IEC 61910-1

Edition 1.0 2014-09

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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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.

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1 Numbers in square brackets refer to the Bibliography.

4 Units and their DICOM storage formats

The numerical values of all quantities shall be stored in a format such that storage rounding introduces less than 1,0 % total additional uncertainty.

5 General requirements

5.1 * Conformance levels

5.1.1 General

The RDSR shall conform to one of the following levels: basic dose documentation or extended dose documentation.

NOTE 1 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.

NOTE 2 In case of equipment component failure leading to incomplete RDSR, these are preferred over no RDSR for the period of such failure.

5.1.2 Basic dose documentation

The RDSR conforming to basic dose documentation shall contain, at least, the following elements (DICOM Type 1 or 2 or "M" or "U") in the applicable TID and RDSR header depending on the type of X-RAY EQUIPMENT:

NOTE Applicability of TID is defined in the condition statements in [1] PS 3.16.

In TID 10004 (Accumulated Projection X-Ray Dose):

- Dose (RP) Total
- Dose Area Product Total
- Distance Source to Reference Point
- If the equipment is providing this information:
  - Total Number of Radiographic Frames
- If there was RADIOSCOPY:
  - Total Fluoro Time

TID 10006 (Accumulated Cassette-based Projection Radiography Dose):

- Total Number of Radiographic Frames

In TID 10007 (Accumulated Integrated Projection Radiography Dose)

- Dose Area Product Total
- If the equipment is providing this information:
  - Total Number of Radiographic Frames

In the RDSR header:

- Device Serial Number
- Manufacturer
- Manufacturer's Model Name
- Software Versions

- Date, Time for the Series

The RDSR conforming to basic dose documentation should contain, in addition, the following elements (DICOM Type 2 or 3 or “U”):

In the RDSR header:

- Institution Name
- Patient’s Size
- Patient’s Weight
- Patient’s Name
- Patient ID
- Patient’s Birth Date
- Referenced Request Sequence (with Requested Procedure Description or Requested Procedure Code Sequence)
- Performed Procedure Code Sequence

In TID 10001 (Projection X-Ray Radiation Dose)

- Use TID 1002 (Observer Context) with “Person Observer’s Role in this Procedure” set to “Irradiation Administering”

In TID 10002 (Accumulated X-Ray Dose):

- Calibration Factor(s)
- Calibration Date
- Calibration Responsible Party
- Calibration Protocol

In TID 10003 (Irradiation Event X-Ray Data):

- Acquisition Protocol
- DateTime Started
- Irradiation Event Type

NOTE 1 The Dose Measurement Device is an independent device with a traceable calibration.

NOTE 2 The Calibration Responsible Party element in the Calibration data contains the information about the party responsible for the most recent calibration service.

NOTE 3 The RDSR contains the values displayed at the equipment, no Calibration Factor delivered in TID 10002 is applied.

5.1.3 Extended dose documentation

The RDSR conforming to extended dose documentation shall comply with 5.1.2 and shall contain, in addition, the following elements (DICOM Type 2 or 3 or “M” or “U”):

In TID 10001 (Projection X-Ray Radiation Dose)

- Use TID 1002 (Observer Context) with “Person Observer’s Role in this Procedure” set to “Irradiation Administering”

In TID 10002 (Accumulated X-Ray Dose):

- Calibration Factor(s)
- Calibration Date

- Calibration Responsible Party
- Calibration Protocol

In TID 10003 (Irradiation Event X-Ray Data) and sub-templates:

- Acquisition Protocol
- DateTime Started
- Irradiation Event Type
- Dose Related Distance Measurements (“Distance Source to Reference Point”)
- Dose Related Distance Measurements (“Distance Source to Detector”)
- If the equipment is isocentric:
  - Dose Related Distance Measurements (“Distance Source to ISOCENTER”)
- If the equipment has a PATIENT SUPPORT and means to determine one or more of the following:
  - Dose Related Distance Measurements (“Table Longitudinal Position”)
  - Dose Related Distance Measurements (“Table Lateral Position”)
  - Dose Related Distance Measurements (“Table Height Position”)
  - Table Head Tilt Angle
  - Table Horizontal Rotation Angle
  - Table Cradle Tilt Angle
  - If the PATIENT SUPPORT moved during the IRRADIATION-EVENT:
    - Dose Related Distance Measurements (“Table Longitudinal End Position”)
    - Dose Related Distance Measurements (“Table Lateral End Position”)
    - Dose Related Distance Measurements (“Table Height End Position”)
- Either Column Angulation or (Positioner Primary Angle and Positioner Secondary Angle)
- If the positioner moved during the IRRADIATION-EVENT:
  - Positioner Primary End Angle
  - Positioner Secondary End Angle
- Patient Table Relationship
- Patient Orientation
- Patient Orientation Modifier
- Collimated Field Area
- Collimated Field Height
- Collimated Field Width
- For each ADDED FILTER that does not spatially modulate the X-RAY BEAM
  - X-Ray Filter Type
  - X-Ray Filter Material
  - X-Ray Filter Thickness Minimum
  - X-Ray Filter Thickness Maximum
- KVP
- X-Ray Tube Current
- Pulse Width
- Focal Spot Size
- Number of Pulses

- Acquisition Plane
- Dose (RP)
- Dose Area Product
- Irradiation Duration

In TID 10004 (Accumulated Projection X-Ray Data):

- Total Number of Radiographic Frames

The RDSR conforming to extended dose documentation should contain, in addition, the following element (Type “U”):

In TID 10003 (Irradiation Event X-Ray Data):

- If pulsed RADIOSCOPY is used:
  - Pulse Rate

The RDSR conforming to extended dose documentation may contain, in addition, the following element (Type “U”):

In TID 10003 (Irradiation Event X-Ray Data):

- “Patient Equivalent Thickness” value on which automatic exposure control (AEC) is based.

5.2 Data flow

5.2.1 General

An RDSR shall be created and exported for each RADIOLOGICAL procedure.

The RDSR shall be sent to one or more destinations, such as an image manager/archive ACTOR or a dose information consumer ACTOR.

NOTE The RDSR is a part of the PATIENT’S medical record. All relevant local regulations pertaining to distribution, security and retention of medical records are therefore applicable.

5.2.2 RDSR STREAMING TRANSMISSION

The RDSR transmitted with RDSR STREAMING TRANSMISSION shall have the following characteristics:

- The IRRADIATION-EVENT X-ray data shall include all IRRADIATION-EVENTs in the current procedure step, up to and including the IRRADIATION-EVENT that triggered this transmission.
- The “Scope of Accumulation” RDSR element shall be set to “Procedure Step To This Point”.

NOTE RDSR STREAMING TRANSMISSION is not intended for transfer to image manager/archive ACTORS.

5.2.3 RDSR END OF PROCEDURE TRANSMISSION

The RDSR transmitted with RDSR END OF PROCEDURE TRANSMISSION shall have the following characteristics:

- The IRRADIATION-EVENT X-ray data shall include all IRRADIATION-EVENTs in the current procedure step.
- The “Scope of Accumulation” RDSR element shall be set to “Performed Procedure Step”.

Annex A
(informative)

General guidance and rationale

A.1 General guidance

The methods for improved dose reporting were jointly developed by IEC SC 62B, DICOM (Working Groups 2 and 6) and the IHE Radiology Technical Committee. This document is the IEC portion of this project.

This standard specifies the required dose information for two conformance levels, provides key definitions and clarifies how several values can be derived.

DICOM PS 3.16 [1] specifies how the dose information and related details for both accumulated summaries and individual IRRADIATION-EVENTs are encoded as DICOM structured report data. (See templates TID 10001 and referenced sub-templates). Definitions from the DICOM Standard and used in this standard are listed in Annex C.

DICOM PS 3.3 specifies how the structured report data are embedded into a DICOM Dose object (with proper PATIENT and procedure step metadata) for transmission, storage and retrieval using DICOM protocols (See DICOM PS 3.3, A.35.8). The module tables referenced in DICOM PS 3.3, A.35.8 define the specific data attributes.

IHE Radiology Technical Framework [2] specifies an architecture and implementation guidance for the creation, distribution and management of DICOM Dose objects along with compliance requirements for systems such as modalities, archives, dose reporters and dose registries. See IHE Radiation Exposure Monitoring Profile Supplement.

See Annex B for more details on DICOM objects, IHE profiles and the IHE REM profile.

Information is usually available (in the X-RAY EQUIPMENT) for each IRRADIATION-EVENT. This information may include system configuration and settings, imaging geometry, x-ray generation and filtration details, dosimetric information, and other data.

Information describing each of the IRRADIATION-EVENTs associated with a RADIOLOGICAL procedure may be grouped together and encoded as a DICOM structured report dataset. This dataset plus an appropriate header constitute a DICOM X-Ray radiation dose structured report object. Such a DICOM dose object is an example of a RADIATION DOSE STRUCTURED REPORT (RDSR).

Elements of the IRRADIATION-EVENT relevant to image review may also be placed into the DICOM image object header when images are stored. An image object may contain a single frame or a series of frames (multi-frame).

IRRADIATION-EVENT data is stored in a DICOM dose object and included in procedure summaries, even if the images produced by that IRRADIATION are not stored.

A.2 Rationale for specific clauses and subclauses

The following rationale for specific clauses and subclauses is numbered in parallel with the clause and subclause numbers in the body of this document.