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NEMA XR 27-2013 With Amendment 1

X-ray Equipment for Interventional Procedures User Quality Control Mode

National Electrical Manufacturers Association

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X-ray Equipment for Interventional Procedures
User Quality Control Mode
with

AMENDMENT 1

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Foreword

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:

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Conventions

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 capital letters, e.g., AIR KERMA.

Member Company List

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 Medical Systems
Toshiba America Medical Systems, Inc.
Ziehm Imaging, Inc.

History

The first edition of this standard, XR 27-2012, *"X-ray equipment for interventional procedures User Quality Control Mode."* set the requirements for fixed x-ray interventional equipment indicated for prolonged x-ray procedures (e.g., neuro and cardiovascular procedures as indicated in the annex AA of IEC 60601-2-43:2010).

This is the first amendment to NEMA standard XR 27-2012, which extends the Scope of the first edition to x-ray interventional *mobile equipment*.

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
- electronic reporting of relevant data and information.

The Scope of the first edition of XR 27 was applicable to fixed x-ray interventional equipment. This first amendment to the first edition of the standard extends the Scope of the first edition to x-ray interventional mobile equipment.

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 many 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.