FDA-Approved Alternative Requirement – iCRco

Correction Period When Components of the iCRco 3600M Full Field Digital Mammography System Fail Quality Control Tests

This alternative standard was approved on December 6, 2013, and becomes effective on that date. It has no time limit. It allows a 30 day period for corrective actions following the failure of specified quality control tests by the ICR3600M Full Field Digital Mammography imaging systems as well as associated devices such as a diagnostic review workstation or film printer. This request was based on the intent of ICRco to consider the FFDM imaging process to consist of three separate and independent stages – the x-ray image acquisition, image processing and final image display.

The original standard is 21 CFR 900.12(e)(8)(ii), which states:

21 CFR 900.12(e)(8): *Use of test results*

(ii) If the test results fall outside of the action limits, the source of the problem shall be identified and corrective actions shall be taken:
(A) Before any further examinations are performed or any films are processed using the component of the mammography system that failed any of the tests, described in paragraphs (e)(1), (e)(2), (e)(4)(i), (e)(4)(iii), (e)(5)(vi), (e)(6), or (e)(7) of this section;
(B) Within 30 days of the test date for all other tests described in paragraph (e) of this section.

The approved alternative is:

21 CFR 900.12(e)(8): *Use of test results*.

(ii) If the test results for the ICR3600M Mammography System fall outside the action limits, the source of the problem shall be identified and corrective actions shall be taken:

(A) If any of the following quality control tests that evaluate the performance of the image acquisition components of the ICR3600M Mammography System produces results that fall outside the action limits as specified by the manufacturer, the source of the problem shall be identified and corrective action shall be taken before any further examinations are performed using that component.

Applicable QC tests:
1. AEC Calibration
2. CNR/SNR
3. System Resolution
4. Phantom Image Quality Evaluation
5. Breast Entrance Exposure
6. Average Glandular Dose
7. Scanner Performance Test and Jitter
8. Modular Transfer Function (MTF)
9. Detective Quantum Efficiency (DQE)
10. Image Plate Erasure (Erasure Thoroughness)
11. Repeated Exposure test
12. Dynamic Range
13. Sensitometric Response
14. Scanner Response Linearity
15. CR Cassette Uniformity

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Technologist
16. Detector Warm-up
17. Signal-to-Noise Ratio and Contrast-to-Noise Ratio
18. Phantom Image Quality Evaluation
19. Compression
20. Image Plate Fog test

(B) If any of the following quality control tests that evaluate the performance of a diagnostic device used for mammographic image interpretation (i.e. DICOM printer, physician's review station) produces results that fall outside the action limits as specified by the manufacturer, the source of the problem shall be identified and corrective action shall be taken before that device can be used for mammographic image interpretation. Clinical imaging may be continued and alternative approved diagnostic devices shall be used for mammographic image interpretation:

Applicable QC tests:
1. Phantom Image Quality Evaluation
2. Monitor Testing
3. Screen Cleaning
4. DICOM Printer Quality Control

(C) If any of the following quality control tests that evaluate the performance of components other than the digital image receptor or the diagnostic devices used for mammographic image interpretation produces results that fall outside the action limits as specified by the manufacturer, the source of the problem shall be identified and corrective action shall be taken within thirty days of the test date. Clinical imaging and mammographic image interpretation may be continued during this period:

Applicable QC Tests:
1. Mammographic Unit Assembly Evaluation
2. Collimation Assessment
3. Beam Quality Evaluation (HVL)
4. AEC Performance
5. kVp Accuracy and Reproducibility
6. Inter Plate Consistency
7. Artifact Evaluation
8. Normalized Power Spectrum (NNPS)
9. Radiation Output

Technologist
10. Visual Checklist
11. Repeat Analysis