

FDA-Approved Alternative Requirement – Lorad

Correction Period When Components of the Lorad Selenia Full-Field Digital Mammography (FFDM) System Fail Quality Control Tests

This amended alternative requirement was amended on October 10, 2007. It allows a 30-day period for corrective actions following the failure of specified quality control tests by the Selenia 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. ***[This alternative standard only applies to Annual Surveys and routine QC; it does not apply to Equipment Evaluations.]***

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 Selenia 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 Selenia 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 before any further examinations are performed:

- (1) Evaluation of System Resolution
- (2) Breast Entrance Exposure and Average Glandular Dose
- (3) Phantom Image Quality Evaluation (Medical Physicist)
- (4) Phantom Image (Radiologic Technologist)
- (5) Signal-to-Noise and Contrast-to-Noise Measurements
- (6) Detector Flat-Field Calibration

- (7) Compression
- (8) Post-Move and Pre-Examination Tests for Mobile Selenia™ 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 can be continued and alternative approved diagnostic devices shall be used for mammographic image interpretation:

- (1) Phantom Image Quality Evaluation (Medical Physicist)
- (2) Phantom Image (Radiologic Technologist)
- (3) Softcopy Workstation QC
- (4) Laser Printer Quality Control
- (5) Dark Room Cleanliness
- (6) Processor Quality Control
- (7) Viewboxes and Viewing Conditions
- (8) Darkroom Fog

(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 can be continued during this period:

- (1) Mammographic Unit Assembly Evaluation
- (2) Collimation Assessment
- (3) Artifact Evaluation
- (4) kVp Accuracy and Reproducibility
- (5) Beam Quality Assessment – HVL Measurement
- (6) Automatic Exposure Control (AEC) Function Performance
- (7) AEC Reproducibility
- (8) Radiation Output Rate
- (9) Viewbox Luminance and Room Illuminance
- (10) Compression Thickness Indicator
- (11) Visual Checklist
- (12) Analysis of Fixer Retention in Film
- (13) Repeat Analysis