NEMA XR 31-2022

Standard Attributes on X-Ray Equipment for Interventional Procedures

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Foreword

This standard is intended to identify key features of fixed X-ray interventional equipment that:
- contribute to optimize patient care; or
- help to perform optimization and/or management of doses of ionizing radiations while still enabling the system to deliver sufficient image quality needed by the physician.

> Note: Examples of interventional X-ray equipment for which this standard is intended include prolonged neuro and cardiovascular procedures as indicated in the annex AA of IEC 60601-2-43:2010.

The Interventional Fluoroscopy Working Group, MITA, and NEMA as a whole convey their determination and commitment to help ensure that clinicians have the tools needed to manage the amount of radiation that is used during extended interventional X-ray procedures.

This standard can enable the designated individuals of the health facilities responsible for maintaining the risk management of the interventional X-ray rooms to evaluate how their equipment manufactured at a given date is positioned regarding the key dose management features specified in this standard. They should take these factors into consideration when performing risk management evaluations on existing equipment.

This standard was developed by the Interventional Fluoroscopy Working 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:

> Executive Director
> Medical Imaging & Technology Alliance (MITA)
> 1300 North 17th Street, Suite 900
> Rosslyn, Virginia 22209

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

> Canon Medical Systems USA
> GE HealthCare
> Philips Healthcare
> Siemens Healthineers

At the time of the approval of the standard, the X-Ray Imaging Section was composed of the following members:

> Agfa HealthCare
> Canon Medical Systems USA
> Capintec, Inc.
> CIRS
> ELEKTA Corporation
> ESAOTE imaging
> FUJIFILM Medical Systems U.S.A., Inc.
> GE HealthCare
> Hitachi Medical Systems America, Inc.
> Hologic Inc.
> IMRIS
> Konica Minolta Medical Imaging USA, Inc.
> MEDIAN Technologies, Inc.
> Medtronic, Inc.

NeuroLogica Corporation
Neusoft Medical Systems, USA, Inc.
Philips Healthcare
Shimadzu Medical Systems USA
Siemens Healthineers
The Phantom Laboratory
Ziehm Imaging, Inc.

Contents

History

The first edition of this standard, NEMA XR 31-2016 *Standard Attributes on X-Ray Equipment for Interventional Procedures*, identified state of the art attributes 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 60601-2-43:10).

This is the first revision to NEMA XR 31-2016; it adds additional attributes that have become state of the art since publication of the first edition.

Section 1
Overview

1.1 Scope

This standard identifies state of the art fixed X-ray interventional equipment attributes that:

a. contribute to optimize patient care;
b. or help optimize/manage doses of ionizing radiation while still enabling the system to deliver the image quality needed by the clinician.

1.2 Normative References

By reference herein the following normative documents are adopted, in whole or in part, as indicated in this technical publication.

International Electrotechnical Commission
3, rue de Varembé
Case postale 131
CH-1211 Geneva 20
Switzerland

- IEC 60601-2-43:2000
- IEC 60601-2-43:2010
- IEC 60601-2-43:2010 A2:2019
- IEC 60601-1-3:1994
- IEC 60601-1-3:2008
- IEC 62220-1-3:2008
- IEC 61910-1:2014

National Council on Radiation Protection and Measurements
7910 Woodmont Avenue, Suite 400
Bethesda, MD 20814-3095

- NCRP 168 Table 3-1
- NCRP 168 Table 3-1 and 3-11

1.3 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:

a. "Shall" means that compliance with a requirement or a test is mandatory for compliance with this standard
b. "Should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard
c. "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 bold italics.

Acceptance criteria used throughout this standard are in italics in the standard.