FDA-Approved Alternative Requirement – Siemens

17. Correction Period When Components of the Siemens Mammomat Novation Full Field Digital Mammography System Fail Quality Control Tests

This alternative requirement was approved on March 19, 2010 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 Siemens Mammomat Novation 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 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 Mammomat Novation DR and Novation S FFDM imaging systems fall outside of the action limits, *the source of the problem shall be identified and corrective actions shall be taken*:

(A) *Before* any further mammographic images are acquired using the image acquisition system that failed any of the following tests as defined in the Siemens Quality Control Manual:

(1) Phantom image quality (Technologist)
(2) Detector Calibration (Technologist)
(3) Compression force
(4) Acquisition workstation monitor check (Physicist)
(5) Detector uniformity and artifact detection (Physicist)
(6) Spatial resolution

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(7) SNR and CNR (Physicist)
(8) Image quality and radiation dose
(9) Post move, pre-examination tests for a mobile Novation DR or Novation S

(B) *Before* any further mammographic images are processed, interpreted or printed using the component of the imaging system that failed any tests as specified by the manufacturer including the following for the Novation DR , Novation S, or MammoReport as defined in the Siemens MammoReport QC Manual:

(1) Printer Check (Technologist)
(2) Printer Check (Physicist)
(3) Reflection (on monitor)
(4) Overall (image) evaluation
(5) Geometric distortion (CRT only)
(6) Luminance response
(7) Luminance uniformity
(8) Resolution
(9) Noise

(C) Within thirty days of the test date for the following tests:

(1) Artifact detection (Technologist)
(2) Repeat analysis
(3) Mechanical inspection (Physicist)
(4) Collimation, dead space and compression paddle position
(5) AEC thickness tracking
(6) AEC reproducibility
(7) Compression thickness printout on image (Physicist)
(8) HVL and radiation output
(9) kVp accuracy and repeatability
(10) Ghost image evaluation (Physicist-optional)
(11) SNR and CNR (Technologist)