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Supplemental Requirements for User Information and System Function Related to Dose in CT

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Foreword

This first edition of this standard is intended to be used by medical imaging device manufacturers in the design and manufacture of CT scanner equipment.

This standard was developed by the CT 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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Section 1
Overview

1.1 Scope

This standard identifies uniform and standardized manufacturer's information provided to users of a CT scanner. Users include people designated through an Access Control system to operate a CT scanner according to the manufacturer's user instructions, to authorize protocols in the facility where the scanner is housed, and to perform recommended quality control testing on the CT scanner. This user information pertains to perfusion scanning, use of Automatic Exposure Control (AEC), organization of dose-related information, and a requirement for listing reference protocols shipped on the CT system. This user information also requires pre-populating the NEMA XR-25
Dose Check "Alert" value at a $CTDI_{Vol}$ value not to exceed 1 Gy (1000 mGy), as well as system function when switching between a manual mA control mode and automatic exposure control.

This standard is established to collect the standardized responses and resolutions to FDA's November 8, 2010 "Letter to the Medical Imaging Technology Alliance Regarding CT Recommendations." (See Appendix D.)

This standard provides supplementary requirements to those already in place for information provided to the user from other normative documents (see Section 1.3, references).

1.2 Rationale

This standard is intended to provide instructions to manufacturers such that users are provided with uniform information. This is accomplished by the use of standardized language as well as templates in the Appendices. This language has been reviewed by stakeholders outside MITA. There are sections within the standard where manufacturer/model specific information should be added.

It is important that CT scanners have a pre-populated Dose Check Alert value entered by the manufacturer prior to turnover to the customer. This action ensures Dose Check is set at an initial established Alert value.

In the transition from manual mA control to/from Automatic Exposure Control the operator must pay close attention to how scan parameters may be affected. This standard sets out options for system functionality to address this transition.

1.3 References

1.3.1 Normative References

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

National Electrical Manufacturers Association
Medical Imaging & Technology Alliance
Rosslyn, Virginia 22209

NEMA XR 25-2010 *Computed Tomography Dose Check*

NEMA XR 26-2012 *Access Controls for Computed Tomography:* Identification, Interlocks, and Logs