FDA-Approved Alternative Requirement – Agfa CR

Correction Period When Components of the Agfa CR Full Field Digital Mammography Imaging System Fail Quality Control Tests

This alternative requirement was approved and became effective on May 21, 2012. It has no time limit. It allows a 30 day period for corrective actions following the failure of specified quality control tests by the Agfa CR Full Field Digital Mammography imaging 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 specifies the quality control tests whose failures require 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 devices used for image interpretation, 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 Agfa CR Full Field Digital Mammography imaging systems fall outside the action limits, *the source of the problem shall be identified and corrective actions shall be taken:*
>
> **(A) To be resolved prior to any image acquisition**
>
> If any of the following quality control tests that evaluate the performance of the image acquisition components produces results that fall outside the action limits as specified, 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).
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> If the component(s) that caused the failure is replaced by an alternative device and the mammography system passes this re-test, image acquisition and interpretation may continue using that combination of devices.
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> Medical Physicist QC:

- Test 2: AEC Thickness Compensation
- Test 3: Mean Glandular Dose
- Test 4: Phantom Image
- Test 5: Spatial Resolution (high-contrast)
- Test 6: Signal Linearity
- Test 8: Ghosting Evaluation
- Test 10: Missed tissue

Radiologic Technologist QC:

- Test 2: Phantom Image
- Test 3: AEC and CNR Constancy
- Test 9: Compression Check

(B) To be resolved prior to any image interpretation

If any of the following quality control tests that evaluate the performance of a diagnostic device used for mammographic image interpretation produces results that fall outside the action limits as specified, 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.

Medical Physicist QC:

- Test 2: AEC Thickness Compensation
- Test 4: Phantom Image
- Test 5: Spatial Resolution (high-contrast)
- Test 11: Viewbox and Ambient Luminance
- Test 12: Monitor Check
- Test 13: Printer Check
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Radiologic Technologist QC:

- Test 1: Viewbox Monitor Cleanliness and Viewing Conditions
- Test 2: Phantom Image
- Test 3: AEC and CNR Constancy
- Test 4: Monitor Check
- Test 5: Printer Check

(C) To be resolved within 30 days

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, 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:

Medical Physicist QC:

- Test 1: Mechanical inspection
- Test 7: Artifact Analysis

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- Test 9: Interplate Absorption and Sensitivity
- Test 14: Technologist's QC program
- Test 15: Collimation Assessment
- Test 16: Radiation Output Rate inspection
- Test 17: kVp Accuracy and Reproducibility
- Test 18: Beam Quality Assessment (HVL)
- Test 19: Density Step Control and AEC Reproducibility

Radiologic Technologist QC:

- Test 6: Mechanical Inspection
- Test 7: Repeat Analysis
- Test 8: Artifact evaluation