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Standard for "Quality Control Manual" Template for Manufacturers of Displays and Workstations Labeled for Final Interpretation in Full-field Digital Mammography

National Electrical Manufacturers Association

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"Quality Control Manual" Template for Manufacturers of Displays and Workstations Labeled for Final Interpretation in Full-field Digital Mammography

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(This foreword is to be removed from the manufacturer's final QC manual.)

Foreword to the Device Manufacturer

When full-field digital mammography (FFDM) systems were first introduced, all components (e.g., image receptor, acquisition workstation, diagnostic workstation, hardcopy output device) were provided or qualified for use by the image receptor manufacturer (IRM). The IRM also provided a comprehensive quality control (QC) plan to enable mammography facilities to meet their responsibilities under the Quality Mammography Standards of the Mammography Quality Standards Act (MQSA). Subsequently the U.S. Food and Drug Administration (FDA) approved manufacturers other than the IRMs to market hardcopy and softcopy displays for FFDM images. This has made system QC more difficult since, under MQSA regulations, the facility is required to follow a quality assurance program substantially the same as the one recommended by the IRM. However, the QC plan of the IRM might not adequately address the needs of components developed by other manufacturers.

This increasing heterogeneity of FFDM systems has created a desire to delegate the responsibility for developing QC procedures for the individual system components to the manufacturers of those components. However, it is also desirable, especially for the end-user, to retain some consistency in the QC documentation that accompanies new FFDM components. The Mammography Group of the NEMA X-ray Imaging Section has developed a template that provides both a consistent presentation format and a minimum set of QC tests that should be included as part of the quality assurance plan of a display or workstation labeled for final interpretation in an FFDM system.

Within this document, "display" refers to an electronic image presentation device with minimal image processing capability. "Workstation" refers to an electronic device capable of sophisticated image processing as well as image storage and retrieval. A workstation is expected to incorporate at least one and most likely more than one display. The tests in this template primarily address the QC of the display either as an independently operating device or as a component of a workstation.

Display and workstation manufacturers who follow this template when developing their quality assurance programs and include at least the tests listed, will have incorporated the essential aspects of quality assurance that the image receptor manufacturers have included in their recommended quality assurance programs. This will ease the burden of the mammography facility to establish and maintain a quality assurance program for the display or workstation substantially the same as the one recommended by the IRM. The sections following this foreword to the device manufacturer constitute the content of the QC template.

Each QC test includes a testing frequency, a set of procedure steps, action limits that define acceptable outcomes for the test, and instructions on the use of the test results. Examples of each of these elements are included in the template. In some cases, test conditions and action limits that have been found to be appropriate and reasonable have been included in the QC tests.

However, it is recognized that it might not be practical or possible on all displays or workstations to implement verbatim the tests as set forth in these examples. The content of this template may be incorporated in whole or in part as deemed appropriate by the manufacturer of the display or workstation. However, it is recommended that the manufacturer include in the QC plan a test for each concept presented in this template. The manufacturer may alter the details of the tests to accommodate the characteristics of a specific display or workstation or particular regulatory requirements.

Within the template are instructions and comments to the manufacturer using the template. These instructions and comments are italicized and enclosed in brackets, e.g., *[Manufacturer to …]*. The

manufacturer of the display or workstation must insert the necessary information. In the context of this document, the “manufacturer” is the entity seeking clearance from FDA to market the device. For example, in the case of a workstation produced by one manufacturer but incorporating displays produced by a second, the producer of the workstation would be considered the manufacturer referred to in the template. However, if the display manufacturer also sells displays that can be incorporated into an imaging network independent of a workstation, the display manufacturer would be the one to provide the material for the template.

The manufacturer may also include additional tests beyond those specified in the template. Each such test must include the elements and follow the form of the tests included in the template. The content of the procedure must be written in regulatory language using auxiliary verbs such as “shall” or “must” or the imperative mood. It may not include references to other documents or commercial products. Such references as well as recommendations regarding test procedures may be included in a **Guidance** section of the QC plan. An example of Guidance is included as the final section of the template. The manufacturer should review the content of this Guidance section and provide material of a similar nature appropriate to the manufacturer’s product.

Test patterns suitable for performing some of the tests in the template have been prepared by Task Group #18 (TG 18) of the American Association of Physicists in Medicine and by the Society of Motion Picture and Television Engineers (SMPTE). The TG 18 report and test patterns are available as “AAPM Online Report #3: Assessment of Display Performance for Medical Imaging Systems” and Supplemental Files, Imaging Informatics Subcommittee Task Group #18. These documents are available at

a. http://www.aapm.org/pubs/reports
b. http://www.aapm.org/pubs/reports/public/OR_03_Supplemental/

The SMPTE pattern is available as “SMPTE Recommended Practice RP 133-1991 - Specifications for Medical Diagnostic Imaging Test Pattern for Television Monitors and Hard-Copy Recording Cameras” and is available at

c. http://www.smpte.org/smpte_store/standards/

and at

d. http://brighamrad.harvard.edu/research/topics/vispercep/tutorial.html

It is recommended to include any required test patterns with the equipment for ease of use by the operator and to ensure that the correct pattern is used for each test.

Foreword

Quality Control (QC) is important in any imaging system, but it is especially important in mammography. MQSA[1] regulations mandate that “each facility shall establish and maintain a quality assurance program to ensure the safety, reliability, clarity, and accuracy of mammography services performed at the facility” (21 CFR 900.12(d)). The steady movement from screen/film mammography to full-field digital mammography (FFDM) makes system quality control more difficult because FFDM systems are becoming increasingly heterogeneous. No longer are all of the system components (e.g., image receptor, acquisition workstation, diagnostic workstation, displays, hardcopy output device) provided or qualified for use by the image receptor manufacturer.

As a result, there is an increasing need for QC at the component level. This manual provides QC procedures for the *[Manufacturer to enter commercial name of device]*, a *[Manufacturer to specify display or workstation]* that receives images from an FFDM system, and presents them for final interpretation. The procedures in this manual represent a minimum set of QC tests that should be included as part of the quality assurance plan of a display or workstation used for final interpretation in an FFDM system.

[1] The United States Mammography Quality Standards Act, as amended by the Mammography Quality Standards Reauthorization Acts of 1998 and 2004 (MQSRA).

Section 1
Overview of The Quality Control Manual

1.1 Scope

This document defines the minimum set of Quality Control (QC) tests to be applied to the *[Manufacturer to enter commercial name]*, a *[Manufacturer to specify display or workstation]* labeled for final interpretation of images acquired using a full-field digital mammography (FFDM) image acquisition system. This document is intended to constitute an element of the Quality Assurance Plan (QAP) of the mammographic facility.

Except for the Phantom Image Quality Test, Sec. 3.5, these tests are intended to monitor the performance of the *[Manufacturer to specify display or workstation]* as a component of the full-field digital mammography system and not the performance of the system as a whole. Hence, a characteristic such as compatibility of the component with the communication protocols used in an imaging network is not an element of these tests.

These tests are intended to monitor the consistency over time of the device's performance. While they may be included as elements of acceptance testing, they are not intended to represent the entirety of an acceptance test.

1.2 Regulatory Considerations

Facilities subject to the provisions of the Mammography Quality Standards Act (MQSA) that use image receptors other than screen/film must follow a quality assurance program substantially the same as the one recommended by the image receptor manufacturer [21 CFR 900.12(e)(6)]. It remains the responsibility of the facility to determine whether or not this QC plan is substantially the same as the one recommended by the image receptor manufacturer for the FFDM system in use at that facility.

1.3 Structure of The Document

This QC Manual consists of three main sections:

a. QC Tests for the Radiologic Technologist (Section 2).
b. QC Tests for the Medical Physicist (Section 3).
c. Guidance (Section 4).

1.4 Alternative Standard on Use Of Test Results

[It is recommended that the manufacturer of the mammographic display or workstation apply to the FDA for an Alternative Requirement to 21 CFR 900.12(e)(8)(ii)(A) to separate the actions to be taken for the display from the actions for acquisition systems and to deal with the actions to be taken by an operator upon the failure of a test in the QC plan of the display or workstation. Wording for such an Alternative Requirement is suggested below.]

The actions to be taken in regard to the QC plan for the mammography *[Manufacturer to specify display or workstation]* are as follows:

21 CFR 900.12(e)(8): Use of test results.
For the image display system

(ii) If the test results for the image display system of the FDA-approved, full-field digital mammography (FFDM) equipment fall outside of the action limits, the source of the problem shall be identified and corrective actions shall be taken: