QUALITY MANAGEMENT AND EQUIP: 2019

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Mount Sinai

11/20/2019

Quality is a daily process

- Never stops
- All modalities
- Involves all staff
  - Schedulers
  - Registrars
  - Technologists
  - Radiologists
  - Administrators

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Quality is a daily process

Correct exam
Correct patient
Properly performed
by personal with appropriate qualifications
Properly interpreted
Properly audited

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ATTENTION TO DETAIL IS CRITICAL TO OPTIMIZE CANCER DETECTION

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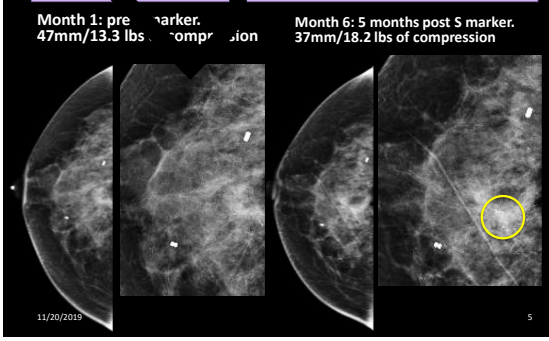
What is wrong with this information?



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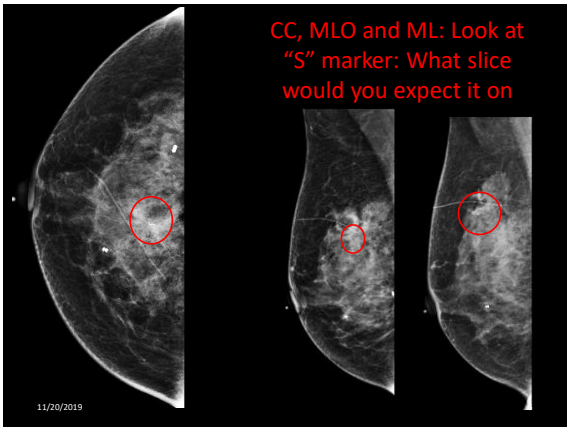

CC, MLO and ML: Look at "S" marker: What slice would you expect it on

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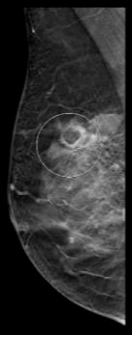
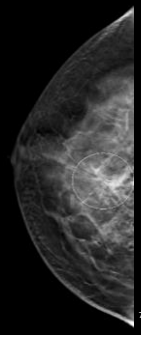
Does this make any sense? How can the tissue marker be on the last slice?

Slice 41/42



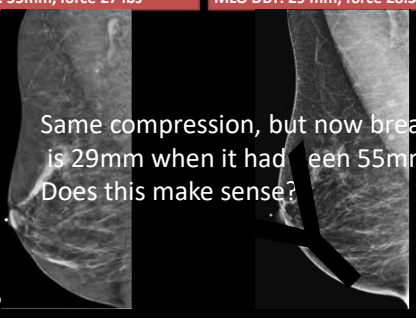
Slice 43/43



Different Patient, but same day: Images are 1 month apart

FFDM: 55mm, force 27 lbs

MLO DBT: 29 mm, force 28.3lbs

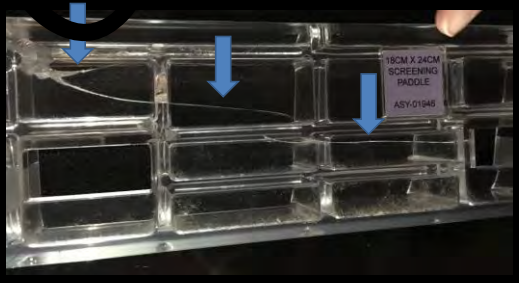


Same compression, but now breast is 29mm when it had been 55mm. Does this make sense?

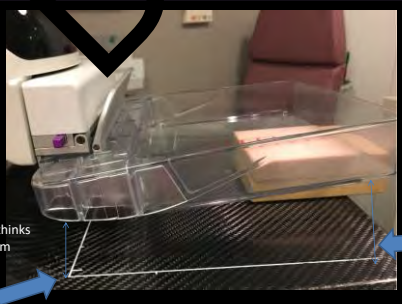
We scratched our heads

- Where was the rest of the breast?
- Why was the breast thickness so much less than what it was previously?

The Paddle is Cracked!



Getting a reverse flex paddle result!



But breast Is 5 cm

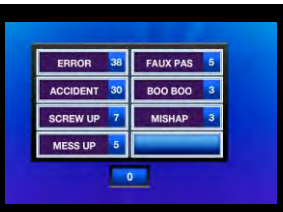
Computer thinks breast is 2cm

What does this mean practically…

- The computer only reconstructs 2cm worth of slices so most of the breast does not benefit from DBT. On the CC, for example, the inferior breast have the "usual" 1mm slices, but the superior breast is excluded from DBT evaluation.
- New paddles came, we thought all was well.

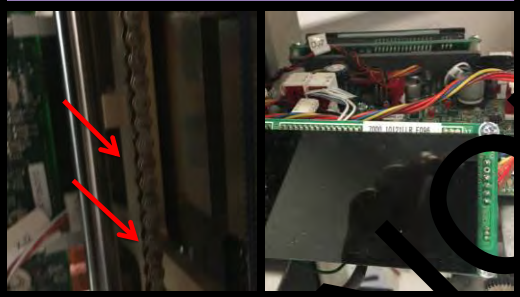
Quality:

- Everyone's responsibility
- Technologist did not think that "checking" paddle was her responsibility



IT HAPPENED AGA IN!!!!!

Chain moves as compress; read out on digital display



Corrective Action – Part 2

- There is a physical sensor on the chain that senses paddle position which gets translated to a digital display
- The digital display information is what the computer uses to create the DBT slices/determine the number.
- Replacing entire sensor mechanism fiexed the problem.

It happened a different time: different location, different unit

- On the left CC the compression was reading at 34mm and slices were reconstructed. Yet both MLO images have same # of slices (80/81) and on the right CC have 72. Looks like we are missing half the breast on the left CC images.
- Vendor said a "fluke" and did not want to address
- After "discussion", replaced sensor
-

EXPECT THE UNEXPECTED: QUALITY IS EVERYONE'S RESPONSIBILITY EVERY DAY. ONE OF THE CORNERSTONES OF EQUIP.

ACR Accreditation Programs

- Mammography
- Breast Ultrasound
- Breast MRI
- Stereotactic Biopsy

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It has taken a long time for ACR to go electronic submission

- Mammography must be electronic unless you have one of the few remaining analog units
- Know your user names and passwords.
- Know when your accreditation expires.
- If the person whose email is the user name, leaves the practice be sure to change or you will not get renewal notices.

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Uploading

- Much harder than one would think
- Be sure staff has uploaded what you selected
- Correct patient
  - Same patient all views or all modalities
- Correct year
  - Not last years mammogram
- Correct images
  - i.e. for US not transverse and oblique

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Mammography ACR Accreditation: every 3 years: Minimal acceptable standards with image review while MQSA inspections are yearly.

Some overlap, but key differences.
Mammography accreditation is mandatory; can use ACR or your state if applicable.

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ACR: Mammography Image Selection

- Fatty – one case per unit
- Dense – one case per unit
- Try to pick cases that don't fall in the "mid-zone"

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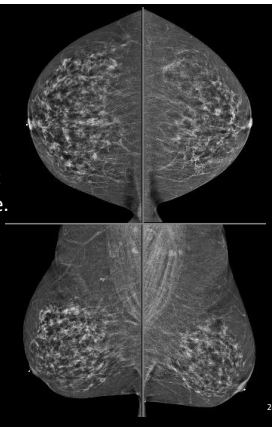
Scattered or Heterogeneous?

- Make it easy for you and the reviewer.
- Pick cases that are not close to the borderline.



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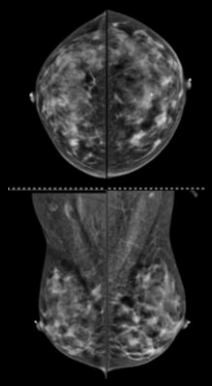
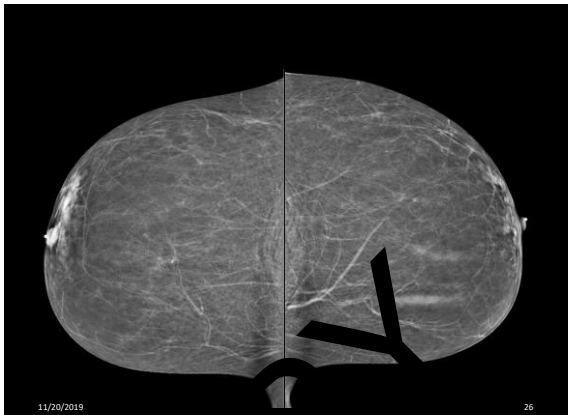
Dense – no question

- If reviewers think a case is not fatty enough or not dense enough, you will be contacted by ACR staff and told to send a different case.





What is a "UNIT"? - Each Mammography Unit that does DBT = 2 units

- The FFDM unit AND the DBT unit
- Both must be ACR accredited – 2 separate units and 2 fees ($1700 + $1500 for the first room, $3000 for each additional room)
- Send Fatty and Dense set of images for each
  - Double the number of images as before
  - Can be same patient, but not preferred
  - DBT images
    - Synthesized or FFDM BUT NOT, the slices! [illegible] will [illegible] returned to you.

Image Criteria: BI-RADS 1

- [illegible] mean that there cannot be an obviously benign calcification
- Does not mean that the axilla is free of nodes
- Don't pick a case with something that one may need to work up if don't have comparisons, i.e. a BI-RADS 2 stable mass.
  - Reviewer will need to type out comments and ACR staff will notify you

Send your best work

- ACR asks for the "best" normal fatty and dense breast case you have.
- ACR understands that not all patients will be perfect, but expects that your facility can acquire a "near" perfect image and that you can recognize it as such in the time allowed.

What is my mammogram window?

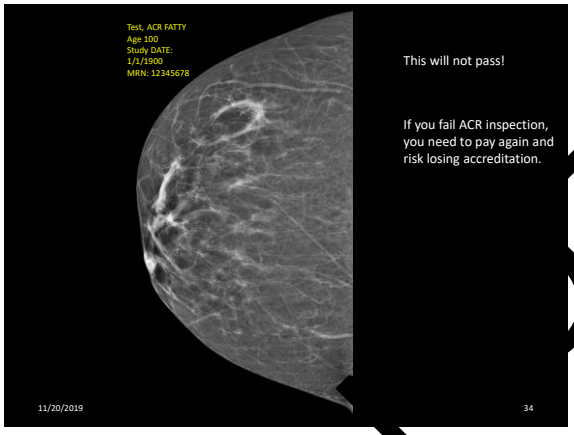
- 30 days before or after you shoot the phantom
- Within 45 days of date your application was deemed "complete"

Extensions for ACR Mammography

- Sorry – not possible
- Since this is FDA mandate, the ACR cannot grant extensions for mammography, but can for other modalities
- But, if there are extenuating circumstances, call the ACR so staff understands what is going on and can attempt to get your review expedited when you do submit
- Every call you make to the ACR is documented in your facility's record.

Image labeling: common cause of failure

- Patient name and MRN or birthdate are mandatory
- Common error
  - Well meaning staff member tries to be HIPAA compliant
  - BAA agreement is part of the sur y agreement
  - Name, other ID are not only allow d but mandated



This will not pass!

If you fail ACR inspection, you need to pay again and risk losing accreditation.

Positioning - #1 reason to fail ACR

When clinical images fail on first accreditation attempt, 92% of time cause is positioning; taking all units applying for accreditation 79% of failures due to positioning

https://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityScorecard/ucm495378.htm

Corre positio ng always was partnership between t chnologist and MD

- MQSA F. l Rul from 1997
  - all IPs are .e final arbiters of the quality of mammography images"
  - Important that IP communicate with technologists whether images are good or bad and give constructive feedback to technologists about positioning
  - 62 Fed. Reg. 55935 (October 28, 1997)

https://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityScorecard/ucm495378.htm

If you did not pass: Appeals

- If you fail ACR accreditation you can appeal
- Must be in writing within 30 days of final report
- Cannot submit new cases/more images
- Must submit both cases even if only appealing one
- A reviewer who did not originally review – a "senior reviewer" will review and the decision is final unless facility appeals directly to FDA
- (if appeal to FDA after 2nd failure, the ACR application is stopped and the facility cannot perform mammography during the appeal process)

https://acrbulletin.org/topics/practice-management/93-radlaw-appeals-of-acr-accreditation-decisions

Once you pass and are accredited…

1.Yearly MQSA inspection

2. Subject to random ACR inspection
- –50 sites/year are visited by the ACR
- –On site team of radiologist, technologist (ACR staff member) and physicist

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MQSA Inspection

Thank you to Dr. David L rner
Medical Officer in the Divi on of
Mammography Quali Stand ds, FDA

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MQSA: Mammography Quality Standards Act

- Passed in 1992/went into effect in 1994.
- All mammography facilities must be accredited by an FDA approved accreditation body and be certified by the FDA or state as meeting requirements
- Facilities undergo an annual inspection
- Facilities must display the certifica issu d by the FDA

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What to expect for the yearly MQSA inspection

- testing
- Review of quality assurance and quality control records including EQUIP – policies and procedures
- Review of Medical physicist reports
- Review of Medical audit and outcomes analysis records
- Review of Personnel records: initial qualifications, CME/CEU and continuing experience
- Will get at least five days notice before the start of the inspection:10 – 14 months after your last inspection

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MQSA Improved Mammography Quality

- After 25 ars, r ogram was augmented with EQUIP (Enh ing Quality Using the Inspection Program)
- Was introduced on October 27, 2016, and marked the beginning of the 25th year since the passage of MQSA.
- 3 EQUIP inspection questions were added

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EQUIP: Enhancing Quality Using the Inspection Program

- 1. Random of audit of mammography image quality – all technologists all interpreting physicians
- 2. Plan and documentation of corrective actions on individual cases
- 3. Lead interpreting physician and physicist greater communication and documentation of working together

Make liberal use of the FDA website for questions and updated information and informational videos.

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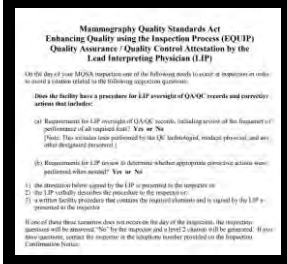
THE EQUIP MQSA PROCESS: DOCUMENTATION AND INSPECTION

Role of the LIP

- The LIP should be present (in person or by telephone) to discuss EQUIP matters with the inspector, or there should at least be a signed and dated LIP attestation available for inspector at the time of inspection.

LIP EQUIP Attestation- signed YEARLY



Mammography Quality Standards Act
Enhancing Quality using the Inspection Process (EQUIP)
Quality Assurance / Quality Control Attestation by the
Lead Interpreting Physician (LIP)

On the day of your MQSA inspection one of the following needs to occur: a) inspectors or order to record a citation related to the following inspection questions:

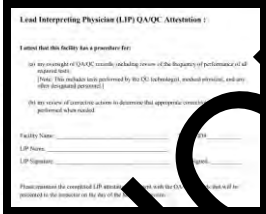
Does the facility have a procedure for LIP oversight of QA/QC records and corrective actions that includes:

(a) Requirement for LIP oversight of QA/QC records, including review of the frequency of performance of all required tests? Yes or No
[Note: This includes tests performed by the QC technologist, medical physicist, and any other designated personnel.]

(b) Requirements for LIP review to determine whether appropriate corrective actions were performed when needed? Yes or No

1) the attestation below signed by the LIP is presented to the inspectors or
2) the LIP verbally describes the procedure to the inspectors or
3) a written facility procedure that contains the required elements and is signed by the LIP is presented to the inspector

If one of these scenarios does not occur on the day of the inspection, the inspection question will be answered "No" by the inspector and a level 2 citation will be generated. If you have questions, contact the inspector at the telephone number provided on the Inspection Confirmation Notice.



Lead Interpreting Physician (LIP) QA/QC Attestation :

I attest that this facility has a procedure for:

(a) my oversight of QA/QC records, including review of the frequency of performance of all required tests;
[Note: This includes tests performed by the QC technologist, medical physicist, and any other designated personnel.]

(b) my review of corrective actions to determine that appropriate corrective actions were performed when needed.

Facility Name: _____ ID: _____

LIP Name: _____

LIP Signature: _____ Dated: _____

Please maintain the completed LIP attestation with the QA records that will be presented to the inspector on the day of the inspection.

Available at: https://www.fda.gov/media/101655/download

MQSA inspection EQUIP deficiencies began to be given after March 2, 2018

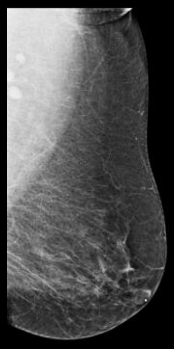
- Deficiencies related to EQUIP result in Level 2 citations
  - Facilities must perform and submit documentation of corrective action to FDA within thirty days of the inspection.
  - During the third year of EQUIP in 2019, any repeat EQUIP violations will trigger a clinical image review of mammograms performed by your facility

Quality Assurance: Clinical Image Corrective Action

- Does the facility have procedures for corrective action when clinical images are of poor quality?
- (a) Do the procedures include a mechanism for providing ongoing IP feedback on image quality to RT's or other designated facility personnel?
- (b) Do the procedures require documenting any corrective actions taken and documenting the effectiveness of any corrective actions taken?

FAQ

- 1. Policy can be written or verbal
- 2. For this portion of EQUIP, the IP determines if images are adequate (could be software)
- 3. Facility determines how to document corrective action and document whether or not effective and the timeline
- 4. Question is only on process not on effectiveness



Left MLO

- There is no IMF and the breast is sagging. This should be flagged on internal EQUIP forms or electronic means as inadequate unless extenuating circumstances documented.

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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?

- Do the procedures include a mechanism for regular reviews of image quality attributes of a sample of mammograms performed by each active RT and a sample of mammograms accepted for interpretation by each active IP?
- Is there documentation of such eview since the last inspection?

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FAQ

- 1. At least annually
- 2. No minimum number of cases
- 3. Must be documented in writing
- 4. Must be done by IP or designated perso
- 5. Must be dated, but signing not neede
- 6. Don't need to include those who hav left the practice at time of on-site insp tion

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- ty not practice specific, i.e. if same doctors and technologists rotate to multiple offices each individual must be evaluated in each office
- 8. does not include interpretation accuracy
- 9. must use current images, i.e. not the priors

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Ima attri tes hat must be a essed are:

- 1. positi ing
- 2. compres
- 3. exposure level
- 4. contrast
- 5. sharpness
- 6. noise
- 7. artifacts
- 8. examination identification

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

- Does the procedure include requirements for LIP oversight of QA/QC records, including review of the frequency of performance of all required tests?
- Does the procedure include requirements for LIP review to determine whether appropriate corrective actions were performed when needed?

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FAQ

- Can be written or verbal policy
- Frequency is not specified – should ensure that the QC tests are done at required intervals and that any needed corrective action is done

How did we do in 2017 and what are the questions?

EQUIP Question	Number of Deficient Inspections	Percent of Total Inspections
Question 1(a) - There is no system in place that includes a mechanism for providing ongoing IP feedback on image quality	990	12%
Question 1(b) - There is no system in place that includes a mechanism for documenting any needed corrective action and the effectiveness of any corrective action taken	1,971	23%
Question 2(a) - There is no mechanism in place for regular reviews of image quality attributes of a sample of mammograms performed by each active RT and a sample of mammograms accepted for interpretation by each active IP	2,776	33%
Question 2(b) - There is no documentation of review since the last inspection	2,586	30%
Question 3(a) - There is no system in place for LIP oversight, including review of the frequency of perfor of all required tests	1,579	19%
Question 3(b) - There is no system in place for LIP review to determine whether appropriate corrective acti were performed when needed	1,891	22%

https://www.fda.gov/rad products/mqsa-insights/equip-first-year

EQUIP Automated: Examples where commercially available products can help

- Monitor all screening mammogram for image quality issues including positioning and compression
- Provide specific performance metrics by technologist that indicate areas where improvement is needed
- Identify poor-quality images for review

Level 1 Violation Examples

- Tech ologist or Physicist License issue
- No system to provide mammography reports in a timely manner
- No system to provide lay letters
- No system to communicate suspicious cases ASAP
- Phantom QC records missing
- No physicist survey – overdue for 2 years

https://www.fda.gov/downloads/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityCertificationandInspection/UCM240433.pdf

Level 2 Violations – Part 1

- MD CME
- Issues with M ial experience (240/6 months) or continuing experience (960 in 24 months)
- MD new modality training issue
- RT mammo training
- RT CEU missing (need 15 in 36 months)
- RT experience issue (need 200/24 months)
- RT new modality training
- Physicist new modality, survey, initial experience and CME (15/36 months)

Level 2 Violations - part 2

- Mammogram reports without assessment category
- Unsigned MG reports
- No corrective action for failed QC phantom
- Physicist survey 14 months overdue
- Physicist survey is missing some tests or name of physicist
- Performance verification test after each mobile unit move

Level 2 violations – part 3

- Missing infection control procedure
- Missing medical outcomes audit
  - No example or attempt to get biopsy results
- Medical Audit not reviewed by interpreting MD
- Audit – positives not entered
- No consumer complaint procedure

If there is a violation

- For a Level 1, repeat Level 1, or repeat Level 2 observation, the facility must correct the problem(s) as soon as possible. Don't wait for a Warning Letter, but send a written response to FDA within 15 days after the inspection.
- For a Level 2, the facility must correct the problem(s) as soon as possible. The facility should respond to FDA within 30 days after the inspection.

Old Level 3 observations now Level 2

- QA program is missing personnel responsibilities or QC test procedures
- Missing repeat analysis or compression device QC
- Physicist survey is missing tests, data or corrective action
- No corrective action documented for survey test failures

If you don't respond or your response is not adequate..

- FDA may need to re-inspect to verify that all problems were corrected.
- The cost of this inspection is $1144.
- FDA may send a Warning Letter, based on several factors, including the severity of the problems, whether the facility responded or responded adequately, and past history of problems.
- Continuing violations at mammography facilities could result in FDA taking regulatory action, such as Directed Plans of Correction, Civil Money Penalties, Suspension or Revocation of an MQSA certificate.

What you really don't want: broadcast email and often media coverage

Facility ID Nu
183764

Adverse Event:
On August 21, 2017, the [illegible] Administration (FDA) initiated an Additional Mammography Review (AMR) of mammograms performed [illegible] facility due to deficiencies noted during the February 28, 2017 MQSA inspection performed by the State of Florida.

On November 30, 2017, the ACR notified the FDA and the facility that the AMR revealed serious deficiencies with clinical image quality and failed to meet the ACR's clinical image evaluation criteria.

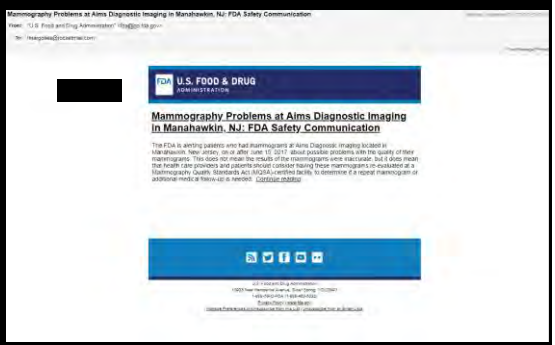
Action Taken:
On November 9, 2017, the ACR revoked the facility's mammography accreditation.

On November 15, 2017, the FDA declared the facility's MQSA certificate to be no longer in effect until such time as the facility's accreditation is reinstated and the facility has complied with all the requirements of the FDA.

Corrective Action:
Based on the serious image quality deficiencies noted during the AMR, the FDA required the facility to perform a Patient and Referring Healthcare Provider Notification (PPN) to alert all at-risk patients and their providers of the mammography quality problems at the facility.

To date, the facility has not complied with the FDA's PPN.

Status of the Facility:
The facility is believed to be closed.



Summary of Problem or Scope

The FDA became aware of potential problems with the quality of mammograms performed at Aims Diagnostic Imaging located at the following address:

1109 Beacon Ave
Manahawkin, NJ 08050

The results of this facility's annual MQSA inspection indicated that required quality control tests were not performed after June 15, 2017. As a result, the FDA notified the facility that it was required to undergo an Additional Mammography Review to determine if the overall quality of mammography performed at the facility was compromised due to the failure of the facility to operate in compliance with the MQSA, and whether there was a need to notify affected patients.

After Aims Diagnostic Imaging repeatedly failed to submit the mammograms needed to perform the Additional Mammography Review, the American College of Radiology, this facility's accreditation body, revoked the facility's accreditation on September 17, 2018 for failing to comply with the Additional Mammography Review order.

The MQSA requires that all mammography facilities meet certain baseline quality standards and be certified to legally operate in the United States. This facility failed to meet the quality standards of the MQSA. On September 19, 2018, the FDA placed the facility's MQSA certificate in a "no longer in effect" status. This facility can no longer legally perform mammography as it does not have an active MQSA certificate.

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Report Wording: BI-RADS 4 subcategories

- MQSA Reporting requirement goal: clear and accurate communication to facilitate patient care.
- Subcategories are allowed, but are not sufficient by themselves to meet the MQSA requirement.
- The BI-RADS number (whether 4, or 4a-b-c, etc.) is not part of the FDA requiremer to have a final assessment, and if used by itself (g., if you just said "Assessment: BI-RADS 4" and othing else) it does not meet MQSA , bu h included (or excluded) as the practitioner sees fi

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Danger of 4a in report

- ACR's 4a subcategory wording is "Low suspicion for malignancy"
- Could be very misleading if used by itself/if the assessment "Suspicious" does not also appear
- As far as MQSA is concerned, the presence of t number is irrelevant, and all you would be ying about this category 4a case is "Low suspic n for malignancy," which might sound a lot like "Benign" or "Probably Benign," when ou re ly are meaning probably needs biopsy

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HOW ARE WE DOING?

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Certific on St istic or October 1, 2019

Certified facilities, as of October	8,704
Certification statistics, as of October	
Total certified facilities / Total	8,668 / 20,952
Certified facilities with 2D digital u / Accredited 2D digital units	8,644 / 12,864
Certified facilities with DBT[14] units / Accredited DBT units	5,607 / 8,059
FY 2019 inspection statistics, as of October 1, 2019	
Facilities inspected	8,332
Total units at inspected facilities	19,069
Percent of inspections where the highest noncompliance was a:	
Level 1 violation	0.7%
Level 2 violation	15.2%
Percent of inspections with no violation	84.2%
Total annual mammography procedures reported, as of October 1, 2019[7]	39,630,813

Facilities with DBT also have FFDM so the DBT facilities count is included within the digital facilities count.
https://www.fda.gov/radiation-emitting-products/mqsa-insights/mqsa-national-statistics

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Comparison: Nationally doing many more mammograms with many more inspections violation free

December 2002	
Certified facilities, as of October 1, 2002	9,306
Certified facilities, as of December 1, 2002	9,235
Facilities inspected in FY 2003, as of December 1, 2002	1,457
Total units at inspected facilities, as of December 1, 2002	2,161
Percent of FY 2003 inspections where the highest noncompliance was:	
a Level 1 violation	2.0%
a Level 2 violation	24.7%
a Level 3 violation	9.1%
Percent of FY 2003 inspections with no violation	64.2%
Total annual mammography procedures reported, as of December 1, 2002[1]	29,097,838

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Most common reason sites fail ACR accreditation are all positioning

- 1. Inadequate pectoralis
- 2. Sagging breast
- 3. Posterior tissue not well see
- 4. Skin folds
- 5. PNL on CC not within 1 cm of MLO
- 6. Excessive exaggeration

Note: Usually a combination of positioning deficiencies

THE MLO VIEW

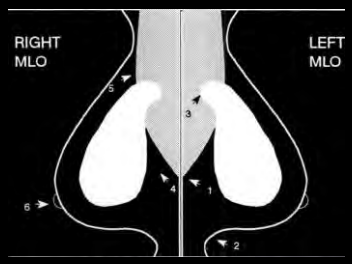
MLO Position

- Muscle to the nipple line, wider at top, narrows at bottom
- Breast looks lifted "out" not sagging down or "camel nosed"
- Posterior tissue (retroglandular fat) from the axilla to the inframammary fold
- No folds
- No unsharpness: front of muscle, imf edge of vessels and near nipple

he MLO IEW

1. ralis Muscle seer evel of nipp.
2. IMF is included and is nicely open
3. Superior glandular tissue is included; may overlap the pectoralis. This tissue is lateral and posterior to the lateral margin of pectoralis so if don't mobilize pectoralis will miss this tissue.
4. Should see retroglandular fat
5. Anterior margin of Pectoralis is convex

Eklund. Radiology 1994: 190: 297 -307



Ni ole on MLO

- The nipp oin to missing tissue
- A nipple tha urns medially = lacking __?__ tissue
- A nipple that turns laterally = lacking __?__ tissue
- A nipple that points to the floor = lacking posterior inferior tissue (imf)

IMF Issues

- 1. No IMF
- 2. Folds in IMF
- 3. Sagging of Breast

4 PATTERNS OF PECTORALIS MUSCLE: What we really see

Very much related to the relaxation of the muscle.

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IDEAL

1. Anterior pectoral muscle is convex.

2. Pectoralis extends to at least the nipple.

3. You get this when the pectoralis, shoulder, arm and hand are relaxed and properly moved or "mobilized " medially and kept in its medial position when compression is applied.

Eklund. Radiology 1994: 190: 297 -307

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LESS THAN IDEAL

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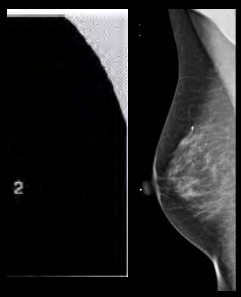
ncave Pectorali

1. ve anterior marg

2. pectora... properly mobilized medially OR was tightened by allowing elevation or abduction of the patient's arm

Eklund. Radiology 1994: 190: 297 -307



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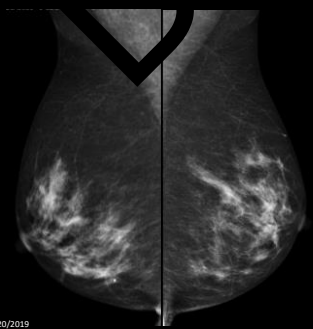
Conc ve Pectoralis



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Parallel Pectoralis

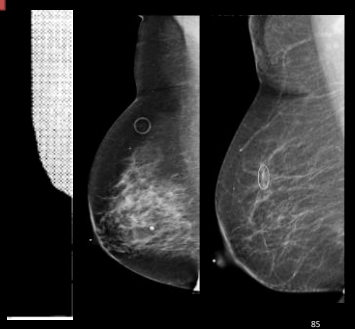
1. Pectoralis parallel to the posterior margin of image

2. Occurs when there is a failure to mobilize the muscle and breast medially

Or

3. Allowing the muscle to move back laterally before compression applied.

Eklund. Radiology 1994: 190: 297 -307



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Muscular

1. Well developed and unusually mobile pectoralis muscle

2. If see this, generally will have great posterior tissue visualization, but must be mindful of anterior tissue - especially subareolar. Might need a supplemental view.

Eklund. Radiology 1994: 190: 297 -307

THE CC VIEW

Include maximum amount of tissue in transverse plane

Should see pectoralis about 30 % of time – what is your %

CC Images

- All medial tissue included (will not see medial on the MLO view)
- Nipple points straight
- All posterior tissue on the film (the CC shall be within 1 cm of the MLO if the MLO is positioned properly)
- No folds or unsharpness: edges of vessels, near nipple

CC Images

- Nipple an indicator
  The nipple points to what is missing
- Muscle an indicator
  The muscle indicates what is gained
- Presence or absence of retroglandular fat

ULTRASOUND

Different than mammography

- Online submission has begun – can be tedious – be careful to upload correct images
- Not mandatory (can get extensions)
- You choose: Diagnostic (cyst and solid mass, core biopsy, FNA)
- This program evaluates diagnostic breast ultrasound NOT screening breast ultrasound

Annotation

- Name
- Date
- Other ID
- Clockface and distance from nipple in CM on all images

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Mammogram MUST accompany US images

- Must be within 60 days PRIOR, but can be from different facility as long as name and DOB the same
- Must be true size or have scale
- For biopsy case, don't send the post-biopsy clip images (fail) – send the pre-mammogram
- Must have the mass/cyst circled or marked
- Must be the same mass/same patien
  - I have seen the contralateral breast im… es sent or at least annotated that way
  - I have seen a different patient's ma… am submitted

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CYST

- Must be a simple cyst
- No septations
- Minimal if any reverb artifact
- Look for a cyst > 5mm

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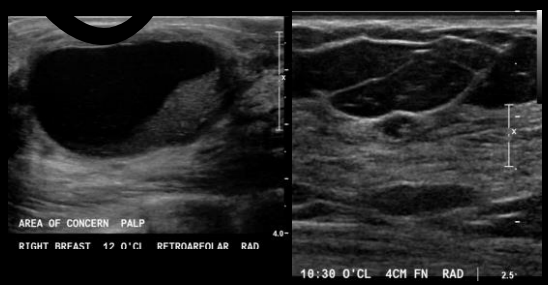
Don't send these for cyst cases



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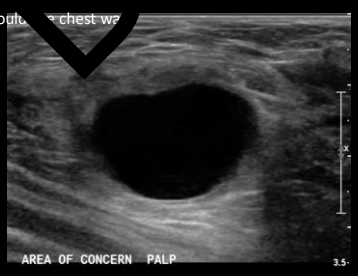
- Better - shoul… chest wa…



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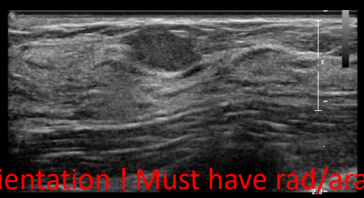
Solid Mass – would this pass?

- Can be benign appearing or malignant appearing

MUCINOUS CARCINOMA



NO, no orientation ! Must have rad/arad
Or sag/trans

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Biopsy

- Best work
- Parallel not angled to chest wall
- You choose pre and post fire or if in non-fire mode just post fire
- Must be appropriate for biopsy, i.e. not a fat lobule

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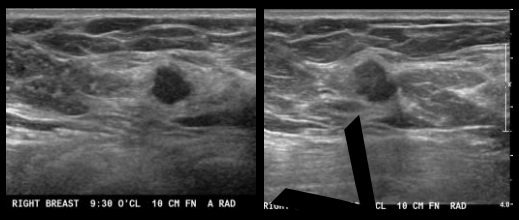
Pre-biopsy images



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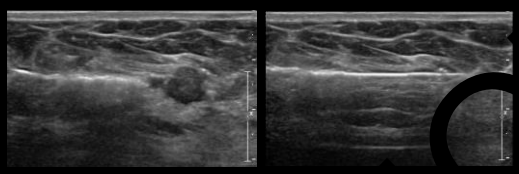
Not ideal needle visualization pre-fire: poorly differentiated IDC



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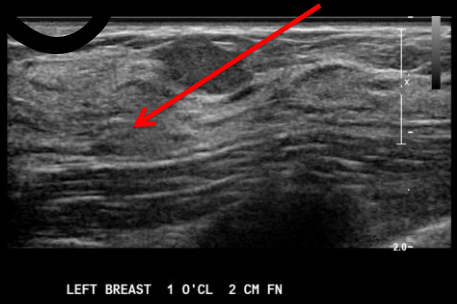
If this is your needle path you will fail



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Do I need to send in FNA images?

- Only if your FNA biopsies
  - Not cyst aspiration
  - Not abscess drainage
  - Not lymph nodes

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Medical Audit

- Is required
- It is separate from the Mammography Audit, i.e. you cannot assume your mammography audit is capturing your US data or include as combination reports.

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MRI: STAND ALONE ACCREDITATION

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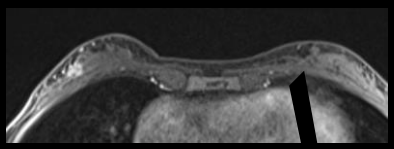
One Cancer Case

- Make it simple!



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What to send

- The Testing Instructions specify that, if possible, you submit ONLY the 4 required sequences:
  - T2-weighted/bright fluid
  - Pre-contrast T1
  - Early phase (first) post-contrast T1
  - Delayed phase (last) post-contrast T1.

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Common Causes of MRI failure

- [illegible]ng
- Delay in imaging after contrast administration
- Motion
- Ghosting
- Chemical Shift
- Aliasing

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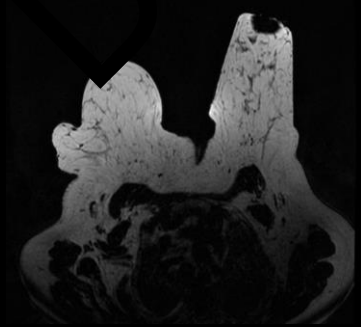
[illegible]mbarr[illegible]sing Positioning



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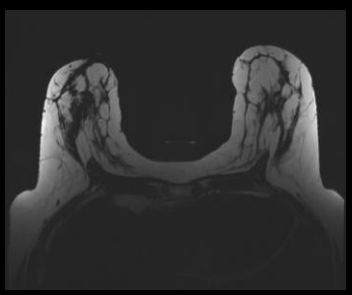
Nipples pointed medially – poor positioning



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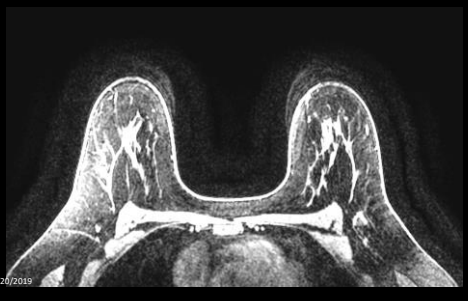
Too much motion



11/20/2019 110

Medical Audit

- Is required
- It is separate from the Mammography Audit, i.e. you cannot assume your mammography audit is capturing your MRI data or include as combination reports.

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STEREOTACTIC BIOPSY

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Pre-Biopsy Mammogram

- CC and MLO/ML/LM views – not spots, mags or DBT slices (just extras that annoy reviewers)
- Must be within 60 days prior to biopsy
- Image must be true size or with scale
- Calcifications must be seen and circled (and not obscured by marking)
- Calcifications must be appropriate for biopsy, i.e. BI-RADS 4 or 5

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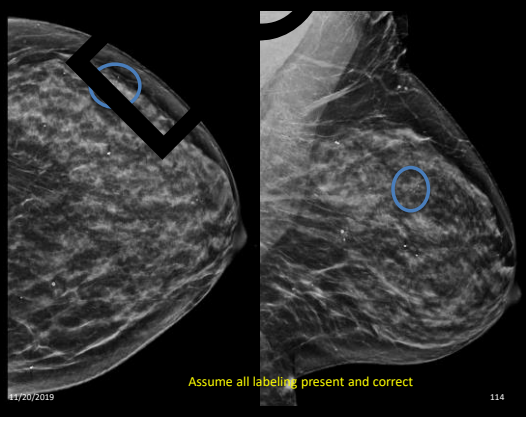

Assume all labeling present and correct

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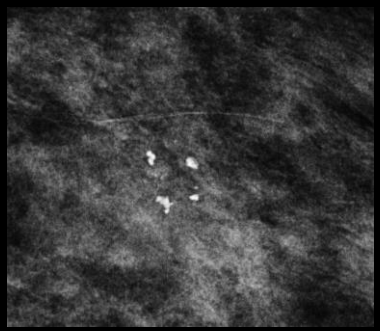

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Case Selection Hint

- Pick a case with one group of calcifications so reviewer does not have to ponder if you circled and biopsied the same group.
- Make sure your circle or other annotation does not obscure the finding.

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Biopsy Images

- Need the reviewer to see the calcifications
- Need Exam ID information
- Pre-fire images: needle in front of or at leading edge of calcification
- Pre-biopsy (post-fire) images: needle positi ed near calcific ions (can be seen n r bowl or at owl even if bowl tur away)

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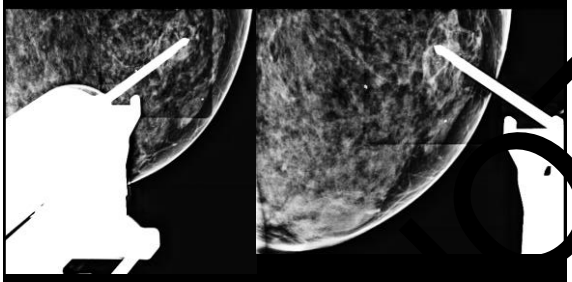
Assuming all labeled correctly with name, etc. This is the post-fire Pre-biopsy pair showing the calcifications



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Specimen Image

- E m ID cluding laterality
- Must be the SAME calcifications as circled
- Just because you got the calcifications don't assume the case will pass

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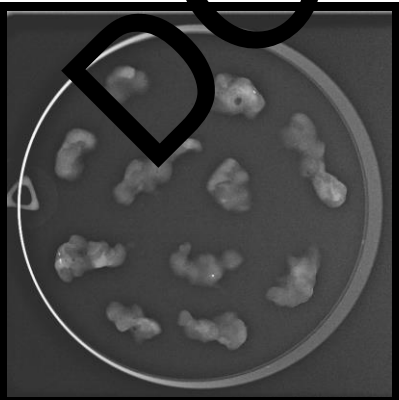
DCIS



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Combined DR/IR residents

- MQSA guidance coming
- Will state that 240 mammograms must be in last 2 years of residency.
  - Either last 2 years of combined residency
  - OR last 2 years of DR, but then the IR resident = mammo attending for MQSA purposes and would need to meet continuing experience requirements.

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Thank you for all you do!
THANK YOU!
THANK YOU
YES, I DID HAVE MY MAMMOGRAM TODAY... WHY DO YOU ASK?
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