NEMA XR 27-2012

X-ray Equipment for Interventional Procedures
User Quality Control Mode

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To: Current Holders of NEMA XR 27-2012
From: NEMA Communications Department
Date: April 12, 2013
Subject: Errata to NEMA XR 27-2012 *X-ray Equipment for Interventional Procedures User Quality Control Mode*

The current publication of NEMA XR 27-2012, *X-ray Equipment for Interventional Procedures User Quality Control Mode* has incorrect information. The phrase, "either by a *manual control mode* or by selecting preset combination values," should be inserted after the words "selection of values," which precedes the second set of bulleted items under Section 2.3, rather than following the words: "Focal spot size," to indicate that it applies to all of the second set of bulleted items.

The current document states on page 6, in Section 2.3, **QUALITY CONTROL TESTING OF THE X-RAY CONTROL PARTS OF THE EQUIPMENT**:

"The *equipment* shall provide x-ray acquisition conditions to perform the QA/QC tests. The *equipment* shall enable selection of values for:

- kV
- mA
- ms
- Spectral filtration
- Focal spot size either by a *manual control mode* or by selecting preset combination values.

The above text should read:

"The *equipment* shall provide x-ray acquisition conditions to perform the QA/QC tests. The *equipment* shall enable selection of values, either by a *manual control mode* or by selecting present combination values, for:

- kV
- mA
- ms
- Spectral filtration
- Focal spot size

Please insert the attached errata page into your standard.

2.3 QUALITY CONTROL TESTING OF THE X-RAY CONTROL PARTS OF THE EQUIPMENT

To enable x-ray dose–related constancy testing, the EQUIPMENT shall provide means for the QUALITY CONTROL USER to perform x-ray dose–related QA/QC tests.

In addition to manufacturer-recommended tests, the EQUIPMENT shall provide means to perform the following tests described in IEC 60601-2-43:

- Half-value layer
- Dose reproducibility
- mA linearity
- kVp, mA, pulse width accuracy
- CAK and DAP accuracy
- x-ray tube output measurement

The EQUIPMENT shall provide x-ray acquisition conditions to perform the QA/QC tests. The EQUIPMENT shall enable selection of values, either by a MANUAL CONTROL MODE or by selecting preset combination values, for:

- kV
- mA
- ms
- Spectral filtration
- Focal spot size

The EQUIPMENT shall ensure that normal x-ray tube protection mechanisms remain active during USER QUALITY CONTROL MODE. In order to protect the x-ray detector from excessive radiation, the user is responsible for shielding the detector with sufficient lead material.

Note 1: Quality control testing of the x-ray control EQUIPMENT parts does not include the imaging detector, therefore there is no need to store images acquired while in this mode.

Note 2: QA/QC of x-ray parameters may be incompatible with INTENDED USE; therefore patient entrance dose rate limits may not be active.

2.4 ACCESS TO AND EXPORT OF BOTH ‘FOR PROCESSING’ AND ‘FOR PRESENTATION’ IMAGES

FOR PROCESSING IMAGES and FOR PRESENTATION IMAGES are not required to be generated during the same acquisition.

2.4.1 FOR PROCESSING IMAGES

The EQUIPMENT shall provide access to the FOR PROCESSING IMAGES acquired during the QUALITY CONTROL MODE in both RADIOSCOPY and RADIOGRAPHY.

EQUIPMENT shall enable the control of one or more of the following parameters:

- kV
- spectral filtration

FORWORD AND CONVENTIONS

This standard is intended to be used by medical imaging device manufacturers in the design and manufacture of x-ray equipment intended to perform interventional procedures.

This standard was developed by the Interventional Group of the x-ray Imaging Section of the Medical Imaging & Technology Alliance (MITA), a division of NEMA. Inquiries, comments, and proposed or recommended revisions should be submitted to the x-ray Imaging Section by contacting:

Vice President
Medical Imaging & Technology Alliance (MITA)
1300 North 17th Street, Suite 1752
Rosslyn, Virginia 22209

At the time of the approval of the standard, the Interventional Group was composed of the following members:

GE Healthcare
Medtronic Navigation
Philips Healthcare
Siemens Healthcare
Shimadzu Corporation
Toshiba America Medical Systems, Inc.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “Shall” means that compliance with a requirement or a test is mandatory for compliance with this standard
- “Should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard
- “May” is used to describe a permissible way to achieve compliance with a requirement or test

Terms and abbreviations used throughout this standard that have been defined in clause 1.4 are in italics, e.g., *air kerma*.

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Section 1
OVERVIEW

1.1 SCOPE

This standard applies to x-ray equipment intended to perform interventional procedures and defines a set of minimum requirements designed to more easily facilitate quality control at the facility level. In particular, items pertinent to the following quality control elements are contained within:

- Physical testing of equipment;
- Electronic audit of system configuration; and,
- Electronic reporting of relevant data and information.

This first edition sets the requirements for fixed x-ray interventional equipment indicated for prolonged x-ray procedures (e.g., neuroradiological and cardiovascular procedures as indicated in the annex AA of IEC 60601-2-43:2010).

The x-ray equipment falling under this standard is hereafter referred to as *equipment*.

1.2 RATIONALE

Numerous applicable international, national or state regulations require medical physics level testing of radiographic and fluoroscopic equipment after specific events (e.g. installation, x-ray tube change) as well as on a routine basis. Specific test requirements and acceptable performance values are included in individual regulations. Many of the current regulations have been in place for decades. In general, these regulatory requirements were established as a means to assure safe and reproducible performance from an x-ray system. X-ray equipment designs that were considered when drafting the regulations were based on open-loop control logic and presumed that irradiation factors were set manually by the technologists before each exposure. Evaluation of irradiation factors such as x-ray tube potential (kV) accuracy, x-ray tube current (mA) linearity, and minimum half-value layer (HVL) are essential to assure safe and adequate performance of this design of equipment.

The evolution of equipment design brought computer-controlled, feedback-stabilized x-ray systems into the market and into clinical practice. Such equipment produces radiation at a level that is inherently more accurate and consistent than open-loop controlled equipment. In addition, newer equipment is much more likely to be used in an automatic exposure control (AEC) or automatic dose-rate control (ADRC) mode instead of with manual settings.

The user interface also evolved from separate manual controls for each irradiation parameter to a single hardware or software exam protocol selection buttons (EPSBs), which are each associated with a full set of programmed technical factors and control algorithms designed to optimize the image acquisition and display. A state-of-the-art radiographic or fluoroscopic system can have hundreds of such EPSBs, some, if not all of which may be editable. Electronic documentation of system configuration and the technical factors invoked by each EPSB are desired to better enable a *responsible organization* to monitor changes and equipment settings being employed in clinical practice.

The presence of automatic control loops can potentially interfere with performing quality control measurements. A non-clinical mode is needed to be able to perform these measurements.