FDA-Approved Alternative Requirement – Lorad

Correction Period When Components of the Lorad Selenia Full Field Digital Mammography (FFDM) System, the Selenia Dimensions 2D FFDM System and the Selenia Dimensions 3D/ Digital Breast Tomosynthesis (3D/DBT) System Fail Quality Control Tests

On February 23, 2011, FDA approved an amendment to Alternative Standard #9 regarding the time period allowed for corrective action to be taken for the Selenia Full Field Digital Mammography (FFDM) system, the Selenia Dimensions 2D FFDM system and the Selenia Dimensions 3D/ Digital Breast Tomosynthesis (3D/DBT) system, if certain quality control test results fall outside of specified action limits. It allows a 30-day period for corrective actions following the failure of specified quality control tests. 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;
> >
> > (B) Within 30 days of the test date for all other tests described in paragraph (e) of this section.

The approved amended alternative is:

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

> (ii) If the test results for the Selenia FFDM System, the Selenia Dimensions 2D FFDM System and the Selenia Dimensions 3D/DBT 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, the Selenia Dimensions 2D FFDM System and the Selenia Dimensions 3D/DBT System (Selenia Dimensions 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 must be taken before any further examinations are performed:

Applicable Quality Control tests:

(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 Ghosting
(7) Detector Flat-Field Calibration
(8) Geometry Calibration (Tomosynthesis Option)
(9) Compression
(10) Post-Move and Pre-Examination Tests for Mobile Selenia Dimensions 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. 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 can be continued and alternative approved diagnostic devices shall be used for mammographic image interpretation:

Applicable Quality Control tests:

(1) Phantom Image Quality Evaluation (Medical Physicist)
(2) Phantom Image (Radiologic Technologist)
(3) Diagnostic Review Workstation Quality Control
(4) DICOM Printer Quality Control
(5) Viewboxes and Viewing Conditions (Radiologic Technologist)

(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:

Applicable Quality Control tests:

(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 (Radiologic Technologist)
(10) Compression Thickness Indicator
(11) Visual Checklist
(12) Repeat/ reject Analysis