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NEMA XR 23-2006 (R2020)

Standard for "Quality Control Manual" Template for Manufacturers of Hardcopy Output Devices Labeled for Final Interpretation in Full-field Digital Mammography

National Electrical Manufacturers Association

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"Quality Control Manual" Template for Manufacturers of Hardcopy Output Devices Labeled for Final Interpretation in Full-field Digital Mammography

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(This page is to be removed from 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/monitor, 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 MQSA[1] final regulations. Subsequently, 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 may 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. NEMA's Mammography Subcommittee 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 hardcopy output device intended for use in an FFDM system. Hardcopy-device manufacturers who follow this template when developing their quality assurance programs, including 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, thus easing the burden of the mammography facility to establish and maintain a quality assurance program for the hardcopy device substantially the same as the one recommended by the IRM. The following sections of this document constitute the content of that template.

Each QC test includes an objective, a testing frequency, an equipment list, a test procedure, action limits that define acceptable outcomes, and instructions on the use of the test results. In some cases, real-world test conditions and action limits that have been found to be appropriate and reasonable have been included in the QC tests. This content may be incorporated in whole, or in part, as deemed appropriate by the manufacturer of the output device. However, it is recognized that it may not be practical, or possible, on all output devices to implement verbatim the tests as set forth in these examples. Therefore, it is recommended that the manufacturer include in its final 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 device, or particular regulatory requirements. If the manufacturer chooses to modify the actions specified in this template, or deviate from current MQSA regulations for tests added to the template, the manufacturer must apply to the FDA for an Alternative Standard (see 21 CFR 900.18).

The device manufacturer may also include additional tests beyond those specified in the template. Each such test must include the same elements as and follow the form of tests in the template. Procedure contents must be written in regulatory language using auxiliary verbs such as "shall" or "must," or in the imperative mood. They may not include references to other documents or commercial products. Recommendations regarding test procedures, and references to documents and commercial products may be included in the **Guidance** section of the QC plan, an example of which 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.

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[1] The United States Mammography Quality Standards Act of 1992, as amended by the Mammography Quality Standards Reauthorization Acts of 1998 and 2004 (MQSRA).

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

All instructions and comments to the manufacturer using the template are italicized, red, and enclosed in square brackets, e.g., *[Manufacturer to …]*. Wherever such notations occur, the manufacturer of the hardcopy output device must insert the necessary information.

The "Equipment Required" section of each test may list one or more digital test images appropriate for the test. While the manufacturer is free to create specific images that fulfill the equipment requirements of each test, or even handle multiple tests, there are also publicly available images produced by various organizations that can be used. Examples of such organizations include the American Association of Physicists in Medicine (TG-18, http://www.aapm.org/pubs/reports/public/OR_03_Supplemental/), the Society of Motion Picture and Television Engineers (http://www.smpte.org/smpte_store/standards/) and the European Reference Organization for Quality Assured Breast Screening and Diagnostic Services (http://www.euref.org/, which contains modified versions of the AAPM TG-18 images). The test images mentioned in the template text are listed in the Guidance (4.1), along with references. It is strongly recommended that any image data required for the QC tests in this template (except QC Test 3.3) be stored on the hardcopy device itself, so that they can be called up by the user at will, without having to send an image file from some other component in the FFDM system.

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Foreword

Quality Control (QC) is important in any imaging system, but it is especially important in mammography. When full-field digital mammography (FFDM) systems were first introduced, all components (e.g., image receptor, acquisition workstation, diagnostic workstation/monitor, hardcopy output device) were provided or qualified for use by the image receptor manufacturer (IRM). The IRM also provided a comprehensive QC plan to enable mammography facilities to meet their responsibilities under the Mammography Quality Standards Act[2] (MQSA). Subsequently, 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 may not adequately address the needs of components developed by other manufacturers.

The 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. This manual provides such procedures for the *[Manufacturer to enter commercial name of device]*, a hardcopy output device that receives images from an FFDM system, and reproduces them on *[Manufacturer to enter description of hardcopy medium/media]* for final interpretation. The procedures in this manual cover two main performance dimensions: grayscale fidelity and spatial/geometric fidelity. The grayscale dimension addresses the ability of the hardcopy device to achieve and maintain constancy in its tone reproduction characteristics relative to established operating levels. The spatial dimension measures the ability of the device to achieve and maintain the appropriate level of spatial resolution, geometric constancy, and freedom from artifacts.

[2] The United States Mammography Quality Standards Act of 1992, as amended by the Mammography Quality Standards Reauthorization Acts of 1998 and 2004 (MQSRA).

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Section 1
Overview of The Quality Control Manual

1.1 Scope of the Document

This document defines the minimum set of quality control (QC) tests to be applied to the *[Manufacturer to enter commercial name of hardcopy device]*, a hardcopy output device that receives images from an FFDM system, and reproduces them on *[Manufacturer to enter description of hardcopy medium]* for final interpretation. It should be considered as one element of the mammography facility's Quality Assurance Plan.

The tests in this manual generally focus on device constancy, that is, the ability of the hardcopy device to maintain its expected imaging performance over time. They do not address system quality control, for example, the ability of the various system components (image receptor, acquisition workstation, diagnostic workstations, hardcopy output device) to communicate properly with each other, and to use the communicated information correctly. Such system QC activities are assumed to have occurred during initial system installation, initial system acceptance, or as part of a Mammography Equipment Evaluation (see 4.11).

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(s) in use at that facility.

1.3 Structure of the Document

This QC manual is categorized according to whether the test must be performed by a:

a. Radiologic technologist (**Section 2**), or a
b. Medical physicist (**Section 3**).

Within each category, QC tests are arranged according to test frequency, starting with daily/weekly tests, and moving on to quarterly, semi-annual, and annual tests. Each QC test is further split into two parts:

a. Establishing operating levels
   The operating levels are the values against which subsequent, periodic QC test results for the device must be compared. While they change relatively infrequently, certain events can trigger the (re)establishment of operating levels. Examples of such events are significant changes to hardware or software, changes in output media (e.g., film) type, or media batch/lot number, and anything that would require the performance of a Mammography Equipment Evaluation. Media type is defined on the labeling provided by its manufacturer, and relates to properties such as base, tint, tone, density range, or other differentiating characteristics. *[Manufacturer to add other triggering events, if applicable.]*
b. Performing the QC/Constancy test
   This test determines if, and by how much, the hardcopy output device is deviating from the currently valid operating levels.

Finally, a Guidance section (**Section 4**) is included that summarizes *[Manufacturer to enter manufacturer name]* current thinking on performing the various QC tests.

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