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MQSA EQUIP – a self-reported pathway to compliance

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OUTLINE

MQSA's EQUIP initiative

- Background and basics.
- Inspection requirements.

- Single-site pathway to compliance.
- Step-by-step how to get compliant.
- Commitments to remaining compliant.

- Inspection analysis.
- Review of persisting citations.

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1992: Congress passes MQSA.

Mammography Quality Standards Act and Program

FDA U.S. FOOD & DRUG ADMINISTRATION

After MQSA passed in Congress - they delegated responsibilities to the FDA.

25th Anniversary

EQUIP: Enhancing Quality Using the Inspection Program

2017: Reassess and reassign resources and accountability.

Boots on the ground: compliance officers of MQSA and EQUIP?

Accrediting Bodies (ABs)

ACR® American College of Radiology — Quality is Our Image

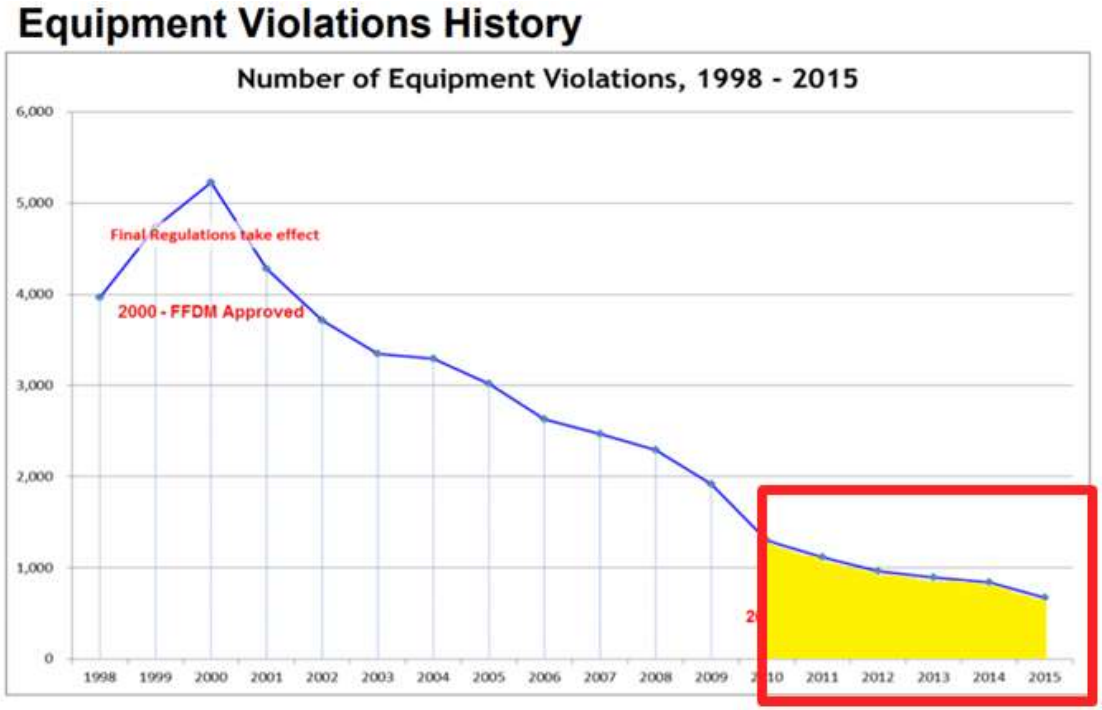
OR state department of health approved ABs: **Arkansas, Texas, and Iowa**

Inspectors (1995)

Federal | **State**

BACKGROUND

FDA considers the 25th anniversary of MQSA to reassess and realign goals of the inspection program:



https://www.fda.gov/media/100194/download

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BACKGROUND

FDA considers the 25th anniversary of MQSA to reassess and realign goals of the inspection program:

- Persisting issues?

The Human Factor!

- MP QC testing: within appropriate time frame.
- Acceptance of images of poor diagnostic quality.
- Lack of corrective action (CA) mechanism.
- Misunderstood chains of responsibility.

Components of EQUIP

- Increase LIP responsibility and oversight.
- Keep MQSA current and committed.

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Components of EQUIP: Question 1

Q1: Clinical image corrective action on an *ongoing basis*.

1. Does the facility have procedures for corrective action (CA) 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?

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[https://www.fda.gov/media/101641/download]

Components of EQUIP: Question 2

Q2: Clinical image quality review (CIQR) at *fixed frequencies*.

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?

(a) 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?

(b) Is there documentation of such review since the last inspection?

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[https://www.fda.gov/media/101641/download]

Components of EQUIP: Question 2

Q2: Clinical image quality review (CIQR) at *fixed frequencies*.

- Must assess mammograms “quality” based on these required 8 attributes:
  - Positioning
  - Compression
  - Exposure Level
  - Contrast
  - Sharpness
  - Noise
  - Artifacts
  - Examination Identification

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[https://www.fda.gov/media/101641/download]

Components of EQUIP: Question 3

Q3: LIP quality control/assurance oversight on an *ongoing basis*.

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

(a) Does the procedure include requirements for LIP oversight of QA/QC records, including review of the frequency of performance of all required tests?

(b) Does the procedure include requirements for LIP review to determine whether appropriate corrective actions were performed when needed?

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[https://www.fda.gov/media/101641/download]

Important takeaways

- The new inspection questions were written broadly and openly.
- From the top – down - FDA inspectors have been encouraged to remain flexible.
- Inspectors are encouraged to consider the broader goals of EQUIP and only then assess compliance.

Important takeaways

	SOP?	Written documentation?	Time frame?	LIP Signature / verbal consent?
▪ Q1	✗	✓	NA	✗

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Important takeaways

	SOP?	Written documentation?	Time frame?	LIP Signature / verbal consent?
▪ Q1	✗	✓	NA	✗
▪ Q2	✗	✓	✓	✗

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Important takeaways

	SOP?	Written documentation?	Time frame?	LIP Signature / verbal consent?
▪ Q1	✗	✓	NA	✗
▪ Q2	✗	✓	✓	✗
▪ Q3	✗	✗	NA	✓

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Single-site pathway to compliance

- At implementation – single facility with:
  - 4 on-site units
  - 7 technologists
  - 4 radiologists
  - ~ 12,000 exams / year
- It was known that a new off-site system was in the works so motivation to streamline these processes was **high**.
- Onboarding of the EQUIP initiative was started in August 2017.
  - An operational workflow was in place by October 2017.

Getting compliant

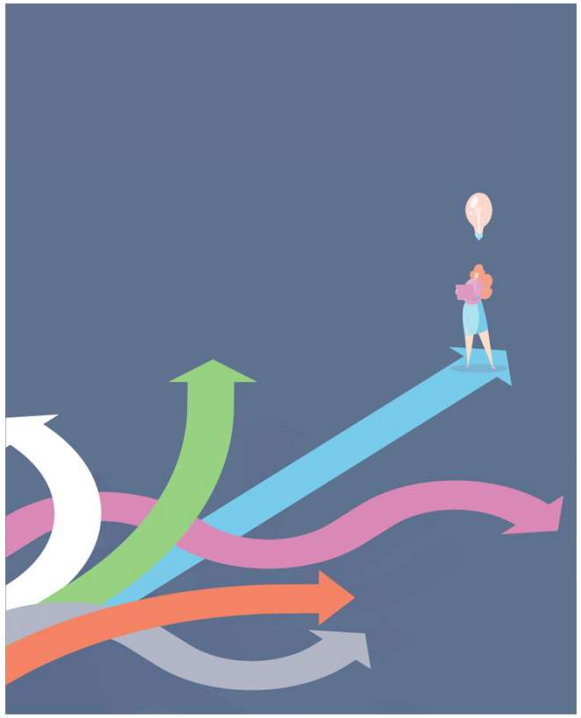
Step wise approach to building out an EQUIP compliant infrastructure.

- Identifying ‘new’ inspection aspects.
- Creating an engaged and knowledgeable task force.
- Conforming current practices to highlight areas already compliant.
- Building in those efforts lacking within our current practice.
- Generating efficient documentation.
- Creating an environment of accountability.

Getting compliant

Step wise approach to building out an EQUIP compliant infrastructure.

- Identifying ‘new’ inspection aspects.
  - Clinical Image Quality Reviews (CIQR) for both RT and IP.
  - Defined system for LIP oversight/signature responsibilities over QA/QC.



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Getting compliant

Step wise approach to building out an EQUIP compliant infrastructure.

- Creating an engaged and knowledgeable task force.
  - Radiologists - Lead interpreting Physician (LIP)
  - Technologists - Mammography Manager
    Mammography QC lead
  - Imaging Physicists
  - Information Technology (IT) team

Getting compliant

Step wise approach to building out an EQUIP compliant infrastructure.

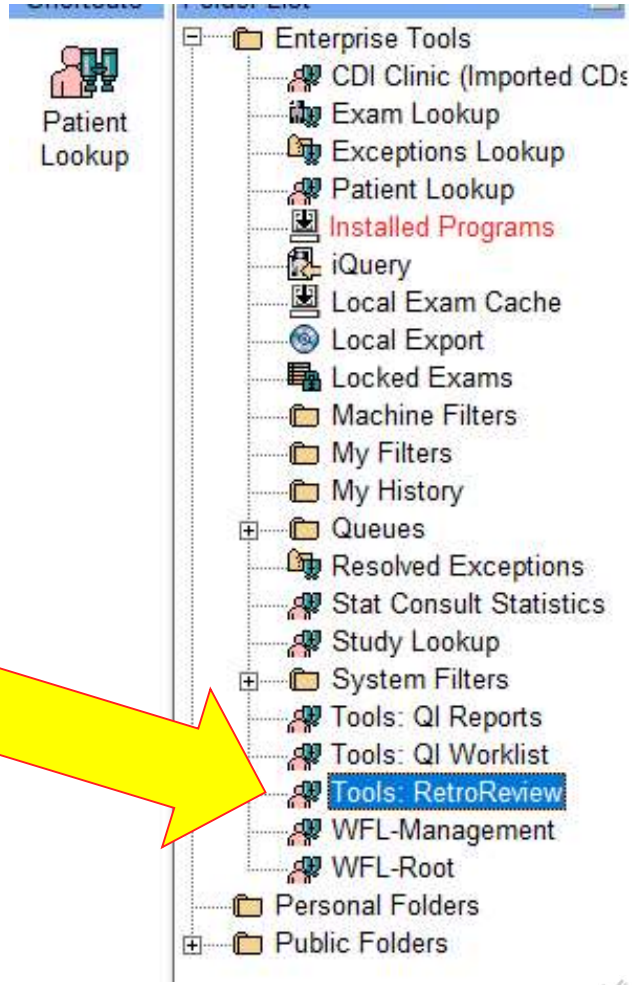
- Conforming current practices to highlight areas already compliant.
  - Q1: Quality Improvement (QI) ticketing system.
  - Q3: QC bi-annual meeting.

Getting compliant

Step wise approach to building out an EQUIP compliant infrastructure.

- Building in those efforts lacking within our current practice.

Q2: Clinical image quality review (CIQR) at *fixed frequencies*.



Getting compliant

Step wise approach to building out an EQUIP compliant infrastructure.

- Creating an environment of accountability.

Lead Interpreting Physician

- Decide how to most effectively implement EQUIP into the section.
- Work alongside IT to develop a streamlined feedback mechanism for the retrospective review of both technologists and interpreting physician images.

IT

- Create a retrospective review portal for the detailed categorization and recording of image quality issues by the LIP.
- Create a retrospective review dashboard to graphically display image quality issues by technologist.

Physics

Manager and QC lead Technologists

Develop a quarterly review system focused on bringing all EQUIP participants together to discuss:

- Previous 3 months technologist QC booklets – review for completion and unexpected findings.
- Prior imaging physics QC report and follow-up on non-compliant findings.
- Repeat and reject rate for section.
- Previous and upcoming inspections, accreditations, and preventative maintenances

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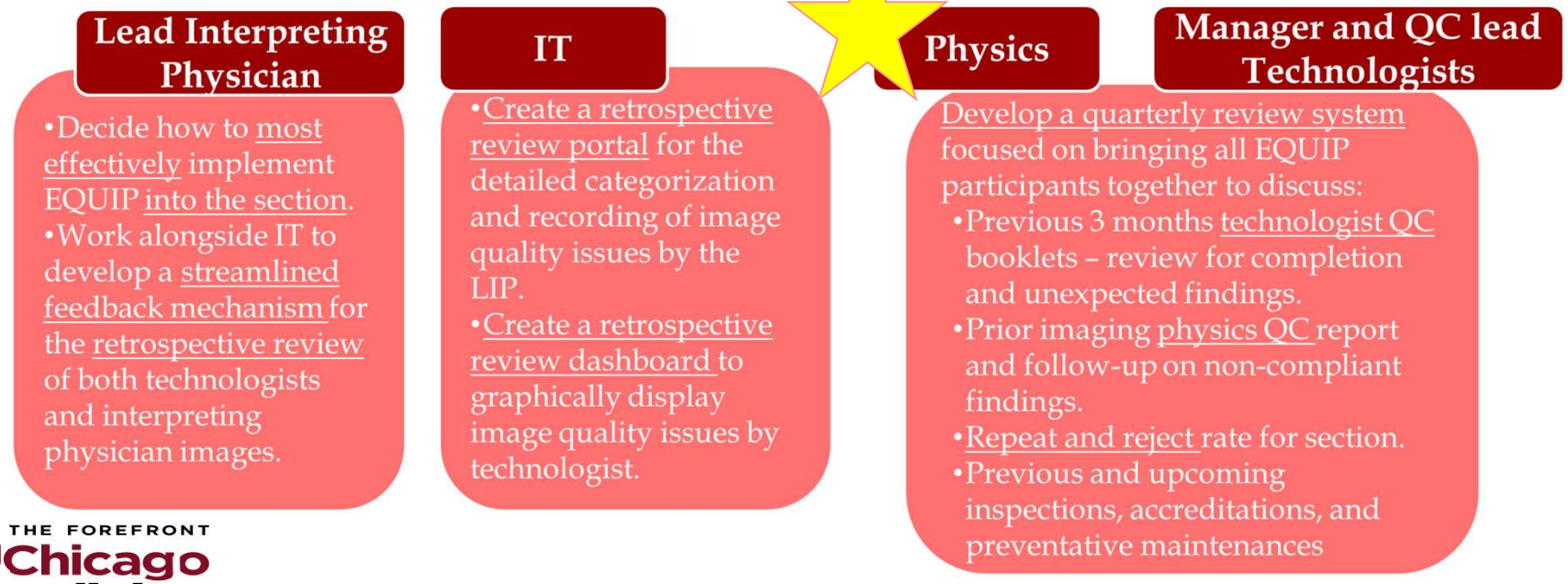

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Getting compliant

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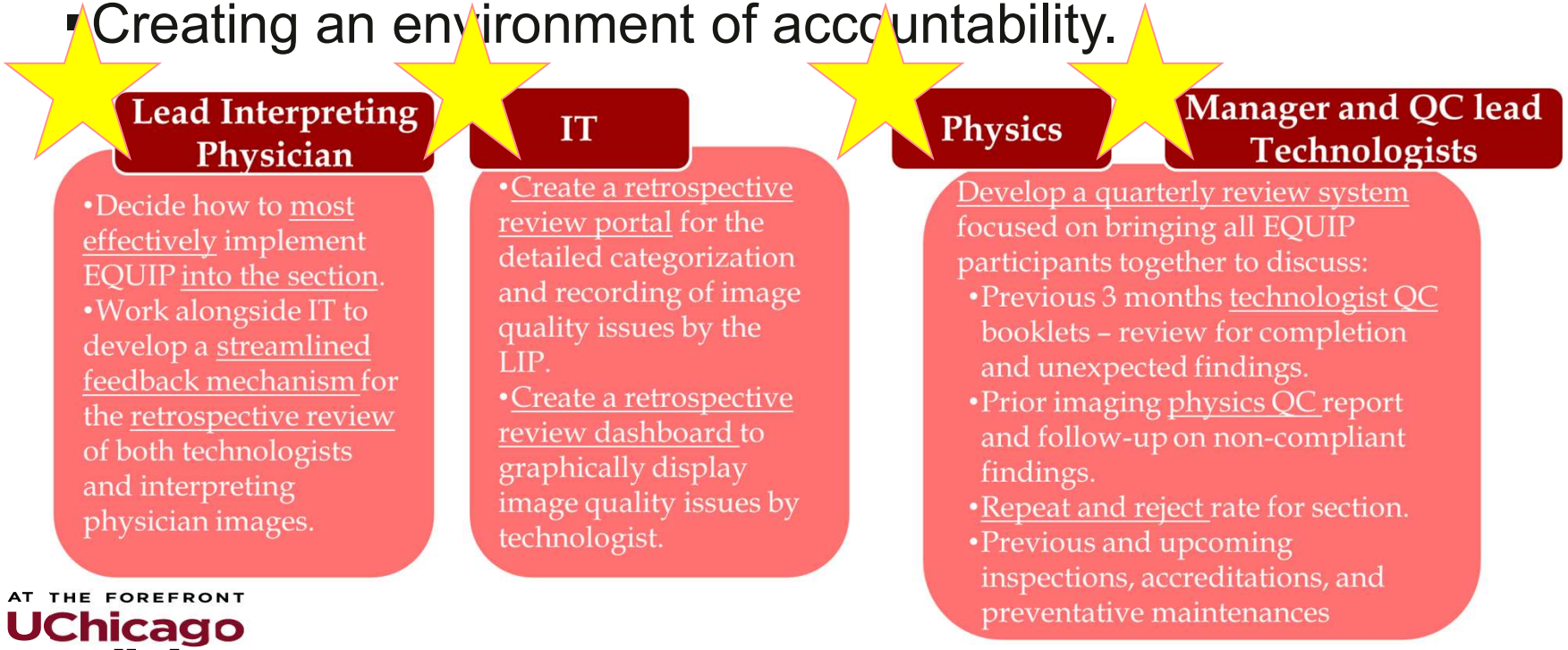

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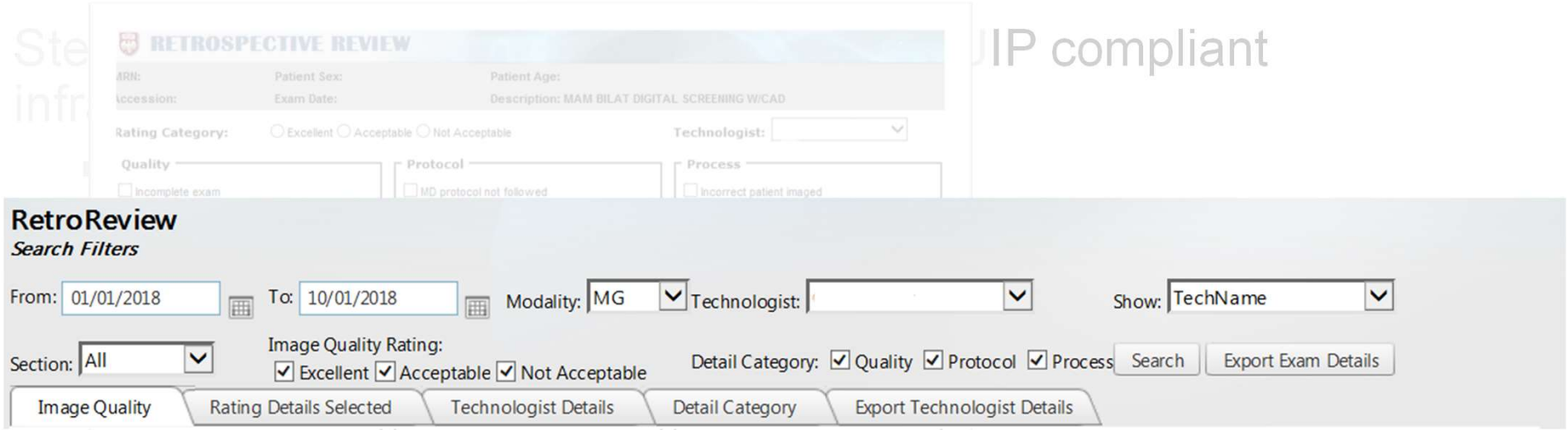
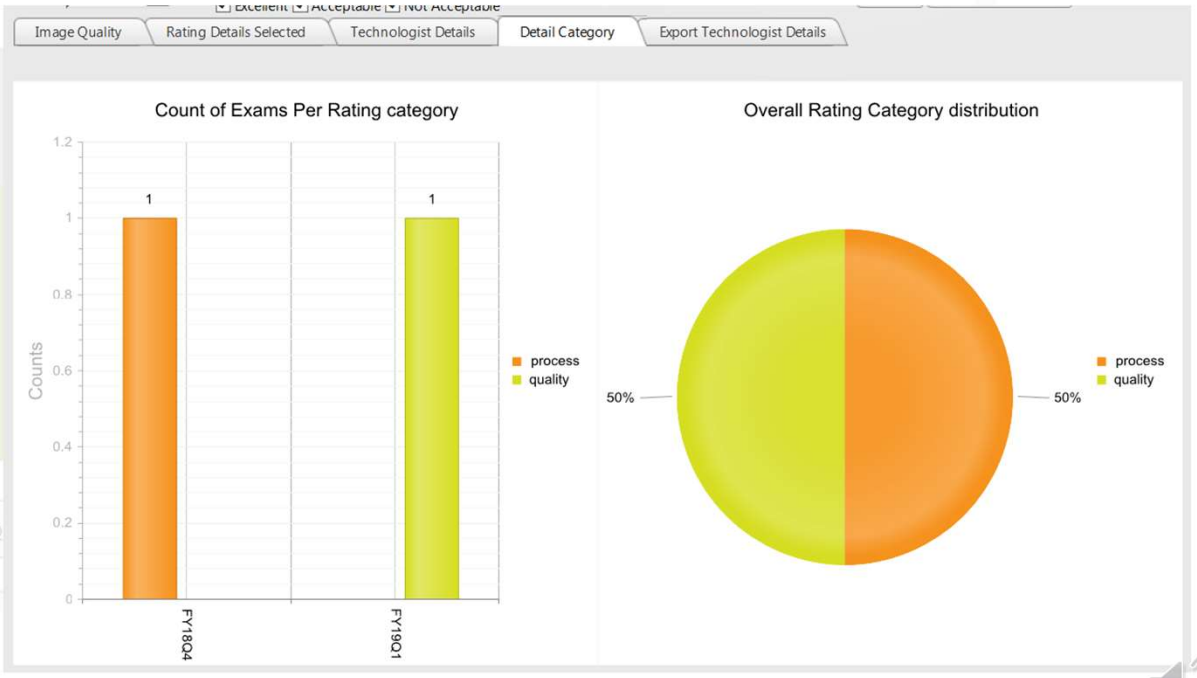
Getting compliant



Getting Compliant

MAM BILAT DIGITAL SCREENING W/CAD	Excellent			
MAM DIGITAL BREAST SCREEN W/CAD/TO... BIL	Not Acceptable	quality	Skin fold over breast tissue	medial folds noted bilaterally
MAM BILAT DIGITAL SCREENING W/CAD	Acceptable			

Technologist	18Q3 Acceptable	18Q
	7	1



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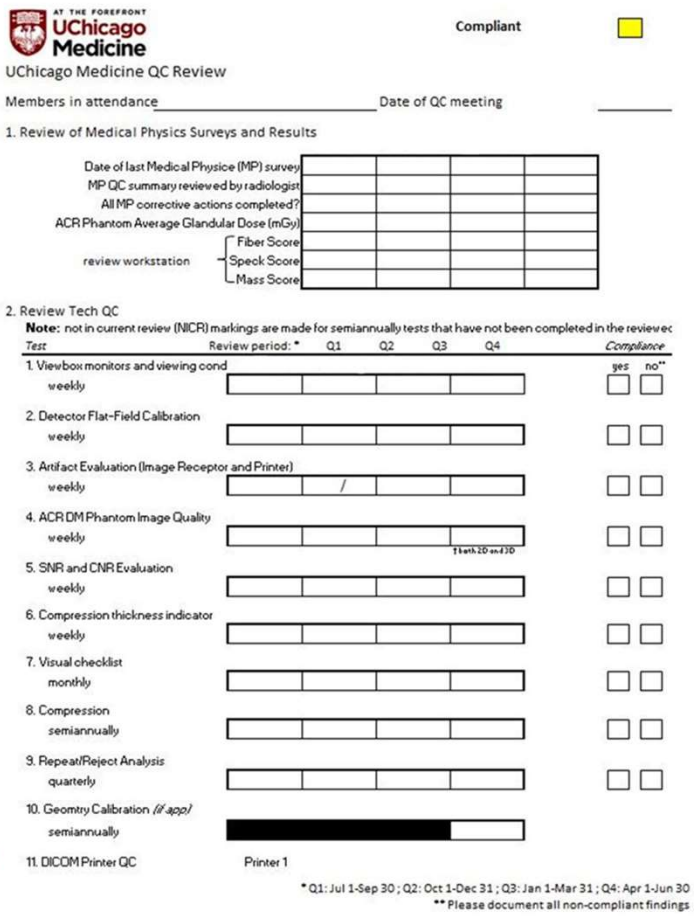
Getting compliant



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Compliant

UChicago Medicine QC Review

Members in attendance _____ Date of QC meeting _____

1. Review of Medical Physics Surveys and Results

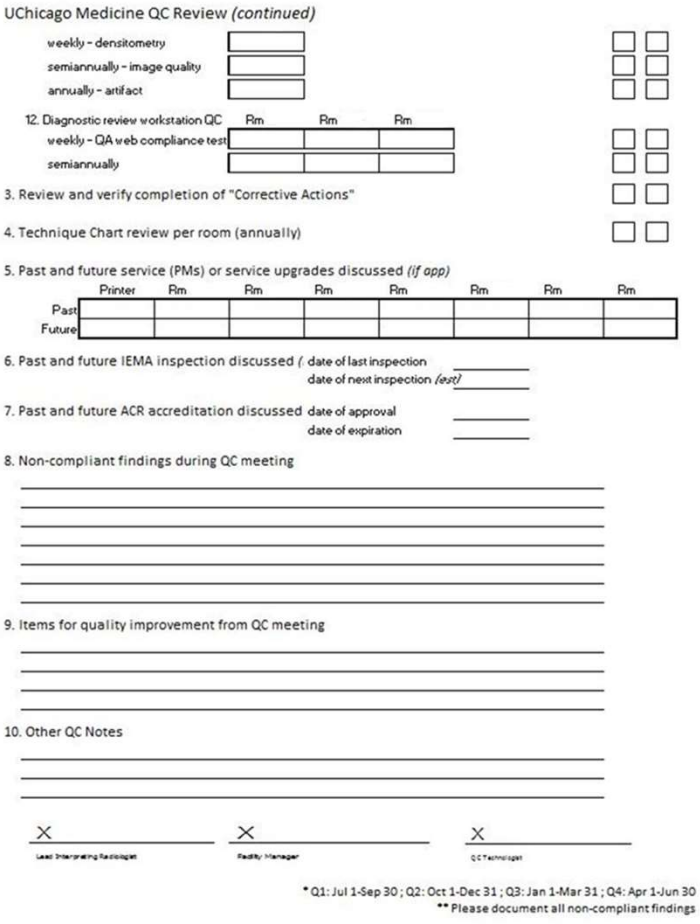
Date of last Medical Physice (MP) survey				
MP QC summary reviewed by radiologist				
All MP corrective actions completed?				
ACR Phantom Average Glandular Dose (mGy)				
review workstation – Fiber Score				
review workstation – Speck Score				
review workstation – Mass Score				

2. Review Tech QC

Note: not in current review (NICR) markings are made for semiannually tests that have not been completed in the review ec

Test	Review period: * Q1	Q2	Q3	Q4	*Compliance* yes	no**
1. Viewbox monitors and viewing cond weekly						
2. Detector Flat-Field Calibration weekly						
3. Artifact Evaluation (Image Receptor and Printer) weekly		/				
4. ACR DM Phantom Image Quality weekly						
5. SNR and CNR Evaluation weekly						
6. Compression thickness indicator weekly						
7. Visual checklist monthly						
8. Compression semiannually						
9. Repeat/Reject Analysis quarterly						
10. Geomtry Calibration *(if app)* semiannually						
11. DICOM Printer QC	Printer 1					

* Q1: Jul 1-Sep 30 ; Q2: Oct 1-Dec 31 ; Q3: Jan 1-Mar 31 ; Q4: Apr 1-Jun 30
** Please document all non-compliant findings



UChicago Medicine QC Review *(continued)*

weekly – densitometry				
semiannually – image quality				
annually – artifact				
12. Diagnostic review workstation QC	Rm	Rm	Rm	
weekly – QA web compliance test				
semiannually				

3. Review and verify completion of "Corrective Actions"

4. Technique Chart review per room (annually)

5. Past and future service (PMs) or service upgrades discussed *(if app)*

	Printer	Rm	Rm	Rm	Rm	Rm	Rm	Rm
Past								
Future								

6. Past and future IEMA inspection discussed (date of last inspection _____
date of next inspection *(est)* _____

7. Past and future ACR accreditation discussed date of approval _____
date of expiration _____

8. Non-compliant findings during QC meeting

9. Items for quality improvement from QC meeting

10. Other QC Notes

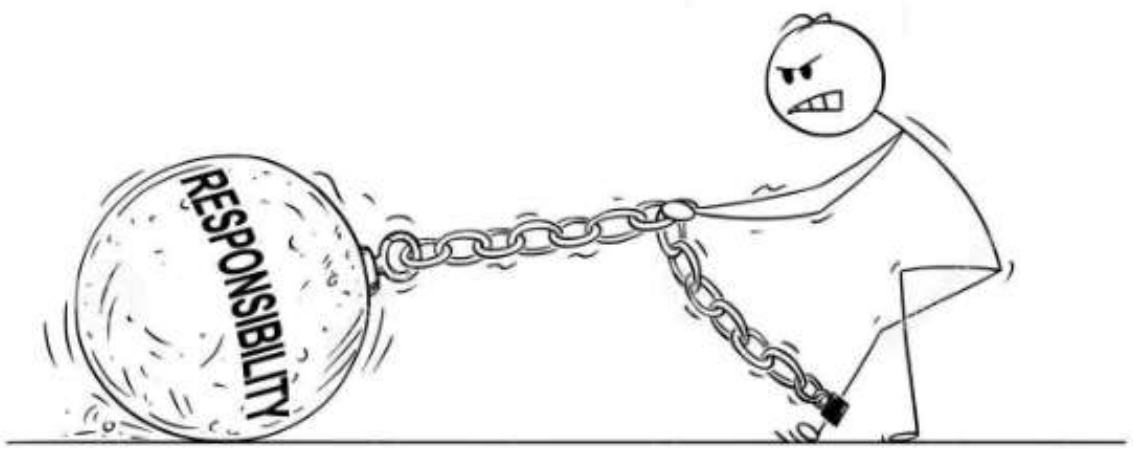
X _____ X _____ X _____

Lead Interpreting Radiologist | Facility Manager | QC Technologist

* Q1: Jul 1-Sep 30 ; Q2: Oct 1-Dec 31 ; Q3: Jan 1-Mar 31 ; Q4: Apr 1-Jun 30
** Please document all non-compliant findings

Remaining Compliant

- Evaluate
- Adjust
- Redistribute



- Revisit MQSA/EQUIP documentation – regularly!!!

Positive Impacts

- Ease of onboarding a new site.
- Smooth state inspection.
- Closer monitoring of new technologists.
- Increased frequency of face-to-face communications.

Lessons Learned

- Build in a positive feedback mechanism for technologists.
- Don’t lose sight of those items NOT emphasized by EQUIP – for us this meant repeat/reject analysis.
- Lets go digital!

FDA EQUIP in review

- First year – 2017:

  43% of inspections resulted in an “educational citation.”

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	2,588	30%
Question 3(a) - There is no system in place for LIP oversight, including review of the frequency of performance of all required tests	1,579	19%
Question 3(b) - There is no system in place for LIP review to determine whether appropriate corrective actions were performed when needed	1,891	22%

[https://www.fda.gov/radiation-emitting-products/mqsa-insights/equip-repeat-citations-have-arrived]

FDA EQUIP in review

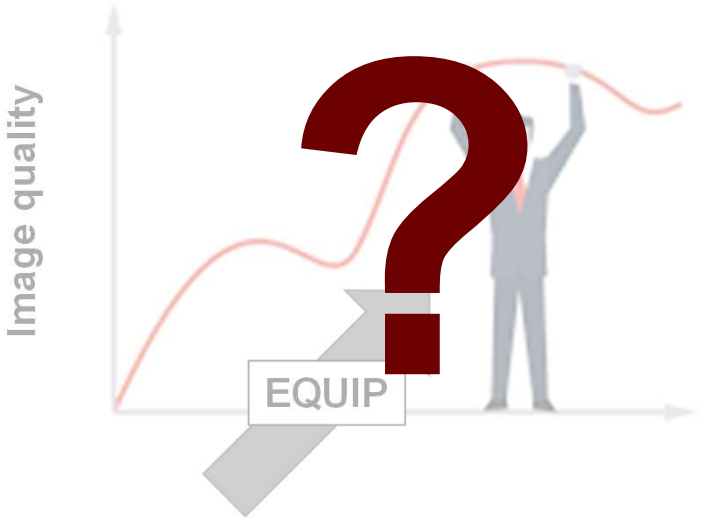
Question 2 –

- Retrospective reviews must be completed **PER SITE.**
- Retrospective reviews frequency?
  - Not defined – but since last inspection.
- Do we need an SOP? Do we need LIP signature? Do we need written proof of this CIQR happening?
  - No, No, Yes.

FDA EQUIP in review

So…. Is it working?

- Limited mammography review:
  Result of repeat level 2
  EQUIP citations
- AMR's since June 2019:
  - 2 passed
  - 3 required CA
  - 2 required PPN



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Questions from Physicists

Why did you not require a written policy or procedure for EQUIP?

Is the Radiologist (IP) Peer Review completed as part of the ACR requirements, sufficient to fulfill the Question 2 IP review requirements in EQUIP?

Questions from Physicists

Why did you not require a written policy or procedure for EQUIP?

Under the MQSA and its implementing regulations there are requirements that state written procedures must be established, and there are requirements that make no mention of a written procedure. As an example, the consumer complaint mechanism regulation [21 CFR 900.12(h)(1)] requires facilities to establish a written policy, whereas the clinical image quality regulation [21 CFR 900.12(i) requires that the clinical images produced by the facility continue to meet the standards for clinical image quality established by the AB. Where possible, FDA has taken the approach to be less prescriptive and provided facilities with some flexibility in meeting the requirements.

Is the Radiologist (IP) Peer Review completed as part of the ACR requirements, sufficient to fulfill the Question 2 IP review requirements in EQUIP?

Questions from Physicists

Why did you not require a written policy or procedure for EQUIP?

If the peer review system, in addition to whatever else it is designed to assess, also includes assessing the quality of the images accepted for interpretation, then the facility may use IP peer reviews to meet the periodic clinical image quality review requirement of EQUIP.
(Answer from Q2.19 of the EQUIP FAQs)

Is the Radiologist (IP) Peer Review completed as part of the ACR requirements, sufficient to fulfill the Question 2 IP review requirements in EQUIP?

EQUIP Resources

- https://www.fda.gov/radiation-emitting-products/facility-certification-and-inspection-mqsa/inspection-news
- https://www.fda.gov/radiation-emitting-products/facility-certification-and-inspection-mqsa/preparing-inspection

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Thank You!

Contact me at . . .

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