrations (e.g., detector calibration). See the manufacturer's documentation for precautions and caveats.

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

The unit *must* meet the prescribed periodic calibrations.

TIMEFRAME FOR CORRECTIVE ACTION

Failures *must* be corrected before further clinical use.

Optional – Repeat Analysis

OBJECTIVES

To determine the number and cause of repeated mammograms. (Analysis of these data will help identify ways to improve efficiency, as well as reduce patient exposures.)

FREQUENCY

As needed. (In order for the repeat rates to be meaningful, a patient volume of at least 250 patients is needed, if possible. Some facilities may choose to conduct routine repeat analyses. Forms are provided for both monthly and quarterly checks.)

> **Note:** Some equipment manufacturers provide an automated system to collect, record, and analyze repeated clinical images. These systems may be used instead of the procedure in this section as long as the system includes the following 2 key elements:
>
> • Count of the total # of exposures made during the evaluation period
>
> • % repeats during the same period: (# Repeat Exposures/Total # Exposures) × 100%

TEST EQUIPMENT

- All repeated mammograms (including data for repeated mammograms that may have been placed in the patient's medical record)

- Means to count the total number of patient exposures made during the test period

- Means for sorting images during analysis

- Optional - Repeat Analysis forms

TEST PROCEDURE

1. Count all repeated images for the length of time needed to examine at least 250 patients (including those repeated images that were saved in the patient's medical record).

2. Also count the **total number of patient exposures** made during the same time period.

3. Sort the repeated images into the categories listed in the Tally Sheet or Daily Counting Sheet.

   a. Images may be repeated for a wide variety of reasons. See examples of images that should and should not be counted as repeats in Table 4.

   b. Good images (which appear to be acceptable mammograms when retrospectively evaluated during the repeat analysis) may have also been repeated.

RADIOLOGIC TECHNOLOGIST'S SECTION

c. Wire or other localization images (e.g., I-125 radioactive seeds) should ***not*** be included in the repeat analysis because they are taken as part of the localization process.

d. Quality control images should not be included in the repeat analysis.

Table 4. Reasons for Repeated Images

Patient-Related Repeats	Technical Repeats	Miscellaneous Repeats	Do Not Count as Repeats
• Poor positioning • Patient motion • Patient-caused artifacts • Incorrect patient ID	• Exposure too low (excessive noise) • Exposure too high (image saturation) • Equipment-caused artifacts • X-ray equipment failure • Software failure • Aborted automated exposure control exposure	• Blank images • Good image (no apparent reason) • Other - miscellaneous	• Wire localizations • I-125 seed localizations • Additional views to image the entire breast (e.g., exaggerated lateral CCs to obtain far post-lateral tissue or multiple views for patients with large breasts) • Quality control

ANALYSIS AND INTERPRETATION

1. Determine the overall percentage of repeated exposures by dividing the total number of repeated exposures by the total number of patient exposures made during the analysis period, and multiply by 100%.

$$\% \ Repeats = \left(\frac{Total \ \# \ Repeat \ Exposures}{Total \ \# \ Exposures} \right) * 100$$

2. Determine the percentage of repeats in each "Reason for Repeat" category by dividing the repeats in the category by the total number of repeated exposures.

$$\% \ Repeats = \left(\frac{\# \ Repeat \ Exposures \ in \ Category}{Total \ \# \ Repeat \ Exposures} \right) * 100$$

PRECAUTIONS AND CAVEATS

All images that are repeated (except for localization purposes) should be included in the repeat analysis, not just those that the radiologist asked to have repeated. Some facilities may keep repeated images in the patient's medical record along with good images. These repeated images must be included in the repeat analysis.

Many facilities include all patients examined in their repeat analyses. Collecting repeated images from a larger number of patients is encouraged because it will yield more reliable data on causes for repeats. In order for the repeat rates to be meaningful, a patient volume of at least 250 patients is needed, if possible.

Repeated images from all mammography units should be collected. The

Digital Mammography Quality Control Manual

facility's analysis and overall % repeats may be determined for the entire facility or for each mammography unit at the facility. (Many facilities choose to calculate both a facility-wide repeat rate **and** a repeat rate for each unit in order to determine if equipment problems result in higher repeat rates.) However, if a facility chooses to collect and analyze its repeat data, it is important that the facility does this in a consistent manner so that valid trends may be noted.

There is a real danger that technologists may alter their routine procedures or criteria for accepting images if they know their repeated images will be analyzed. This should be avoided.

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

The overall repeat rate ideally should be 2% or less, but a rate of 5% is probably adequate if the radiologist and medical physicist agree that this is a reasonable level. Too low or no repeat rate may also indicate that poor image quality is being tolerated. These rates should be based on a volume of at least 250 patients to be meaningful. A "Reason for Repeat" that is significantly higher than the others indicates an area for potential improvement.

If the repeat rate exceeds the selected acceptance level of either 2% or 5%, or if the repeat rate changes from the previously measured rate by more than 2%, the change should be investigated and corrective action taken, if necessary. For example, if the previous repeat rate was 1.8% and the new repeat rate is 4.2%, then the follow-up described above is required.

Any corrective actions should be recorded on the Corrective Action Log. In addition, the effectiveness of the corrective actions should be assessed by performing another Repeat Analysis or carefully evaluating the next quarterly Repeat Analysis after the corrective actions have been implemented.

TIMEFRAME FOR CORRECTIVE ACTION

The source of the problem should be identified and corrective action taken within 30 days of the repeat analysis.

RADIOLOGIC TECHNOLOGIST'S SECTION

Optional – System QC for Radiologist

OBJECTIVES

To enable the radiologist to perform a quick and relevant evaluation of the entire mammographic imaging chain that focuses primarily on the detector and monitors. (This test is not intended to evaluate technologist issues such as positioning and compression.)

FREQUENCY

As needed.

TEST EQUIPMENT

Optional – System QC for Radiologist form.

TEST PROCEDURE

Part 1 – The Technologist

1. The technologist should complete step 1 on the form by first finding an MLO image (acquired within the last two weeks) from each digital mammography unit or computed radiography (CR) reader and then entering the Room or CR ID to be evaluated.

2. Step 1 should be repeated on an additional form for each digital mammography unit within a facility.

3. The technologist should deliver the form(s) to the radiologist for completion.

4. Example: A radiologist can sit at one workstation and view the images for all the digital mammography units or CR readers within a facility. The radiologist does not need to evaluate every monitor at every workstation.

Part 2 – The Radiologist

1. Complete steps 2 through 5 on the form.

2. Pull up the study listed in step 1 on the form.

3. Place the same MLO image from the same case and breast on each monitor (or, for wide-screen monitors, on each side of the monitor, if possible).

4. Evaluate the images for artifacts and check the appropriate boxes.

DATA ANALYSIS AND INTERPRETATION

None

PRECAUTIONS AND CAVEATS

This test can be performed by the radiologist for all digital mammography or CR units on the same workstation.

Digital Mammography Quality Control Manual

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

If any box is checked "Yes", take appropriate corrective action.

TIMEFRAME FOR CORRECTIVE ACTION

1. If an image quality problem or artifact impedes clinical interpretation, seek service before using the workstation to interpret images.

2. If the artifact does not impede clinical interpretation, seek service within 30 days.

RADIOLOGIC TECHNOLOGIST'S SECTION

Optional – Radiologist Image Quality Feedback

OBJECTIVES

To ensure that radiologists provide feedback to the mammography technologists on the quality of the examinations they interpret and the need for additional images to complete the patient's breast imaging examination.

FREQUENCY

As needed.

TEST EQUIPMENT

Optional – Radiologist Image Quality Feedback form.

TEST PROCEDURE

1. The radiologist should check image quality assessment observations as the cases are interpreted.

2. The radiologist should also give positive feedback if the image quality is excellent.

3. Following the facility's established internal protocol, the radiologist should ensure that the mammography technologist receives all pertinent feedback.

DATA ANALYSIS AND INTERPRETATION

The facility management and staff should routinely evaluate this information to examine possible areas for quality improvement.

PRECAUTIONS AND CAVEATS

The MQSA Final Rule requires that "All interpreting physicians interpreting mammograms for the facility shall follow the facility procedures for corrective action when the images they are asked to interpret are of poor quality." Utilizing this procedure will help facilities meet this requirement.

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

If the image-quality deficiency is severe, as judged by the interpreting radiologist, the patient should be called back for additional imaging. However, it is also useful for the radiologist to provide feedback for image-quality issues that may not be so severe that the patient needs to be recalled. It is also important to provide positive feedback to the technologist for a job well done, for example, in cases where good image quality is obtained on difficult-to-image patients.

TIMEFRAME FOR CORRECTIVE ACTION

Not applicable

B. Quality Control Forms for 2D and DBT

Routine and complete documentation of QC and corrective actions is a critical part of quality mammography and is required by the FDA mammography regulations. The QC forms in this section have been developed to help you meet this goal and to comply with FDA requirements. The QC form number corresponds to the test procedure number provided in the previous section. Each form has been set up with a brief summary of the test procedure, an area to record the test conditions and techniques (to ensure that you do not change test conditions that could cause variability in the results), and with reminders of action limits and timeframes for corrective action. Be sure to consult the quality control test procedure for the complete instructions if you have questions about performing tests or analyzing data.

For simplicity and uniformity, the DBT tests are intended to use the same forms as the 2D tests. Document that the DBT tests were performed by selecting the correct image "mode" on the form. (If you are using an electronic version of the form, use the pull-down menu to select the mode.) For example, on the ACR DM Phantom Image Quality form, create a form for testing the 2D mode by entering "2D" in the heading of the form. Then copy the form to create one to test the DBT mode and enter "DBT" in the heading of the form. Note that for DBT you will need to use a second or third page of the form for complete QC documentation.

The forms are also downloadable as Excel spreadsheets from the [ACR Digital Mammography QC Manual Resources](#) website (go to Digital Mammography Quality Control Test Forms). Although they have been designed to help you record and analyze your QC results on a computer, they may also be printed and completed manually.

1. **[ACR Digital Mammography (DM) Phantom Image Quality](#)**

2. **[Computed Radiography (CR) Cassette Erasure (if applicable)](#)**

3. **[Compression Thickness Indicator](#)**

4. **[Visual Checklist](#)**

5. **[Acquisition Workstation (AW) Monitor QC](#)**

6. **[Radiologist Workstation (RW) Monitor QC](#)**

7. **[Film Printer QC (if applicable)](#)**

8. **[Viewbox Cleanliness (if applicable)](#)**

9. **[Facility QC Review](#)**

RADIOLOGIC TECHNOLOGIST'S SECTION

10. Compression Force

11. Manufacturer Calibrations *(if applicable)*

Optional – Repeat Analysis

Optional – System QC for Radiologist

Optional – Radiologist Image Quality Feedback

Digital Mammography Quality Control Tests
Radiologic Technologist's Tests (2D and DBT)

> **Important:** Before a facility may start using the procedures in the ACR Digital Mammography QC Manual for the first time on a unit, the medical physicist must first conduct an annual survey of the digital mammography unit and display devices using the manual and the ACR Digital Mammography Phantom.

Note: Complete Facility, Unit and Test Equipment Data tab first to populate facility information into forms

Test*	Minimum Frequency**	Corrective Action Timeframe***
1. ACR Digital Mammography Phantom Image Quality	Weekly	Before clinical use
2. CR Cassette Erasure *(if applicable)*	Weekly	Before clinical use
3. Compression Thickness Indicator	Monthly	Within 30 days
4. Visual Checklist	Monthly	Critical: before clinical use; less critical: w/in 30 days
5. Acquisition Workstation (AW) Monitor QC	Monthly	W/in 30 days; before clinical use for severe defects
6. Radiologist Workstation (RW) Monitor QC	Monthly	W/in 30 days; before clinical use for severe defects
7. Film Printer QC *(if applicable)*	Monthly	Before clinical use
8. Viewbox Cleanliness *(if applicable)*	Monthly	Before clinical use
9. Facility QC Review	Quarterly	Not applicable
10. Compression Force	Semiannual	Before clinical use
11. Manufacturer Calibration *(if applicable)*	Mfr. Recommendation	Before clinical use
Optional - Repeat Analysis	As Needed	Within 30 days after analysis
Optional - System QC for Radiologist	As Needed	W/in 30 days; before clinical use for severe artifacts
Optional - Radiologist Image Quality Feedback	As Needed	Not applicable

* All required tests (except Facility QC Review) must be performed upon installation of new equipment and before clinical use.

** This is a minimum frequency; tests may be performed more often if problems are noted. Also, weekly tests do not need to be performed if mammography is not performed during that week. However, the test must be performed prior to examining patients once mammography resumes. In these cases, be sure to note in the QC charts that mammography was not performed during this time period.

*** Corrective action for MEEs must be performed before clinical use.

Management Forms

ACR Technique and Procedure Summaries

Corrective Action Log

Facility Offsite Display Locations

Digital Mammography Unit QC Summary Checklist

Facility Display Device QC Summary Checklist

Mobile Systems

In addition to meeting the minimum frequencies outlined in the table above, the following tests must be performed, evaluated, and pass after each move of the mobile system to a new location:

• ACR Digital Mammography Phantom Image Quality - after each move and prior to examining patients

• Compression Thickness Indicator - after each move and prior to interpretation

• Radiologist Workstation (RW) Monitor QC (mobile RW only) - after each move and prior to interpretation

• Film Printer QC (mobile film printers only) - after each move and prior to printing patient images

QC Equipment List - Technologist

ACR Digital Mammography Phantom	Scale	Appropriate monitor cleaning materials
Densitometer	Towels	

1. ACR DM Phantom Image Quality

Image Mode *(2D, 2D w/Add-on DBT, DBT)* _____

Facility _____ **Room ID** _____

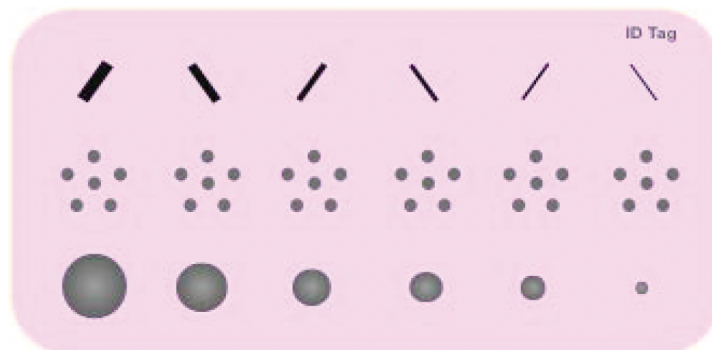**MAP ID-Unit#** *(00000-00)* _____ - _____ **Unit Mfr & Model** _____

		Year					
		Date *(month & day)*					
		Tech Initials					
Resulting Techniques		Image receptor size					
		View or selected image					
		Slice or slab # *(DBT only)*					
		AEC mode					
		Target/filter					
		kVp					
		mAs					
ACR DM Phantom		Artifacts P/F					
		Fiber score					
		Speck group score					
		Mass score					
		Overall Pass/Fail					

P = Pass   **F = Fail**

Analyses:

Scoring		Full Point	Half Point
	Fibers	≥ 8 mm long	≥ 5 and < 8 mm long
	Specks	4 - 6 specks	2 - 3 specks
	Masses	≥ ¾ border	≥ ½ & < ¾ border

Action Limits	**Required:**	ACR DM Phantom image must be free of clinically significant artifacts.
		Fiber score must be ≥ 2.0; speck group score must be ≥ 3.0; mass score must be ≥ 2.0.
	Timeframe:	Required items must be corrected before clinical use.

2. Computed Radiography (CR) Cassette Erasure

(if applicable)

Weekly

Image Mode   2D

Facility _____   **CR Room** _____

MAP ID-Unit# *(00000-00)* _____ - _____   **CR Reader Mfr & Model** _____

Year													
Month	Jan			Feb			Mar			Apr		May	Jun
Date													
Tech Initials													
Month	Jul			Aug			Sep			Oct		Nov	Dec
Date													
Tech Initials													

Date and initial each test -

date
initial

Action Taken on Cassette *(include date & cassette #)* **:**

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Action Limits	**Required:**	Each cassette should successfully pass the CR cassette erasure process
	Timeframe:	Failing cassettes must be corrected before clinical use.

3. Compression Thickness Indicator

Monthly

Image Mode *(2D, 2D w/Add-on DBT, DBT)* _____

Facility _____ **Room ID** _____

MAP ID-Unit# *(00000-00)* _____ - _____ **Unit Mfr & Model** _____

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Year												
Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Date												
Tech Initials												
Description of compression thickness indicator phantom												
Actual thickness of phantom	☐ cm ☐ mm (Use the same unit displayed on the indicator)											
Indicated thickness												
Difference between indicated and actual thicknesses (Indicated - Actual)												
Overall Pass/Fail												

P = Pass   F = Fail

Action Limits	**Required:**	Compression thickness indicator **must** be accurate to within ±0.5 cm (±5 mm) of the actual thickness.
	Timeframe:	Failures **must** be corrected within 30 days.

4. Visual Checklist

_

Image Mode *(2D, 2D w/Add-on DBT, DBT, All)* _____

Facility _____ **Room ID** _____

MAP ID-Unit# *(00000-00)* _____ - _____ **Unit Mfr & Model** _____

Procedure	Inspect the unit and evaluate the functionality according to the checklist below.

	Year												
	Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
	Date												
	Tech Initials												
Room Cleanliness	Mag stands and paddles free from dust												
	Room and countertops free from dust												
	Cleaning solution available*												
X-Ray Unit	Indicators working												
	Locks *(all)***												
	Collimator light working												
	Are cables safely positioned												
	Smoothness of C-arm motion												
	Smoothness of compression paddle												
	Paddles/face shields not cracked*												
	Breast support not cracked*												
CR *(if app)*	**Cassette holder and lock** *(small and large)***												
	Condition of imaging plates and cassettes*												
Scanning Detector System *(if app)*													
DBT *(if app)*	**DBT assembly moves as designed***												
Other													

P = Pass   **F = Fail**   **NA = Not Applicable**

Action Limits	Required:	All items, both critical (*) and noncritical, must pass.
	Timeframe:	Failures of critical items (*) must be corrected before clinical use; less critical items must be corrected within 30 days.

5. Acquisition Workstation (AW) Monitor QC   *Monthly*

Image Mode *(2D, DBT)* _____

Facility _____   **Room ID** _____

MAP ID-Unit# *(00000-00)* _____ - _____

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Year												
Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Date												
Tech Initials												
Monitor Condition P/F *(significant findings)*												
Test Pattern Image Quality *(if available)* — 0%-5% contrast boxes visible?												
95%-100% contrast boxes visible?												
Line-pair images distinct (center)?												
Line-pair images distinct (corners)?												
Test pattern P/F												
Monthly Check - Mfr Automated Test P/F *(if avail)*												
Overall Pass/Fail												

P = Pass   F = Fail

Action Limits	**Required:**	Any identified screen blemish that could interfere with clinical information must be removed.
		Test pattern image quality must pass all visual tests.
		Manufacturer's automated tests, if available, must pass mfr specifications (if 1 test fails, indicate F).
	Timeframe:	Significant monitor cleanliness defects must be corrected before clinical use; all other required tests must be corrected within 30 days.

RW Location and ID

MAP ID# *(00000)* _____ Monitor Mfr _____ Model _____ SN: Right _____ Left _____

	Year																							
	Month	**Jan**		**Feb**		**Mar**		**Apr**		**May**		**Jun**		**Jul**		**Aug**		**Sep**		**Oct**		**Nov**		**Dec**
	Date																							
	Tech Initials																							
	Monitor	**R***	**L***	**R**	**L**	**R**	**L**	**R**	**L**	**R**	**L**	**R**	**L**	**R**	**L**	**R**	**L**	**R**	**L**	**R**	**L**	**R**	**L**	**R**	**L**
	Monitor Condition P/F *(significant findings)*																							
ACR DM Phantom	Phantom P/F																							
	Mass score																							
	Speck group score																							
	Fiber score																							
	Artifacts P/F																							
Test Pattern Image Quality	0%–5% contrast boxes visible																							
	95%–100% contrast																							
	Line-pair images distinct (center)																							
	Line-pair images distinct (corners)																							
	Test pattern P/F																							
	Monthly Check - Mfr Automated Test P/F *(if avail)*																							
	Overall Pass/Fail																							

* R and L - right and left monitors; if only 1 monitor, use "R" column

P = Pass   F = Fail

Action Limits

Required: Any identified monitor blemish that could interfere with clinical information must be removed.
ACR DM Phantom image must be free of clinically significant artifacts.
Fiber score must be ≥ 2.0; speck group score must be ≥ 3.0; mass score must be ≥ 2.0.
Test pattern image quality must pass all visual tests.
Manufacturer's automated tests, if available, must pass mfr specifications (if 1 test fails, indicate F).

Timeframe: Phantom must pass and significant monitor cleanliness defects must be corrected before clinical use; all other tests must be corrected within 30 days.

Film Printer Location and ID _____

Film Printer and Model _____

Workstation for printing _____ **Film size** _____

Procedure	**Applicability:** If film printer is used clinically for mammography (i.e., for interpretation and to provide images to referring physicians and patients)
	Equipment: Densitometer
	Print an ACR DM Phantom image acquired from any DM unit within facility network.
	Do not change window/level settings from acquired image prior to printing.
	Print the phantom image from the workstation/computer typically used to print clinical films.
	Dmax should be measured either at extreme left or right edge of film or at extreme non-chest wall edge.

		Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
	Year												
	Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
	Date												
	Tech Initials												
ACR DM Phantom	Artifacts P/F												
	Fiber score												
	Speck group score												
	Mass score												
	Phantom P/F												
Back-ground	Bkgd OD *(Outside cavity)*												
	Bkgd OD ≥ 1.6 (P/F)												
Contrast	Cavity OD												
	Bkgd OD *(use value from above)*												
	Contrast = Cavity OD - Bkgd OD												
	Contrast ≥ 0.1 (P/F)												
D_{max}	D_{max} OD												
	D_{max} OD ≥ 3.1 (P/F)												
	Overall Pass/Fail												

P = Pass   **F = Fail**

Action Limits	**Required:**	The ACR DM Phantom image must be free of clinically significant artifacts.
		Fiber score must be ≥ 2.0; speck group score must be ≥ 3.0; mass score must be ≥ 2.0.
		Background OD must be ≥ 1.6 (1.7 to 2.2 is recommended; approx 2.0 is optimal).
		Contrast (Cavity OD - Background OD) must be ≥ 0.1.
		D_{max} must be ≥ 3.1 (≥ 3.5 is recommended).
	Timeframe:	Failures of required items must be corrected before printing clinical images.

8. *Viewbox Cleanliness* *(if applicable)*

Viewbox Location and ID

Procedure	**Required Equipment:** Viewbox manufacturer-recommended cleaner; soft paper or cotton towels Clean viewbox surfaces and assure all marks have been removed. Visually inspect the viewboxes for uniformity of luminance and assure masking equipment is functioning.

	Year												
Month		Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Date													
Tech Initials													
Viewbox Designation													

P = Pass   F = Fail

Action Limits	**Required:**	Viewboxes must be clean and free of marks and uniform in brightness.
	Timeframe:	Failures must be corrected before clinical images are viewed on the viewbox.

9. Facility QC Review

Image Mode *(2D, 2D w/Add-on DBT, DBT)* _____

Facility _____   **Date of QC Mtg** _____

Reviewed

1. Review Medical Physics Surveys and Results   ☐

	Room 1	Room 2	Room 3	Room 4	Room 5
Room ID					
Date of last Medical Physicist (MP) survey					
MP DM QC Test Summary reviewed by radiologist?					
All MP corrective actions completed?					
ACR DM Phantom Average Glandular Dose (mGy)					
Fiber Score					
Speck Score					
Mass Score					

2. Review Tech QC   ☐

Test	Frequency	Summary Comments from Last Quarter	
1. ACR DM Phantom Image Quality	Weekly	_____	☐

		Room 1	Room 2	Room 3	Room 4	Room 5
Scores of most recent phantom image:	Date					
	Fiber score					
	Speck group score					
	Mass score					

Test	Frequency	Summary Comments from Last Quarter	
2. CR Cassette Erasure *(if app)*	Weekly	_____	☐
3. Compression Thickness Indicator	Monthly	_____	☐
4. Visual Checklist	Monthly	_____	☐
5. AW Monitor QC	Monthly	_____	☐
6. RW Monitor QC	Monthly	_____	☐
7. Film Printer QC	Monthly	_____	☐
8. Viewbox Cleanliness *(if app)*	Monthly	_____	☐
9. Facility QC Review	Quarterly	_____	☐
10. Compression Force	Semiannual	_____	☐
11. Manufacturer Calibrations *(if app)*		_____	☐
Optional - Repeat Analysis	As Needed	% Repeats _____	☐

3. Review and verify completion of all "Corrective Action"   ☐

4. Technique Chart review for each room (see MP report for recommendations) - (Annually)   ☐

5. Infection Control procedures followed   ☐

6. Offsite RW(s) & Film Printer(s) QC reviewed   ☐

7. Past and future service or service upgrades discussed *(if app)*   ☐

8. Past and future State and/or MQSA inspections discussed *(if app)*   ☐

9. Past and future ACR Accreditation issues discussed *(if app)*   ☐

Facility _____   **Date of QC Mtg** _____

Follow-up Confirmed *(If App.)*

10. Notable findings during QC meeting

_____   _____
_____   _____
_____   _____
_____   _____
_____   _____
_____   _____
_____   _____
_____   _____

11. Items for quality improvement from QC Meeting

_____   _____
_____   _____
_____   _____
_____   _____
_____   _____
_____   _____
_____   _____
_____   _____
_____   _____

12. Other QC Notes

_____   _____
_____   _____
_____   _____
_____   _____
_____   _____
_____   _____

Overall Pass/Fail [_____]

_____   _____   _____
Lead Interpreting Radiologist   Facility Manager (If App)   QC Technologist
signature   *signature*   *signature*

Action Limit:	**Required:**	Lead interpreting radiologist and facility manager must review QC quarterly.
		The test passes if meeting held.
	Recommended:	Technologist and lead interpreting radiologist should review technique charts at least annually for each DM system.
	Timeframe:	Not applicable.

10. Compression Force

Image Mode *(2D, 2D w/Add-on DBT, DBT)* _____

Facility _____   **Room ID** _____

Unit Mfr & Model _____   **MAP ID-Unit#** *(00000-00)* _____ - _____

Procedure	**Required Equipment:** Bathroom scale; towels Place towel on detector, place bathroom scale on towel with dial or read-out positioned for reading. Place another towel on top of scale. Using manual fine-adjustment mode, activate compression until at least 25 pounds reached. Read and record the compression force. Using initial power-drive mode, activate compression until it stops automatically. Read and record the compression force. Check that force is maintained. <u>Note</u>: Ensure the scale used produces accurate readings as pressure is increased.

Year				
Date *(month & day)*				
Tech Initials				
	Compression Force	**Units**	**Compression Force**	**Units**
Manual fine-adjustment compression force				
Force is at least 25 lbs (11.1 daN) P/F				
Initial power-drive compression force				
Force is at least 25 lbs (11.1 daN) but no more than 45 lbs (20.0 daN) P/F				
Compression remains at least 25 lbs (11.1 daN) throughout typical exposure P/F				
Overall Pass/Fail				

Enter number where appropriate.   **P = Pass   F = Fail**

Legend: lbs = pounds

daN = decanewton

Action Limit	**Required:**	Manual fine-adjustment compression force must be least 25 lbs (11.1 daN).
		Initial power-drive compression force must be at least 25 lbs (11.1 daN) but no greater than 45 lbs (20 daN).
		Compression remains at least 25 lbs (11.1 daN) throughout typical exposure.
	Timeframe:	Failures must be corrected before further examinations are performed.

11. Manufacturer Calibrations *(if applicable)*

Image Mode *(2D, 2D w/Add-on DBT, DBT)* _____

Facility _____ _____   **Room ID** _____

MAP ID-Unit# *(00000-00)* _____ - _____   **Unit Mfr & Model** _____

Manufacturer Procedure	**Frequency:** _____
	Frequency: Per manufacturer recommendations (if app).
	Note: See medical physicist and manufacturer for instructions (if any).

Year					
Date *(month & day)*					
Tech Initials					
Name of Calibration					

P = Pass   **F = Fail**

Action Limits	**Required:**	Unit must pass manufacturer's prescribed periodic calibrations.
	Timeframe:	Failures must be corrected before further examinations are performed.

Optional - Repeat Analysis - Summary Form

Facility _____   **Year** _____

MAP ID *(00000)* _____

Procedure	Required Equipment: All repeated mammograms and means to count and sort them Record the **_total number of exposures_** for the collection period (month or quarter). Record the **_total number of repeat exposures_** for that time period. Calculate by hand, or use formulas in spreadsheet, to calculate repeat rate. **Note:** Some units may automatically calculate % Repeats. If so, enter this number into "% Repeats".

	Monthly Analysis				Quarterly Analysis			
	Total # of Exposures	# of Repeat Exposures	% Repeats	Pass or Fail	Total # of Exposures	# of Repeat Exposures	% Repeats	Pass or Fail
Jan								
Feb								
Mar								
Apr								
May								
Jun								
Jul								
Aug								
Sep								
Oct								
Nov								
Dec								

% Repeats = (# of Repeat Exposures / Total # of Exposures) * 100   **P = Pass   F = Fail**

Action Limits	Recommended:	If repeat rate changes from the previously determined rate by more than 2.0% of the total images included in the analysis, the reason(s) for the change must be determined.
	Timeframe:	Failures must be corrected within 30 days after analysis.

Optional - Repeat Analysis A - Tally Sheet

Facility _____   **Date Start** *(month/day/yr)* _____

MAP ID *(00000)* _____   **Date End** *(month/day/yr)* _____

Procedure	Record all repeat exposures on the form below.
	Transfer the <u>Total Number of Repeats</u> from below to the "Repeat Analysis -Summary Form" for final calculation of Repeat Analysis.

Total # of images for time period [ ]

Reason	Comments/Notes	Total # of Repeat Exposures	% Repeats
Patient-Related Repeats:			
Poor positioning			
Patient motion			
Patient-caused artifacts			
Incorrect patient ID			
Technical Repeats:			
Exposure too low (excessive noise)			
Exposure too high (image saturation)			
Equipment-caused artifacts			
X-ray equipment failure			
Software failure			
Aborted AEC exposure			
Miscellaneous Repeats:			
Blank images			
Good images (no apparent reason)			
Other - miscellaneous			
Do Not Count as Repeats:			
Wire localization images			Not Included in Repeat Analysis
I-125 seed localization images			
Additional views to image entire breast			
Quality control			
Total:			

Note: Some equipment manufacturers provide an automated system to collect, record and analyze repeated clinical images. These systems may be used instead of these forms as long as the system includes the following 2 key elements:
   1. Count of the total # of exposures made during the evaluation period
   2. % Repeats during the same period: (# Repeat Exposures/Total # Exposures)*100

Optional - Repeat Analysis B - Daily Counting Sheet

Facility _____

MAP ID *(00000)* _____

Date Start *(Month/Day/Yr)* _____

Date End *(Month/Day/Yr)* _____

Procedure	**Record these counts daily.** For each patient, record all images including repeat exposures. Transfer the <u>Total Number of Repeats</u> from below to the "Repeat Analysis - Tally Sheet" for final calculation of Repeat Analysis.

Patient Name and/or ID	Total Number of Images	# of Repeat Expo-sures	Positioning	Patient motion	Patient-caused artifacts	Incorrect patient ID	Exposure too low	Exposure too high	Equipment-caused artifacts	X-ray equipment failure	Software failure	Aborted AEC exposure	Blank images	Good images (no apparent reason)	Other - miscellaneous	Localization images (wire and I-125)	Additional views for entire breast	Quality control
Total																		

Note: Some equipment manufacturers provide an automated system to collect, record and analyze repeated clinical images. These systems may be used instead of these forms as long as the system includes the following 2 key elements:
1. Count of the total # of exposures made during the evaluation period
2. % Repeats during the same period: (# Repeat Exposures/Total # Exposures)*100

Optional - System QC for Radiologist
(For Quality Improvement)
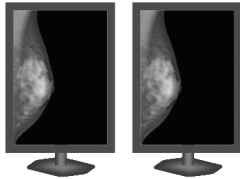
Facility _____

MAP ID-Unit# *(00000-00)* _____ - _____

Procedure	This test is to be performed or supervised by the lead interpreting radiologist.
	The technologist should deliver this form to the radiologist, ensure correct completion, follow-up on any failures, and place the form into QC notebook.
	This test can be performed on the same workstation for multiple DM or CR units.
	Example: A radiologist can sit at one workstation and view the images for all the DM and/or CR units within a facility.
	The radiologist does not need to evaluate every monitor at every workstation.

Objective   This test is for the Radiologist to perform an evaluation of the entire mammographic imaging chain with the focus being primarily on the detector and secondarily on the monitors. This test is not intended to evaluate technologist issues such as positioning, compression, etc.

Procedure for Radiologist

Step 1:   Complete the demographics:

Room ID _____
DM or CR Unit Mfr & Model _____
Monitor ID _____
Radiologist Name _____
Date of Evaluation _____

Step 2.   Pull up the recent mammographic study from the above listed DM unit and record ID & Study Date.

Image ID: _____
Study Date: _____

Step 3.   Place the same MLO image on each monitor.

Left Monitor   Right Monitor

Step 4.   Evaluate the images for artifacts and check the appropriate boxes.

For examples and more detailed descriptions, please see the Guide on Identifying Artifacts.

Step 5.   If necessary, document any failures on the "Corrective Action Log" form and ensure items are resolved.

	Yes	No
Comparing the monitors (or sides), do the background areas (outside of breast) appear different (darker or lighter, etc.)?	☐	☐
Is there a difference in contrast between monitors/sides?	☐	☐
Does the image contain excessive noise (not patient motion)?	☐	☐
Do you see ghosting?	☐	☐
Do you see "bad pixels" (singular or clusters) (white or black)?	☐	☐
Do you see white dots that could be from excessive dust?	☐	☐
Do you see any image distortion (not architectural distortion)?	☐	☐
Do you see gridlines?	☐	☐
Do you see artifacts that could be due to image processing?	☐	☐
Do you see "line artifacts" (single or multiple pixels that form lines extending across image - horizontally or vertically)?	☐	☐
Are there any other artifacts that are present and clinically significant (impeding interpretation)?	☐	☐

Action Limits	**Recommended:**	If any box is checked "Yes", then seek service.
	Timeframe:	If an image quality problem or artifact impedes clinical interpretation, seek service before further imaging or interpretations are performed.
		If the artifact does not impede clinical interpretation, seek service within 30 days.

Optional - Radiologist Image Quality Feedback   *As Needed*
(For Quality Improvement)

Radiologist's Name _____

Date _____

Procedure	This report is to be completed by the Interpreting Radiologist when asked to interpret sub-optimal cases requiring the patient to be called back.
	The form may also be used to provide feedback on excellent quality.
	The radiologists should complete this form as needed for each case.
	A system should be in place for analyzing feedback and taking measures for improvement as necessary.

Objective   For the Radiologist to provide routine feedback to the technologists and manager on the quality of images.

Patient Identifier: _____

Technologist's Name: _____

Date of Exam: _____

Overall Assessment

☐ Excellent   ☐ Good   ☐ Needs improvement, but do not repeat   ☐ Sub-Optimal, and should be repeated

Image Evaluation

	RCC	LCC	RMLO	LMLO	Other View	Other View
Positioning						
Missing tissue						
Laterally						
Posteriorly						
Medially						
Inferiorly						
Nipple not in profile						
Skin fold						
Pectoralis not down to PNL						
Tissue droopy (camel nose)						
Narrow/concave pectoralis						
Inframammary fold						
Not open						
Not shown						
Centering not correct						
Technical Issues						
Not enough compression						
Exposure Too Low (Excessive Noise)						
Exposure Too High (Image Saturation)						
Patient Motion						
Artifacts						
Incorrect Patient ID						
Other						

Additional Images Needed for Complete Breast Evaluation

Requested views   ☐ RCC   ☐ LCC   ☐ RMLO   ☐ LMLO   ☐ Other View _____

Action Limits	**Recommended:**	Patients should be called back for additional images if the quality is suboptimal according to the interpreting radiologist's request.
	Timeframe:	Not applicable.

C. Management Forms

1.   ACR Technique and Procedure Summaries

The ACR Technique and Procedure Summaries form provides a central location to record technical parameters and setup instructions used for imaging the ACR DM Phantom and evaluating the AAPM TG-18 QC or SMPTE test patterns. These forms should be kept at the front of each respective set of data for each test. These pages give instructions and keep a log of previous and current techniques for subsequent tests.

2.   Corrective Action Log

The Corrective Action Log provides a method for documenting any and all QC events needing corrective action that occur within a mammography facility. This includes problems detected during the Radiologic Technologist QC Tests, Medical Physicist Equipment Evaluation and Annual Survey, and any other miscellaneous events that may arise.

3.   Facility Offsite Display Locations

The Facility Offsite Display Locations form is provided to maintain a current list of all locations or facilities providing final interpretations of clinical images produced at your facility. This will aid your medical physicist in ensuring that all offsite displays used for interpretation are adequately tested.

The form should be reviewed annually and updated when there are any changes in locations or facilities that provide interpretations.

4.   QC Summary Checklists

To assist with the oversight of the QC program, mammography checklists are provided to record the Weekly, Monthly, Quarterly, and Semi-Annual Tests for both the mammography system and the display devices. These checklists provide quick reminders of when QC tasks are due and also provide records indicating that the tasks have been completed in a timely manner. In addition, the ACR will request copies of these checklists during the accreditation process to document that all required QC tests were performed at the required frequencies.

All dates should be filled in prior to use of the checklist. Each time a task is completed, the individual carrying out the task should initial the appropriate area on the checklist. If a test is not performed because a system is not in use (for example, one of the RW monitors is being repaired, is not being clinically used, or is not available to test), the QC technologist should put an "X" in the box and include a note of why the test is not being performed.

DIGITAL MAMMOGRAPHY UNIT QC SUMMARY CHECKLIST

This checklist is for the digital mammography imaging unit located at the mammography facility.

FACILITY DISPLAY DEVICE QC SUMMARY CHECKLIST

This checklist is for the display devices (including the RW monitors, film printers, and viewboxes) that may or may not be at a different location from the mammography imaging system.

ACR Technique and Procedure Summaries

Image Mode *(2D, 2D w/Add-on DBT, DBT)* _____

Facility _____ **Room ID** _____

MAP ID-Unit# *(00000-00)* _____ - _____ **Unit Mfr & Model** _____

ACR DM Phantom Image Quality

Procedure: Use the technique typically used for a 4.2 cm thick compressed breast of 50% glandular and 50% adipose tissue.
Obtain exposure mode, phantom setup, and operating levels from medical physicist.
Use largest image receptor size available and matching clinically used paddle.
Use 5 daN or 12 lbs compression force.
Score and analyze on acquisition workstation (radiologist workstation for DBT).
For DBT, record the slice or slab where the test objects are best visualized.
Adjust W/L to optimize test objects and record; do not subtract for artifacts.
Zoom and pan across entire image to evaluate for artifacts.

	Date				
Phantom Setup	AEC mode				
	Paddle size (IR size)				
	Paddle type (reg or flex)				
	View or selected image				
	Slice or slab # (DBT only)				
	Compression force				
	AEC cell position *(if avail)*				
	Target/filter *(if app)*				
	kVp *(if app)*				
	Density setting *(if app)*				
	Window width & window level *(approx)*				
	Image name *(if app)*				
	Image ID *(if app)*				
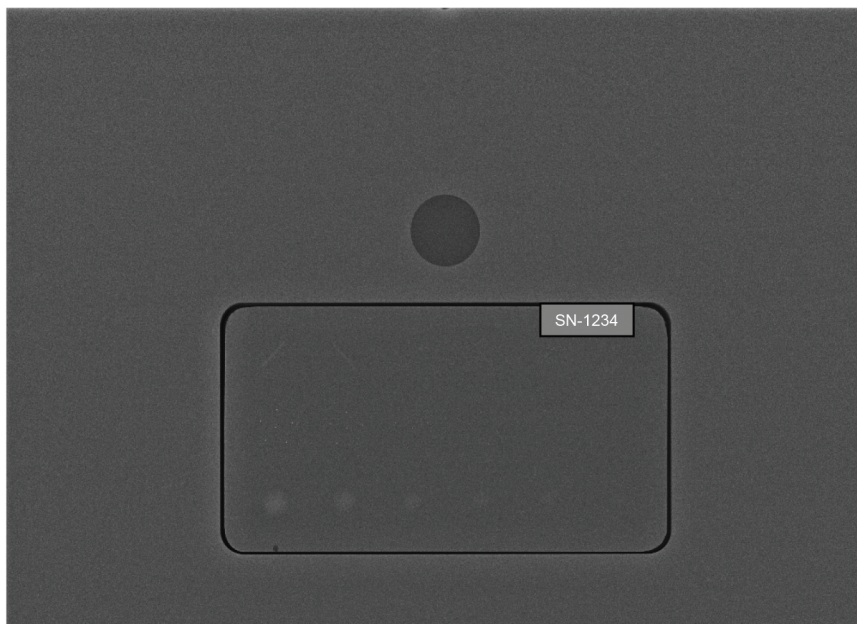
ACR Technique and Procedure Summaries (cont)

Facility

Room ID

MAP ID-Unit# *(00000-00)* _____ - _____   **Unit Mfr & Model** _____

AW & RW Monitor QC

Procedure: Display the AAPM TG 18-QC or SMPTE test pattern.
(Another pattern that allows relevant measurements may also be used.)
Check the monitor screens to verify they are clean.
Verify that 0%-5% and 95%-100% boxes are visible (red circles).
Verify that line-pair images are sharp and distinguishable (red rectangles).
Score the ACR DM Phantom & evaluate for artifacts (RW only).
If applicable, perform monitor calibration tests per manufacturer's recommendations.

Monitor manufacturer instructions for finding & viewing TG 18-QC test pattern:

_____

_____

_____

_____

SMPTE Test Pattern   **TG 18-QC Test Pattern**

Facility _____ **Room ID** _____

    MAP ID-Unit# *(00000-00)* _____ - _____ **Unit Mfr & Model** _____

Film Printer QC

Procedure: Required equipment - ACR DM Phantom image and densitometer
Print image acquired in "ACR DM Phantom Image Quality" test.
Print from workstation/computer/PACS used for printing most clinical films.
Do not adjust window and level settings prior to printing.
Evaluate the phantom for artifacts & score.
Note: If possible, print phantom image from same x-ray unit each time for this test.
Note: Use film size most commonly used for mammography.
Note: For each printer, only print a single image from a single x-ray unit or workstation.

Film Printer Setup					
	Date:				
	Film Size (8 x 10 or 10 x 12):				
	ID of x-ray unit or workstation for printed phantom:				

Dmax Note: Dmax to be measured on perimeter of film.
If not available, print a clinical image and measure
in the non-breast area.

Background OD   **Cavity OD**   **Dmax**

Corrective Action Log

Facility _____   **MAP ID#** *(00000-00)* _____ - _____

Room or Equipment ID _____   **Date** _____

QC Test Name and # (if app):

Description:

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

Relevant Personnel Notified: **Personnel Name:**   **Date/Time of Call/Notification:**

(Radiologist, MP, tech, manager,   _____   _____
service engineer)   _____   _____
                                       _____   _____

Describe Actions Taken:

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

Confirmation of Resolution:

	Yes	To Be Monitored	NA	
Event resolved?	☐	☐	☐	**Tech Signature** _____
Documentation from service engineer obtained?	☐	☐	☐	**Date** _____

Facility Offsite Display Locations

Facility _____   **MAP ID#** _(00000)_ _____

Address _____

Offsite Locations or Facilities Where Images are Interpreted for this Facility
(list facility name, address, and MAP ID)

Location or Facility Name	Address	MAP ID

Digital Mammography Unit QC Summary Checklist

Image Mode (2D, 2D w/Add-on DBT, DBT, All) _____

Facility _____

MAP ID# (00000-00) _____ - _____

Unit Mfr & Model _____

Room ID _____

Year						
Month	**Jan**	**Feb**	**Mar**	**Apr**	**May**	**Jun**
ACR DM Phantom Image Quality (weekly)						
CR Cassette Erasure, if app (weekly)						
Compression Thickness Indicator (monthly)						
Visual Checklist (monthly)						
AW Monitor QC (monthly)						
Compression (semiannual)						
Mfr Detector Calibration, if app						
Facility QC Review (quarterly)						
Repeat Analysis (optional - as needed)						

Overall (only need to complete once for the facility)

Detector Calibration Freq: [____]

Date and initial each test:

date
initial

Cross out boxes where mfr calibration test is not required:

X
X

Digital Mammography Unit QC Summary Checklist

Facility _____

MAP ID# *(00000-00)* _____ - __ __

Unit Mfr & Model _____

Image Mode *(2D, 2D w/Add-on DBT, DBT, All)*

Room ID _____

Month	Jul	Aug	Sep	Oct	Nov	Dec
Year						
ACR DM Phantom Image Quality (weekly)						
CR Cassette Erasure, if app (weekly)						
Compression Thickness Indicator (monthly)						
Visual Checklist (monthly)						
AW Monitor QC (monthly)						
Compression (semiannual)						
Mfr Detector Calibration, if app						
Facility QC Review (quarterly)						
Repeat Analysis (optional - as needed)						

Overall *(only need to complete once for the facility)*

Detector Calibration Freq: [_____]

Date and initial each test: [date / initial]

Cross out boxes where mfr calibration test is not required: [X / X]

Facility Display Device QC Summary Checklist

Facility _____   **MAP ID#** *(00000)* _____

Address _____

Address _____

QC Summary information for display devices at this MAP ID								
Physical Location at Facility/ ID Designation								
Device *(RW, film printer, viewbox)*								
Manufacturer								
Model								
Jan	Date								
	Tech Initials								
Feb	Date								
	Tech Initials								
Mar	Date								
	Tech Initials								
Apr	Date								
	Tech Initials								
May	Date								
	Tech Initials								
Jun	Date								
	Tech Initials								
Jul	Date								
	Tech Initials								
Aug	Date								
	Tech Initials								
Sep	Date								
	Tech Initials								
Oct	Date								
	Tech Initials								
Nov	Date								
	Tech Initials								
Dec	Date								
	Tech Initials								
Medical Physicist Survey Date								
Medical Physicist Name(s)								

D. Mobile Mammography

Mobile mammography systems are subject to all the QC requirements and frequencies that apply to stationary mammography systems, including DBT. In addition, the tests outlined in Table 5 ***must*** be performed after each move of the mobile system at each examination location. For example, if the mobile unit moves to 2 different locations within the same day, all the applicable tests outlined below must be performed prior to using the equipment at each location, so the tests would be performed twice on that day.

> **Note:** The tests outlined in Table 5 ***must*** be performed after each move of the mobile system at each examination location.

The evaluations should be made at the mobile unit's site of operation to verify that the mobile unit is performing adequately before any patient examinations are conducted, before the mobile RW is used for interpretation, or before the mobile film printer is used to generate hardcopy of patient images. If the image quality is inadequate, then immediate corrective action is required and the results of the corrective action need to be verified via repeat testing before proceeding.

Table 5. Tests That Must Be Performed by the Technologist After Each Mammography System Move to a New Location

QC Tests
• ACR DM Phantom Image Quality - after each move and prior to examining patients
• Compression Thickness Indicator - after each move and prior to examining patients
• Radiologist Workstation (RW) Monitor QC (for mobile RW only) - after each move and prior to interpretation
• Film Printer QC (for mobile film printers only) - after each move and prior to printing patient images

> *900.7 Mobile Units. The facility shall verify that mammography units used to produce mammograms at more than one location meet the requirements in paragraphs (e)(1) through (e)(6) of this section. [Quality assurance— equipment requirements] In addition, at each examination location, before any examinations are conducted, the facility shall verify satisfactory performance of such units using a test method that establishes the adequacy of the image quality produced by the unit.*

E. Infection Control

OBJECTIVE

To prevent and control the spread of infection to employees, patients, and visitors within the mammography facility.

GENERAL INFORMATION

Mammography personnel must follow the facility's established Infection Control procedures. For additional guidance on infection control, refer to OSHA's Bloodborne Pathogens Standard (29 CFR 1910.1030), any additional state and local regulations on this subject that may be applicable to the facility, and the manufacturer's procedures specific to its equipment.

RESPONSIBILITIES

- The department manager/supervisor must ensure that the mammography facility has written procedures for cleaning and disinfecting mammography equipment that has come in contact with blood or other body fluids or potentially infectious materials. If reference material is cited in the facility's procedures, the facility must have a copy of the referenced material. The procedures must comply with applicable federal, state, and local regulations as well as manufacturer's recommendations.

- The department manager/supervisor must also ensure that mammography personnel follow the infection control procedures.

FREQUENCY

This procedure should be carried out between patients.

EQUIPMENT

- Facility-approved disinfectant (the QC technologist should verify with manufacturer that approved disinfectant will not damage equipment)

- Disposable wipes

PROCEDURE STEPS

1. All surfaces in contact with the patient are to be wiped clean with a facility-approved disinfectant at the end of each exam.

2. All linens are for single patient use. Following use, they are to be deposited in appropriate bags for transport to laundry.

3. Any spills or drips on floors or equipment must be washed with a facility-approved disinfectant.

4. *If mammography equipment comes into contact with blood or other potentially infectious agents,* mammography personnel **must** document that infection control procedures were performed on a log or chart.

900.13 Infection control. Facilities shall establish and comply with a system specifying procedures to be followed by the facility for cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials. This system shall specify the methods for documenting facility compliance with the infection control procedures established and shall:
(i) Comply with all applicable Federal, State, and local regulations pertaining to infection control; and

(ii) Comply with the manufacturer's recommended procedures for the cleaning and disinfection of the mammography equipment used in the facility; or

(iii) If adequate manufacturer's recommendations are not available, comply with generally accepted guidance on infection control, until such recommendations become available.

References

A. Downloadable from the ACR Website (www.acr.org)

- ACR Mammography Accreditation Program

- ACR Digital Mammography QC Manual Resources

- Destouet JM, Bassett LW, Yaffe MJ, Butler PF, Wilcox PA. The ACR's mammography accreditation program: ten years of experience since MQSA. *J Am Coll Radiol.* 2005;2(7):585-594.

- ACR Appropriateness® Criteria - Breast Imaging

- ACR BI-RADS® Atlas

- ACR Practice Parameter for the Performance of Screening and Diagnostic Mammography

- ACR–AAPM–SIIM Practice Parameter for Determinants of Image Quality in Digital Mammography

B. References

1. Department of Health and Human Services. FDA Mammography Quality Standards, Final Rule. *Fed Reg.,* 1997;62(208):55852-55994.

2. U.S. Food and Drug Administration. Mammography Quality Standards Act (MQSA) Policy Guidance Help System.

3. FDA Mammography Quality Standards Act and Program, Facility Certification and Inspection (MQSA) - Digital Accreditation.

4. Hendrick RE, Bassett L, Botsco MA, et al. Mammography Quality Control Manual. Reston, Va: American College of Radiology; 1999.

5. Samei E, Badano A, Chakraborty D, et al. Assessment of display performance for medical imaging systems: executive summary of AAPM TG18 report. *Med Phys.* 2005;32:1205-1225.

6. Gray JE. Use of the SMPTE test pattern in picture archiving and communication systems. *J Digit Imaging.* 1992;5:54-58.

C. Additional Resources

- Berns EA, Hendrick RE, Cutter GR. Optimization of technique factors for a silicon diode array full-field digital mammography system and comparison to screen-film mammography with matched average glandular dose. *Med Phys.* 2003;30:334-340.

- Bloomquist AK, Yaffe MJ, Pisano ED, et al. Quality control for digital mammography in the ACRIN DMIST trial: part I. Med Phys 2006;33:719-736.

- Kruger RL, Schuler BA. A survey of clinical factors and patient dose in mammography. *Med Phys.* 2001;28:1449-1454.

- Quality Control Manual Template for Manufacturers of Displays and Workstations Devices Labeled for Final Interpretation in Full-Field Digital Mammography. Rosslyn, Va: National Electrical Manufacturers Association; XR 22-2006; 2006.

- Quality Control Manual Template for Manufacturers of Hardcopy Output Devices Labeled for Final Interpretation in Full-Field Digital Mammography. Rosslyn, Va: National Electrical Manufacturers Association; XR 23-2006; 2006.

2018

Digital Mammography

QUALITY CONTROL MANUAL

Medical Physicist's Section

Contents

**MEDICAL
PHYSICIST'S SECTION**

Revisions

Date	Page(s)	Section	Description of Revisions
November 2018			2nd edition with digital breast tomosynthesis QC
May 2020	121	Introduction	Clarified FDA position regarding QC for contrast enhancement mammography systems
May 2020	143-149	2. ACR Digital Mammography (DM) Phantom Image Quality	Clarified that phantom QC needs to be performed using clinical system settings, and that artifacts must be assessed for all target-filter combinations in clinical use
May 2020	163	4. Spatial Resolution	Clarified 2D magnification mode criteria
May 2020	167	6. Automatic Exposure Control System Performance	Clarified Performance Criteria
May 2020	201	15. Manufacturer Calibration	Clarified Objectives
May 2020	202-203	16. Collimation Assessment	Clarified Frequency and Test Procedure as they pertain to 2D vs. DBT and MEE vs. Annual Survey vs. service events

MEDICAL PHYSICIST'S SECTION

II. Introduction

A. MQSA and Quality Control

For the purposes of this manual, quality control (QC) is defined as the routine performance and interpretation of equipment function tests and of the corrective actions taken. The objective of QC is to detect, identify, and correct equipment-related problems before they have a deleterious effect on clinical images. Together with the radiologist, the radiologic technologist, and equipment service personnel, medical physicists can help identify and eliminate these problems before patient care is affected. The purpose of this section of the manual is to provide the medical physicist with effective and consistent methodology for detecting and identifying image quality problems.

The 1999 American College of Radiology (ACR) Mammography Quality Control Manual was developed specifically for screen-film mammography to assist facility staff in complying with the Mammography Quality Standards Act (MQSA) Final Rule, which went into effect on April 28, 1999 [1]. Since that time, screen-film has been almost entirely replaced by digital mammography. Furthermore, a growing number of digital mammography systems include digital breast tomosynthesis (DBT) capability. The 1998 MQSA Final Rule specifies that "For systems with image receptor modalities other than screen-film [i.e., 2D or DBT], the quality assurance program shall be 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." See the MQSA Policy Guidance Help System by the Food and Drug Administration (FDA) for more information [2].

> *900.12(e) Quality assurance—equipment. (6) Quality control tests—other modalities. 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, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems in paragraph (e)(5)(vi) of this section.*

As of the publication date, five models and manufacturers of DBT systems have been cleared by the FDA for sale in the U.S. [3], each with its own QC manual. (Over 30 models and manufacturers of digital mammography systems have been cleared.) These manuals all have different manufacturer- and model-specific tests, procedures, frequencies, and performance criteria [4]. This variation is necessary in most cases to accommodate the design differences inherent to each device. Many of the tests, however, could be made more consistent across platforms. The ACR Digital Mammography Quality Control Manual has been designed to create a generic digital mammography QC program by providing uniform test procedures, performance criteria, and minimum test frequencies that can be used for all manufacturers and models. Due to the unique manufacturer-specific design of certain equipment features, a few tests and criteria in the manual refer to the instructions and performance

levels established by the manufacturer. For example, the Manufacturer Calibrations test/procedure (if available) is software-dependent and thus unique to each manufacturer.

Some digital mammography systems include contrast enhancement. The FDA has approved the use of the new ACR Digital Mammography QC Manual for digital mammography systems with contrast enhancement. *Facilities with contrast enhancement systems may follow this manual for QC of the 2D and DBT applications of these units, but should follow manufacturer QC procedures for contrast enhancement applications.*

> **Note:** Facilities *may* use the new ACR Digital Mammography QC Manual for digital mammography systems with contrast enhancement, but only for the 2D and DBT applications. Facilities should follow manufacturer QC procedures for contrast enhancement applications.

To legally allow facilities to use these new procedures instead of the procedures required by their system's QC manual, the ACR applied to the FDA and was granted an amendment to the existing Alternative Standard for Using the Quality Assurance Program Recommended by the ACR Quality Control Manual for Full-Field Digital Mammography Systems, for Systems without Advanced Imaging. The amended alternative standard specifies that facilities must use the approved ACR Digital Mammography (DM) Phantom in concert with all of the applicable manual's procedures, performance criteria, and minimum test frequencies for both 2D and DBT QC. This phantom has been designed to cover most of the detector area and provide the same attenuation as the small ACR mammography phantom used in the 1999 Mammography Quality Control Manual, which approximates a 4.2 cm thick compressed breast consisting of 50% glandular and 50% adipose tissue. If you have multiple phantoms, use the same phantom each time on a given unit (Figure 1).

Figure 1. ACR DM Phantom. *(Different manufacturer's phantoms may appear slightly different. Use of one manufacturer's phantom photo does not imply ACR endorsement of one phantom manufacturer over another.)*

MEDICAL PHYSICIST'S SECTION

If a facility chooses to follow the ACR manual for its QC program, it is no longer required to follow its manufacturer's QC manual (for 2D or DBT). However, facilities should maintain their manufacturer's QC manual to refer to when performing ACR-required calibration or troubleshooting tests.

Facilities *may not* use the new procedures with the small ACR mammography phantom or use the newly developed ACR DM Phantom with the old test procedures. *The ACR DM Phantom was explicitly designed as a tool for the ACR Digital Mammography Quality Control Manual (for both 2D and DBT QC) and for the ACR Mammography Accreditation Program to meet FDA MQSA phantom image quality and dose requirements.*

Note: The ACR Digital Mammography Phantom is required for the majority of the QC tests in this manual. ACR-approved manufacturers of the ACR Digital Mammography Phantom are listed on the ACR website. (For more information, visit https://www.acraccreditation.org/Resources/Digital-Mammography-QC-Manual-Resources.)

Although the ACR DM Phantom is the primary phantom used with this manual, facilities should not discard any manufacturer-provided phantoms since they may be needed for manufacturer-specified calibrations or service personnel testing.

The new medical physics digital mammography test procedures and forms were designed to simplify the conduct, documentation, and evaluation of mammography equipment evaluations (MEEs) and annual surveys for digital mammography. Commonly performed tests that seldom, if ever, identified deficiencies have been eliminated, and low-yield tests will now only be conducted during MEEs and not during routine annual surveys. All tests are applicable to all manufacturers and models of digital mammography equipment unless otherwise noted. Medical physicists are encouraged to use the forms within this manual for data documentation and their final reports, although they are not required. However, the Medical Physicist's ACR DM QC Test Summary form (or a copy with identical tests recreated in the physicist's software) *must* be submitted to the ACR as part of the accreditation application.

For each of the required medical physicist tests included in this manual, the purpose and frequency of each test is clearly stated. The equipment and materials required to carry out each test are listed, and a step-by-step procedure is provided. Note that other methodologies for these tests may be used, provided that they yield the same results as the methodologies provided in this manual. Following each procedure is a discussion of precautions and caveats. Performance criteria are provided along with suggestions for the types of corrective actions that may be needed to resolve problems.

Relevant MQSA regulations are provided to supplement responsibilities and tests in this ACR Digital Mammography Quality Control Manual if they apply.

Digital Mammography Quality Control Manual

B. Responsibilities

The MQSA Final Rule requires that the facility's lead interpreting physician (typically a radiologist) has the general responsibility of ensuring that the quality assurance program meets all requirements.

In a facility where more than one technologist does mammography, one technologist must be assigned the responsibilities of QC (the QC technologist). Other qualified individuals may perform specific QC tests, but they must be reviewed and evaluated by the primary QC technologist. The primary QC technologist is responsible for ensuring that QC tasks are done properly by standardizing test methodology, reviewing all data, overseeing repeat testing before calling the medical physicist or service personnel, and conferring with the radiologist and medical physicist.

Each facility must have the services of a medical physicist to survey mammography equipment and oversee the equipment-related quality assurance practices of the facility.

> *900.12(d) Quality assurance—general. (1) Responsible individuals. (iii) Medical physicist.*
>
> *Each facility shall have the services of a medical physicist available to survey mammography equipment and oversee the equipment-related quality assurance practices of the facility. At a minimum, the medical physicist(s) shall be responsible for performing the surveys and mammography equipment evaluations and providing the facility with the reports described in paragraphs (e)(9) [Surveys] and (e)(10) [Mammography equipment evaluations] of this section.*

The medical physicist is required to conduct an MEE of new equipment and after major repairs. This survey must be done and all relevant tests must be passed prior to use of digital mammography equipment on patients.

> **Note:** During the MEE, the medical physicist should complete the Technologist's ACR Technique and Procedure Summaries form (located in the Technologist Section) to help the QC technologist use the appropriate techniques during routine QC. This form should be reviewed and updated as necessary during annual surveys.

MEDICAL PHYSICIST'S SECTION

> *900.12(e) Quality assurance—equipment. (10) Mammography equipment evaluations. Additional evaluations of mammography units or image processors shall be conducted whenever a new unit or processor is installed, a unit or processor is disassembled and reassembled at the same or a new location, or major components of a mammography unit or processor equipment are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in paragraphs (b) and (e) of this section. All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing. The mammography equipment evaluation shall be performed by a medical physicist or by an individual under the direct supervision of a medical physicist.*

The medical physicist is also required to perform an annual survey on each unit. (An occasional period of up to 14 months between surveys is acceptable.) During this annual survey, the medical physicist must also review the technologist's QC test results and provide written recommendations if there are problems or suggestions for improvement. Review of the technologist's QC program by the radiologist and medical physicist ensures that the QC program is carried out consistently and provides oversight to make sure that changes in image quality are not inadvertently overlooked.

> *900.12(e) Quality assurance—equipment. (9) Surveys.*
>
> *(i) At least once a year, each facility shall undergo a survey by a medical physicist or by an individual under the direct supervision of a medical physicist. At a minimum, this survey shall include the performance of tests to ensure that the facility meets the quality assurance requirements of the annual tests described in paragraphs (e)(5) and (e)(6) of this section and the weekly phantom image quality test described in paragraph (e)(2) of this section.*
>
> *(ii) The results of all tests conducted by the facility in accordance with paragraphs (e)(1) through (e)(7) [quality control tests] of this section, as well as written documentation of any corrective actions taken and their results, shall be evaluated for adequacy by the medical physicist performing the survey.*
>
> *(iii) The medical physicist shall prepare a survey report that includes a summary of this review and recommendations for necessary improvements.*

It is the responsibility of the medical physicist conducting these tests to convey test results accurately to the facility in a written report, to make recommendations to the facility for corrective actions according to the test results, and to review the results with the radiologist and QC technologist. The report must include a summary form outlining the pass or fail results of each test along with documentation of the data obtained during the test. The facility should provide this detailed information to the equipment service engineer to facilitate repair. MQSA inspectors check the medical physicist's report to determine if the facility is in compliance with MQSA regulations and if the medical physicist's recommendations have been considered by the facility.

Digital Mammography Quality Control Manual

> **Note:** If there is need for corrective action, the medical physicist should instruct the facility to provide a copy of its full report for the equipment service engineer.

> *900.12(e) Quality assurance—equipment. (9) Surveys.*
>
> *(iv) The survey report shall be sent to the facility within 30 days of the date of the survey.*
>
> *(v) The survey report shall be dated and signed by the medical physicist performing or supervising the survey. If the survey was performed entirely or in part by another individual under the direct supervision of the medical physicist, that individual and the part of the survey that individual performed shall also be identified in the survey report.*

To assist the medical physicist in communicating test results and recommendations, a Medical Physicist's ACR DM QC Test Summary form has been included in the Medical Physicist's section of the QC manual. A new report, the Medical Physicist QC Letter for the Radiologist, has been added to help the medical physicist communicate essential, select aspects of his or her report to the lead interpreting radiologist. A form is provided for each test to guide the medical physicist in performing the test, recording data, and evaluating the results. These test data forms are flexible guides and can be modified by the medical physicist as necessary.

For many tests, a facility may not conduct mammography with that equipment until a failure is corrected. Although the MQSA Final Rule allows the medical physicist 30 days from the date of the survey to send a report to the facility, a 30-day delay allows the facility no time to take corrective actions. To help facilities comply with MQSA regulations, the medical physicist should immediately communicate any failures both verbally and in writing.

Communication of test results and recommendations of corrective actions are areas that can be improved in the practices of most medical physicists. Corrective actions should not be limited to the repair of x-ray equipment by qualified service personnel but should include recommendations that will improve image quality, including recommendations concerning detectors, technique factors, viewing conditions in the reading room, and technologist QC. The medical physicist must, at a minimum, annually review the results of technologist QC tests and make recommendations regarding these tests, if needed. Furthermore, the medical physicist must participate in annual reviews of the mammography QC program as a whole to make sure that the program is meeting its objectives.

Mammography team members are strongly encouraged to review other sections of the ACR Digital Mammography QC Manual that are not directed towards them. For example, the radiologist should be familiar with Technologist's Test Facility QC Review and the Technologist's Optional Tests System QC for Radiologist and Radiologist Image Quality Feedback. The radiologic technologist should review the Medical

MEDICAL PHYSICIST'S SECTION

Physicist's Test Evaluation of Site's Technologist QC Program and Evaluation of Display Device Technologist QC Program. The medical physicist should be familiar with all of the radiologic technologist's tests. The radiologist, medical physicist, QC technologist, and facility manager, working together as a team, are the keys to providing optimum quality mammography images, which will ultimately provide the best medical care possible to the patient.

> **Note:** Facility management, along with the QC technologist and medical physicist, should work together to ensure that all "display devices" are QC'd and reviewed properly.

C. QC Tests, Frequencies, and Timeframes for Corrective Action

Before a facility QC technologist may start using the procedures in the ACR Digital Mammography QC Manual for the first time on a unit, the medical physicist must first conduct an annual survey of the digital mammography unit and display devices using the manual and the ACR DM Phantom. This is important to provide testing techniques and procedures for the QC technologist to use during routine QC. After this is done, the QC technologist may start performing routine QC using the ACR Digital Mammography QC Manual. For current information and more details on transitioning to the ACR Digital Mammography QC Manual, visit the Digital Mammography QC Manual: Frequently Asked Questions on the ACR Digital Mammography QC Manual Resources website.

> **Important:** Before a facility may start using the procedures in the ACR Digital Mammography QC Manual for the first time on a unit, the medical physicist must first conduct an annual survey of the digital mammography unit and display devices using the manual and the ACR Digital Mammography Phantom.

The minimum frequencies for both the technologist and medical physicist tests are listed in Table 1. The tests designated for DBT must be conducted in addition to the applicable tests for the 2D full-field digital mammography system. *Applicable 2D tests must be performed whether or not the system is used for 2D imaging since they test system components that may impact DBT performance.*

> **Important:** All applicable 2D tests must be performed in addition to the DBT tests for each system.

If the DBT system employs an "add-on" device, applicable 2D tests must be repeated with the "add-on" device in place.

The technologist and medical physicist will use the same forms they use for most of the digital mammography tests to record the data and results of the DBT tests. The previous digital mammography forms have been revised to allow for this. New forms have been added for DBT-unique tests (e.g., DBT Volume Coverage).

If problems are occurring or if equipment is unstable, it may be necessary to carry out some or all tests more frequently to identify problems before they affect clinical image quality or patient safety. If the QC program is just being initiated, it may be valuable to carry out QC tests more frequently for the first few months. This will provide the QC technologist with more experience in a shorter period of time and also will provide better baseline data regarding the reliability of imaging equipment. The necessity of performing tests designated as "Optional" or "If applicable" is left to discretion of the Quality Assurance Committee, especially the lead interpreting radiologist, QC technologist, and medical physicist team, who are most familiar with the facility's equipment and the quality needs of the mammography practice.

In addition to performing the mammography QC tests at the minimum frequencies indicated, tests also should be carried out for new equipment, both when problems are suspected and after any service or preventive maintenance. For example, the compression test should be carried out both when a new x-ray system is installed and after any service adjustment of compression force.

If any test fails, it is critical that the setup and techniques employed in the test be checked and the test repeated to verify performance before initiating corrective action. Upon confirmation of test failure, the MQSA Final Rule requires that the source of the problem be identified and corrective action be taken. In some cases, if test results fall outside of action limits, MQSA requires that the source of the problem be identified and corrective action taken *before* any further examinations are performed or any films are processed using the component of the mammography system that failed the test. Other test failures must be corrected within 30 days of the test date (Table 1).

MEDICAL PHYSICIST'S SECTION

II. Introduction

Table 1. Digital Mammography (2D and DBT) Quality Control Tests

Test	Minimum Frequency	Corrective Action Timeframe
Technologist Tests		
1. ACR DM Phantom Image Quality	Weekly	Before clinical use
2. Computed Radiography Cassette Erasure *(if applicable)*	Weekly	Before clinical use
3. Compression Thickness Indicator	Monthly	Within 30 days
4. Visual Checklist	Monthly	Critical items: before clinical use; less critical items: within 30 days
5. Acquisition Workstation Monitor QC	Monthly	Within 30 days; before clinical use for severe defects
6. Radiologist Workstation Monitor QC	Monthly	Within 30 days; before clinical use for severe defects
7. Film Printer QC *(if applicable)*	Monthly	Before clinical use
8. Viewbox Cleanliness *(if applicable)*	Monthly	Before clinical use
9. Facility QC Review	Quarterly	Not applicable
10. Compression Force	Semiannual	Before clinical use
11. Manufacturer Calibrations *(if applicable)*	Mfr. Recommendation	Before clinical use
Optional - Repeat Analysis	As Needed	Within 30 days after analysis
Optional - System QC for Radiologist	As Needed	Within 30 days; before clinical use for severe artifacts
Optional - Radiologist Image Quality Feedback	As Needed	Not applicable
Medical Physicist Tests		
1. Mammography Equipment Evaluation (MEE) - MQSA Requirements	MEE	Before clinical use
2. ACR DM Phantom Image Quality	MEE and Annual	Before clinical use
3. DBT Z Resolution	MEE and Annual	Within 30 days
4. Spatial Resolution	MEE and Annual	Within 30 days
5. DBT Volume Coverage	MEE and Annual	Before clinical use
6. Automatic Exposure Control System Performance	MEE and Annual	Within 30 days
7. Average Glandular Dose	MEE and Annual	Before clinical use
8. Unit Checklist	MEE and Annual	Critical items: before clinical use; less critical items: within 30 days
9. Computed Radiography *(if applicable)*	MEE and Annual	Before clinical use
10. Acquisition Workstation Monitor QC	MEE and Annual	Within 30 days; before clinical use for severe defects
11. Radiologist Workstation Monitor QC	MEE and Annual	Within 30 days; before clinical use for severe defects
12. Film Printer QC *(if applicable)*	MEE and Annual	Before clinical use
13. Evaluation of Site's Technologist QC Program	Annual	Within 30 days
14. Evaluation of Display Device Technologist QC Program	Annual	Within 30 days
15. Manufacturer Calibrations *(if applicable)*	Mfr. Recommendation	Before clinical use
16. Collimation Assessment	MEE or Troubleshooting Annual (DBT only)	Within 30 days
MEE or Troubleshooting - Beam Quality (Half-Value Layer) Assessment	MEE or Troubleshooting	Before clinical use
MEE or Troubleshooting - kVp Accuracy and Reproducibility	MEE or Troubleshooting	MEE: before clinical use; troubleshooting: within 30 days
Troubleshooting - Ghost Image Evaluation	Troubleshooting	Before clinical use
Troubleshooting - Viewbox Luminance	Troubleshooting	NA

Digital Mammography Quality Control Manual

> **Important:** Corrective action for any test performed for MEEs must be made before clinical use.

Documentation of QC and corrective action is essential. Data forms are provided in this manual and may be copied or downloaded from the ACR Digital Mammography QC Manual Resources website for use in performing and documenting the digital mammography QC program. QC data forms may be stored as either hardcopy (for example, in a notebook) or as a file on the computer. For some tests, it may be preferable to use software provided by equipment manufacturers or third-party vendors that can accumulate, trend, and print out QC data. However, the QC technologist and medical physicist must verify that all required information is available from such software before use. If QC records are stored electronically, all records should be periodically backed up to prevent loss.

> **Note:** If QC records are stored electronically, all records should be periodically backed up to prevent loss.

For detailed guidance on the FDA's requirements for record retention, see Quality Assurance Records and Retention of Personnel Records in the FDA's MQSA Policy Guidance Help System. All documentation must be made available to MQSA inspectors during the annual inspection and the facility's accreditation body upon application and request.

> *900.12(d) Quality assurance—general. (2) Quality assurance records. The lead interpreting physician, quality control technologist, and medical physicist shall ensure that records concerning mammography technique and procedures, quality control (including monitoring data, problems detected by analysis of that data, corrective actions, and the effectiveness of the corrective actions), safety, protection and employee qualifications to meet assigned quality assurance tasks are properly maintained and updated. These quality control records shall be kept for each test specified in paragraphs (e) and (f) of this section 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.*

Table 2 provides a complete list of all the digital mammography tests and summarizes those tests that must be performed (as applicable) for the **modes that the facility uses clinically on its 2D and DBT systems**.

MEDICAL PHYSICIST'S SECTION

Table 2. Required Tests for Imaging Modes Used on 2D and DBT Systems

Test	System Used for Both 2D and DBT Acquisition			System Used for DBT Acquisition Only
	2D	2D w/Add-On DBT Device	DBT	DBT
Technologist Tests				
1. ACR DM Phantom Image Quality	✓*	✓	✓	✓ & 2D*
2. Computed Radiography Cassette Erasure (if applicable)	✓*			
3. Compression Thickness Indicator	✓*	✓*		✓*
4. Visual Checklist	✓*	✓	✓	✓
5. Acquisition Workstation Monitor QC	✓*			✓*
6. Radiologist Workstation Monitor QC	✓*			✓*
7. Film Printer QC (if applicable)	✓*			✓*
8. Viewbox Cleanliness (if applicable)	✓*			✓*
9. Facility QC Review	✓*	✓	✓	✓
10. Compression Force	✓*	✓*		✓*
11. Manufacturer Calibrations (if applicable)	✓*	✓	✓	✓
Medical Physicist Tests				
1. Mammography Equipment Evaluation (MEE)	✓*			✓*
2. ACR DM Phantom Image Quality	✓*	✓	✓	✓ & 2D*
3. DBT Z Resolution			✓	✓
4. Spatial Resolution	✓*	✓	✓	✓
5. DBT Volume Coverage			✓	✓
6. Automatic Exposure Control System Performance	✓*	✓	✓	✓
7. Average Glandular Dose	✓*	✓	✓	✓
8. Unit Checklist	✓*	✓	✓	✓
9. Computed Radiography (if applicable)	✓*			
10. Acquisition Workstation Monitor QC	✓*			✓*
11. Radiologist Workstation Monitor QC	✓*			✓*
12. Film Printer QC (if applicable)	✓*			✓*
13. Evaluation of Site's Technologist QC Program	✓*	✓	✓	✓
14. Evaluation of Display Device Technologist QC Program	✓*			✓*
15. Manufacturer Calibrations (if applicable)	✓*	✓	✓	✓
16. Collimation Assessment	✓*	✓*	✓	✓
MEE or Troubleshooting - Beam Quality (Half-Value Layer [HVL]) Assessment	✓*TF			✓*TF
MEE or Troubleshooting - kVp Accuracy and Reproducibility	✓*TF			✓*TF

*Follow the procedures and frequency outlined for 2D QC

TFHVL and kVp tests must include kVp, target, and filter combinations used for DBT

As an example, if a facility has a system that performs 2D, 2D with an add-on DBT device, and DBT, both the technologist and the medical physicist must evaluate phantom images for the 2D, 2D with an add-on DBT device, and DBT imaging modes. However, the Acquisition Workstation Monitor QC and Radiologist Workstation Monitor QC tests are only required to be evaluated using the 2D procedure and images.

If a system is not used for 2D mammography and is only used for DBT imaging, the technologist and the medical physicist are required to evaluate phantom images for the DBT **and 2D** imaging modes. For the Acquisition Workstation and Radiologist Workstation QC Tests, the 2D procedures should be used to evaluate the 2D image.

> **Important:** During MEEs of DBT systems, the medical physicist must evaluate the kVp, target, and filter combinations used in DBT imaging.

D. Surveys of Systems with Multiple Units and Display Devices (Including Offsite Equipment)

More and more mammography facilities are consolidating sites containing a single mammography unit into facilities with multiple units and radiologist workstations. Improved digital communications technology also enables remote routine interpretation of breast images by offsite radiologists. This introduces a new level of complexity for the medical physicist when conducting and managing annual surveys and mammography equipment evaluations (MEEs) of new equipment (and after major repairs). The following scenarios provide guidance to the medical physicist for the combination of testing that must be performed for MEEs and annual surveys.

For purposes of these examples, "display devices" refers to acquisition workstations (AWs), radiologist workstations (RWs), or film printers (if applicable). The solid and dashed arrows in the figures indicate that the ACR DM Phantom image must be sent along this pathway and evaluated (see the ACR DM Phantom Image Quality test) on the designated display device. The gray shaded box indicates that all applicable testing from this manual must be done for the devices included in the box.

MEEs and annual surveys of *radiologist workstations must be conducted on site by the medical physicist* since the quality of the image displayed on the monitor itself must be evaluated. This cannot be done remotely. However, if the workstation is located at a great distance from the mammography facility (e.g., another part of the country) the facility may use the services of a medical physicist closer to the location of the radiologist workstation. It is essential that MEE and annual survey reports of offsite radiologist workstations be available at the facility where the mammography unit is located in order to satisfy inspection and accreditation requirements.

MEEs and annual surveys of *film printers (if applicable) may be conducted remotely by the medical physicist* since the quality of the

image displayed may be evaluated on the resultant film that is shipped to the medical physicist for review. Again, it is essential that MEE and annual survey reports of offsite film printers be available at the facility where the mammography unit is located in order to satisfy inspection and accreditation requirements.

1. Mammography Equipment Evaluation – All New Digital Mammography Units and Display Devices

In the scenario shown in Figure 2, all equipment (digital mammography units, acquisition workstations, radiologist workstations, and film printers) are replaced or newly installed at the facility. This may occur at a new facility or an existing, previously accredited and certified facility. The equipment may be new, previously owned, or relocated from another facility under the same ownership. The phantom images used for evaluation should have been acquired from any of the facility's digital mammography units within the past month.

The following combination of testing must be performed:

Figure 2. MEE – All New Digital Mammography Units and Display Devices.

2. Mammography Equipment Evaluation – New Digital Mammography Units (with Existing Display Devices)

In the scenario shown in Figure 3, only the digital mammography unit 1 (DM 1) is new (including the acquisition workstation). The display devices (radiologist workstations and film printers) are pre-existing, as is digital mammography unit 2 (DM 2). The new digital mammography unit may be new, previously owned, or relocated from another facility under the same ownership.

Digital Mammography Quality Control Manual

The following combination of testing must be performed:
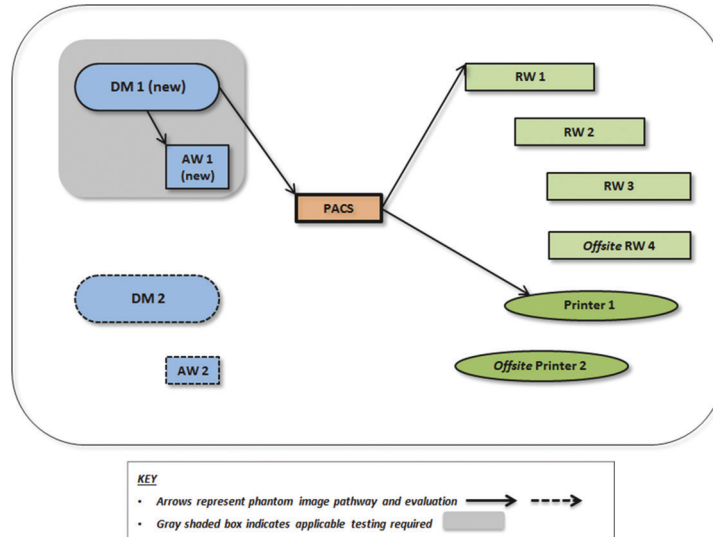
Figure 3. MEE – New Digital Mammography Units (with Existing Display Devices).

3. Mammography Equipment Evaluation – New Display Devices (with Existing Digital Mammography Units)

In the scenario in Figure 4, only display devices (an acquisition workstation 2 (AW 2), radiologist workstations 1 and 4 (RW 1 and RW 4), and film printer 2) are new. The digital mammography unit 2 (DM 2) is pre-existing. Digital mammography unit 1 (DM 1) and acquisition workstation 1 (AW 1) are also pre-existing. The display devices may be new, previously owned, or relocated from another facility under the same ownership. The phantom images used for evaluation should have been acquired from any of the facility's digital mammography units within the past month.

The following combination of testing must be performed:
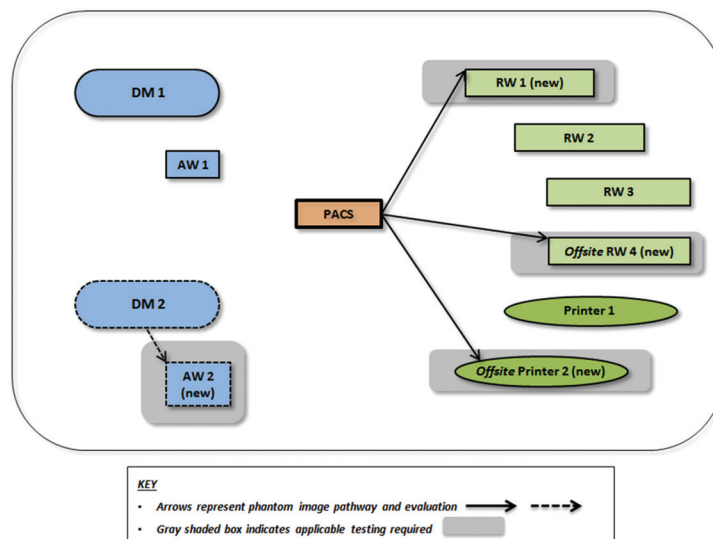
Figure 4. MEE – New Display Devices (with Existing Digital Mammography Units).

MEDICAL PHYSICIST'S SECTION

4. Annual Surveys

Medical physicists must conduct annual surveys on all digital mammography units, acquisition workstations, radiologist workstations, and film printers (if applicable). At some facilities, it is possible for the medical physicist to do this at one time. However, many medical physicists choose to separate the annual survey for the digital mammography units from that of the display devices because the workstations or printers are located at different physical locations from the digital mammography units or equipment repair has shifted the timing of the survey(s). For this reason, the annual survey scenarios in Figure 5 are presented separately for the digital mammography units and the display devices. However, it is important to note that the annual survey of the digital mammography units and the display devices may be done at one time.

If the annual surveys for the display devices are done separately from the digital mammography unit, a phantom image stored on the facility's picture archiving and communication system (PACS) may be used. This image should have been acquired from any of the facility's digital mammography units within the past month.

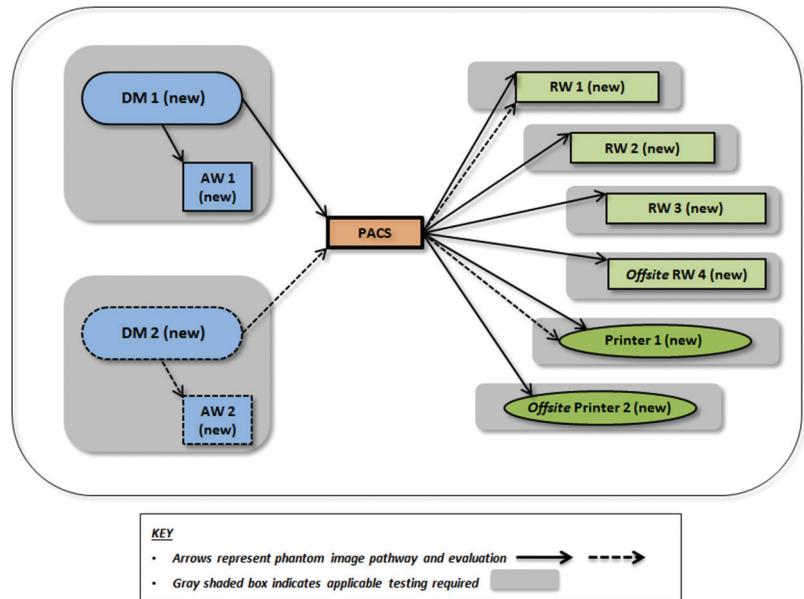The following combination of testing must be performed:
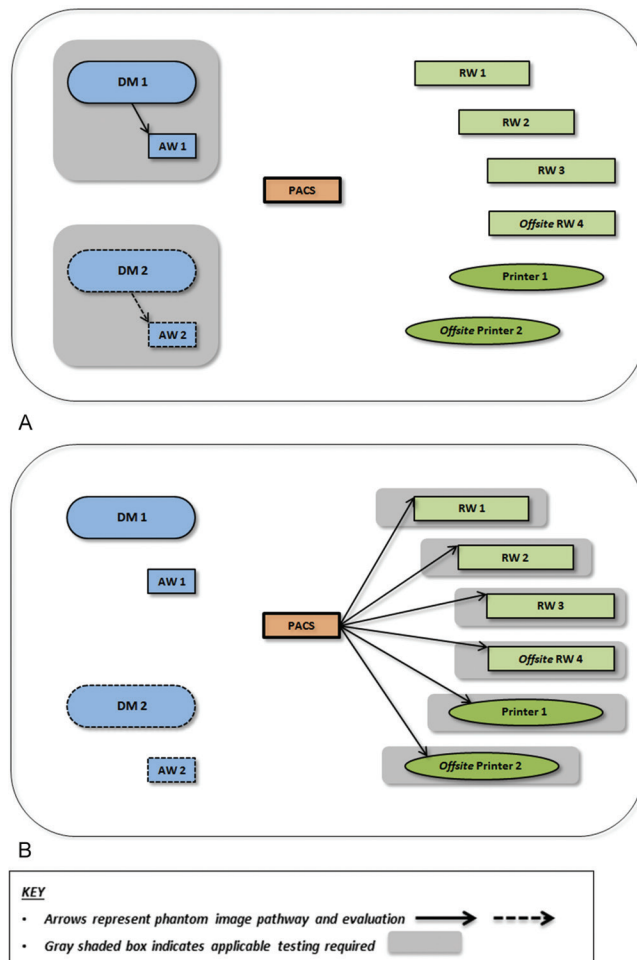
Figure 5 – Annual Surveys A. Digital Mammography Units. B. Display Devices.

Digital Mammography Quality Control Manual

5. Major Component Service/Upgrade/Replacement/Repair

The medical physicist must perform additional evaluations whenever major components of the mammography equipment are changed or repaired. The solid and dashed arrows in the figures indicate that the ACR DM Phantom image must be sent along this pathway and evaluated. The gray shaded box indicates that all *applicable* testing from this manual must be done for the devices included in the shaded box. For major component service, upgrade, replacement, or repair, ***the tests that are applicable will depend on the component involved***. For example, if the collimator was repaired, the ACR DM Phantom Image Quality and Collimation Assessment tests should be performed but the other tests outlined in the QC manual may not be necessary.

In Figure 6, part A, a digital mammography unit (DM 1) has undergone major service, while in part B, an acquisition workstation (AW 2), a radiologist workstation (RW 1), and an offsite printer have undergone major service.

The following combination of testing must be performed:

MEDICAL PHYSICIST'S SECTION
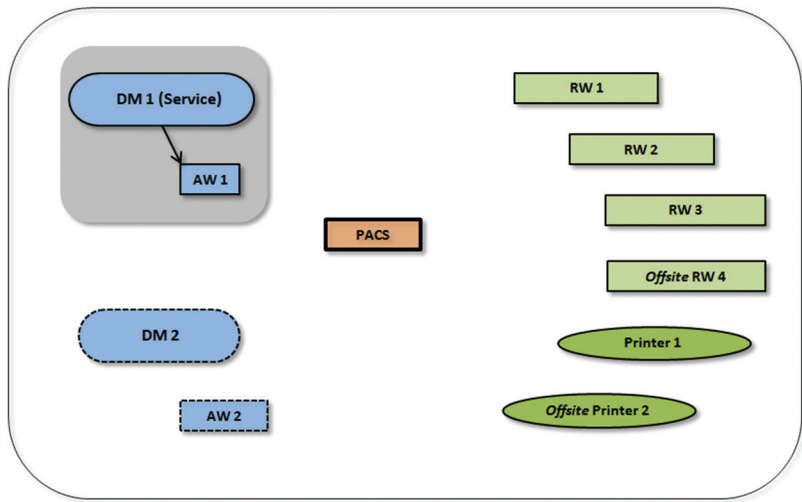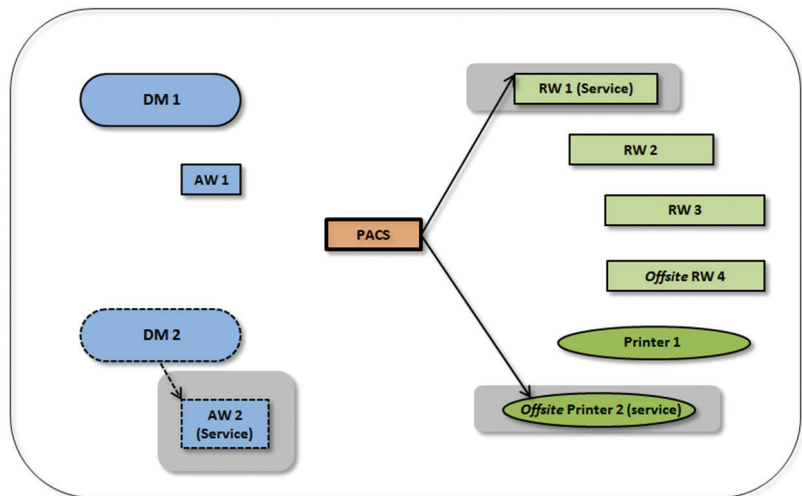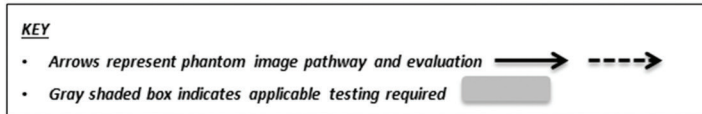
Figure 6. Major Component Service/Upgrade/Replacement/Repair A. Digital Mammography Unit 1. B. Display Devices (AW 2, RW 1, and Offsite Printer 2).

E. Equipment Adjustments, Changes, or Repairs

At a minimum, the medical physicist must be on-site to perform or to provide direct supervision for the performance of

- The annual survey

- Mammography equipment evaluations

Determining when a medical physicist must be on-site in connection with adjustments, changes, or repair of equipment requires further discussion. Adjustments, changes, or repairs of equipment can occur as corrective actions for problems that caused the equipment to fail a quality control test, as the result of an unexpected equipment failure, or as a measure intended to prevent possible future inadequate equipment performance. *All adjustments, changes, or repairs must include some form of verification testing to demonstrate that the affected equipment meets the applicable standards.* The FDA outlines 3 situations:

1. In the case of *major* adjustments, changes, or repairs, the FDA regulations require the medical physicist to conduct an *on-site* MEE.

2. The FDA also recommends that the medical physicist have a role in some other changes or repairs through the provision of *medical physicist oversight* where the facility consults with the medical physicist to determine if an on-site visit is required or if other personnel can verify that the standards are met.

3. The FDA recognizes that there are adjustments, changes, or repairs for which verification (that the adjusted, changed, or repaired equipment meets standards) can be performed by *other qualified personnel* (e.g., radiologic technologist or service representative with appropriate training/experience) without involving the medical physicist. However, the facility can consult its medical physicist in these situations if it wishes.

Table 3 lists typical component adjustments, changes, or repairs that may occur in a digital mammography system along with medical physicist involvement (i.e., on-site, oversight, or optional) recommended by the FDA and the ACR. *Be sure to check the FDA's MQSA Policy Guidance Help System for current guidance on testing.*

Table 3. Medical Physicist Involvement in Equipment Adjustments, Changes, or Repairs

Item	Component	Major Repair	Medical Physicist Involvement
Automatic Exposure Control (AEC)	*AEC replacement*	*Y*	*On-site*
	AEC recalibration that affects dose	*Y*	*On-site*
	AEC sensor replacement	*Y*	*On-site*
	AEC circuit board replacement	*Y*	*On-site*
	Density control - internal adjustment*	N	Oversight
	Thickness compensation - internal* adjustment	N	Oversight
Bucky Replacement	*AEC sensor also replaced*	*Y*	*On-site*
	AEC sensor not replaced	N	Oversight
	DM detector also replaced	*Y*	*On-site*
	DM detector not replaced	N	Oversight
Collimator	*Replacement*	*Y*	*On-site*
	Reassembly with blade replacement	*Y*	*On-site*
	Adjustment	N	Oversight
Compression Device	Pressure adjustment	N	Optional
	Thickness scale accuracy adjustment but only if it affects AEC performance	N	Oversight
	Repair of auto decompression	N	Optional
Compression Paddle	Paddle (new to facility)	N	Oversight
	Deflection adjustment	N	Oversight
	Adjustment due to extension beyond allowable limit, or visible on images	N	Oversight
X-ray Unit	*Installation*	*Y*	*On-site*
	Reassembly	*Y*	*On-site*
	X-ray tube replacement	*Y*	*On-site*
	High voltage generator replacement	*Y*	*On-site*
	Filter replacement	*Y*	*On-site*
	Manufacturer's software upgrade or modifications	*Y*	*On-site*
	DM detector replacement or repair	*Y*	*On-site*
	kVp, mA, or time - internal* adjustments	N	Oversight
Display Devices	*New installation or replacement*	*Y*	*On-site*
	New video card or software upgrade	*Y*	*On-site*
	Relocation	N	Oversight
Computed Radiography (CR) and Photostimulable Phosphor (PSP) Plates	*New installation or replacement of CR reader*	*Y*	*On-site*
	Replacement of all PSP plates	*Y*	*On-site*
	One or 2 new PSP plates	N	Oversight
Internal adjustments refer to equipment adjustments that typically cannot be made by the operator.			

Mammography Equipment Evaluation and Annual Survey

A. Test Procedures

1. Mammography Equipment Evaluation (MEE) – MQSA Requirements for Equipment

OBJECTIVES

To ensure that mammography equipment meets Section 900.12(b) of FDA's Final Rule for Mammography and complies with MEE-only required tests.

FREQUENCY

- As part of the MEE of new units, after relevant service, and after component replacement.

- Because generators used in digital mammography are very stable, the kVp Accuracy and Reproducibility tests that are based on the FDA screen-film annual survey rule in Section 900.12(e)5(ii) need to be done only for MEEs or if additional troubleshooting is needed to diagnose a potential problem. Similarly, the Beam Quality (Half-Value Layer) Assessment based on the FDA screen-film annual survey rule in Section 900.12(e)5(iv) only needs to be done for MEEs or if additional troubleshooting is needed to diagnose a potential problem. See the procedures and forms in the MEE or Troubleshooting Test section for instructions.

> **Note:** For the kVp Accuracy and Reproducibility and Beam Quality (Half-Value Layer) Assessment tests, see the procedures and forms in the MEE or Troubleshooting Test section.

TEST EQUIPMENT

General [Section 900.12(b)]

Mammography Equipment Evaluation - MQSA Requirements checklist *(required)*

TEST PROCEDURE

General [Section 900.12(b)]

1. Evaluate each applicable item listed on the MQSA Requirements for Mammography Equipment Checklist.

2. Check whether each assessment meets FDA requirements.

DATA ANALYSIS AND INTERPRETATION

General [Section 900.12(b)]

None

PRECAUTIONS AND CAVEATS

General [Section 900.12(b)]

There are several digital mammography scenarios that may not be applicable to FDA Rule Sec. 900.12 (b) (14) and (15), which outlines the

requirements for hotlighting or film masking devices. "Lighting" and "Film masking" may be marked as "NA" if

1. No hardcopy interpretations are made

2. No hardcopy comparisons are made

3. For new units at existing facilities, these items were previously evaluated and have not changed

X-ray Beam Limiting Device Illumination [Section 900.12(b)5(ii)]

This test may not apply to systems without x-ray beam limiting devices such as slot-scan systems.

Compression Paddle Deflection [Section 900.12(b)8(ii)(B)]

This test ensures that adequate compression is applied uniformly over the breast for paddles that are designed to be flat and parallel to the breast support.

Some paddles are designed not to be flat and parallel to the breast support during compression. These paddles should not be evaluated using the procedure described above but rather must meet the manufacturer's design specifications and maintenance requirements.

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

General [Section 900.12(b)]

1. Evaluate each applicable item listed on the MQSA Requirements for Mammography Equipment checklist.

2. Check whether each assessment meets FDA requirements.

X-Ray Beam Limiting Device Illumination [Section 900.12(b)5(ii)]

The light *must* provide an average illumination of not less than 160 lux (15 ft-candles) at 100 cm or the maximum source-image receptor distance, whichever is less.

Compression Paddle Deflection [Section 900.12(b)8(ii)(B)]

The compression paddle must be flat and parallel to the breast support table and shall not deflect from parallel by more than 1.0 cm at any point on the surface of the compression paddle when compression is applied. (This does not apply to compression paddles not designed to be "flat and parallel.")

TIMEFRAME FOR CORRECTIVE ACTION

All failures *must* be corrected before clinical use.

APPLICABLE MQSA REQUIREMENTS

900.12(b) Equipment.

(3) Motion of tube-image receptor assembly.

(i) The assembly shall be capable of being fixed in any position where it is designed to operate. Once fixed in any such position, it shall not undergo unintended motion.

(ii) The mechanism ensuring compliance with paragraph (b)(3)(i) of this section shall not fail in the event of power interruption.

(4) Image receptor sizes.

(iii) Systems used for magnification procedures shall be capable of operation with the grid removed from between the source and image receptor.

(5) Light fields. For any mammography system with a light beam that passes through the X-ray beam-limiting device, the light shall provide an average illumination of not less than 160 lux (15 foot-candles) at 100 cm or the maximum source-image receptor distance (SID), whichever is less.

(6) Magnification.

(i) Systems used to perform non-interventional problem solving procedures shall have radiographic magnification capability available for use by the operator.

(ii) Systems used for magnification procedures shall provide, at a minimum, at least one magnification value within the range of 1.4 to 2.0.

(7) Focal spot selection.

(i) When more than one focal spot is provided, the system shall indicate, prior to exposure, which focal spot is selected.

(ii) When more than one target material is provided, the system shall indicate, prior to exposure, the preselected target material.

(iii) When the target material and/or focal spot is selected by a system algorithm that is based on the exposure or on a test exposure, the system shall display, after the exposure, the target material and/or focal spot actually used during the exposure.

(8) Compression. All mammography systems shall incorporate a compression device.

(i) Application of compression. Effective October 28, 2002, each system shall provide:

(A) An initial power-driven compression activated by hands-free controls operable from both sides of the patient; and

(B) Fine adjustment compression controls operable from both sides of the patient.

(ii) Compression paddle.

(A) Systems shall be equipped with different sized compression paddles that match the sizes of all full-field image receptors provided for the system. Compression paddles for special purposes, including those smaller than the full size of the image receptor (for "spot compression") may be provided. Such compression paddles for special purposes are not subject to the requirements of paragraphs (b)(8)(ii)(D) and (b)(8)(ii)(E) of this section.

(B) Except as provided in paragraph (b)(8)(ii)(C) of this section, the compression paddle shall be flat and parallel to the breast support table and shall not deflect from parallel by more than 1.0 cm at any point on the surface of the compression paddle when compression is applied.

MEDICAL PHYSICIST'S SECTION

(C) Equipment intended by the manufacturer's design to not be flat and parallel to the breast support table during compression shall meet the manufacturer's design specifications and maintenance requirements.

(D) The chest wall edge of the compression paddle shall be straight and parallel to the edge of the image receptor.

(E) The chest wall edge may be bent upward to allow for patient comfort but shall not appear on the image.

(9) Technique factor selection and display.

(i) Manual selection of milliampere seconds (mAs) or at least one of its component parts (milliampere (mA) and/or time) shall be available.

(ii) The technique factors (peak tube potential in kilovolt (kV) and either tube current in mA and exposure time in seconds or the product of tube current and exposure time in mAs) to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls (AEC) are used, in which case the technique factors that are set prior to the exposure shall be indicated.

(iii) Following AEC mode use, the system shall indicate the actual kilovoltage peak (kVp) and mAs used during the exposure. The mAs may be displayed as mA and time.

(14) Lighting. The facility shall make special lights for film illumination, i.e., hot-lights, capable of producing light levels greater than that provided by the view box, available to the interpreting physicians.

(15) Film masking devices. Facilities shall ensure that film masking devices that can limit the illuminated area to a region equal to or smaller than the exposed portion of the film are available to all interpreting physicians interpreting for the facility.

2. ACR Digital Mammography (DM) Phantom Image Quality

OBJECTIVES

To ensure that the image acquisition chain is consistently producing adequate image quality, that artifacts are not clinically significant, and that the signal-to-noise ratio and contrast-to-noise ratio are adequate.

FREQUENCY

As part of the mammography equipment evaluation (MEE) of new units, annually, and after relevant service.

TEST EQUIPMENT

- ACR DM Phantom *(required)*. This phantom has been designed to cover the majority of the DM detector area and provide the same attenuation as the small ACR mammography phantom used in the 1999 Mammography Quality Control Manual; it approximates a 4.2 cm thick compressed breast consisting of 50% glandular and 50% adipose tissue. If you have multiple phantoms, use the same phantom each time on a given unit (Figure 1).

- ACR DM Phantom Image Quality form.

> **Important:** Do **not** follow the phantom imaging instructions or technical factors provided in the manufacturer's QC manual. Be sure to follow the instructions below. This technique must be the same as that used clinically for a 4.2 cm thick compressed breast consisting of 50% glandular and 50% adipose tissue, as defined by the FDA.

> **Important:** If clinical images are acquired using a combination mode (i.e. 2D plus DBT), then acquire the phantom using the clinical combination mode and evaluate the combination image set (2D and DBT). If clinical 2D and DBT images are acquired using separate acquisition modes, then acquire the 2D and DBT phantom images independently using their respective clinical modes.

> *900.2 Definitions. (uu) Standard breast means a 4.2 centimeter (cm) thick compressed breast consisting of 50 percent glandular and 50 percent adipose tissue.*

TEST PROCEDURE

ACR DM Phantom Image Acquisition - 2D

1. Initiate an exam at the acquisition workstation as you would for a patient.

2. Use a name and image designation system that allows tracking of QC images. It is important to be able to match and identify the DM unit to the printed image from that same unit. See example below:

   a. Last Name: ACR DM Phantom

   b. First Name: Room 1

   c. Patient ID: "Date of Phantom Acquisition"

   d. Date of Birth: "Date of Phantom Acquisition"

3. Use the largest available image receptor size and corresponding paddle for the ACR DM Phantom image acquisition. Ensure that

the type of paddle chosen (e.g., flex or fixed) is the one used for the majority of clinical imaging.

Important: For computed radiography (CR), completely erase the CR cassette prior to obtaining the phantom image.

---

4. Place the ACR DM phantom on the breast support surface as shown in <u>Figure 7</u>. Be sure to position the phantom in the same location each time the test is performed to limit exposure variability. Check that

   a. The pink wax insert is on the top side of the phantom and nearer the chest wall,

   b. The phantom is centered left-to-right, and

   c. The edge of the phantom is aligned with the chest-wall edge of the digital image receptor.

Figure 7. ACR DM Phantom positioned for image acquisition on a 2D system.

5. Manually compress the paddle to approximately 5 decanewtons (daN) or 12 pounds of compression force. It is important to use the same compression force each time for this test. Note that at this compression force, the compressed breast thickness indicator may not read 4.2 cm.

6. At the acquisition workstation, select the imaging mode and technique that would be used for a clinical screening exam acquisition of a 4.2 cm thick compressed breast consisting of 50% glandular and 50% adipose tissue. *If a combination exposure mode (i.e. 2D plus DBT) is most commonly used clinically, use the combination mode for this test, record the data from the 2D and DBT acquisitions, and use those images for analysis. If a 2D-only mode is most commonly used clinically for screening, use the 2D-only mode for this procedure step.* (If the system uses selectable AEC sensor positions, be sure to use the same position each time the phantom is acquired.)

> **Note:** This technique **must** match the technique used by the technologist for his or her weekly QC. This technique should be listed in the ACR Technique and Procedure Summaries form that the technologist maintains.

7. Record or verify the following demographic information at the top of the form:

   a. Facility

   b. Mammography Accreditation Program (MAP) ID number

   c. ACR DM phantom manufacturer and serial number

   d. Room ID

   e. X-ray unit manufacturer and model

   f. Unit source-image receptor distance (SID) in centimeters (cm)

8. Record or verify and use the following technique parameters in the "Phantom Setup" box at the top of the form. These parameters should match the techniques found on the Technologist's ACR Technique and Procedure Summaries form, which should be located in the phantom section of the technologist's QC notebook.

   a. AEC mode

   b. Paddle and image receptor (IR) size

   c. Paddle type (regular or flex)

   d. View or selected image

   e. Compression force

   f. AEC cell position (if applicable)

   g. Target/filter (if applicable)

   h. kVp (if applicable)

   i. Density setting (if applicable)

> **Note:** These parameters **must** be used for all subsequent phantom exposures. Consistent exposure parameters will help in troubleshooting problems.

9. Acquire an image of the phantom.

10. Record the following parameters that appear after the exposure on the form:

    a. Target/filter material (e.g., Mo/Mo, W/Ag, etc.)

    b. kVp (e.g., 28)

MEDICAL PHYSICIST'S SECTION

    c.   mAs (e.g., 78.5)

    d.   The unit-indicated average glandular dose (AGD) in milligray (mGy) for the phantom exposure, if available. (This will be compared to the measured AGD in the <u>Average Glandular Dose</u> test.)

11.   Repeat for magnification mode and all target/filter combinations in clinical use.

ACR DM Phantom Image Acquisition - DBT

1.   Initiate an exam at the acquisition workstation as you would for a patient.

2.   Use a name and image designation system that allows tracking of QC images. It is important to be able to match and identify the DM unit to the printed image from that same unit. See example below:

    a.   Last Name: ACR DM Phantom

    b.   First Name: Room 1

    c.   Patient ID: "Date of Phantom Acquisition"

    d.   Date of Birth: "Date of Phantom Acquisition"

3.   Use the largest available image receptor size and corresponding paddle for the ACR DM Phantom image acquisition. Ensure that the type of paddle chosen (e.g., flex or fixed) is the one used for the majority of clinical imaging.

4.   Place the DM phantom on the breast support surface as shown in <u>Figure 8</u>. Be sure to position the phantom in the same location each time the test is performed to limit exposure variability. Check that

    a.   The pink wax insert is on the top side of the phantom and nearer the chest wall,

    b.   The phantom is centered left-to-right, and

    c.   The edge of the phantom is aligned with the chest-wall edge of the digital image receptor.

5.   Manually compress the paddle to 5 daN or 12 pounds of compression force. It is important to use the same compression force each time for this test. Note that at this compression force, the compressed breast thickness indicator may not read 4.2 cm.

6.   At the acquisition workstation, select the DBT imaging mode and technique that would be used for a clinical exam acquisition of a 4.2 cm thick compressed breast consisting of 50% glandular and 50% adipose tissue. ***If a combination exposure mode (i.e. 2D plus DBT) is most commonly used clinically, use the combination mode for this test, record the data from the 2D and DBT acquisitions, and use those images for analysis. If a DBT-only mode is most commonly***
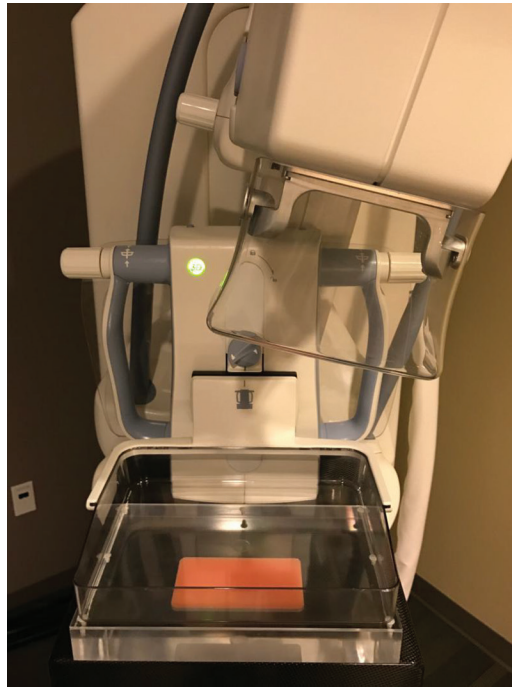
Figure 8. ACR DM Phantom positioned for image acquisition on a DBT system.

used clinically for screening, use the DBT-only mode for this procedure step. (If the system uses selectable AEC sensor positions, be sure to use the same position each time the phantom is acquired.)

Note: This technique **must** match the technique used by the technologist for his or her weekly QC. This technique should be listed in the ACR Technique and Procedure Summaries form that the technologist maintains.

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7. Record or verify the following demographic information at the top of the form:

   a. Facility

   b. MAP ID number

   c. ACR DM phantom manufacturer and serial number

   d. Room ID

   e. X-ray unit manufacturer and model

   f. Unit SID in cm

8. Record or verify and use the following technique parameters in the "Phantom Setup" box at the top of the form. These parameters should match the techniques found on the Technologist's ACR Technique and Procedure Summaries form, which should be located in the phantom section of the technologist's QC notebook.

   a. AEC mode

   b. Paddle and IR size

    c. Paddle type (regular or flex)

    d. View or selected image

    e. Compression force

    f. AEC cell position (if applicable)

    g. Target/filter (if applicable)

    h. kVp (if applicable)

    i. Density setting (if applicable)

> **Note:** These parameters **_must_** be used for all subsequent phantom exposures. Consistent exposure parameters will help in troubleshooting problems.

9. Acquire an image of the phantom.

10. Record the following parameters that appear after the exposure on the form:

    a. Target/filter material (e.g., Rh/Rh, W/Ag, etc.)

    b. kVp (e.g., 32)

    c. mAs (e.g., 78.5)

    d. The unit-indicated AGD in mGy for the phantom exposure, if available (This will be compared to the measured AGD in the Average Glandular Dose test.)

11. If the system uses an add-on device for DBT, repeat steps 3-11 in 2D mode with the DBT fixture in place.

DATA ANALYSIS AND INTERPRETATION

ACR DM Phantom – 2D and DBT

1. If possible, reduce the lighting in the acquisition room to be similar to that in the radiologist's reading room before image evaluation.

2. View the phantom image on the acquisition workstation (AW) display monitor. If review is not possible on the AW, then review on a radiologist workstation.

> **Note:** Digital mammography phantom images must be "for presentation" (i.e., "processed," not "for processing" or "raw") for viewing and scoring (if applicable).

3. *For DBT images*, scroll to the one slice in which the test objects are best visualized. If "slices" are not available, then proceed to use the slab in which the objects are best visualized.

4. Adjust the window width (WW) and window level (WL) settings to optimize visualization of test objects (the test objects will be scored in the next section). It is important not to use unreasonably narrow WWs that may enhance the appearance of artifacts.

5. Record the approximate WW and WL settings (and best visualized slice or slab # for DBT scoring) on the Technologist's <u>ACR Technique and Procedure Summaries</u> form.

6. Using approximately the same WW and WL settings used to evaluate the test objects, examine the entire phantom for both broad area artifacts and detailed artifacts. (See <u>Figure 9</u> for examples of a properly windowed ACR digital phantom images without artifacts.)

   a. Broad area artifacts (e.g., non-uniformities, blotches, and streaks) usually are best seen while observing the phantom image as a whole and not in pieces (i.e., not magnified or at full resolution).

   b. Detailed artifacts (e.g., black or white pixels, clusters of pixels, lines, or dust particles) usually are best seen while observing the phantom image at full spatial resolution, where one pixel on the display matches one pixel in the image, or with magnification, using a zoom factor greater than 1.0.

7. See the <u>Artifact Evaluation Guide</u> in Appendix III for examples of "good" or "artifact free" images and some common digital artifacts.

8. For phantom images from each mode and target/filter combination, record the absence or presence of artifacts on the form as a Pass or Fail (P or F).

9. To score the phantom image, adjust the WW and WL settings to optimize visualization of test objects. You may need to slightly adjust the WW and WL to obtain optimum visualization of each test object. The zoom or magnification tool should also be used. Use a WW and WL that permit the best visualization of fibers, speck groups, and masses. Using the scoring methods described below, score the number of fibers, speck groups, and masses seen in the phantom and record the scores on the form. (See <u>Figure 10</u>.)

10. Do not deduct for artifacts. (Deducting for artifacts is ***no longer part of*** the ACR DM Phantom scoring procedure.)

11. Scoring method (see <u>Figure 11</u> and <u>Table 4</u>):

    a. Count the number of visible objects, from the largest object of a given type (fiber, speck group, or mass) downward, until a score of 0 or ½ is reached, then stop counting for that object type. (This step is the same as used in the 1999 Mammography Quality Control Manual [5].) For each test object type, the minimum possible score is 0 objects and the maximum possible score is 6 objects.
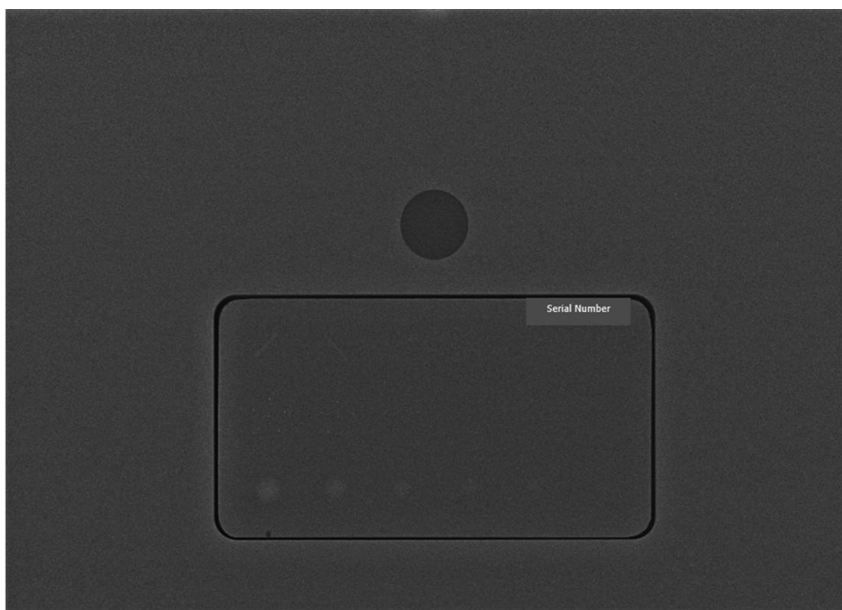
A

B

Figure 9. Images of a properly windowed ACR DM Phantom with no artifacts.
A. 2D. B. DBT.

    b. Fibers

        i. The fibers are manufactured to be 10 mm in length. If the entire length of the fiber is not visible, measure it using the display device's electronic calipers.

        ii. Count each fiber as 1 point if 8 mm or more of the fiber is visible in the correct location and orientation.

        iii. Count a fiber as ½ point if the fiber appears to be equal to or greater than 5 mm and less than 8 mm in length and is in the correct location and orientation.
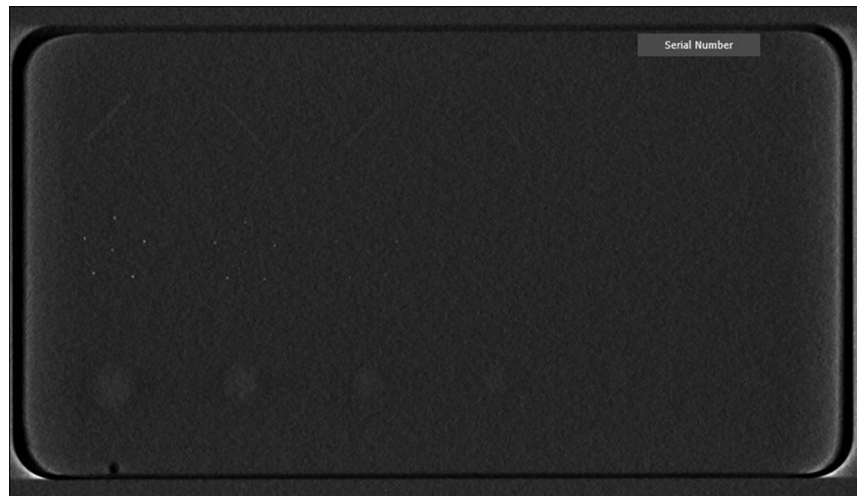
Figure 10. DBT image of a magnified and properly windowed ACR DM Phantom.
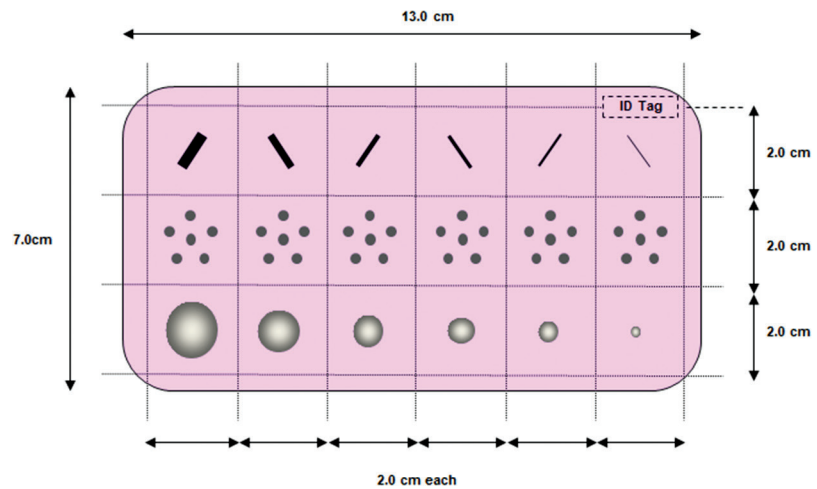
Figure 11. ACR DM Phantom wax insert map (test object sizes are not to scale).

Table 4. ACR DM Phantom Image Scoring Key

Test Object	Full Point	Half Point
Fibers (6)	• Full length visible (≥8 mm long) • Correct location • Correct orientation • 1 break allowed (must be ≤ width of fiber)	• At least half of length visible (≥5 and <8 mm long) • Correct location • Correct orientation • 1 break allowed (must be ≤ width of fiber)
Speck Groups (6)	• 4 to 6 specks visible • Correct locations	• 2 to 3 specks visible • Correct locations
Masses (6)	• Density difference visible • Border is continuous and generally circular (≥ ¾ border visible) • Correct location	• Density difference visible • Border is not continuous or generally circular (≥ ½ and < ¾ border visible) • Correct location

MEDICAL PHYSICIST'S SECTION

    iv. If a small gap in the fiber is visible, and it is less than the width of the fiber, count the fiber as a full or half point depending on the total visible length.

  c. Speck groups

    i. Count each speck group as 1 point if 4 to 6 specks are visible in the proper locations in the group.

    ii. Count a speck group as ½ point if 2 or 3 specks are visible in the proper locations in the group.

  d. Masses

    i. Count each mass as 1 point if an object is visible in the correct location and the mass appears to be generally circular against the background (at least ¾ of the border is continuous and generally round).

    ii. Count a mass as ½ point if a mass-like object is visible in the correct location but does not have a generally circular appearance (greater than ½ but less than ¾ of a circle).

12. Enter the final scoring result in each category (fibers, speck groups, and masses) on the form.

13. If the system uses a separate breast support system for DBT, repeat steps 1-12 for the 2D mode image acquired with the DBT breast support system in place.

14. If 2D add-on devices are used clinically, repeat the above steps to score the resulting 2D image.

15. See the [ACR DM Phantom Scoring Guide](#) in Appendix II for examples on scoring.

Signal-to-Noise Ratio (SNR) and Contrast-to-Noise Ratio (CNR) – 2D Only

> **Note:** Some systems do not permit CNR measurements. Other systems permit CNR measurements, but care must be taken to ensure that measurements are being made on the appropriate image type ("raw" or "for-processing," rather than "processed").

1. If the manufacturer provides a DC offset, record this value on the form.

2. Record the last MEE's CNR on the form if available. (This does not apply to MEEs.)

3. Calculate the lower limit for the current CNR as 85% of the last MEE's CNR, and record.

4. Verify that the appropriate image for region of interest (ROI) analysis is being used. This can be done by verifying that the signal value

           Digital Mammography Quality Control Manual

measured in the CNR cavity of the ACR DM Phantom is higher than the signal value measured in the background area of the ACR DM Phantom, using steps 5-7 below. This verifies that a thinner region of the phantom has higher signal at the detector.

5. With the image displayed so that the CNR cavity is clearly visible, place a circular or rectangular ROI of approximately 1 cm diameter over and entirely contained within the 2 cm diameter CNR cavity. Record the mean signal value (or mean analog to digital units) as Mean Cavity Signal on the form. This number will be used to calculate the CNR. (See Figure 12.)

6. In a similarly sized ROI as used above, but adjacent to and outside the CNR cavity, measure the Mean Background (Bkgd) Signal and record it on the form.

7. Using the same background ROI outside the CNR cavity as above, enter the standard deviation (Std Dev) of background signal on the form.

8. Calculate the SNR as:

$$SNR = \frac{(Mean\ Bkgd\ Signal - DC\ offset)}{Std\ Dev\ of\ Bkgd}$$

(Omit the DC offset if this does not apply for the DM unit being tested.)

9. Record the SNR on the form.

10. Calculate the CNR as:

$$CNR = \frac{(Mean\ Cavity\ Signal - Mean\ Bkgd\ Signal)}{Std\ Dev\ of\ Bkgd}$$

11. Record the CNR on the form.

Figure 12. Image of ROI placement on ACR DM Phantom.

MEDICAL PHYSICIST'S SECTION

Distance Measurement – 2D and DBT

1. Using a measurement tool within the manufacturer software, measure the distance across the wax insert in the anode-cathode (A-C) direction. For **DBT, *this measurement should be made in the test object slice (or slab)*.** (See Figure 13.)

2. Record the measurement on the form.

PRECAUTIONS AND CAVEATS

The phantom image must be scored and all criteria pass on the AW for this test. Scoring the phantom image on the radiologist workstation may be helpful to determine the source of a failure as seen on the AW. However, if a failing AW-evaluated phantom image quality test passes on the
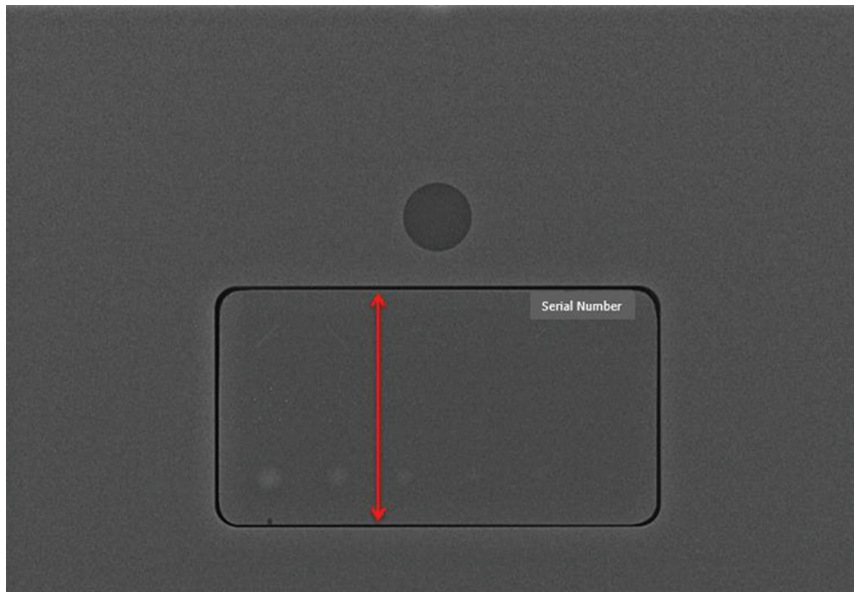
A
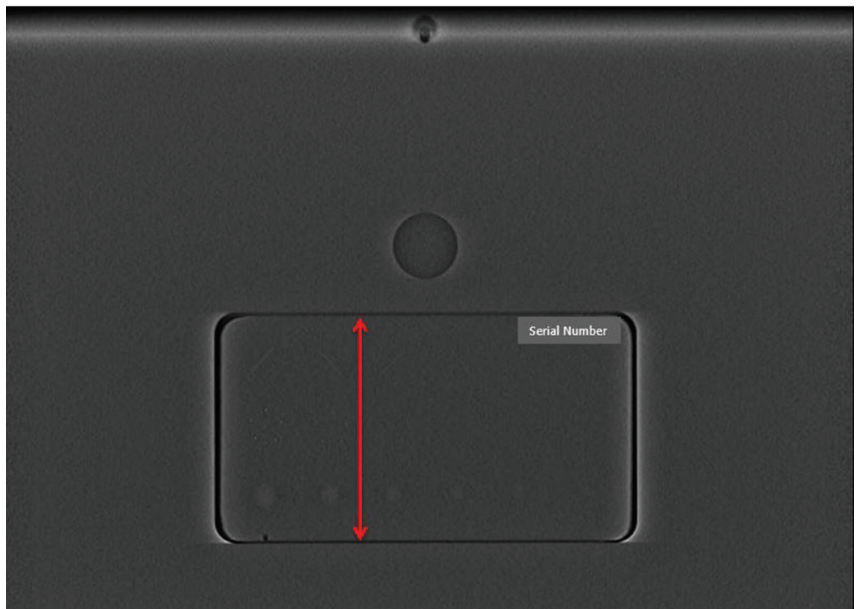
B

Figure 13. Images of distance measurement on ACR DM Phantom. A. 2D. B. DBT.

radiologist workstation, the phantom image quality test remains a failure.

If any of these quantities is outside of the action limits stated below, the test should be repeated. Make sure the correct exposure mode has been used.

The ROI placed over the 2 cm diameter CNR cavity should not touch or extend beyond the edges of the area. The ROI placed outside the CNR cavity should be to the left or right of the area to avoid any possible influence of heel effect on signal.

CNR results from the last MEE may not be available for many reasons such as a change in medical physicist, loss of QC records greater than three years, etc. If CNR results from the last MEE are not available, use the CNR results from the oldest relevant annual survey as a baseline to compare the current results. Be sure to note this in the annual survey report.

Changes in detectors, software changes, and recalibration may significantly impact CNR. In these situations, medical physicist testing after these changes should be considered an MEE, so the CNR should not be compared against values from the last MEE. The type of change that prompted the MEE should be documented in the medical physicist's report.

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

ACR DM Phantom – 2D and DBT

1. Artifacts **must not** be clinically significant. This aspect of the test fails if any artifacts are in a location that could impact clinical interpretation and

   a. Artifacts are as prominent as (or more prominent than) the visible test objects in the phantom image, or

   b. Artifacts obscure test objects in the phantom, or

   c. Artifacts could affect clinical interpretation.

   The cause of the artifact should be identified and isolated to determine if it originates from the x-ray system, the detector, or the monitor. If the artifact is confirmed to originate from the detector, a recalibration or flat-fielding of the detector may be needed. Artifacts isolated to other components of the imaging chain should be investigated.

   After the artifact is resolved, repeat the phantom artifact test. If a clinically significant artifact persists, contact your authorized service representative. If the clinically significant artifact originated from the x-ray/detector system, do not image patients until it is corrected. If the clinically significant artifact originated from the monitor, do not use the monitor until it is corrected.

2. The fiber score **must** be ≥2.0.

3. The speck group score **must** be ≥3.0.

4. The mass score **must** be ≥2.0.

MEDICAL PHYSICIST'S SECTION

SNR and CNR – 2D Only

1. The SNR *must* be ≥40.0.

2. The CNR *must* be ≥2.0.

3. The CNR *must* be ≥85% of the last MEE's CNR. (This component of the test does not apply to MEEs.)

> **Note:** During annual surveys, the CNR is compared to the value measured during the most recent MEE. The deviation of the CNR from this original value is used to monitor changes in the imaging chain over time. A deviation more than -15% from the value measured at the time of the last MEE would result in a failure. Corrective actions would be required prior to clinical use. During a MEE, the value measured would be used for future comparisons.

Distance Measurement – 2D and DBT

The distance measured across the wax insert parallel to the A-C axis *must* be 70.0 mm ±14.0 mm.

General

1. If any of these quantities are not within action limits, the test should be repeated, making sure the correct AEC mode has been used. If phantom scores are below the stated minimum score, the facility should contact its authorized service representative.

2. Record and date any comments and required corrective action in the Technologist's Corrective Action Log form.

TIMEFRAME FOR CORRECTIVE ACTION

All failures of required items *must* be corrected before clinical use.

Digital Mammography Quality Control Manual

3. DBT Z Resolution

OBJECTIVES To ensure that blurring in the z-direction is not excessive.

FREQUENCY As part of the mammography equipment evaluation (MEE) of new units, annually, and after relevant service.

TEST EQUIPMENT
- DBT image from ACR Digital Mammography (DM) Phantom Image Quality test.

- DBT Z Resolution form.

TEST PROCEDURE
1. If annual testing, record the baseline full width at half maximum (FWHM) value from the MEE (or the oldest annual survey if the MEE is not available). Otherwise, perform the following steps to create a baseline Z-resolution value.

2. Using the phantom image acquired from the ACR DM Phantom Image Quality test (Figure 14), obtain signal data over the specks as follows:

Figure 14. ACR DM Phantom Image.

> **Note:** Use the reconstructed DBT slices (for presentation) for Z-resolution measurements.

   a. Scroll to the slice (slab) where the center speck in the largest speck group is most in focus and brightest. This is slice 0.

   b. Zoom in on the largest speck group on the ACR DM Phantom image (Figure 15).

   c. Place a region of interest (ROI) over the center speck (Figure 16).

   d. Record the maximum signal value on the form at the Slice Location 0.

3. Repeat step 2 for the other 5 specks in the group.

4. Determine mean background signal as follows:

   a. Place an ROI over the background adjacent to the center speck (Figure 17).
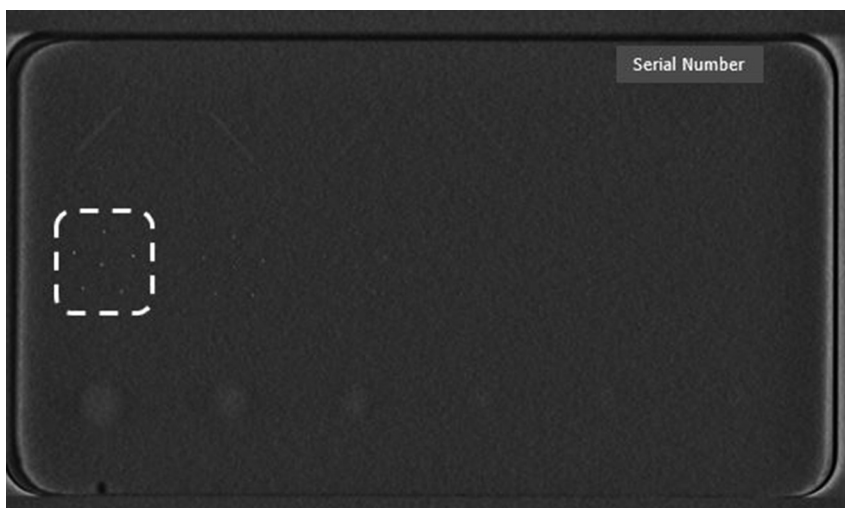
Figure 15. Zoom in on largest speck group.

Figure 16. ROI placement over center speck in largest speck group.
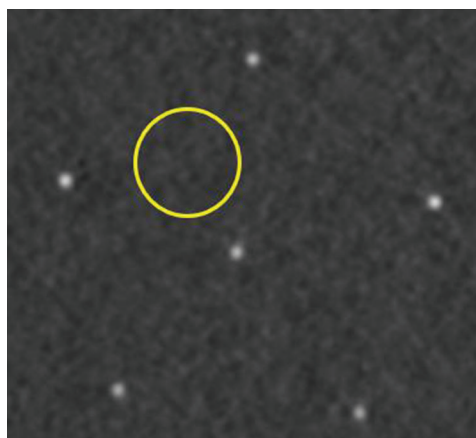
Figure 17. ROI placement over the background.

    b. Record the mean background signal value on the form at the Slice Location 0.

5. Repeat steps 2-4 for the following slices and record the signal values on the form at the appropriate slice locations:

    a. 2 slices below slice 0 (-2)

      b.   1 slice below slice 0 (−1)

      c.   1 slice above slice 0 (+1)

      d.   2 slices above slice 0 (+2)

6. See Figures 18 through 20 for illustrations of DBT slice identification and ROI placements.

7. Average the maximum signal values of the six specks on each slice to get the **Average Max Speck Signal** over the six specks.

8. If **Δ Z-Res Diff,** as calculated below, is greater than or equal to 0.5 for slice −2 or slice +2, repeat steps 4-9 for slice −3 and/or slice +3, as needed, as indicated in the next section.
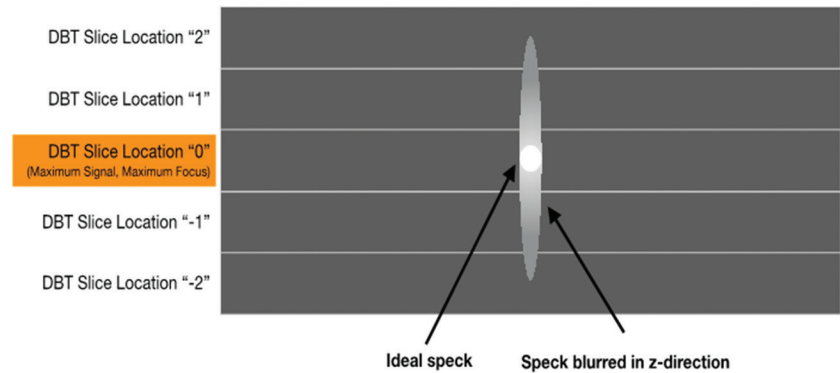
Figure 18. Illustration of the blurring of the largest speck through the five DBT slices.
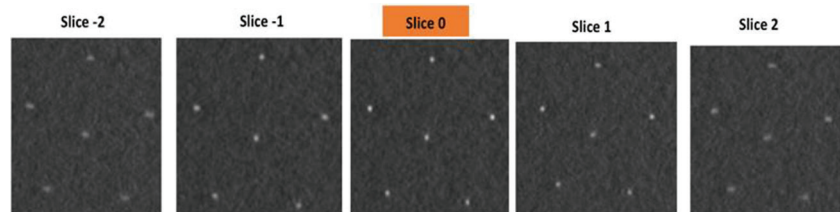
Figure 19. Images of the 5 different slice locations for Z-resolution signal measurements.
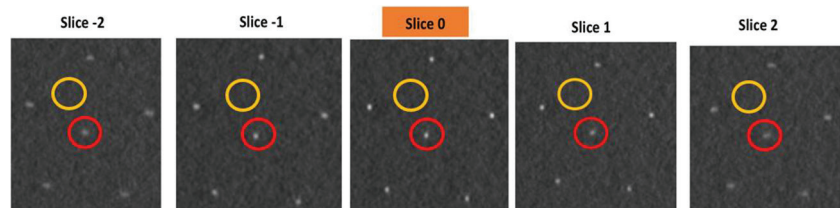
Figure 20. Images of the 5 different slice locations for Z-resolution measurements with ROI placement locations.

DATA ANALYSIS AND INTERPRETATION

1. For each DBT slice $(−2, −1, 0, +1, +2)$, subtract the **Mean Background Signal** from the **Average Maximum Speck Signal**, yielding Z-Resolution Signal Difference (**Z-Res Diff**):

    Z-Res Diff = Average Max Speck Signal – Mean Background Signal

2. For DBT slices −2, −1, +1, and +2, calculate the Δ Z-Res Diff, the fraction of Z-Res Diff of that slice relative to DBT slice 0:

$$\Delta \text{ Z-Res Diff}_i = \text{Z-Res Diff}_i \, / \, \text{Z-Res Diff}_0$$

3. If Δ **Z-Res Diff**$_2$ is greater than or equal to 0.5, calculate Δ **Z-Res Diff**$_3$.

4. If Δ **Z-Res Diff**$_{-2}$ is greater than or equal to 0.5, calculate Δ **Z-Res Diff**$_{-3}$.

5. From the DBT Z Resolution form, determine the FWHM.

Note: FWHM is the distance between points on the curve at which the function reaches half its maximum value. In this test, the curve represents ratios of signal in each slice compared to Slice 0, so the maximum is 1.0 and half maximum is 0.5. The x-axis represents distance in the depth (z) direction. Therefore, FWHM is in units of mm and is the distance that the speck is spread in the z-direction. For a more complete description of the graphical plot measurement, see the American College of Radiology Digital Mammography QC Manual: Frequently Asked Questions.

PRECAUTIONS AND CAVEATS

It may be helpful to review the DBT Z-Resolution form, which illustrates the Δ **Z-Res Diff**$_i$ calculation.

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

MEEs

The initial (MEE) Z-Resolution measurement becomes the baseline value for future Z-Resolution measurements. ***There is no action limit for the initial Z-Resolution measurement.***

Annual Surveys

The FWHM value of the current image set must be ***within ±30% of the baseline value***. If the Performance Criteria are not met, a qualified service engineer must be contacted to correct the problem.

TIMEFRAME FOR CORRECTIVE ACTION

Failures ***must*** be corrected within 30 days.

4. Spatial Resolution

OBJECTIVES

To measure the limiting spatial resolution as an indicator of detector performance.

FREQUENCY

As part of the mammography equipment evaluation of new units, annually, and after relevant service.

TEST EQUIPMENT

- ACR Digital Mammography (DM) Phantom.

- Line pair (lp) pattern with frequencies up to 10 lp/mm.

- Spatial Resolution form.

TEST PROCEDURE – 2D AND DBT

1. Create a test patient.

2. Turn off all image processing to acquire a "for processing" (e.g., "raw") image.

3. Install a compression paddle.

4. Place the ACR DM Phantom on the breast support with the wax insert facing up and away from the chest-wall edge (rotated 180° from the normal orientation of the phantom).

5. Place the line pair pattern on the phantom at a 45° angle (see Figure 21).

6. Lightly compress the line pair pattern to ensure that it remains secure during the exposure.

7. Make one exposure using a manual technique as close to the ACR DM Phantom technique as possible.

8. Repeat steps 3-7 for any other targets used clinically.

9. Install the magnification stand and paddle and enter the unit's most frequently used clinical magnification mode. Repeat steps 3-7 for clinically used targets.

10. Repeat steps 3-8 in the DBT imaging mode.

11. If the system uses an add-on device for DBT, repeat steps 3-8 in 2D mode with the DBT fixture in place.

MEDICAL PHYSICIST'S SECTION
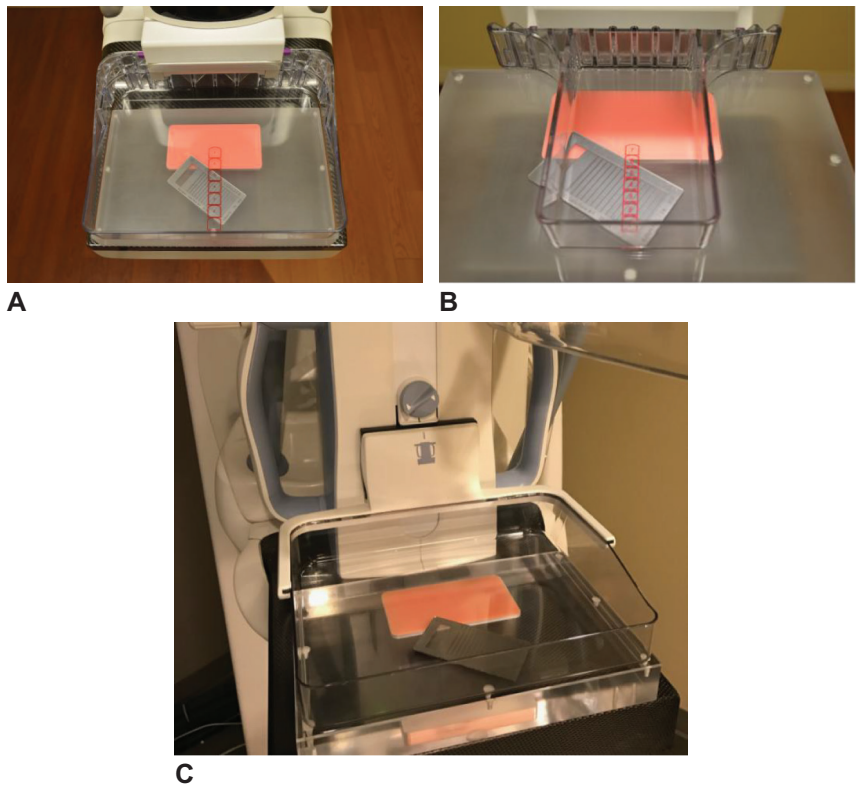
Figure 21. A. Bar pattern placement for the Spatial Resolution test on a 2D system. The bar pattern is at a 45° angle to the chest-wall edge. B. Magnification setup. C. DBT setup.

DATA ANALYSIS AND INTERPRETATION

1. At the acquisition station, view each image using full resolution and the greatest zoom available. (See Figures 22 and 23.)

2. Record the highest frequency for which at least half the length of the lines can be continuously resolved in each image. (See Figure 23.)

3. Ensure that the polarity of the lines does not reverse. If reversal occurs, the limiting resolution has been surpassed.

Figure 22. Image of bar pattern properly visualized for the Spatial Resolution Test.

Digital Mammography Quality Control Manual
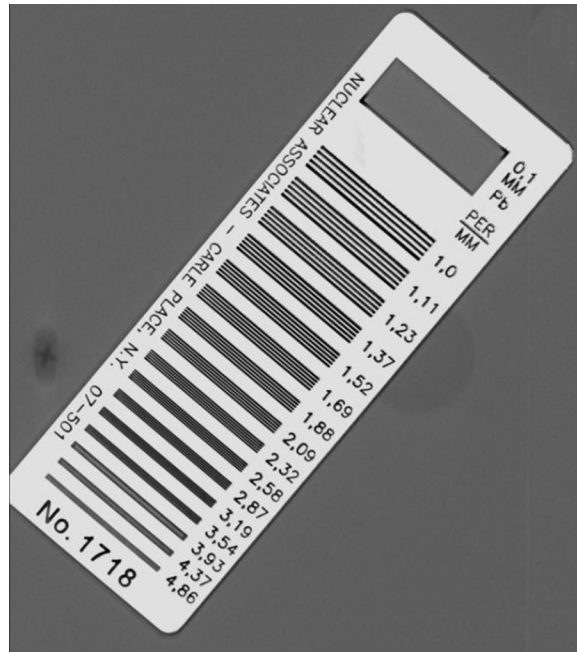
Figure 23. Bar pattern magnified for analysis. In this pattern, 4.0 lp/mm are distinguishable.

4. If the system uses an add-on device for DBT, repeat steps 1-3 for the 2D image acquired with the DBT fixture in place.

PRECAUTIONS AND CAVEATS

It is recognized that limiting spatial resolution is an imperfect substitute for a detailed determination of modulation transfer function. However, limiting spatial resolution is more easily measured in the field and serves as an acceptable analog for purposes of detector performance consistency.

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

1. Spatial resolution of the 2D image(s) must be ≥4.0 lp/mm.

2. Spatial resolution of the 2D magnification mode image(s) must be ≥6.0 lp/mm.

3. Spatial resolution of the DBT image(s) must be ≥2.0 lp/mm.

4. If limiting spatial resolution does not meet these criteria, service must be scheduled.

TIMEFRAME FOR CORRECTIVE ACTION

Failures *must* be corrected within 30 days.

MEDICAL PHYSICIST'S SECTION

5. DBT Volume Coverage

OBJECTIVES

A visual test to assure that the entire breast volume is imaged during the DBT acquisition.

FREQUENCY

As part of the mammography equipment evaluation of new units, annually, and after relevant service.

TEST EQUIPMENT

- ACR Digital Mammography (DM) Phantom.

- Two 0.1-mm thick sheets of aluminum.

- DBT Volume Coverage form.

TEST PROCEDURE

1. Initiate an exam at the acquisition workstation as you would for a patient.

2. Use a name and image designation system that allows tracking of QC images. It is important to be able to match and identify the mammography unit to the printed image from that same unit. See example below:

   a. Last Name: ACR Volume Coverage

   b. First Name: Room 1

   c. Patient ID: "Date of Phantom Acquisition"

   d. Date of Birth: "Date of Phantom Acquisition"

3. Enter DBT mode.

4. Use the largest available image receptor size and corresponding paddle for the ACR DM Phantom image acquisition. Ensure that the type of paddle chosen (e.g., flex or fixed) is the one used for the majority of clinical imaging.

5. Place the DM phantom on the breast support surface as shown in Figure 24. Be sure to position the phantom in the same location each time the test is performed to limit exposure variability. Check that

   a. The pink wax insert is facing up and away from the chest-wall edge (rotated 180° from the normal orientation of the phantom),

   b. The phantom is centered left-to-right, and

   c. The edge of the phantom is aligned with the chest wall edge of the digital image receptor.

6. Place 0.1 mm aluminum sheets on top of and below the DM phantom as shown in Figure 24.

7. Manually compress the paddle to 5 decanewtons or 12 pounds of compression force. It is important to use the same compression force each time for this test. Note that at this compression force, the compressed breast thickness indicator may not read 4.2 cm.

8. Make one exposure in the DBT mode using a manual technique as close to the ACR DM Phantom DBT technique as possible.
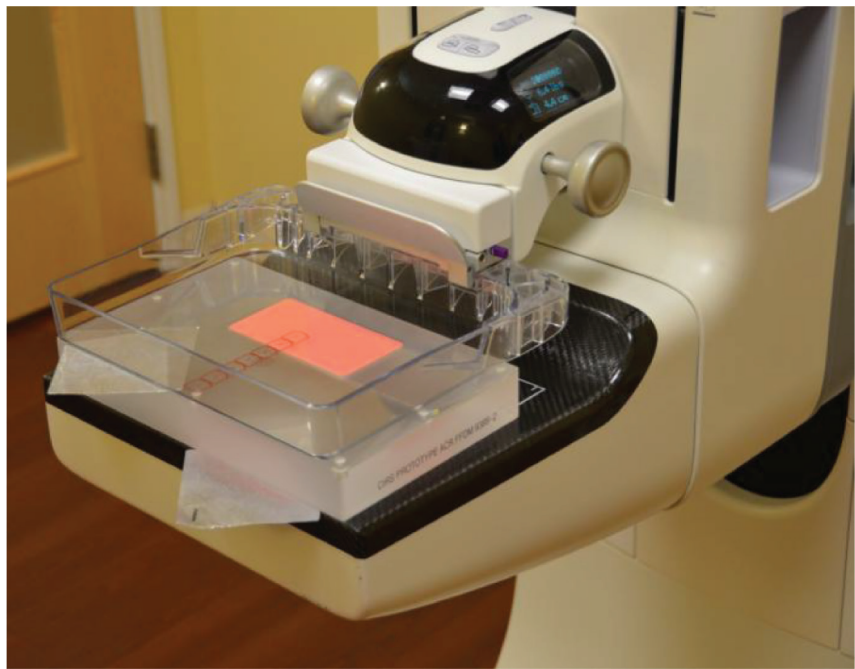
A
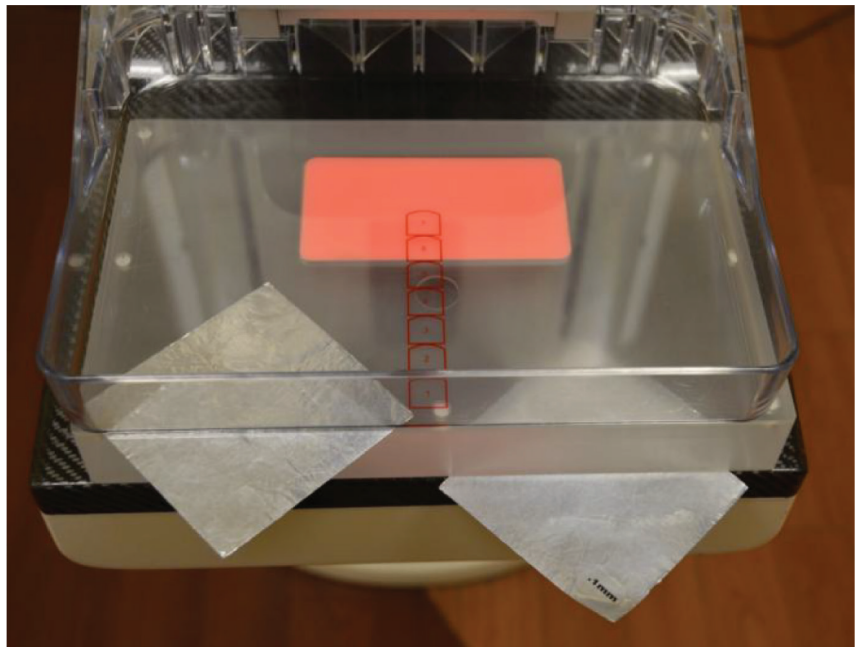
B

Figure 24. A. ACR DM Phantom with 0.1 mm aluminum sheets positioned for image acquisition. B. Zoomed photograph of DBT Volume Coverage setup.

DATA ANALYSIS AND INTERPRETATION

At the acquisition workstation, scroll through the image set using the thinnest slices available. Determine if both the top and bottom aluminum sheets are well defined and in focus in their respective planes. (See Figure 25.)

A **B**
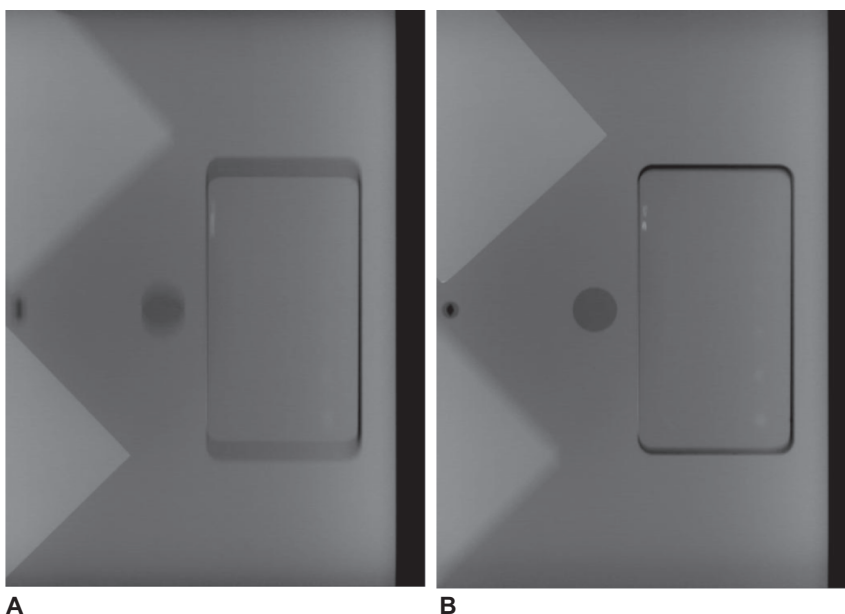
Figure 25. A. Image of ACR DM Phantom with aluminum sheets in focus at bottom of phantom. B. Image of ACR DM Phantom with aluminum sheets in focus at top of phantom.

PRECAUTIONS AND CAVEATS

If the system fails the test, verify that the aluminum sheets are properly positioned and repeat the test.

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

Each aluminum sheet must be well defined within one slice, or the system is not imaging the entire breast volume.

TIMEFRAME FOR CORRECTIVE ACTION

Failures *must* be corrected before clinical use.

6. Automatic Exposure Control System Performance

OBJECTIVES To assess the performance of the automatic exposure control (AEC) function and to verify consistency in detector signal-to-noise level for a range of breast thickness.

FREQUENCY As part of the mammography equipment evaluation (MEE) of new units, annually, and after relevant service.

TEST EQUIPMENT

- Compression paddles.

- Four or more tissue-equivalent attenuators (e.g., acrylic, BR-12, BR-50) providing approximate thicknesses of 2, 4, 6, and 8 cm and of sufficient area to resemble an average-sized compressed breast and cover the AEC area.

- Magnification stand, if used clinically for 2D imaging.

- Automatic Exposure Control System Performance form.

TEST PROCEDURE

1. Create a test patient on the acquisition workstation.

2. Install the small size paddle, if available. Otherwise, install the large size paddle.

3. Center 2.0 cm of tissue-equivalent attenuator on the image receptor and position it so the chest-wall edge of the attenuator is aligned with the chest-wall edge of the image receptor. (See Figure 26.)

4. Lower the compression paddle to 2 cm compression thickness (or 5 decanewtons per 12 lbs of compression force).

5. If applicable, set the density control function (or exposure compensation step) to 0.

6. If applicable, set the AEC sensor to the center of the phantom.

7. Select the large focal spot.

8. Acquire an image using the AEC mode used clinically.

9. Make an exposure.

A   B
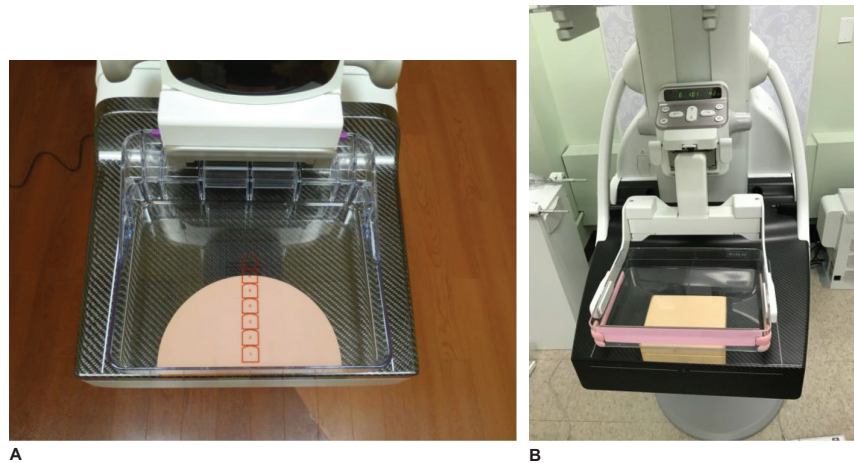
Figure 26. Position of attenuator for Automatic Exposure Control System Performance test in contact mode. A. 2D. B. DBT.

MEDICAL PHYSICIST'S SECTION

10. Record the relevant technique information (AEC Mode, Density Setting or Exposure Compensation, target, filter, kVp, mAs, and indicated average glandular dose) on the form.

11. Repeat steps 3-10 for the 4, 6, and 8 cm phantoms.

12. Set up the equipment with the magnification stand as shown in Figure 27 and repeat steps 3-10 for the 4 cm phantom.

13. Repeat steps 3-11 in DBT mode.

14. If the system uses an add-on device for DBT, repeat steps 3-11 in 2D mode with the DBT fixture in place.

Figure 27. Position of attenuator for Automatic Exposure Control System Performance test in magnification mode.

DATA ANALYSIS AND INTERPRETATION

1. If the manufacturer provides a DC offset, record this value on the form.

2. Record the signal-to-noise ratio (SNR) results from the last MEE on the form. (This does not apply to MEEs.)

3. Calculate the lower limit and the upper limit for each mode/attenuator SNR as ±15% of the last MEE's SNR, and record.

4. Use only "for processing" (e.g., "raw") images for analysis.

5. For DBT, find the center slice or slab in the image set and use the thinnest available slice.

6. On the radiologist workstation, use a circular or rectangular region of interest (ROI; approximately 3 cm from chest wall and centered left to right) to measure the mean signal value (or mean analog to digital units) in the middle of the phantom. (See Figure 28.)

7. Record the mean signal value as Mean Bkgd Signal on the form; record the standard deviation as Std Dev of Bkgd.

A   **B**
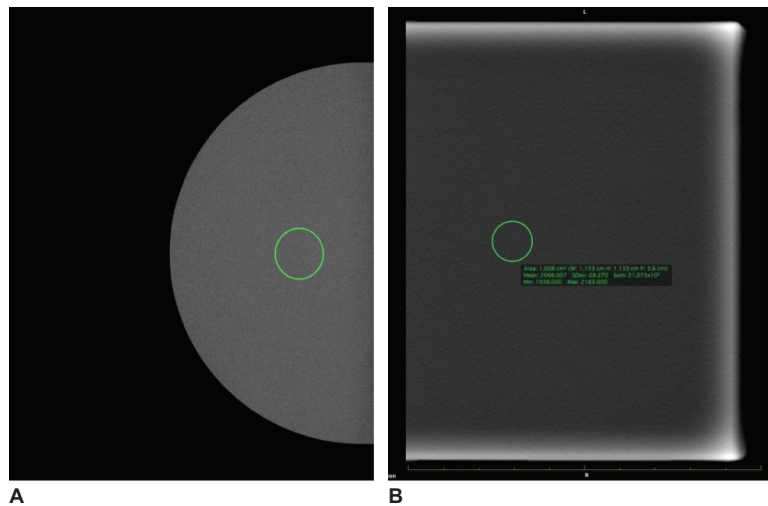
Figure 28. Position of ROI to measure pixel value (approximately 3 cm from chest wall and centered left to right). A. 2D. B. DBT.

8.   Calculate the SNR as

$$SNR = \frac{(Mean\ Bkgd\ Signal - DC\ offset)}{Std\ Dev\ of\ Bkgd}$$

(Omit the DC offset if this does not apply for the DM unit being tested.)

Note: If the acquisition workstation **does not have ROI** capability, the medical physicist should use one of the following alternatives to complete the test:

- Make the ROI measurement on the radiologist workstation.

- Using image analysis software, make the ROI measurement on an external computer system.

- If neither of the above alternatives are available, use the manufacturer's AEC evaluation procedure, equipment, and form.

PRECAUTIONS AND CAVEATS

Manufacturer operating manuals and/or guidance documents should be checked to see if there are DC offset values that should be used for the calculation of the SNR.

It is important to note that tissue-equivalent attenuators (e.g., acrylic, BR-12, BR-50) do not have exactly same attenuation characteristics as breast tissue. These materials may be more accurately correlated to breast tissue by using data available in published articles such as the one by Dance [6].

SNR results from the last MEE may not be available for many reasons such as a change in medical physicist, loss of QC records greater than three years, etc. If SNR results from the last MEE are not available, use the SNR results from the oldest relevant annual survey as a baseline to compare the current results. Be sure to note this in the annual survey report.

MEDICAL PHYSICIST'S SECTION

It is recognized that SNR is not strictly defined for DBT images. However, these calculated values should remain consistent year-to-year if the AEC is performing consistently.

Note that if components in the imaging chain are replaced (i.e., detector, x-ray tube, etc.) SNR may not meet the annual survey performance criteria of ±15% of the last MEE's SNR. If this is the case, the reason should be noted, a new baseline should be established, and the test should be passed.

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

MEE and Annual Surveys

The SNR *must* be ≥40.0 for the 4.0 cm phantom in 2D contact mode.

Annual Surveys

The SNR must be within ±15% of the last MEE's SNR for each thickness and mode tested. (This component of the test does not apply to MEEs.)

General

1. If any of these quantities are not within action limits, the test should be repeated. If the results remain below the performance criteria, the facility should contact its authorized service representative.

2. Record and date any comments and required corrective action in the Technologist's Corrective Action Log form.

TIMEFRAME FOR CORRECTIVE ACTION

Failures *must* be corrected within 30 days; for MEEs, before clinical use.

7. Average Glandular Dose

OBJECTIVES

To measure the entrance exposure for an average patient (approximately a 4.2 cm thick compressed breast consisting of 50% glandular and 50% adipose tissue), calculate the associated average glandular dose and ensure that the unit-indicated average glandular dose (if available) is reasonably accurate.

FREQUENCY

As part of the mammography equipment evaluation (MEE) of new units, annually, and after relevant service.

TEST EQUIPMENT

- Ionization chamber and electrometer or other appropriate dosimetry device calibrated at mammographic x-ray beam energies.

- An integrated, solid-state instrument (one that automatically measures kVp, half-value layer [HVL], and dose) is also acceptable. (The instrument must be calibrated for the target/filter combination in use or be adjusted with an appropriate correction factor. See Precautions and Caveats.)

- Average Glandular Dose form.

TEST PROCEDURE

Breast Entrance Exposure and Average Glandular Dose – 2D and DBT

> **Note:** This procedure uses the technique factors that result from the ACR Digital Mammography (DM) Phantom Image Quality test. This technique must be the same as that used clinically for a **4.2-cm thick compressed breast consisting of 50% glandular and 50% adipose tissue, as defined by the FDA.** Exposure measurements made at a corresponding manual technique in **2D mode** (or fixed mode) can be used to calculate average glandular dose **for DBT images**.

1. Place a lead sheet or other protective device on the image receptor. This is intended to protect the detector from repeated exposures.

2. Position the center of the dosimeter at a height of 4.2 cm above the breast support and just under the paddle. Center the dosimeter approximately 4 cm in from the chest-wall edge of the image receptor. Make sure that the entire dosimeter is exposed (see Figure 29).

3. Secure the dosimeter in position, and do not change its position during the following measurements.

> **Note:** Mammographic imaging systems have a significant x-ray intensity gradient along the anode-cathode direction due to the anode heel effect. Maintaining a constant dosimeter position during measurements is critical. When measurements are to be compared with others made previously, it is also critical that the original measurement position be re-established as closely as possible.

4. Position the compression device in the x-ray beam, just in contact with the dosimeter (as shown in Figure 29).

MEDICAL PHYSICIST'S SECTION
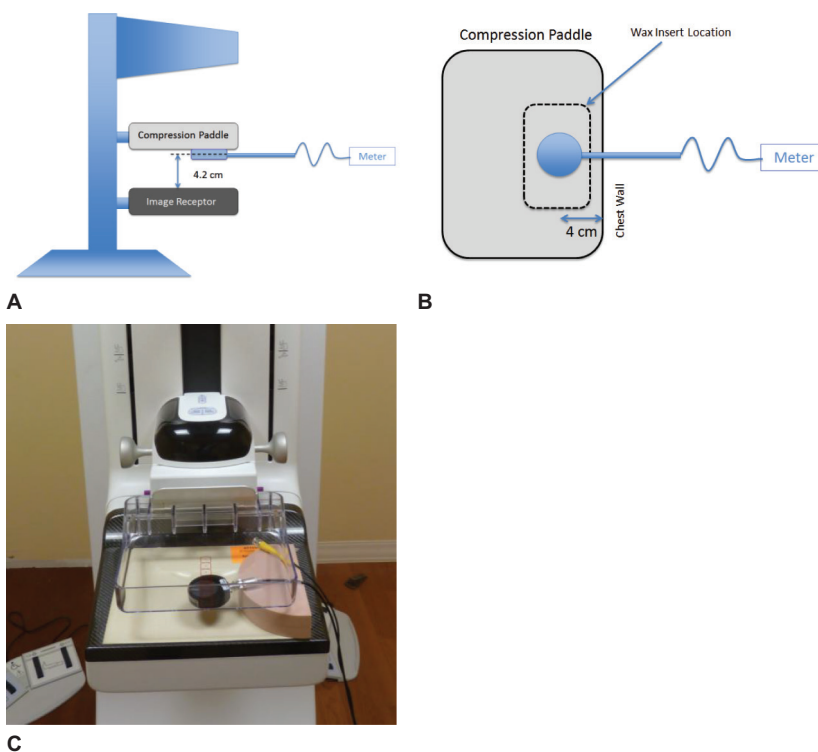
Figure 29. Exposure setup. Compression device positioned so that it is just in contact with the dosimeter. A. Side view diagram. B. Top view diagram. C. Photo.

5. Set the target material, filtration, and kVp at the values at which the ACR DM Phantom image was acquired *in the 2D mode*, and record the settings on the form. Also, record the HVL (previously measured during the MEE) for those same parameters on the form. Finally, record on the form the automatic exposure control (AEC) mode and mAs at which the ACR DM Phantom image was acquired *in the 2D mode*.

6. Manually set mAs as close as possible to that obtained under the AEC exposure of the ACR DM Phantom and record the value on the form.

7. Make a manual exposure and record the measured exposure on the form.

8. Repeat step 7 until three exposures have been recorded.

9. If available, record the unit-indicated average glandular dose from the ACR DM Phantom Image Quality test form.

10. Set the target material, filtration, and kVp at the values at which the ACR DM Phantom image was acquired *in the DBT mode*, and record the settings on the form. Also, record the HVL (previously measured during the MEE) for those same parameters on the form. Finally, record on the form the AEC mode and mAs at which the ACR DM Phantom image was acquired *in the DBT mode*. *Repeat steps 6-9 for the DBT mode*.

> **Note:** If the phantom image was acquired in a combination mode, only use the technical factors associated with the DBT portion of the exposure for the DBT average glandular dose assessment.

DATA ANALYSIS AND INTERPRETATION

1. If necessary, correct the average exposure with the dosimeter's appropriate energy correction factor.

2. Determine the mR/mAs at the skin entrance.

3. Calculate the total AEC exposure at the skin entrance by multiplying the mR/mAs by the mAs obtained during the AEC exposure of the ACR DM Phantom.

> **Note:** Use the ***acrylic g-factor * c-factor * 8.76 mGy/R*** values when determining the average glandular dose from the ACR DM Phantom techniques for a 4.2-cm thick compressed breast consisting of 50% glandular and 50% adipose tissue. Both acrylic and BR-12 values are provided for breast thicknesses of 2 to 8 cm if the medical physicist wishes to determine average glandular doses for a broader range of breast thicknesses.

4. Compute the average glandular dose using the following equation:

$$AGD = Kgcs$$

AGD = Average Glandular Dose (mGy)

K = Entrance Exposure (mR)

g = g-factor for breast simulated with acrylic or BR-12

c = c-factor for breasts simulated with acrylic or BR-12

s = s-factor for clinically used spectra

a. K is the exposure in the absence of backscatter at the entrance surface of the breast. (The amount of backscatter in the described setup is small enough to be ignored while maintaining adequate accuracy for this test.)

b. The factor g corresponds to a glandularity of 50% and is derived from values calculated from Dance [6].

c. The factor c corrects for any difference in breast composition from 50% glandularity. (See Table 5 and Table 6; additional phantom thicknesses are provided if the medical physicist would like to determine dose for other breast thicknesses.)

d. The factor s corrects for differences due to the choice of x-ray spectrum (see Table 7) [6, 7, 8, 9].

MEDICAL PHYSICIST'S SECTION

Table 5. g-factor * c-factor * 8.76 mGy/R for Acrylic

Breast Thickness (cm)	g-factor * c-factor * 8.76 mGy/R for Acrylic						
	HVL (mm Al)						
	0.3	0.35	0.4	0.45	0.5	0.55	0.6
2	2.944	3.301	3.639	3.945	4.226	4.490	4.720
4	1.672	1.897	2.114	2.348	2.589	2.820	3.071
4.2	1.609	1.828	2.037	2.261	2.499	2.736	2.972
6	1.164	1.320	1.471	1.639	1.781	2.015	2.220
8	0.847	0.967	1.087	1.195	1.315	1.483	1.647

Table 6. g-factor * c-factor * 8.76 mGy/R for 50% Glandularity BR-12

Breast Thickness (cm)	g-factor * c-factor * 8.76 mGy/R for BR-12						
	HVL (mm Al)						
	0.3	0.35	0.4	0.45	0.5	0.55	0.6
2	3.4164	3.7931	4.1435	4.4588	4.7567	5.0195	5.1421
4	1.8133	2.0586	2.2864	2.5316	2.7857	3.0310	3.2762
4.2	1.7292	1.9640	2.1847	2.4230	2.6700	2.9083	3.1536
6	1.1826	1.3490	1.5067	1.6819	1.8746	2.0674	2.2864
8	0.8585	0.9811	1.1038	1.2264	1.3490	1.5330	1.7082

Table 7. s-factors for Acrylic and BR-12 [6, 7, 8, 9]

s-factors for Acrylic and BR-12	
Target/Filter	s-factor
Mo/Mo	1.000
Mo/Rh	1.017
Rh/Rh	1.061
Rh/Al	1.044
Rh/Ag	1.087
W/Rh	1.042
W/Al (0.5 mm)	1.134
W/Al (0.7 mm)	1.082
W/Ag	1.042

PRECAUTIONS AND CAVEATS

Current and accurate calibration of dosimeters is essential and required under the FDA MQSA Final Rule [1]. See the FDA's MQSA Policy Guidance Help System [2] frequently asked questions on air kerma calibration. It is well known that the energy response for ionization chamber-based air kerma measuring instruments is typically flat in the 20-40 kVp range. For solid-state air kerma measuring instruments, however, the energy response is not flat, and because of this, the air kerma readings from these instruments may need to be adjusted by an appropriate correction factor. The correction may already be handled internally by the instrument, or

you may need to contact the instrument manufacturer for the correction factor [10].

The medical physicist should ensure that the HVL has been determined for the target/filter and kVp combination used for DBT imaging during the MEE.

If the facility has changed its target/filter and kVp combination for an average patient (and the corresponding HVL was not determined during the MEE), or if the medical physicist suspects that the HVL may have significantly changed since the MEE, the medical physicist should re-evaluate the HVL for use in the current Average Glandular Dose test.

The previously published 1999 ACR Mammography Quality Control Manual [5] used a method adapted from Barnes and Wu to calculate average glandular dose. This method was limited to four target/filter combinations, a limited range of kVp and HVL settings, one breast thickness (4.2 cm), and one tissue glandularity value (50% adipose-50% glandular). This manual is using a different method published by Dance [6], which utilizes a single formula ($D = Kgcs$), where D is the average glandular dose, K is the entrance exposure at the upper surface of the breast without backscatter, g is the entrance exposure to mean glandular dose conversion factor, c corrects for differences in breast composition from 50% glandularity, and s corrects for differences in x-ray spectra. This method accommodates most target/filter combinations used in modern systems, nearly all clinically relevant breast thicknesses, a wider range of beam qualities, and a wider range of breast glandularity.

There is a minor difference between the two methodologies: an average of 1.0% difference in AGD values using the Barnes and Wu method [5] compared to the Dance method [6] for a cross-section of target/filter combinations and kVps used in the 1999 manual.

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

1. The average glandular dose for a single cranio-caudal view of the ACR DM Phantom in either 2D or DBT mode must not exceed 3.0 mGy. (Dose from a mode that combines a 2D view with a DBT view, such as "Combo" mode, is not subject to the 3.0 mGy performance criteria. Each view within the mode should be compared separately against the performance criteria.)

2. If the calculated value exceeds these levels, action **must** be taken to evaluate and eliminate the cause of excessive dose.

3. If the unit-indicated average glandular dose is available, it should be within ±25% of the calculated average glandular dose.

TIMEFRAME FOR CORRECTIVE ACTION

- Doses exceeding 3 mGy **must** be corrected before clinical use.

- Failures of the unit-indicated average glandular dose **must** be corrected within 30 days; for MEEs, before clinical use.

APPLICABLE MQSA REQUIREMENTS

900.12(e)(6) Quality control tests—other modalities.

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, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems in paragraph (e)(5)(vi) of this section.

900.12(e)(5)(vi) Dosimetry.

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. The dose shall be determined with technique factors and conditions used clinically for a standard breast.

8. Unit Checklist

OBJECTIVES   To ensure that all locks, detents, angulation indicators, and mechanical support devices for the x-ray tube and breast support assembly are operating properly and that the DICOM image file headers are correctly populated.

FREQUENCY   As part of the mammography equipment evaluation (MEE) of new units, annually, and after relevant service.

TEST EQUIPMENT   Unit Checklist form.

TEST PROCEDURE

1. Verify that the freestanding dedicated mammography unit is mechanically stable under normal operating conditions *(*critical test)*.

2. Verify that all moving parts move smoothly, without undue friction; that cushions or bumpers limit the range of available motions; and that no obstructions hinder the full range of motions within these limits.

3. Set and test each lock and detent independently to ensure that mechanical motion is prevented when the lock or detent is set *(*critical test)*.

4. Verify that the detector or image receptor holder assembly is free from wobble or vibration during normal operation *(*critical test)*.

5. If cassette-based, verify that the image receptor slides smoothly into the proper position in the image receptor holder assembly.

6. If cassette-based, verify that the cassette is held securely for any orientation of the image receptor holder assembly *(*critical test)*.

7. Verify that in normal operation the patient and operator are not exposed to sharp or rough edges or other hazards including electrical hazards *(*critical test)*.

8. Verify that the compression paddles are all intact with no cracks or sharp edges *(*critical test)*.

9. Verify that the mammography area is clean and free from significant dust and debris that may cause artifacts.

10. Verify that the operator is protected by adequate radiation shielding during exposure *(*critical test)*.

11. Verify that all indicators work properly.

12. Verify that automatic decompression can be overridden to maintain compression (for procedures such as needle localizations) and its status displayed continuously (if automatic decompression is available) *(*critical test)*.

13. Verify that compression can be manually released in the event of a power or automatic release failure by turning power off to the equipment. This can be verified by placing a phantom under compression and using manual controls to release the compression *(*critical test)*.

14. Verify that the audible exposure indicator is at an appropriate volume level.

15. Verify that the DBT assembly moves as designed through its range of motion *(*critical test)*.

16. Verify that current and accurate technique charts are posted, confirmed by consulting with the mammography technologist if possible.

17. Add other unit-specific checks as necessary.

18. Record the pass or fail of each inspection item on the form.

DATA ANALYSIS AND INTERPRETATION

Not applicable

PRECAUTIONS AND CAVEATS

None

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

Critical items that are hazardous, inoperative, or operate improperly **must** be repaired by appropriate service personnel or replaced.

TIMEFRAME FOR CORRECTIVE ACTION

Failures of critical tests (*) **must** be corrected before clinical use; less critical tests **must** be corrected within 30 days; for MEEs, before clinical use.

APPLICABLE MQSA REQUIREMENTS

> *900.12(e)(5)(xi) Decompression.*
>
> *If the system is equipped with a provision for automatic decompression after completion of an exposure or interruption of power to the system, the system shall be tested to confirm that it provides:*
>
> *(A) An override capability to allow maintenance of compression;*
>
> *(B) A continuous display of the override status; and*
>
> *(C) A manual emergency compression release that can be activated in the event of power or automatic release failure.*

9. Computed Radiography *(if applicable)*

OBJECTIVES

To meet the additional QC needs of computed radiography (CR) system photostimulable phosphor (PSP) imaging plates.

FREQUENCY

As part of the mammography equipment evaluation (MEE) of new units, annually, and after relevant service or acquisition of new PSP plates. (If a new PSP plate is acquired, this test may be performed by the QC technologist with oversight by the medical physicist; see Precautions and Caveats.)

> **Important:** This test is only applicable to computed radiography systems.

TEST EQUIPMENT

- ACR Digital Mammography (DM) Phantom.
- Computed Radiography form.

TEST PROCEDURE

Plate-to-Plate Uniformity

1. Erase all CR cassettes.

2. Create a patient ID as outlined in the ACR DM Phantom Image Quality test to acquire images or use manufacturer software to acquire images.

3. Place the ACR DM Phantom on the breast support, and lower the compression paddle to achieve a force of 5 daN.

4. Using AEC, expose the plate using a technique as close as possible to the ACR DM Phantom technique acquired in the ACR Digital Mammography Phantom Image Quality test.

5. Record the mAs on the form.

6. Process the acquired CR image using no image processing if possible.

7. At a workstation, place a region of interest having an area of approximately 5 cm² in the center of each image. Record the measured mean signal values and standard deviation on the form. Calculate the signal-to-noise ratio (SNR) for each image using the procedure described in the ACR Digital Mammography Phantom Image Quality test.

8. Repeat steps 1-7 for all plates at the facility (i.e., large and small).

Plate-Specific Artifact Analysis

1. View the images acquired as described above on a workstation, with the window width and window level set to optimize the viewing of the test objects.

2. Record all clinically significant artifacts on the form.

CR Reader Scanner Performance

1. Place a cassette on top of the breast support plate.

2. Place a pair of thin steel rulers or another thin metal object on top of the cassette in a T shape. (See Figure 30.)

3. Make a manual exposure at a technique close to 25 kVp and 4 mAs.

4. Process the cassette.

> **Note:** The CR Reader Scanner Performance procedure only needs to be performed on one cassette for each reader. (It does not need to be conducted for each plate.)
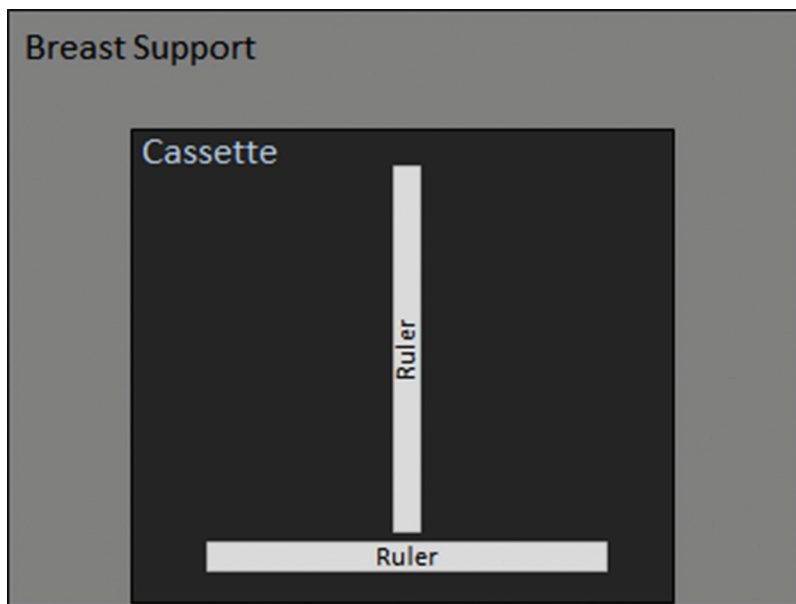
Figure 30. CR reader scanner performance.

DATA ANALYSIS AND INTERPRETATION

None

PRECAUTIONS AND CAVEATS

Most plate manufacturers recommend a delay of 15 minutes prior to processing plates. However, the main requirement is that the same time delay between exposure and processing (±1 minute) be used for all plates. Time can be saved by sequentially exposing the cassettes and waiting approximately 2 minutes between each exposure. Then, sequentially process the plates in the same order so that each subsequent plate enters the reader approximately 2 minutes after the prior plate.

If one or two new PSP plates are acquired between the medical physicist's annual surveys, the QC technologist **must** first check the plate before putting it into clinical service. This **must** be done by following the Technologist's ACR Digital Mammography Phantom Image Quality procedure and sending the completed form to the medical physicist for review.

> **Note:** If the facility replaces all of its PSP plates with new ones, the medical physicist **must** perform an MEE consisting of applicable tests.

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

Plate-to-Plate Uniformity

1. The mAs of any plate exposure **must not** differ by more than ±10% from the mean mAs of all plates of the same size.

2. If the mAs of a plate differs by more than ±10% from the mean, the plate **must** be removed from service and replaced.

3. The SNR of any plate **must not** differ by more than ±15% from the mean SNR of all plates of the same size.

4. If the SNR of a plate is more than ±15% from the mean, the plate **must** be removed from service and replaced.

Plate-Specific Artifact Analysis

1. Artifacts should be below a level at which they could obscure important structures or pathology and **must not** mimic important structures or pathology. Setting the window level and width to have good visualization of test objects in the ACR DM Phantom provides reasonable settings to assess artifacts.

2. The cause of objectionable artifacts **must** be further investigated.

3. If only a subset of plates demonstrate artifacts, clean the plates and retest. If the artifacts persist, the plates should be removed from service and replaced. If the artifact appears on all images, the cause is likely in the x-ray unit or in the CR reader. The source should be isolated and appropriate service called.

CR Reader Scanner Performance

It is recommended that the edges of the steel ruler in both directions be crisp and linear. There should be no jagged or non-linear edges visible at the ruler's edge.

TIMEFRAME FOR CORRECTIVE ACTION

Failures of required items **must** be corrected before clinical use.

MEDICAL PHYSICIST'S SECTION

10. Acquisition Workstation (AW) Monitor QC

OBJECTIVES

- To ensure that AW monitors are clean and free from dust, fingerprints, and other marks that may interfere with clinical information.

- To ensure that monitors are calibrated correctly and brightness and contrast settings are set correctly.

- To ensure that monitors meet manufacturer specifications via the conduct of Monitor Manufacturer Automated Tests (if available).

> **Important:** Monitor Manufacturer Automated Tests are required if such tests are available in the manufacturer's documentation.

FREQUENCY

As part of the mammography equipment evaluation of new equipment, annually, and after relevant service.

TEST EQUIPMENT

- The American Association of Physicists in Medicine (AAPM) TG18-QC test pattern [11] is strongly preferred. If one is not available on the monitor, ask the authorized service representative to install one. If this is not possible, a SMPTE test pattern [12] or another pattern that allows relevant measurements may be used. See Figure 31. If it is not possible to install a relevant test pattern on the monitor, this part of the test is not applicable.

- AAPM TG18 LN8-01 and LN8-18 test patterns for the luminance check, or other patterns that allow for measurement of L_{min} and L_{max} (if available). See Figure 32.

- AAPM TG18 UNL80 test pattern for luminance uniformity, or other patterns that allow for measurement of luminance uniformity (if available). See Figure 33.

- Luminance meter

- Acquisition Workstation Monitor QC form

A   B
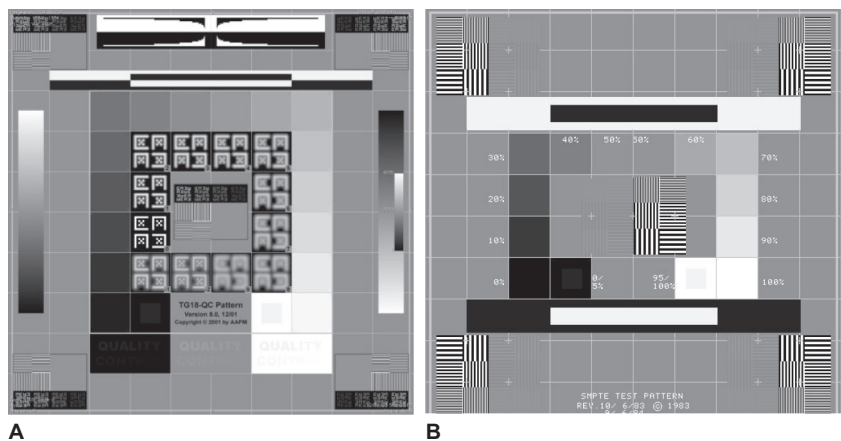
Figure 31. Test patterns: A. AAPM TG18-QC test pattern. B. SMPTE test pattern.
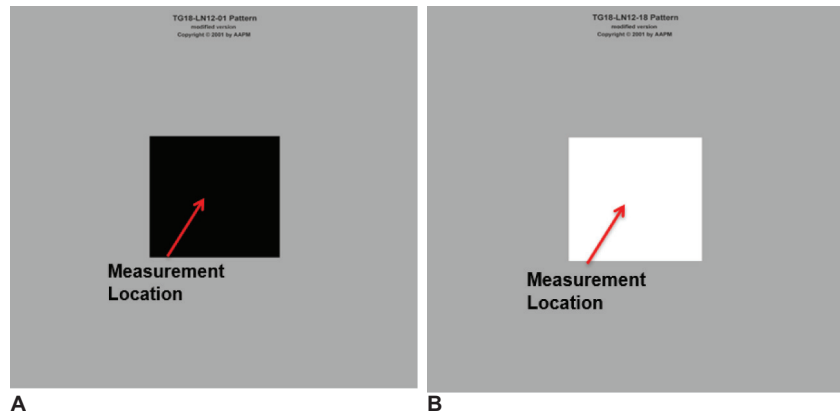
Figure 32. Test patterns: A. AAPM TG18 LN8-01 test pattern. B. AAPM TG18 LN8-18 test pattern.
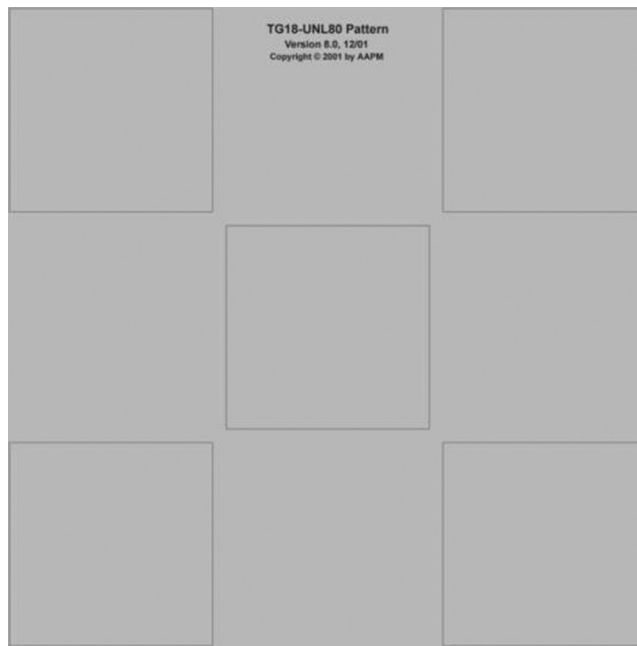
Figure 33. AAPM TG18 UNL80 test pattern.

TEST PROCEDURE

Monitor Condition

1. Visually inspect the surface of the monitor for the presence of dust, scratches, defects, fingerprints, shiny patches (from grease or gel), and other foreign material (e.g., pen marks, etc.).

2. Record significant findings on the form (see Performance Criteria and Corrective Actions).

Test Pattern Image Quality (if available)

1. Reduce the lighting in the acquisition room to be similar to that in the radiologist's reading room before image evaluation.

2. Display the test pattern on the monitor. (If an appropriate test pattern is not available on the AW, skip this test.)

3. Evaluate the test pattern for the following visible targets and record pass or fail on the form:

   a. Is the test pattern centered appropriately?

   b. Are the 0%-5% contrast boxes visible?

   c. Are the 95%-100% contrast boxes visible?

   d. Are the alphanumerics sharp and legible?

   e. Are the line-pair images at the center and four corners visible and clearly distinguishable?

   f. Are the grayscale ramps smooth and continuous?

Luminance Check (if available)

1. Using the TG18 LN8-01 and LN8-18 test patterns, measure L_{min} and L_{max} with a luminance meter in the center of each box. (See Figure 32.)

2. Record these values on the form.

3. If possible, obtain the manufacturer specifications for L_{min} and L_{max} and enter them on the form.

Luminance Uniformity (if available)

1. Using the TG18 UNL80 test pattern, measure the luminance at each of the four corners of the monitor and at the center of monitor. (See Figure 33.)

2. Record these values on the form.

DICOM Grayscale Display Function (GSDF) Evaluation (if available)

1. If possible, use the monitor manufacturer's built-in software to verify that the result of the DICOM GSDF grayscale test meets the monitor manufacturer's performance criteria.

2. The medical physicist may perform this test manually if he or she believes an independent verification is needed or if the manufacturer does not provide built-in software.

Monitor Manufacturer Automated Test (if available)

1. Open the monitor manufacturer automated test program.

2. For initial setup, review the monitor manufacturer's frequencies, action limits, and other test parameters to verify if appropriate for mammography.

3. Review the results and verify that all tests have passed.

4. Record an overall pass or fail on the form.

DATA ANALYSIS AND INTERPRETATION

Luminance Uniformity (if available)

Calculate the percent difference of the luminance values measured in the image display area using the following equation:

$$\% \: difference = \frac{200 * (Lmax - Lmin)}{(Lmax + Lmin)}$$

where L_{max} and L_{min} are the maximum and minimum measured luminance values, respectively.

PRECAUTIONS AND CAVEATS

Ideally, monitor screens should be free of dust, fingerprints, and other marks. Similarly, there should be no "shiny" patches or obvious non-uniformities on the surface. As described below, significant blemishes that interfere with the interpretation or QC of images must be corrected.

Most problems can be corrected by cleaning according to the manufacturer's instructions. However, if cleaning does not correct the problem, the manufacturer should be contacted to evaluate and correct the problem.

In most cases, Monitor Manufacturer Automated Tests and action limits are available in manufacturer manuals or documents published by the manufacturer. These tests are extremely valuable in maintaining quality and are specific to each manufacturer. If a Monitor Manufacturer Automated Test is available, the medical physicist should assist the facility in verifying that the automated system is set up and functioning properly.

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

Monitor Condition

Any large, significant blemish that interferes with the visualization or QC of images is a failure. (If there are questions regarding the significance of a monitor blemish, the lead interpreting radiologist should be consulted.)

Test Pattern Image Quality (if available)

1. The test pattern *must* be centered appropriately.

2. The 0%-5% and 95%-100% contrast boxes *must* be visible.

3. The alphanumerics *must* be sharp and legible.

4. The high-contrast line-pair patterns *must* be distinguishable at the center and corners.

5. The grayscale ramps *must* be smooth and continuous.

Luminance Check (if available)

L_{min} *must* be within ±30% of the value specified by the manufacturer, if available. L_{max} *must* be within ±10% of the value specified by the manufacturer, if available. If no specified values are available, luminance values *must* be L_{min} ≤1.5 cd/m^2 and L_{max} ≥150 cd/m^2.

Luminance Uniformity (if available)

The calculated % difference for an individual monitor must be ≤30%.

MEDICAL PHYSICIST'S SECTION

DICOM GSDF Evaluation (if available)

The measured contrast response values *must not* deviate from the targeted contrast response by more than ±10%.

Monitor Manufacturer Automated Test (if available)

Monitors *must* pass all manufacturer tests.

TIMEFRAME FOR CORRECTIVE ACTION

Monitor Condition

All failures *must* be corrected before clinical use.

Test Pattern Image Quality, Luminance Check, Luminance Uniformity, DICOM GSDF, and Monitor Manufacturer Automated Test (if available)

All failures *must* be corrected within 30 days.

11. Radiologist Workstation (RW) Monitor QC

OBJECTIVES

- To ensure that RW monitors are clean and free from dust, fingerprints, and other marks that may interfere with clinical information.

- To ensure monitors are calibrated correctly and the brightness and contrast settings are set correctly.

- To ensure that the image acquisition chain is producing adequate image quality and working consistently and that there are no obvious artifacts.

- To ensure that monitors meet manufacturer specifications via the conduct of Monitor Manufacturer Automated Tests (if available).

> **Important:** Monitor Manufacturer Automated Tests are required if such tests are available in the manufacturer's documentation.

FREQUENCY

As part of the mammography equipment evaluation of new equipment, annually, and after relevant service.

TEST EQUIPMENT

- Acquired ACR Digital Mammography (DM) Phantom image.

- The American Association of Physicists in Medicine (AAPM) TG18-QC test pattern is strongly preferred. If one is not available on the monitor, ask the authorized service representative to install one. If this is not possible, a SMPTE test pattern or another pattern that allows relevant measurements may be used. (See Figure 31.)

- AAPM TG18 LN8-01 and LN8-18 test patterns for the luminance check, or other patterns that allow for measurement of L_{min} and L_{max}. (See Figure 32.)

- AAPM TG18 UNL80 test pattern for luminance uniformity, or other patterns that allow for measurement of luminance uniformity. (See Figure 33.)

- Luminance meter.

- Radiologist Workstation Monitor QC form.

TEST PROCEDURE

Ambient Light

Evaluate the reading room environment where the RW resides for appropriate ambient light levels for mammography interpretation.

Monitor Condition

1. Visually inspect the surface of the monitor for the presence of dust, scratches, defects, fingerprints, shiny patches (from grease or gel), and other foreign material (e.g., pen marks, etc.).

2. Record significant findings on the form (see Performance Criteria and Corrective Actions).

MEDICAL PHYSICIST'S SECTION

ACR DM Phantom

1. Display a phantom image that was acquired on one of the digital mammography units per instructions in the ACR Digital Mammography Phantom Image Quality test.

2. Evaluate for artifacts and score the phantom test objects as in the ACR Digital Mammography Phantom Image Quality test.

Distance Measurement

1. Using a measurement tool within the manufacturer software, measure the distance across the wax insert as shown in Figure 34.

2. Record results on the form.
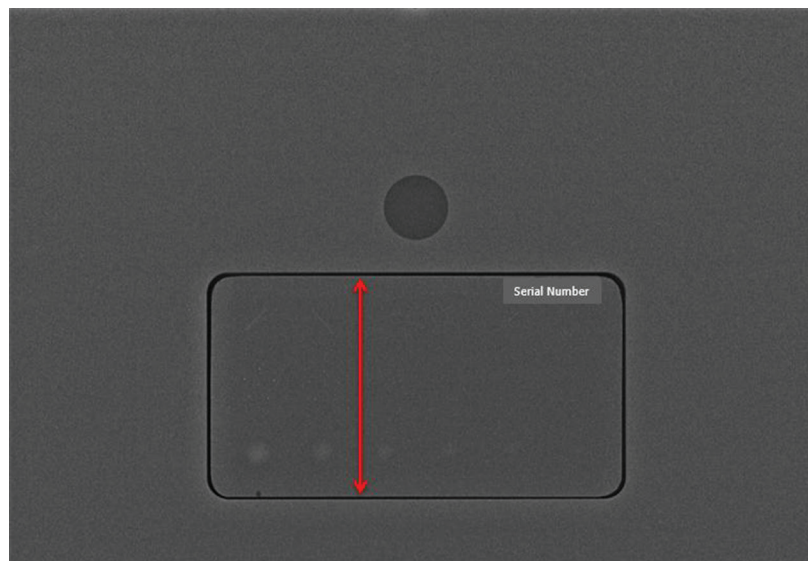
Figure 34. Distance measurement on ACR DM Phantom.

Test Pattern Image Quality

1. Display the test pattern on the monitor.

2. Evaluate the test pattern for the following visible targets and record pass or fail on the form:

   a. Is the test pattern centered appropriately?

   b. Are the 0%-5% contrast boxes visible?

   c. Are the 95%-100% contrast boxes visible?

   d. Are the alphanumerics sharp and legible?

   e. Are the line-pair images at the center and four corners visible and clearly distinguishable?

   f. Are the grayscale ramps smooth and continuous?

Digital Mammography Quality Control Manual

Luminance Check

1. Using the TG18 LN8-01 and LN8-18 test patterns (or other appropriate phantom as indicated above), measure L_{min} and L_{max} with a luminance meter in the center of each box. (See Figure 32.)

2. Record these values on the form.

3. If possible, obtain the manufacturer specifications for L_{min} and L_{max} and enter them on the form.

Luminance Uniformity

1. Using the TG18 UNL80 test pattern, measure the luminance at each of the four corners of the monitor and at the center of monitor. (See Figure 33.)

2. Record these values on the form.

DICOM Grayscale Standard Display Function (GSDF) Evaluation (if available)

1. If possible, use the monitor manufacturer's built-in software to verify that the result of the DICOM GSDF grayscale test meets the monitor manufacturer's performance criteria.

2. The medical physicist may perform this test manually if he or she believes an independent verification is needed or if the manufacturer does not provide built-in software.

Monitor Manufacturer Automated Test (if available)

1. Open monitor manufacturer automated test program.

2. For initial setup, review the monitor manufacturer's frequencies, action limits, and other test parameters to verify if appropriate for mammography.

3. Review the results and verify that all tests have passed.

4. Record an overall pass or fail on the form.

DATA ANALYSIS AND INTERPRETATION

ACR DM Phantom

1. Evaluate the phantom image for artifacts following the instructions under Data Analysis and Interpretation in the ACR Digital Mammography Phantom Image Quality test.

2. Score the phantom image following the instructions under Data Analysis and Interpretation in the ACR Digital Mammography Phantom Image Quality test.

3. Record results on the form.

MEDICAL PHYSICIST'S SECTION

Luminance Uniformity

1. Calculate the percent difference of the luminance values measured in the image display area using the following equation:

$$\% \: difference = \frac{200 * (Lmax - Lmin)}{(Lmax + Lmin)}$$

   where L_{max} and L_{min} are the maximum and minimum measured luminance values respectively.

2. Compare the center luminance measurements on both monitors. The % difference should be ≤20%.

PRECAUTIONS AND CAVEATS

Ideally, monitor screens should be free of dust, fingerprints, and other marks. Similarly, there should be no "shiny" patches or obvious non-uniformities on the surface. As described below, significant blemishes that interfere with the interpretation or QC of images must be corrected.

Most problems can be corrected by cleaning according to the manufacturer's instructions. However, if cleaning does not correct the problem, the manufacturer should be contacted to evaluate and correct the problem.

In most cases, Monitor Manufacturer Automated Tests and action limits are available in manufacturer manuals or documents published by the manufacturer. These tests are extremely valuable in maintaining quality and are specific to each manufacturer. If a Monitor Manufacturer Automated Test is available, the medical physicist should assist the facility in verifying that the automated system is set up and functioning properly.

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

Ambient Light

This recommended test is a subjective evaluation by the medical physicist using his or her professional judgment to determine if the reading environment is appropriate for interpreting mammograms. The [ACR-AAPM-SIIM Practice Parameter for Determinants of Image Quality in Digital Mammography](#) recommends 20-45 lux as appropriate ambient light illuminance in digital mammography reading rooms. (Note: there are varying data on optimal light levels for reading environments.)

Monitor Condition

Any large, significant blemish that interferes with the interpretation or QC of images is a failure. (If there are questions regarding the significance of a monitor blemish, the lead interpreting radiologist should be consulted.)

ACR DM Phantom

1. Artifacts ***must not*** be clinically significant. This aspect of the test fails if any artifacts are in a location that could impact clinical interpretation and

   a. They are as prominent as (or more prominent than) the visible test objects in the phantom image, or

    b.   They obscure test objects in the phantom, or

    c.   They could affect clinical interpretation.

The cause of the artifact should be identified and isolated to determine if it originates from the x-ray system, the detector, or the RW monitor. If the artifact is confirmed to originate from the detector, a recalibration or flat-fielding of the detector may be needed. Artifacts isolated to other components of the imaging chain should be investigated.

After the artifact is resolved, repeat the phantom artifact test. If a clinically significant artifact persists, contact your authorized service representative. If the clinically significant artifact originated from the x-ray/detector system, do not image patients until it is corrected. If the clinically significant artifact originated from the RW monitor, do not use the monitor to interpret patient images until it is corrected.

2.   The fiber score ***must*** be ≥2.0.

3.   The speck group score ***must*** be ≥3.0.

4.   The mass score ***must*** be ≥2.0.

Distance Measurement

The distance measured across the wax insert parallel to the anode-cathode axis ***must*** be 70.0 mm ±14.0 mm.

Test Pattern Image Quality

1.   The test pattern ***must*** be centered appropriately.

2.   The 0%-5% and 95%-100% contrast boxes ***must*** be visible.

3.   The alphanumerics ***must*** be sharp and legible.

4.   The high-contrast line-pair patterns ***must*** be distinguishable at the center and corners.

5.   The grayscale ramps ***must*** be smooth and continuous.

Luminance Check

L_{min} ***must*** be within ±30% of the values specified by the manufacturer, if available. L_{max} ***must*** be within ±10% of the values specified by the manufacturer, if available. If no specified values are available, luminance values ***must*** be L_{min} ≤1.5 cd/m^2 and L_{max} ≥420 cd/m^2.

Luminance Uniformity

The calculated % difference for an individual monitor ***must*** be ≤30%.

The calculated % difference between a pair of monitors for the center luminance value ***must*** be ≤20%.

DICOM GSDF Evaluation (if available)

The measured contrast response values *must* not deviate from the targeted contrast response by more than ±10%.

Monitor Manufacturer Automated Test (if available)

Monitors *must* pass all manufacturer tests.

TIMEFRAME FOR CORRECTIVE ACTION

Monitor Condition, ACR DM Phantom and Distance Measurement

All failures *must* be corrected before clinical use.

Test Pattern Image Quality, Luminance Check, Luminance Uniformity, DICOM GSDF Evaluation, and Monitor Manufacturer Automated Test (if available)

All failures *must* be corrected within 30 days.

12. Film Printer QC *(if applicable)*

OBJECTIVES

To ensure adequate and consistent image quality of printed images provided to referring physicians, patients, and other radiologists.

FREQUENCY

As part of the mammography equipment evaluation of new units, annually, and after relevant service.

> **Note:** Testing film printers during equipment evaluations and annual surveys is only required if they are used clinically for mammography (i.e., for interpretation and to provide images to referring physicians and patients). If such is the case, it is important that the facility document in its QC logs that that the film printer is not used clinically.

TEST EQUIPMENT

- ACR Digital Mammography (DM) Phantom image *(required)*.
- Densitometer.
- Ruler.
- Film Printer QC form.

TEST PROCEDURE

1. Print the ACR DM Phantom image (acquired in the ACR Digital Mammography Phantom Image Quality test) without adjusting any parameters (window width/window level, sizing, etc.) using the film size used for the majority of clinical printing. Print the digital images without magnification or minification and as close to "true size" as possible. The ACR recommends printing the phantom image so that it is within 25% of the actual phantom size.

2. On the form, note the workstation used to print the image.

3. Optional – print images on other size film.

4. View the image.

DATA ANALYSIS AND INTERPRETATION

ACR DM Phantom Scoring

1. Evaluate the phantom image on film for artifacts following the instructions under Data Analysis and Interpretation in the ACR Digital Mammography Phantom Image Quality test.

2. Score the phantom image(s) on film following the instructions under Data Analysis and Interpretation in the ACR Digital Mammography Phantom Image Quality test.

3. Record results on the form.

Background Optical Density

1. Measure the background optical density (OD) outside of the cavity on the printed phantom image.

2. Record on the form.

Contrast

1. Record the background OD from above in the "Contrast" section of the form.

2. Measure the OD inside the cavity and record the measurement on the form.

3. Subtract the background OD from outside of the cavity from the OD inside the cavity and record it on the form. This is the film contrast.

Contrast = Cavity OD – Background OD

Maximum Optical Density (D$_{max}$)

1. Measure the OD near the outside edge of the film at a location where the phantom image (including the detector area) is not located. If the phantom image covers the entire film and there is insufficient room, print a breast image and make this measurement in the non-breast area.

2. See the Technologist's ACR Technique and Procedure Summaries form in the Technologist Section for a detailed schematic of where to measure the ODs.

Distance Measurement

1. With a ruler, measure the distance across the wax insert in the anode-cathode (A-C) direction and record on the form. (See Figure 35.)
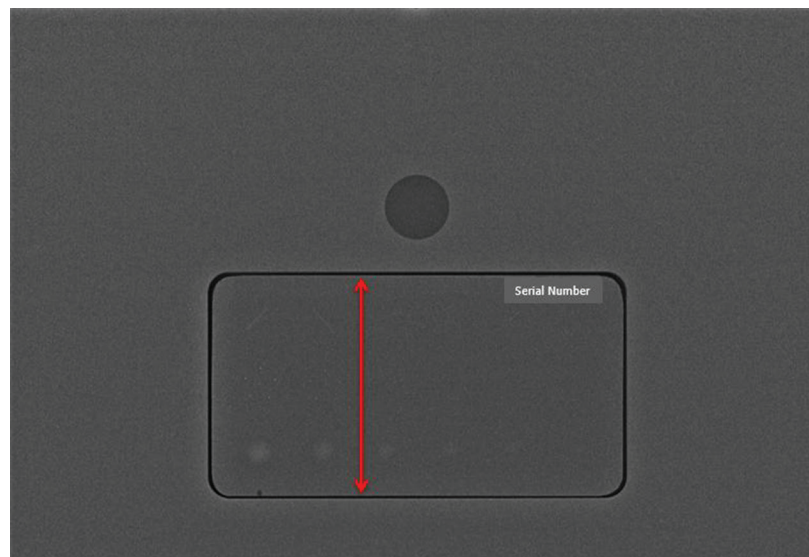
Figure 35. Image of distance measurement on ACR DM Phantom.

PRECAUTIONS AND CAVEATS

None

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

ACR DM Phantom

1. Artifacts **must not** be clinically significant. This aspect of the test fails if any artifacts are in a location that could impact clinical interpretation and

    a. They are as prominent as (or more prominent than) the visible test objects in the phantom image, or

    b. They obscure test objects in the phantom, or

    c. They could affect clinical interpretation.

        If the artifact evaluation fails, check the softcopy images to determine if the same artifact appears. If the same artifact appears on the workstation, the problem should be addressed as described in the workstation test. If the artifact does not appear on the workstation, retest and seek service for the printer if the problem persists. Do not print patient images until clinically significant artifacts are corrected.

2. The fiber score **must** be ≥2.0.

3. The speck group score **must** be ≥3.0.

4. The mass score **must** be ≥2.0.

Background Optical Density

Background optical density **must** be ≥1.6. (Background optical densities between 1.7 and 2.2 are recommended; approximately 2.0 is optimal.)

Contrast

Contrast (cavity OD – background OD) **must** be ≥0.1.

Dmax

The D_{max} **must** be ≥3.1 (≥3.5 is recommended).

Distance Measurement

The distance measured across the wax insert parallel to the A-C axis **must** be 70.0 mm ±14.0 mm.

TIMEFRAME FOR CORRECTIVE ACTION

All failures of required items **must** be corrected before clinical use.

13. Evaluation of Site's Technologist QC Program

OBJECTIVES

- To ensure that technologist QC is being performed correctly, to compare the QC technologist's and the medical physicist's ACR Digital Mammography (DM) Phantom scores, and to identify areas where image quality and QC testing can be improved.

- To enable the medical physicist to provide an external assessment of quality and possibly compare image quality and QC practices with those of other mammography sites.

- To present an opportunity for the medical physicist to provide or recommend further education to the QC technologist, if deficiencies are noted.

FREQUENCY

Annually.

TEST EQUIPMENT

1. Technologist QC forms since the last medical physicist's survey.

2. Evaluation of Site's Technologist QC Program form.

TEST PROCEDURE

General Procedures

1. Evaluate if each technologist's QC test

   a. Is being performed correctly and at the appropriate frequency and that QC data appear to be correct

   b. Is analyzed correctly, that calculations are performed according to the Technologist Section procedures, and that results are compared to the procedures' action limits

   c. Results in needed corrective actions being performed and documented

2. On the form, record any deficiencies such as missing data, incorrect scoring or calculations, missing corrective action documentation, and any other observed problems.

3. Provide comments and findings as necessary. If the QC technologist is doing a good job on the routine QC, it is helpful to provide this positive feedback, as well as feedback on items that need improvement.

ACR DM Phantom Image Quality

1. Record the medical physicist and QC technologist ACR DM Phantom scores in their respective boxes.

2. If there are significant differences, discuss them with the QC technologist.

DATA ANALYSIS AND INTERPRETATION

1. Although all noted deficiencies should be recorded on the form, only significant deficiencies should lead to a "Fail" assessment for the Overall Technologist QC Program. For the program to receive an overall PASS,

   a. There must be no significant missing data,

    b. The tests must be analyzed without gross errors, and

    c. Appropriate corrective action for failures must be taken and documented.

2. The following FDA Level 2 non-compliance items can be used as guidance to determine whether the Overall Technologist QC Program fails:

    a. Not conducting a phantom image test for 2-3 weeks in a consecutive 12-week working period,

    b. Failure to conduct a phantom image test at clinical settings, and

    c. Not taking timely corrective action for failed items.

3. The medical physicist should use his or her judgment to determine what constitutes a significant deficiency. The following are examples:

    a. Two weeks of the weekly ACR DM Phantom Image Quality testing were missing in the entire year (one in April, another in November). Although the medical physicist should note this on the form, the overall evaluation for the site's technologist QC program should be PASS.

    b. The 2 most recent consecutive weeks of the weekly ACR DM Phantom Image Quality testing were missing in the evaluated year (with no explanation or corrective action in the QC records). The overall evaluation for the site's technologist QC program should be FAIL, and the medical physicist should point out that this may be a trend in need of correction.

    c. All weekly QC tests were missing 4 weeks in a row, but in the QC records the facility manager and lead interpreting radiologist noted that they are aware of this occurrence, why it occurred, and that corrective action was taken so it would not occur again. The site's technologist QC program would PASS since corrective action was taken to prevent future occurrences. The medical physicist should make a note of the circumstances and corrective action on the form. For example, "the QC technologist was on temporary disability; since that time a backup QC technologist was trained to assume QC responsibilities in case of future unexpected absences."

    d. The QC technologist was routinely subtracting for artifacts when scoring the ACR DM Phantom. Although the medical physicist should note this on the form, the overall evaluation for the site's technologist QC program should PASS. (However, if the medical physicist notes during the following year's annual survey that the same QC technologist continues to subtract for artifacts, the overall evaluation for the site's technologist QC program should FAIL.)

4. Be sure to note on the Evaluation of Site's Technologist QC Program form if the QC technologist is performing his or her QC responsibilities well.

MEDICAL PHYSICIST'S SECTION

PRECAUTIONS AND CAVEATS

The medical physicist should conduct this review so that he or she is confident that all required tests have been correctly completed at the required intervals and appropriate corrective action was taken if necessary. For example, when reviewing the tests of a QC technologist or facility that is new to the medical physicist, he or she should review all the tests and corrective action for the previous year. Similarly, if the equipment is new to the facility, a thorough review of QC should be done. If the medical physicist establishes confidence that QC is being conducted as required, he or she may only need to review samples of the QC during future surveys. If the samples reveal missing data, irregular results, or missing corrective action, a complete review should be conducted.

This important evaluation helps the facility prepare for its annual MQSA inspection by identifying missing tests or inadequate documentation. If tests are found missing, however, it is imperative that the QC technologist does not perform and back-date any tests to compensate for the omissions. The medical physicist should advise the facility to make a note that they are aware of the missing tests and document efforts to prevent occurrence in the future. See the FDA's topic on [Radiologic Technologists: Falsification of Documentation](#) for information on QC records.

Medical physicists should provide the QC technologist with one-on-one training or recommend sources of appropriate training if deficiencies in the conduct of the tests are noted. Although it is the medical physicist's responsibility to perform this review annually and to bring any deficiencies to the attention of the facility and lead interpreting physician, it is the responsibility of the facility and lead interpreting physician to see that measures are taken to ensure that all required tests are performed as specified by the medical physicist and at the required frequencies.

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

1. The Site's Technologist QC Program *must* receive an overall PASS evaluation.

2. If significant deficiencies are found, they *must* be documented in the form, and action should be taken to correct the problems. Depending on the nature of the deficiency, correction may entail actions such as obtaining appropriate test equipment or providing additional training or coursework for the QC technologist, or facility management could decide to provide sufficient time for the QC technologist to perform the required duties. QC technologists should be assisted by both the medical physicist and facility management to resolve any identified issues.

TIMEFRAME FOR CORRECTIVE ACTION

Failures *must* be corrected within 30 days.

APPLICABLE MQSA REQUIREMENTS

> *900.12(e) Quality assurance—equipment. (9) Surveys. (ii) The results of all tests conducted by the facility in accordance with paragraphs (e)(1) through (e)(7) [mostly technologist quality control tests] of this section, as well as written documentation of any corrective actions taken and their results, shall be evaluated for adequacy by the medical physicist performing the survey.*

14. Evaluation of Display Device Technologist QC Program

OBJECTIVES

- To ensure that technologist QC tests for radiologist workstation (RW) monitors, film printers (if applicable), and viewboxes are being performed correctly at both local and offsite locations.

- To identify areas where image quality and QC testing can be improved.

FREQUENCY

Annually.

TEST EQUIPMENT

- Technologist QC forms.

- Evaluation of Display Device Technologist QC Program form.

TEST PROCEDURE

1. Evaluate whether all technologist's QC tests for the RW monitors, film printers, and viewboxes are being performed correctly, that QC data appear to be correct, and that analysis and calculations are performed according to the Radiologic Technologist's Section procedures and action limits.

2. Review the Corrective Action Log to ensure it is being used appropriately, documentation of corrective action appears to be written correctly, and all items have been corrected.

3. On the form, record any deficiencies such as missing data, incorrect scoring or calculations, missing corrective action documentation, and any other observed problems.

4. Provide comments and findings at the bottom of the form.

> **Note:** This evaluation may be done by the primary site's medical physicist or the medical physicist providing services for the offsite equipment. In any case, the evaluation must be performed and documented at least annually for each display device.

DATA ANALYSIS AND INTERPRETATION

Not applicable

PRECAUTIONS AND CAVEATS

See the Evaluation of Site's Technologist QC Program test.

This evaluation may be performed by either the primary site's medical physicist performing the facility's annual survey or, if the display devices are at an offsite location, by another medical physicist local to the site. If another medical physicist evaluates the QC, he or she must provide annual documentation to the primary mammography site (e.g., a completed Evaluation of Display Device Technologist QC Program form).

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

1. All Technologist Quality Control Tests for the RW monitors and film printers **must** be performed correctly with correct documentation. If deficiencies are found by the medical physicist and documented in the form, action **must** be taken to correct the problems. Technologists should be assisted by both the medical physicist and facility management to resolve these issues.

MEDICAL PHYSICIST'S SECTION

2. Additionally, this test is meant to serve as an external assessment of quality and a comparison of image quality and QC practices with those of other mammography sites. This review provides an opportunity for valuable feedback to the site on methods of quality improvement.

TIMEFRAME FOR CORRECTIVE ACTION

Failures *must* be corrected within 30 days.

APPLICABLE MQSA REQUIREMENTS

900.12(e) Quality assurance—equipment. (9) Surveys. (ii) The results of all tests conducted by the facility in accordance with paragraphs (e)(1) through (e)(7) [mostly technologist's quality control tests] of this section, as well as written documentation of any corrective actions taken and their results, shall be evaluated for adequacy by the medical physicist performing the survey.

15. Manufacturer Calibrations (if applicable)

OBJECTIVES

To detect and automatically correct equipment problems, especially related to digital detector performance. This may include compensating for dead or over-responding pixels, structured or other noise, nonlinear response, and other technical performance parameters.

FREQUENCY

As part of the mammography equipment evaluation of new units, annually, and after relevant service.

> **Important:** This test is applicable if the manufacturer's documentation includes routine calibration

TEST EQUIPMENT

- Manufacturer Calibrations form.

- Other forms per manufacturer's recommendations.

TEST PROCEDURE

1. See manufacturer's documentation for exact procedure steps. The medical physicist should help the facility in locating and implementing these procedures.

2. Enter the results or verification of completion on the form.

DATA ANALYSIS AND INTERPRETATION

Follow manufacturer's recommendations.

PRECAUTIONS AND CAVEATS

Most manufacturers provide specific instructions for system calibrations (e.g., detector calibration). See the manufacturer's documentation for precautions and caveats.

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

Manufacturers' recommendations should be followed.

TIMEFRAME FOR CORRECTIVE ACTION

Manufacturers' recommendations should be followed.

MEDICAL PHYSICIST'S SECTION

16. Collimation Assessment

OBJECTIVES
- To ensure that the x-ray field aligns with the light field.

- To ensure that the collimator allows for full coverage of the image receptor by the x-ray field but does not allow significant radiation beyond its edges.

- To ensure that the chest-wall edge of the compression paddle aligns acceptably with the chest-wall edge of the image receptor.

FREQUENCY
- *For 2D*: as part of the mammography equipment evaluation (MEE) of new units, after relevant service, and after component replacement (Because digital mammography units are very stable, the Collimation Assessment test, which is based on the FDA screen-film annual survey rule in Section 900.12(e)5(vii), only needs to be done for MEEs or if additional troubleshooting is needed to diagnose a potential problem.)

- *For DBT*: as part of the MEE of new units, ***annually***, and after relevant service.

TEST EQUIPMENT
- Five coins, four of one size (e.g., pennies), one of a larger size (e.g., a nickel). Other flat, radiopaque objects may be used in place of coins.

- A collimation test tool—the detector used to record the collimation test images (e.g., film, computed radiography [CR] plates, electronic instruments, etc.)—is left to the discretion of the medical physicist. Several alternatives are possible:
  - film-screen cassettes
  - diagnostic x-ray CR cassettes
  - mammography CR cassettes
  - self-developing film
  - electronic radiation "rulers"

  As each of these requires substantially different setup and exposure conditions than the others, only general directions are provided below. Specific implementation must be adapted to the particular detector used.

- [Collimation Assessment](#) form.

TEST PROCEDURE
1. Create a test patient.
2. Remove the compression paddle.
3. Select the largest field of view (FOV).
4. If testing a DBT system, set up the unit to make an exposure in the 2D mode.

Note: The Collimation test for DBT units is performed in 2D mode, not DBT mode.

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5. If the detector is CR, place an appropriately sized cassette in the normal orientation in the image receptor holder.

6. Place the external radiation detector on top of the breast support. If the detector does not cross each edge of the radiation field, use either multiple detectors or multiple exposures to capture all four borders of the x-ray field.

7. Align the edge of one of the four smaller coins with each edge of the light field, with the center of the coin positioned within the light field.

8. Tape the larger coin to the underside of the compression paddle and within the paddle so that the outer edge of the coin is aligned with the inner chest-wall edge of the paddle. Be sure to position this coin so that it does not interfere with the smaller coin indicating the chest-wall edge light field border.

9. Replace the paddle and position it 4–6 cm from the breast support.

10. Make an exposure appropriate to achieve a useable image on both the unit's detector and the external detector.

11. For MEE of new unit, or after relevant service or component replacement, repeat steps 2-10 for all available anode tracks.

12. For MEE of new unit, or after relevant service or component replacement, repeat steps 2-10 for the small FOV. If the unit shifts the small FOV across the detector for left and right breast laterality, all three positions (left, center, and right) must be evaluated.

DATA ANALYSIS AND INTERPRETATION

1. From the external detector(s), determine the distance between the light field and the radiation field. For step 3 below, record the sign of the deviation: if the radiation field extends beyond the edge of the light field, record the value as positive; if the radiation field does not extend fully to the edge of the light field, record the value as negative.

2. From the image in the acquisition workstation, determine the difference between each light field edge and the border of the visible image, maintaining the sign: if the coin is fully visible, the difference will be positive; if the coin is only partially visible, the difference will be negative.

3. For each edge, sum the values determined in steps 1 and 2 of this section; this is the deviation between the radiation field and the visible image.

4. For the larger coin, measure the distance between the diameter of the coin in the image on the acquisition workstation and the dimension of the coin perpendicular to the chest-wall edge as the distance from the paddle edge to the image receptor edge, maintaining the sign. (See Figure 36.)

   a. If the coin is not fully visible, record the value as positive.

   b. If the coin is fully visible, record the value as negative.

Example 1   Example 2
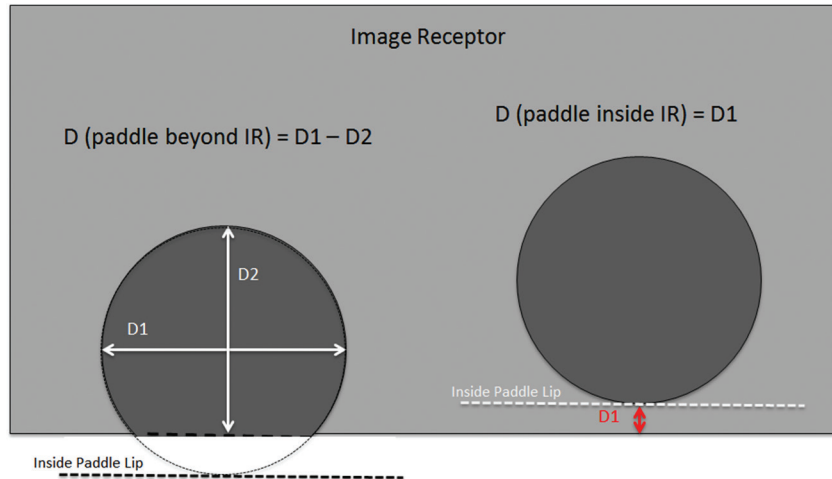
Figure 36. Chest-wall side collimation assessment with larger coin.

PRECAUTIONS AND CAVEATS

It may be necessary to correct for magnification effects in the images. As necessary corrections will depend on the exact methodology used and the system being tested, only this general warning can be provided.

> **Note:** If a large exposure is required for the external detector (such as self-developing film), care must be taken to protect the unit's detector. Either use an appropriate attenuator between the external detector and unit's detector or make one exposure to capture the coins on the image, then place adequate lead over the unit's detector to complete the light field/radiation field measurement with the external detector. A 3 mm (1/8") aluminum plate, large enough to cover the entire detector, also may be laid directly on the breast support surface.

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

1. If a light localizer is used, congruence of the light field with the radiation field should be such that the total misalignment (sum of misalignments on opposite sides) is within 2% of source-image receptor distance (SID) as required by 21 CFR §1020.31(f)(3) [13]. The x-ray field should not extend beyond any of the four sides of the image receptor by more than +2% of the SID. At the chest wall side, the radiation field *must* extend to the edge of the image to minimize excluding breast tissue adjacent to the chest wall. Ideally, the entire image receptor should be exposed. However, since most manufacturers have designed their collimators to meet the FDA manufacturer's requirement for general x-ray equipment, which specifies that the x-ray field not exceed the size of the image receptor, a tolerance of −2% of the SID on the right and left sides is acceptable. (For example, an image with a 1.1-cm "white gap" on its left side would be acceptable on a unit with a SID of 60 cm). A greater tolerance of −4% of SID is acceptable at the anterior side of the film to allow for appropriate image marking.

2. The chest-wall edge of the compression paddle should be aligned just beyond the chest-wall edge of the image receptor such that the chest-wall edge of the compression paddle does not appear in the digital mammography image. In addition, the chest-wall edge of the compression paddle should not extend beyond the chest-wall edge of the image receptor by more than 1% of the SID. Proper alignment of the edge of the compression paddle with the chest-wall edge of the image receptor holder assembly is necessary for proper positioning and compression of the breast. If the edge of the compression paddle extends too far beyond the image receptor edge, the patient's chest is pushed away from the image receptor and some breast tissue will be excluded from the image. This situation is unacceptable and is not permitted. If the edge of the compression paddle does not extend far enough, the breast tissue will not be properly pulled away from the chest wall and compressed for visualization in the image, and a shadow of the vertical edge of the compression paddle may be visible in the image, possibly obscuring clinical information.

3. If the Suggested Performance Criteria are exceeded, a qualified service engineer should be contacted to correct the problem as soon as possible.

TIMEFRAME FOR CORRECTIVE ACTION

- All failures ***must*** be corrected within 30 days.

- For MEEs, failures must be corrected before clinical use.

MEDICAL PHYSICIST'S SECTION

MEE or Troubleshooting – Beam Quality (Half-Value Layer) Assessment

OBJECTIVES

To ensure that the half-value layer (HVL) of the x-ray beam is adequate to minimize patient breast dose but not so excessive that contrast is lost in the resultant image.

FREQUENCY

As part of the mammography equipment evaluation (MEE) of new units, if technique factors impacting beam quality are changed for a 4.2-cm thick compressed breast consisting of 50% glandular and 50% adipose tissue (and, thus, the ACR Digital Mammography [DM] Phantom) and after relevant service.

> **Note:** If the facility changes technique factors (that impact beam quality and dose) for a 4.2-cm thick compressed breast consisting of 50% glandular and 50% adipose tissue, and the HVL was not previously determined for those factors, the medical physicist should measure the HVL for the appropriate factors during the annual survey. Also, if there is any concern regarding a significant dose change, the HVL should be re-evaluated.

TEST EQUIPMENT

- Ionization chamber and electrometer or other appropriate dosimetry device calibrated at mammographic x-ray beam energies.

- 0.1-mm thick sheets of high-purity aluminum (99.9% pure) or 99% pure aluminum (type 1100 aluminum alloy) of length and width sufficient to cover the dosimeter fully. (The stated thickness should be accurate to within ±0.005 mm.)

> **Note:** The use of type 1100 aluminum alloy for HVL measurement can give (depending on specific samples) HVL values up to 7.5% lower than those measured using high-purity aluminum. If type 1100 aluminum is used, results should be corrected to agree with those obtained using high-purity aluminum.

- An integrated, solid-state instrument (one that automatically measures kVp, HVL, and dose) is also acceptable. See Precautions and Caveats.

- Beam Quality (Half-Value Layer) Assessment form.

TEST PROCEDURE

1. Raise the breast compression paddle as close as possible to the x-ray tube.

2. Cover the detector with a protective device (e.g., a lead sheet or lead apron).

3. Place the dosimeter 4.2 cm above the image receptor holder assembly, centered left to right and 4 cm in from the chest-wall edge of the image receptor. The dosimeter should be fully within the x-ray field. (See Figure 37.)
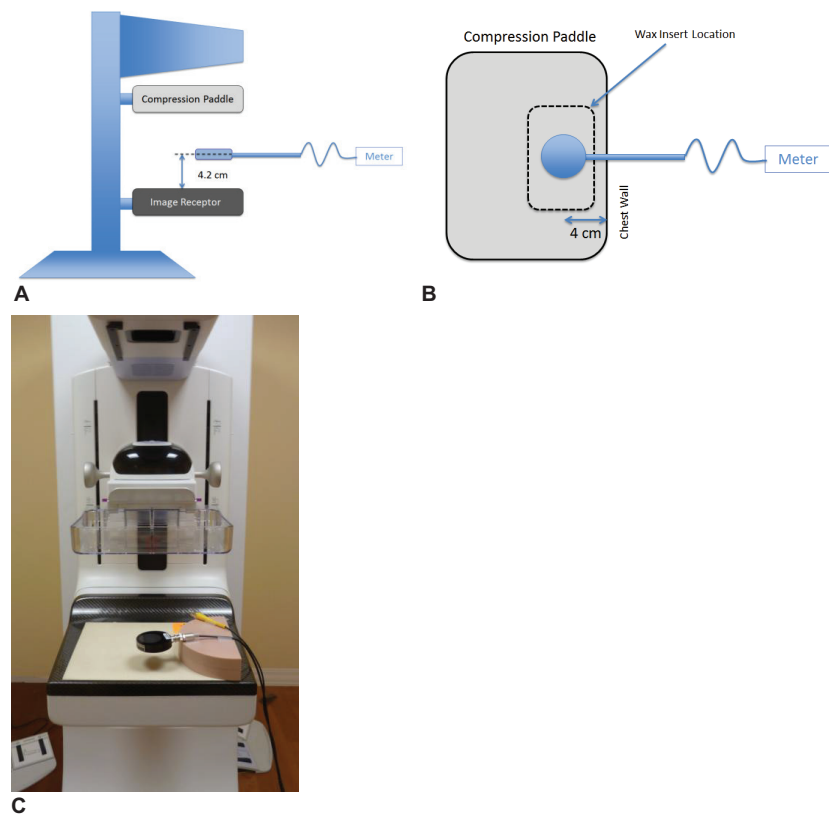
Figure 37. HVL setup. Compression device positioned so that it is as close to the x-ray tube as possible. A. Side view diagram. B. Top view diagram. C. Photo.

4. Select the target/filter and kVp used for the ACR DM Phantom acquisition, and record the information on the data form.

5. Set the unit to manual mAs, with a time setting long enough to provide an exposure sufficiently close to the ACR DM Phantom technique.

6. Use the collimator, if possible, to collimate the x-ray beam so that the dosimeter is just fully exposed (to minimize backscatter).

7. Make an exposure without aluminum sheets between the x-ray tube and the dosimeter.

8. Only 2 additional exposures are necessary to complete the test. Select two thicknesses that will most likely result in exposures just above and just below one-half the original exposure reading (taken without any added aluminum sheets between the x-ray tube and dosimeter).

   a. Add sufficient aluminum (e.g., 0.3 mm) between the x-ray tube and the dosimeter by placing the aluminum on top of the compression paddle. Use the light field (if available) to verify that the x-ray path to the dosimeter is fully blocked by the aluminum sheet(s). Make an exposure and record the dosimeter reading. This reading should be greater than one-half the original exposure reading.

MEDICAL PHYSICIST'S SECTION

b. Repeat with an additional 0.1-mm sheet of aluminum between the x-ray tube and dosimeter, and record the dosimeter reading. This last reading should be less than one-half the original exposure reading.

9. Repeat steps 4-8 for other kVp/target/filter settings ranging from the lowest to the highest used clinically. Be sure to check at least 1 HVL for each target/filter combination.

DATA ANALYSIS AND INTERPRETATION

To calculate the HVL by logarithmic interpolation, use the following notation and procedure. Denote the direct exposure reading, without any added aluminum, as E_0. Divide this value in half and find the two exposure readings and added aluminum thicknesses that bracket the $E_{0/2}$ exposure. Let E_a be the exposure reading that is just greater than one-half of E_0, and let t_a be the corresponding aluminum thickness. Let E_b be the exposure reading that is just less than one-half of E_0, and let t_b the corresponding aluminum thickness. E_a will be greater than E_b, while t_a will be less than t_b. With this notation, the HVL may be computed using the formula

$$HVL = \frac{t_b \ln[\frac{2E_a}{E_0}] - t_a \ln[\frac{2E_b}{E_0}]}{\ln[\frac{E_a}{E_b}]}$$

where the HVL will be given in the same units as t_a and t_b (i.e., millimeters of aluminum).

PRECAUTIONS AND CAVEATS

During MEEs the medical physicist must determine HVLs for all target/filter combinations and a range of clinically used kVps. If, after the MEE, the facility uses a new clinical kVp, it may not be necessary for the medical physicist to perform another HVL measurement. If the new kVp is bracketed by kVps used for previous HVL measurements, the medical physicist may interpolate a new HVL to use in average glandular dose assessments for the new kVp.

If an integrated, solid-state instrument (one that automatically measures kVp, HVL, and dose) is used, the above procedures would not apply. The HVL may be entered into the results area of the form.

Using solid-state detectors for determining half-value layers may provide accuracy challenges if they are not calibrated for the target/filter combination in use. The FDA has provided guidance for medical physicists on this topic. See the FDA's MQSA Policy Guidance Help System topic on non-invasive solid state instruments.

Digital Mammography Quality Control Manual

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

At a given kVp setting in the mammographic kilovoltage range (below 50 kVp), the HVL determined with the compression paddle in place *must* be equal to or greater than the values in the table from the FDA regulations below.

> *The HVL shall meet the specifications of FDA's Performance Standards for Ionizing Radiation Emitting Products (Part 1020.30) for the minimum HVL. These values, extrapolated to the mammographic range, are shown in the table below. Values not shown may be determined by linear interpolation or extrapolation.*
>
> | *X-ray Tube Voltage (kilovolt peak) and Minimum HVL* | | |
> |---|---|---|
> | *Designed Operating Range (kV)* | *Measured Operating Voltage (kV)* | *Minimum HVL (millimeters of aluminum)* |
> | *Below 50* | *20* | *0.20* |
> | | *25* | *0.25* |
> | | *30* | *0.30* |

TIMEFRAME FOR CORRECTIVE ACTION

All failures *must* be corrected before clinical use.

MEE or Troubleshooting – kVp Accuracy and Reproducibility

OBJECTIVES

To ensure that the kVp is accurate (within ±5% of the indicated kVp) and that the kVp is reproducible, having a coefficient of variation equal to or less than 0.02.

FREQUENCY

As part of the mammography equipment evaluation (MEE) of new units, after relevant service, and after component replacement. (Because generators used in digital mammography are very stable, the kVp Accuracy and Reproducibility test, which is based on the FDA screen-film annual survey rule in Section 900.12(e)5(ii), only needs to be done for MEEs or if additional troubleshooting is needed to diagnose a potential problem.)

TEST EQUIPMENT

- kVp meter capable of determining kVp to an accuracy of ±1.5 kVp and a precision of 0.5 kVp within the mammographic kVp range.

- Lead sheet or other attenuator to protect the image receptor.

- An integrated, solid-state instrument (one that automatically measures kVp, half-value layer [HVL], and dose) is also acceptable. (See Precautions and Caveats.)

- kVp Accuracy and Reproducibility form.

TEST PROCEDURE

1. In manual timing mode, select the most commonly used clinical kVp setting (within the specified accuracy range of the meter) and record on the data form. Also record nominal focal spot size, exposure time, and mA (or mAs) setting.

2. Set up the test device following the manufacturer's instructions.

3. Make three exposures in the same manual mode settings, and record the measured kVp values.

4. Repeat the procedure at the lowest clinically used kVp that can be measured by the kVp test device and the highest available clinically used kVp, but make only one exposure at each setting. (Reproducibility needs to be checked only at the most commonly used clinical kVp unless variability is suspected at other settings.)

DATA ANALYSIS AND INTERPRETATION

1. To determine kVp accuracy, average the readings for each kVp setting tested and compare this average value with the value of the preset nominal kVp.

2. To determine kVp reproducibility, compute the standard deviation of the kVp values for each kVp setting and calculate the coefficient of variation of kVp (standard deviation divided by the mean).

PRECAUTIONS AND CAVEATS

If an integrated, solid-state instrument (one that automatically measures kVp, HVL, and dose) is used, the above procedures may not apply. Be sure that the meter is calibrated for the target/filter combination as well as the kVp range in use. Using solid-state detectors for assessing kVp may provide challenges if they are not calibrated for the target/filter combination in use. The FDA has provided guidance for medical physicists on this topic. See the FDA's MQSA Policy Guidance Help System topic on non-invasive kVp meters.

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

1. If the average measured kVp differs by more than ±5% (e.g., ±1.5 kVp at 30 kVp) from the nominal kVp setting, the unit should be checked by appropriate service personnel.

2. If the coefficient of variation exceeds 0.02 for any kVp setting, the unit should be checked by appropriate service personnel.

TIMEFRAME FOR CORRECTIVE ACTION

- When the test is performed for an MEE, all failures *must* be corrected before clinical use.

- When the test is performed for troubleshooting, all failures *must* be corrected within 30 days.

MEDICAL PHYSICIST'S SECTION

Troubleshooting – Ghost Image Evaluation

OBJECTIVES

To evaluate the extent to which previous exposures impact later exposures on the detector. (This may be manifested in two ways. The earlier exposures may cause a change in the sensitivity of the detector, leading to under- or over-response to a later exposure, which is called "ghosting." Also, residual signal (shadows) of prior images may be retained. This is also known as "lag." For simplicity, both phenomena will be referred to in this document as "ghosting.")

TEST EQUIPMENT

- ACR Digital Mammography (DM) Phantom.

- 0.1-mm thick aluminum, approximately 10 cm × 10 cm (aluminum used for half-value layer attenuation works well).

- Timer (watch, stopwatch, etc.).

- Ghost Image Evaluation form.

TEST PROCEDURE

1. Create a test patient.

2. Turn off all image processing, if possible.

3. Install the largest compression paddle.

4. Place the ACR DM Phantom on the right half of the breast support plate with the edge placed at the middle of the image receptor, running from chest wall to the anterior edge such that it extends approximately 2.5 cm beyond the left-to-right center line of the breast image. If the system has automatic exposure control (AEC) sensors, they must be fully covered by the phantom. (See Figure 38.)

5. If possible, select an AEC detector location approximately 5 cm from the chest wall.

6. Lower the paddle and compress to 5 decanewtons.

7. Acquire an image using the technique used for imaging the ACR DM Phantom.

Figure 38. Phantom placed offset on the detector.

Digital Mammography Quality Control Manual

8. Immediately start timing.

9. Move the uniform attenuator so that it covers the entire breast imaging area. Place the aluminum in the center of the imaging field, on top of the uniform attenuator, and aligned with the chest-wall edge of the paddle, ensuring that it extends at least 2 cm beyond the previous edge of the acrylic attenuator. (See Figure 39.)

Figure 39. Phantom placed on the image receptor with the aluminum sheet placed correctly.

10. One minute after the first image was acquired, or within as short a time as the system will allow if longer than 1 minute, acquire a second image using the same techniques as the first image.

11. Use a circular or rectangular region of interest tool (area ~1 cm^2) to measure the mean signal value in the following 3 regions in the raw version of the second image acquired (see Figure 40):

    a. The mean signal (S_1) value over the uniform attenuator on the side where the attenuator was present in the first image

    b. The mean signal (S_2) value over the uniform attenuator plus the aluminum square on the side where the attenuator was present in the first image

    c. The mean signal (S_3) value over the uniform attenuator plus the aluminum square on the side where no uniform attenuator was present in the first image
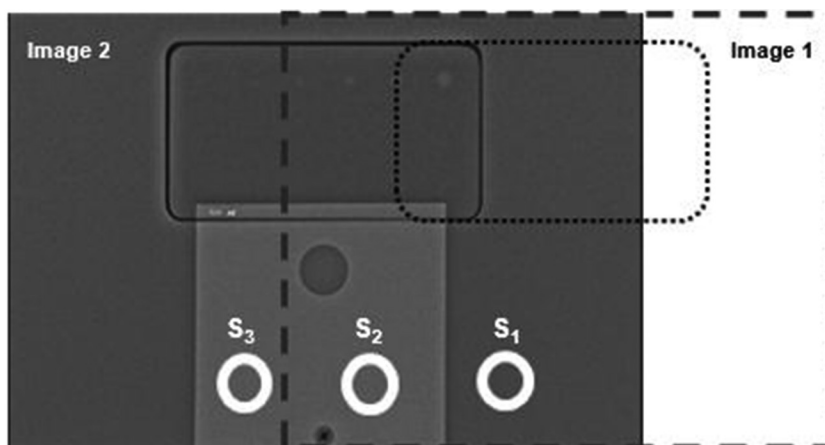
Figure 40. Signal measurement locations.

DATA ANALYSIS AND INTERPRETATION

Calculate the Ghosting Index using the formula:

$$Ghosting\ Index = \frac{S_3 - S_2}{S_1 - S_2}$$

PRECAUTIONS AND CAVEATS

None

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

If the ghosting index is more than ±0.3, repeat the test. If the ghosting index still exceeds ±0.3, service personnel should be contacted.

TIMEFRAME FOR CORRECTIVE ACTION

Failures *must* be corrected before clinical use.

Troubleshooting – Viewbox Luminance

OBJECTIVES

To ensure that the luminance of viewboxes used for interpretation of mammograms meets or exceeds minimum levels.

TEST EQUIPMENT

- Luminance meter.

- Viewbox Luminance form.

TEST PROCEDURE

> **Note:** The measurement procedures described below follow, as closely as possible, those recommended by the National Association of Photographic Manufacturers (NAPM). Additional measurements are described in the NAPM standard that the medical physicist may wish to include, e.g., luminance uniformity.

1. Reproduce the typical ambient lighting conditions for the reading room, including overhead and task lighting, that is used when mammograms are interpreted.

2. For each viewbox used for mammographic interpretation, turn on the lights in the viewbox at least 30 minutes before making the following measurements.

3. Place the luminance meter with its detector parallel to and facing the viewbox surface.

4. Make the measurement and record the result as the viewbox luminance.

5. Visually inspect each viewbox for uniformity of luminance and for uniformity of color of the lighting. Note nonuniformities. Also evaluate viewboxes for proper function of masking devices and the presence of dirt or marks.

6. Repeat the tests for all viewboxes used for interpreting mammograms on film.

DATA ANALYSIS AND INTERPRETATION

Compare the measured luminance to the action limit and determine pass or fail.

PRECAUTIONS AND CAVEATS

Many photometric units of measurement exist but are seldom used. For simplicity we will consider only the SI photometric unit of luminance, the candela per square meter.

Luminance is the amount of light either scattered or emitted by a surface, measured in cd/m^2 (formerly "nit"). Other units often used for luminance are foot-lamberts. To convert foot-lamberts to cd/m^2, multiply the numerical value by $10.764/\pi$ (3.426).

Viewbox Reading Conditions

Ambient room lighting and masking of film to exclude bright areas of the viewbox from being seen by the radiologist are very important. In particular, any unmasked area of the viewbox or bright ambient light results in loss of low-contrast perceptibility, which is of primary

MEDICAL PHYSICIST'S SECTION

importance in mammography interpretation. This decreased perceived image contrast is a result of light scattered and reflected from the surface of the film being viewed as well as light scattered in the eye (veiling glare).

PERFORMANCE CRITERIA AND CORRECTIVE ACTIONS

Viewboxes used for interpreting mammograms and clinical image quality review by the technologist should be capable of producing a luminance of at least 3,000 candela per square meter (cd/m^2). The illumination levels should be 45 lux, or preferably less. All viewboxes used for mammographic interpretation must be masked to the exposed area of the film.

It is essential to mask the area around mammograms to exclude extraneous light, which reduces low-contrast perceptibility and also limits the maximum densities that can be seen without "bright-lighting" each image. Viewboxes should be positioned to avoid light from windows, other viewboxes, and other sources of bright light, either direct or reflected. Visually check the viewboxes to ensure that all bulbs are producing light of the same color and luminance level.

If the luminance level of the viewbox is less than 3,000 cd/m^2, or if the luminance or the color of light of the individual lamps appears significantly different from others in the same viewbox, all bulbs in the viewbox should be replaced at the same time.

B. Test Forms

Routine and complete documentation of QC and corrective actions are a critical part of quality mammography and are required by the FDA mammography regulations. The QC forms in this section have been developed to help meet this goal and to comply with FDA requirements. The QC form number corresponds to the test procedure number provided in the previous section. Each form has been set up with a brief summary of the test procedure, an area to record the test conditions and techniques (to ensure that test conditions that could cause variability in the results are not changed), and reminders of action limits and timeframes for corrective action. Be sure to consult the quality control test procedure for the complete instructions if there are questions about performing tests or analyzing data.

For simplicity and uniformity, the DBT tests are intended to use the same forms as the 2D tests. Document that the DBT tests were performed by selecting the correct image "mode" on the form. (If you are using an electronic version of the form, use the pull-down menu to select the mode.) Note that for some DBT tests you will need to use a second or third page of the form for complete QC documentation.

The forms are also downloadable as Excel spreadsheets from the ACR Digital Mammography QC Manual Resources website (go to Digital Mammography Quality Control Test Forms). Although they have been designed to help you record and analyze your QC results on a computer, they may also be printed and completed manually.

1. **Mammography Equipment Evaluation and MQSA Requirements**

2. **ACR DM Phantom Image Quality**

3. **DBT Z Resolution**

4. **Spatial Resolution**

5. **DBT Volume Coverage**

6. **Automatic Exposure Control System Performance**

7. **Average Glandular Dose**

8. **Unit Checklist**

9. **Computed Radiography** *(if applicable)*

MEDICAL PHYSICIST'S SECTION

10. **Acquisition Workstation (AW) Monitor QC**

11. **Radiologist Workstation (RW) Monitor QC**

12. **Film Printer QC** *(if applicable)*

13. **Evaluation of Site's Technologist QC Program**

14. **Evaluation of Display Device Technologist QC**

15. **Manufacturer Calibrations** *(if applicable)*

16. **Collimation Assessment**

Digital Mammography Quality Control Tests
Medical Physicist's Tests (2D and DBT)

Important: Before a facility may start using the procedures in the ACR Digital Mammography QC Manual for the first time on a unit, the medical physicist must first conduct an annual survey of the digital mammography unit and display devices using the manual and the ACR Digital Mammography Phantom.

Note: Complete Facility, Unit and Test Equipment Data tab first to populate facility information into forms

Test	Minimum Frequency	Corrective Action Timeframe*
1. Mammography Equipment Evaluation - MQSA Requirements	MEE	Before clinical use
2. ACR DM Phantom Image Quality	MEE and Annual	Before clinical use
3. DBT Z Resolution	MEE and Annual	Within 30 days
4. Spatial Resolution	MEE and Annual	Within 30 days
5. DBT Volume Coverage	MEE and Annual	Before clinical use
6. Automatic Exposure Control System Performance	MEE and Annual	Within 30 days
7. Average Glandular Dose	MEE and Annual	Before clinical use
8. Unit Checklist	MEE and Annual	Critical: before clinical use; less critical: w/in 30 days
9. Computed Radiography *(if applicable)*	MEE and Annual	Before clinical use
10. Acquisition Workstation (AW) Monitor QC	MEE and Annual	W/in 30 days; before clinical use for severe defects
11. Radiologist Workstation (RW) Monitor QC	MEE and Annual	W/in 30 days; before clinical use for severe defects
12. Film Printer QC *(if applicable)*	MEE and Annual	Before clinical use
13. Evaluation of Site's Technologist QC Program	Annual	Within 30 days
14. Evaluation of Display Device Technologist QC Program	MEE and Annual	Within 30 days
15. Manufacturer Calibrations *(if applicable)*	MEE and Annual	Before clinical use
16. Collimation Assessment	DBT-MEE and Annual DM-MEE and Troubleshooting	Within 30 days
MEE or Troubleshooting - Beam Quality (Half-Value Layer) Assessment	MEE or Troubleshooting	MEE - before clinical use; troubleshooting - w/in 30 days
MEE or Troubleshooting - kVp Accuracy and Reproducibility	MEE or Troubleshooting	MEE - before clinical use; troubleshooting - w/in 30 days
Troubleshooting - Ghost Image Evaluation	Troubleshooting	Before clinical use
Troubleshooting - Viewbox Luminance	Troubleshooting	NA

* Corrective action for MEEs must be performed before clinical use.

Summary Report Forms

Medical Physicist's ACR DM QC Test Summary

Mammography Technique Chart

Medical Physicist QC Letter for the Radiologist

Supplemental Forms

Facility, Unit and Test Equipment Data

QC Equipment List - Medical Physicist

ACR Digital Mammography (DM) Phantom	Dosimeter
(may use facility's phantom)	Lead sheet or equivalent
0.1 mm aluminum sheets	Photometer to measure luminance
Hi-resolution bar pattern - 2 to 10 lp/mm	Thin metal ruler (for CR)
2, 4, 6 and 8 cm thick acrylic, BR-12 or BR-50 sheets	Coins, ready-pack film, electronic collimation test tools, or equivalent
kV meter	

1. Mammography Equipment Evaluation (MEE)

Facility Name _____ **MAP ID-Unit#** _(00000-00)_ _____ - _____

Mfr & Model _____ **Room ID** _____

Survey Date _____

MQSA Requirements for Equipment [FDA Rule Sec. 900.12 (b)] - only applies to MEE

Feature	FDA Rule	Requirement	Meets? Yes/No/NA
Motion of tube-image receptor assembly	3(i)	The assembly shall be capable of being fixed in any position where it is designed to operate. Once fixed in any such position, it shall not undergo unintended motion.	
	3(ii)	This mechanism shall not fail in the event of power interruption.	
Image receptor sizes	4(iii)	Systems used for magnification procedures shall be capable of operation with the grid removed from between the source and image receptor.	
Light fields	5	For any mammography system with a light beam that passes through the X-ray beam-limiting device, the light shall provide an average illumination of not less than 160 lux (15 ft-candles) at 100 cm or the maximum source-image receptor distance (SID), whichever is less.	
Magnification	6(i)	Systems used to perform noninterventional problem-solving procedures shall have radiographic magnification capability available for use by the operator.	
	6(ii)	Systems used for magnification procedures shall provide, at a minimum, at least one magnification value within the range of 1.4 to 2.0.	
Focal spot selection	7(i)	When more than one focal spot is provided, the system shall indicate, prior to exposure, which focal spot is selected.	
	7(ii)	When more than one target material is provided, the system shall indicate, prior to exposure, the preselected target material.	
	7(iii)	When the target material and/or focal spot is selected by a system algorithm that is based on the exposure or on a test exposure, the system shall display, after the exposure, the target material and/or focal spot actually used during the exposure.	
Application of compression	8(i)(A)	Each system shall provide an initial power-driven compression activated by hands-free controls operable from both sides of the patient.	
	8(i)(B)	Each system shall provide fine adjustment compression controls operable from both sides of the patient.	
Compression paddle	8(ii)(A)	Systems shall be equipped with different sized compression paddles that match the sizes of all full-field image receptors provided for the system.	
	8(ii)(B)	Compression paddle shall be flat and parallel to the breast support table and shall not deflect from parallel by more than 1.0 cm at any point on the surface of the compression paddle when compression is applied.	
	8(ii)(C)	Equipment intended by the manufacturer's design to not be flat and parallel to the breast support table during compression shall meet the manufacturer's design specifications and maintenance requirements.	
	8(ii)(D)	Chest wall edge of the compression paddle shall be straight and parallel to the edge of the image receptor.	
	8(ii)(E)	Chest wall edge may be bent upward to allow for patient comfort but shall not appear on the image.	
Technique factor selection and display	9(i)	Manual selection of mAs or at least one of its component parts (mA and/or time) shall be available.	
	9(ii)	The technique factors (kVp and either mA and seconds or mAs) to be used during an exposure shall be indicated before the exposure begins, except when AEC is used, in which case the technique factors that are set prior to the exposure shall be indicated.	
	9(iii)	Following AEC mode use, the system shall indicate the actual kVp and mAs (or mA and time) used during the exposure.	
Lighting**	14	The facility shall make special lights for film illumination, i.e., hot-lights, capable of producing light levels greater than that provided by the view box, available to the interpreting physicians.	
Film masking devices**	15	Film masking devices that can limit the illuminated area to a region equal to or smaller than the exposed portion of the film are available to all interpreting physicians interpreting for the facility.	
Beam quality assessment	*	Must meet the specifications of FDA's Performance Standards for Ionizing Radiation Emitting Products (Part 1020.30)	
kVp accuracy & reproducibility	*	The mean kVp must not differ from the nominal by more than + 5% of the nominal kVp.	
	*	The coefficient of variation must be ≤0.02.	
Collimation assessment	*	If sum of left plus right edge deviations or anterior plus chest edge deviations exceeds 2% of SID, seek service adjustment.	
	*	If X-ray field exceeds image receptor at any side by more than + 2% of SID or if X-ray field falls within image receptor on the chest wall side, seek service adjustment.	
	*	If chest-wall edge of compression paddle is within the image receptor or projects beyond the chest-wall edge of the image receptor by more than 1% of SID, seek service correction.	
		Overall Pass/Fail	

** NA is acceptable if 1) no hard copy interpretations are made, 2) no hard copy comparisons are made or 3) for new units at existing facilities if these were previously evaluated and have not changed

2. ACR DM Phantom Image Quality

Facility Name _____ MAP ID-Unit# *(00000-00)* _____ - _____

Mfr & Model _____ Room ID _____

ACR DM Phantom Mfr and S/N _____ Survey Date _____

Phantom Setup	Equipment: ACR DM Phantom *(required)*	Phantom Setup:	AEC mode:
	Follow procedure in the Technologist's ACR Technique & Procedure Summaries:		Paddle size (IR size):
	• Use clinical technique for typical screening exam of 4.2 cm 50/50 breast		Paddle type (reg or flex):
	• Largest IR & paddle, 5 daN or 12 lbs, score on AW		View or selected image:
	• Adjust W/L to optimize test objects, zoom & pan entire image		Compression force:
	WL _____ WW _____		AEC cell position (if avail):
	• For DBT, scroll to best slice/slab to visualize test objects	Target/filter (if app): _____	kVp (if app):
	Slice/slab # _____		Density setting (if app):
	Phantom patient name: _____		Mag factor (mag mode only):
	Phantom patient ID: _____		Image sent to which PACS?

	Image Mode *(2D, 2D w/Add-on DBT, DBT)*	2D					Mag Mode 2D
Resulting Techniques *(if available)*	Target/filter						
	Image receptor size						
	kVp						
	mAs						
	Unit-indicated AGD (mGy)						
ACR DM Phantom Evaluation	Artifacts P/F						
	Fiber score						
	Speck group score						
	Mass score						
	Phantom P/F						
SNR & CNR Raw Image *(does not apply to DBT)*	DC offset *(if applicable)*		CNR from MEE (if avail; does not apply to MEEs)	CNR Lower Limit (85% of MEE)	CNR ≥ -15% of MEE (P/F)		
	Mean cavity signal						
	Mean background signal						
	Std dev of background						
	Calculated SNR						
	Calculated CNR						
	SNR ≥ 40.0 (P/F)						
	CNR ≥ 2.0 (P/F)						
Distance Measurement	Parallel to A-C axis (mm)						
	Meas = 70.0 ±14.0 mm (P/F)						
Overall Pass/Fail							

Initiated (or updated) technologist's ACR Technique and Procedure Summaries form _____

Analysis

	Full Point	Half Point
Fibers	≥ 8 mm long	≥5 & <8 mm
Specks	4 - 6 specks	2 - 3 specks
Masses	≥ ¾ border	≥ ½ & < ¾ border
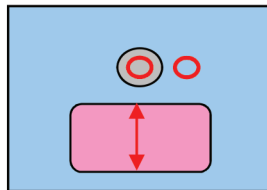
$$SNR = \frac{(Mean\ Bkgd\ Signal - DC\ offset)}{Std\ Dev\ of\ Bkgd}$$

$$CNR = \frac{(Mean\ Cavity\ Signal - Mean\ Bkgd\ Signal)}{Std\ Dev\ of\ Bkgd}$$

Action Limits	**Required:**	ACR DM Phantom image must be free of clinically significant artifacts.
		Fiber score must be ≥ 2.0; speck group score must be ≥ 3.0; mass score must be ≥ 2.0.
		2D Only - MEE & Annual: SNR must be ≥ 40.0; CNR ≥ 2.0. Annual: CNR must be ≥ 85% of MEE.
		Measured wax insert distance must be 70.0 ± 14.0 mm.
	Timeframe:	Failures of required items must be corrected before clinical use.

3. DBT Z Resolution

Facility Name	_____	MAP ID-Unit# *(00000-00)*	_____	-	_____
Mfr & Model	_____	Room ID	_____
		Survey Date	_____

| Procedure | Equipment: | DBT image from ACR DM Phantom Image Quality test | MEE Date: | _____ |
| | | | MEE Baseline FWHM: | |

| | | Maximum Speck Signal | | | | | | | | Mean Background Signal |
Slice #	Relative Slice Location	Center Speck	12:00 Speck	2:00 Speck	5:00 Speck	7:00 Speck	10:00 Speck	Ave Max Signal	
	-3								
	-2								
	-1								
	0								
	1								
	2								
	3								

Z-Axis Point Spread

Z-Res Diff (Ave Max - Background Mean)	△ Z-Res Diff relative to DBT Slice 0

Current FWHM	0.00	mm
MEE Baseline FWHM		mm
% Change (Current vs MEE)		
Overall Pass/Fail		

| Slice -2 | Slice -1 | Slice 0 | Slice 1 | Slice 2 |
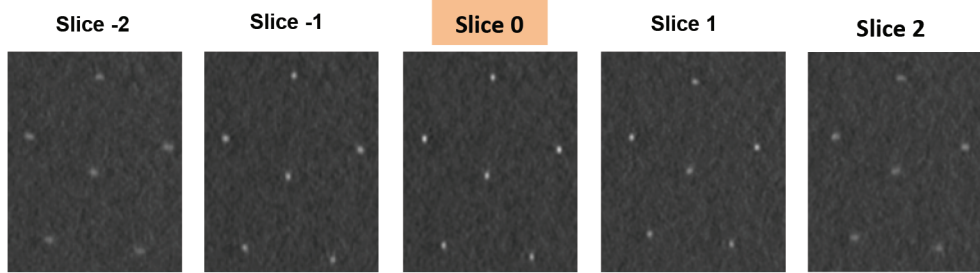
ROI Placement:
Mean Background Signal -
Next to Center Speck

ROI Placement:
Maximum Signal - Over
Each Speck
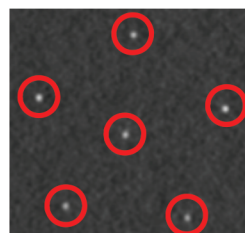
| Action Limits | Required: | Annual Survey: FWHM must be within ±30% of the baseline (MEE) value. MEE: No action limit. |
| | Timeframe: | Failures must be corrected within 30 days. |

4. Spatial Resolution

Facility Name _____ **MAP ID-Unit#** *(00000-00)* _____ - _____

Mfr & Model _____ **Room ID** _____

Survey Date _____

Procedure	**Equipment:** ACR DM Phantom, line-pair test tool	**Phantom Setup:**
	Place ACR DM Phantom reversed on breast support (wax insert away from chest edge)	Paddle size (IR size): _____
	Place bar pattern on top of phantom and under paddle at ~45°	Paddle type (reg or flex): _____
	Lightly compress paddle to touch bar pattern	
	Acquire "raw" images using manual mode closest to ACR DM Phantom technique	

		Image Mode (2D, 2D w/Add-on DBT, DBT)				**Mag Mode 2D**
Setup Techniques		Mag factor	Contact			
		Target/filter				
		kVp				
		mAs				
Spatial Resolution Score		Line-pair score				
		Overall Pass/Fail				

Action Limits	**Required:** For 2D, spatial resolution must be ≥ 4.0 lp/mm for contact mode and 6.0 lp/mm for magnification mode.
	For DBT, spatial resolution must be ≥ 2.0 lp/mm for contact mode.
	Timeframe: Failures must be corrected within 30 days; for MEEs, before clinical use.

~45°

Chest Edge
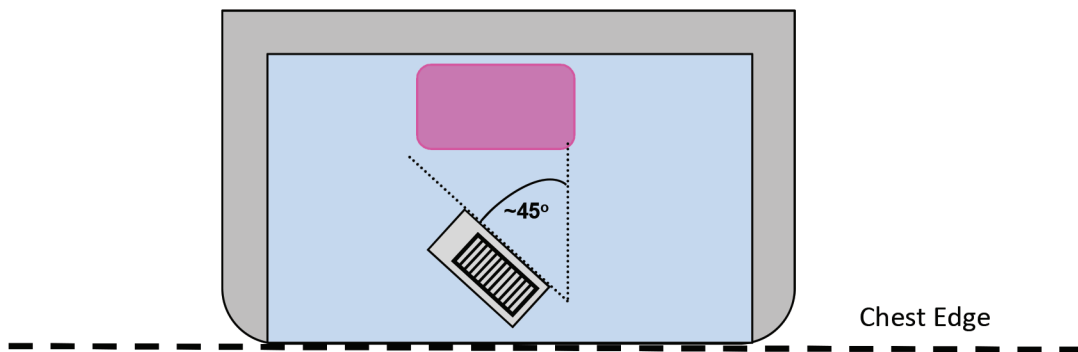
5. DBT Volume Coverage

Facility Name _____ MAP ID-Unit# *(00000-00)* _____ - _____

Mfr & Model _____ Room ID _____

Survey Date _____

Procedure		
	Equipment: ACR DM Phantom, 2 sheets of 0.1 mm Al	**Phantom Setup:**
	Place ACR DM Phantom on breast support in the usual position	Paddle size (IR size): _____
	Place Al sheets on top and bottom of DM phantom, diagonally across chest wall	Paddle type (reg or flex): _____
	Acquire DBT image of phantom	
	View reconstructed image and verify that both Al sheets are in focus within the volume	

		Contact Mode
Setup Techniques	Mag factor	Contact
	Target/filter	
	kVp	
	mAs	
Results (Yes/No/ NA)	Lower Al sheet in focus within the volume	
	Upper Al sheet in focus within the volume	
	Overall Pass/Fail	

Action Limits		
	Required:	Both sheets must be focused in volume
	Timeframe:	Failures must be corrected before clinical use.

6. Automatic Exposure Control System Performance (2D)

Image Mode *(2D, 2D w/Add-on DBT, DBT)* _____

Facility Name _____	**MAP ID-Unit#** *(00000-00)* _____ - ____
Mfr & Model _____	**Room ID** _____
	Survey Date _____

| **Procedure** | **Equipment:** 2, 4, 6, 8 cm of BR-12, BR-50 or acrylic
 Install small paddle (reg or flex) (Use large if small not available)
 Use regular or flex paddle used for most clinical imaging
 Set thickness at actual thickness of phantom (2, 4, or 6 cm)
 Acquire images using clinical techniques
 SNR data must be obtained from raw image
 Magnification stand, if used clinically for 2D | **Phantom Setup:** Paddle size (IR Size): _____
 Paddle type (reg or flex): _____
 AEC cell position (if avail): _____
 Mag setting: _____
 Mfr DC offset, if app: _____
 Other settings: _____
 _____
 _____
 _____ |

AEC Thickness Tracking

Mode	Thick-ness (cm)	Setup Techniques		Resultant Techniques				Signal and Noise Measurements			
		AEC Mode	Density setting	Target/ Filter	kVp	mAs	Other	Mean Bkgd Signal	Std Dev of Bkgd	DC Offset (if app)	SNR
Contact	2										
Contact	4										
Contact	6										
Contact	8										
Mag*	4										

*2D only

$$SNR = \frac{(Mean\ Bkgd\ Signal - DC\ offset)}{Std\ Dev\ of\ Bkgd}$$

Analysis

Mode	Thick-ness (cm)	SNR	MEE and Annual		Annual			
			Lowest Limit for SNR*	Pass/Fail	MEE SNR	Lower Limit	Upper Limit	SNR within ±15% of MEE (P/F)
Contact	2							
Contact	4		40.0					
Contact	6							
Contact	8							
Mag*	4							
							Overall Pass/Fail	

*2D only

Action Limits	**Required:** MEE and Annual: SNR must be ≥ 40.0 for 4.0 cm in contact mode. Annual: SNR must be within ±15% of MEE over the clinically used phantom thickness and imaging modes. **Timeframe:** Failures must be corrected within 30 days; for MEEs, before clinical use.

6. Automatic Exposure Control System Performance (DBT)

Image Mode *(2D, 2D w/Add-on DBT, DBT)* _____

Facility Name _____	**MAP ID-Unit#** *(00000-00)* _____ - ____
Mfr & Model _____	**Room ID** _____
	Survey Date _____

Procedure	
	Equipment: 2, 4, 6, 8 cm of BR-12, BR-50 or acrylic **Phantom Setup:** Paddle size (IR Size): _____
	Install small paddle (reg or flex) (Use large if small not available) Paddle type (reg or flex): _____
	Use regular or flex paddle used for most clinical imaging AEC cell position (if avail): _____
	Set thickness at actual thickness of phantom (2, 4, or 6 cm) Mag setting: _____
	Acquire images using clinical techniques Mfr DC offset, if app: _____
	SNR data must be obtained from raw image Other settings: _____
	Magnification stand, if used clinically for 2D _____
	_____
	_____

AEC Thickness Tracking

Mode	Thick-ness (cm)	Setup Techniques		Resultant Techniques				Signal and Noise Measurements			
		AEC Mode	Density setting	Target/ Filter	kVp	mAs	Other	Mean Bkgd Signal	Std Dev of Bkgd	DC Offset (if app)	SNR
Contact	2										
Contact	4										
Contact	6										
Contact	8										
Mag*	4										

*2D only

$$SNR = \frac{(Mean\ Bkgd\ Signal - DC\ offset)}{Std\ Dev\ of\ Bkgd}$$

Analysis

Mode	Thick-ness (cm)	SNR	MEE and Annual		Annual			
			Lowest Limit for SNR*	Pass/Fail	MEE SNR	Lower Limit	Upper Limit	SNR within ±15% of MEE (P/F)
Contact	2							
Contact	4							
Contact	6							
Contact	8							
Mag*	4							

*2D only   **Overall Pass/Fail** [_____]

Action Limits	
	Required: MEE and Annual: SNR must be ≥ 40.0 for 4.0 cm in contact mode.
	Annual: SNR must be within ±15% of MEE over the clinically used phantom thickness and imaging modes.
	Timeframe: Failures must be corrected within 30 days; for MEEs, before clinical use.

7. Average Glandular Dose

Facility Name	
Mfr & Model	
ACR DM Phantom Mfr & S/N	

MAP ID-Unit# *(00000-00)*   -

Room ID

Survey Date

Procedure	Equipment:	Dosimeter	Dosimetry system:	
		ACR DM Phantom	Calibration date:	
	Use the technique from the ACR DM Phantom image page.		Correction factor, if app:	
	Measure mR/mAs or total exposure for dose calculation(s).		SID (cm):	
	Make exposure measurements at 4.2 cm			

	Imaging Mode *(2D, 2D w/Add-on DBT, DBT)*					
Technique Factors Resulting From ACR DM Phantom Acquisition	ACR DM Phantom equivalent breast thickness (cm)	4.2				
	ACR DM Phantom material	Acrylic				
	AEC mode					
	Target/filter					
	kVp					
	mAs					
Exposure Data (at skin surface)	Measured HVL (mm Al)					
	mAs setting for manual exposure measurement					
	Exposure #1 (mR)					
	Exposure #2 (mR)					
	Exposure #3 (mR)					
	Average exposure (mR)					
	Exposure/mAs at skin entrance (mR/mAs)					
	Total exposure (mR)					
AGD Calculation D = Kgcs	Average entrance exposure - K (mR)					
	g-factor x c-factor x (8.76 mGy/R)					
	s-factor					
	Computed AGD (mGy)					
AGD Result	**Pass/Fail**					
Indicated vs. Calculated AGD (if avail)	Unit-indicated AGD from DM Phantom image (mGy)					
	% Difference					
	Indicated within ±25% of measured?	#DIV/0!				

Action Limits	**Required:**	AGD for a single cranio-caudal view of the ACR DM Phantom in either 2D or DBT mode must not exceed 3.0 mGy.
	Recommended:	If available, unit-indicated AGD should be within ±25% of calculated AGD.
	Timeframe:	Doses > 3 mGy must be corrected before clinical use; failures of the unit-indicated AGD must be corrected within 30 days.

8. Unit Checklist

Facility Name	_____	MAP ID-Unit# (00000-00)	_____ - _____
Mfr & Model	_____	Room ID	_____
		Survey Date	_____

Procedure	**Equipment:** None
	Inspect the unit and evaluate the functionality according to the checklist below

Item	Yes/No/NA
1. Free-standing unit is mechanically stable.*	
2. All moving parts move smoothly, without obstructions to motion.	
3. All locks and detents work properly.*	
4. Image receptor holder assembly is free from vibrations.*	
5. Image receptor slides smoothly into holder assembly (if applicable).	
6. Image receptor is held securely by assembly in any orientation (if applicable).*	
7. Patient or operator is not exposed to sharp or rough edges, or other hazards.*	
8. Paddles are all intact with no cracks or sharp edges.*	
9. Mammography area is clean and free from significant dust and debris that may cause artifacts.	
10. Operator protected during exposure by adequate radiation shielding.*	
11. All indicators working properly.	
12. Autodecompression can be overridden to maintain compression (and status displayed).*	
13. Manual emergency compression release can be activated in the event of a power failure.*	
14. Is the audible exposure indicator at an appropriate volume level?	
15. DBT assembly moves as designed through its range of motion.*	
16. Operator technique charts are current and posted.	
17. Other:	
18. Other:	
19. Other:	
20. Other:	
Overall Pass/Fail	

Action Limits	**Required:**	All items, both critical (*) and noncritical, must pass.
	Timeframe:	Failures of critical items (*) must be corrected before clinical use; less critical items must be corrected within 30 days.

9. Computed Radiography *(if applicable)*

Facility Name		**MAP ID-Unit#** *(00000-00)*	-
Mfr & Model		**CR Room**	
CR Reader Mfr & Model		**Survey Date**	
CR Serial Number		**Medical Physicist**	
CR Date of Manufacture		**Signature**	

Inter-Plate Consistency & Artifact Evaluation

Procedure	**Equipment:** ACR DM Phantom	**AEC mode:**	**AEC detector position:**
	ACR DM Phantom on breast support plate with associated paddle.		**Target/filter:**
	Auto-Time, Set kV to ACR DM Phantom kV, cell position 2 if available.		**kVp:**

Small Cassettes

Cassette ID	mAs Evaluation		SNR Evaluation *(if available)*				Artifact Pass/Fail	Overall Pass/Fail
	mAs	P/F	Signal	Std Dev	SNR	P/F		
1								
2								
3								
4								
5								
6								
7								
8								

	Allowable			Allowable
Minimum mAs:		**Minimum SNR:**		
Mean mAs:		**Mean SNR:**		
Maximum mAs		**Maximum SNR**		

Small Cassettes

Cassette ID	mAs Evaluation		SNR Evaluation *(if available)*				Artifact Pass/Fail	Overall Pass/Fail
	mAs	P/F	Signal	Std Dev	SNR	P/F		
1								
2								
3								
4								
5								
6								
7								
8								

	Allowable			Allowable
Minimum mAs:		**Minimum SNR:**		
Mean mAs:		**Mean SNR:**		
Maximum mAs		**Maximum SNR**		

Action Limits	**Required:**	mAs must be within ±10% of average mAs.
		SNR must be within ±15% of average SNR.
		Must be free of clinically significant artifacts.
	Timeframe:	Failures must be corrected before clinical use.

9. Computed Radiography *(cont)*

Facility Name _____   **MAP ID-Unit#** *(00000-00)* _____ - _____

Mfr & Model _____   **Room ID** _____

Survey Date _____

CR Reader Scanner Performance

Procedure	**Equipment:** 2 thin metal rulers (or equivalent).
	Place rulers in the shape of a T on a cassette which is placed on top of the breast support.
	Expose at extremely low manual technique (~25 kVp, 4 mAs).

	Pass/Fail
Parallel to Chest Wall	
Perpendicular to Chest Wall	

Action Limits	**Recommendation:**	The edges of the "T" should appear smooth and sharp. If they are not, and appear jagged or nonsmooth, then this could indicate a problem with the CR reader performance.

10. Acquisition Workstation (AW) Monitor QC

Facility Name	_____	**MAP ID-Unit#** *(00000-00)*	_____	- _____
Mfr & Model	_____	**Room ID**	_____	
Medical Physicist	_____	**Survey Date**	_____	
Signature	_____			

Procedure	**Equipment:** Luminance meter
	Note: Some of these QC tests may or may not be possible to perform depending on the monitor QC capabilities
	Test Pattern Image Quality: Use TG18-QC, SMPTE or other relevant pattern (if available)
	Luminance Check: TG18 LN8-01 & LN8-18 test patterns, or others that provide measure of L_{min} & L_{max} (if available)

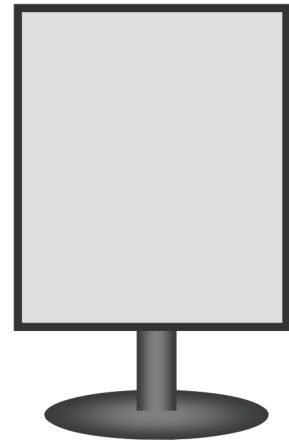| Monitor manufacturer:	Model:	
	Monitor serial number	
	Monitor date of manufacture	
Monitor Condition	Significant findings P/F	
Test Pattern Image Quality *(if available)*	Test pattern centered appropriately?	
	0%-5% contrast boxes visible?	
	95%-100% contrast boxes visible?	
	Alphanumerics sharp and legible?	
	3 "Quality Control" patches visible (TG18)?	
	Line-pair images distinct (center)?	
	Line-pair images distinct (corners)?	
	Grayscale ramps smooth *(if avail)* ?	
	Test pattern P/F	
Luminance Check *(if available)*	Measured Luminance minimum (cd/m^2)	
	Mfr recommendation for L_{min} *(if avail)*	
	L_{min} meets mfr recommendation ±30%?	
	Measured Luminance maximum (cd/m^2)	
	Mfr recommendation for L_{max} *(if avail)*	
	L_{max} meets mfr recommendation ±10%?	
	Luminance check P/F	
DICOM GSDF	W/in ±10% of targeted contrast response P/F *(if avail)*	
Mfr Automated Test	Most recent set of mfr automated tests P/F	
Overall Pass/Fail		

Significant findings indicated on figure below

Luminance Uniformity

Center	
Upper Left	
Upper Right	
Lower Left	
Lower Right	
Max	
Min	
% Diff	
P/F	

| Action Limits	**Required:** Any identified screen blemish that could interfere with clinical information must be removed.
	Test pattern image quality must pass all visual tests.
	L_{min} must be within ±30% of mfr specifications (or, if not available ≤ 1.5 cd/m^2).
	L_{max} must be within ±10% of mfr specifications (or, if not available ≥ 150 cd/m^2).
	Luminance uniformity must be ≤ 30%
	GSDF measured contrast response must be within ±10% of targeted contrast response.
	Mfr's automated tests must pass mfr specifications (if 1 test fails, indicate "F").
	Timeframe: Significant monitor cleanliness defects must be corrected before clinical use; all other required tests must be corrected within 30 days.

11. Radiologist Workstation (RW) Monitor QC

Facility Name _____   MAP ID-Unit# *(00000-00)* _____ - _____

Workstation ID _____   Survey Date _____

Medical Physicist _____   Signature _____

Procedure	
Equipment: ACR DM Phantom Image, luminance meter	
Note: Some of these QC tests may or may not be possible to perform depending on the monitor QC capabilities	
ACR DM Phantom: use phantom acquired from any DM within facility network, preferably one MP has acquired	
Test Pattern Image Quality: Use TG18-QC, SMPTE or other relevant pattern	
Luminance: TG18 LN8-01, LN8-18 & TG18 UNL80 test patterns or other relevant test patterns	

		Left*	Right*
Monitor manufacturer:	**Model:**		
	Monitor serial number		
	Monitor date of manufacture		
Ambient Light	Are ambient light conditions adequate for DM?		
Monitor Condition	Significant findings P/F		
ACR DM Phantom Evaluation	Artifacts P/F		
	Fiber score		
	Speck group score		
	Mass score		
	Phantom P/F		
Distance Measurement	Parallel to A-C axis (mm)		
	Meas = 70.0 ±14.0 mm (P/F)		
Test Pattern Image Quality	Test pattern centered appropriately?		
	0%-5% contrast boxes visible?		
	95%-100% contrast boxes visible?		
	Alphanumerics sharp and legible?		
	3 "Quality Control" patches visible (TG18)?		
	Line-pair images distinct (center)?		
	Line-pair images distinct (corners)?		
	Grayscale ramps smooth?		
	Test pattern P/F		
Luminance Check	Measured Luminance minimum (cd/m^2)		
	Mfr recommendation for L_{min} *(if avail)*		
	L_{min} meets mfr recommendation ±30%?		
	Measured Luminance maximum (cd/m^2)		
	Mfr recommendation for L_{max} *(if avail)*		
	L_{max} meets mfr recommendation ±10%?		
	Luminance check P/F		
DICOM GSDF *(if avail)*	W/in ±10% of targeted contrast response P/F		
Mfr Automated Test	Most recent set of mfr automated tests P/F		
	Overall Pass/Fail		

Significant findings indicated on figures below
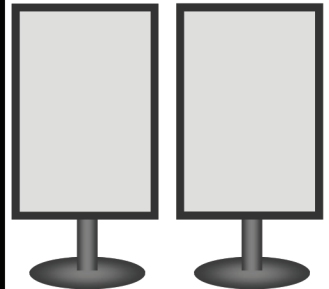
Left and right monitors; complete additional forms if more than 2 monitors used

Luminance Uniformity

Monitor	Left	Right
Center		
Upper L		
Upper R		
Lower L		
Lower R		
Max		
Min		
% Diff		
P/F		

Luminance Matching

P/F	

Action Limits	
Required:	Any identified monitor blemish that could interfere with clinical information must be removed.
	ACR DM Phantom image must be free of clinically significant artifacts.
	Fiber score must be ≥ 2.0; speck group score must be ≥ 3.0; mass score must be ≥ 2.0.
	Measured distance of wax insert must be 70.0 ±14.0 mm.
	Test pattern image quality must pass all visual tests.
	L_{min} must be within ±30% of mfr specifications (or, if not available ≤ 1.5 cd/m^2).
	L_{max} must be within ±10% of mfr specifications (or, if not available ≥ 420 cd/m^2).
	Luminance uniformity must be ≤30%; luminance matching must be ≤ 20%.
	GSDF measured contrast response must be within ±10% of targeted contrast response.
	Mfr's automated tests must pass mfr specifications (if 1 test fails, indicate "F").
Recommended:	Ambient light conditions should be appropriate for mammography; max of 45 lux is recommended.
Timeframe:	Phantom must pass and significant monitor cleanliness defects must be corrected before clinical use; all other required tests must be corrected within 30 days.

12. Film Printer QC *(if applicable)*

Facility Name		**MAP ID-Unit#** *(00000-00)*	-
Printer ID		**Survey Date**	
Medical Physicist		**Signature**	

Procedure	**Applicability:** If film printer is used clinically for mammography (i.e., for interpretation and to provide images to referring physicians and patients) **Equipment:** Densitometer Print an ACR DM Phantom image acquired from any DM unit within facility network, preferably one MP has just acquired. Do not change window/level settings from acquired image prior to printing. Print the phantom image from the workstation/computer typically used to print clinical films. Dmax should be measured either at extreme left or right edge of film or at extreme non-chest wall edge.

Film Printer Manufacturer		**Film Printer Serial Number**	
Film Printer Model		**Film Printer Date of Manufacture**	
Workstation for printing		**DM ID or workstation ID**	

	Film size		
ACR DM Phantom	Artifacts P/F		
	Fiber score		
	Speck group score		
	Mass score		
	Phantom P/F		
Back-ground	Bkgd OD *(Outside cavity)*		
	Bkgd OD ≥ 1.6 (P/F)		
Contrast	Cavity OD		
	Bkgd OD *(use value from above)*		
	Contrast = Cavity OD - Bkgd OD		
	Contrast ≥ 0.1 (P/F)		
D_{max}	D_{max} OD		
	D_{max} OD ≥ 3.1 (P/F)		
Distance Measurement	Parallel to A-C axis (mm)		
	Meas = 70.0 ±14.0 mm (P/F)		
	Overall Pass/Fail	#VALUE!	#VALUE!

Action Limits	**Required:**	ACR DM Phantom image must be free of clinically significant artifacts.
		Fiber score must be ≥ 2.0; speck group score must be ≥3.0; mass score must be ≥ 2.0.
		Background OD must be ≥ 1.6 (1.7 to 2.2 is recommended; approx 2.0 is optimal).
		Contrast (Cavity OD - Background OD) must be ≥ 0.1.
		D_{max} must be ≥ 3.1 (≥ 3.5 is recommended).
		Measured distance of wax insert must be 70.0 ±14.0 mm.
	Timeframe:	Failures of required items must be corrected before printing of clinical images.

13. Evaluation of Site's Technologist QC Program

Facility Name _____   **MAP ID-Unit#** *(00000-00)* _____ - _____

Mfr & Model _____   **Room ID** _____

Survey Date _____

Radiologic Technologist's Quality Control Tests	Frequency	Test Performed, Analyzed & Documented	Missing Data	Incorrect Scoring or Calculations	Missing Corrective Action Documentation	Other	Comments
1. ACR DM Phantom Image Quality	Weekly						

Medical physicist comparison scores of latest phantom image:		Tech Score	MP Score	
	Fiber			
	Speck group			
	Mass			
	Artifacts			

Radiologic Technologist's Quality Control Tests	Frequency	Test Performed, Analyzed & Documented	Missing Data	Incorrect Scoring or Calculations	Missing Corrective Action Documentation	Other	Comments
2. CR Cassette Erasure *(if app)*	Weekly						
3. Comp Thickness Indicator	Monthly						
4. Visual Checklist	Monthly						
5. AW Monitor QC	Monthly						
9. Facility QC Review	Quarterly						
10. Compression Force	Semiannual						
11. Mfr Calibrations *(if app)*							
Optional - Repeat Analysis	As Needed						
Optional - System QC for Radiologist	NA						
Optional - Radiologist IQ Feedback	NA						
Corrective Action Log documentation adequate?							

Overall Pass/Fail for Performance of Technologist QC Program _____

Additional Comments: _____
_____
_____
_____
_____

Action Limits	**Required:**	MQSA regulations [FDA Rule 900.12(d)(1)(iii) specify that "each facility shall have the services of a medical physicist available to survey mammography equipment and oversee the equipment-related quality assurance practices of the facility. " Completion of this "Evaluation of Site's Technologist QC Program" form documents that this oversight has been conducted. In order for the overall evaluation to pass, there must be a) no significant missing data, b) the tests must be analyzed without gross errors, and c) appropriate corrective action for failures must be taken (and documented). See test procedures for more information.
	Timeframe:	Failures must be corrected within 30 days.

14. Evaluation of Display Device Technologist QC Program

Facility Name _____ **MAP ID-Unit#** *(00000-00)* _____ - _____

Medical Physicist _____ **Display Device Location** _____

Signature _____ **Survey Date** _____

Display Device ID & Room	Display Device Description (RW, Printer, Viewbox)	Test Performed, Analyzed & Documented Incorrectly	Missing Data	Incorrect Scoring or Calculations	Missing Corrective Action Documentation	Mfr Automated Tests (if Applicable)	Other	Comments	P/F
Example: Mammography reading room	RW	✓	✓	✓	✓			Discussed with manager	P
Corrective Action Log documentation adequate?									
Overall Pass/Fail for Performance of Display Device Technologist QC Program									

Additional Comments: _____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Action Limits	**Required:**	MQSA regulations [FDA Rule 900.12(d)(1)(iii) specify that "each facility shall have the services of a medical physicist available to survey mammography equipment and oversee the equipment-related quality assurance practices of the facility. " Completion of this "Evaluation of Site's Technologist QC Program" form documents that this oversight has been conducted. In order for the overall evaluation to pass, there must be a) no significant missing data, b) the tests must be analyzed without gross errors, and c) appropriate corrective action for failures must be taken (and documented). See test procedures for more information.
	Timeframe:	Failures must be corrected within 30 days.

15. Manufacturer Calibrations *(if applicable)*

Facility Name _____   **MAP ID-Unit#** *(00000-00)* _____ - _____

Mfr & Model _____   **Room ID** _____

Survey Date _____

Procedure	Follow manufacturer's instructions.
	Notes: _____
	_____

	Name of Calibration	Detector	
Results (P/F)	2D		
	2D w/Add-on DBT Device		
	DBT		
	Overall Pass/Fail		

Action Limits	**Required:**	Unit must pass all manufacturer's calibrations to pass overall.
	Timeframe:	Failures must be corrected before clinical use.

16. Collimation Assessment

Image Mode *(2D, 2D w/Add-on DBT, DBT)* _____

Facility Name _____   MAP ID-Unit# *(00000-00)* _____ - _____

Mfr & Model _____   Room ID _____

Survey Date _____

Procedure	**Equipment:** Coins, film, electronic collimation test tool(s), etc.		
	Eqpt used: _____ kVp: _____ mAs: _____		

		Largest Detector Size Available	Small Detector Size (CR only)
Technique	Target material		
	Collimator size (cm)		
	SID (mm)		
Deviation Between X-ray Field and Light Field	Left edge deviation (mm)		
	Right edge deviation (mm)		
	Sum of left and right edge deviations		
	Sum as % of SID		
	Anterior edge deviation (mm)		
	Chest edge deviation (mm)		
	Sum of anterior and chest edge deviations		
	Sum as % of SID		
	Pass/Fail		

Deviation Between X-ray Field and Edges of the Image Receptor	Left edge deviation		
	% of SID (retain sign)		
	Right edge deviation		
	% of SID (retain sign)		
	Anterior edge deviation		
	% of SID (retain sign)		
	Chest edge deviation		
	% of SID (retain sign)		
	Pass/Fail		

Alignment of Chest-Wall Edges of Compression Paddle and IR	Difference between paddle edge and film		
	Difference as % of SID		
	Pass/Fail		

Overall Pass/Fail [____]

Action Limits	**Required:**	If sum of left plus right edge deviations or anterior plus chest edge deviations exceeds 2% of SID, seek service adjustment.
		If X-ray field exceeds image receptor at any side by more than +2% of SID or if X-ray field falls within image receptor on the chest wall side, seek service adjustment.
		If chest-wall edge of compression paddle is within the image receptor or projects beyond the chest-wall edge of the image receptor by more than 1% of SID, seek service correction.
	Timeframe:	Failures must be corrected within 30 days; for MEEs, before clinical use.

C. MEE or Troubleshooting Test Forms

1. **MEE or Troubleshooting – Beam Quality (Half-Value Layer) Assessment**

2. **MEE or Troubleshooting – kVp Accuracy and Reproducibility**

3. **Troubleshooting – Ghost Image Evaluation**

4. **Troubleshooting – Viewbox Luminance**

Digital Mammography Quality Control Manual

MEE or Troubleshooting
Beam Quality (Half-Value Layer) Assessment

Facility Name _____   **MAP ID-Unit#** *(00000-00)* _____ - _____

Mfr & Model _____   **Room ID** _____

Survey Date _____

Procedure	Equipment: Dosimeter, 0.1 mm Al sheets, lead sheet	Dosimetry system:
	Cover the detector with lead sheet or apron	Calibration date:
	Make at least 1 measurement for each available target-filter combination used for 2D and DBT (as applicable)	

		Target/Filter 1		Target/Filter 2		Target/Filter 3		Target/Filter 4		Target/Filter 5		Target/Filter 6	
Target/filter													
Nominal kVp setting													
mAs													
		Exposure Measurements												
		mm AL	X (mR)	mm AL	X (mR)	mm AL	X (mR)	mm AL	X (mR)	mm AL	X (mR)	mm AL	X (mR)
No Aluminum	E_0	0		0		0		0		0		0	
Al Thickness (mm) t_a	E_a												
Al Thickness (mm) t_b	E_b												
Calculated or measured HVL (mm Al)													
Minimum allowed HVL													
Overall Pass/Fail													

$$HVL = \frac{t_b \ln[2E_a/E_0] - t_a \ln[2E_b/E_0]}{\ln[E_a/E_b]}$$

Action Limits	**Required:** The HVL must meet the specifications of FDA's Performance Standards for Ionizing Radiation Emitting Products (Part 1020.30) as shown below.
	Timeframe: All failures must be corrected before clinical use.

FDA X-ray Tube Voltage (kilovolt peak) and Minimum HVL		
Designed Operating Range (kV)	Measured Operating Voltage (kV)	Minimum HVL (mm of Al)
Below 50	20	0.2
	25	0.25
	30	0.3

MEE or Troubleshooting
kVp Accuracy and Reproducibility

Facility Name _____ **MAP ID-Unit# (00000-00)** _____ - _____

Mfr & Model _____ **Room ID** _____

Survey Date _____

kVp Accuracy and Reproducibility

Procedure	**Equipment:** kVp meter, lead sheet Cover the <u>entire detector</u> with lead sheet, a lead apron or other device. Remove the paddle.

kVp meter _____ **Setting** _____

Calibration Date: _____

		Low Clinical kVp*	ACR DM Phantom Clinical kVp (2D)	ACR DM Phantom Clinical kVp (DBT)	High Clinical kVp*
Technique	Nominal kVp setting				
	Target/filter				
	Focal spot				
	mAs				
Data	Measured kVp value 1				
	Measured kVp value 2				
	Measured kVp value 3				
Analysis	Mean kVp				
	Standard deviation (SD)				
	Mean kVp - nominal kVp				
	0.05 x nominal kVp				
	% error				
	% error P/F				
	Coefficient of variation (CV)				
	CV P/F				
Overall Pass/Fail					

* The low and high kVps may be either those used for 2D or DBT imaging, whichever are lowest or highest

Action Limits	**Required:**	Mean kVp must not differ from the nominal by more than ±5% of the nominal kVp.
		Coefficient of variation must be ≤ 0.02.
	Timeframe:	Failures must be corrected within 30 days; for MEEs, before clinical use.

Troubleshooting
Ghost Image Evaluation

	Image Mode	2D	
Facility Name	**MAP ID-Unit#** *(00000-00)*	-	
Mfr & Model	**Room ID**		
	Survey Date		

Procedure	Equipment: ACR DM Phantom, 0.1 mm Al sheet (10 cm x 10 cm)	Phantom Setup	
	Largest image receptor size	**Paddle Size** *(IR size)* **:**	
	Clinical paddle (reg or flex)	**Paddle Type** *(reg or flex)* **:**	
	Apply 5 daN or 12 lbs comp force	**Exposure Mode:**	
		Compression Force:	12 lbs or 5 daN
	Position ACR DM Phantom with wax insert opposite from chest wall edge.	**AEC Cell Position** *(if avail)* **:**	
	AEC cell position to position "3".	**Density Setting:**	
	Use clinical (AEC) technique for both images		
	Image 1: Position phantom like Setup Image #1 (edge extends 1" beyond midline).		
	Image 2: Position phantom like Setup Image #2 with Al placed on top.		
	Signal data must be obtained from raw image		

		Image 1	**Image 2**
Resulting Techniques from Image Acquisition	Target/filter		
	kVp		
	mAs		
Ghosting Analysis *(see images below)*	S_1		
	S_2		
	S_3		
	Ghosting Index		
Overall Pass/Fail			

$$\text{Ghosting Index} = \frac{(S_3 - S_2)}{(S_1 - S_2)}$$

Action Limits	**Required:**	The ghosting index must be within 0±0.3.
	Timeframe:	Failures must be corrected before clinical use.

Setup Image 1

Setup Image 2

Evaluation Image

Image 2

Image 1
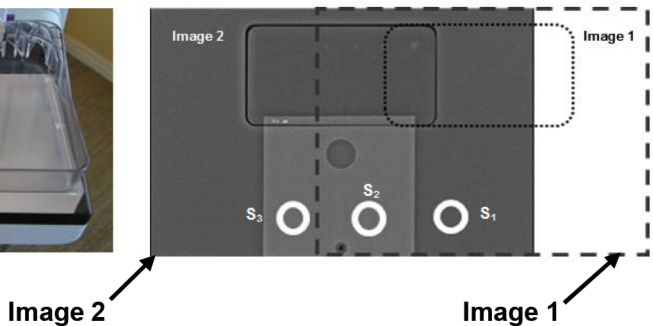
Troubleshooting
Viewbox Luminance

Facility Name _____ **MAP ID-Unit#** *(00000-00)* _____ - _____

Medical Physicist _____ **Viewbox Location** _____

Signature _____ **Survey Date** _____

Procedure	**Equipment:** Luminance meter Measure luminance for all viewboxes, record the luminance value for the viewbox with the lowest luminance. Note: Only check a deficiency if it is significant and could impact interpretation; if the observation is not significant, just make a note in comments

Viewbox Designation	Measurements Viewbox Luminance (cd/m^2)	Significant Deficiencies Dirt and Marks	Color Difference	Luminance Difference	Non-Uniformity	Functioning Masks Missing	Pass/Fail
1.							
2.							
3.							
4.							
5.							
6.							
7.							
8.							
9.							
10.							
				Tech QC Review for Viewbox Luminance			
				Overall Pass/Fail			

Comments: _____
_____
_____
_____
_____
_____

Action Limits	**Recommended:** Mammography viewboxes should be capable of a luminance of 3,000 cd/m^2, be uniform, clean and have functioning masks; if these are not met, corrective action should be taken.

D. Summary Report Forms

1. **Medical Physicist's ACR DM QC Test Summary**

2. **Mammography Technique Chart**

3. **Medical Physicist QC Letter for the Radiologist**

MEDICAL PHYSICIST'S SECTION

Medical Physicist's ACR DM QC Test Summary

Facility Name _____ **MAP ID-Unit#** _____ - _____

Address _____ **Room ID** _____

_____ **Report Date** _____

_____ **Survey Date** _____

X-Ray Unit Manufacturer _____ **Model** _____

Control Panel Serial # _____ **Manufacture Date** _____ **Installation Date** _____

DM Unit Type: ☐ Digital radiography (DR) ☐ Computed radiography (CR) ☐ Digital Breast Tomosynthesis (DBT)

Unit Use: ☐ Diagnostic and screening mammography ☐ Diagnostic only ☐ Screening only

Survey Type: ☐ Mammography equipment evaluation (MEE) - Full ☐ MEE - Partial ☐ Annual survey

Equipment Tested: ☐ DM unit ☐ AW monitor ☐ RW monitor ☐ Viewbox ☐ Printer Other: _____

Oversight Level: ☐ Medical physicist on-site ☐ Medical physicist oversight

Quality Control Manual Used for Survey and Facility QC: *2018 ACR Digital Mammography QC Manual (with 2D and DBT QC)*

Medical Physicist _____ **Signature** _____

QC Test Results

Test	Pass/Fail* 2D**	Pass/Fail* 2D Add-on DBT	Pass/Fail* DBT	CA
Medical Physicist Tests				
1. Mammography Equipment Evaluation - MQSA Reqs		▨	▨	
2. ACR DM Phantom Image Quality				
3. DBT Z Resolution	▨	▨		
4. Spatial Resolution				
5. DBT Volume Coverage	▨	▨		
6. Automatic Exposure Control System Performance				
7. Average Glandular Dose				
8. Unit Checklist				
9. Computed Radiography (if applicable)		▨	▨	
10. Acquisition Workstation Monitor QC		▨	▨	
11. Radiologist Workstation Monitor QC		▨	▨	
12. Film Printer QC (if applicable)		▨	▨	
13. Evaluation of Site's Technologist QC Program		▨	▨	
14. Evaluation of Display Device Technologist QC Program		▨	▨	
15. Manufacturer Calibrations (if applicable)				
16. Collimation Assessment				
MEE/Troubleshooting - Beam Quality (HVL) Assessment		▨	▨	
MEE/Troubleshooting - kVp Accuracy and Reproducibility		▨	▨	
Troubleshooting - Ghost Image Evaluation				
Troubleshooting - Viewbox Luminance		▨	▨	
Technologist QC Evaluation Date reviewed if after new unit MEE:				
1. ACR DM Phantom Image Quality				
2. Computed Radiography Cassette Erasure (if applicable)		▨	▨	
3. Compression Thickness Indicator				
4. Visual Checklist				
5. Acquisition Workstation Monitor QC		▨	▨	
6. Radiologist Workstation Monitor QC		▨	▨	
7. Film Printer QC (if applicable)		▨	▨	
8. Viewbox Cleanliness (if applicable)		▨	▨	
9. Facility QC Review				
10. Compression Force			▨	
11. Manufacturer Calibration (if applicable)		▨	▨	
Optional - Repeat Analysis		▨	▨	

Your Phantom Results - 2D

Fiber (≥ 2.0) ☐
Speck grp (≥ 3.0) ☐
Mass (≥ 2.0) ☐
AGD (≤ 3.0 mGy) ☐

Your Phantom Results - DBT

Fiber (≥ 2.0) ☐
Speck grp (≥ 3.0) ☐
Mass (≥ 2.0) ☐
AGD (≤ 3.0 mGy) ☐

* "Pass" means all components of test passes; "Fail" means any or all components fail; if "CA" checked, see Corrective Action Summary
** or DBT aquistition only

Medical Physicist's ACR DM QC Test Summary *(cont)*

Facility Name _____   **MAP ID-Unit#** *(00000-00)* _____ - _____

Mfr & Model _____   **Room ID** _____

Survey Date _____

Corrective Action Summary*

Note: This is only a summary page, the Corrective Action Log Form may contain further details.

Required/ Recommended	Time Frame	Description	Utilize Corrective Action Log Form	Date Completed	Initials
_____	_____	_____	___	_____	___
_____	_____	_____	___	_____	___
_____	_____	_____	___	_____	___
_____	_____	_____	___	_____	___
_____	_____	_____	___	_____	___
_____	_____	_____	___	_____	___
_____	_____	_____	___	_____	___
_____	_____	_____	___	_____	___
_____	_____	_____	___	_____	___
_____	_____	_____	___	_____	___
_____	_____	_____	___	_____	___
_____	_____	_____	___	_____	___
_____	_____	_____	___	_____	___
_____	_____	_____	___	_____	___
_____	_____	_____	___	_____	___
_____	_____	_____	___	_____	___
_____	_____	_____	___	_____	___
_____	_____	_____	___	_____	___
_____	_____	_____	___	_____	___
_____	_____	_____	___	_____	___
_____	_____	_____	___	_____	___
_____	_____	_____	___	_____	___
_____	_____	_____	___	_____	___
_____	_____	_____	___	_____	___

Mammography Technique Chart

Image Mode *(2D, 2D w/Add-on DBT, DBT)* _____

Facility Name _____   **MAP ID-Unit#** *(00000-00)* _____ - _____

Mfr & Model _____   **Room ID** _____

Survey Date _____

Screening/Diagnostic Digital Mammography

Compressed Breast Thickness	50% Fatty - 50% Dense Breast		
	AEC Mode	**Target/Filter**	**kVp**
< 3 cm			
3 to 5 cm			
5 to 7 cm			
> 7 cm			

Implant Displaced Mammography Views (Manual Technique)

Breast Size	Target/Filter	kVp	mAs
Small			
Medium			
Large			

ACR DM Phantom Technique (Weekly QC)

	Digital Mammography	DBT	2D w/DBT Fixture
AEC mode			
Paddle size (IR Size)			
Paddle type (reg or flex)			
View/selected image type			
Slice or Slab # (DBT only)			
Compression force			
AEC cell position *(if avail)*			
Target/filter *(if app)*			
kVp *(if app)*			
Density setting *(if app)*			

Medical Physicist QC Letter for the Radiologist

Re: Medical Physicist Survey of

Dear Lead Interpreting Radiologist,

The above mammography unit at your facility recently underwent an Annual Medical Physics Survey. Below is the relevant summary information as a result of this survey. Please note that your facility must follow-up on the Action Items below and obtain relevant documentation from the service engineer. Please evaluate the ACR Digital Mammography Phantom image acquired during the medical physicist testing (Image ID information listed below) and see my comments. If you have any questions please don't hesitate to call.

● *Image Quality*

Patient Name (Phantom): _____

Patient ID (Phantom): _____

Date: _____

ACR Digital Mammography Phantom Scores

	2D	DBT	Passing Criteria	Pass /Fail
		0		
Fiber score			≥ 2.0	
Speck group score			≥ 3.0	
Mass score			≥ 2.0	
Artifacts			No Clinically Significant Artifacts	

Comments on phantom image:

● Radiation Dose

ACR Digital Mammography Phantom Radiation Dose Values

	2D	DBT	Passing Criteria	Pass /Fail
		0		
ACR Phantom Dose (mGy)			≤ 3.0	

Note: The above dose is an estimate determined with a phantom representing the FDA-defined 4.2 cm thick, 50% glandular/50% adipose standard breast. Doses will vary with patient size and density. Specific patient doses can be estimated by your medical physicist.

Comments on radiation dose:

● *Required Action Items*

Time Frame	Description
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

● *Recommended Action Items*

Time Frame	Description
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

● *Comments on Monitors, Monitor QC, & Viewing Conditions*

Time Frame	Description
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

● *Comments on Tech QC*

Time Frame	Description
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

If you have any questions, please do not hesitate to call.

Sincerely,

_____

Phone _____

Email _____

E. Supplemental Forms

1.   **Facility, Unit, and Test Equipment Data**

MEDICAL
PHYSICIST'S SECTION

Facility, Unit and Test Equipment Data
Medical Physicist's Tests

Facility Information	
Facility Name	
Address	
Address	
City, State, Zip	
MAP ID# *(00000)*	
MAP Unit# *(00)*	
Lead Interpreting Radiologist	
Quality Control Technologist	

Survey Information	
Room ID	
Survey Date	
MP Report Date	
Date of Previous Survey	

Unit Information	
Digital Radiography (DR)	
Digital Breast Tomosynthesis (DBT)	
Computed Radiography (CR)	
X-Ray Unit Manufacturer	
X-Ray Unit Model	
X-Ray Unit Gantry Serial #	
X-Ray Unit Date of Manufacture	
X-Ray Unit Date of Installation	
SID (cm)	
DC Offset	
mA Large	
mA Small	
Magnification Stand Factor Used	
Nominal Pixel Size (µm)	
CR Reader Manufacturer	
CR Reader Model	
CR Reader Serial #	
CR Date of Manufacture	
CR Date of Installation	

Test Equipment Info	
ACR DM Phantom Manufacturer and S/N	
Dosimeter Manufacturer/Model	
Dosimeter Calibration Date	
kVp Meter Manufacturer/Model	
kVp Meter Calibration Date	

Medical Physicist Info	
Medical Physicist Name	
Telephone Number	
email	
Signature	

References

A. Downloadable from the ACR Website (www.acr.org)

- ACR Mammography Accreditation Program

- ACR Digital Mammography QC Manual Resources

- Destouet JM, Bassett LW, Yaffe MJ, Butler PF, Wilcox PA. The ACR's mammography accreditation program: ten years of experience since MQSA. *J Am Coll Radiol*. 2015;2(7):585-594.

- ACR Appropriateness°Criteria - Breast Imaging

- ACR BI-RADS°Atlas

- ACR Practice Parameter for the Performance of Screening and Diagnostic Mammography

- ACR–AAPM–SIIM Practice Parameter for Determinants of Image Quality in Digital Mammography

B. References

1. Department of Health and Human Services. FDA Mammography Quality Standards, Final Rule. *Fed Reg*. 1997;62(208):55852-55994.

2. U.S. Food and Drug Administration. Mammography Quality Standards Act (MQSA) Policy Guidance Help System.

3. FDA Mammography Quality Standards Act and Program, Facility Certification and Inspection (MQSA) - Digital Accreditation.

4. Williams MB, Goodale PJ, Butler PF. The current status of full-field digital mammography quality control. *J Am Coll Radiol*. 2004;1:936-951.

5. Hendrick RE, Bassett L, Botsco MA, et al. *Mammography Quality Control Manual*. Reston, Va: American College of Radiology; 1999.

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7. Dance DR, Young KC, van Engen RE. Further factors for the estimation of mean glandular dose using the United Kingdom, European and IAEA breast dosimetry protocols. *Phys Med Biol*. 2009;54(14):4361-4372.

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C. Additional Resources

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– Bloomquist AK, Yaffe MJ, Pisano ED, et al. Quality control for digital mammography in the ACRIN DMIST trial: part I. *Med Phys*. 2006;33:719-736.

– Kruger RL, Schuler BA. A survey of clinical factors and patient dose in mammography. *Med Phys*. 2001;28:1449-1454.

– Pollard BJ, Samei E, Chawla AS, et al. The influence of increased ambient lighting on mass detection in mammograms. *Acad Radiol*. 2009;16:299-304.

– Quality Control Manual Template for Manufacturers of Displays and Workstations Devices Labeled for Final Interpretation in Full-Field Digital Mammography. Rosslyn, Va: National Electrical Manufacturers Association; XR 22-2006; 2006.

– Quality Control Manual Template for Manufacturers of Hardcopy Output Devices Labeled for Final Interpretation in Full-Field Digital Mammography. Rosslyn, Va: National Electrical Manufacturers Association; XR 23-2006; 2006.

2018
Digital Mammography

QUALITY CONTROL MANUAL

Appendices

Contents

Revisions

Date	Page(s)	Section	Description of Revisions
November 2018			2nd edition with digital breast tomosynthesis QC

APPENDICES

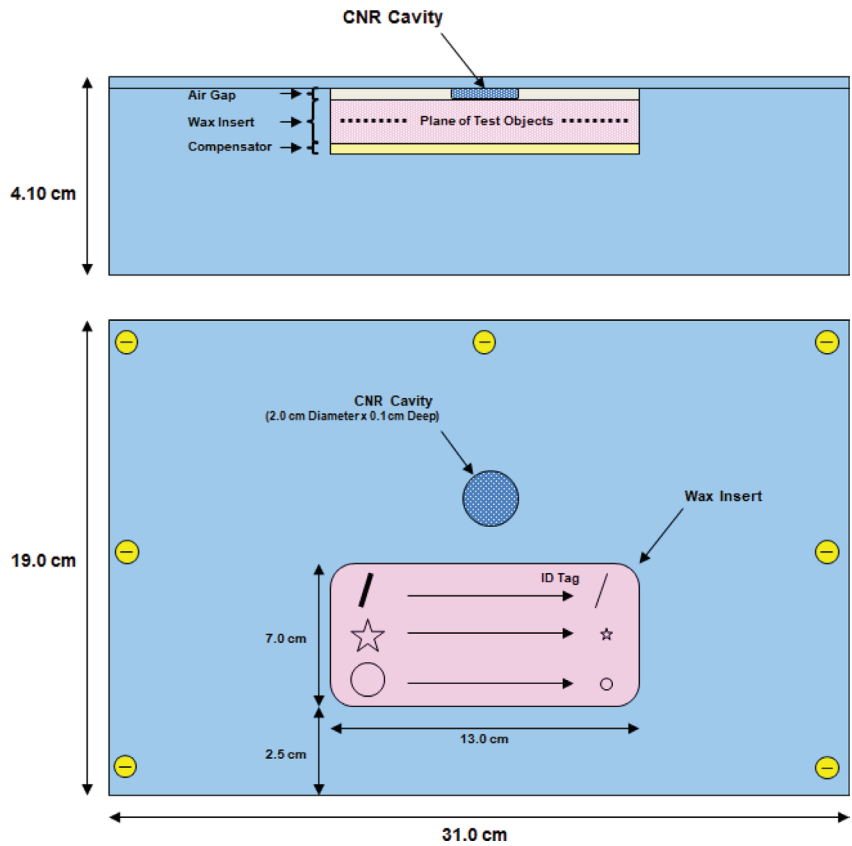# ACR Digital Mammography (DM) Phantom Scoring Guide

A. Phantom

Figure 1. ACR DM Phantom diagram, showing locations of contrast-to-noise ratio (CNR) cavity and test objects for scoring.
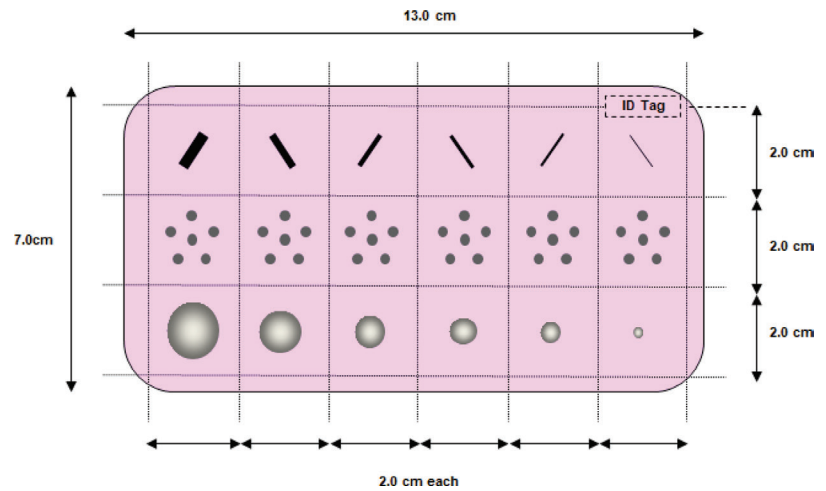
Figure 2. ACR DM Phantom wax insert map (test object sizes are not to scale).

Table 1. ACR DM Phantom Test Object Sizes

	Fibers (diameter)	Speck Groups (glass sphere diameter)	Masses (thickness)
1	0.89 mm	0.33 mm	1.00 mm
2	0.75 mm	0.28 mm	0.75 mm
3	0.61 mm	0.23 mm	0.50 mm
4	0.54 mm	0.20 mm	0.38 mm
5	0.40 mm	0.17 mm	0.25 mm
6	0.30 mm	0.14 mm	0.20 mm

APPENDICES

B. Scoring

1. *For digital breast tomosynthesis images*, scroll to the slice or slab in which the test objects are best visualized.

2. Adjust window width and window level to optimize visualization of each set of test objects.

3. Count total number of fibers, speck groups, and masses.

4. Do not subtract for artifacts.

Table 2. ACR DM Phantom Image Scoring Key

Test Object	Full Point	Half Point
Fibers (6)	• Full length visible (≥8 mm long) • Correct location • Correct orientation • 1 break allowed (must be ≤ width of fiber)	• At least half of length visible (≥5 and <8 mm long) • Correct location • Correct orientation • 1 break allowed (must be ≤ width of fiber)
Speck Groups (6)	• 4-6 specks visible • Correct locations	• 2-3 specks visible • Correct locations
Massas (6)	• Density difference visible • Border is continuous and generally circular (≥ ¾ border visible) • Correct location	• Density difference visible • Border is not continuous or generally circular (≥ ½ and < ¾ border visible) • Correct location

5. Example below: Score - 3.5 fibers, 4.0 specks, 4.5 masses
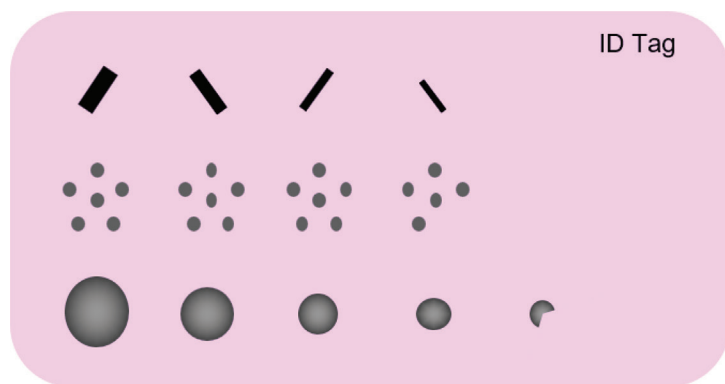

Figure 3. ACR DM Phantom wax insert scoring example.

Artifact Evaluation Guide

A. Procedure

1. Zoom image to full resolution and pan.

2. Using approximately the same window width and window level settings used to evaluate the test objects, examine the entire phantom for both broad area artifacts and detailed artifacts. Entire field of view should be free of artifacts that may impede clinical interpretation.

3. Artifact evaluations are assigned a "Fail" if artifacts are present that impede clinical interpretation.

4. Artifact evaluation passes if the image is free of artifacts (see Figure 4) or artifacts are clinically insignificant.

Figure 4. ACR DM Phantom with no artifacts.

APPENDICES

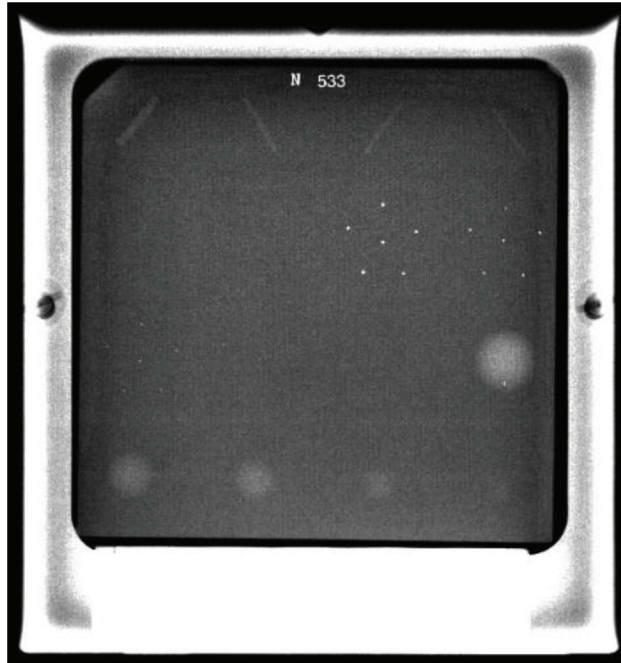## B. Examples of Clinically Significant Artifacts

1. Gridlines.

Figure 5. Unacceptable appearance of gridlines on small ACR mammography phantom image.
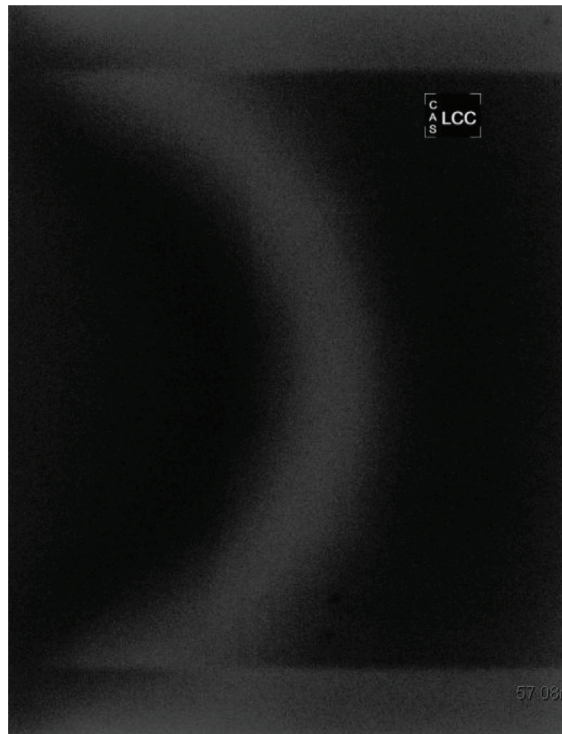
2. Ghosting.

Figure 6. Flat-field image illustrating unacceptable ghosting.

3. Collimator cut-off.

Figure 7. White line along chest-wall edge of image due to collimator misalignment.

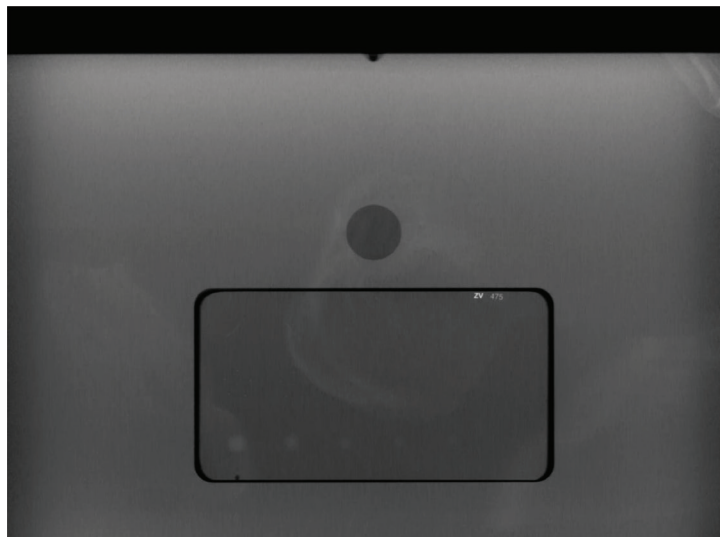4. Blotchiness (digital breast tomosynthesis [DBT]).

Figure 8. Example of DBT image of ACR Digital Mammography Phantom positioned at the optimal slice location for optimal test object visualization. Artifacts appear as blotchy density differences in different locations across the phantom These artifacts should not pass the artifact evaluation.

C. Examples of Minor, Clinically Insignificant Artifacts
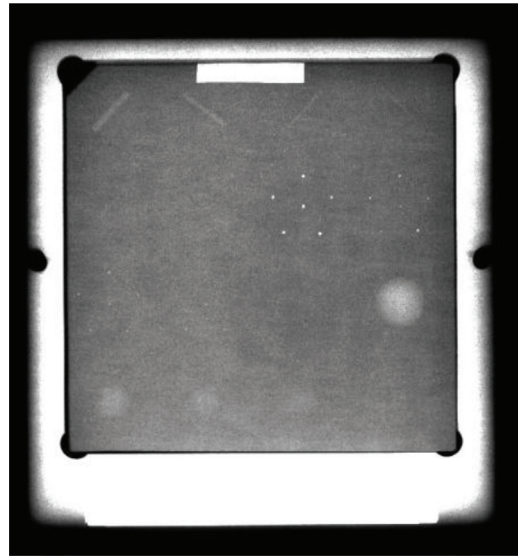
1. Blotchiness.

Figure 9. Clinically insignificant blotchiness on small ACR mammography phantom image due to filter.