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

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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:

Vice President
Medical Imaging & Technology Alliance (MITA)
1300 North 17th Street, Suite 900
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
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Hologic, Inc.
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Stryker Communications
The Phantom Laboratory
Toshiba America Medical Systems, Inc.

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CONTENTS

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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 and 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. Also of 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.

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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*

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International Organization for Standardization (ISO)
1, rue de Varembé
Case postale 56
CH-1211 Geneva 20
Switzerland

ISO 12052 *Health informatics–Digital imaging and communication in medicine (DICOM) including workflow and data management*

1.4 Definitions

administrative privileges: Granted to a qualified healthcare professional (e.g., radiologist, technologist, physicist, department administrator) as determined by the healthcare facility to be sufficiently qualified to competently assign, maintain, and oversee the assignments of personnel to *scanning privileges* and/or *protocol privileges* on the particular CT system which they administer. In addition, this person is also authorized and qualified to retrieve system logs associated with this Standard for quality assurance review and to assign this ability to others. A healthcare professional with *administrative privileges* does not necessarily have to have *scanning privileges* or *protocol privileges* on the particular CT system.

clinical operation: Operation of the CT system that involves scanning of live humans and/or creating or editing protocols intended for use on live humans.

clinical protocol: A protocol on the system intended for use on live humans.

clinical scan/clinical scanning: Operation of the CT system that involves scanning of live humans.

operator of record: Operator or health care professional who is currently logged on and authorized to use the CT system via their unique identifier.

protocol privileges: Granted to a qualified healthcare professional (e.g., radiologist, technologist, physicist). This is determined by the healthcare facility and assigned via a user with administrative privileges who is sufficiently qualified to competently save *clinical protocols* (either new or modified) on the particular model of CT system on which they are working. A healthcare professional with *protocol privileges* does not necessarily have to have *scanning privileges* on the particular CT system.

qualified operator: The operators (e.g., technologists, radiologists) as determined by the healthcare facility and assigned via a user with administrative privileges to be sufficiently qualified to competently perform *clinical scans* on the particular model of CT system which they are to use.

scanning privileges: Granted to a *qualified operator* who has been assigned by a user with administrative privileges to conduct clinical scans on the particular model of CT system, which they are to use. This level of privilege allows the use of all *clinical protocols* on the system, including necessary adjustments to the scan parameters at scan time to properly scan the given patient.

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Section 2
Access Controls—Identification, Interlocks, and Logs

2.1 General

The CT system shall support the establishment of various access/authorization levels (privileges) that must be assigned to users by the facility for clinically related privileges or by the facility, field engineer, or manufacturer only for service, applications, or engineering-related privileges.

The CT system shall also support a log file where changes and information described in this Standard are recorded.

These features shall initially be enabled; however, they may be implemented and configured by a facility user with *administrative privileges*. The system shall record any such change in the log file and the *operator of record* who made the change.

2.2 Access and Authorization Levels

The CT systems shall have at least three categories of access and authorization levels. These are *scanning privileges*, *protocol privileges*, and *administrative privileges*. Additional access levels may include service, applications, engineering, or other privileges on the system. Each privilege shall be independent of each other, and a user may be assigned one or multiple privileges.

2.2.1 Establishment of a User with *Administrative Privileges*

The manufacturer's installation instructions shall require that prior to turnover of the system, the field engineer/assembler obtain from the site at least one person to assign as a user with administrative privileges initially.

Note*:* Manufacturers' installation instructions should also advise sites to set up the other clinical access privileges promptly.

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2.2.2 List of Users

The CT scanner shall be able to maintain a list of all users and their associated privileges. There shall be a unique identifier associated with each user. A user with *administrative privileges* shall be able to review and retrieve this list upon request. The scanner shall record all changes made to this list in the log file and the *operator of record* who made the change.

The manufacturers' information for users shall contain information to define users to adequately describe the operation and establish privilege assignments based upon facilities' needs.

2.3 System Access

In order to operate the CT system, the system shall require that a user is logged on and authorized to use that system. This user shall be the *operator of record*. The system shall only allow one *operator of record* to be logged on at a given time. In order to be authorized with *administrative privileges* or *protocol privileges,* a password may also be required.

2.4 System Interlocks

2.4.1 Clinical Scanning

There shall be an interlock to preclude the *clinical operation* of CT equipment without entry of a user with *scanning privileges*. The *operator of record* at scan time shall be recorded for each exam.

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2.4.2 Saving of Clinical Protocols

There shall be an interlock to preclude establishing or saving a *clinical protocol* unless the operator has been assigned to have *protocol privileges*. The system shall record the *operator of record*, date and time, the protocol identifier, and the parameters that changed in the log file.

2.4.3 Patient Identifier

There shall be an interlock to prevent *clinical operation* of CT equipment without entry of a patient identifier. However, a provision shall be made to allow scanning for trauma cases or other cases where the patient identifier may not be known. These cases shall be recorded in the log file with a unique exam identifier, date and time, and *operator of record*.

2.4.4 Patient Height, Weight, Age, and Gender

The system shall also have the ability to enter patient height, weight, age, and gender for *clinical scanning*. In cases where the patient height/weight/age/gender entry is not known, failure to populate these fields shall not prevent scanning.

2.5 System Lock

The system shall provide the ability to lock the user interface. However, if the scan was in the confirmed/go/load status, the confirmed/go/load status shall not be maintained when the system is locked (i.e., a system is no longer “armed” or in ready-state).

This lock shall be accomplished by user demand (manual lock).

Any listed user shall be able to unlock the interface and become the *operator of record* with his/her associated privilege level.

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2.6 Scanning for Unforeseen Circumstances, Emergency Access

Means shall be provided to allow scanning under unforeseen circumstances when a *qualified operator* is unable to gain authorized access for *clinical operation* of that system (e.g., when an operator is not entered into the system but is approved by the institution to perform the scan). In such cases, a field must be provided requiring the operator to enter his/her name before proceeding (this scenario is considered emergency access). This event shall be recorded in the log file along with the operator name, date and time, and unique exam identifier. This event shall be highlighted such that it is easily identifiable for quality review. Additionally, when authorized under emergency access mode, the operator must re-enter his/her name before proceeding after not more than five examinations.

The manufacturers’ information for users shall contain information for maintaining an appropriate number of users with *scanning privileges* (and other privileges) to avoid these types of circumstances.

2.7 Log File

Access to the log file shall be made available on-demand for users with *administrative privileges*. Additionally, the system shall allow the user with *administrative privileges* to assign others with privileges access to the log file.

A message shall be provided to the user before the log file becomes full, instructing them to archive the file. A mechanism shall be made available such that the log file is preserved during, or archived prior to, any potential software updates, reloads, or scanner de-installation.

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2.8 Protocol Export

The scanner shall have the capability to export protocols upon user request.

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