FDA-Approved Alternative Requirement – Fuji

Correction Action Period When Components of the Fuji Computed Radiography for Mammography (FCRm) Full-Field Digital Mammography (FFDM) System Fail Quality Control Tests

FDA approved this alternative requirement on August 2, 2006 and made effective on that date. It allows a 30 day period for corrective actions following the failure of specified quality control tests by the FCRm Full Field Digital Mammography System. The specified tests are equivalent to quality control tests for screen-film systems for which a 30 day correction period is already allowed. The alternative standard also divides into two groups the quality control tests whose failure requires corrective action before the failing component is used again during patient examinations. This division makes it clear that when the test failure is related to the acquisition of images only, image acquisition must cease until the problem is corrected but image interpretation can continue. Similarly if the test failure is related to the interpretation of images, image acquisition can continue but image interpretation with the failed component must cease until the problem is corrected. The alternative was approved for an indefinite period.

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;

The approved alternative is:

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

(ii) If the test results for the FCRm FFDM 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 FCRm FFDM 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 on the component(s) that caused the failure before any further examinations are performed using the failed component(s). If the component(s) that caused the failure (e.g. exposure unit, CR reader, display device) is replaced by an alternative device and the mammography system passes the re-test, image acquisition and interpretation may continue using that combination of devices.

(1) CNR Weekly Check

(2) Phantom Image

(3) Compression

(4) System Resolution
(5) CR Reader Scanner Performance
(6) Imaging Plate (IP) Fog
(7) Image Quality Evaluation
(8) Dynamic Range
(9) Primary Erasure
(10) Dose
(11) Post-move and pre-examination tests (CNR Weekly Check and Phantom Image) for mobile FCRm FFDM systems

(B) If any of the following quality control tests that evaluate the performance of a diagnostic device used for mammographic image interpretation (i.e. laser 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. If available, an alternative approved diagnostic device may be used for mammographic image interpretation:
(1) Phantom Image
(2) Monitor QC
(3) Printer QC
(4) CR Reader Scanner Performance
(5) Image Quality Evaluation
(6) Dynamic Range
(7) Viewing and Viewing Conditions

(C) If any of the following quality control tests that evaluate the performance of other X-ray room or exposure function 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:
(1) Visual Checklist
(2) Repeat Analysis
(3) Mammographic Unit Assembly Evaluation
(4) Collimation Assessment
(5) Automatic Exposure Control (AEC) System Performance Assessment
(6) System Artifact Evaluation
(7) kVp Accuracy and Reproducibility
(8) Beam Quality Assessment and Half –value Layer Measurement
(9) Radiation Output
(10) Inter-Plate Consistency
(11) S value Confirmation