

WHAT'S HAPPENING IN MAMMOGRAPHY COMPLIANCE

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Overview, The Year of 2009

- Full Field Digital Mammography is taking over.
- There was a total of 522 mammography facilities in 2009
- 146 were film screen
- 376 Full Field Digital
- Texas is 72% Digital

Violation Severity Levels

- Severity Level IV (the lowest) = 11
- Severity Level III = 124
- Severity Level II = 91
- Severity Level I (the worst) = 2

Good News!!!

- Most facilities don't violate.
- Total Inspections for 2009 = 569
- No violations or only severity level IV violations were found on 449!
- 79% of the inspections revealed no serious violations!!

The 10 most frequently found violations.

- #10 Failure to perform or analyze image quality at the correct interval
 - Required at no more than 7 days for f/s
 - Required weekly by FFDM manufacturers
- Most occur in the absence of the QC Technologist or following the absence of the QC Technologist

10 Most Frequent Violations

- # 9 The Lead Interpreting Physician failed to review QC records
 - Required quarterly
 - Most common where the physician is remotely located
 - Remote interpretation of FFDM is making this more difficult
 - The licensed facility is ultimately responsible

10 Most Frequent Violations

- # 8 Failure to perform or analyze fixer retention at the correct interval
 - No common reasons revealed in the analysis
 - Required of only 28% of the Texas facilities

10 Most Frequent Violations

- # 7 Failure to include the overall final assessment of findings in the medical report
 - *“Negative”*
 - *“Benign”*
 - *“Probably Benign”*
 - *“Suspicious”*
 - *“Highly suggestive of malignancy”*
 - *“Incomplete: Need additional imaging evaluation”*
- Bi-Rads Codes alone are not acceptable

10 Most Frequent Violations

- # 6 Failure to notify the Agency of personnel changes i. e., physicians, technologists and physicists

- See

- <http://www.dshs.state.tx.us/radiation/pdffiles/Mammo/RC230R-1B.pdf>

- for an amendment form

- Fill out the part that changes

- A letter works as well as the form

10 Most Frequent Violations

- # 5 Allowing physicians to interpret mammography, before confirming their mammography qualifications
 - Most common with locum tenens
 - The facility must maintain records to prove compliance
 - Qualification records must be available upon request

Interpreting Physician Requirement Questions

- - Licensed?
- - Certified or 3 months training?
- - 60 category I CME hours?
- - Initial experience adequate? (240 exams/6 months)
- Date completed initial requirements mm/dd/yyyy
- New modality training (8 hrs.) (if applicable)

Dr. No, successfully completed his residency in diagnostic radiology on June 30, 2007. During the period of his residency program June 1, 2003 to June 30, 2007 Dr. No received the following training and experience specific to mammography:

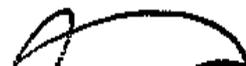
1. At least three months of training in the interpretation of mammograms, including instruction in radiation physics, radiation effects, and radiation protection.
2. At least eight hours of training in both film screen and full field digital mammography.
3. Read or interpreted, under the direct supervision of an interpreting physician, the mammograms from the examinations of at least 240 patients within the last 6-month period of the residency program.

- Signed (Program Chairman)

██████████, MD successfully completed his residency in Diagnostic Radiology on June 30, 2007. During the period of his residency program, July 1, 2003 to June 30, 2007, Dr. ██████ received the following training and experience specific to mammography:

1. Dr. ██████ did not pass the American Board of Radiology Diagnostic Radiology Certifying Examination at the “first allowable time” in June 2007.
2. Dr. ██████, during his diagnostic radiology residency, received more than 60 hours of medical education in mammography, including instruction in the interpretation of mammograms and education in basic breast anatomy, pathology, physiology, technical aspects of mammography, and quality assurance and quality control. The educational experience also included instruction in radiation physics, radiation effects and radiation protection.
3. According to the records of the ██████ County Hospital District, Dr. ██████ read or interpreted, under the direct supervision of a certified MQSA/FDA interpreting physician, the digital or analog mammograms from the examinations of three patients during the six-months prior to his passing the American Board of Radiology examination at the second attempt.
4. Dr. ██████ has received more than 10 hours of medical education in digital mammography.

Sincerely,



10 Most Frequent Violations

- #4 Failure to take corrective action following an image quality evaluation failure
 - This is the density difference or background density
 - Density selection can be used to correct if the same correction is applied to patient exp.
 - If the density selection doesn't work, consult your physicist

10 Most Frequent Violations

- # 3 Failure to record Contrast to Noise Ratio (CNR)
 - Maybe due to the record location on a busy form
- What if a computer crash wipes out the QC records?—Still a violation!

10 Most Frequent Violations

- # 2 Quality Control Film Crossover calculation errors
- Only affects 28% of the facilities in Texas

New Emulsion ###					Old Emulsion ###				
Film#	Low Density (LD) Step#_10__	Mid Density (MD) Step#_11__	High Density (HD) Step#_13__	B+F	Film#	(LD) Stp_10	MD Stp_11	HD Stp_13	B+F
1	0.50	1.25	2.39	0.18	1	0.46	1.27	2.33	0.17
2	0.50	1.23	2.43	0.18	2	0.48	1.30	2.36	0.17
3	0.49	1.26	2.40	0.17	3	0.46	1.27	2.28	0.18
4	0.53	1.28	2.41	0.18	4	0.48	1.28	2.32	0.17
5	0.49	1.28	2.43	0.18	5	0.47	1.31	2.35	0.18
Avg.	0.50	1.26	2.41	0.18	Avg	0.47	1.29	2.31	0.17

Average Density Difference: DD=HD-LD = 1.91 Average DD: DD=HD-LD = **1.84**

MD difference between new and old film (New MD - Old MD)	-0.03
DD difference between new and old film (New DD - Old DD)	+0.07
B+F difference between new and old film (New B+F - Old B+F)	+ 0.01

	MD	DD	B+F
Old operating levels	1.29	1.84	0.017
Difference between new and old	-0.03	0.07	0.01
New operating levels	1.26	1.91	0.027

10 Most Frequent Violations

- # 1 Mechanical Alignments
 - Light field to x-ray field
 - X-ray field to image receptor
- Facility may test per instructions in ACR QC Manual
- Have it checked frequently by the repairmen







Most Significant Violations

- # 5 Failure to have a physicist survey new installed equipment
 - Most were on remote work stations
 - Facility is responsible, but may not be aware of all the remote workstations in use
 - May need to be the subject of a contract clause
- Our most severe case was with a facility with a PACS that could be accessed via the internet

Most Significant Violations

- # 4 Interpreting mammograms more than 30 days post examination
 - Facilities were found holding interpretations until priors were obtained
 - One had a policy of trying to obtain priors for up to 6 months
 - The physicians may be at fault, but the facility is responsible

Most Significant Violations

- # 3 Failure to provide original mammograms upon request
 - Some FFDM facilities insist on providing only a CD
 - Some facilities try to refuse to give up the original mammogram
 - At this time all FFDM facilities must have the capability to print images for accreditation

Most Significant Violations

- #2 Failure to maintain mammography records
 - Closing facility capitalizes on salvage value of film

Most Significant Violations

- #1 None or very little quality control records available for inspection!

Out of town inspections are scheduled up to a month in advance.

- The inspectors sets up 3 for a week of remote location inspections.
- One facility requests a reschedule
- All 3 inspections are rescheduled

Day before the rescheduled Inspection

- Inspector is called by QC Tech
- QC manual was sent to main site for LIP review and courier forgot to return it
- QC tech will retrieve manual and be ready for inspection by 10 a.
- Inspector can start with equipment, physics surveys and the P&P manual—OK so far

Day of Inspection (DOI), 8:00 a.m.

- Upon arrival inspector is advised that the P&P manual has been “accidentally taken home” by the QC Tech
- Still OK, inspection starts with machine testing and review of the physics survey reports

DOI--10:40 a.m.

- One of the staff techs receive a text—The QC Tech has witnessed an automobile accident and is waiting for the authorities to arrive
- Still ok, but the Inspector will be a little late getting home.

DOI—12:30 a.m.

- Another text—QC Tech has cleared the accident, but the Main Office is now closed until 1:00 p.m.--can't get back to the inspection before 2:30 p.m.—very sorry--will ship manual tomorrow a.m. if inspector can't wait
- A few minutes later another message indicates QC Tech's car is dead and now waiting on a tow
- Since this was the last inspection of the trip, the Inspector is interested in avoiding another trip for one inspection so, the Inspector decides to go by the Main Office on the way home and informs the QC Tech of the plan

DOI—3:00 p.m. Main Office

- No QC manual
- Staff claims manual has NEVER been there
- Lead Interpreting Physician (LIP) doesn't remember being asked to review the QC records—EVER!
- LIP notifies remote office to suspend mammography services until the quality control status can be assessed

The return visit,

- Two qc tests had been recorded in the past year
- The physics survey report didn't indicated any problems with the Technologist's QC records
- The Inspector found the physicist didn't actually get to review the Technologist's QC records
- The courier had forgot to bring the QC manual back from main office on the day or the survey!

Questions

