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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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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.
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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.

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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