Recently Approved Alternative Standards

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Alternative Standards Approval

Under § 900.18 of the MQSA Regulations, FDA may approve an alternative to a quality standard under § 900.12, when the Agency determines that:

1. The proposed alternative standard will be at least as effective in assuring quality mammography as the standard it proposes to replace; and
2. The proposed alternative:
    i. Is too limited in its applicability to justify an amendment to the standard; or
    ii. Offers an expected benefit to human health that is so great that the time required for amending the standard would present an unjustifiable risk to the human heath; and
3. The granting of the alternative is in keeping with the purpose of the Statute 42 U.S.C. 263b.

Alternative Standard Approval Actions

Since the last NMQAAC meeting, the Division has approved five Alternatives to two Quality Standards:

- Four Alternative Standards for 21 CFR 900.12(e)(8)(ii), *Use of Test Results*
- One Alternative Standard for 21 CFR 900.12(e)(6), *Quality control tests--Other Modalities*

Alternative Standard for *Use of Test Results*

The current 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 text of each of the approved Alternative Standards is:

"The specified tests are **equivalent to quality control tests for screen-film syst**ems 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."

Alternative Standards for *Use of Test Results*

- #20: Correction Period When Components of the Planmed Nuance and Nuance Excel Full Field Digital Mammography Imaging System Fail Quality Control Tests
  - This alternative requirement was approved and became effective on January 10, 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 Planmed Nuance and Planmed Nuance Excel Full Field Digital Mammography imaging system.

http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/Regulations/ucm288294.htm

- #21: 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.

http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/Regulations/ucm306157.htm

Alternative Standards for *Use of Test Results*

- #22: Correction Period When Components of the Giotto Image 3D-3DL Full Field Digital Mammography Imaging System Fail Quality Control Tests
  - This alternative requirement was approved and became effective on January 25, 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 Giotto Image 3D-3DL Full Field Digital Mammography imaging system.

http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/Regulations/ucm323908.htm

- #23: Correction Period When Components of the Fuji Aspire HD, Aspire HD Plus and Aspire HD-s Full Field Digital Mammography imaging systems Full Field Digital Mammography imaging systems Fail Quality Control Tests
  - This alternative requirement was approved and became effective on February 28, 2013. It has no time limit. It allows a 30 day period for corrective actions following the failure of specified quality control tests by the Fuji Aspire HD, Aspire HD Plus and Aspire HD-s Full Field Digital Mammography imaging systems.

http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/Regulations/ucm343659.htm

Alternative Standard for *Quality control tests--Other Modalities*

#24: Approval of an Alternative Standard for Using the Quality Assurance Program Recommended by the ACR Digital Mammography Quality Control Manual for Full-Field Digital Mammography Systems, for Systems without Advanced Imaging Capabilities

Alternative Standard #24

This alternative standard was approved and became effective on February 17, 2016. It has no time limit. The alternative standard allows for the use by mammography facilities of the ACR Digital Mammography Quality Control Manual as an alternative to the quality assurance program recommended by the image receptor manufacturer. The FDA has determined that the ACR's quality control manual is, as required in § 900.18(a)(1): Alternative Requirements, “at least as effective in assuring quality mammography” as following the manufacturers’ QC manuals.

The original standard is 21 CFR 900.12(e)(6), which states:

900.12(e)(6): Quality control tests--other modalities. For systems with image receptor modalities other than screen-film, the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems in paragraph (e)(5)(vi) of this section.

The approved alternative is:

900.12(e)(6): Quality control tests--other modalities. For full-field digital mammography systems without advanced imaging capabilities, the quality assurance program shall be substantially the same as the quality assurance program recommended by the ACR Digital Mammography Quality Control Manual when used with the ACR Digital Mammography Phantom, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems in paragraph (e)(5)(vi) of this section.

Any facility may avail itself of the approved alternative standard for the described imaging systems.