Overview

1. Brief overview of MITA/NEMA
2. Active NEMA Standards (Subset):
   a. NEMA XR22: Quality Control Manual Template for Manufacturers of Displays and Workstations Labeled for Final Interpretation in Full-Field Digital Mammography (FFDM)
   b. NEMA XR23: Quality Control Manual Template for Manufacturers of Hardcopy Output Devices Labeled for Final Interpretation in FFDM
   c. NEMA XR25: Computed Tomography Dose Check
   d. NEMA XR26: Access Controls for Computed Tomography—Identification, Interlocks, and Logs
   e. NEMA XR27: X-ray Equipment for Interventional Procedures—User Quality Control Mode
   f. NEMA XR28: Supplemental Requirements for User Information and System Function Related to Dose in CT
   g. NEMA XR29: Standard Attributes on CT Equipment Related to Dose Optimization and Management
   h. NEMA XR31: Standard Attributes on X-ray Equipment for Interventional Procedures
3. Other MITA/NEMA Documents
   b. "The Image Quality of Image Display of Interventional X-ray Equipment—Issues to be Considered"
   c. "WMA-ED P1-2019: Understanding the Clinical Implications of Dose Measurements in Modern Medical X-ray Imaging Equipment"
4. Other Activities
   a. FDA/EPRC to IEC, AAPM TGs, Local Engagements (OSHPD, RAMPS, Texas EPE), Accreditation (TJC), etc., etc.

Focus of This Talk

Getting under the hood in the IR/Cath Lab: Utilizing new standards for performance evaluations

Member Company List

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

- Canon (Toshiba) Medical Systems
- GE Healthcare
- Medtronic Navigation
- Philips Healthcare
- Siemens Healthineers (Healthcare)
- Shimadzu Medical Systems
- Ziehm Imaging, Inc.
Overview of MITA / NEMA

1. Medical Imaging & Technology Alliance
   - Leading organization and collective voice of medical imaging equipment manufacturers (90% representation)
   - Secretariat of DICOM and US TAG to IEC SC62B (diagnostic imaging equipment), SC62C and TC87
   - Division of NEMA – ANSI accredited standards developer

2. Vision: Medical imaging drives effective patient care through screening, diagnosis and treatment
3. Mission: Reduce regulatory barriers, establish standards, and advocate for the medical imaging industry
4. Current Strategic Priorities:
   1. Adopt Uniform Standards for Medical Imaging Service Providers
   2. Ensure Patient Access to Medical Imaging
   3. Promote Cybersecurity for Medical Imaging
   4. Develop Standards to Ensure Patient Safety and Timely Access to Market
   5. Improve Regulatory Environment to Promote Growth and Innovation
   6. Remove Barriers and Reduce Costs in Federal and Overseas Markets

5. MITA Code of Ethics on Interactions with Healthcare Professionals

Structure of MITA

Committees
1. Technical & Regulatory Committee
2. Global Affairs Committee
3. Government Relations
   1. Washington Representatives
   2. State Issues
4. Standards Committee
5. Coverage Committee
6. Environmental Committee
7. Reimbursement Committee
8. Service Committee
9. PET Group
10. DICOM Standards Committee
11. Cybersecurity Committee
12. AI Committee

Sections
1. Ultrasound
2. X-Ray
   1. Interventional
   2. CT
   3. Mammography
   4. CRDR
   5. General Fluoroscopy
3. Magnetic Resonance
4. Molecular Imaging
5. Focused Ultrasound
6. Medical Imaging Informatics

NEMA XR27 Background and Timeline

2011-2012: Concept proposal and discussions @ AAPM, RSNA, SPIE (Stakeholder Lead: Dr. Stephen Balter)
   a. Objective: Standard equipment provided with a set of hardware and software tools to facilitate physical testing of the equipment, digital audit of system configuration, and digital reporting of important functional logs
7/2012: Draft circulated for comments
   a. Resolution of 44 comments from AAPM membership (34) and FDA (10)
11/2012: Publication of Standard
   a. 18 months turnaround (light speed)
   b. Voluntary agreement to implement with 3 year transition period target
11/2015: Publication of Amendment 1
   a. Extend scope to include mobile C-arm (indicated for use in interventional procedures)
   b. Inclusion of reference to AAPM TG190
5/2016: Implementation of new production units
2018: Balloted with 100% Reaffirmation
   a. Stability period extended to 2023

NEMA XR-27 Introduction

Scope: 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:
   a. Physical testing of equipment
   b. Electronic audit of system configuration
   c. Electronic reporting of relevant data and information

Rationale: Regulations require medical physics level testing after specific events (e.g., installation, x-ray tube change) as well as on a routine basis.
   • Assure safe and reproducible performance
   • A non-clinical mode is needed to perform quality control measurements
The ACCOMPANYING DOCUMENTS shall contain quality control procedures to be performed on the INTERVENTIONAL X-RAY EQUIPMENT by the RESPONSIBLE ORGANIZATION. These shall include acceptance criteria and frequency for the tests.

General Requirements / Control of Access

1. QC interface different from user interface
2. Means to prevent operator from using QC mode during clinical use (ultimate responsibility of the responsible organization)
3. Instructions to exit on display monitors
4. Prohibit permanent modification to system
5. Maintain safety functions
6. Instructions to protect image chain in accompanying documents
7. Should require user login and authorization with free-form text field (e.g. name of qc user)

NEMA XR-27 Features

1. General Requirements
2. Control of Access
3. Quality Control Testing of the XRAY Control Parts of the Equipment (kVp, mA, time, filtration, focal spot)
4. Access To and Export of both “For Processing” and “For Presentation” Images
5. Dose Calibration Factors in RDSR
6. Electronic Documentation of System Configuration
7. Access to RDSR
8. Informative Annex including Rationales

*Relevant portions have been incorporated into IEC (in italics above)
1. Provide means to perform x-ray dose-related QA/QC tests (e.g. constancy)
2. Provide means to perform the following tests described in IEC 60601-2-43:
   - HVL, dose reproducibility, mA linearity, kVp, mA, pulse width accuracy, Cumulative Air Kerma (CAK) and DAP accuracy, x-ray tube output measurement
3. Selection of values for (manual or preset): kV, mA, ms, filter, focal spot
4. Normal x-ray tube protection mechanisms remain active (user responsible for protecting detector)

**Outcome:**
- Dose data as measured
- Image run if needed
- Shield detector with Pb if image run not needed

Access to and export of both “For Processing” and “For Presentation” images:
1. Both are not required to be generated during the same acquisition
2. Provide access to “for processing” images during QC mode (fluoroscopy and radiography)
   A. Control of one or more: kV, spectral filtration, detector dose target
3. Provide access to “for presentation” images (fluoroscopy and radiography)
4. Image export in non-proprietary format
1. Provide an interface to enter the dose calibration factor(s)
   1. Calibration date
   2. Calibration responsible party
   3. Calibration factor

   Note: AAPM Task Group Number 190 — Accuracy and Calibration of Integrated Radiation Output Indicators in Diagnostic Radiology, is in the process of defining a procedure to measure the calibration factor(s). This is currently a work in progress.

2. If the calibration factor leads to deviation from displayed value beyond specified maximum (e.g., +/- 35%) then a message should draw attention to QC user.

Dose Calibration Factors in RDSR

Electronic Documentation of System Configuration

1. Electronic documentation of system configuration and technical factors invoked by each available EPSB in a defined format file (e.g., EXCEL compatible) to an output device during the quality control mode
   A. Includes all dose-related parameters
   B. Should also include the date of configuration of the EPSB
   C. May include identity of individual configuring the EPSB

2. Access to a media output device or networked output device to transmit the electronic documentation
   Note: Additional equipment may be required (e.g., PC, CD/DVD drive, approved USB device, laptop wired by Ethernet connection, etc.) to enable export.

3. Factory default EPSB documentation should be available.

4. A comparison tool to flag differences between two or more EPSBs to assist in the local review and clinical audit
   Note: the comparison tool can be external to the equipment and not be classified as a medical device.

Electronic Documentation of System Configuration

Access to RDSR

1. Capability to store RDSR data associated with image data.
   1. In the case when a patient examination is performed only in radioscopry or without any x-ray images (e.g., exam limited to ultrasounds), the equipment should also be capable to store the RDSR associated with that patient examination.
   2. Since RDSR data may be linked to the associated image data, it may be that RDSR data is available on the equipment only as long as the associated image data are available.

2. Direct export of RDSR data stored on the equipment if the RDSR data is not available by other means.
   Note: Additional equipment may be required (e.g., PC, CD/DVD drive, approved USB device, laptop wired by Ethernet connection, etc.) to enable export.

3. RDSR associated with user quality control mode should be handled (e.g., store, archive, delete) in the same way as for medical images.
Explains reasons for the requirements and provides additional guidance where appropriate.

**NEMA XR-31**

1. **Rationale:** Instances of health care and third party providers modifying medical imaging equipment by utilizing image displays that have not been validated for use have been documented.

2. **White paper published 9/2018:** intended to give a broad range of stakeholders (including regulators, facility administrators, radiologists, medical doctors and medical physicists) information on some of the issues and associated risks with the use of non-validated third-party image displays.

3. **Collaborative Activities:** 2017 AAPM Poster, 2018 AHRA Article

**Third Party Display White Paper**

1. **Attributes recommended by professional societies**
   - Dosimetric indications
   - Additional filtration
   - Range of Air Kerma Rates in Fluoroscopy
   - Variable Pulsed Fluoroscopy Rate
   - Last-Image-Hold (LIH)
   - Virtual Collimation
   - Stored Fluoroscopy
   - Digital X-ray Imaging Device

2. **NEMA XR-31:** develop a radiation dose management voluntary standard to assist health care facilities in performing risk evaluations on their fixed interventional installations

3. **Content:** 8 attributes recommended by professional societies

4. **Collaborative Activities:** 2017 AAPM Poster, 2018 AHRA Article

*Relevant portions have been incorporated into IEC (in italics above)*
1. **Background:** Request from AAPM TG 272 to manufacturers to provide industry perspectives on measuring air kerma at the entrance of the image receptor.

2. **White Paper Published 8/19:** Understanding the Limited Usefulness of Detector Dose Measurements in Modern Medical X-ray Imaging Equipment

3. **Key Takeaway:** Detector dose is only one of many contributing variables that may be considered in design rules and does not provide complete insight into patient dose risk and IQ benefit.

4. **Alignment with AAPM TG 272**

5. **Article in AAPM Newsletter**

---

**Detector Dose White Paper**

1. Background: Request from AAPM TG 272 to manufacturers to provide industry perspectives on measuring air kerma at the entrance of the image receptor.

2. White Paper Published 8/19: Understanding the Limited Usefulness of Detector Dose Measurements in Modern Medical X-ray Imaging Equipment

3. Key Takeaway: Detector dose is only one of many contributing variables that may be considered in design rules and does not provide complete insight into patient dose risk and IQ benefit.

4. Alignment with AAPM TG 272

5. Article in AAPM Newsletter

---

**How to Access MITA / NEMA Content**

https://www.nema.org/Standards/  
https://www.medicalimaging.org/standards/

---

**THANK YOU!**