NEMA Standards Publication

NEMA XR 26-2012

Access Controls for Computed Tomography: Identification, Interlocks, and Logs

National Electrical Manufacturers Association

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

Published by:

National Electrical Manufacturers Association
1300 North 17th Street, Suite 1752
Rosslyn, Virginia 22209

www.nema.org

© Copyright 2012 by National Electrical Manufacturers Association

NOTICE AND DISCLAIMER

The information in this publication was considered technically sound by the consensus of persons engaged in the development and approval of the document at the time it was developed. Consensus does not necessarily mean that there is unanimous agreement among every person participating in the development of this document.

The National Electrical Manufacturers Association (NEMA) standards and guideline publications, of which the document contained herein is one, are developed through a voluntary consensus standards development process. This process brings together volunteers and/or seeks out the views of persons who have an interest in the topic covered by this publication. While NEMA administers the process and establishes rules to promote fairness in the development of consensus, it does not write the document and it does not independently test, evaluate, or verify the accuracy or completeness of any information or the soundness of any judgments contained in its standards and guideline publications.

NEMA disclaims liability for any personal injury, property, or other damages of any nature whatsoever, whether special, indirect, consequential, or compensatory, directly or indirectly resulting from the publication, use of, application, or reliance on this document. NEMA disclaims and makes no guaranty or warranty, express or implied, as to the accuracy or completeness of any information published herein, and disclaims and makes no warranty that the information in this document will fulfill any of your particular purposes or needs. NEMA does not undertake to guarantee the performance of any individual manufacturer or seller's products or services by virtue of this standard or guide.

In publishing and making this document available, NEMA is not undertaking to render professional or other services for or on behalf of any person or entity, nor is NEMA undertaking to perform any duty owed by any person or entity to someone else. Anyone using this document should rely on his or her own independent judgment or, as appropriate, seek the advice of a competent professional in determining the exercise of reasonable care in any given circumstances. Information and other standards on the topic covered by this publication may be available from other sources, which the user may wish to consult for additional views or information not covered by this publication.

NEMA has no power, nor does it undertake to police or enforce compliance with the contents of this document. NEMA does not certify, test, or inspect products, designs, or installations for safety or health purposes. Any certification or other statement of compliance with any health or safety–related information in this document shall not be attributable to NEMA and is solely the responsibility of the certifier or maker of the statement.

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:

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 CT Group was composed of the following members:

GE Healthcare
Hitachi Medical Systems America, Inc.
Neusoft Medical Systems USA, Inc.
Neurologica
Philips Healthcare
Siemens Medical Solutions USA, Inc.
Toshiba America Medical Systems

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

Advanced Instrument Development, Inc.
Agfa Healthcare
Bioptics, Inc.
Biospace Med
Capintec, Inc.
Carestream Health, Inc.
CIRS
Eizo Nanao Corporation
Fujifilm Medical Systems, U.S.A., Inc.
Gamma Medica Ideas, Inc.
GE Healthcare
Hitachi Medical Systems America, Inc.
Hologic, Inc.
Konica Minolta Medial Imaging USA, Inc.
Medtronic Navigation
Neusoft Medical
NeuroLogica
Philips Healthcare
Shimadzu Medical Systems
Siemens Medical Solutions USA, Inc.
Stryker Communications
The Phantom Laboratory
Toshiba America Medical Systems, Inc.

Table of Contents

Section 1
OVERVIEW

1.1 SCOPE

This standard applies to the particular functioning of a CT system (as covered by the scope of IEC 60601-2-44) as it relates to who has access/permission to use the system for clinical or other uses. This includes being able to assign specific permissions to selected uses that are above those needed for daily routine scanning, such as the authorization to save protocols. This also includes provisions to secure the user interface based on a manual lock. XR 26 includes functionality for use in a facility's quality assurance program such as capturing operator and patient information as well as information related to saved changes in protocols.

This standard is not intended to change the existing service or applications access or permissions currently available on CT scanners, nor is it intended to define all access or quality assurance related functionality.

1.2 RATIONALE

This standard intends to provide for additional and standardized access controls and quality assurance tools for CT scanners that may be in addition to existing HIPAA functionality. These controls and tools have been identified by the CT community as an important addition to today's CT systems, their proper use by *qualified operators*, quality assurance oversight, and focus on practice according to ALARA principles.

It is important that CT scans be performed only by authorized users and that only facility personnel who are authorized to do so are permitted to save new/changed protocol. Of equal importance is that the scanner is able to record a log of users, patients, patient information, and changed protocols. These records are intended to be used for both quality assurance, dose management, and more complete inputs to dose registries.

The standard, IEC 60601-2-44 Ed. 2.1 and Ed. 3 (*Particular requirements for the basic safety and essential performance of X-Ray equipment for computed tomography*) currently does not contain these types of access controls and quality assurance tools. This NEMA standard supplements IEC standard 60601-2-44.

1.3 REFERENCES

1.3.1 Normative References

The following normative documents contain provisions, which through reference in this text constitute provisions of this standards publication. By reference herein, these publications are adopted in whole or in part as indicated.

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

IEC 60601-2-44 Ed. 2.1 and Ed. 3 *Particular requirements for the basic safety and essential performance of X-Ray equipment for computed tomography*