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INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment – Radiation dose documentation – Part 1: Radiation dose structured reports for radiography and radioscopy

Appareils électromédicaux – Documentation sur la dose de rayonnement – Partie 1: Rapports structurés sur la dose de rayonnement pour la radiographie et la radioscopie

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT – RADIATION DOSE DOCUMENTATION –

Part 1: Radiation dose structured reports for radiography and radioscopy

FOREWORD

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This International Standard has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This first edition cancels and replaces IEC/PAS 61910-1, published in 2007. It constitutes a technical revision.

This edition includes the following significant technical changes with respect to IEC/PAS 61910-1:2007:

The previously defined three conformance levels have been restructured to two. The mapping between DICOM and IEC terms is explicitly described in an annex and is decoupled from the conformance level content requirements. A general update to the revised contents of the DICOM RDSR definition has occurred.

The text of this standard is based on the following documents:

FDIS	Report on voting
62B/948/FDIS	62B/952/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

– Requirements and definitions: roman type.

– *Test specifications: italic type.*

– Informative material appearing outside of tables, such as notes, examples and references: smaller type. Normative text of tables is also in a smaller type.

– TERMS DEFINED IN CLAUSE 3 OF THIS STANDARD OR IN OTHER IEC PUBLICATIONS REFERENCED IN THIS STANDARD: SMALL CAPITALS.

In referring to the structure of this standard, the term

– “clause” means one of the numbered divisions within the table of contents, inclusive of all subdivisions (e.g., Clause 5 includes subclauses 5.1, 5.2, etc.);

– “subclause” means a numbered subdivision of a clause (e.g., 5.1, 5.2 and 5.2.1 are all subclauses of Clause 5).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or”, so a statement is true if any combination of the conditions is true.

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:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

– “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

INTRODUCTION

Documentation of the amount of IONIZING RADIATION used during a RADIOLOGICAL procedure is valuable for several reasons. For all procedures dose documentation provides information needed to estimate radiogenic risk to the population. It also plays a role in general institutional quality assurance by providing data for performance validation against established RADIATION dose reference levels. Detailed documentation makes a significant contribution to clinical management of PATIENTS following those interventional procedures that might induce tissue reactions.

The transition from imaging on film to digital imaging opened the possibility of automatically recording dose and other data with the images. The Digital Imaging and Communications in Medicine (DICOM) protocol traditionally provides some relevant facilities for doing this in image headers. This has had several limitations. The most obvious of these is the lack of a means for storing dose data without storing images. Thus, radioscopic data was seldom stored; and no dose data was stored if the images were not stored.

Improving dose documentation was addressed jointly by the International Electrotechnical Commission (IEC) and the DICOM Standards Committee. Supplement 94 to the DICOM standard was approved in 2005 and incorporated since the 2006 edition of the standard. The DICOM standard now provides the technical format needed to store the entire description of the dose used to perform a single imaging procedure. This first edition of IEC 61910-1 replaces the Publicly Available Specification (PAS) and can become a companion document to IEC 60601-2-43 and IEC 60601-2-54. It defines the reporting of relevant RADIATION dose information and establishes conformance levels for dose documentation, to be referred to by requirements in the aforementioned equipment standards. The conformance levels represent a combination of increasing PATIENT risk and an increasing interest in quality assurance. The basic dose documentation conformance level is intended for X-RAY EQUIPMENT that produces dose levels below significant deterministic thresholds for all INTENDED USES. The extended dose documentation conformance level is intended for X-RAY EQUIPMENT used for procedures that could cause significant tissue reactions.

The process resulting from this work is summarized as follows. Information is gathered into a radiation dose structured report (RDSR). This new object is designed to be stored in a picture archiving and communication system (PACS), in a medical informatics system, in a freestanding dose management workstation, or in the X-RAY EQUIPMENT itself. A performed procedure step (resulting in a single RDSR) is related to the RADIATION applied to a single PATIENT by a single piece of X-RAY EQUIPMENT in one session. The data structure permits the transfer of entire studies at once or the streaming of information per individual IRRADIATION-EVENT. The Integrating the Healthcare Enterprise (IHE) Radiation Exposure Monitoring (REM) Profile describes an IT architecture for the creation, storage, analysis and distribution (including submission to centralized registries) of DICOM RDSR objects.

MEDICAL ELECTRICAL EQUIPMENT – RADIATION DOSE DOCUMENTATION –

Part 1: Radiation dose structured reports for radiography and radioscopy

1 Scope

This International Standard applies to RADIATION DOSE STRUCTURED REPORTS (RDSR) produced by X-RAY EQUIPMENT that falls within the scope of IEC 60601-2-43:2010 or IEC 60601-2-54:2009.

NOTE 1 The intent is to develop and publish similar documents for other X-ray imaging modalities capable of producing RDSRs.

NOTE 2 This document does not impose specific requirements on the accuracy of the reported or displayed data. Existing standards or regulations can have applicable requirements for accuracy and precision.

This standard provides specific units and quantities and prescribes data storage formats.

NOTE 3 The data formats are specified such that the numerical uncertainty attributable to the format is likely to be small compared to other data uncertainties.

NOTE 4 This document does not present any requirements on the form of display of dose information to OPERATORS or other individuals.

The objective of this International Standard is to specify the minimum dataset to be used for reporting dosimetric and related information associated with the production of projection RADIOLOGICAL IMAGES.

NOTE 5 The data fields and report structure are intended to facilitate the collection of dosimetric data useful for: management of procedures delivering significant dose, facility quality programs, establishment of reference levels, education.

NOTE 6 A public structure facilitates data analysis by any appropriate individual or organization.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012

IEC 60601-1-3:2008, *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment*
IEC 60601-1-3:2008/AMD1:2013

IEC 60601-2-43:2010, *Medical electrical equipment – Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures*

IEC 60601-2-54:2009, *Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy*

IEC TR 60788:2004*, Medical electrical equipment – Glossary of defined terms*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 + IEC 60601-1:2005/AMD1:2012, IEC 60601-1-3:2008 + IEC 60601-1-3:2008/AMD1:2013, IEC 60601-2-43:2010, IEC 60601-2-54:2009, IEC TR 60788:2004 and the following apply.

3.1
*** IRRADIATION-EVENT**
LOADING of X-RAY EQUIPMENT caused by a single continuous actuation of the equipment's IRRADIATION SWITCH, from the start of the LOADING TIME of the first pulse until the LOADING TIME trailing edge of the final pulse

Note 1 to entry: An IRRADIATION-EVENT can produce a single image (e.g. chest-radiograph) or a series of images (e.g. RADIOSCOPY, Cine or DSA acquisition).

Note 2 to entry: The RADIOLOGICAL IMAGES resulting from an IRRADIATION-EVENT can be stored in the X-RAY EQUIPMENT or image archive or not.

Note 3 to entry: Corresponding statement in the DICOM standard [1][1] PS 3.16, Annex D: An IRRADIATION-EVENT is the occurrence of radiation being applied to a patient in a single continuous time-frame between the start (release) and the stop (cease) of the irradiation. Any on-off switching of the irradiation source during the event shall not be treated as separate events, rather the event includes the time between start and stop of irradiation as triggered by the user. E.g., a pulsed fluoro X-ray acquisition shall be treated as a single IRRADIATION-EVENT.

Note 4 to entry: LOADING TIME is defined in IEC 60601-1-3:2008, 3.37, and described in IEC 60601-2-54:2009, 203.4.101.3.

3.2
ACTOR
information system or component of information system that produces, manages, or acts on categories of information required by operational activities in the RESPONSIBLE ORGANIZATION

Note 1 to entry: Details on IHE terms are provided in Clauses B.2 and B.3

Note 2 to entry: See IHE Radiology Technical Framework:2011 [2], Volume 1, Section 1.6.1.

3.3
RADIATION DOSE STRUCTURED REPORT
RDSR
structured digital record of RADIATION dose delivered to a PATIENT during a RADIOLOGICAL procedure, encoded as DICOM dose structured report object

3.4
*** RDSR STREAMING TRANSMISSION**
process of sending the current partial RDSR after completion of each IRRADIATION-EVENT

3.5
RDSR END OF PROCEDURE TRANSMISSION
process of sending a final RDSR after completion or discontinuation of a RADIOLOGICAL procedure

Note 1 to entry: Resetting the dose indicators defines the end of the previous RADIOLOGICAL procedure.

[1] Numbers in square brackets refer to the Bibliography.