SLOVENSKI STANDARD
SIST EN 61910-1:2015

01-maj-2015

Medicinska električna oprema - Dokumentacija o dozi obsevanja - 1. del: Strukturirana poročila o stopnji sevanja za radiografijo in radioskopijo (IEC 61910-1:2014)

Medical Electric Equipment - Radiation dose documentation - Part 1: Radiation dose structured reports for radiography and radioscopy (IEC 61910-1:2014)

Medizinische elektrische Geräte - Dokumentation der Strahlungsdosis - Teil 1: Strukturierte Strahlungsdosis-Berichte für die Radiographie und Radioskopie (IEC 61910-1:2014)

Appareils électromédicaux - Documentation sur la dose de rayonnement - Partie 1 : Rapports structurés sur la dose de rayonnement pour la radiographie et la (IEC 61910-1:2014)radioscopie

Ta slovenski standard je istoveten z: **EN 61910-1:2014**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment

SIST EN 61910-1:2015 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 61910-1

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Medical electrical equipment - Radiation dose documentation - Part 1: Radiation dose structured reports for radiography and radioscopy (IEC 61910-1:2014)

Appareils électromédicaux - Documentation sur la dose de rayonnement - Partie 1: Rapports structurés sur la dose de rayonnement pour la radiographie et la radioscopie (CEI 61910-1:2014)

Medizinische elektrische Geräte - Dokumentation der Strahlungsdosis - Teil 1: Strukturierte Strahlungsdosis-Berichte für die Radiographie und Radioskopie (IEC 61910-1:2014)

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European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

The text of document 62B/948/FDIS, future edition 1 of IEC 61910-1, prepared by SC 62B “Diagnostic imaging equipment” of IEC/TC 62 “Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 61910-1:2014.

The following dates are fixed:

• latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2015-07-29
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2017-10-29

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Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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.

NOTE 1 When an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu

Publication	Year	Title	EN/HD	Year
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1 + corr. Mars +A11	2006 2010 2011
+A1	2012		+A1 +A1/corr. July +A12	2013 2014 2014
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	EN 60601-1-3 + corr. Mars	2008 2010
+A1	2013		+A1 +A1/corr. May	2013 2014
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	EN 60601-2-43 + corr. July	2010 2014
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	EN 60601-2-54	2009
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-

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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

MEDICAL ELECTRICAL EQUIPMENT – RADIATION DOSE DOCUMENTATION –

Part 1: Radiation dose structured reports for radiography and radioscopy

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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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.