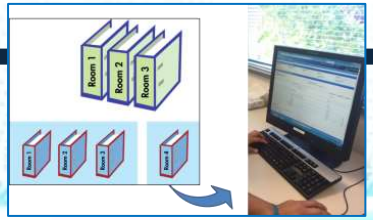
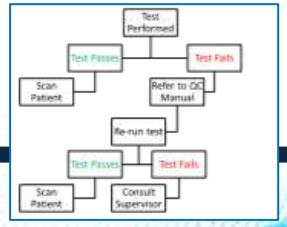
MTMI Medical Technology Management Institute
Your Global Medical Imaging Education Partner

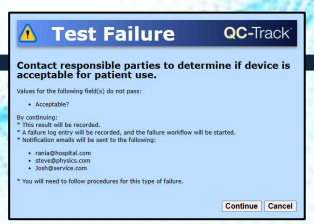
QC-Track
ATIRIX® Medical Systems

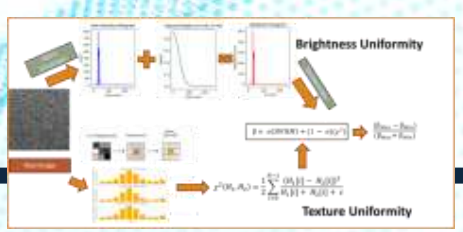
Paperless Mammography QC

Part 2: *Making it Work for You*









May 7, 2026

Disclosures

Rania Johnson, R.T.(R)(M)(QM)
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Atirix Medical Systems

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CEO
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Rania and Steve are executives with Atirix Medical Systems.

Atirix offers the QC-Track® product for paperless enterprise quality control, including in mammography.

Contributors

- **Aide Atayde-Law**, R.T.(R)(M), Mammography Supervisor, University of New Mexico Hospital

- **Trey Slauter**, M.S., DABR, Diagnostic Medical Physicist, University of New Mexico Hospital

- **Patricia Collins,** Ph.D., DABR, Diagnostic Medical Physicist, University of Virginia Health System

- **Jim Holder,** Imaging Director, 2000 – 2021 (retired), Palo Alto Medical Foundation, Sutter Health

- **Jaqueline Gallet**, Ph.D., Ultrasound Physicist, UT Southwestern, Dallas (retired 2026)

Learning Objectives

- ✓Gain understanding of general paperless QC topics
- ✓Be able to describe the latest in MQSA QC compliance
- ✓Be aware of the advantages of paperless QC inspection
- ✓Learn about ways for paperless QC to help with department operations
- ✓Learn about interesting research in QC

Rania Johnson, RT(R)(M)(QM), VP Client Services
Steve Backes, CEO

Paperless Mammography QC Part 2: Making it Work for You

Outline

1. Introduction to Quality Control
2. Regulations Overview
3. How Paperless QC Works
4. Challenges
5. Hot Topics!
6. Case Studies: University of New Mexico Hospital
7. Research
8. Conclusions

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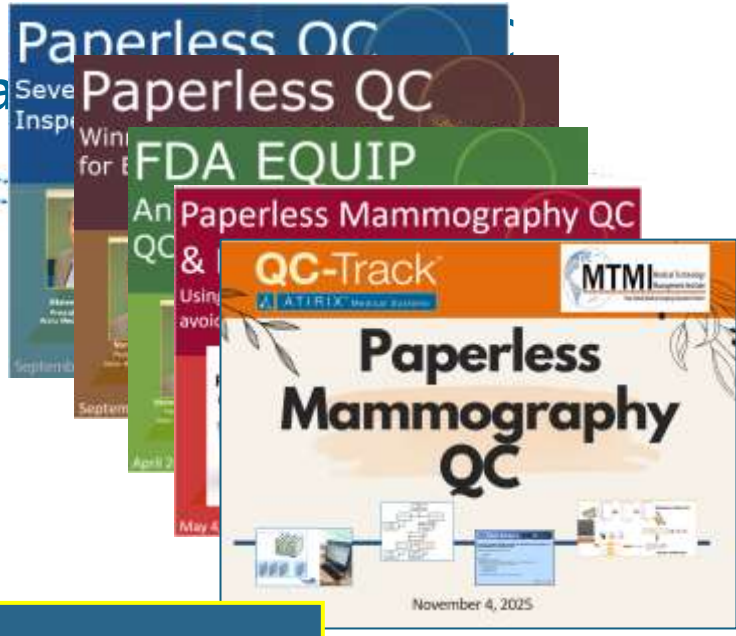
Paperless Part 2: Ma



Re-cap from Nov, 2025:
750+ signed up, 385+ attendees, 199 post-webinar surveys, strong marks, and many nice comments…

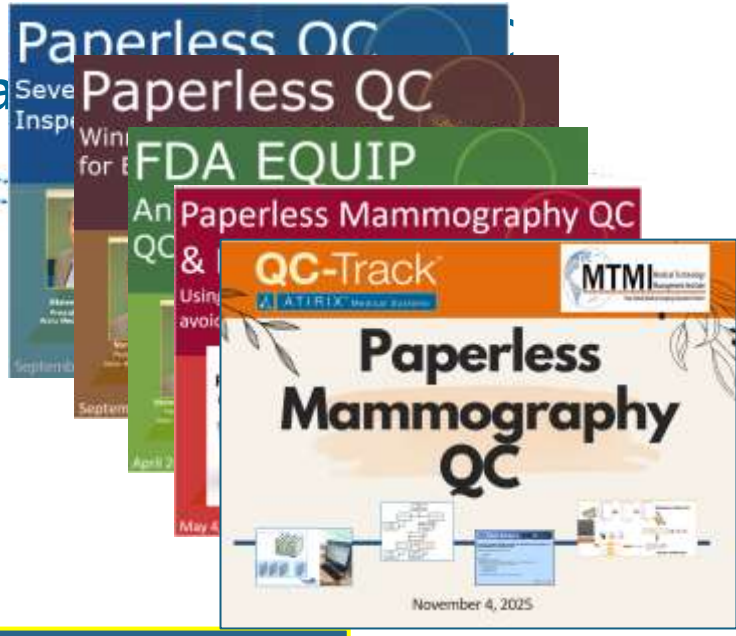
Give me paperless! Looks like we will go in this direction in the future. I wish we could integrate it now

The future of QC is something I am passionate about as I'm currently at a facility with all binders and need more info on next steps to implement!

I liked how easy everything was presented. Very organized.

Very interesting as our QC processes advance in complexity and we move into a paperless world.

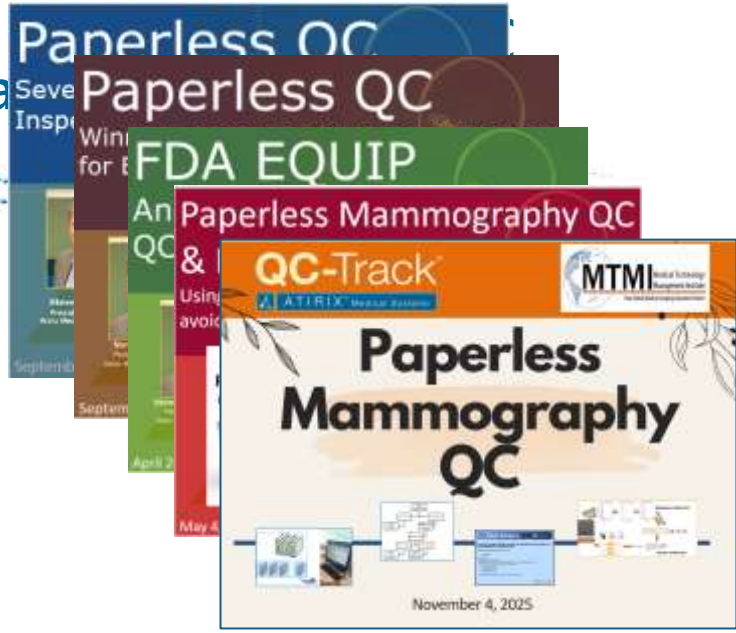
Very good info - the presenters were great and organized. Lots of good material to digest!



A reminder – this is for Mammography, MQSA, and Paperless QC…

I didn't realize it was intended primarily for MQSA audiences.

Some of the content was a little hard to follow, but also this subject isn't relative to my area of radiology. But thank you for offering it!



Comments from previous webinars …interest in specifics…

Slow down the slides. Great information would have liked to have more time to read them.

The last 20 min demonstrating their product was valuable .

An opportunity to see how a digital QC book would look.

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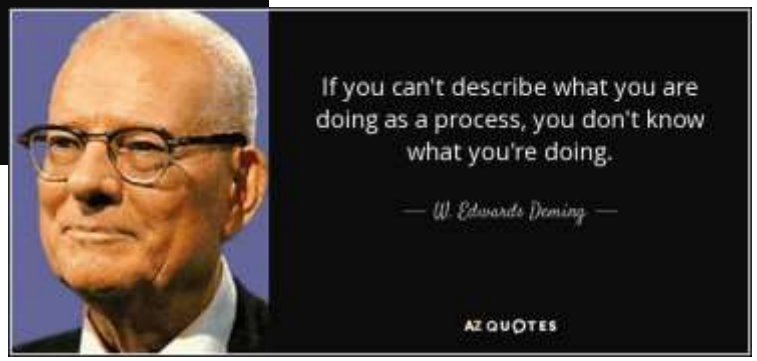
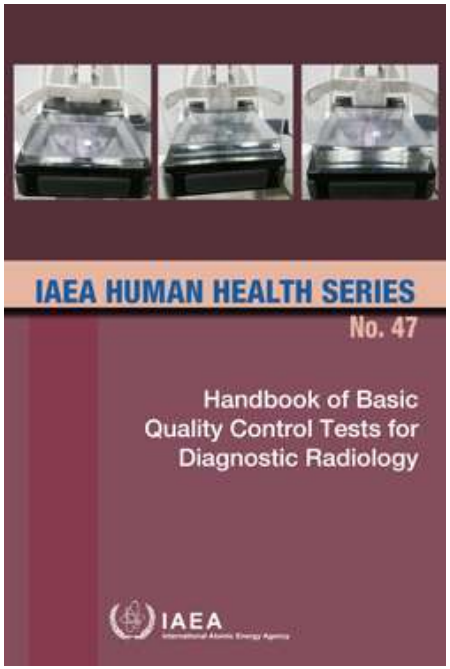


Introduction to Quality Control

What is Quality Control?



Quality control (QC) represents the basic level of managing safety and quality in diagnostic radiology.

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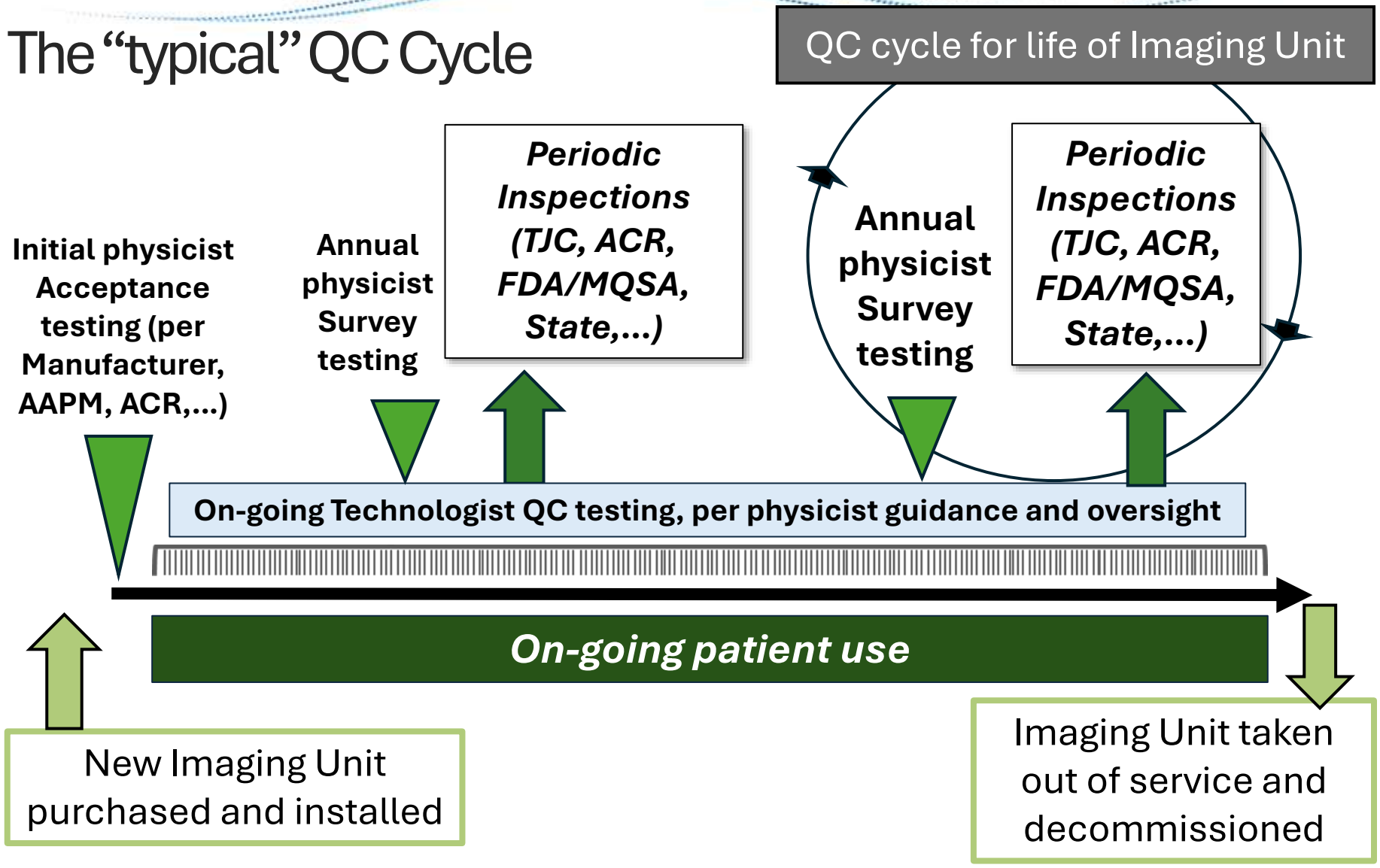
Paperless Mammography QC Part 2: Making it Work for You

The "typical" QC Cycle



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Steve Backes, CEO

The Case for QC

Quality is about more than meeting regulations…

Would you put a family member or friend on that scanner with a QC failure or with QC not done for that day?

Patty Collins, PhD, DABR
Medical Physicist
UVA Health

My standard "old consultant" question…

"*Why would an imaging director care about paperless QC?*"

Rania Johnson, RT(R)(M)(QM), VP Client Services
Steve Backes, CEO

Classic response from 2015 – *think about inspection risk management*

> "The shorter the inspector is in the department the easier it is on ***me***."

Jim Holder, Imaging Director, 2000 – 2021 (retired)
Implemented QC-Track in 2015 across 25+ locations, and fleet of 150+ imaging units
Palo Alto Medical Foundation, Sutter Health
Palo Alto, CA

Jim explained…"*back to my nuc med days*"

- Reality: 30+ years being regularly inspected
- Jim's Goal: Make it as easy as possible for the inspectors
- Electronic system: "*big benefits*"
  - Easier and faster for inspectors
  - Minimizes/eliminates staff disruption
    - prepping for inspection, and
    - when the inspector is in the department

"The shorter the time the inspector is in the department, the easier it is on me!"

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Steve Backes, CEO

Paperless Mammography QC
Part 2: Making it Work for You

What's reality in a lot of departments in 2026?

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Steve Backes, CEO

Why not Paper? *Risk and Waste*

- Vulnerable, can be lost or tampered with
- Risk of fire or water damage
- Backed up?
- Secured?
- Monitoring? Oversight?
- (Younger staff expectations)

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Steve Backes, CEO

Keep the inspector happy? Makes sense…

"How do I explain paperless QC to my management?"

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Steve Backes, CEO

SBAR Primer

SBAR (Situation, Background, Assessment, Recommendation) is an effective and efficient way to communicate important information.

S=Situation

- a concise statement of the problem

B=Background

- pertinent and brief information related to the situation

A=Assessment

- analysis and considerations of options — what you found/think

R=Recommendation

- action requested/recommended — what you want

Background
Kaiser Permanente Colorado identified **differences** in physician and nurse **perceptions of teamwork.**

Physicians "*fairly collaborative*"

Nurses – "*much less so…*"

Response: Kaiser Permanente developed a communication tool called SBAR, based on a source document from the US Navy

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Paperless Mammography QC Part 2: Making it Work for You

Example: Actual SBAR decision document used by a large regional system to help justify getting a centralized QC system

Situation

Background

Assessment

Recommendation

SITUATION:

- *MQSA and the FDA require each site that performs Mammography to complete several quality control tests on the Mammography unit, (daily, weekly, monthly, etc). The recording of these results is currently done manually, where the Technologist documents the test results on paper graphs and charts and kept in a binder.*
- *Technologists, Radiologists, and Physicists (Tech/Rad/Phys) are required to maintain their license current, keep copy of their initial training in Mammography, and maintain a certain number of credits over a rolling time period. This is currently done manually, where copies of each are kept in a binder at each site that performs Mammography.*

BACKGROUND:

- *Each site performing Mammography must perform daily, weekly, monthly, quarterly, semi-annually, and annual quality control tests, which are all documented by hand on paper. These original paper logs are subject to be destroyed by a flood, fire, or person, or even lost. It is required that these documents be kept from inspection to inspection, which is done annually.*
- *Each Tech/Rad/Phys maintains their initial training, licenses, and continuing education credits from year to year. They must send a copy of everything to each site that performs Mammography whenever there is a change. Because each person is on a different schedule, there are always changes and updates to the person's file, which is maintained by the site.*

ASSESSMENT:

- *Any manual process opens up the potential for errors. An error in the Mammography quality control process can result in the department being shut down or subjected to fines.*
- *A back up or copy of all quality control tests would also be a manual process because the originals are all done by hand. All original charts and graphs have the potential to be lost or tampered with, and are exposed to fire or water damage.*
- *At least 1 person in charge of maintaining the training, licenses, and continuing education credits for each Tech/Rad/Phys at each Mammography site. This person requests copies of the updated material when it expires for each Tech/Rad/Phys that works at that site. This ultimately is the responsibility of the individual, but lack of compliance can result in fines and/or closures for the site.*
- *During each annual inspection, the FDA inspector goes through all the binders that hold the QC test results and Tech/Rad/Phys credentials. Their assessment of the site is based on what they find/don't find in those manual logs.*

RECOMMENDATION: *Provide a web-based system to record quality control tests and required Technologist, Radiologist, and Physicist documentation.*

This system can/will:

- *Streamline how each site records the data collected so it's the same, correct way across all of the PHC sites, reducing the chance for human error.*
- *Provide automatic quality alerts throughout the PHC network so the proper people are notified as soon as a QC test does not pass or when a Tech/Rad/Phys has expired credentialing.*
- *Allow the sites' Imaging Technical Consultants and Physicists to review the QC process and track credentials remotely.*
- *Provide FDA inspectors a neatly organized report of all test results and credentialing, which will streamline and speed up the inspection process.*
- *Speed up the time it takes for the QC Mammography Tech to complete the recording process of all the required tests, which can allow for additional patients to be seen.*

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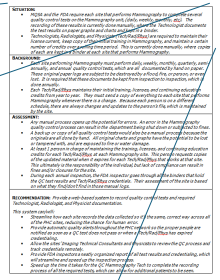
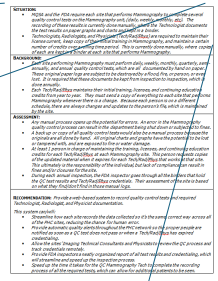
Actual SBAR: **Situation**

- **MQSA and the ACR** require each site that performs Mammography to complete several **quality control tests** on the Mammography unit, (daily, weekly, monthly, etc). The recording of these results is currently done manually, where the Technologist documents the test results on paper graphs and charts and kept in a **binder**.

- Technologists, Radiologists, and Physicists (Tech/Rad/Phys) are required to **maintain their license** current, **keep copy** of their initial training in Mammography, and **maintain a certain number of credits** over a rolling time period. This is currently done manually, where **copies of each are kept in a binder** at each site that performs Mammography.



Actual SBAR: **Background**



- Each site performing Mammography must perform daily, weekly, monthly, quarterly, semi-annually, and annual quality control tests, which are all **documented by hand on paper**. These **original paper logs are subject to be destroyed by a flood, fire, or person, or even lost**. It is required that these documents be kept from inspection to inspection, which is done annually.

- Each Tech/Rad/Phys maintains their initial training, licenses, and continuing education credits from year to year. They must send a copy of everything to each site that performs Mammography whenever there is a change. Because each person is on a different schedule, **there are always changes and updates to the person's file**, which is maintained by the site.

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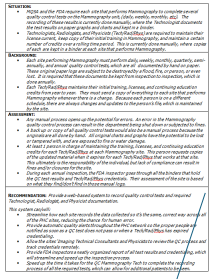
Actual SBAR: **Assessment**



- **Any manual process opens up the potential for errors**. An error in the Mammography quality control process can result in the department being shut down or subjected to fines.

- A **back up or copy of all quality control tests would also be a manual process** because the originals are all done by hand. **All original charts and graphs have the potential to be lost or tampered with, and are exposed to fire or water damage**.

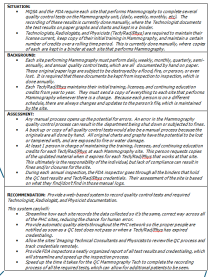
- At least 1 person in charge of maintaining the training, licenses, and continuing education credits for each Tech/Rad/Phys at each Mammography site. This person requests copies of the updated material when it expires for each Tech/Rad/Phys that works at that site. This ultimately is the responsibility of the individual, but **lack of compliance can result in fines and/or closures for the site**.

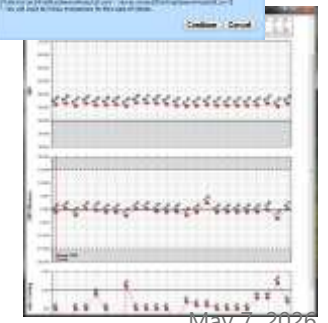
- During each annual inspection, the **inspector** goes through all the binders that hold the QC test results and Tech/Rad/Phys credentials. Their **assessment of the site is based on what they find/don't find in those manual logs.**

Actual SBAR: Recommendation

- Provide a web-based system to record quality control tests and required **Technologist**, **Radiologist**, and **Physicist** documentation.

- This system can/will:
  - **Streamline** how each site records the data collected so it's the **same, correct way across all** of the [hospital] sites, reducing the chance for human error.
  - Provide **automatic quality alerts** throughout the [hospital] network so the proper people are notified as soon as a QC test does not pass or when a Tech/Rad/Phys has expired credentialing.
  - Allow the sites' Imaging Technical Consultants and Physicists to **review the QC process and track credentials remotely**.
  - Provide **inspectors** a neatly organized report of all test results and credentialing, which will **streamline and speed up the inspection process**.
  - **Speed** up the time it takes for the QC Mammography Tech to complete the recording process of all the required tests, which can **allow for additional patients to be seen**.





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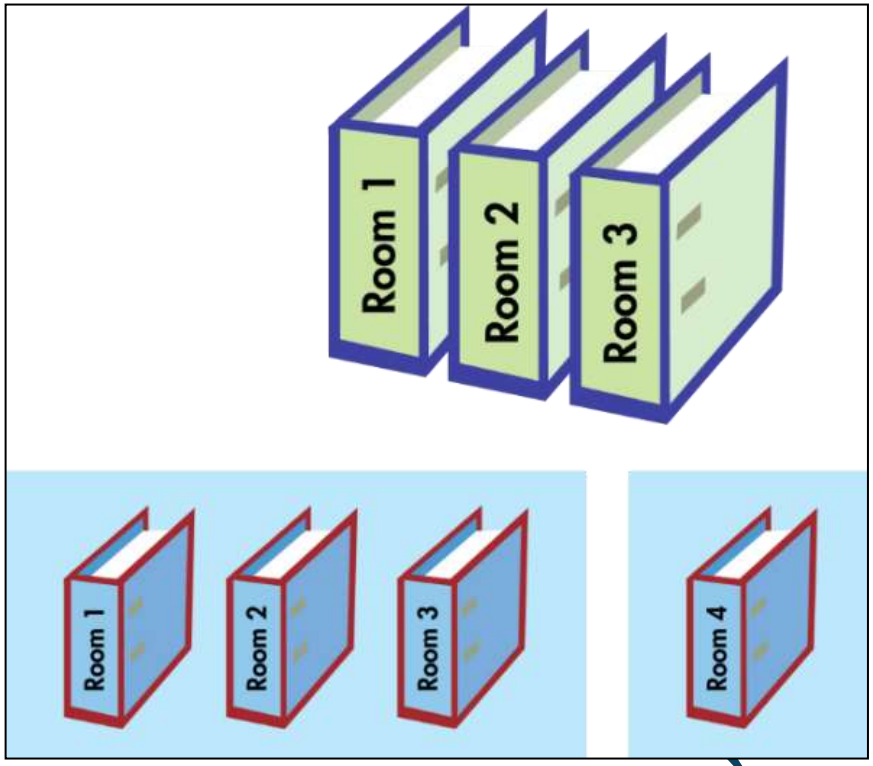
Steve Backes, CEO

Paperless QC = Centralized QC



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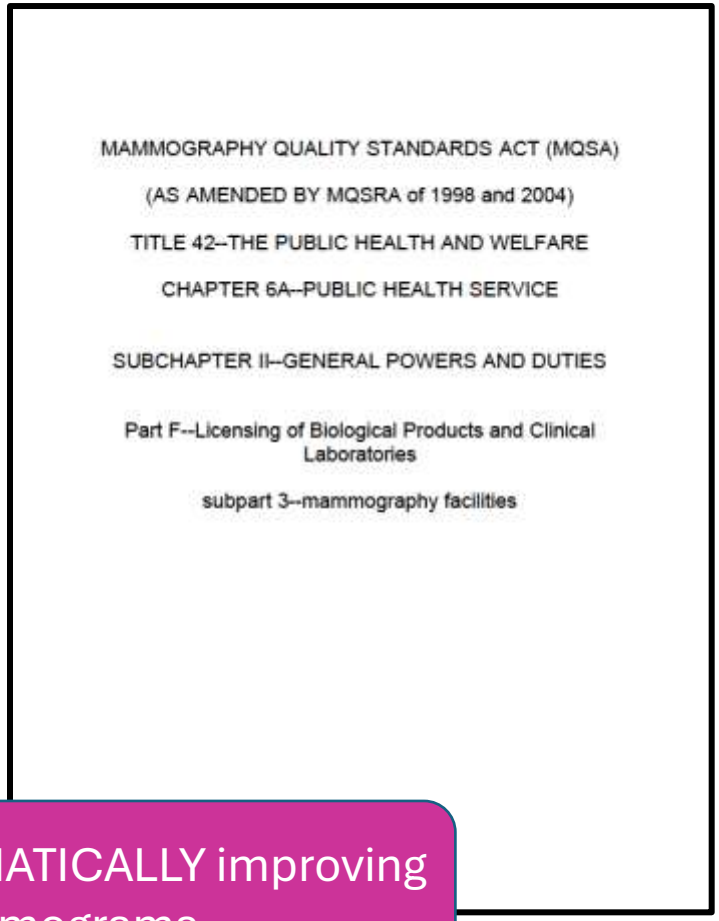
Regulations

MQSA

THE JOINT COMMISSION

The Case for QC- MQSA

- 1992 - MQSA act passed
- 1994 - all mammography facilities in the U.S. were required to be MQSA-certified
- 1997 - FDA published the Quality Mammography Standards; Final Rule
- 1999 - the Final Rule went into effect
- 2002 - more stringent equipment regulations went into effect
- 2023 - Final Rule Amended
- 2026?


MAMMOGRAPHY QUALITY STANDARDS ACT (MQSA)

(AS AMENDED BY MQSRA of 1998 and 2004)

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 6A--PUBLIC HEALTH SERVICE

SUBCHAPTER II--GENERAL POWERS AND DUTIES

Part F--Licensing of Biological Products and Clinical Laboratories

subpart 3--mammography facilities

MQSA set the stage for DRAMATICALLY improving the Quality of Mammograms.

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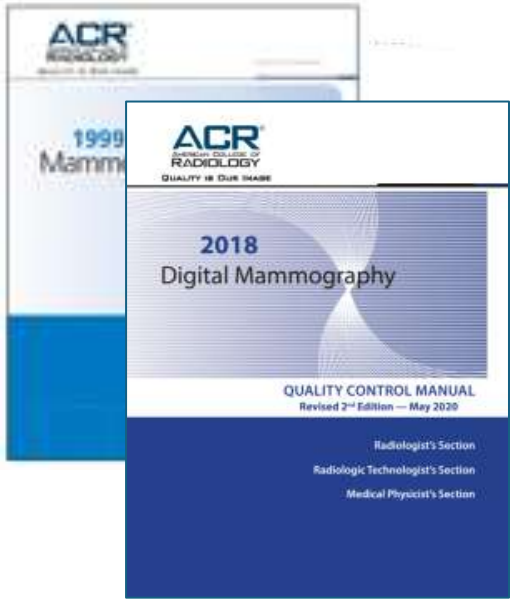
MQSA -- Quality Assurance



Sec. 900.12 *Quality standards* (d)(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.

FDA reinforced this in a 2010 letter: "***Radiologic Technologist: Falsification of Documentation***"

- "Relying on a single individual at a facility to assure compliance with MQSA for QA and other requirements may put a facility at risk. The requirement above indicates that QA oversight is the responsibility of, at a minimum, the three individuals mentioned above and possibly others. Facility management should ensure the involvement of all of the responsible parties in the review of QC records and the oversight of the QA program, particularly the lead interpreting physician."

Facility Management
+
Responsible Parties:
- ✓ Radiologist/LIP
- ✓ Technologist
- ✓ Medical Physicist

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Quality Control

- FDA delegated rights to define QC process to ACR and manufacturers
  - Manufacturers are required to define a process consistent with MQSA

- Today all digital sites follow manufacturer's or ACR Digital QC process

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ARRT and MQSA -- summary

	ARRT	MQSA
New Modality		8 hrs CEU per modality
Ongoing	24 CEU per 24 months	15 CEU per 36 months
Exams		Minimum of 200 exams in previous 24 months
Records		Mammo technique and procedure, QC, safety, protection, qualifications are properly maintained and updated
QC		Extensive testing – daily, weekly, monthly, quarterly, semi-annual ACR or manufacturer
Medical Audit		Exam tracking, outcomes reporting, patient letters

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Mammography QC – FDA EQUIP

"Enhancing Quality Using the Inspection Program"

Quality Assurance - Clinical Image Corrective Action

1. Does the facility have procedures for corrective action (CA) when clinical images are of poor quality?

Quality Assurance - Clinical Image Quality

2. Does the facility have procedures to ensure that clinical images continue to comply with the clinical image quality standards established by the facility's accreditation body?

Quality Control

3. Does the facility have a procedure for LIP oversight of QA/QC records and corrective actions?

TJC & Imaging QC – *'Evolving'*

2011 – current
TJC Sentinel Event Alert 47
Radiation risks of diagnostic imaging and fluoroscopy


The Joint Commission
Sentinel Event Alert

A complimentary publication of The Joint Commission

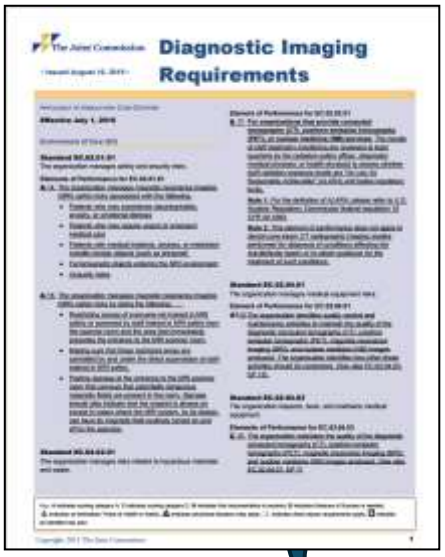
Issue 47, August 24, 2011
Revised: February 2016 (in red)

Radiation risks of diagnostic imaging and fluoroscopy

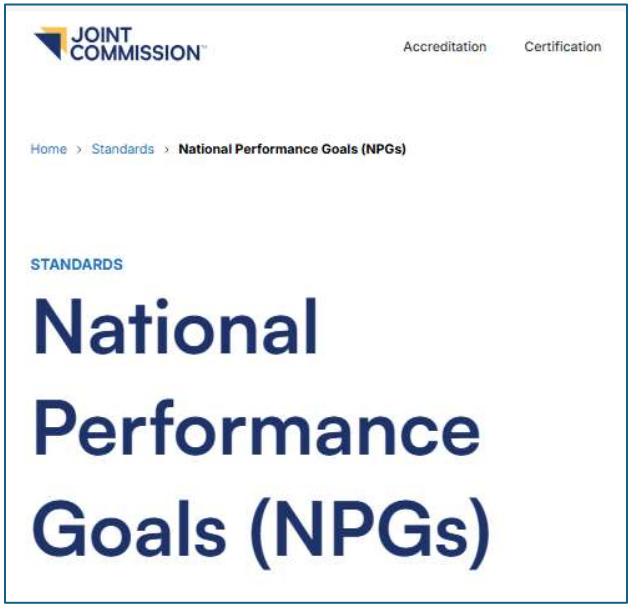
Diagnostic radiation, which includes fluoroscopy, is an effective tool that can save lives. The higher the dose of radiation delivered at any one time, however, the greater the risk for long-term damage. If a patient receives repeated doses, harm can also occur as the cumulative effect of those multiple doses over time.[1,2,3] Conversely, using insufficient radiation may increase the risk of misdiagnosis, delayed treatment, or, if the initial test is inadequate, repeat testing with the attendant exposure to even more radiation.[4] The risks associated with the use of ionizing radiation in diagnostic imaging include cancer, burns and other injuries.[1,4,5,6,7] X-rays are officially classified as a carcinogen by the World Health Organization's International Agency for Research on Cancer, the Agency for Toxic Substances and Disease Registry of the Centers for Disease Control and Prevention, and the National Institute of Environmental Health Sciences.[1]

Over the past two decades, the U.S. population's total exposure to ionizing radiation has nearly doubled.[8] Diagnostic imaging and fluoroscopy services can be provided in hospitals, imaging centers, physician and dental offices, and practitioners can order tests and procedures that involve exposure to radiation, with no knowledge of when the patient was last irradiated or how much radiation the patient had previously received. From the 74 million CT (computerized tomography) scans performed in the U.S. during 2017, it has been estimated that 29,000 future cancers and 14,500 future deaths could develop due to radiation (cancer incidence = 0.04 percent).[9] Another study estimates the incidence of cancer related to CT radiation at 0.02 to 0.04 percent.[10] While these studies' conclusions rely upon some currently unverified scientific assumptions – namely, a linear relationship between radiation dose and risk even at very low exposures – they do highlight the need to maintain radiation doses as low as reasonably achievable when obtaining needed diagnostic information and performing fluoroscopic procedures.

2015 – 2025
Diagnostic Imaging Requirements


The Joint Commission
Diagnostic Imaging Requirements

Jan 1, 2026 –
(new)
Accreditation 360/
National Performance Goals


JOINT COMMISSION
Accreditation Certification

Home › Standards › National Performance Goals (NPGs)

STANDARDS

National Performance Goals (NPGs)

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Steve Backes, CEO

Paperless Mammography QC Part 2: Making it Work for You

Do the quality control requirements of TJC Diagnostic Imaging Requirements still apply?

Yes, The Joint Commission (TJC) diagnostic imaging quality control (QC) requirements remain in effect and are critical for accreditation, with updated National Performance Goals (NPGs) in place through 2026. These standards mandate documented QC, preventative maintenance (PM) following manufacturer guidelines, staff qualifications, and, as of January 1, 2026, reinforced NPGs for safe imaging practices, including specialized requirements for CT, MRI, PET, and nuclear medicine. Joint Commission +3

Key, ongoing TJC imaging requirements include:

- **Equipment Maintenance:** Routine, documented inspection, testing, and maintenance of all imaging equipment (CT, MRI, PET, NM).
- **Quality Control (QC):** Annual and periodic measurements of imaging equipment must be performed, often with input from a medical physicist.
- **Radiation Safety:** Requirements for imaging safety, including dose optimization and monitoring, as outlined in Sentinel Event Alert 47.
- **Staff Qualifications:** Definition and verification of education and experience for imaging staff. Joint Commission +4

While specific technologist certification deadlines were previously suspended, the core standards focusing on equipment performance and safety remain central to TJC surveys. Radiology Today Magazine +2

Dive deeper in AI Mode

According to AI - "*Sure!*"

[BUT please do NOT use AI to decide on what's needed for QC!!]

Rania Johnson, RT(R)(M)(QM), VP Client Services
Steve Backes, CEO

Paperless Mammography QC Part 2: Making it Work for You

TJC Imaging Requirements start with SEA 47…

Sentinel Event Alert 47
"Radiation risks of diagnostic imaging and fluoroscopy"
Aug 2011, May 2017, Jan 2019

The Joint Commission
Sentinel Event Alert

A complimentary publication of The Joint Commission

Issue 47, August 24, 2011
Revised: February 2019 (in red)

Radiation risks of diagnostic imaging and fluoroscopy

Diagnostic radiation, which includes fluoroscopy, is an effective tool that can save lives. The higher the dose of radiation delivered at any one time, however, the greater the risk for long-term damage. If a patient receives repeated doses, harm can also occur as the cumulative effect of these multiple doses over time.[1,2,3] Conversely, using insufficient radiation may increase the risk of misdiagnosis, delayed treatment, or, if the initial test is inadequate, repeat testing with the attendant exposure to even more radiation.[4] The risks associated with the use of ionizing radiation in diagnostic imaging include cancer, burns and other injuries.[1,4,5,6] X-rays are officially classified as a carcinogen by the World Health Organization's International Agency for Research on Cancer, the Agency for Toxic Substances and Disease Registry of the Centers for Disease Control and Prevention, and the National Institute of Environmental Health Sciences.[7]

Over the past two decades, the U.S. population's total exposure to ionizing radiation has nearly doubled.[8] Diagnostic imaging and fluoroscopy services can be provided in hospitals, imaging centers, physician and dental offices, and practitioners can order tests and procedures that involve exposure to radiation, with no knowledge of when the patient was last irradiated or how much radiation the patient had previously received. From the 74 million CT (computerized tomography) scans performed in the U.S. during 2017, it has been estimated that 29,000 future cancers and 14,500 future deaths could develop due to radiation (cancer incidence = 0.04 percent).[9] Another study estimates the incidence of cancer related to CT radiation at 0.02 to 0.04 percent.[10] While these studies' conclusions rely upon some currently unverified scientific assumptions – namely, a linear relationship between radiation dose and risk even at very low exposures – they do highlight the need to maintain radiation doses as low as reasonably achievable when obtaining needed diagnostic information and performing fluoroscopic procedures.

- **Action Item 13**: "… **Implement a system for centralized quality and safety performance monitoring**…"
- **Action Item 15: "Ensure** that recommended **quality control,** testing (including daily functional tests) and preventive maintenance activities **are performed** in accordance with manufacturer's guidelines. The health care organization, in consultation with the medical physicist, should identify these activities, their frequencies, and who will perform them. "

(The Joint Commission, 2019), https://www.jointcommission.org/resources/sentinel-event/sentinel-event-alert-newsletters/sentinel-event-alert-issue-47-radiation-risks-of-diagnostic-imaging-and-fluoroscopy/

TJC & Imaging QC – *today*

2011 – current
TJC Sentinel Event Alert 47

The Joint Commission
Sentinel Event Alert

A complimentary publication of The Joint Commission

Issue 47, August 24, 2011
Revised: February 2019 (in red)

Radiation risks of diagnostic imaging and fluoroscopy

Diagnostic radiation, which includes fluoroscopy, is an effective tool that can save lives. The higher the dose of radiation delivered at any one time, however, the greater the risk for long-term damage. If a patient receives repeated doses, harm can also occur as the cumulative effect of those multiple doses over time.[1,2] Conversely, using insufficient radiation may increase the risk of misdiagnosis, delayed treatment, or, if the initial test is inadequate, repeat testing with the attendant exposure to even more radiation.[3] The risks associated with the use of ionizing radiation in diagnostic imaging include cancer, burns and other injuries.[1,4,5] X-rays are officially classified as a carcinogen by the World Health Organization's International Agency for Research on Cancer, the Agency for Toxic Substances and Disease Registry of the Centers for Disease Control and Prevention, and the National Institute of Environmental Health Sciences.[1]

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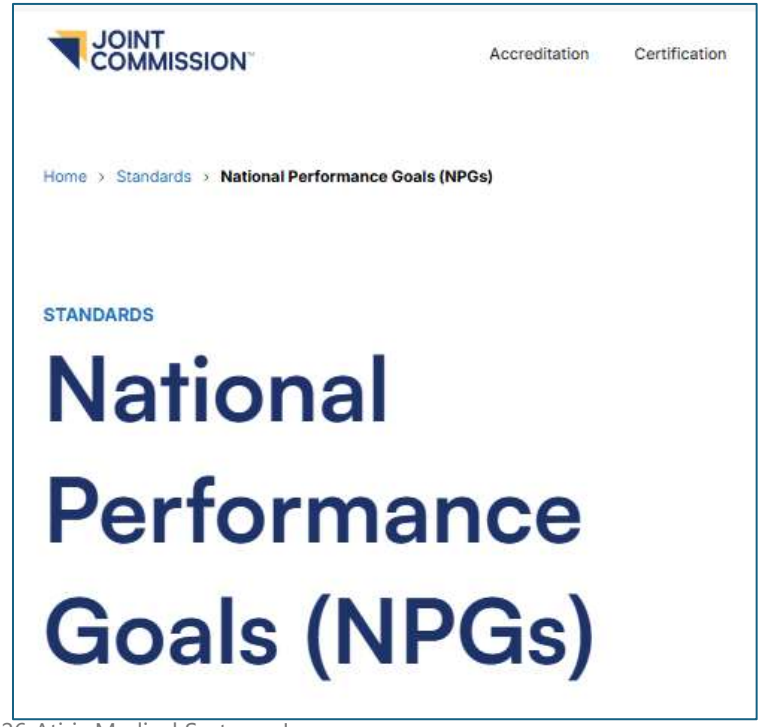
Jan 1, 2026 –
(new)
Accreditation 360/
National
Performance Goals



JOINT COMMISSION

Accreditation Certification

Home › Standards › National Performance Goals (NPGs)

STANDARDS

National Performance Goals (NPGs)

Rania Johnson, RT(R)(M)(QM), VP Client Services
Steve Backes, CEO

Paperless Mammography QC Part 2: Making it Work for You

JOINT COMMISSION

Hospital Accreditation

Survey Process Guide

TJC Survey Process Guide, Page 620

Imaging Document Review Guide

The following documents and data need to be made available to the surveyor for review, based on the imaging modalities provided by your organization. Note: It is not necessary for you to copy these documents for the surveyor, just ensure that they are available for review. This document will assist you with compiling those documents.

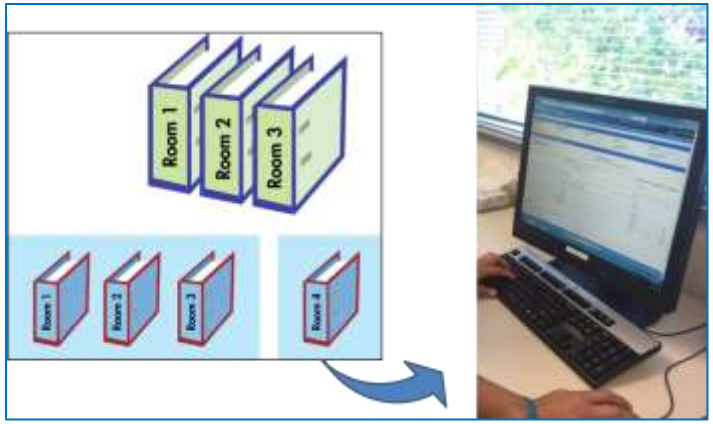
1. Facilities and Equipment:

☐ Equipment quality control (QC) and performance maintenance (PM) activities for CT, MRI, PET, and NM equipment, with the dates completed (last 12 months) NPG.13.03.01 EP 4

☐ CT annual equipment performance evaluation:NPG.13.03.01 EP 5
Must be documented, done by medical physicist, and include:

- Image uniformity
- Slice thickness accuracy
- Alignment light accuracy
- Table travel accuracy
- Radiation beam width
- High contrast resolution
- Low contrast resolution
- Geometric or distance accuracy
- CT number accuracy and uniformity
- Artifact evaluation

☐ MRI annual equipment performance evaluation: NPG.13.03.01 EP 6
Must be documented, done by medical physicist or MRI scientist, and include



Paperless QC: How it Works

Rania Johnson, RT(R)(M)(QM), VP Client Services
Steve Backes, CEO

May 7, 2026

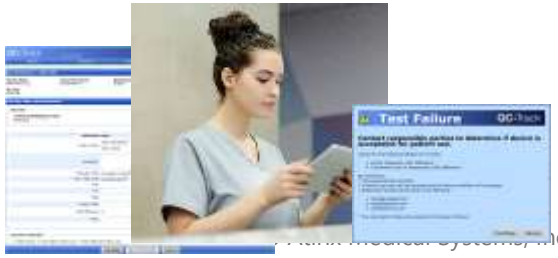
Paperless QC Workflow

1. **QC notification**
The QC Dashboard or email notice indicates QC activities are due for a device, apron, US transducer,...

2. QC data gathering
QC data is gathered from the room, device or apron.
Phantom data is gathered and processed.

4. QC Reporting
QC data available for tracking, reporting, and sign off, including MQSA, TJC aprons, ACR, AAPM, and Ultrasound programs.

3. **QC Data entry**
Results are matched to devices and tests, comments added, and data is entered the tracking system. Failures are recorded and tracked.



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Steve Backes, CEO

How it works: Devices

Each imaging unit or accessory is set up as a unique device.

Device ID/ Tag ID	Name	Doc	QC Status	Manufacturer Model	Worksheet Family Worksheet Group	Model Type	Status	Location
11420211	Affirm		Okay	Hologic Affirm	Stereotactic Biopsy Hologic Affirm - Upright	Stereotactic Breast Biopsy	In Service	Breast Care Center - St. Paul, MN
11320211	Barco - Display		Okay	Barco MFGD5421	Diagnostic Review Workstations Barco	View Station	In Service	Breast Care Center - St. Paul, MN
62626262	Dimensions 2D		Failed	Hologic Dimensions 2D	Hologic Dimensions 2D	FFDM	In Service	Breast Care Center - St. Paul, MN
702201301	Dimensions Tomo		Okay	Hologic Dimensions Tomo	Hologic Dimensions Tomo	FFDM	In Service	Breast Care Center - St. Paul, MN
11320212	GE Pristina		Okay	GE Pristina	Mammography GE Pristina	FFDM	In Service	Breast Care Center - St. Paul, MN

How it works: Scheduling

Quality Control Manual for Selenia Dimensions and 3Dimensions Systems
Appendix B: Quality Control Forms for the Radiologic Technologist

Appendix B Quality Control Forms for the Radiologic Technologist

Caution:
If electronic forms or forms other than the forms listed in this appendix are used with the current revision of this manual, it is the responsibility of the user to verify that the alternative forms are equivalent to

Table 42: Quality Control Tests To be Performed by th

Quality Control Test Procedure	Frequency
DICOM Printer Quality Control	Weekly
Detector Flat Field Calibration (includes CEDM option)	Weekly
Geometry Calibration (Tomosynthesis Option)	Semiannually
Artifact Evaluation	Weekly
Phantom Control Chart	Weekly
Signal-To-Noise and Contrast-To-Noise Measurements	Weekly
Compression Thickness Indicator	Biweekly

Per the appropriate protocol (ACR, vendor, internal, etc.), worksheets are set up for each device.

Location and Device

Location: Breast Care Center | Device: Dimensions Tomo - ID 702201301 | Test Frequency: - Show All - | Find Device

Scheduled and On Demand Worksheets

QC Test	Test Frequency					
Artifact Evaluation - AWS - Tomo	Weekly	Show History	10/27/2025	11/03/2025	Worksheet	
Detector Flat-Field Calibration	Weekly	10/20/2025 Show History	10/27/2025	11/03/2025	Worksheet	
Phantom Image - 2D	Weekly	10/20/2025 Show History	10/27/2025	11/03/2025	Worksheet	
Phantom Image - Tomo	Weekly	10/20/2025 Show History	10/27/2025	11/03/2025	Worksheet	
SNR/CNR	Weekly	10/20/2025 Show History		11/03/2025	Worksheet	
Compression Thickness Indicator	Biweekly	10/20/2025 Show History		11/03/2025	Worksheet	
Compression Thickness Indicator FAST Mode	Biweekly	10/20/2025 Show History		11/03/2025	Worksheet	
Visual Checklist	Monthly	09/01/2025 Show History	10/06/2025	11/03/2025	Worksheet	

When tests become due, they display on the QC Dashboard

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Steve Backes, CEO

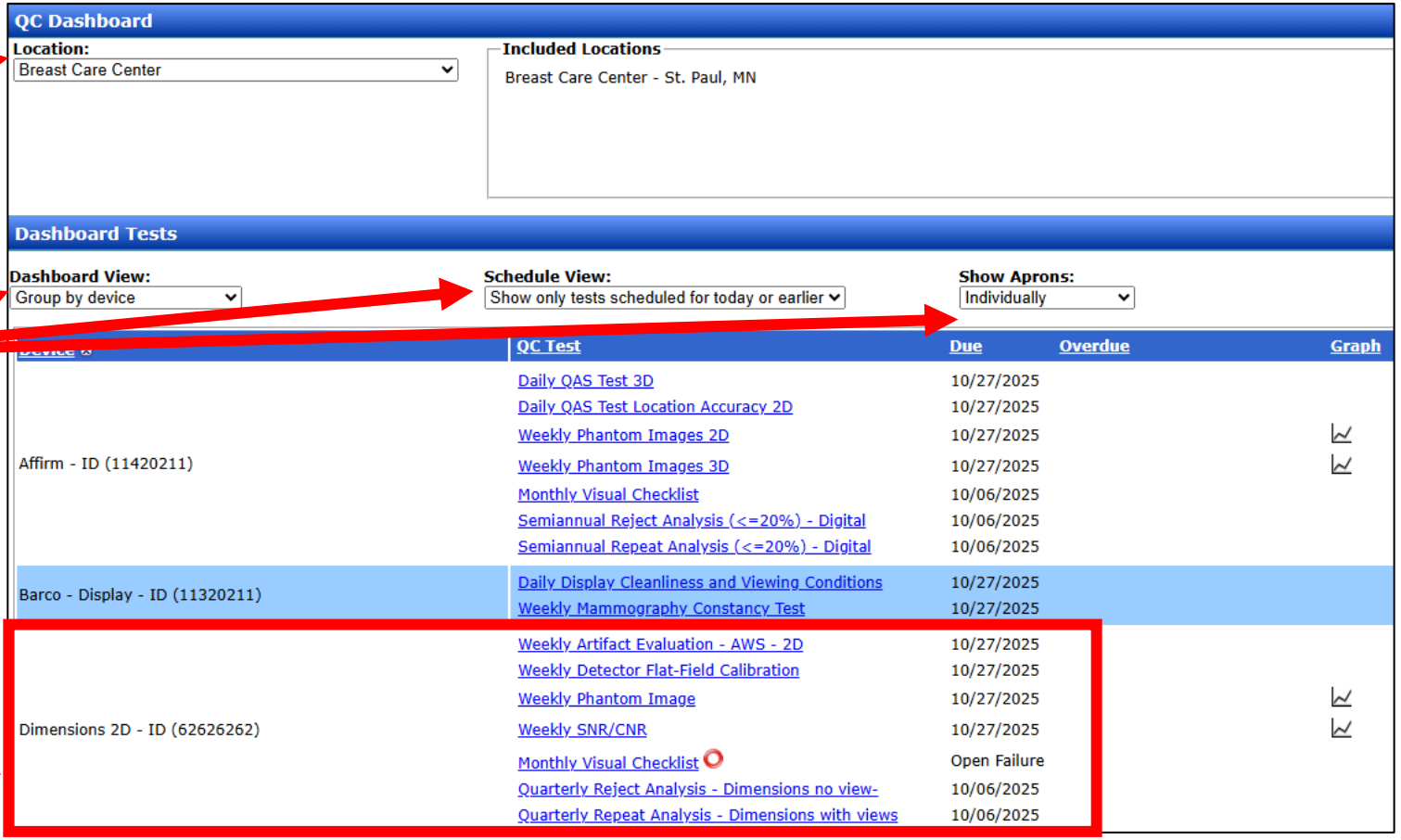
How it works: Dashboard

A “virtual to-do list” of device and tests organized by facility.

Location

Views

Devices and Tests



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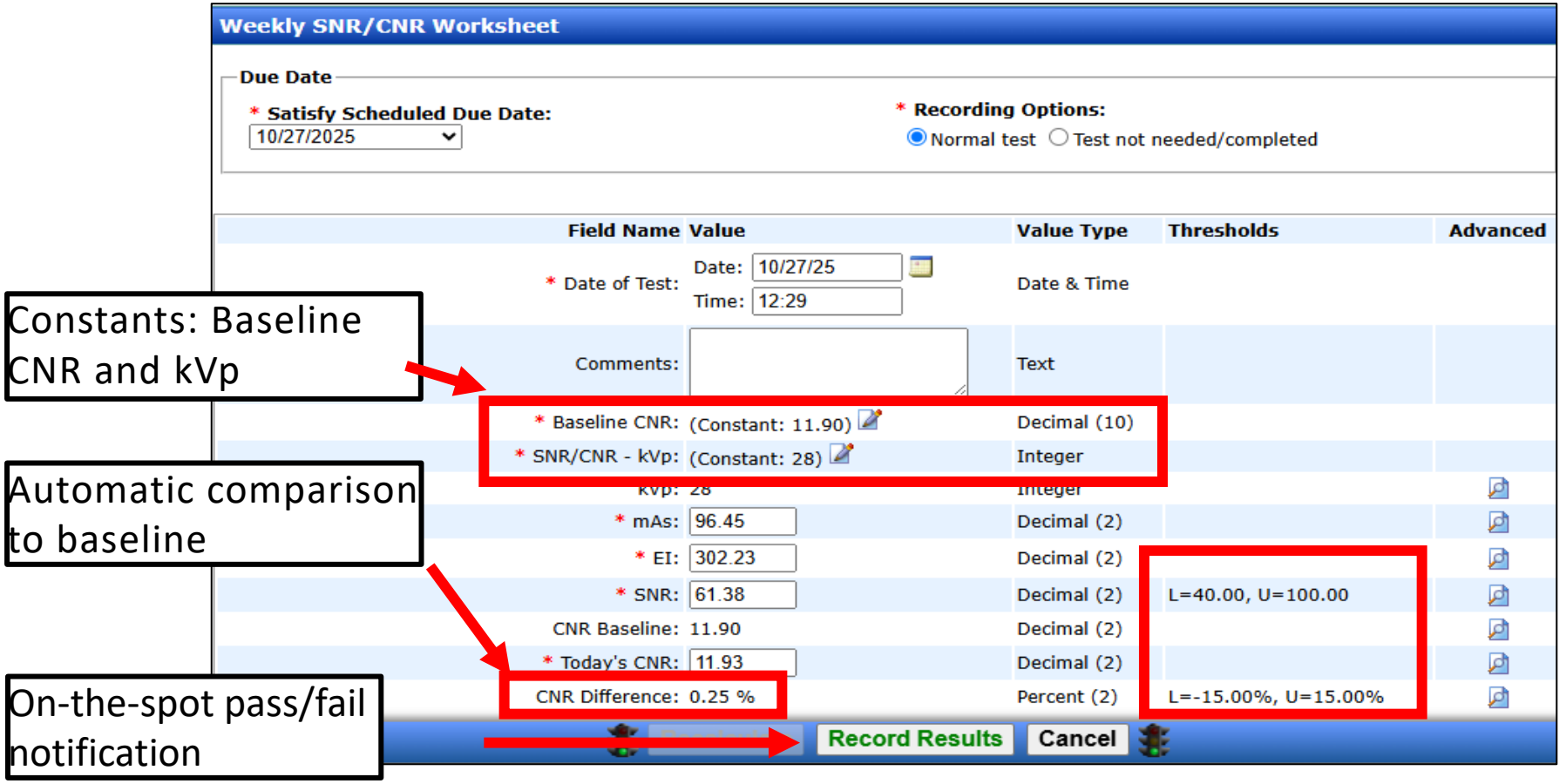
How it works: Entering QC

Technologist simply enters raw data; calculations, baselines, and limits are built-in.



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How it works: Reports

Data is immediately available as reports, which can be saved as PDFs to print and email.

QC Device Worksl

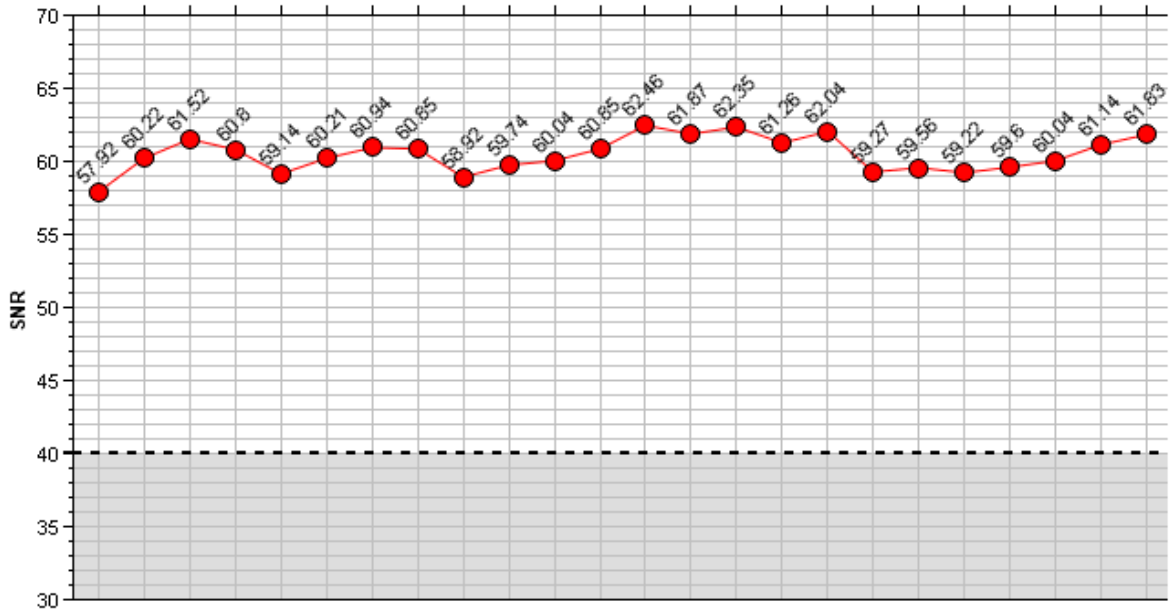
Breast Care Center
158467 Washington Street, St. Pau
Dimensions Tomo Dimensions Tom
SNR/CNR
9/22/2025 to 10/27/2025

Worksheet Field	9/22/2025	9
Overall Pass/Fail	Pass	Pas
Performed By	Stacy Ferson	Sta
kVp	28	28
mAs	95.42	95.
EI	271.19	308
SNR (L=40.00, U=70.00)	59.22	59.
CNR Baseline	12.10	12.
Today's CNR	12.12	12.
CNR Difference (L=-15.00%, U=15.00%)	0.17 %	-0.
Comments		

Signal-To-Noise and Contrast-To-Noise

Breast Care Center
158467 Washington Street, St. Paul, MN 55102
Dimensions Tomo - ID 702201301
5/12/2025 to 10/27/2025

Year:	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25	25
Month:	5	5	5	6	6	6	6	6	7	7	7	7	8	8	8	8	9	9	9	9	9	10	10	10
Day:	12	19	26	2	9	16	23	30	7	14	21	28	4	11	18	25	1	8	15	22	29	6	13	20
Initials:	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF	SF



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And back to the comments from last webinar…

An opportunity to see how a digital QC book would look.

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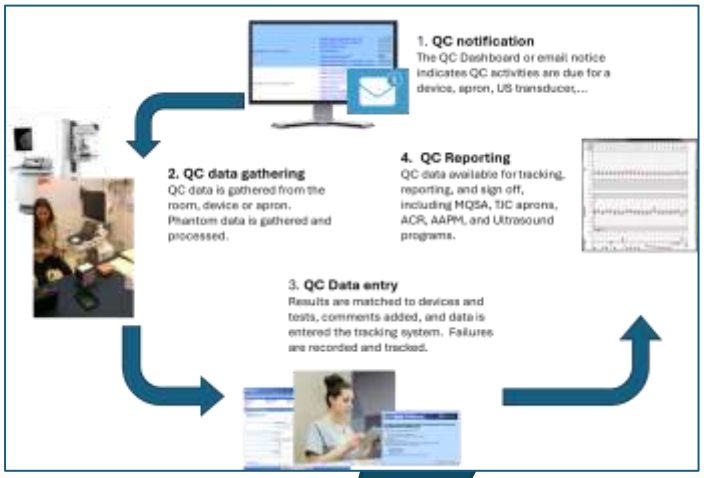
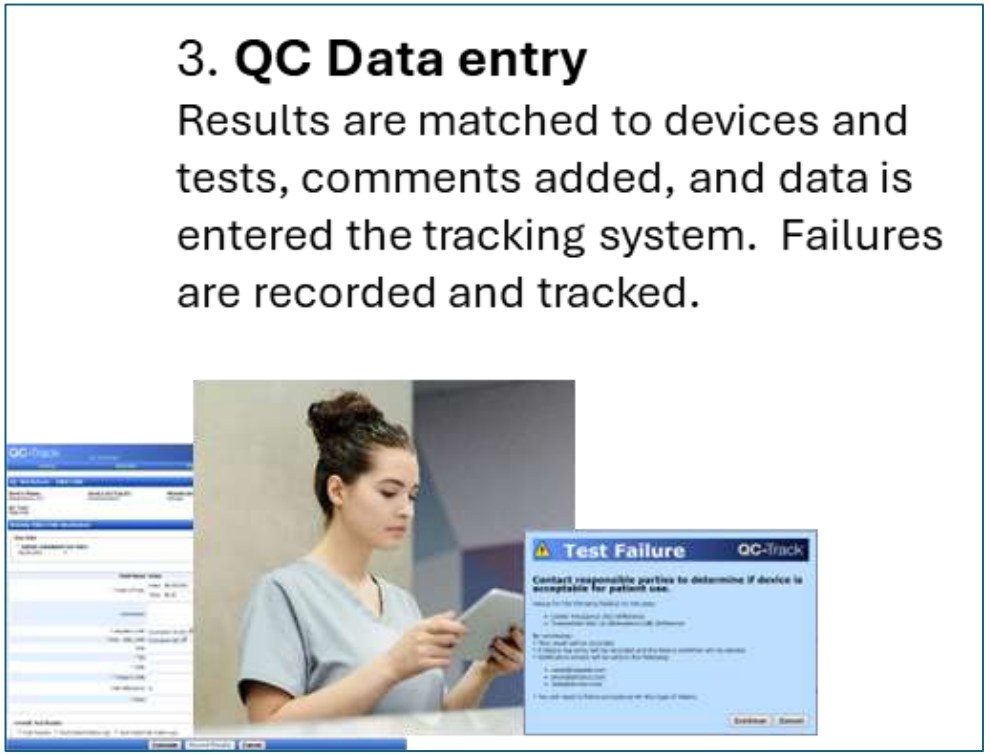
The answer is: *the book has been built along the way*





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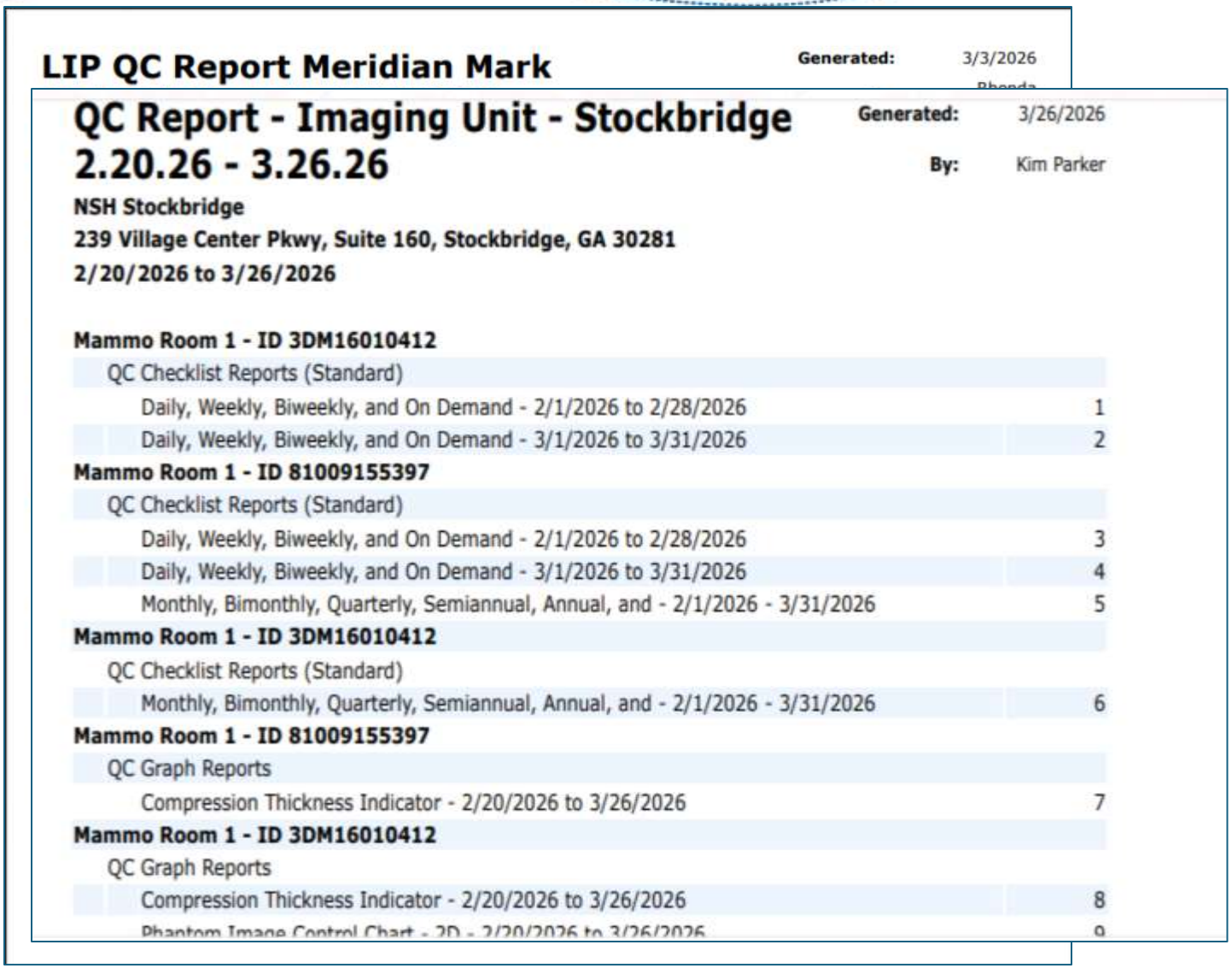
Paperless Mammography QC Part 2: Making it Work for You

For the LIP and the inspector, it's all in PDF reports that you can generate at any time



LIP QC Report Meridian Mark — **Generated:** 3/3/2026

QC Report - Imaging Unit - Stockbridge 2.20.26 - 3.26.26

Generated: 3/26/2026
By: Kim Parker

NSH Stockbridge
239 Village Center Pkwy, Suite 160, Stockbridge, GA 30281
2/20/2026 to 3/26/2026

Mammo Room 1 - ID 3DM16010412		
QC Checklist Reports (Standard)		
	Daily, Weekly, Biweekly, and On Demand - 2/1/2026 to 2/28/2026	1
	Daily, Weekly, Biweekly, and On Demand - 3/1/2026 to 3/31/2026	2
Mammo Room 1 - ID 81009155397		
QC Checklist Reports (Standard)		
	Daily, Weekly, Biweekly, and On Demand - 2/1/2026 to 2/28/2026	3
	Daily, Weekly, Biweekly, and On Demand - 3/1/2026 to 3/31/2026	4
	Monthly, Bimonthly, Quarterly, Semiannual, Annual, and - 2/1/2026 - 3/31/2026	5
Mammo Room 1 - ID 3DM16010412		
QC Checklist Reports (Standard)		
	Monthly, Bimonthly, Quarterly, Semiannual, Annual, and - 2/1/2026 - 3/31/2026	6
Mammo Room 1 - ID 81009155397		
QC Graph Reports		
	Compression Thickness Indicator - 2/20/2026 to 3/26/2026	7
Mammo Room 1 - ID 3DM16010412		
QC Graph Reports		
	Compression Thickness Indicator - 2/20/2026 to 3/26/2026	8
	Phantom Image Control Chart - 2D - 2/20/2026 to 3/26/2026	9

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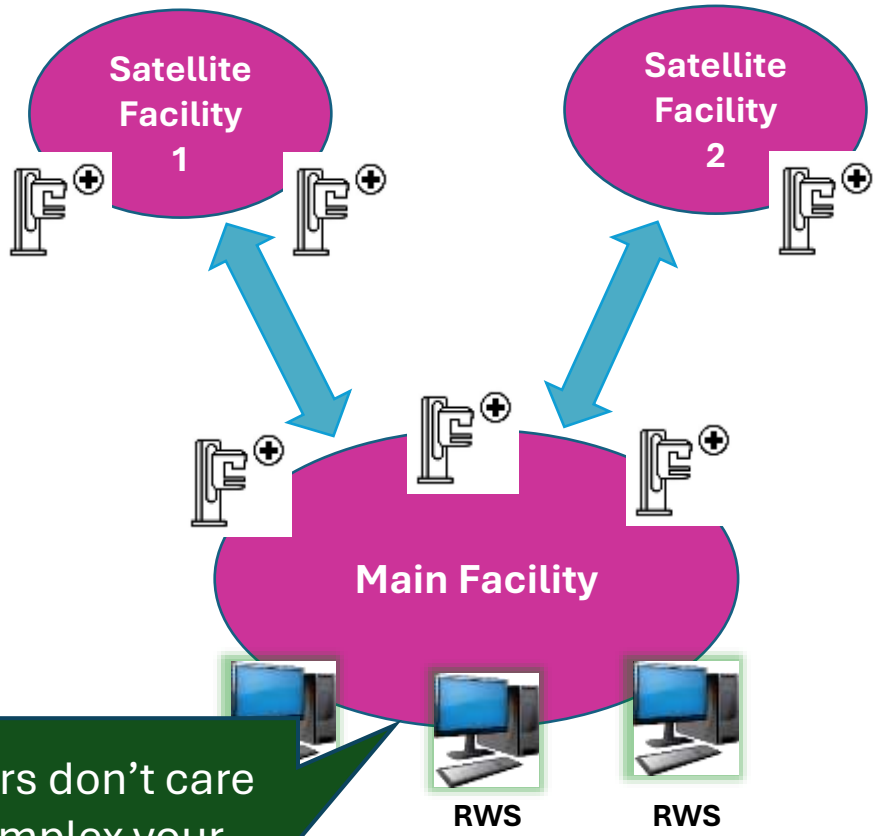
Steve Backes, CEO

Challenges in Managing Quality Control

1) WEB OF FACILITIES
2) COMMUNICATIONS
3) PERSONNEL
4) FAILURES

1) A Web of Facilities

- Often, facilities have a complicated and intertwined network of mammo machines and displays
- Sometimes management is varied for facilities
- Complex environments with a trend towards larger and larger facilities
- Some QC-Track clients have 6 or more hubs, and 7 or 8 sate around each hub



Inspectors don't care how complex your system is- they merely want to see your QC

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Steve Backes, CEO

2) Communication is Critical

Workflow in a busy mammo clinic is VERY important!

- Visibility – leadership needs to easily access QC data
- Reminders when tests are missed
- Notification when tests fail
  - Alert leadership to possible or necessary changes in workflow
  - Remind technologists to document and record notes around failure
- Defined workflow - who is doing what, when

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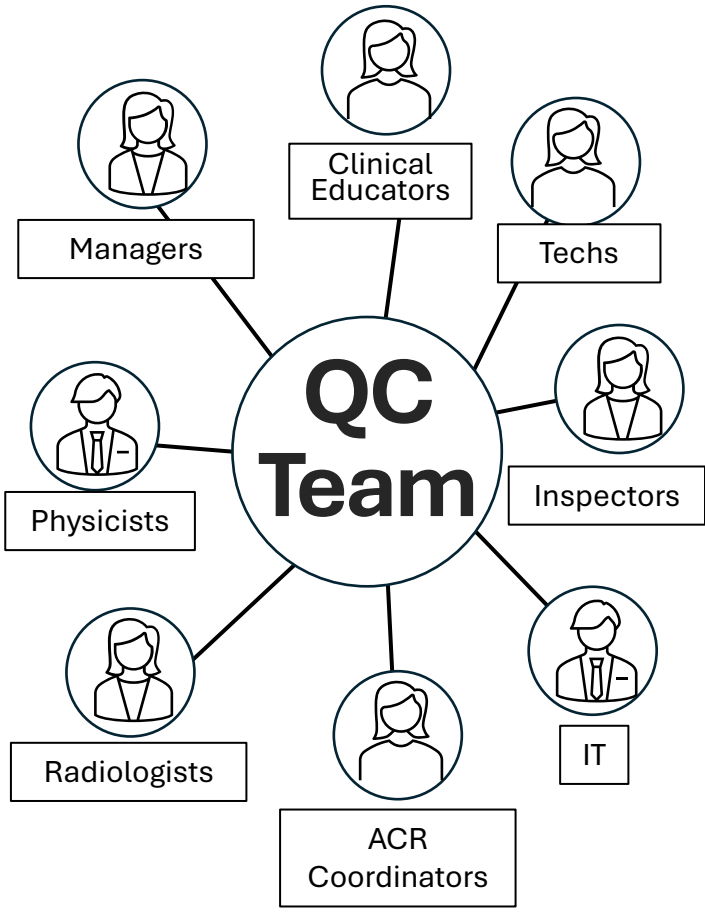
3) Personnel Considerations

- Post-COVID, teams are doing more with less
- Lots of new techs - can take several inspection cycles to build “muscle memory”
- Mergers/acquisitions, and general growth mean the number of people involved keeps getting bigger
- **How will you keep everyone on the same page about QC workflow expectations?**
- **How will you know QC is being done, and done correctly?**



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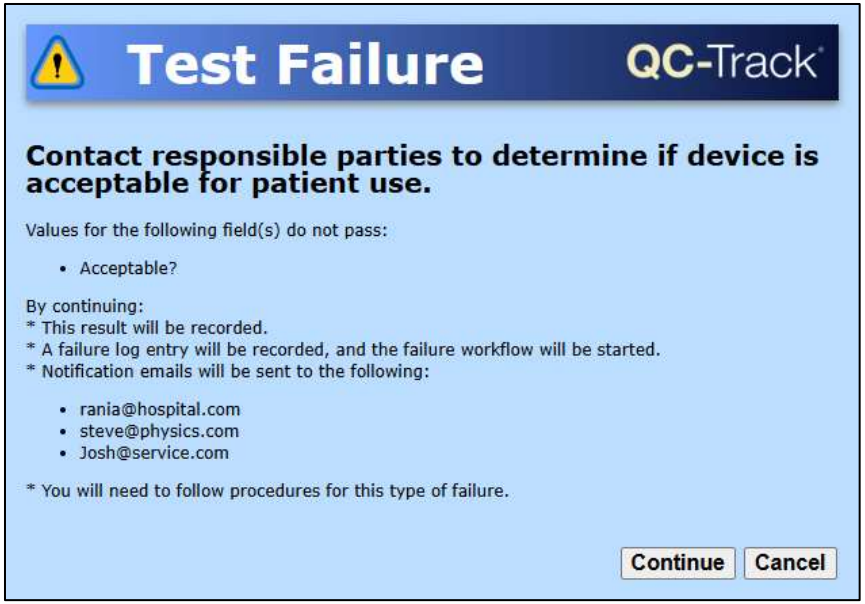
4) QC Fails!

- If we lived in a perfect world – devices would never have any issues – but that is simply not the case
- Machines fail tests
- QC is sometimes missed
- **The challenge is to minimize the impact of these failures or missed QC tests**



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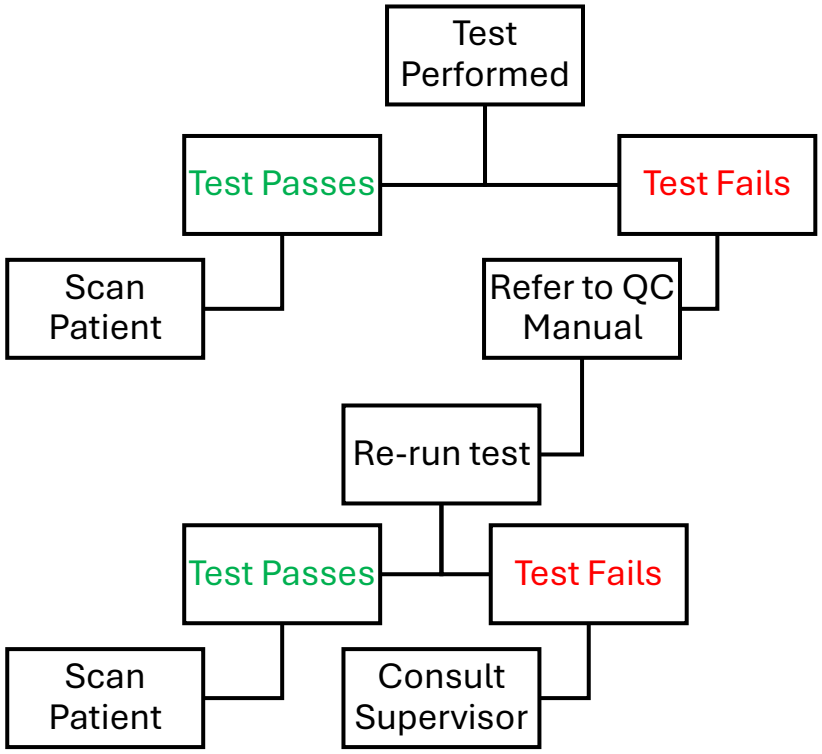
4. QC Failures & "Failure Guilt"

- Sometimes failures go unreported because equipment failure feels like a "personal failure"
- Decision trees and clear chain of command can help facilitate effective communication
- Emphasize the importance of failure tracking in fixing issues that could affect patient safety and image quality
- **"Fail on the phantom, not on the patient"**



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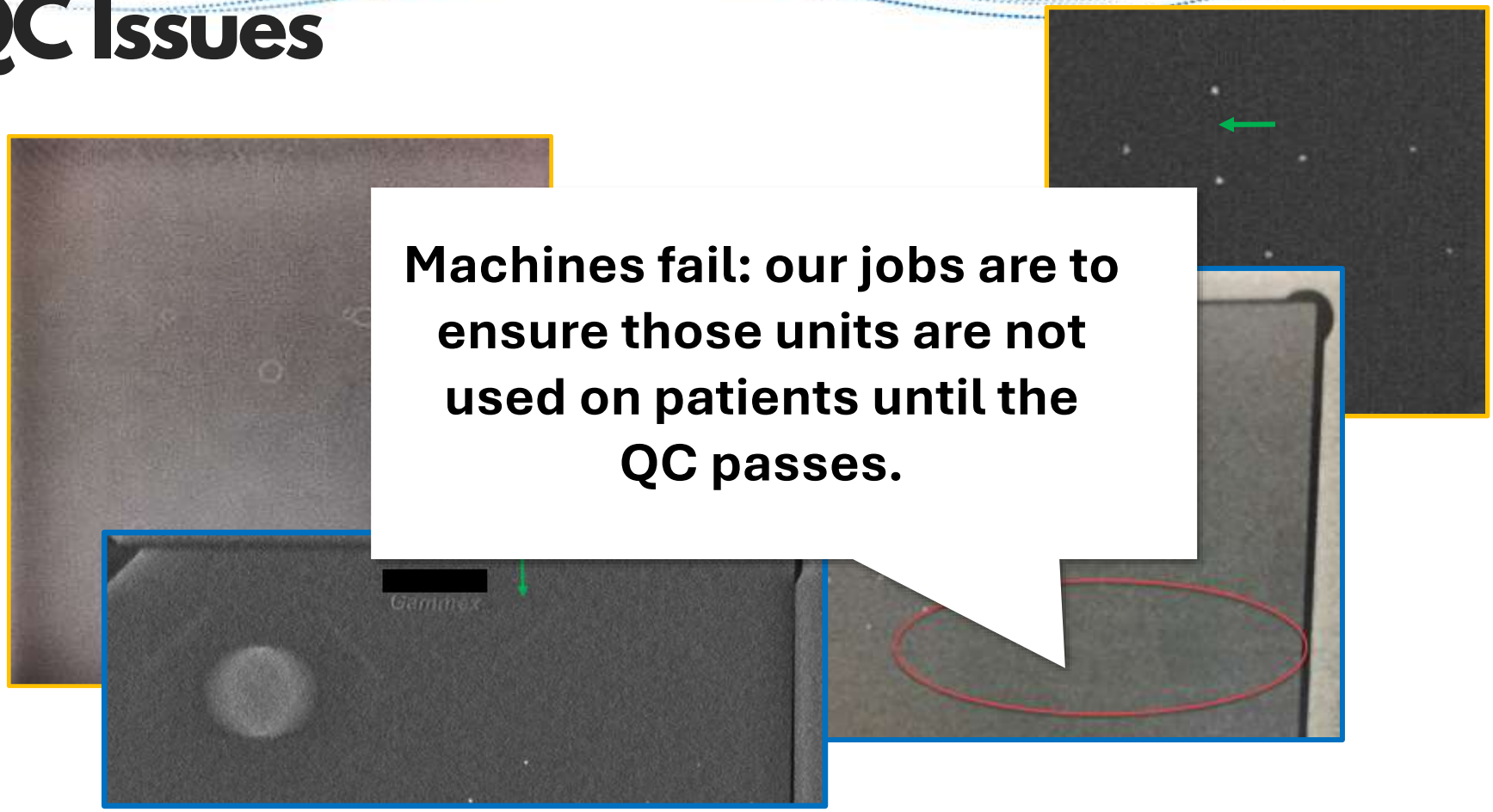
QC Issues



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Hot topics!

1) Hologic FAST mode
2) Changes in displays qc
3) In-home reading

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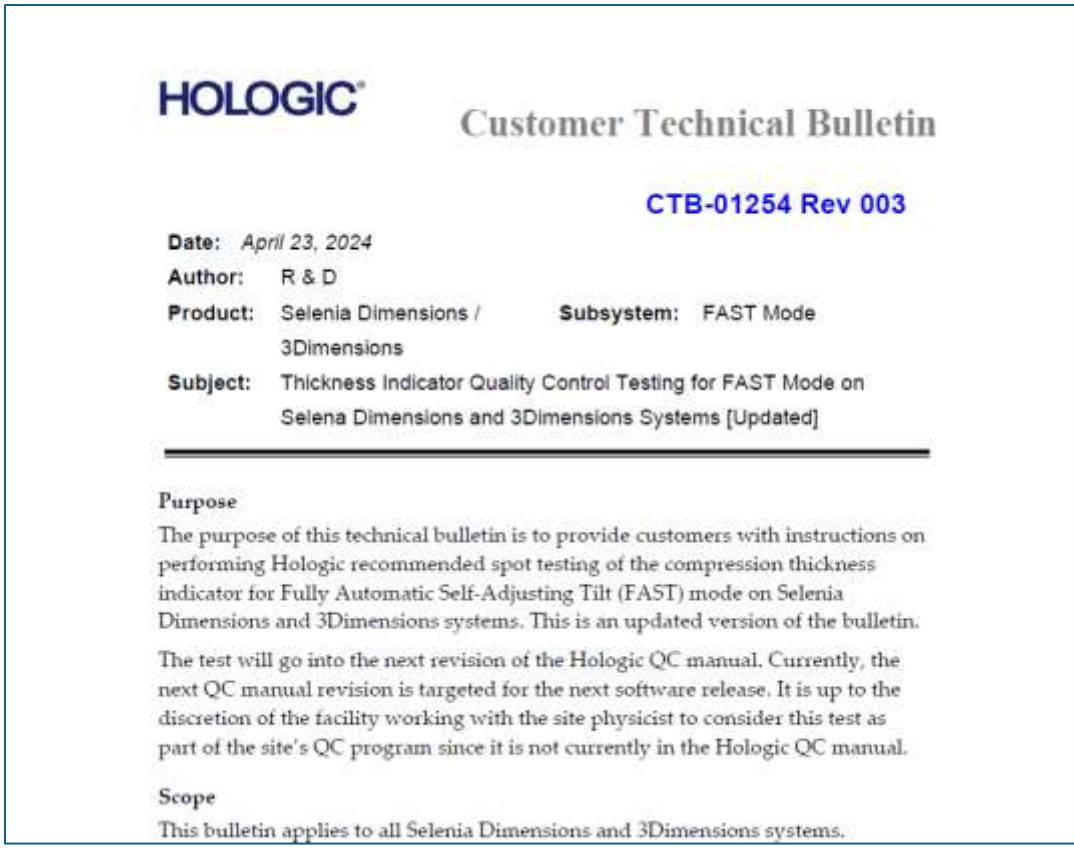
1) FULLY AUTOMATED SELF-ADJUSTING TILT (FAST) MODE

- Late 2023 – Hologic clients from around the US started sharing notifications on a new discretionary option for Compression testing
- New worksheets added to the QC-Track product
- April 2024, Hologic released updated Customer Technical Bulletin
- What's next? **Hologic FAST Mode** coming in next Hologic QC manual



HOLOGIC

Customer Technical Bulletin

CTB-01254 Rev 003

Date: *April 23, 2024*
Author: R & D
Product: Selenia Dimensions / 3Dimensions **Subsystem:** FAST Mode
Subject: Thickness Indicator Quality Control Testing for FAST Mode on Selena Dimensions and 3Dimensions Systems [Updated]

Purpose

The purpose of this technical bulletin is to provide customers with instructions on performing Hologic recommended spot testing of the compression thickness indicator for Fully Automatic Self-Adjusting Tilt (FAST) mode on Selenia Dimensions and 3Dimensions systems. This is an updated version of the bulletin.

The test will go into the next revision of the Hologic QC manual. Currently, the next QC manual revision is targeted for the next software release. It is up to the discretion of the facility working with the site physicist to consider this test as part of the site's QC program since it is not currently in the Hologic QC manual.

Scope

This bulletin applies to all Selenia Dimensions and 3Dimensions systems.

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Steve Backes, CEO

1) FAST MODE – What to do

"Currently, the next QC manual revision is targeted for the next software release. It is up to the discretion of the facility working with the site physicist to consider this test as part of the site's QC program since it is not currently in the Hologic QC manual…"

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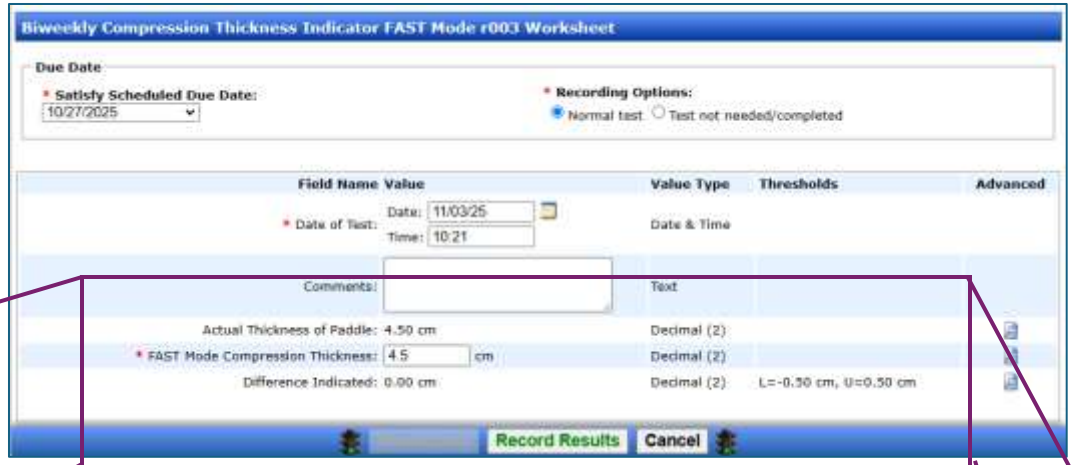
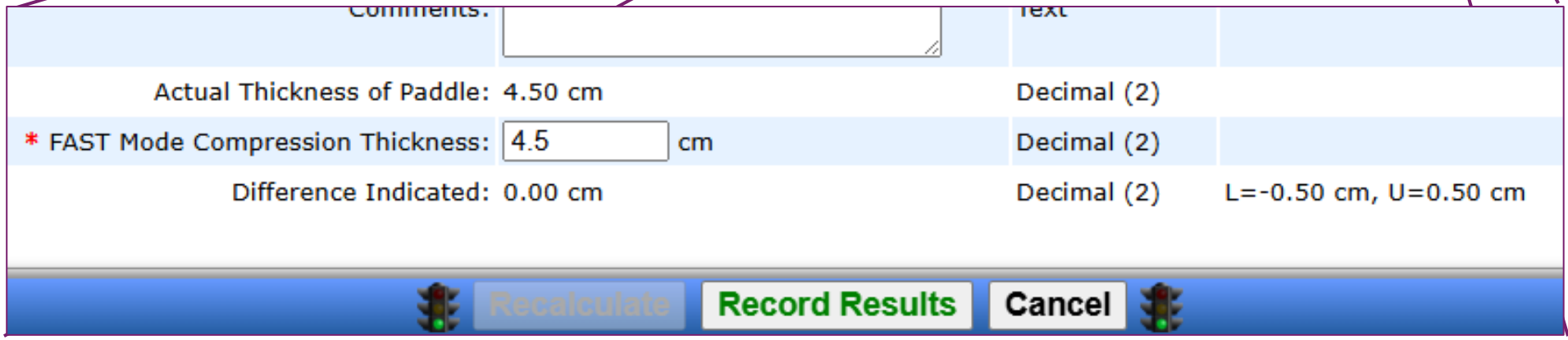
1) Hologic FAST Mode





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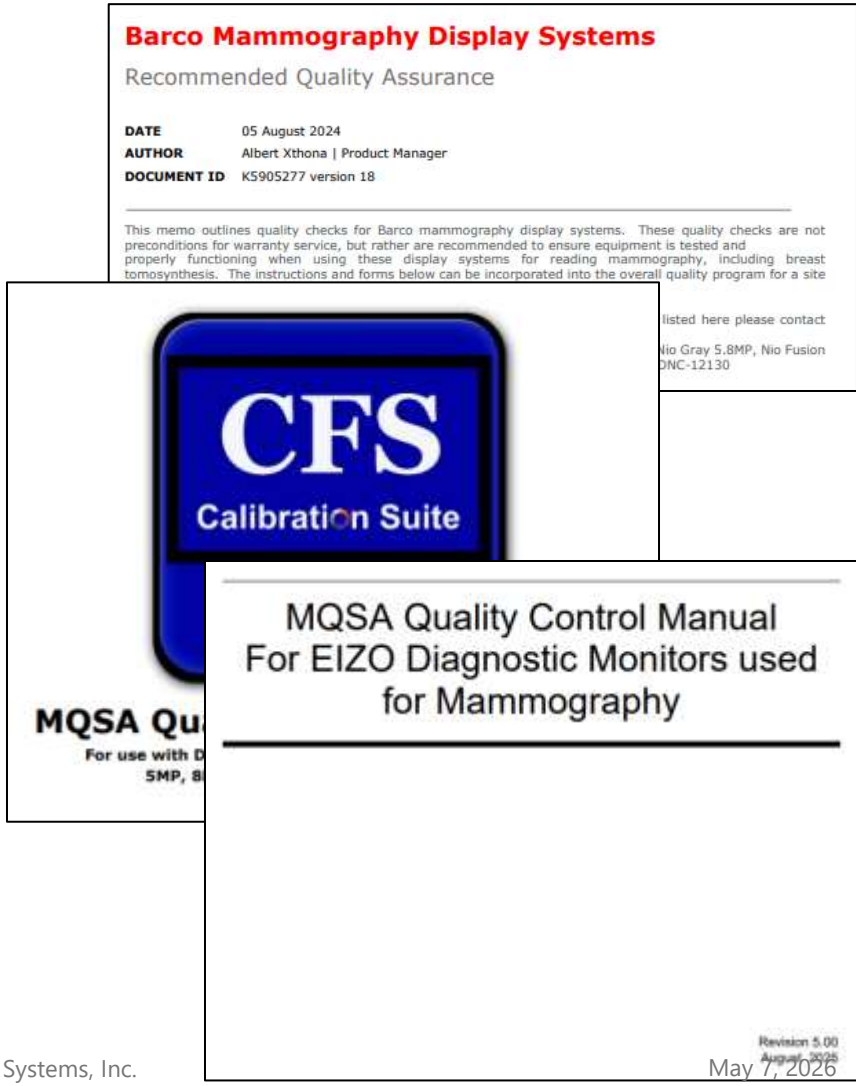
2) Mammography Display QC

Three major manufacturers -- Barco, Double Black, and Eizo -- have recently made changes to simplify QC requirements

1. Cleaning requirements removed or reduced
2. Fewer tests
3. For Barco and Double Black displays, annual physics test can be performed by physicist's trained designee



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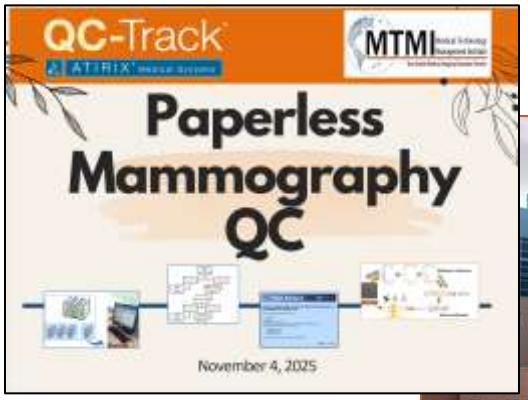
3) At-home Workstations and Mammography Display QC

- Many mammography MDs are requesting to read at home, requiring deployment of vendor supplied RWS off-site
- Completely different non-clinical environment
- How do you know QC is up to date on off-site displays?



Case Study (Nov 2025)

PAPERLESS MAMMOGRAPHY QC AT UNIVERSITY OF NEW MEXICO HOSPITAL

QC-Track at UNM Hospital

Interview: October 23, 2025

Trey Slauter, MS, DABR, CIIP

Diagnostic Medical Physicist

Interview: October 29, 2025

Aide Atayde-Law, R.T.(R)(M)

Mammography Supervisor

QC-Track at UNM Hospital

University of New Mexico is an academic health system in the Albuquerque area

- 300,000+ imaging scans each year
- Over 30 clinics

Timeline

- 2018 – initial implementation for nuclear medicine tracking
- 2021 – mammography tracking added at Sandoval Regional Medical Center
- 2023 – mammography tracking added at University of New Mexico OSIS

QC-Track Volume Statistics at UNM	2025 YTD	Since Day 1 in 2018
Mammo Worksheets DBT, Stereo, Displays QC	4,058	16,303
All Modality Worksheets Includes Mammo	21,852	120,323
Number of Reports Run	759	5,029
Number of Failures Logged	90	499

Today:

- 15 CTs
- 7 MRIs
- 4 SPECT, 2 PET
- 15 Ultrasound Base Units
- 6 Mammo Rooms
- 85 Professional Credentials

Rania Johnson, RT(R)(M)(QM), VP Client Services
Steve Backes, CEO

QC-Track at UNM - Objectives

- Centralize quality control data
- Automate data entry and calculations
- Improve communication with email reminders
- Make reporting fast and easy
- Make it easy for managers and physicists to review QC

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Steve Backes, CEO

QC-Track at UNM - Impact

From Aide:
"It's really easy. Before, we were spending a lot of time flipping through the books and counting CEs by hand – now, QC-Track does those calculations for us."

From Trey:
"QC-Track helped eliminate ambiguity around who is responsible for which step in the QC process"

Rania Johnson, RT(R)(M)(QM), VP Client Services
Steve Backes, CEO

Paperless QC @ UNM – Lessons Learned

1. *Change is hard!* – be present to answer questions and prevent bad habits
2. Technologists have different learning styles – be prepared to use different training approaches for different people
3. Have a computer in the mammo room that is physically close to the scanner, or on wheels
4. Commit to the transition – don't double up on books; enter test results straight into QC-Track

From Aide:
"It's no different from books. You just set a schedule, enter in the data, and review every quarter. Don't be afraid of change!"

Rania Johnson, RT(R)(M)(QM), VP Client Services
Steve Backes, CEO

OK, after the last webinar… Aide and I talked

- Aide – "LOVED the presentation"
- "Now do a follow up webinar that goes to the next step -- Making it work for you!"
- Aide and I worked out the scenarios

Aide Atayde-Law R.T. (R) (M)
OSIS Mammography Supervisor

Rania Johnson, R.T.(R)(M)(QM)
Vice President, Client Services
Atirix Medical Systems

Case Study – "QC is a Team Sport!"

PAPERLESS MAMMOGRAPHY QC AT UNIVERSITY OF NEW MEXICO HOSPITAL

Rania Johnson, RT(R)(M)(QM), VP Client Services
Steve Backes, CEO

May 7, 2026

QC-Track at UNM Hospital

Aide Atayde-Law, R.T.(R)(M)

Mammography Supervisor

Interviews:

- February 19, 2026
- March 24, 2026

Aide: "Think like an inspector"

1. Aligned Team
2. Credentials
3. Failure handling
4. Reports

Rania Johnson, RT(R)(M)(QM), VP Client Services
Steve Backes, CEO

1 – Align the Team

- Radiologists, physicists, and inspectors like to see consistency
  - QC-Track helps enforce structure
- Have staff backups identified and delegate responsibilities
  - QC-Track makes it easy for everyone to access data
- Challenge: *time lags* can impact operational buy-in
  - Between decision and funding
  - Between funding and getting going

Rania Johnson, RT(R)(M)(QM), VP Client Services
Steve Backes, CEO

1 – Align the Team

- "The Triad" team is involved in helping Aide with decisions when issues come up
  - LIP
  - Medical Physics
  - Clinical Engineering
- With QC-Track, simultaneous emails help speed up communications, get everyone on the same page

From Aide:
"Make sure everyone understands the decision tree for when issues come up"

Rania Johnson, RT(R)(M)(QM), VP Client Services
Steve Backes, CEO

2 – Credentials

- At UNM the technologists manage their own credentials, and are responsible for keeping their credits and exams up to date

- Aide's Pro tip -- Get a decent scanner!
  - Orient it properly and get the right settings
  - Train the team

From Aide:
"Cleaned up credentials helps head off one of the issues inspectors look for first"

Rania Johnson, RT(R)(M)(QM), VP Client Services
Steve Backes, CEO

3 – Clear rules for failure handling

When and how to involve "the Triad" when failures happen

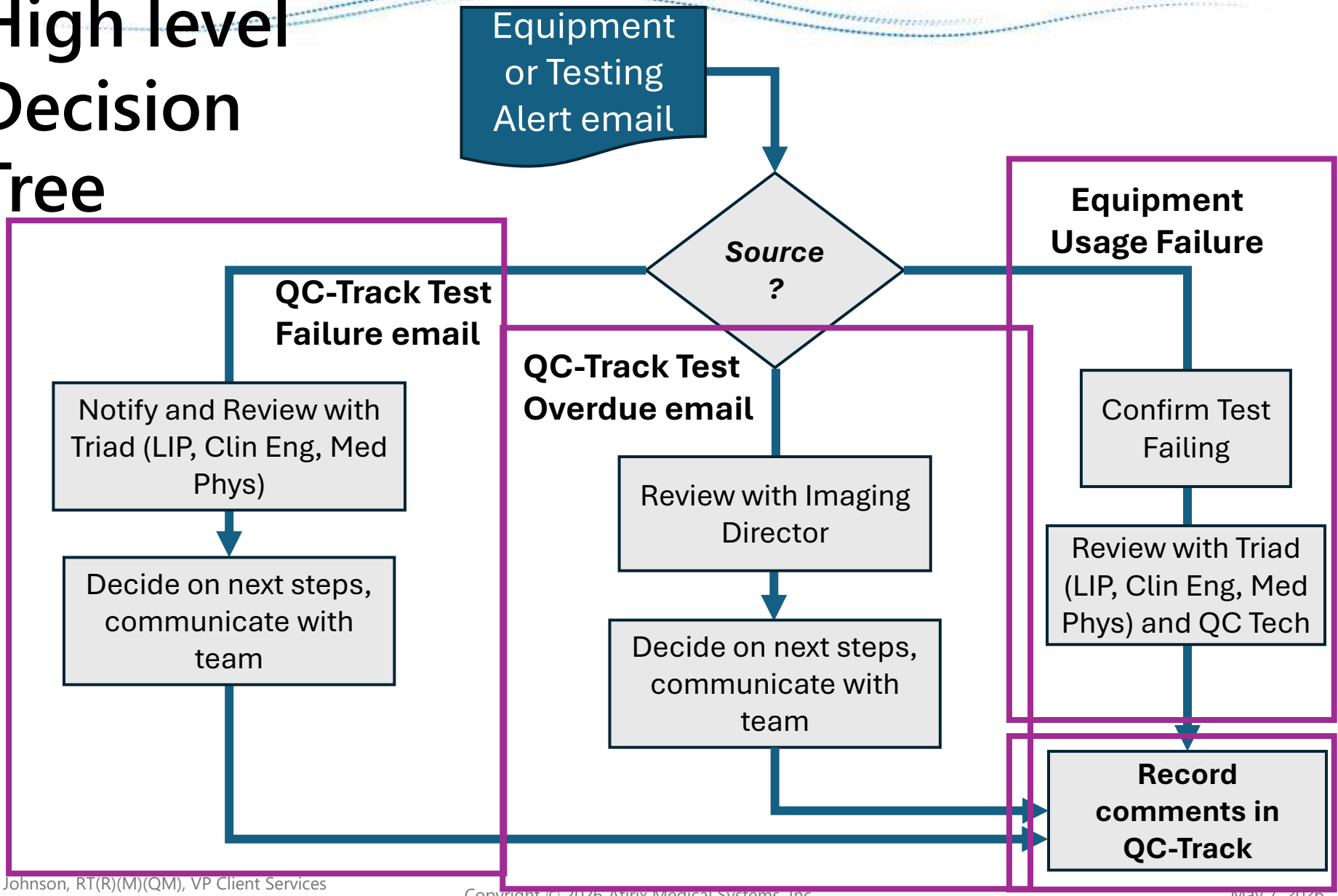
Aide sees 2 types of failures

- 1) Equipment failures
  - 1) Failure identified during QC
  - 2) Equipment failure during day-to-day use
    - QC fails are emailed by QC-Track so seen simultaneously
    - Process include confirming the equipment is still failing
- 2) Process failures
  - Overdue QC tests
    - Automatically emailed, and Aide reviews these with Jane, her Imaging Director
    - Typical situation – Affirm QC not done because the unit wasn't used
- In all cases, the group decides on next steps, then communicates with the team

From Aide:
"The decision tree helps make sure the right team is involved, and the QC-Track emails help that process"

Rania Johnson, RT(R)(M)(QM), VP Client Services
Steve Backes, CEO

High level Decision Tree



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4 - Reports

1. QC Reports include LIP Sign-Off, Physicist oversight, ACR renewal, Internal management, Repeat/ reject analysis, Inspection, Credentials, …

2. New tools for staff engagement
   - In staff meetings for on-going learning and process improvement
   - Easy communications and signoffs with the LIP

From Aide:
"Big win: Inspection preparation - goes from 2 weeks of prep to generating PDF reports the day before inspection"

Rania Johnson, RT(R)(M)(QM), VP Client Services
Steve Backes, CEO

More Aide Advice: "*Keep your sites in synch*"

- Sister site : Sandoval Medical Center
  - Part of UNM Health System
  - New mammo supervisor
- The sites share an LIP and a physicist – so easier for the LIP and Physicist if everything is consistent
  - QC
  - Credentials Tracking
  - LIP Signoff
- Observation – the more sites use the product, the more comfortable they are with it

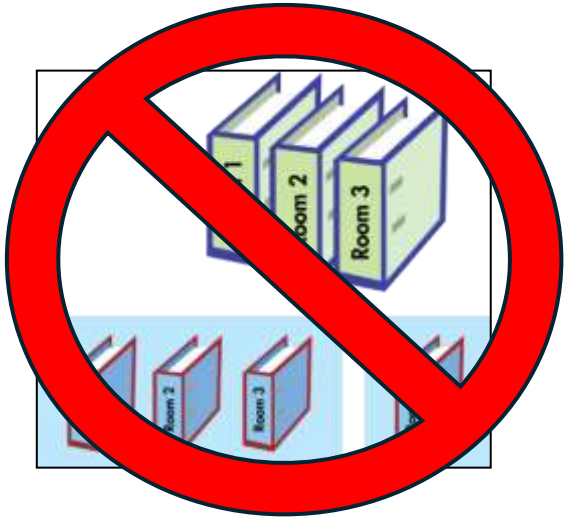
From Aide:

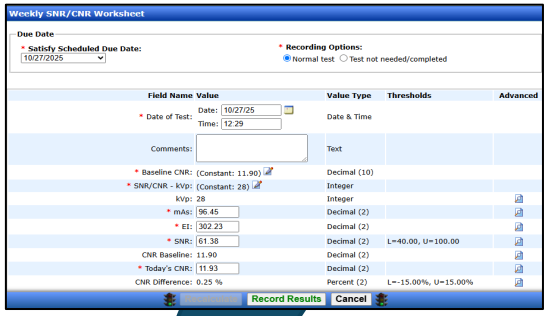
"If you don't use it, you lose it"

Rania Johnson, RT(R)(M)(QM), VP Client Services
Steve Backes, CEO

Paperless Mammography QC
Part 2: Making it Work for You

Aide's Final Advice: "*Rip the band aid off!*"




Weekly SNR/CNR Worksheet

Due Date

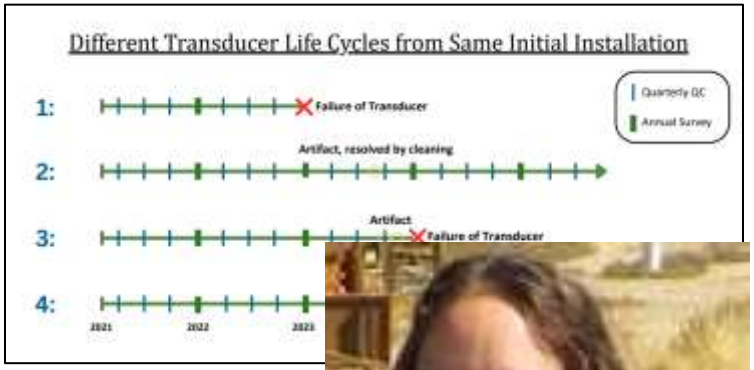
* Satisfy Scheduled Due Date: 10/27/2025

* Recording Options: Normal test / Test not needed/completed

Field Name	Value	Value Type	Thresholds	Advanced
* Date of Test:	Date: 10/27/25 Time: 12:29	Date & Time		
Comments:		Text		
* Baseline CNR:	(Constant: 11.90)	Decimal (10)		
* SNR/CNR - kVp:	(Constant: 28)	Integer		
kVp:	28	Integer		
* mAs:	96.45	Decimal (2)		
* Et:	302.23	Decimal (2)		
* SNR:	61.38	Decimal (2)	L=40.00, U=100.00	
CNR Baseline:	11.90	Decimal (2)		
* Today's CNR:	11.93	Decimal (2)		
CNR Difference:	0.25 %	Percent (2)	L=-15.00%, U=15.00%	

Record Results | Cancel

Rania Johnson, RT(R)(M)(QM), VP Client Services
Steve Backes, CEO



ATIRIX RESEARCH: DENSE BREAST TECHNOLOGIES

Angela Snyder, PhD
VP, Biomedical Engineering and Research

1) Contrast-Enhanced Mammography

2) Breast Ultrasound

3) Molecular Breast Imaging (MBI)

4) Breast MRI

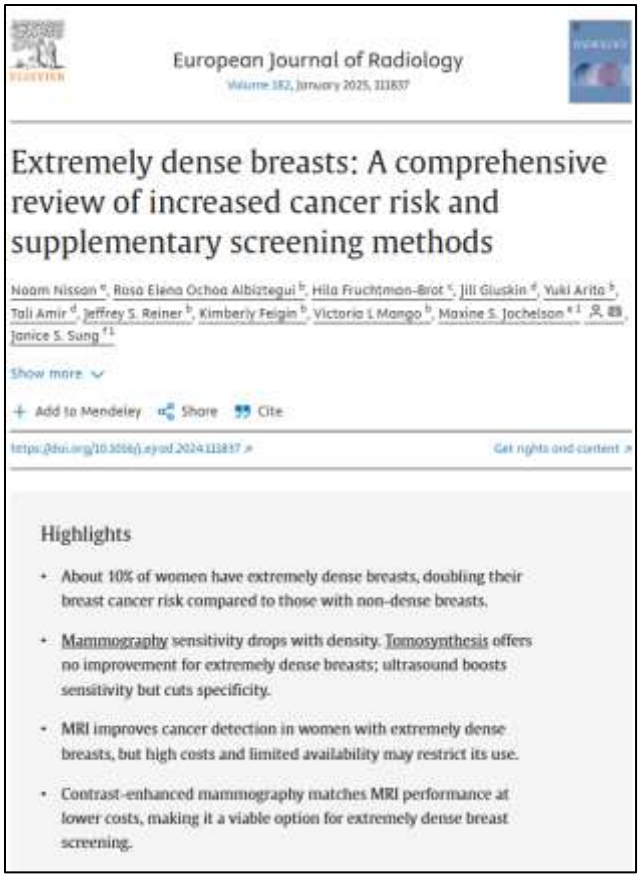
Rania Johnson, RT(R)(M)(QM), VP Client Services
Steve Backes, CEO

Atirix Research and Future Directions

Major Question: How to improve *screening* for patients with extremely dense breasts?

1. Contrast-Enhanced Mammography
2. Breast Ultrasound
3. Molecular Breast Imaging (MBI)
4. Breast MRI

And what are the implications for QC?



European Journal of Radiology

Extremely dense breasts: A comprehensive review of increased cancer risk and supplementary screening methods

Noam Nissan [a], Rosa Elena Ochoa Albiztegui [b], Hila Fruchtman-Brot [c], Jill Gluskin [d], Yuki Arita [b], Tali Amir [d], Jeffrey S. Reiner [b], Kimberly Feigin [b], Victoria L Mango [b], Maxine S. Jochelson [e,1], Janice S. Sung [f,1]

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Highlights

- About 10% of women have extremely dense breasts, doubling their breast cancer risk compared to those with non-dense breasts.
- Mammography sensitivity drops with density. Tomosynthesis offers no improvement for extremely dense breasts; ultrasound boosts sensitivity but cuts specificity.
- MRI improves cancer detection in women with extremely dense breasts, but high costs and limited availability may restrict its use.
- Contrast-enhanced mammography matches MRI performance at lower costs, making it a viable option for extremely dense breast screening.

Rania Johnson, RT(R)(M)(QM), VP Client Services
Steve Backes, CEO

Research and Future Directions

Modality	Pros	Cons	New Considerations
Contrast-Enhanced Mammography	Sensitivity, Cost	Department workflow challenges	Expanding QC requirements, workflow development
Breast Ultrasound	Sensitivity, Availability, Cost	Less Specificity	Better QC
Molecular Breast Imaging (MBI)	High Sensitivity	Limited Availability, Cost, Workflow challenges	Cadmium Zinc Telluride (CZT) detectors with very high resolution
Breast MRI	High Sensitivity	Cost	Low-cost systems and higher sensitivity receive coils being developed

How does QC need to evolve to keep up with these advances in dense breast screening technologies?

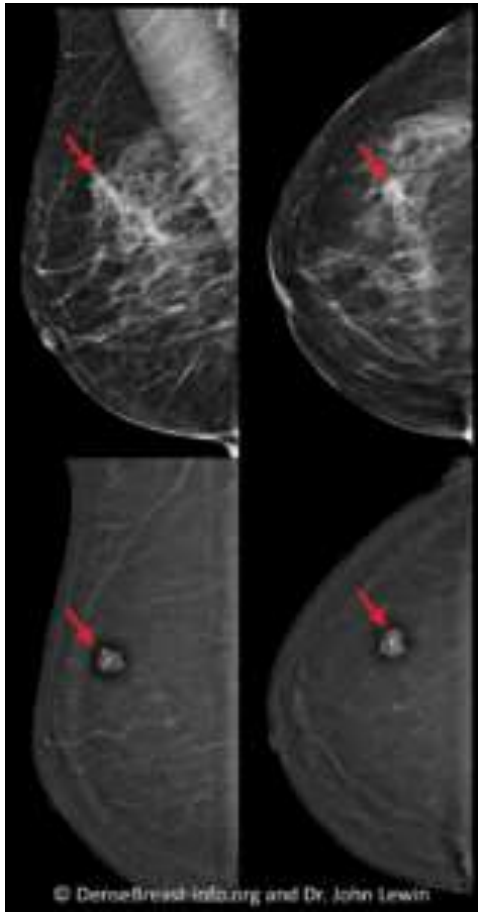
Rania Johnson, RT(R)(M)(QM), VP Client Services
Steve Backes, CEO

1. Contrast-Enhanced Mammography

- Effective and affordable – starting to see a more uptake
- Logistical challenges – starting an IV, additional patient screening, contrast reaction procedures

QC Considerations testing requirements vary greatly across vendors; how to compare?

Research Objectives – *Future Work…*



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2. Research – Breast Ultrasound QC

Collaboration with UT Southwestern / Parkland Hospital and Health System, Dallas, TX

If you want to add screening ultrasound - QC Considerations

- ACR Ultrasound QC has few requirements, especially relative to mammography
  - Annual testing required per ACR
  - QC Teams need to determine test and frequencies
- Image quality is still important for diagnostic power
- Uniformity is an important aspect of quality and a frequent source of failure in ultrasound

Research Objective: Faster and less subjective uniformity test method

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Steve Backes, CEO

Toward an Objective Metric of Uniformity in Ultrasound

Asher Shertok
University of Minnesota, student, Biomedical Engineering
Intern, Atirix Medical Systems, 2024 - present

"Annual testing alone is inadequate to ensure image quality as an issue arising shortly after annual inspection could result in a whole year of inadequate image quality."

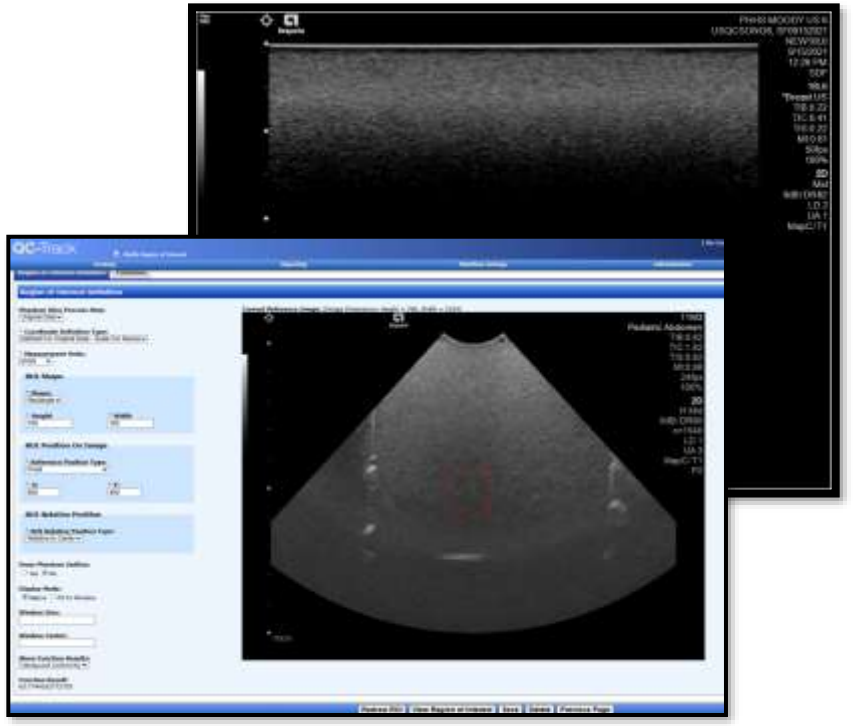
-Jaqueline Gallet, PhD,
Ultrasound Physicist at UT Southwestern (retired 2026)

Toward an Objective Metric of Uniformity in Ultrasound

Asher Shertok
University of Minnesota, student, Biomedical Engineering
Intern, Atirix Medical Systems, 2024 - present

Features of a good metric for US uniformity:

- Quantitative and objective
- Captures speckle and brightness variation
- Practical to measure routinely



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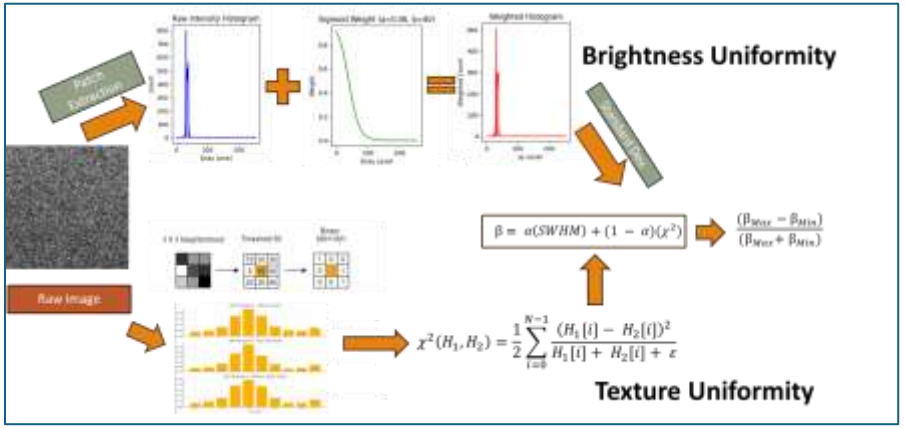
Toward an Objective Metric of Uniformity in Ultrasound

Asher Shertok

Approach

- Algorithm analyzes brightness and texture uniformity



Data from Parkland/UT Southwestern

- 6 ultrasound units with 20 transducers
- 2 Manufacturers
- Quarterly uniformity images acquired by technologists on each transducer

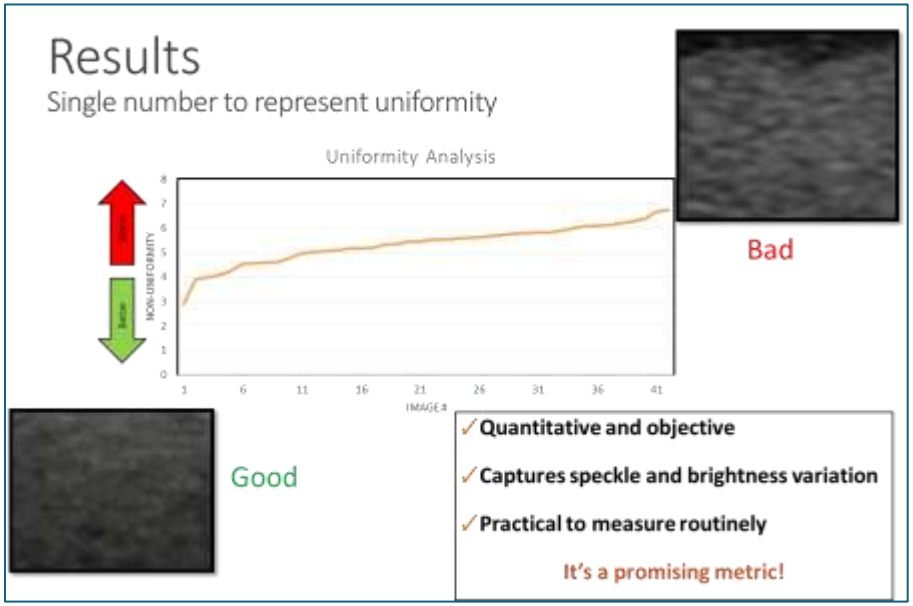
New

Asher's work was presented at
NCC-AAPM Meeting
Young Investigators' Competition
La Crosse, WI, October 17, 2025
** *and* **
Accepted as a Poster!
AAPM Annual Meeting,
Vancouver, BC, Jul 19-22, 2026

Toward an Objective Metric of Uniformity in Ultrasound

Asher Shertok

- Conclusion: Promising metric!
- Next steps
  - Continue testing against data sets
  - Evaluate in a radiology department
  - Poster (AAPM), Paper?
    - Accepted as a Feature Article in AHRA LINK



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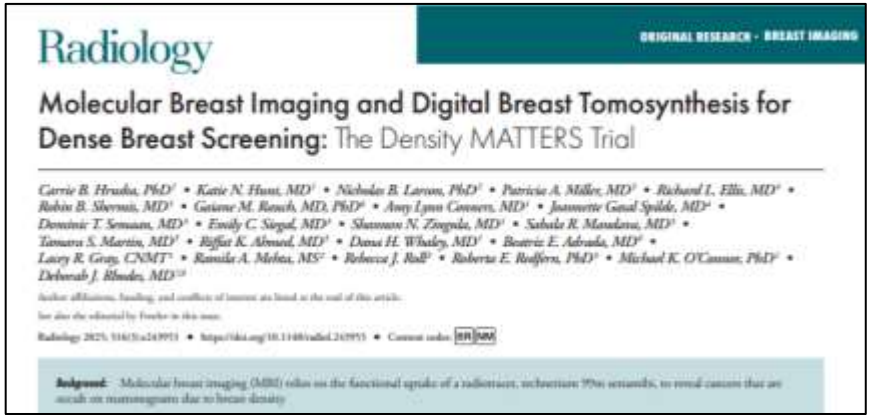
3. Research – MBI QC

MBI shows increased cancer detection over mammography alone, particularly for dense breast tissue (See Radiology Sept 2025 article)


Radiology

ORIGINAL RESEARCH • BREAST IMAGING

Molecular Breast Imaging and Digital Breast Tomosynthesis for Dense Breast Screening: The Density MATTERS Trial

QC Considerations

- QC recommendations largely follow standard gamma camera QC
- MBI units commonly have CZT detectors
- CZT (Cadmium Zinc Telluride) detectors are a new technology for nuc med with much higher resolution than previous detectors

Research Objective
Determine a method to monitor resolution changes for MBI

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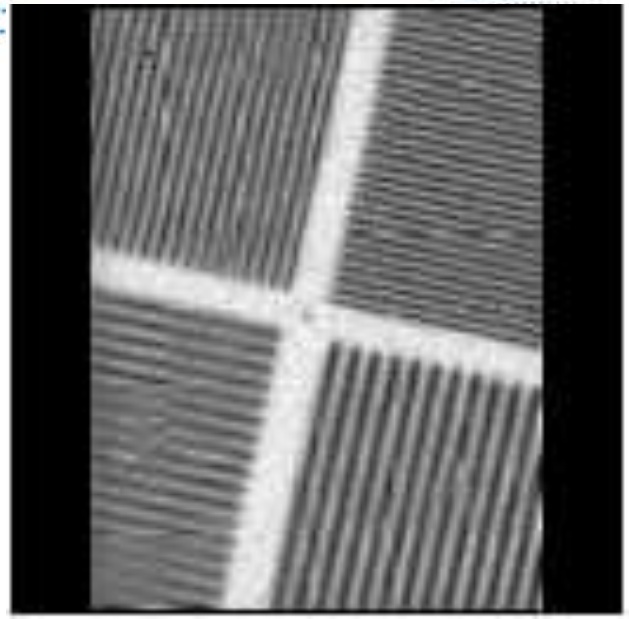
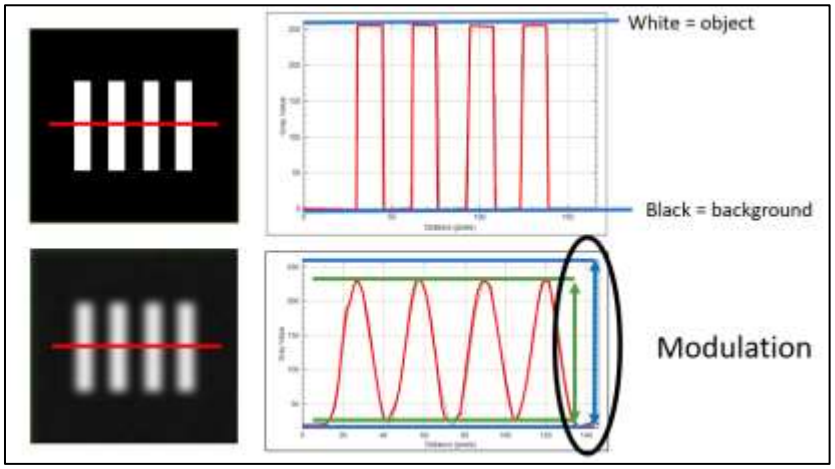
3. Research – MBI QC



- Typical testing: determine largest bars section that is “resolvable” (not blurry)
- Reality with CZT: *all bars are resolvable!*

- Research is demonstrating that a mathematical method for evaluation of resolution works for MBI



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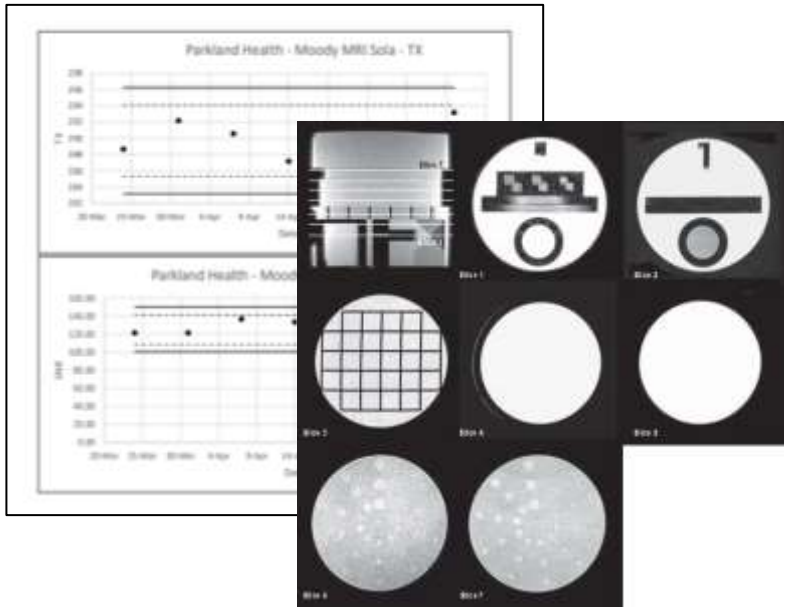
4. Breast MRI QC

- Challenge: QC needs to capture the bilaterality
- Initial implementation at a busy breast center shows good sensitivity and consistency



Research Objective: Validate method for breast MRI testing with bilateral coils

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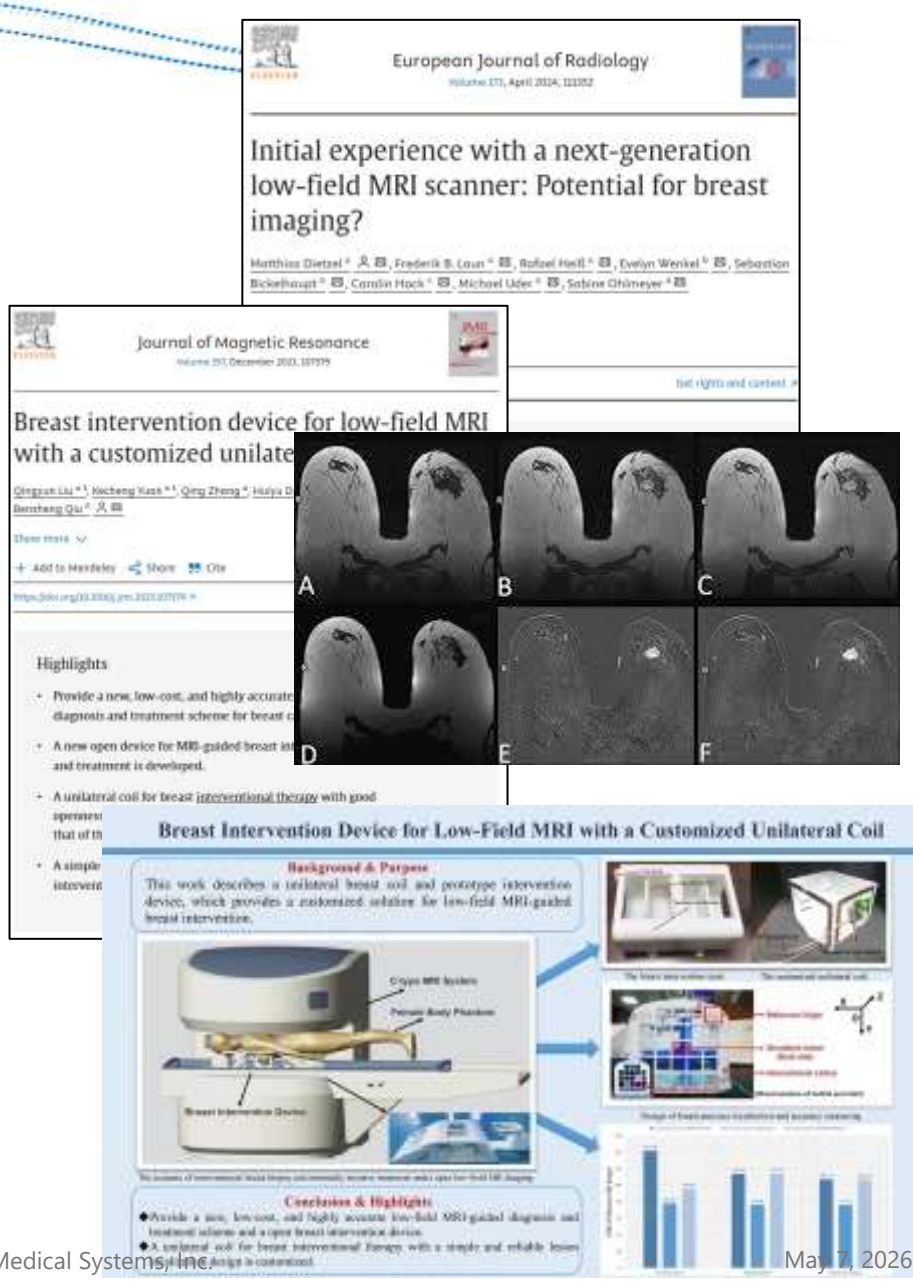
Paperless Mammography QC Part 2: Making it Work for You

4. Breast MRI QC

Promising research on Low-Field, Low-Cost MRI, as low as .2 T, could impact its accessibility as a screening tool

- Local multi-channel bilateral receive coils increase SNR
- *Note*: new QC approach should work for low field units



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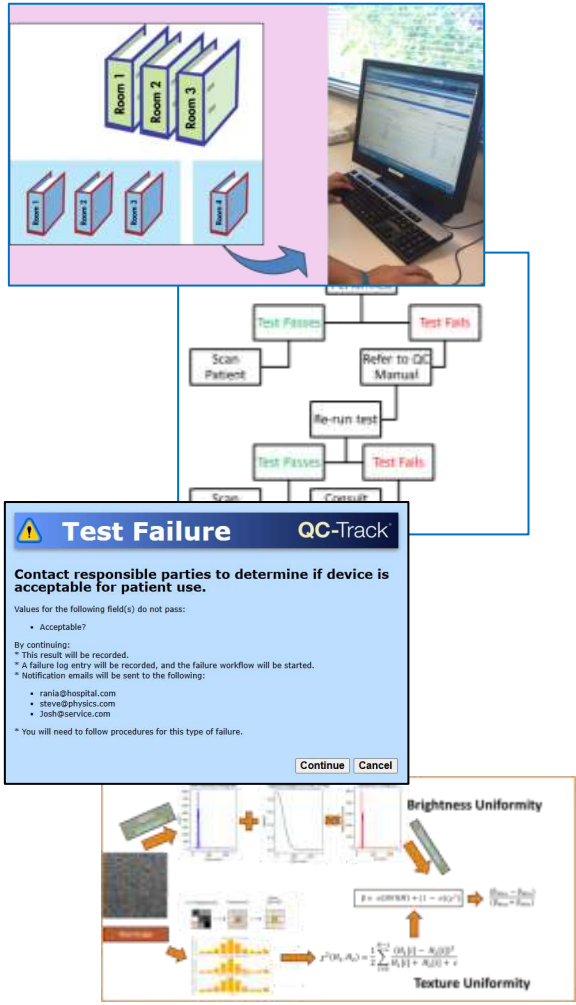
Conclusions

- Paperless QC involves a team, and can be a helpful tool for delegation
- A paperless QC solution also can help improve communication and enhance team harmony
- QC continues to change, e.g. compression thickness testing for FAST Mode
- Implementing paperless? *"Rip the band aid off!"*
- Keep an eye out for new diagnostic technologies and QC approaches



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Paperless Mammography QC
Part 2: Making it Work for You

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Questions?

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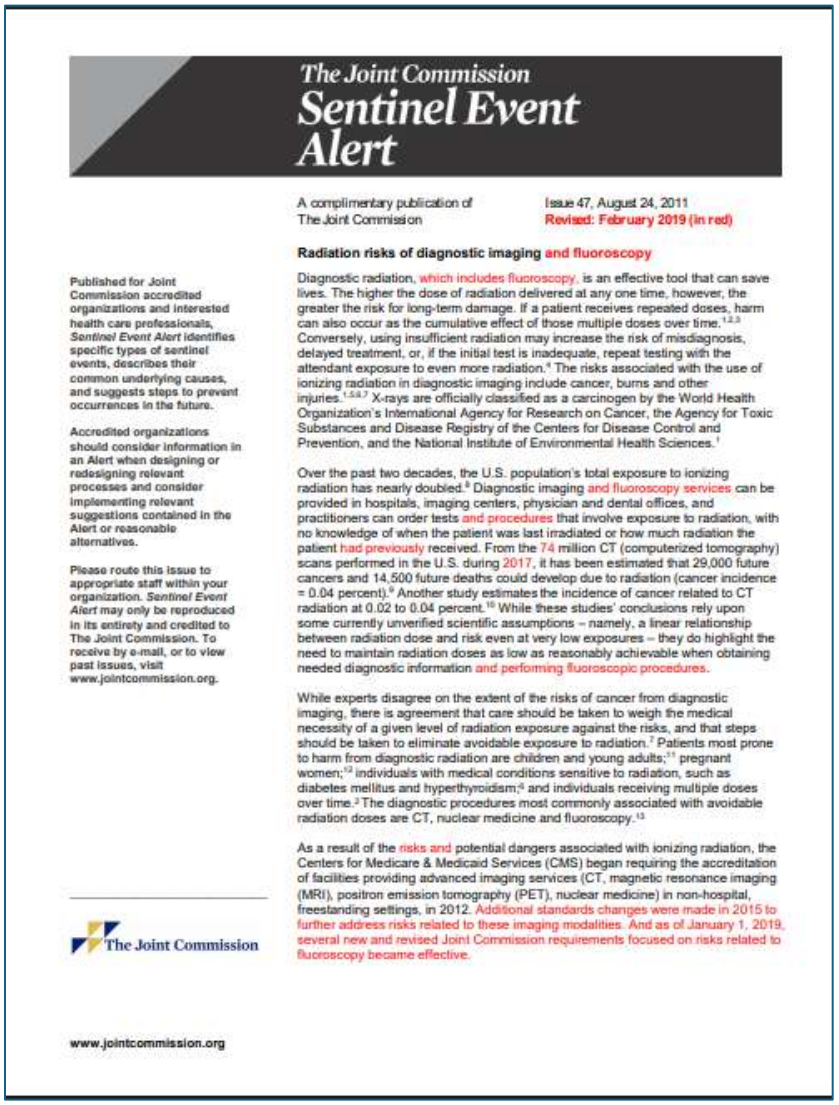
References

- Handbook of Basic Quality Control Tests for Diagnostic Radiology, 2023.
  - https://www.iaea.org/publications/14890/handbook-of-basic-quality-control-tests-for-diagnostic-radiology
- Institute for Healthcare Improvement, "SBAR Tool: Situation-Background-Assessment-Recommendation", ihi.org
- Sentinel Event Alert 47 is published by The Joint Commission.
  - See Addendum 1 for the entire Sentinel Event Alert 47
- Hospital Accreditation Survey Process Guide is published by The Joint Commission.

Paperless Mammography QC Part 2: Making it Work for You

Addendum 1, TJC Sentinel Event Alert 47



The Joint Commission
Sentinel Event Alert

A complimentary publication of The Joint Commission

Issue 47, August 24, 2011
Revised: February 2019 (in red)

Published for Joint Commission accredited organizations and interested health care professionals, *Sentinel Event Alert* identifies specific types of sentinel events, describes their common underlying causes, and suggests steps to prevent occurrences in the future.

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Radiation risks of diagnostic imaging and fluoroscopy

Diagnostic radiation, which includes fluoroscopy, is an effective tool that can save lives. The higher the dose of radiation delivered at any one time, however, the greater the risk for long-term damage. If a patient receives repeated doses, harm can also occur as the cumulative effect of those multiple doses over time.[1,2,3] Conversely, using insufficient radiation may increase the risk of misdiagnosis, delayed treatment, or, if the initial test is inadequate, repeat testing with the attendant exposure to even more radiation.[4] The risks associated with the use of ionizing radiation in diagnostic imaging include cancer, burns and other injuries.[1,5,6,7] X-rays are officially classified as a carcinogen by the World Health Organization's International Agency for Research on Cancer, the Agency for Toxic Substances and Disease Registry of the Centers for Disease Control and Prevention, and the National Institute of Environmental Health Sciences.[1]

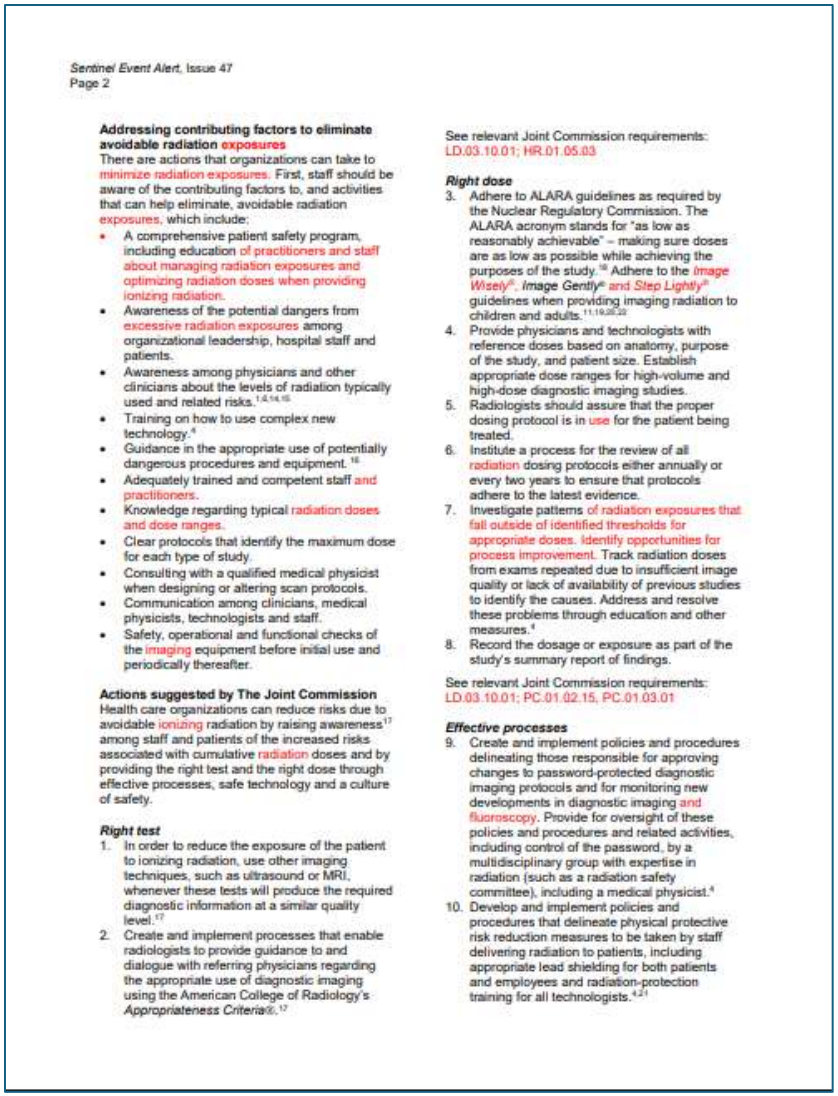
Over the past two decades, the U.S. population's total exposure to ionizing radiation has nearly doubled.[8] Diagnostic imaging and fluoroscopy services can be provided in hospitals, imaging centers, physician and dental offices, and practitioners can order tests and procedures that involve exposure to radiation, with no knowledge of when the patient was last irradiated or how much radiation the patient had previously received. From the 74 million CT (computerized tomography) scans performed in the U.S. during 2017, it has been estimated that 29,000 future cancers and 14,500 future deaths could develop due to radiation (cancer incidence = 0.04 percent).[9] Another study estimates the incidence of cancer related to CT radiation at 0.02 to 0.04 percent.[10] While these studies' conclusions rely upon some currently unverified scientific assumptions – namely, a linear relationship between radiation dose and risk even at very low exposures – they do highlight the need to maintain radiation doses as low as reasonably achievable when obtaining needed diagnostic information and performing fluoroscopic procedures.

While experts disagree on the extent of the risks of cancer from diagnostic imaging, there is agreement that care should be taken to weigh the medical necessity of a given level of radiation exposure against the risks, and that steps should be taken to eliminate avoidable exposure to radiation.[7] Patients most prone to harm from diagnostic radiation are children and young adults;[11] pregnant women;[12] individuals with medical conditions sensitive to radiation, such as diabetes mellitus and hyperthyroidism;[6] and individuals receiving multiple doses over time.[3] The diagnostic procedures most commonly associated with avoidable radiation doses are CT, nuclear medicine and fluoroscopy.[13]

As a result of the risks and potential dangers associated with ionizing radiation, the Centers for Medicare & Medicaid Services (CMS) began requiring the accreditation of facilities providing advanced imaging services (CT, magnetic resonance imaging (MRI), positron emission tomography (PET), nuclear medicine) in non-hospital, freestanding settings, in 2012. Additional standards changes were made in 2015 to further address risks related to these imaging modalities. And as of January 1, 2019, several new and revised Joint Commission requirements focused on risks related to fluoroscopy became effective.

The Joint Commission

www.jointcommission.org



Addressing contributing factors to eliminate avoidable radiation exposures

There are actions that organizations can take to minimize radiation exposures. First, staff should be aware of the contributing factors to, and activities that can help eliminate, avoidable radiation exposures, which include:

- A comprehensive patient safety program, including education of practitioners and staff about managing radiation exposures and optimizing radiation doses when providing ionizing radiation.
- Awareness of the potential dangers from excessive radiation exposures among organizational leadership, hospital staff and patients.
- Awareness among physicians and other clinicians about the levels of radiation typically used and related risks.[1,4,14,15]
- Training on how to use complex new technology.[4]
- Guidance in the appropriate use of potentially dangerous procedures and equipment.[16]
- Adequately trained and competent staff and practitioners.
- Knowledge regarding typical radiation doses and dose ranges.
- Clear protocols that identify the maximum dose for each type of study.
- Consulting with a qualified medical physicist when designing or altering scan protocols.
- Communication among clinicians, medical physicists, technologists and staff.
- Safety, operational and functional checks of the imaging equipment before initial use and periodically thereafter.

Actions suggested by The Joint Commission

Health care organizations can reduce risks due to avoidable ionizing radiation by raising awareness[17] among staff and patients of the increased risks associated with cumulative radiation doses and by providing the right test and the right dose through effective processes, safe technology and a culture of safety.

Right test

1. In order to reduce the exposure of the patient to ionizing radiation, use other imaging techniques, such as ultrasound or MRI, whenever these tests will produce the required diagnostic information at a similar quality level.[17]
2. Create and implement processes that enable radiologists to provide guidance to and dialogue with referring physicians regarding the appropriate use of diagnostic imaging using the American College of Radiology's *Appropriateness Criteria*®.[17]

See relevant Joint Commission requirements: LD.03.10.01; HR.01.05.03

Right dose

3. Adhere to ALARA guidelines as required by the Nuclear Regulatory Commission. The ALARA acronym stands for "as low as reasonably achievable" – making sure doses are as low as possible while achieving the purposes of the study.[18] Adhere to the *Image Wisely*®, *Image Gently*® and *Step Lightly*® guidelines when providing imaging radiation to children and adults.[11,19,20,21]
4. Provide physicians and technologists with reference doses based on anatomy, purpose of the study, and patient size. Establish appropriate dose ranges for high-volume and high-dose diagnostic imaging studies.
5. Radiologists should assure that the proper dosing protocol is in use for the patient being treated.
6. Institute a process for the review of all radiation dosing protocols either annually or every two years to ensure that protocols adhere to the latest evidence.
7. Investigate patterns of radiation exposures that fall outside of identified thresholds for appropriate doses. Identify opportunities for process improvement. Track radiation doses from exams repeated due to insufficient image quality or lack of availability of previous studies to identify the causes. Address and resolve these problems through education and other measures.[4]
8. Record the dosage or exposure as part of the study's summary report of findings.

See relevant Joint Commission requirements: LD.03.10.01; PC.01.02.15, PC.01.03.01

Effective processes

9. Create and implement policies and procedures delineating those responsible for approving changes to password-protected diagnostic imaging protocols and for monitoring new developments in diagnostic imaging and fluoroscopy. Provide for oversight of these policies and procedures and related activities, including control of the password, by a multidisciplinary group with expertise in radiation (such as a radiation safety committee), including a medical physicist.[4]
10. Develop and implement policies and procedures that delineate physical protective risk reduction measures to be taken by staff delivering radiation to patients, including appropriate lead shielding for both patients and employees and radiation-protection training for all technologists.[4,21]

Paperless Mammography QC Part 2: Making it Work for You

11. Designate an individual to serve as radiation safety officer. Ensure that the role has the needed leadership support to intervene when unsafe practices related to the provision of ionizing radiation are noted. The radiation safety officer should participate on the organization's patient safety committee.
12. Ensure all practitioners (including physicians) and technologists who either prescribe, supervise, or operate equipment used to perform patient exams or procedures that involve radiation exposures receive dosing education and are trained on the specific make and model of equipment being used.[4,17,21] Institute a process for annual education, review and competency testing.

See relevant Joint Commission requirements: HR.01.02.01, HR.01.02.05, HR.01.04.01, HR.01.05.03, HR.02.02.01, LD.04.01.05, MS.03.01.01, MS.03.01.03, MS.06.01.03

Safe technology

13. Perform an organization-wide audit/survey of imaging equipment that have the potential of emitting high amounts of radiation. Implement a system for centralized quality and safety performance monitoring of this inventoried equipment under the supervision of a medical physicist, radiation safety officer, or your organization's multidisciplinary group with radiation expertise or both. (This equipment may no longer solely be within the province of the radiology department and may be located within a variety of hospital or clinical departments, including the cardiac catheterization suite and the OR. In the ambulatory setting, this equipment may be found in physician or dental offices.)
14. Have a medical physicist test all imaging equipment initially and at least annually for CT, NM, PET, and fluoroscopic units to assure proper installation and calibration, and to review scanning protocols and doses.[4] Such tests should be conducted in accordance with Joint Commission requirements and/or applicable state and federal laws and regulations. Where no such regulations exist, tests should be conducted in accordance with the applicable standards as promulgated by the American Association of Physicists in Medicine.
15. Ensure that recommended quality control, testing (including daily functional tests) and preventive maintenance activities are performed in accordance with manufacturer's guidelines. The health care organization, in consultation with the medical physicist, should identify these activities, their frequencies, and who will perform them.
16. Invest in technologies that optimize or reduce dose.[4,18,22,23]

See relevant Joint Commission requirements: EC.02.02.01, EC.02.04.01, EC.02.04.03, EC.04.01.01-EC.04.01.05, EC.02.04.01, EC.02.04.03, LD.04.01.05

Safety culture

17. Use the following Joint Commission standards to support the use of safe and effective diagnostic radiation and fluoroscopic imaging: LD.03.01.01, LD.03.04.01, LD.03.05.01, LD.03.06.01, LD.04.01.05. The concepts in these standards promote a safety culture, which is necessary for the safe use of diagnostic radiation. A safety culture is expressed in the beliefs, attitudes and values of an organization's employees regarding the pursuit of safety. It is present in the organization's structures, practices, controls, and policies, which are used to achieve greater safety. For more information about safety culture, see *Sentinel Event Alert* Issue 57: The essential role of leadership in developing a safety culture.

In addition, The Joint Commission:

18. Endorses the creation of a national registry to track radiation doses as the start of a process to identify optimal and reference doses.[1,7,16]
19. Encourages manufacturers to incorporate dosage safeguards into equipment and to capture dose information in the patient's electronic medical record and national dose registry.[13]
20. Supports stricter regulations designed to eliminate avoidable radiation exposures and monitor the appropriateness of self-referred imaging studies (referral of a patient to a facility in which the referring physician has a financial interest).[18]

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Resources

The Joint Commission: Standards FAQs on radiation overdose

American College of Radiology: 2018 ACR-AAPM Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures

Patient Safety Advisory Group

The Patient Safety Advisory Group informs The Joint Commission on patient safety issues and, with other sources, advises on topics and content for *Sentinel Event Alert*.