Mammography Quality Control: A Refresher

MATT WAIT, MS, DABR

Objectives

- Attendees will re-familiarize themselves with the purpose of quality assurance and quality control
- Attendees will re-familiarize themselves with the various bodies that govern quality assurance and quality control in mammography

Objectives

- Attendees will re-familiarize themselves with the Kaiser SoCal process of performing mammography quality control for technologists and corrective action
- Attendees will re-familiarize themselves with MITI tools for mammography quality control and corrective action

Outline

1. A Brief History of Mammography Regulation
2. Standards Driving Mammography QC
3. What is Quality Control?
4. Review of Kaiser Mammography Quality Assurance Program

A Brief History of Mammography Regulation: Why Regulate?

- Mammography identified in 1960s and 70s studies as an ideal screening modality
- In the 1980s, dedicated mammographic machines were developed

A Brief History of Mammography Regulation: Why Regulate?

- The proliferation of mammography equipment, combined with the screening recommendations, created a need for standardization from a public health perspective

A Brief History of Mammography Regulation

- Mammography Quality Standards Act (MQSA) signed into law in 1992
- Congress tasked FDA with developing and implementing MQSA regulations
- Interim regulations were issued in December 1993 and became effective on Oct 1, 1994. Accreditation and certification provisions began to be enforced on this date

A Brief History of Mammography Regulation

- Annual inspections of mammography facilities began in January 1995
- On October 28, 1997, the FDA issued more comprehensive regulations, which became effective on April 28, 1999.

A Brief History of Mammography Regulation

- Amended by Mammography Quality Standard Reauthorization Acts of 1998 and 2004 (MQSRA)
- The Division of Mammography Standards, formerly the Division of Mammography Quality and Radiation Programs, moved to the new Office of In Vitro Diagnostics and Radiological Health in October 2012

Standards Governing Mammography QC

- MQSA
- ACR
- Hologic QC Manual
- Kaiser QC Manual

Standards Governing Mammography QC: MQSA

- Passed in 1992
- Steered by the National Mammography Quality Assurance Advisory Committee
- Specifies qualifications for radiologist, technologist, physicist

Standards Governing Mammography QC: MQSA

- Specifies essential features and functions of mammography equipment
- Specifies scoring and communication of results to patients, as well as image identifiers

Standards Governing Mammography QC: MQSA

- Defines Alternative Standards for some requirements
- Specifies outcomes audits, patient grievances, infection control

Standards Governing Mammography QC: MQSA

- Specifies Quality Assurance tests, frequencies, and acceptable values, as well as follow-up intervals. QC must be *substantially the same as that recommended by manufacturer*
- Specifies Accreditation and Certification requirements as well as scope of accreditation bodies

Standards Governing Mammography QC: ACR

- Independent Accrediting Body approved by FDA for meeting MQSA requirements
- Specifies physician, technologist, physicist qualifications
- Specifies report, record keeping requirements

Standards Governing Mammography QC: ACR

- Specifies process for consumer complaints and facility closure
- Specifies QC activities and audits (ACR 1999 Mammography QC Manual)

Standards Governing Mammography QC: Hologic QC Manual

- Empowered by MQSA and ACR to dictate proper quality control processes
- Defines specific procedure for each unit
- Sets acceptable phantom scores
- Available in each mammography room
- Updated with each software version

Standards Governing Mammography QC: Kaiser QC Manual

- Prepared by MITI Department based on manufacturer QC manual
- Reviewed by each Physicist
- Hard copy should be available on site
- Most recent revision: September 2018
- Covers Selenia and Dimensions systems

Standards Governing Mammography QC: Kaiser QA Manual

- Visit MITI.kp.org from any Kaiser computer

Standards Governing Mammography QC: Kaiser QA Manual

- Scroll down, select iQAT

Standards Governing Mammography QC: Kaiser QA Manual

- On the iQAT webpage, select "Mammography QA Manual"

What is Quality Control?

- Quality Assurance: A proactive process that is preventative in nature. It is an overall methodology for ensuring quality
- Quality Control: A reactive process that is detective in nature. The specific testing that seeks to identify defects

Review of Kaiser Mammography Quality Assurance Program

Roles and Responsibilities

- Lead Interpreting Physician
- Medical Physicist
- Mammography QC Technologist
- Service Engineer

Roles and Responsibilities

Technologist QC

- Mammographic Unit
- Diagnostic Review Station

Technologist QC: Action Categories

- Category A: If any of the following QC produces results that fall outside of the control limits, the source of the problem shall be identified and corrective action shall be taken **before any further clinical examinations are performed**

Technologist QC: Action Categories

- Category A:
  - Detector Flat-Field calibration
  - Signal-to-Noise and Contrast-to-Noise Measurement
  - Phantom Image Evaluation
  - Compression Force Measurement

Technologist QC: Action Categories

- Category B: If any of the following QC produces results that fall outside of the control limits, the source of the problem shall be identified and corrective action shall be taken **before that device can be used for mammographic image interpretation**

Technologist QC: Action Categories

- Category B:
  - Phantom Image Evaluation
  - Display Screen Cleanliness
  - Viewing Condition Check
  - Diagnostic Review Workstation Image Quality Check

Technologist QC: Action Categories

- Category C: If any of the following QC produces results that fall outside of the control limits, the source of the problem shall be identified and corrective action shall be taken **within 30 days of the test date**

Technologist QC: Action Categories

- Category C:
  - Image Receptor Artifact Evaluation
  - Compression Thickness Indicator
  - Visual Check
  - Repeat and Reject Analysis

Technologist QC: When is QC Required?

- After major component changes or repairs (including software changes or updates) **before clinical examinations**
- If changes or repairs impact patient dose or image quality – must be evaluated by medical physicist **before clinical examinations**

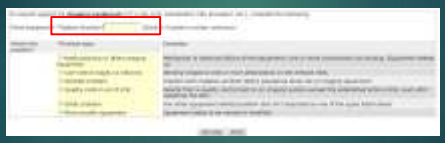
Technologist QC: What if QC fails?

1. Repeat the test
2. If the test fails a second time, place a service call either by calling **866-529-0933** or through **MITI.kp.org/support**

Technologist QC: What if QC fails?

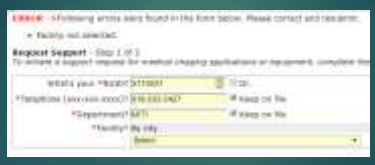
Technologist QC: What if QC fails?

Technologist QC: What if QC fails?



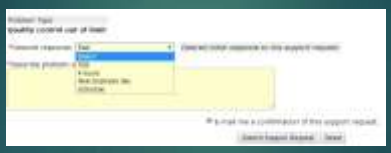
Technologist QC: What if QC fails?

Technologist QC: What if QC fails?



Technologist QC: What if QC fails?

Technologist QC: What if QC fails?



Technologist QC: Overview

- Daily: Viewing condition check, Workstation display cleanliness
- Weekly: Detector Flat-Field Calibration, Artifact Evaluation, SNR & CNR, Phantom image evaluation, Workstation image quality
- Biweekly: Thickness indicator check
- Monthly: Visual check, Repeat/reject analysis
- Semi-Annually: Compression Force Measurement

Technologist QC: Detector Flat-Field Calibration (Weekly)

- Preparation
  1. Wait for detector to come to temperature
  2. Remove compression paddle, raise compression device to 5-7 cm (Dimensions)
  3. Wipe down Flat Field phantom and detector, place phantom on detector

Technologist QC: Detector Flat-Field Calibration (Weekly)

- Performing
  1. Select "Flat Field Calibration" from system
  2. Follow on-screen instructions
  3. Review preview image for foreign objects, gross artifacts, non-uniformities, or collimation interference

Technologist QC: Detector Flat-Field Calibration (Weekly)

- Corrective Action
  - Category A – Put in "stat" support request. System cannot be used on patients until issue is corrected

Technologist QC: Artifact Evaluation (Weekly)

- Preparation
  1. Remove compression paddle, raise compression device to 5-7 cm (Dimensions)
  2. Wipe down Flat Field phantom and detector, place phantom on detector

Technologist QC: Artifact Evaluation (Weekly)

- Performing
  1. Create a test patient (Selenia) or select Artifact QC (Dimensions)
  2. Select Kaiser QAC Output
  3. Acquire an image at 28 kVp, Rh filter, Auto-Time, AEC Cell 2
  4. Acquire an image at 28/31 kVp (Selenia/Dimensions), Ag filter, Auto-Time, AEC Cell 2

Technologist QC: Artifact Evaluation (Weekly)

- Performing
  5. Set window width to 500, window level to image EI
  6. Review entire image **at full resolution** for any artifacts/dead pixels
  7. Rotate flat field phantom 180 degrees
  8. Acquire an image at 28/31 kVp (Selenia/Dimensions), Ag filter, Auto-Time, AEC Cell 2

Technologist QC: Artifact Evaluation (Weekly)

- Corrective Action
  - Clean flat field/phantom again, rotate phantom, repeat
  - Notify lead interpreting physician to get permission to continue to use the unit
  - Category C – Put in "schedule" support request. System can be used on patients immediately

Technologist QC: Signal-to-Noise and Contrast-to-Noise Measurements (Weekly)

- Preparation
  1. Attach 18 x 24 compression paddle
  2. Select Kaiser QAC Output

Technologist QC: Signal-to-Noise and Contrast-to-Noise Measurements (Weekly)

- Performing
  1. Create a test patient and select "phantom view" (Selenia) or select Phantom Image Quality (Dimensions)

Technologist QC: Signal-to-Noise and Contrast-to-Noise Measurements (Weekly)

- Performing
  2. Selenia: Select clinical (Auto-filter) exposure. Lower paddle to 4.5 cm and note technique. Select auto-time with displayed kVp and filter, AEC cell 2 (Dimensions automatically selects correct technique)

Technologist QC: Signal-to-Noise and Contrast-to-Noise Measurements (Weekly)

- Performing
  3. Center ACR phantom on front of detector, with "nipple" facing the correct direction. Lower paddle to barely touch phantom and acquire image
  4. Select the SNR/CNR button

Technologist QC: Signal-to-Noise and Contrast-to-Noise Measurements (Weekly)

- Performing
  5. Record the kVp, Filter, mAs, Exposure Index, SNR and CNR. Plot SNR and CNR on the weekly control chart with date/initials

Technologist QC: Signal-to-Noise and Contrast-to-Noise Measurements (Weekly)

- Corrective Action
  - If the SNR/CNR values fall in the light gray region, repeat test. If the same result is obtained, machine can be used. If the SNR and CNR values fall in the light grey region for 2 consecutive weeks, contact the assigned physicist to investigate
  - Category A – Put in "stat" support request. System cannot be used on patients until issue is corrected

Technologist QC: Phantom Image Evaluation (Weekly)

- Preparation
  1. Use acquired phantom image from SNR/CNR test

Technologist QC: Phantom Image Evaluation (Weekly)

- Performing
  1. Selenia: technically phantom image must be evaluated and scored on a Diagnostic Review Workstation. A preliminary evaluation on the acquisition workstation before final review is acceptable

Technologist QC: Phantom Image Evaluation (Weekly)

- Performing
  2. Dimensions: the phantom image can be evaluated and scored on the acquisition workstation because it is equipped with a DICOM-conformant display

Technologist QC: Phantom Image Evaluation (Weekly)

- Performing
  3. Window/level and zoom as necessary to score the phantom. Count complete fibrils, speck groups, and masses. ½ scores are acceptable
  4. Minimum passing score on both systems: **5 fibrils, 4 speck groups, 4 masses**

Technologist QC: Phantom Image Evaluation (Weekly)

- Corrective Action
  - Selenia: If a minimum passing score is not achieved on the acquisition workstation, the unit may not be used clinically until the final score on a Diagnostic Review Workstation meets or exceeds the minimum passing score

Technologist QC: Phantom Image Evaluation (Weekly)

- Corrective Action
  - Category A – Put in "stat" support request. System cannot be used on patients until issue is corrected
  - Document any corrective actions in Comments section of log

Technologist QC: Compression Thickness Indicator Check (Biweekly)

- Preparation
  1. The ACR phantom thickness is the base measurement

Technologist QC: Compression Thickness Indicator Check (Biweekly)

- Performing
  1. Center ACR phantom on image receptor
  2. Install the spot compression paddle (Dimensions: labeled "for QC only")
  3. Apply about 30 lbs of force to the phantom
  4. Record displayed thickness
  5. Must be within **0.5 cm (5 mm)** of actual thickness

Technologist QC: Compression Thickness Indicator Check (Biweekly)

- Corrective Action
  - Category C – Put in "schedule" support request. System can be used on patients immediately
  - Document any corrective actions in Comments section of log

Technologist QC: Visual Check (Monthly)

- Performing
  1. Inspect each of the following elements:
     - SID indicator (n/a for Dimensions and Selenia)
     - Angulation indicator
     - Smoothness of motion
     - High tension/other cables (n/a for Dimensions and Selenia)

Technologist QC: Visual Check (Monthly)

- Performing
  1. Inspect each of the following elements:
     - Control booth window
     - Control switches/lights
     - Technique charts
     - Cones/collimators
     - Other accessories (paddles)

Technologist QC: Visual Check (Monthly)

- Performing
  1. Inspect each of the following elements:
     - Gonadal shield/aprons/gloves
     - Cleaning Solution
     - Routine items listed below

Technologist QC: Visual Check (Monthly)

- Corrective Action
  - Category C – Put in "schedule" support request. System can be used on patients immediately **UNLESS** the item is of importance to patient or operator safety or image quality
  - Document any corrective actions in Comments section of log

Technologist QC: Visual Check (Monthly)

- Corrective Action
  - Note: It is assumed that technologist will notice problems with any items involved in the daily operation of the machine. **Immediately** report the following items for service when found defective: Locks, field light, compression device, compression scale, grid, or any other problem which is of importance to patient safety, operator safety, or image quality.

Technologist QC: Compression Force Measurement (Semiannually)

- Performing
  1. Place towel on the image receptor to prevent damage to receptor. Place bathroom scale on towel and center under 24 x 30 cm compression paddle. Place towel on top of scale to prevent damage to paddle.
  2. Set full compression force to maximum (100%)

Technologist QC: Compression Force Measurement (Semiannually)

- Performing
  3. Compress paddle until it stops automatically
  4. Measured force must be between 25-45 lbs

Technologist QC: Compression Force Measurement (Semiannually)

- Corrective Action
  - Category A – Put in "stat" support request if force is below 25 lbs or more than 45 lbs. System cannot be used on patients until issue is addressed
  - Document any corrective actions in Comments section of log

Technologist QC: Repeat and Reject Analysis (Monthly)

- Preparation
  1. Refer to QC manual for detailed preparation instructions

Technologist QC: Repeat and Reject Analysis (Monthly)

- Performing
  1. Print, initial, date and file the reject and repeat reports
  2. Record the reject and repeat percentages on the Monthly Reject and Repeat Log
  3. Compare the reject and repeat percentages of this month to the percentage of previous month

Technologist QC: Repeat and Reject Analysis (Monthly)

- Performing
  4. The two numbers should not differ from each other by more than 2.0 percentage points (eg 3.9% and 6.0%)
  5. Best practice: repeat/reject rates should typically be in the range of 2-3%. If they are consistently higher than this, practices should be evaluated. If there is a month that is unusually high, document the reason. This is often due to new staff training.

Technologist QC: Repeat and Reject Analysis (Monthly)

- Corrective Action
  - Notify the radiology supervisor if the difference exceeds 2%. They will determine the cause of change and take corrective action if necessary
  - Category C – Corrective action must be taken within 30 days
  - Document any corrective actions in Comments section of log

Technologist QC: Diagnostic Review Workstation Display Clean Cleanliness (Daily)

- Performing
  1. **MUST** be performed prior to daily clinical use
  2. Identify the reading room by the room number located above the door. Verify the system number matches the system number recorded on the QC log

Technologist QC: Diagnostic Review Workstation Display Clean Cleanliness (Daily)

- Performing
  3. Verify all monitors are free of dust, fingerprints and other marks
  4. Clean display monitor screens using a dry, soft, lint-free cloth and a cleaning solution of 25% either ethanol or isopropyl if necessary

Technologist QC: Diagnostic Review Workstation Display Clean Cleanliness (Daily)

- Corrective Action
  - Category B – If the system cannot be properly cleaned or the system number does not match the one on the log, put in a MITI support request. The system cannot be used to review and interpret mammographic images until the workstation is approved by the physicist
  - Document any corrective actions in Comments section of log

Technologist QC: Viewing Condition Check (Daily)

- Performing
  1. **MUST** be performed prior to daily clinical use
  2. Identify the reading room by the room number located above the door.

Technologist QC: Viewing Condition Check (Daily)

- Performing
  3. Compare the reading room configuration to the one described in the Reading Room Configuration Diagram. Radiologists *should not* be reading with open windows or full lights on
  4. Refer to detailed instructions in QC manual for verifying monitor self-QC

Technologist QC: Viewing Condition Check (Daily)

- Corrective Action
  - Category B – If the system configuration has changed or the QC is not shown as passing, the system must be returned to its prior configuration and/or the QC must be passing before the system can be used to interpret mammograms

Technologist QC: Viewing Condition Check (Daily)

- Corrective Action
  - If the new system configuration is more desirable, put in a "stat" MITI service request for the system to be verified by a medical physicist before use
  - Document any corrective actions in Comments section of log

Technologist QC: Diagnostic Review Workstation Image Quality Check (Weekly)

- Performing
  1. **MUST** be performed prior to daily clinical use
  2. Refer to detailed instructions in QC manual for verifying viewing conditions (different for Barco and Double Black)

Technologist QC: Diagnostic Review Workstation Image Quality Check (Weekly)

- Corrective Action
  - Category B – If the system QC fails, put in a "stat" support request to MITI. The system cannot be used for mammographic image interpretation until the issue is resolved
  - Document any corrective actions in Comments section of log

References

- Houn, F. Franke , K.A. Elliott, M.L. Finder, C.A. Burkhart, R.L. Fischer, R. "The Mammography Quality Standards Act of 1992. History and process." Food Drug Law J. 1995;50(4):485-92. (https://heinonline.org/HOL/LandingPage?handle=hein.journals/fooddl50&div=51&id=&page=)
- MQSA: "About the Mammography Program" (https://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/AboutTheMammographyProgram/default.htm)
- 21 CFR 900.1-12 (MQSA)
- ACR: Mammography Accreditation Program Requirements (Updated 3-16-18) (https://www.acraccreditation.org/-/media/ACRAccreditation/Documents/Mammography/Requirements.pdf?la=en)
- Hologic Selenia & Dimensions QC Manual
- MITI Mammography Quality Control Manual (September 2018)
- "What is the difference between quality control and quality assurance?" Quora. (https://www.quora.com/What-is-the-difference-between-quality-control-and-quality-assurance-)
- Helpful MQSA Resources: https://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/default.htm