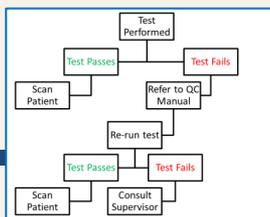
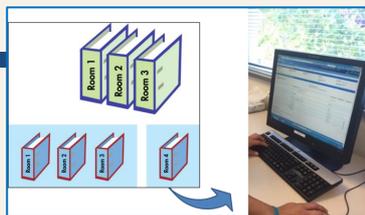




Paperless Mammography QC



Test Failure QC-Track

Contact responsible parties to determine if device is acceptable for patient use.

Values for the following fields do not pass:

- Acceptable?

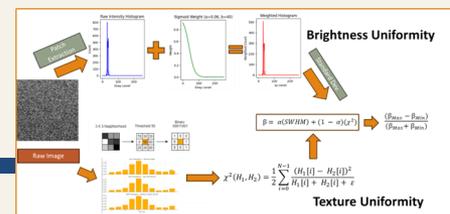
By continuing:

- This result will be recorded.
- A failure log entry will be recorded, and the failure workflow will be started.
- Notification emails will be sent to the following:

- ran@ghospital.com
- dmr@ghospital.com
- 300@ghospital.com

* You will need to follow procedures for this type of failure.

Continue | Cancel





Happy Radiologic
Technology Week!



Atirix celebrates and recognizes the significant work that radiologic professionals provide!

Disclosures



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



Steve Backes, B.S
CEO
Atirix Medical Systems

Rania and Steve are executives with Atirix Medical Systems.

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

Contributors

- **Trey Slauter**, M.S., DABR, Diagnostic Medical Physicist, University of New Mexico Hospital
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- **Allen Goode**, M.S., DABR, Chief Diagnostic Medical Physicist, University of Virginia Health System
- **Patricia Collins**, PhD, DABR, Diagnostic Medical Physicist, University of Virginia Health System
- **John Ferguson**, MBA, CRA, R.T. (R), Formerly System Director, Imaging and Lab, Adventist Health



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 interesting research in QC

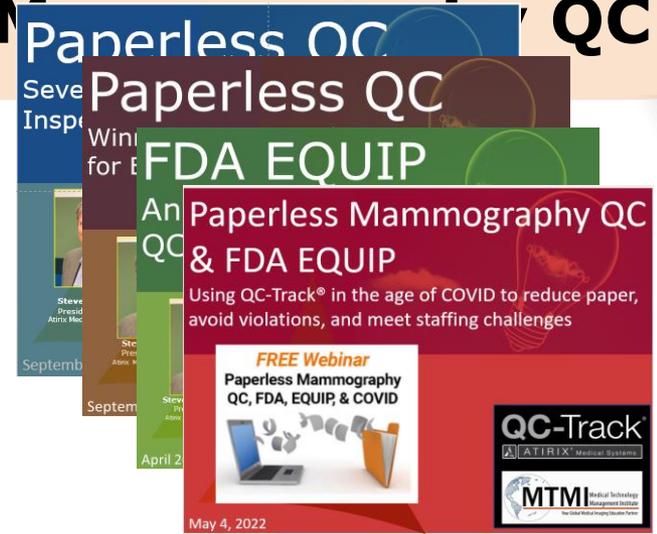


Outline

1. Introduction to Quality Control
2. Regulations
3. Options for Managing QC
4. Paperless QC
5. Challenges
6. Hot Topics!
7. Case Study: University of New Mexico Hospital
8. Research
9. Conclusions



**Re-cap from May, 2022:
Lots signed up, 275+ attendees, 200+
post-webinar surveys, strong marks,
and many nice comments...**



My inspection in July will be the first time that I will have used EQUIP. The seminar helped so much!

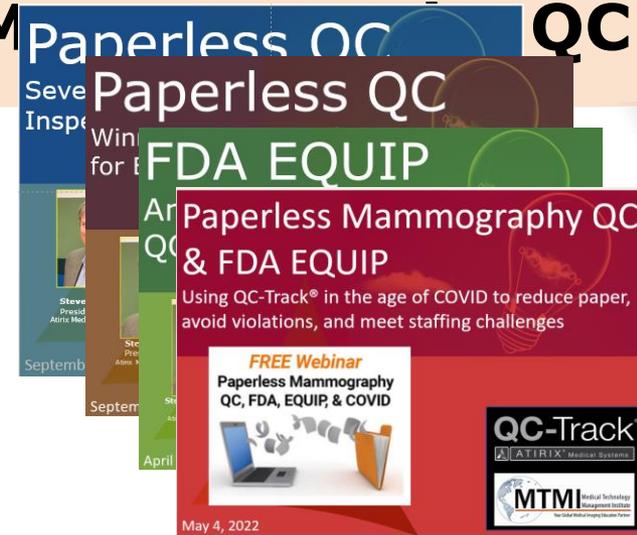
This was a great webinar. I learned a lot tonight. I am always impressed with the presentation and education MTMI provides.

I too am not a Mammo tech, but I like knowing the Mammo department at the facility where work has everything in order, since I get my personal Mammo there.

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!

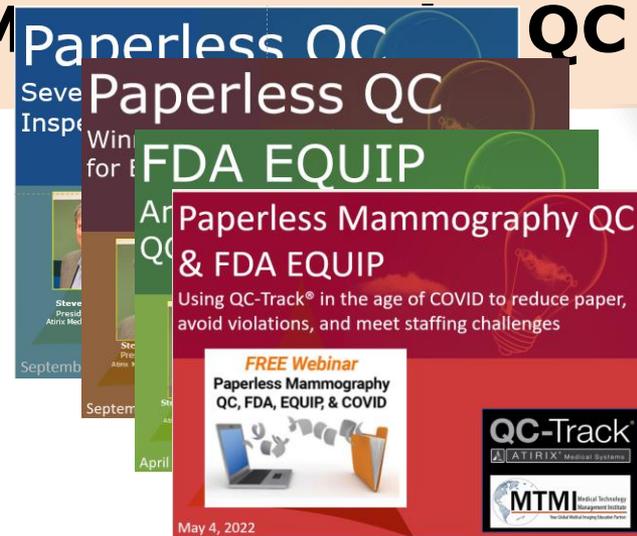
A reminder – this is for Mammography, MQSA, and Paperless QC...



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!

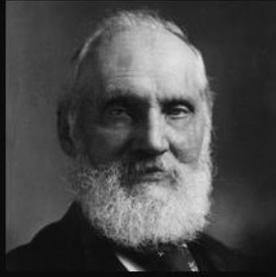
Comments from previous webinars ...interest in specifics...



Appreciated that this addressed some of the areas that were not covered last year; i.e. liked that you posted comments from last year's session

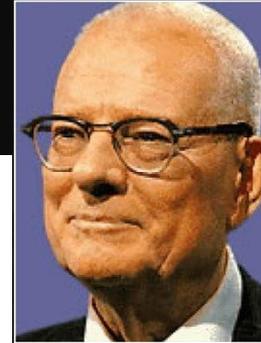
System seems very user friendly. Inspectors want to be in and out of a facility as fast as possible. They also want to be reassured that compliance isn't just a "just get it done" or a bare minimum process. I would've loved to inspect a facility that had this workflow .

need an actual example of the application in use by the technologist



If you can not measure it, you
can not improve it.

~ Lord Kelvin



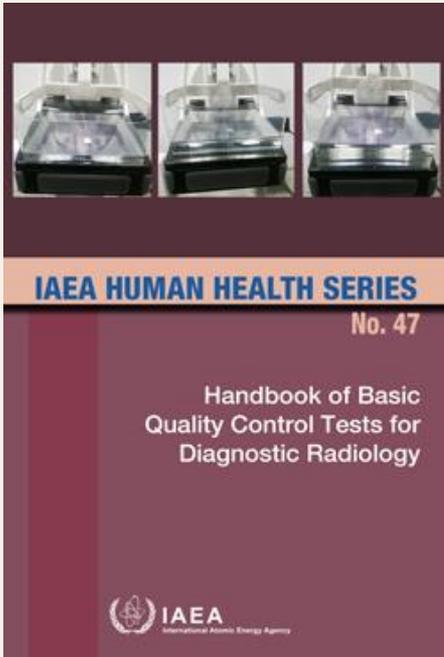
If you can't describe what you are
doing as a process, you don't know
what you're doing.

— *W. Edwards Deming* —

AZ QUOTES

Introduction to Quality Control

What is Quality Control?



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>

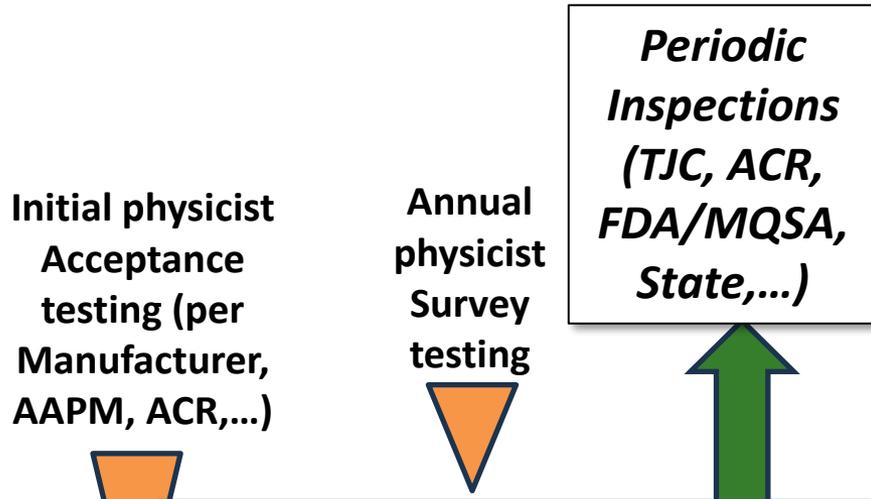
“Medical X-ray equipment technology has evolved exponentially in the last decades, shifting steadily from analogue to digital radiology, from single slice to multidetector-row computed tomography or from fluoroscopy to complex angiography systems.

This, however, comes with associated radiation risk for patients and staff.

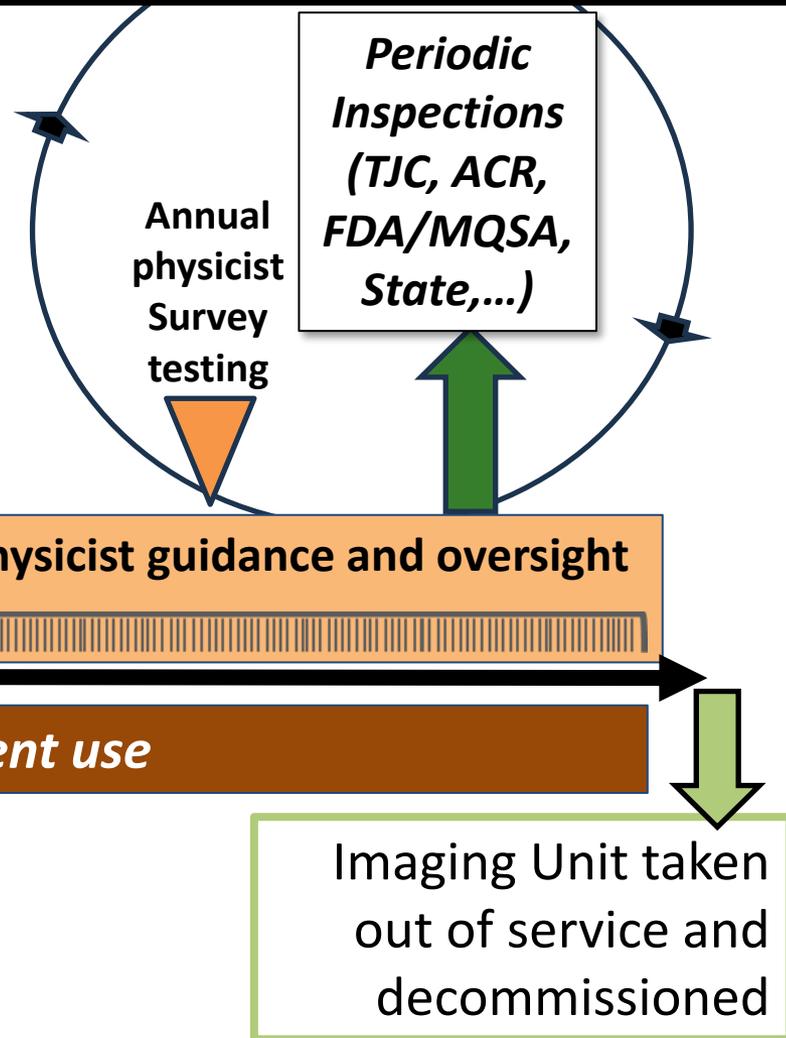
It is therefore vital that all X-ray equipment is monitored in terms of performance to ensure accurate and safe use.

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

The "typical" QC Cycle



QC cycle for life of Imaging Unit



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

It usually begins innocently enough, with my standard “old consultant” question...

“Why would an imaging director care about enterprise QC?”

This classic response was all about 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

On the other hand, here's a C-suite response:

“Think about Maslow’s hierarchy of needs. Every imaging director has ‘hopes and dreams’.

But there’s no quicker way to give up on your dreams if you get tripped up on the basics. And QC compliance is one of the basics.”

John Ferguson, MBA, CRA, R.T. (R)
Former Executive Director, Imaging and Lab Services
Adventist Health

Maslow and imaging directors



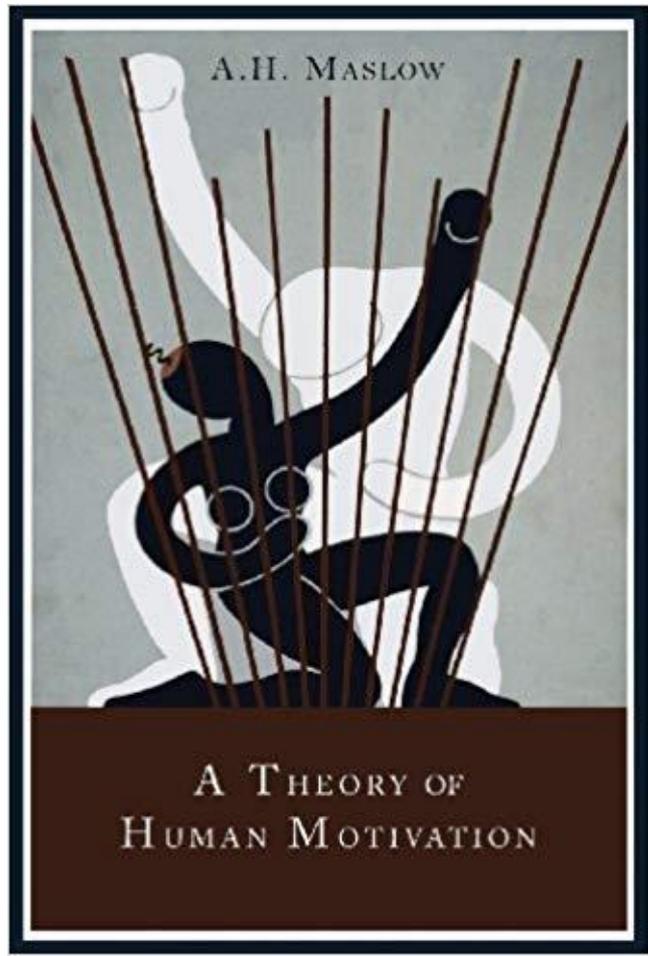
“Insights on imaging compliance and paperless QC”

John Ferguson, MBA, CRA, R.T. (R)

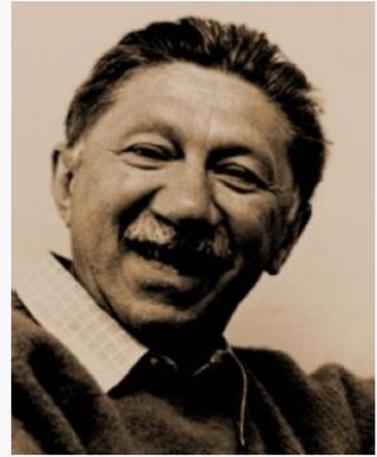
Formerly System Director, Imaging and Lab

Adventist Health

“A Theory of Human Motivation” 1943



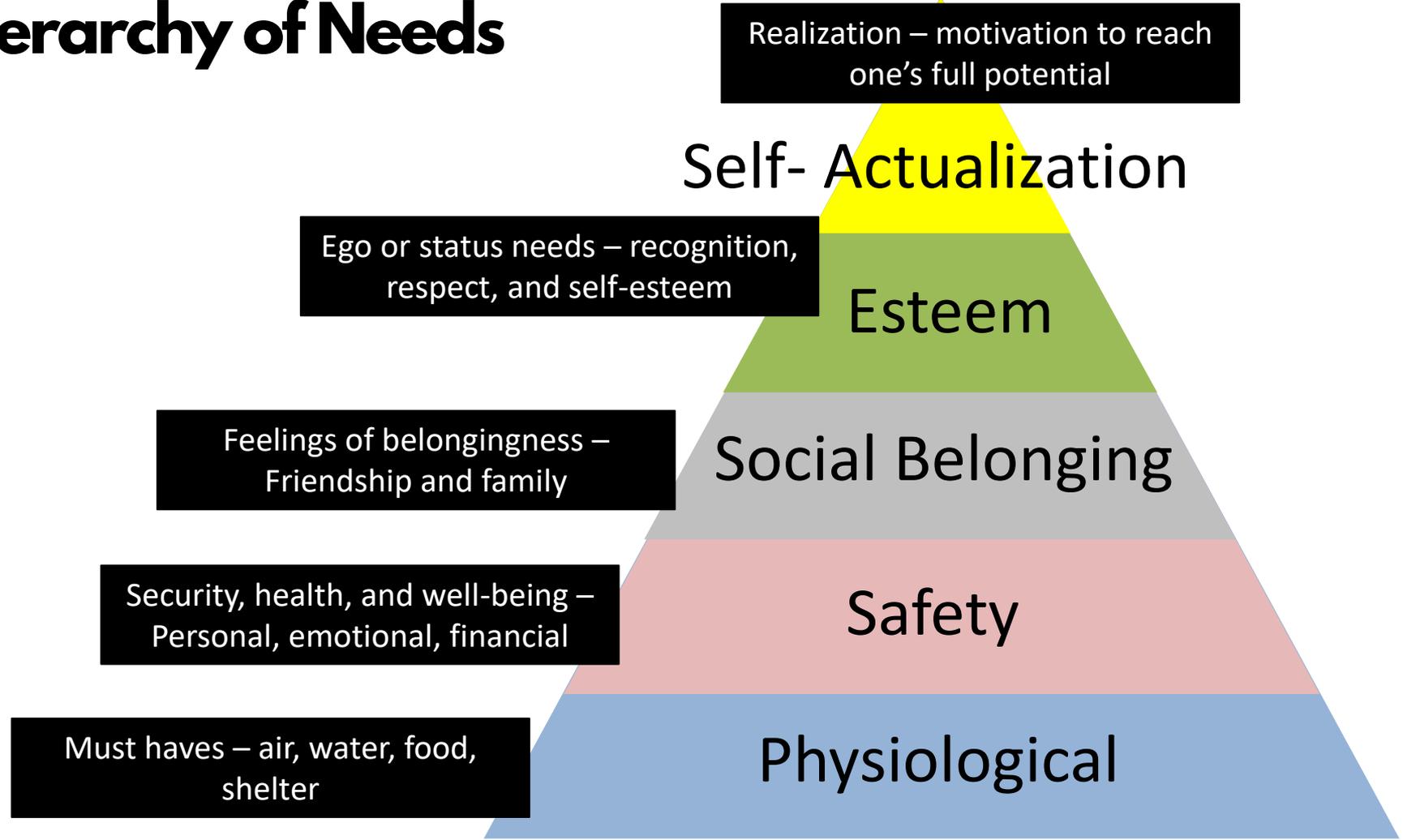
Abraham Maslow



Born	Abraham Harold Maslow April 1, 1908 Brooklyn, New York City, New York, U.S.
Died	June 8, 1970 (aged 62) Menlo Park, California, U.S.
Nationality	American
Alma mater	University of Wisconsin–Madison
Known for	Maslow's hierarchy of needs
Spouse(s)	Bertha Goodman Maslow (m. 1928)
Children	Ann Maslow · Ellen Maslow
Scientific career	
Fields	Psychology
Institutions	Cornell University Brooklyn College Brandeis University
Doctoral advisor	Harry Harlow
Influences	Alfred Adler · Kurt Goldstein · Henry Murray
Influenced	Douglas McGregor · Roberto Assagioli ^[1] · Colin Wilson · Abbie

Wikipedia

Hierarchy of Needs



Hierarchy of Needs – *Imaging*

Expansion, ground breaking research,...

Self-Actualization

Ego or status needs – Center of Excellence - DICOE, BICOE

Esteem

Feelings of belongingness – optional accreditation – ACR, AIUM

Social Belonging

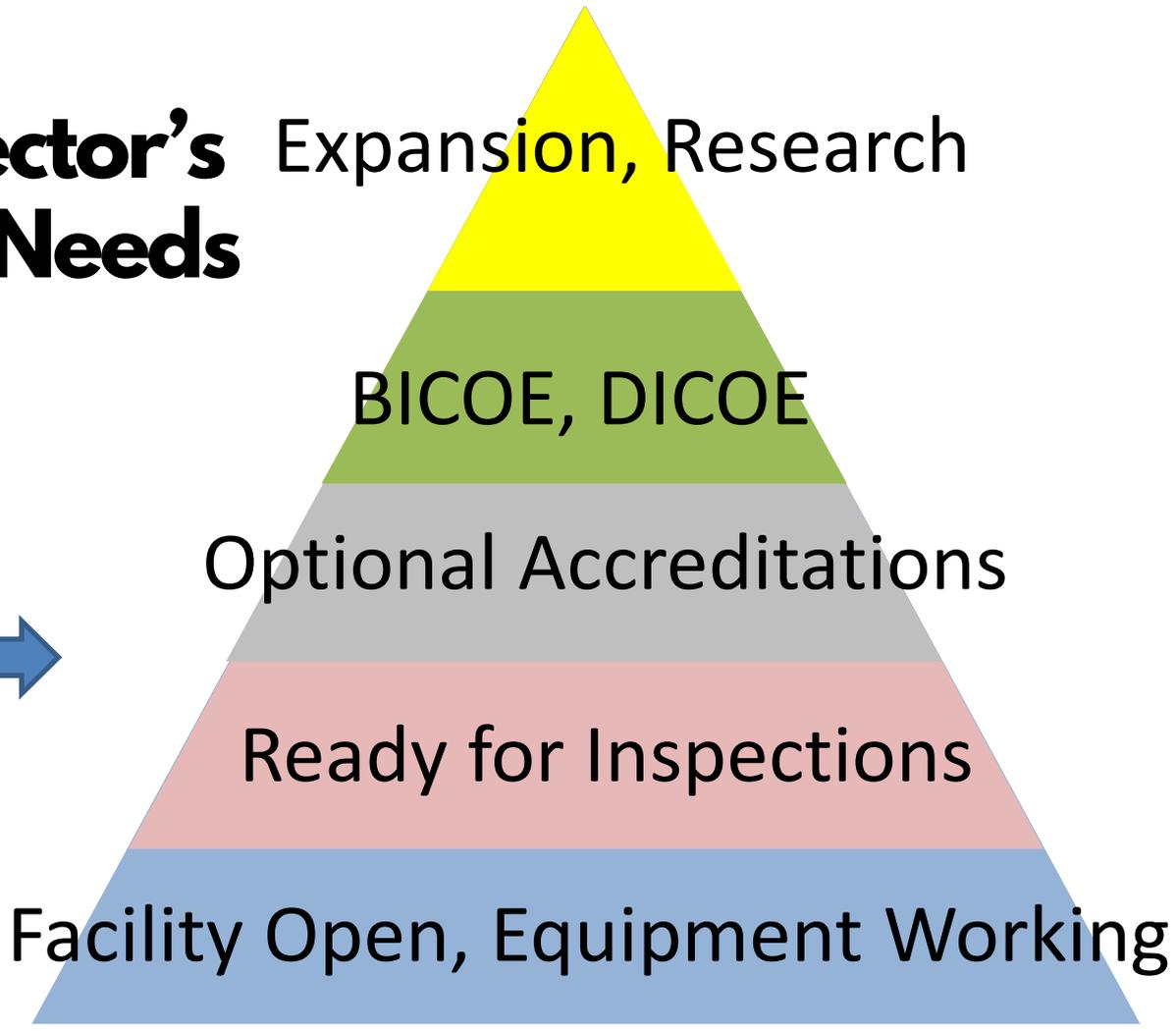
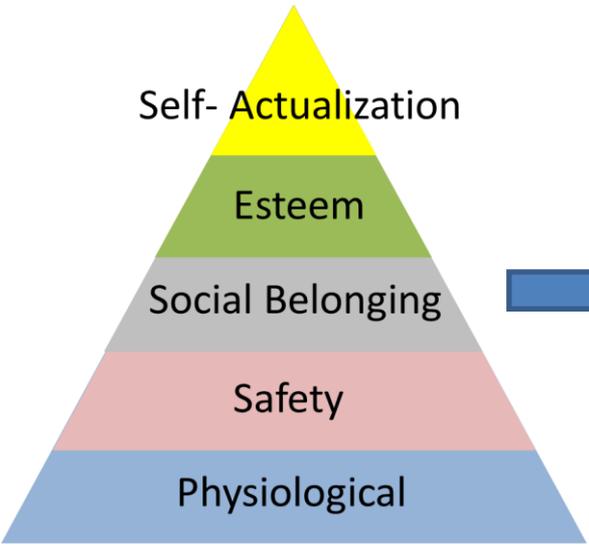
Security, health, and well-being – not in fear at every inspection, financial

Safety

Must haves for the department to function – working equipment, physicist survey, TJC Accreditation

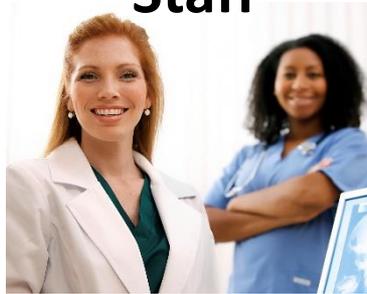
Physiological

A new model: The Imaging Director's QC Hierarchy of Needs



*So, what's
reality?*

Staff



Executive Oversight



Physicians



Inspectors!



Patients



“Leave at 5 PM!”



John's version:

Quick transactions

Expansion, Research

Minimally disruptive inspections

BICOE, DICOE

Optional Accreditations

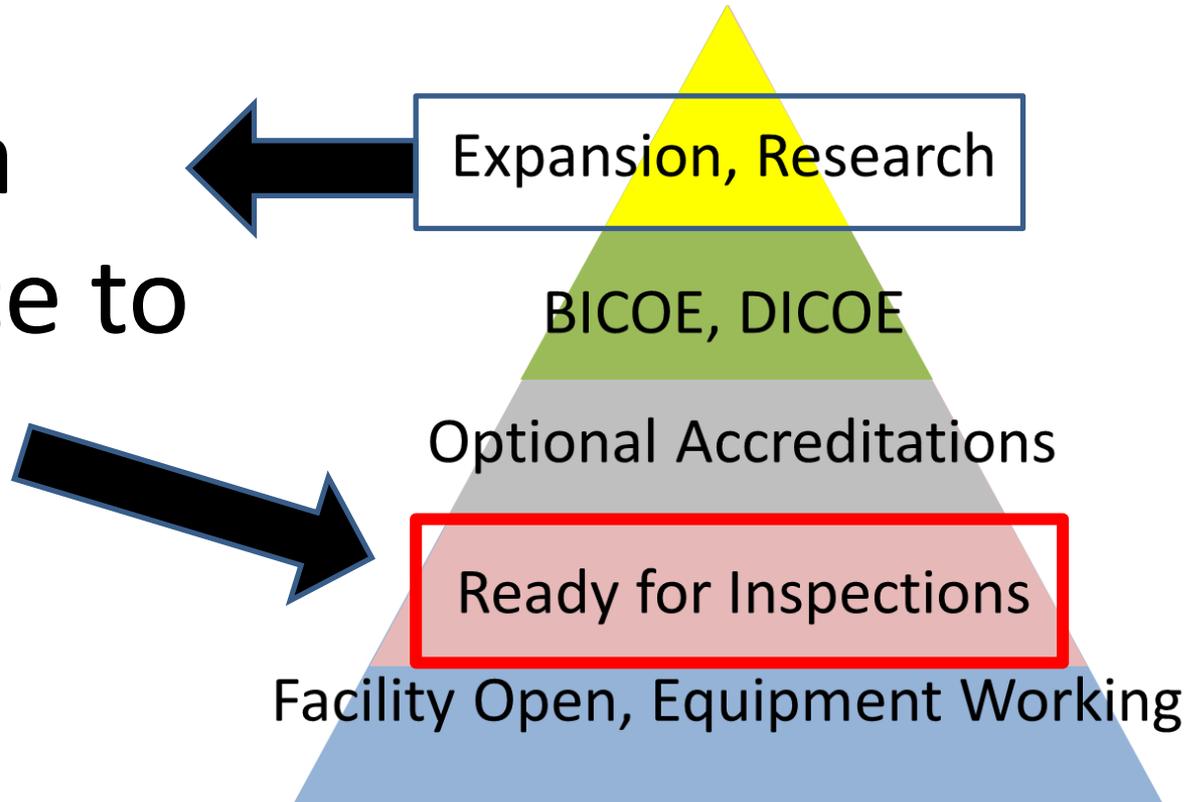
"Leave at 5 PM!"

Ready for Inspections

Facility Open, Equipment Working

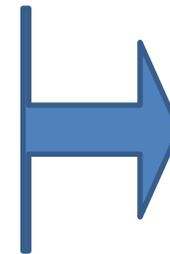
John's observation: think about due diligence

Where's a good place to start?



John's observations: *think about due diligence*

- You've been asked to review a facility that your hospital system is considering acquiring... what to do?
- John's experience: a good place to start is with "operational indicators"
 - Image Quality
 - Credentials
 - Records from past inspections



Easy to find?
Organized?
Accurate?

Uh-oh!



John's challenge: *how do your operations stack up?*

Those operational indicators are the ones that can trip up YOUR plans. Why?



***Easy to find?
Organized?
Accurate?***

Auditors look at those same “operational indicators” during an inspection



***Easy to find?
Organized?
Accurate?***

That all sounds good. *How is QC data tracked?*



QC paper – *lots of sources*

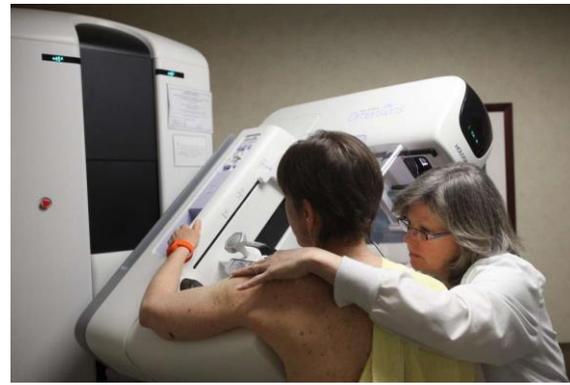
Professional Credentials



Breast Ultrasound QC



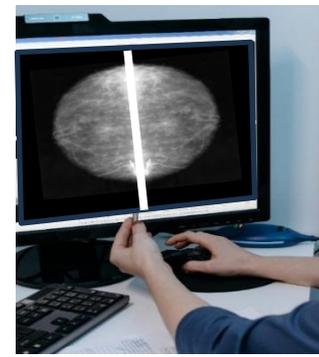
Mammography and SBB QC



Survey, PM, safety Documents



Displays QC

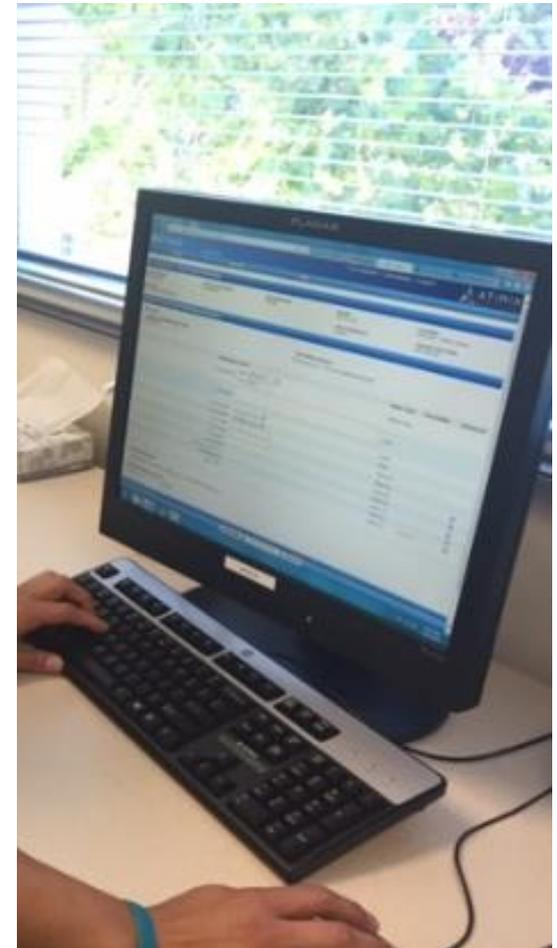
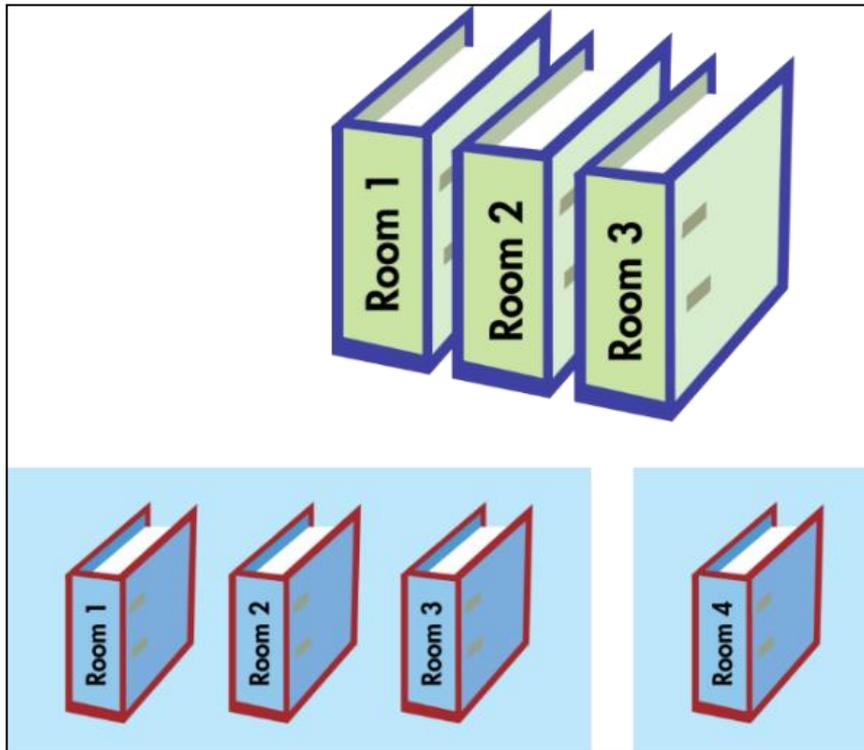


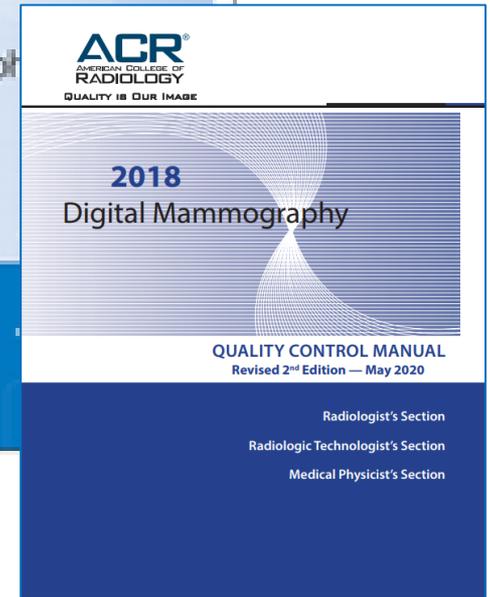
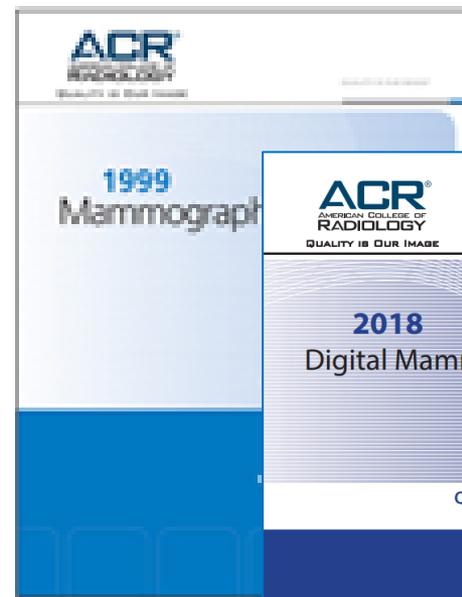
Why not Paper? *Risk and Waste*

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



Paperless QC – all data in one place





Regulations

MQSA

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
- 2025?

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

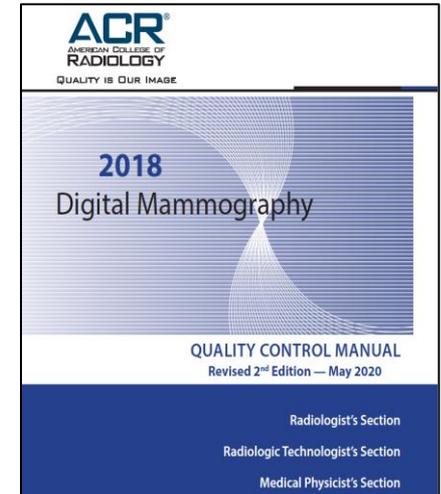
Part F--Licensing of Biological Products and Clinical
Laboratories

subpart 3--mammography facilities

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

The Case for QC - Accreditation

- Accreditation is the ‘seal of approval’ that Facilities are following MQSA and manufacturers QC
- Largest Accrediting body – American College of Radiology (ACR)
- Accreditation is not an accident! It takes a team of individuals to make it happen
- **Quality Control** is a major component of Accreditation
- Multivendor QC at the same site poses a significant challenge for the QC team



In 2025, how do we manage QC in a way that supports ALL of the efforts put into MQSA and ensures women have quality breast images?

MQSA QC

It all started with regulations from ARRT...

(from an Atirix MTMI 2015 Webinar)

- In 1991, the American Registry of Radiologic Technologists (ARRT) announced it would begin phasing in CEU requirements
 - Required continuing education for all technologists:
 - 24 Continuing Education Units (CEU) every 24 months
- In 1995, Continuing Education (CE) became a mandatory requirement for renewal or reinstatement of registration.

Source: www.ARRT.org

Why require CE?

- Purpose: provide a mechanism for Registered Technologists to fulfill their responsibility to maintain competence in their categories of certification
- Ongoing: advancing technology and changing job responsibilities may require technologists to update their knowledge and skills consistent with any new developments in medical imaging, radiation therapy, and interventional procedures



Source: www.ARRT.org, 2015



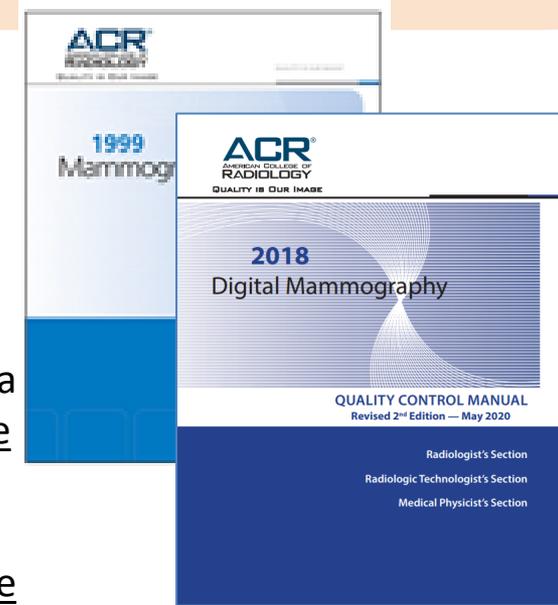
...and then came legislation: Mammography Quality Standards Act (MQSA) 1994

- MQSA became law on Oct. 27, 1992, went into effect in 1994, and first inspections were in 1995
- Enacted to ensure that all women have access to quality mammography for the detection of breast cancer in its earliest, most treatable stages
 - Screening modality, so concern with cumulative radiation exposure
 - Introduced new QC processes and inspections
 - Frequent testing with tight limits
 - Rigorous annual inspection

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

MQSA -- Continuing Education

- Sec.900.12 (iii) Continuing education requirements.
 - (A) Following the third anniversary date of the end of the calendar quarter in which the requirements of paragraphs (a)(2)(i) and (a)(2)(ii) of this section were completed, the radiologic technologist shall have taught or completed at least 15 continuing education units in mammography during the 36 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 36-month period.



CFR 21 -- Qualification

- (E) Before a radiologic technologist may begin independently performing mammographic examinations using a mammographic modality other than one of those for which the technologist received training under paragraph (a)(2)(ii)(C) of this section, the technologist shall have **at least 8 hours of continuing education units in the new modality.**
- (iv) Continuing experience requirements. (A) Following the second anniversary date of the end of the calendar quarter in which the requirements of paragraphs (a)(2)(i) and (a)(2)(ii) of this section were completed or of April 28, 1999, whichever is later, the radiologic technologist shall have **performed a minimum of 200 mammography examinations during the 24 months immediately preceding** the date of the facility's annual inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 24-month period.



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



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

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?

MQSA – Manufacturer test examples

Hologic 3D

- Artifact Evaluation – AWS (Weekly)
- Detector Flat-Field Calibration (Weekly)
- Phantom Image 2D (Weekly)
- Phantom Image 3D (Weekly)
- SNR/CNR (Weekly)
- Compression Thickness Indicator (Bi-weekly)
- Visual Checklist (Monthly)
- Repeat Analysis (Quarterly)
- Reject Analysis (Quarterly)
- Compression Force (Semiannual)
- Geometry Calibration (Semiannual)

MQSA – Manufacturer test examples

GE Senographe Pristina

- Acquisition Monitor Cleaning (Daily)
- ACR Phantom Score 2D Auto Implant (Weekly)
- ACR Phantom Score 2D AWS (Weekly)
- ACR Phantom Score 3D (Slabs or Planes) (Weekly)
- Bucky Flat Field 2D Mo/Mo (Weekly)
- Bucky Flat Field 3D Mo/Mo (Weekly)
- Bucky Flat Field 3D Rh/Ag (Weekly)
- Bucky Flat-Field 2D Rh/Ag (Weekly)
- Bucky Flat-Field CESM Mo/Cu (Weekly)
- Bucky Flat-Field CESM Rh/Cu (Weekly)
- Bucky IQST Mo/Mo (Weekly)
- Bucky IQST Rh/Ag (Weekly)
- Flat Field Test and Detector - Magstand 1.8 Flat Field 2D Mo/Mo (Weekly)
- Flat Field Test and Detector - Magstand 1.8 Flat Field 2D Rh/Ag (Weekly)
- Acquisition Station Monitor Check (Monthly)
- AOP and SNR Check - 2D and CESM - Bucky AOP 30mm (Monthly)
- AOP and SNR Check - 2D and CESM - Bucky AOP 50mm (Monthly)
- AOP and SNR Check - Bucky AOP 30mm (Monthly)
- AOP and SNR Check - Bucky AOP 50mm (Monthly)
- AOP and SNR Check - Magstand 1.8 AOP 30mm (Monthly)
- AOP and SNR Check - Magstand 1.8 AOP 50mm (Monthly)
- Visual Checklist (Monthly)
- GE Repeat/Reject Analysis (Quarterly)
- Compression Force Test (Semi-annual)

Options for Managing Quality Control Data and Processes



BINDERS

SPREADSHEETS

DATABASE MANAGEMENT SYSTEM

QC Documentation Requirements

BASIC TRACKING REQUIREMENTS

- Must meet physicist requirements and inspector needs
- Must have a QC plan, follow the plan, keep records



WHICH MEANS

- **Define QC workflow** – by modality, room, location, tests, who performs QC and when
- **Schedule QC activities** and monitor that QC activities have been completed
- **Record QC data**, per calculations, baselines, limits/thresholds, date/time/user stamps
- Detect, notify and track **QC failures**
- **Enforce security** – access to QC records, changes to forms
- **Generate reports** needed to monitor QC processes and meet the information requirements of responsible parties
- Be able to **back up the QC data** (and recover)

Classic Approach: Binders

- **Source:** Usually made up of forms provided by ACR, physicists or manufacturer
- **Advantages** – “business as usual”
 - Inexpensive
 - Meets “Letter of the Law”, accepted by inspectors
- **Disadvantages**
 - Manual scheduling, manual calculations, manual failure notices
 - Monitoring? Difficult, not timely
 - Usually need to “clean things up” before inspection
 - Difficult to meet remote data access needs
 - Only one person can use a binder at a time
 - Security and control
 - Backup and recovery

1 Date of Test Year	2 Table OK?	3 Console OK?	4 CF (Hz) Data (F0)	5 TX Gain/Attenuation (dB) (F0)	Phantom Distances (mm)			Slice 1 HR Holes #		Slice # 8 Number of LCD Spokes	Artifacts ?	Test By	NOTES
					6 Sep Loc Length	7 AP (180)	8 RL (180)	9 UL	10 LR				
12/3	Y	Y	127737266	0.0562	147	189	189	1.0	1.0	9	NO	RS	EXAMPLE
12/11	Y	Y	127737269	0.0562	148	189	190	1.0	1.0	9	NO	DW	
12/17	Y	Y	127737399	0.0562	147	189	189	1.0	1.0	10	NO	DW	
12/18	Y	Y	127737394	0.0562	147	189	189	1.0	1.0	10	NO	DW	



Inspector experience

Famous last words?

“I know we have it somewhere...”

Needed at point of inspection

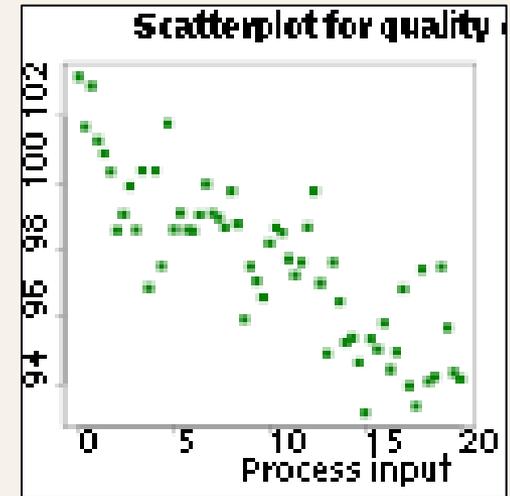
- QC Records
- Credentials
- PM/Service docs
- Safety documents
- ...



Option: Spreadsheets

- **Source:** Usually “in house”
- **Advantages**
 - Inexpensive
 - Able to build in calculations
 - Backup
- **Disadvantages**
 - Testing?
 - Facility still relies on manual scheduling, manual failure notices, and monitoring can be difficult
 - Reports can be difficult to build
 - Few controls around data modification or deletions so difficult to identify if occurred
 - Only one person can use a spreadsheet at a time
 - Security limited to network access, cell locking
 - On-going support, if changes needed

Apron ID	Who?	Type	Date Checked
1234	Dr. Smith	skirt	1/1/2013
1235	Dr. Smith	collar	1/1/2013
1236	Al		1/5/2013



Caution: QA TESTING?

JOURNAL OF APPLIED CLINICAL MEDICAL PHYSICS, VOLUME 16, NUMBER 1, 2015

A survey of Canadian medical physicists: software assurance of in-house software

Greg J. Salomons,^{1,2a} and Diane Kelly³
 Department of Physics,¹ Queen's University, Kingston, ON; Department of Medical Physics,² Cancer Center of Southeastern
 Mathematics and Computer Science,³ Kingston, ON, Canada
 greg.salomons@krcc.on.ca

- Type of Testin
- Preventing Modificati
- Documentati
- User Traini
- Types of Tasks Allow
- Programming Standar
- Archiving of Old Versio
- Who is Allowed to U
- Type of Softwa

Fig. 1. Relative interest in guideline.

Forbes / Tech

FEB 13, 2013 @ 8:37 AM 119,0

Microsoft's Dangerous S

"After subtracting the o sum instead of their ave effect of muting volatili

To translate that into the bets (tens of billions of dollars of money) in London. playing around in Excel. we might hope, all integr

pasting from one spreadsheet to another. And yes, they got one of the equations wrong as a result of which the bank lost several billion dollars (perhaps we might drop the gee here but it's still golly gosh that's a lot of money).

What We Know About Spreadsheet Errors

Raymond R. Panko
 University of Hawai'i
 College of Business Administration
 2404 Maile Way
 Honolulu, HI 96822

Abstract

Although spreadsheet programs are used for small "scratchpad" applications, they are also used to develop many large applications. In recent years, we have learned a good deal about the errors that people make when they develop spreadsheets. In general, errors seem to occur in a few percent of all cells, meaning that for large spreadsheets, the issue is how many errors there are, not whether an error exists. These error rates, although troubling, are in line with those in programming and other human cognitive domains. In programming, we have learned to follow strict development disciplines to eliminate most errors. Surveys of spreadsheet developers indicate that spreadsheet creation, in contrast, is informal, and few organizations have comprehensive policies for spreadsheet development. Although prescriptive articles have focused on such disciplines as modularization and having assumptions sections, these may be far less important than other innovations, especially cell-by-cell code inspection after the development phase.

Conclusion

All in all, the research done to date in spreadsheet development presents a very disturbing picture. Every study that has attempted to measure errors, without exception, has found them at rates that would be unacceptable in any organization. These error rates, furthermore, are completely consistent with error rates found in other human activities. With such high cell error rates, most large spreadsheets will have multiple errors, and even relatively small "scratch pad" spreadsheets will have a significant probability of error.

Despite the evidence, individual developers and organizations appear to be in a state of denial. They do not regularly implement even fairly simple controls to reduce errors, much less such bitter pills as comprehensive code inspection. One corporate officer probably summarized the situation by saying that he agreed with the error rate numbers but felt that comprehensive code inspection is simply impractical. In other words, he was saying that the company should continue to base critical decisions on bad numbers.

A major impediment to implementing adequate disciplines, of course, is that few spreadsheet developers have spreadsheeting in their job descriptions at all, and very few do spreadsheet development as their main task. In addition, because spreadsheet development is so dispersed, the implementation of policies has to be left to individual department managers. While organizations might identify critical spreadsheets and only impose hard disciplines on them (Panko, 1988), this would still mean that many corporate decisions would continue to be made on the basis of questionable analyses.

Option: Database

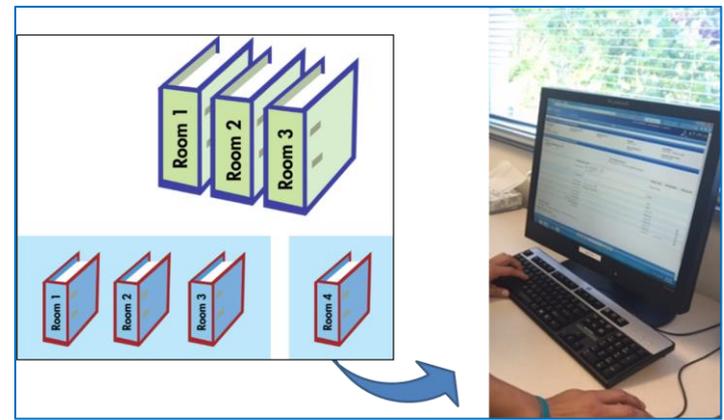
- **Source:** professional software engineers (internal or vendor)
- **Scope:** “point” (apron tracking) or “complete” (Enterprise QC across modalities)
- **User:** QC dashboard, QC scheduler, tests specialized for QC, reporting, multi-user, provisioning,
- **Server:** database, centralized, secure, revision management, audit logging
- **Security:** per IT Security requirements
- **Workflow:** standardized or customized
- **Other:** on-going improvements, training, documentation, testing per professional standards



Option: Database

- **Advantages**
 - Complete solution – that can cover normal and uncommon (holidays, down for PM) circumstances
 - Training and documentation, on-going support and upgrades
 - Collective needs and ideas from multiple locations are built into a product
- **Considerations**
 - Product scope and stability? Get references!
 - Expenses for licensing + support
 - Look for vendor with experience in your specific area of interest
 - Look for vendor that is committed to quality control
 - Control over improvements



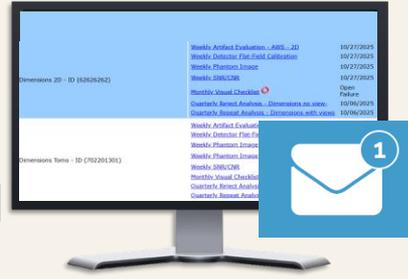


Paperless QC: How Does it Work

Paperless QC Workflow

1. QC notification

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



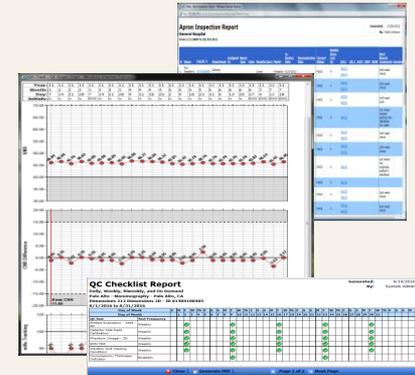
2. QC data gathering

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



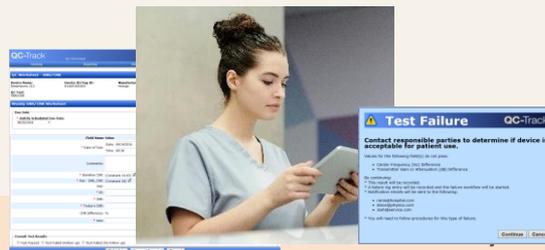
4. QC Reporting

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.



How does it work? Devices

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

<u>Device ID/ Tag ID</u>	<u>Name</u>	<u>Doc</u>	<u>QC Status</u>	<u>Manufacturer Model</u>	<u>Worksheet Family Worksheet Group</u>	<u>Model Type</u>	<u>Status</u>	<u>Location</u>
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 does it work? 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

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

Table 42: Quality Control Tests To be Performed by the

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

Location and Device

Location: Device: Test Frequency:

Scheduled and On Demand Worksheets

QC Test	Test Frequency	10/27/2025	11/03/2025	Worksheet
Artifact Evaluation - AWS - Tomo	Weekly			
Detector Flat-Field Calibration	Weekly	Show History		
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	10/27/2025	11/03/2025 Worksheet
Compression Thickness Indicator	Biweekly	10/20/2025 Show History		11/03/2025 Worksheet
Compression Thickness Indicator FAS 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

How does it work? Dashboard

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

QC Dashboard

Location: Breast Care Center

Included Locations: Breast Care Center - St. Paul, MN

Dashboard Tests

Dashboard View: Group by device

Schedule View: Show only tests scheduled for today or earlier

Show Aprons: Individually

Device	QC Test	Due	Overdue	Graph
Affirm - ID (11420211)	Daily QAS Test 3D	10/27/2025		
	Daily QAS Test Location Accuracy 2D	10/27/2025		
	Weekly Phantom Images 2D	10/27/2025		
	Weekly Phantom Images 3D	10/27/2025		
	Monthly Visual Checklist	10/06/2025		
	Semiannual Reject Analysis (<=20%) - Digital	10/06/2025		
	Semiannual Repeat Analysis (<=20%) - Digital	10/06/2025		
Barco - Display - ID (11320211)	Daily Display Cleanliness and Viewing Conditions	10/27/2025		
	Weekly Mammography Constancy Test	10/27/2025		
Dimensions 2D - ID (62626262)	Weekly Artifact Evaluation - AWS - 2D	10/27/2025		
	Weekly Detector Flat-Field Calibration	10/27/2025		
	Weekly Phantom Image	10/27/2025		
	Weekly SNR/CNR	10/27/2025		
	Monthly Visual Checklist	Open Failure		
	Quarterly Reject Analysis - Dimensions no view-	10/06/2025		
Quarterly Repeat Analysis - Dimensions with views	10/06/2025			

How does it work? Entering QC

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

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)		
* EI:	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**

Constants: Baseline CNR and kVp

Automatic comparison to baseline

On-the-spot pass/fail notification

Challenges in Managing Quality Control

WEB OF FACILITIES

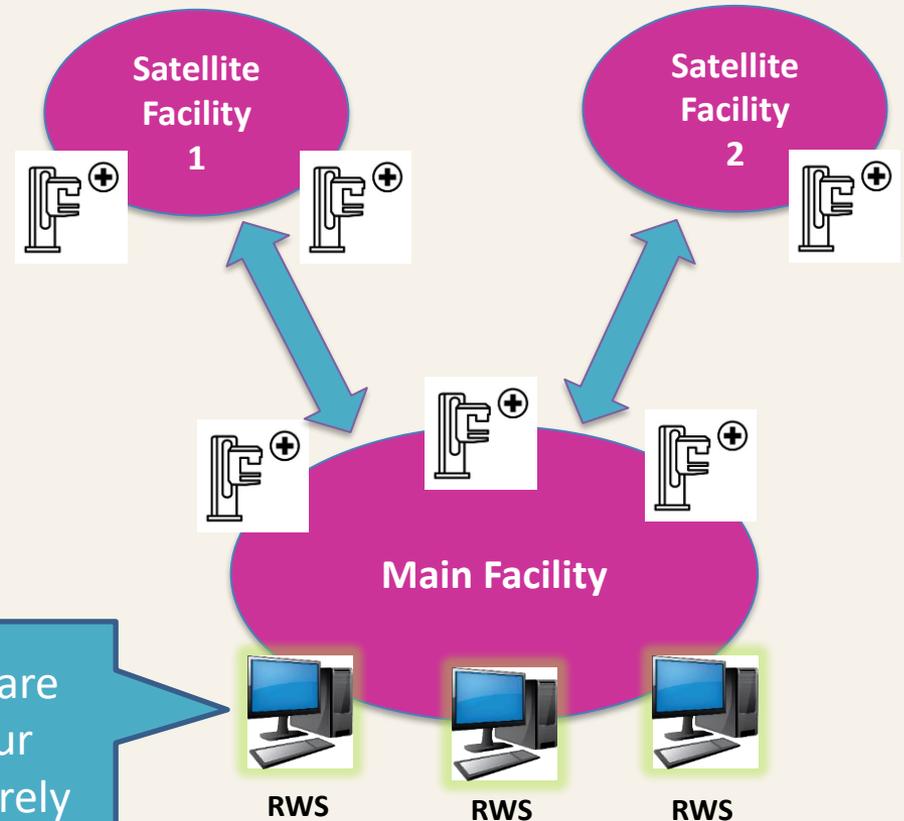
COMMUNICATIONS

PERSONNEL

FAILURES

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



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

Communication is Critical



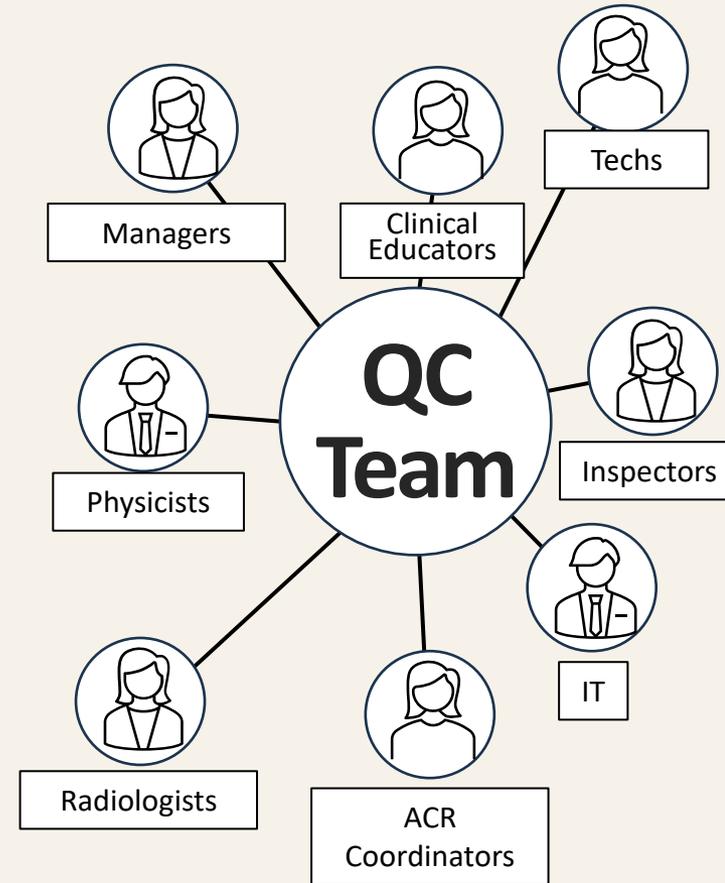
Workflow in a busy mammo clinic is VERY important!

- 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



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?**



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**



Test Failure
QC-Track[®]

Contact responsible parties to determine if device is acceptable for patient use.

Values for the following field(s) do not pass:

- Acceptable?

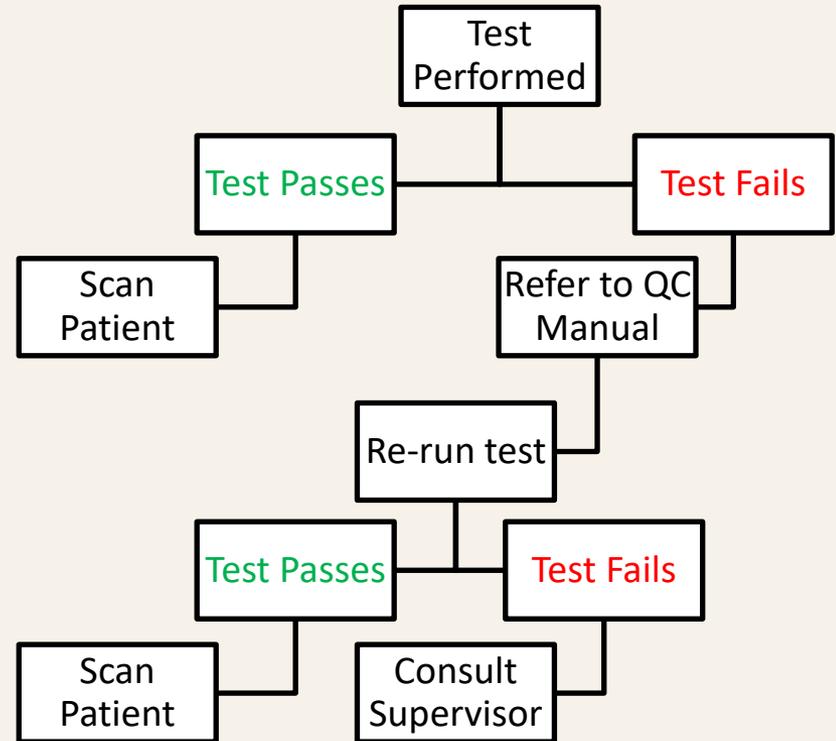
By continuing:

- * This result will be recorded.
- * A failure log entry will be recorded, and the failure workflow will be started.
- * Notification emails will be sent to the following:
 - rania@hospital.com
 - steve@physics.com
 - Josh@service.com
- * You will need to follow procedures for this type of failure.

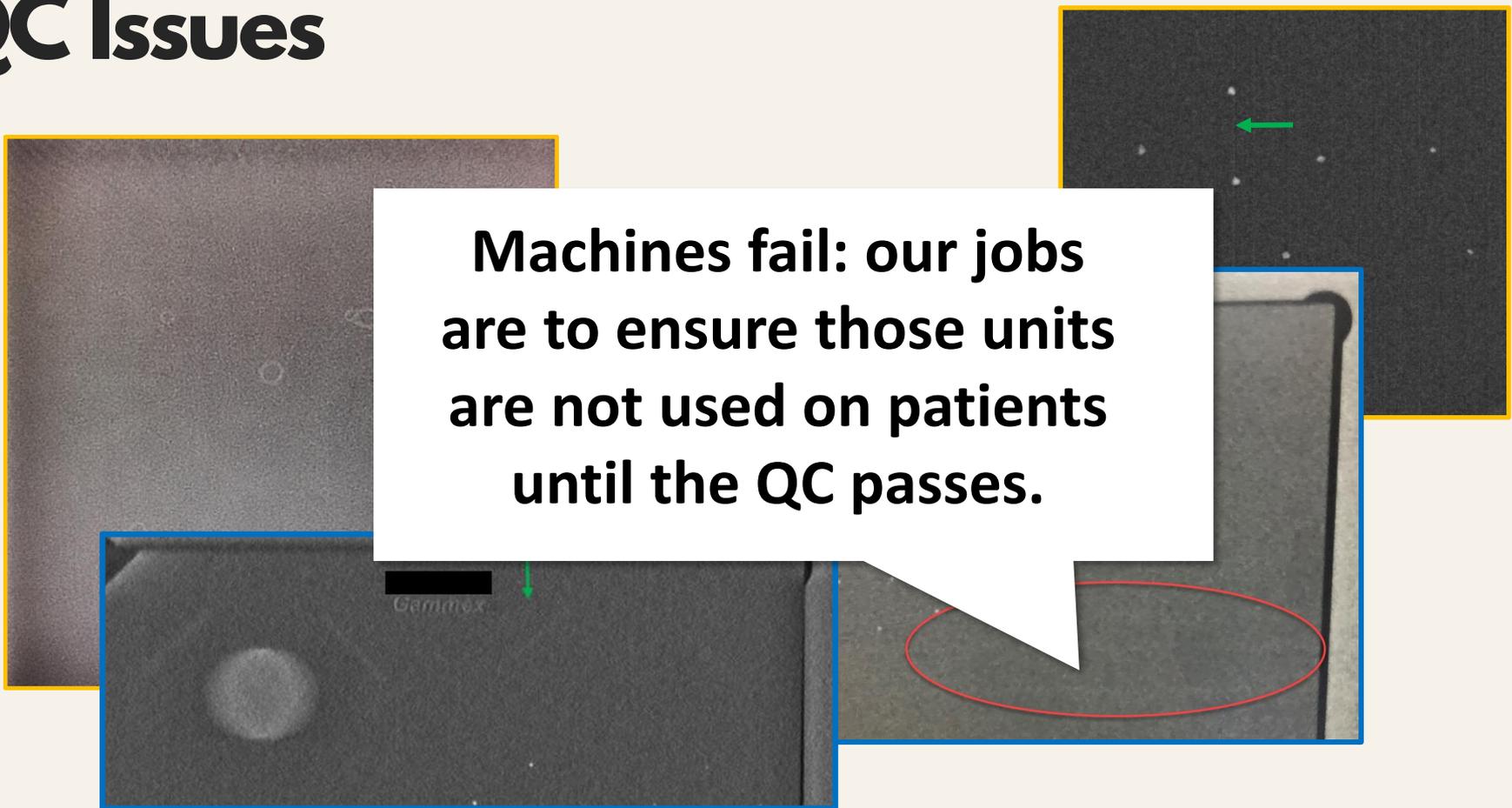
Continue
Cancel

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”**



QC Issues



Machines fail: our jobs are to ensure those units are not used on patients until the QC passes.

Hot topics!

- 1) HOLOGIC FAST MODE
- 2) CHANGES IN DISPLAYS QC
- 3) IN-HOME READING

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 / **Subsystem:** FAST Mode
 3Dimensions

Subject: Thickness Indicator Quality Control Testing for FAST Mode on
 Selenia 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.

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...”

1) Hologic FAST Mode

Biweekly Compression Thickness Indicator FAST Mode r003 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: 11/03/25 Time: 10:21	Date & Time		
Comments:		Text		
Actual Thickness of Paddle:	4.50 cm	Decimal (2)		
* FAST Mode Compression Thickness:	4.5 cm	Decimal (2)		
Difference Indicated:	0.00 cm	Decimal (2)	L=-0.50 cm, U=0.50 cm	

Recalculate Record Results Cancel

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

Barco Mammography Display Systems

Recommended Quality Assurance

DATE 05 August 2024
AUTHOR Albert Xthona | Product Manager
DOCUMENT ID K5905277 version 18

This memo outlines quality checks for Barco mammography display systems. These quality checks are not preconditions for warranty service, but rather are recommended to ensure equipment is tested and properly functioning when using these display systems for reading mammography, including breast tomosynthesis. The instructions and forms below can be incorporated into the overall quality program for a site

listed here please contact
 Nio Gray 5.8MP, Nio Fusion
 DNC-12130



MQSA Qu
 For use with D
 SMP, 8

**MQSA Quality Control Manual
 For EIZO Diagnostic Monitors used
 for Mammography**

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

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

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



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"



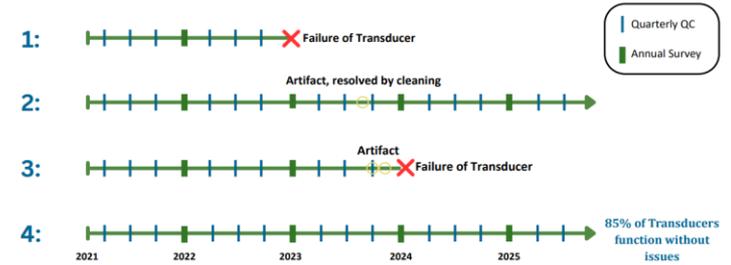
Paperless QC @ UNM – Lessons Learned

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!"



Different Transducer Life Cycles from Same Initial Installation



ATIRIX RESEARCH: DENSE BREAST TECHNOLOGIES

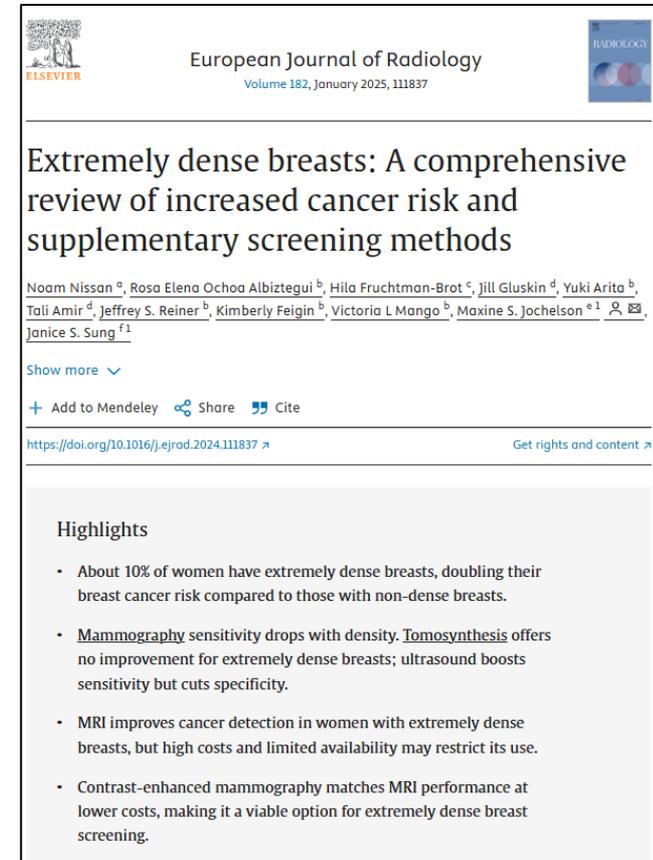
- 1) CONTRAST-ENHANCED MAMMOGRAPHY
- 2) BREAST ULTRASOUND
- 3) MOLECULAR BREAST IMAGING (MBI)
- 4) BREAST MRI

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
 Volume 182, January 2025, 111837

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

Noam Nissan^a, Rosa Elena Ochoa Albiztegui^b, Hila Fruchtmann-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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<https://doi.org/10.1016/j.ejrad.2024.111837> Get rights and content

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.

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

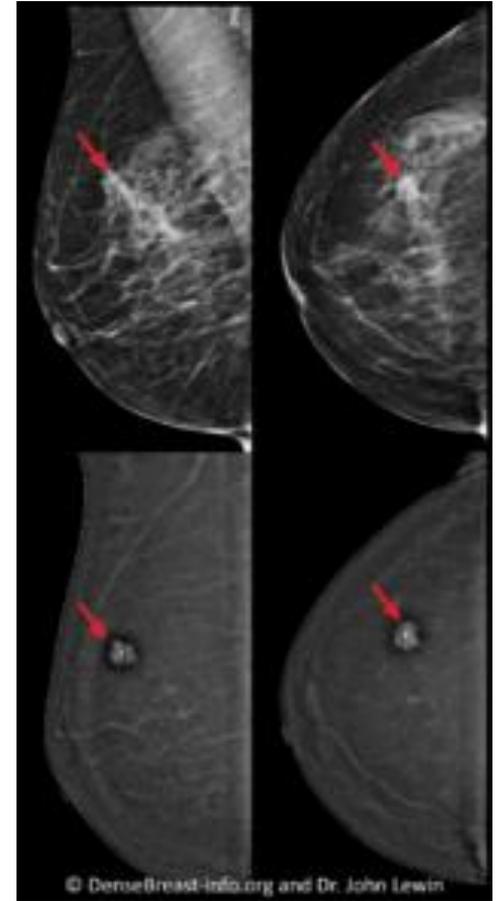
How does QC need to evolve to keep up with these advances in dense breast screening technologies?

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...*



2. Research – Breast Ultrasound QC

Collaboration with UT Southwestern Parkland

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

Toward an Objective Metric of Uniformity in Ultrasound

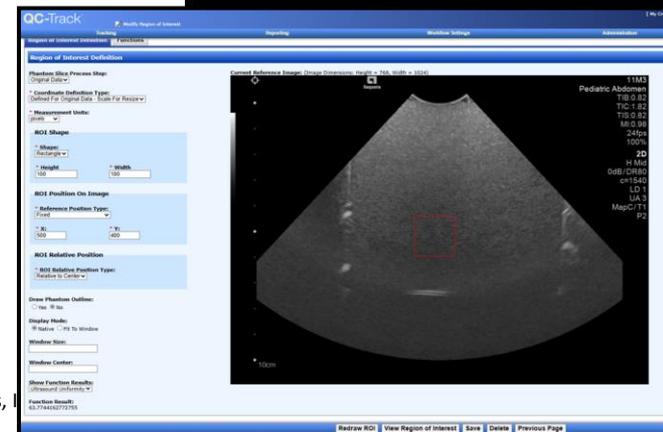
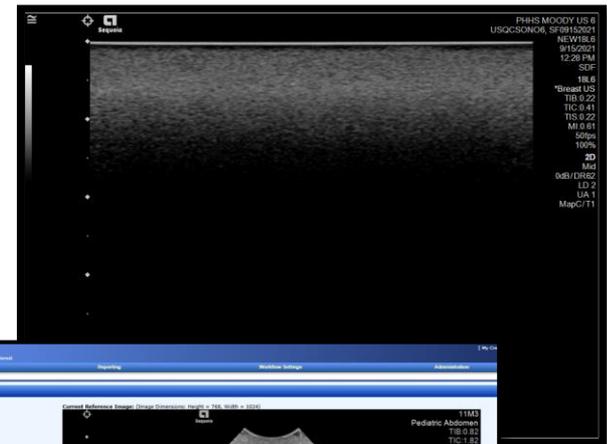
Asher Shertok

“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

Features of a good metric for US uniformity:

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



Toward an Objective Metric of Uniformity in Ultrasound

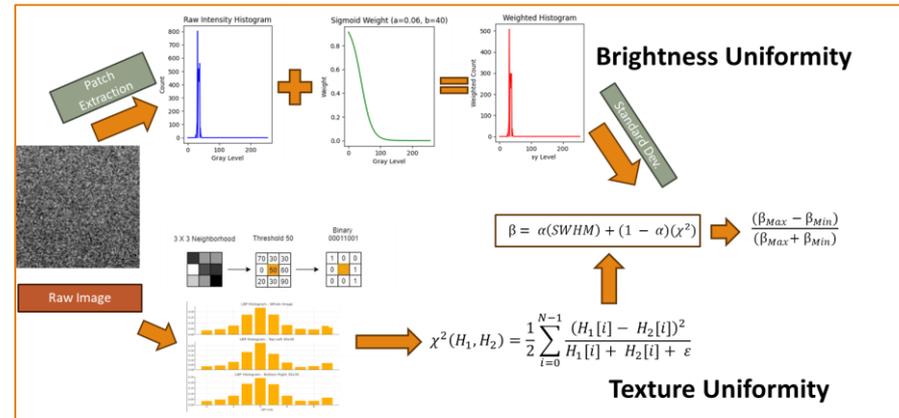
Asher Shertok

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

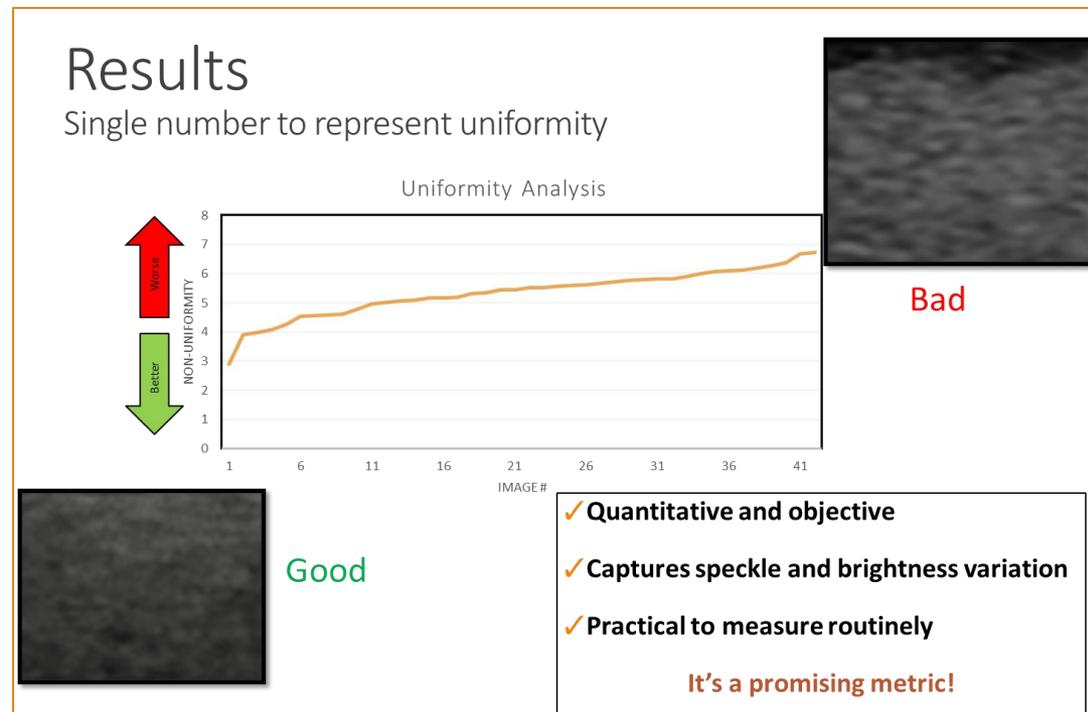


Asher's work was presented at
 NCC-AAPM Meeting
 Young Investigators' Competition
 La Crosse, WI
 October 17, 2025

Toward an Objective Metric of Uniformity in Ultrasound

Asher Shertok

- Conclusions
 - Promising metric!
- Next steps
 - Continue testing against data sets
 - Evaluate in a radiology department
 - Poster? Paper?

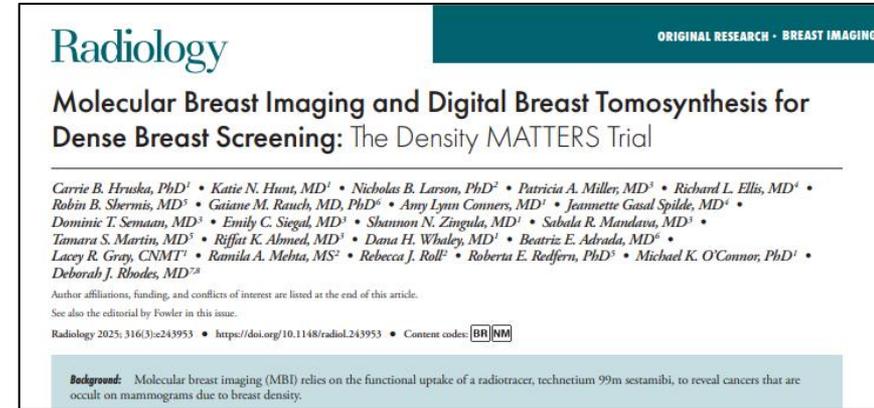


3. Research – MBI QC

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

QC Considerations

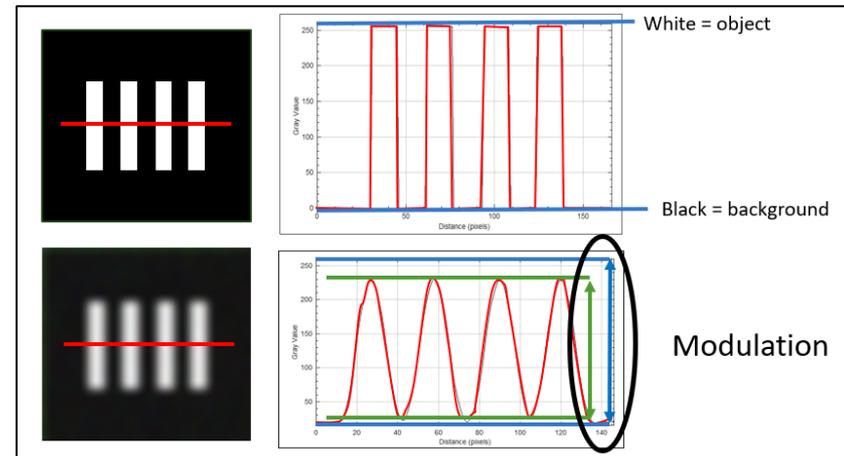
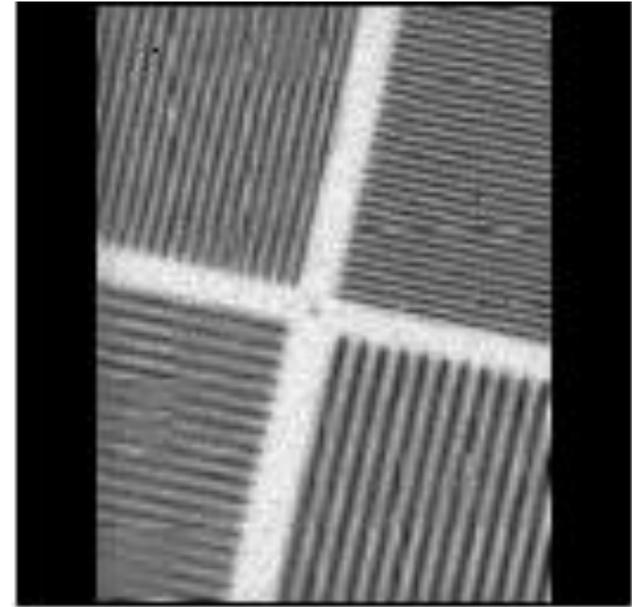
- QC recommendations largely follow standard gamma camera QC
- MBI units commonly have CZT detectors
- CZT (Cadmium Zinc Telluride) detectors are a new technology for nuc med with much higher resolution than previous detectors



Research Objective
 Determine a method to monitor resolution changes for MBI

3. Research – MBI QC

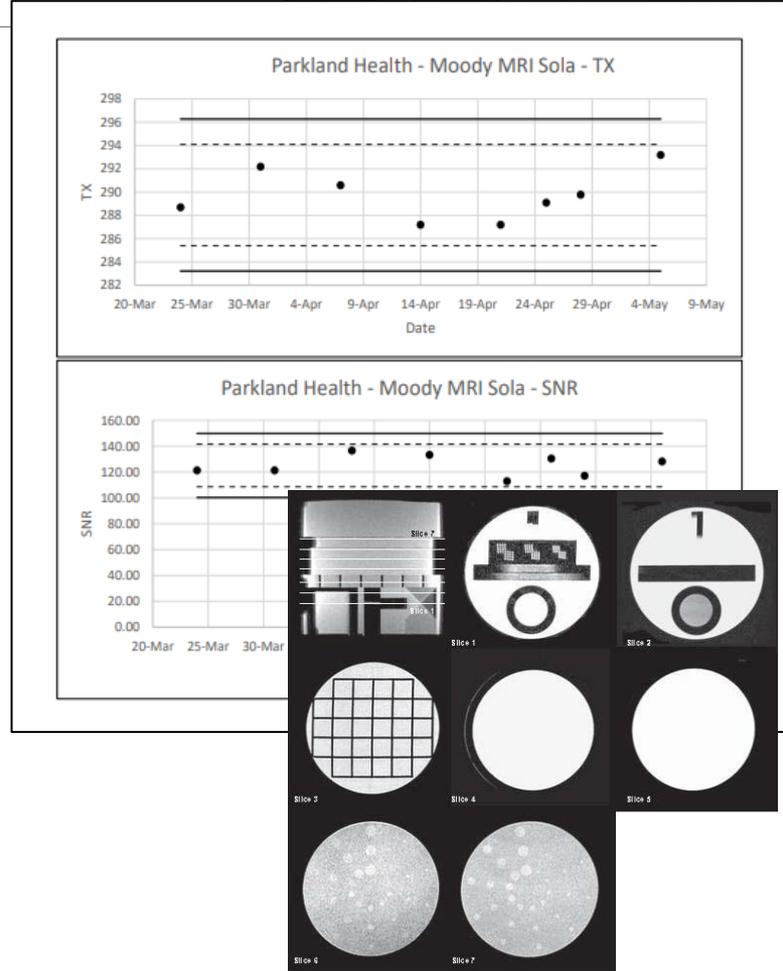
- Typical testing: determine largest bars section that is “resolvable” (not blurry)
- Reality with CZT: *all bars are resolvable!*
- Research is demonstrating that a mathematical method for evaluation of resolution works for MBI





4. Breast MRI QC

- Research Objective: Validate method for breast MRI testing with bilateral coils
 - QC needs to capture the bilaterality
- Initial implementation at a busy breast center shows good sensitivity and consistency



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
- New QC approach should work for low field units

European Journal of Radiology
 Volume 173, April 2024, 111352

Initial experience with a next-generation low-field MRI scanner: Potential for breast imaging?

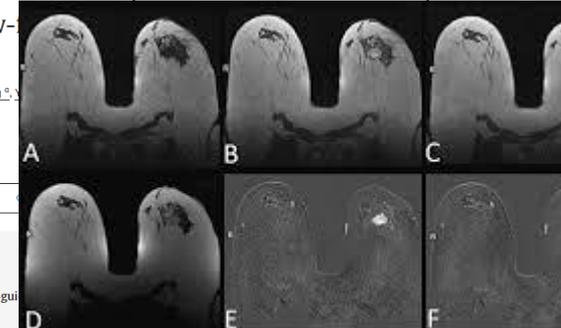
Matthias Dietzel^a, Frederik B. Laun^a, Rafael Heiß^a, Evelyn Wenkel^b, Sebastian Bickelhaupt^a, Carolin Hack^c, Michael Uder^a, Sabine Ohlmeyer^a

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Breast intervention device for low-field MRI with a customized unilateral coil

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- Highlights
- Provide a new, low-cost, and highly accurate low-field MRI-guided diagnosis and treatment scheme for breast cancer patients.
 - A new open device for MRI-guided breast interventional diagnosis and treatment is developed.
 - A unilateral coil for breast interventional therapy with good openness that of th
 - A simple intervent

Breast Intervention Device for Low-Field MRI with a Customized Unilateral Coil

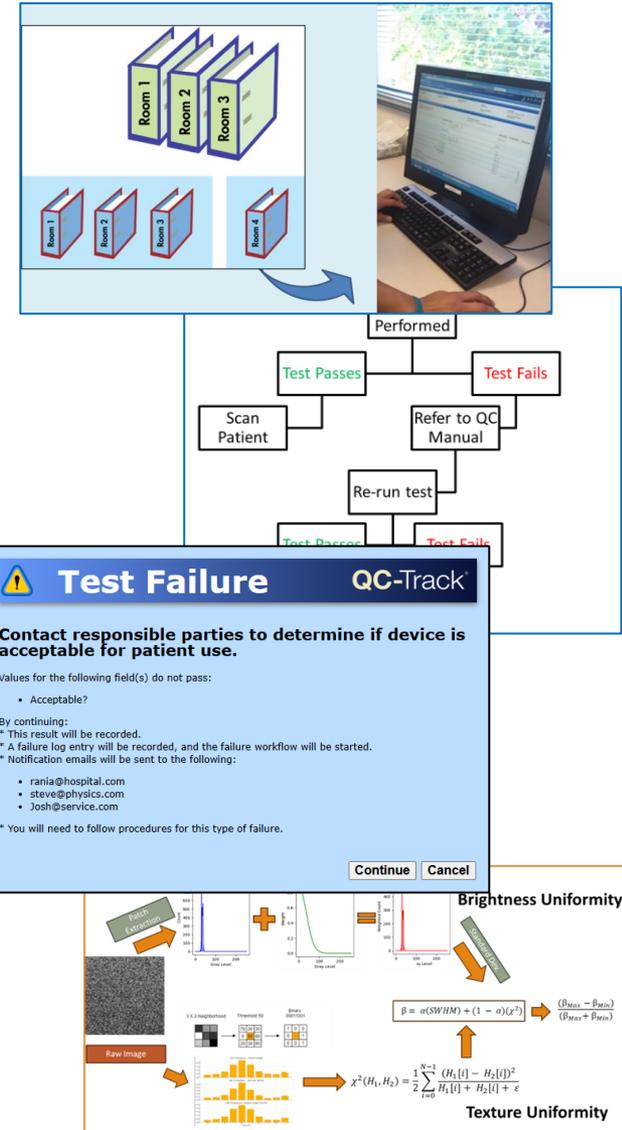
Background & Purpose
 This work describes a unilateral breast coil and prototype intervention device, which provides a customized solution for low-field MRI-guided breast intervention.

Conclusion & Highlights

- Provide a new, low-cost, and highly accurate low-field MRI-guided diagnosis and treatment solution and a open breast intervention device.
- A unilateral coil for breast interventional therapy with a simple and reliable lower localization design is customized.

Conclusions

- Quality control involves a web of people
- A digital “paperless” QC solution can help improve communication and enhance team harmony, esp. in larger, more complex networks
- QC continues to change, e.g. compression thickness testing for FAST Mode
- Keep an eye out for new diagnostic technologies and the changing QC approaches that might be needed





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