

MQSA Hot Topics

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1. Continuing Experience Documentation for Interpreting Physicians Who Read at Multiple Sites

Comments

Physicians continuing experience documentation may include the following:

- A letter, table, or printout from each facility
- Signed by a responsible facility official
- Stating that he/she has interpreted a given number of mammograms at the facility in a given time period

The inspector will no longer accept printouts from the interpreting physician's office that include all sites where they read.

*The only exception to this would be if the ownership of the facilities where the interpreting physicians read is the same person(s) signed by the same responsible facility official.

For example: If a radiologist's office owns 5 different sites where they read and one coordinator who keeps up with their continuing experience for all sites, that coordinator can provide a list documenting their continuing experience. This list must be signed by a responsible facility official who may be the same person if the official is employed by the owner of all of the facilities.

The radiologist viewing stations (monitors) if off site need the physicist evaluation also and it needs to be on site for the inspector

Training of radiologists in residency mostly now is digital. FDA requires that they also have 8 hours film screen if they read for a facility that is still analog.

Records may be kept electronically but must be available for the inspector at the time of inspection.

2. Using the +/- Density Settings on the Phantom

Comments

The +/- density control settings on the mammography equipment should not be used to keep the phantom chart in limits. Only if a change in film optical density is confirmed to be due to a change in the film emulsion batch, and if the magnitude of the change is within the expected batch-to-batch variation for that film type, then an adjustment of the density control setting to bring the phantom background optical density back into control is an appropriate corrective action. If for any other reason your phantom falls out of limits, then the service provider must be called to correct the problem.

3. When a Facility Has More Than One Processor

The annual survey or equipment evaluation requirement for all clinically used mammography processors is addressed in MQSA as the following:

- 21 CFR 900.12 (e)(9)(i) At least once a year, each facility shall undergo a survey by a medical physicist or by an individual under the direct supervision of a medical physicist. At a minimum this survey shall include the performance of tests to ensure that the facility meets the quality assurance requirements of the annual test described in 900.12(e)(5) and (6) and the weekly phantom image quality test described in 900.12(e)(2).
- 21 CFR 900.12(e)(10) Mammography equipment evaluations. Additional evaluations of mammography units or image processors shall be conducted whenever a new unit or processor is installed, a unit or processor is disassembled and reassembled at a new location or major components of a mammography unit or processor equipment are changed or repaired. These evaluations shall be used to determine whether
- the new or changed equipment meets the requirements of applicable standards in 900.12(b) and (e). All problems shall be corrected before the

new or changed equipment is put into service for examinations or film processing. The mammography equipment evaluation shall be performed by a medical physicist or by an individual under the direct supervision of a medical physicist.

Comments

The annual survey or equipment evaluation must include all processors used clinically, even those at remote sites or back-up processors. It is the responsibility of the facility to inform the medical physicist prior to introducing a different processor into mammography and at the annual survey. The equipment evaluation requirement for the processors is the following:

- Sensitometric testing as described in 900.12(e)(1)
- Phantom testing as described in 900.12(e)(2)
- System artifact evaluation as described in 900.12(e)(5)(ix)
- Dose determination as described in 900.12(e)(5)(vi) if clinical techniques increase significantly
- Verification of the appropriate processing solutions as described in 900.12(b)(13)

4. Quality Assurance Records and Written Standard Operating Procedures for QC Tests

The Quality Assurance Policy is addressed in MQSA as the following:

21 CFR 900.12 (d)(2) Quality assurance records. The lead interpreting physician, quality control technologist, and medical physicist shall ensure that records concerning employee qualifications, 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, and protection are properly maintained and updated in the mammography facility's quality assurance manual. These quality control records shall be kept for each test specified in 900.12(e) and (f) until the next annual inspection has been completed and FDA has determined that the facility is in compliance with the quality assurance requirements or until the test has been performed two additional times at the required frequency, whichever is longer.

Comments

The quality assurance (QA) records that must be maintained are the following:

- Personnel Responsibilities: qualified mammography personnel assigned appropriate QA tasks
- Technique Charts/Tables: the mammography techniques and procedures used in conducting mammograms
- Quality Control (QC) test Records: including QC test procedures, test performance and monitoring, data analysis and timely corrective actions for each.

- Procedures for safety and protection of patients and person

Facilities have the flexibility to use procedures that best enable them to meet the required QC test criteria and outcomes (tests to be done, frequency, and especially the action limits to be met), just as long as they are consistent with the MQSA regulations. The inspector will look for the written standard operating procedures for the QC tests. If the facility has not written their standard operating procedures, then they must document what they use for their standard operating procedures. If a facility has adopted the ACR manual for their QC test procedures, they must adhere to it. The ACR manual has listed a number of circumstances under which it may be appropriate to re-establish the processor QC operating levels. These events include:

- When a film manufacturer makes a change to a film currently in use and recommends that the processor QC program be re-established;
- A change in film volume;
- A change of brand or types of chemicals used;
- A change in film brand or type;
- A change in replenishment rates;
- A change in development time (e.g., going from extended to standard cycle);
- A change in the settings on a specific gravity automixer; Using a different sensitometer or densitometer;
- A change in film processor;
- Running out of film thus preventing a crossover from being done correctly.

Keep in mind that changing the chemistry as part of routine preventative maintenance is NOT justification for changing the QC operating levels. The reason for re-establishing the operating levels must be noted in the remarks section of the QC chart.