BS EN 61910-1:2014

BSI Standards Publication

Medical electrical equipment — Radiation dose documentation

Part 1: Radiation dose structured reports for radiography and radioscopy

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National foreword

This British Standard is the UK implementation of EN 61910-1:2014. It is identical to IEC 61910-1:2014.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electrical Equipment in Medical Practice, to Subcommittee CH/62/2, Diagnostic imaging equipment.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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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• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2017-10-29

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

Endorsement notice

The text of the International Standard IEC 61910-1:2014 was approved by CENELEC as a European Standard without any modification.

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	2013 2014
			+A12	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	-	-

CONTENTS

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.

Subclause 3.1 – IRRADIATION-EVENT

This term is introduced to subdivide a procedure step into a series of elements small enough to permit near-real time dose analysis and reconstruction and, further, to enable a detailed retrospective dose analysis of the procedure for quality improvement and audit.

Many IRRADIATION-EVENTs that occur during a RADIOLOGICAL procedure, such as those used for RADIOSCOPY, are only of transient medical value. The images produced by these events are seldom stored.

Capturing the dose and dose related quantities (including geometry details) from all IRRADIATION-EVENTs provides complete documentation of the use of RADIATION during the procedure.

Subclause 3.4 – RDSR STREAMING TRANSMISSION

RDSR STREAMING TRANSMISSION data flow is intended to enable near-real time dose analysis per IRRADIATION-EVENT during a procedure and thus to provide immediate feedback to the OPERATOR. Real-time analysis might include dose mapping.

Sending a new RDSR that contains all the IRRADIATION-EVENTS in the procedure step and an updated summary provides the receiving system with the most complete available data on a particular procedure step. It is assumed that the receiver will discard earlier partial reports after receiving a later partial report or a complete report.

Subclause 5.1 – Conformance levels

The RADIATION risks to which PATIENTS are exposed are a function of RADIATION levels. Therefore, the data needed from X-RAY EQUIPMENT corresponds to the RADIATION level associated with NORMAL USE of that X-RAY EQUIPMENT.

The two conformance levels defined in this standard attempt to provide information commensurate with increasing risk from the types of procedure.

Higher level of conformance provides more information that can be of use for public health purposes.

The basic dose documentation conformance level is intended to supply:

– basic dose information;
– general patient and physician information;
– basic tools for quality management;
– educational information.

The extended dose documentation conformance level is intended to supply:

– dose information for managing potential tissue reactions;
– specific patient and procedure information;
– advanced tools for quality management;
– educational information.

A.3 Biological background

Medical uses of ionizing radiation have associated risks. These risks can be reduced by minimizing the use of radiation for diagnostic purposes or for the visual guidance of therapeutic interventions. However, the quality of an X-ray image will decrease if too little radiation is used to create it. The lack of sufficient radiation for the intended purpose is almost

always immediately visible to a radiologist. In the era of digital images, the use of too much radiation is much less apparent. Documenting radiation usage is of increasing importance in this environment.

Radiation effects are divided into two classes: “stochastic” and “tissue reaction”.

Stochastic injuries occur when a radiation event damages the DNA in a single cell beyond its ability to repair itself. Depending on the type of cell, this causes cellular death, genetic mutation, or malignant transformation. There is a very small chance that this will occur after any single RADIOLOGICAL procedure. However, the dose-response model (see [3]) used by the International Commission on Radiation Protection (ICRP) predicts that a number of events will occur in an irradiated population. Dose documentation of all procedure steps provides the information needed to assess this risk as well as information that can be used to manage radiation usage for particular examinations in individual institutions. Epidemiological studies of radiation induced risk may have a time span of decades between data collection and data analysis.

Tissue reactions occur when large numbers of cells are killed by radiation. This often produces an observable injury. This occurs as the result of a large radiation dose, such as it might be generated by a prolonged interventional procedure. Typical results are skin injuries and hair loss. More extensive dose documentation is needed for these cases. This documentation provides information needed for clinical care after a RADIOLOGICAL procedure and for planning a subsequent procedure step.

Annex B
(informative)

DICOM and IHE outline

B.1 DICOM objects

The following description is copied from the DICOM Standard PS 3.1 [1], section 6.3.

> PS 3.3 of the DICOM Standard specifies a number of Information Object Classes which provide an abstract definition of real-world entities applicable to communication of digital medical images and related information (e.g., waveforms, structured reports, radiation dose structured reports, etc.). Each Information Object Class definition consists of a description of its purpose and the Attributes which define it. An Information Object Class does not include the values for the Attributes which comprise its definition.
>
> Two types of Information Object Classes are defined: normalized and composite.
>
> Normalized Information Object Classes include only those Attributes inherent to the real-world entity. For example the study Information Object Class, which is defined as normalized, contains study date and study time Attributes because they are inherent in an actual study. Patient name, however, is not an Attribute of the study Information Object Class because it is inherent to the patient on whom the study was performed and not the study itself.
>
> Composite Information Object Classes may additionally include Attributes which are related to but not inherent to the real-world entity. For example, the Computed Tomography Image Information Object Class, which is defined as composite, contains both Attributes which are inherent in the image (e.g. image date) and Attributes which are related to but not inherent in the image (e.g. patient name).
>
> Composite Information Object Classes provide a structured framework for expressing the communication requirements of images where image data and related data needs to be closely associated.
>
> To simplify the Information Object Class definitions, the Attributes of each Information Object Class are partitioned with similar Attributes being grouped together. These groupings of Attributes are specified as independent modules and may be reused by other Composite Information Object Classes.
>
> DICOM PS 3.3 defines a model of the Real World along with the corresponding Information Model that is reflected in the Information Object Definitions. Future editions of the DICOM Standard may extend this set of Information Objects to support new functionality.
>
> To represent an occurrence of a real-world entity, an Information Object Instance is created, which includes values for the Attributes of the Information Object Class. The Attribute values of this Information Object Instance may change over time to accurately reflect the changing state of the entity which it represents. This is accomplished by performing different basic operations upon the Information Object Instance to render a specific set of services defined as a Service Class. These Service Classes are defined in DICOM PS 3.4.

Sending RDSR involves the Storage Service Class. An RDSR is the real world instance of the X-ray RDSR Information Object Definition encoded with the TID 10001 “Projection X-Ray Radiation Dose Report” exported as file or sent over a DICOM network.

B.2 IHE profiles

The following description is a condensed copy quoted from IHE Radiology Technical Framework, Volume 1: Integration Profiles (Revision 11.0, 2012). See sections 1 and 1.1 of [2].

> Integrating the Healthcare Enterprise (IHE) is an initiative promoting the use of standards to achieve interoperability of health information technology (HIT) systems and effective use of electronic health records (EHRs). IHE provides a forum for volunteer committees of care providers, HIT experts and other stakeholders in several clinical and operational domains to reach consensus on standards-based solutions to critical interoperability issues. IHE publishes the implementation guides they produce (called IHE profiles), first to gather public comment and then for trial implementation by HIT vendors and other system developers.
>
> IHE provides a process for developers to test their implementations of IHE profiles, including regular testing events called Connectathons. After a committee determines that a profile has undergone sufficient successful testing and deployment in real-world care settings, it is incorporated in the appropriate IHE Technical Framework, of which the present document is a volume. The Technical Frameworks provide a unique resource for developers and users of HIT systems: a set of proven, standards-based solutions to address common interoperability issues and support the convenient and secure use of EHRs.
>
> The current versions of this and all IHE Technical Framework documents are available at http://www.ihe.net/Technical_Framework/index.cfm/.
>
> The IHE Technical Framework identifies a subset of the functional components of the healthcare enterprise, called IHE Actors, and specifies their interactions in terms of a set of coordinated, standards-based transactions. It describes this body of transactions in progressively greater depth. The present volume provides a high-level view of IHE functionality, showing the transactions organized into functional units called Integration Profiles that highlight their capacity to address specific clinical needs.

B.3 IHE Radiation Exposure Monitoring Profile

The following description is a condensed copy quoted from IHE Radiology Technical Framework, Volume 1: Integration Profiles (Revision 11.0, 2012). See Sections 22, 22.1 and 22.3.1 of [2].

> This Integration Profile specifies how details of radiation exposure resulting from imaging procedures are exchanged among the imaging systems, local dose information management systems and cross-institutional systems such as dose registries. The data flow in the profile is intended to facilitate recording individual procedure step dose information, collecting dose data related to specific patients, and performing population analysis.
>
> Use of the relevant DICOM objects (CT Dose SR, Projection X-ray Dose SR) is clarified and constrained.
>
> The Profile focuses on conveying the details of individual irradiation events. A proper radiation exposure management program at an imaging facility would involve a medical physicist and define such things as local policies, local reporting requirements, annual reviews, etc. Although this Profile is intended to facilitate such activities, it does not define such policies, reports or processing, or in itself constitute a radiation exposure management program.

The Profile addresses dose reporting for imaging procedures performed on CT and projection X-ray systems, including mammography. It does not currently address procedures such as nuclear medicine (PET or SPECT), radiotherapy, or implanted seeds.

Typically, irradiation events occur on X-ray based imaging modalities, which record them in Dose objects that are part of the same study as the images and stored to the Image Manager/Archive.

In many organizations, a Dose Information Reporter will collect Dose objects covering a particular period (e.g., today, this week or last month), analyze them, compare to site policy and generate summary reports.

All, or a sampled subset of the Dose objects might be submitted to a National Registry to facilitate composing population statistics and other research. Such Dose objects will generally undergo a configurable de-identification process prior to submission.

By profiling automated methods of distribution, dose information can be collected and evaluated without imposing a significant administrative burden on staff otherwise occupied with caring for patients.

MANUFACTURERS are encouraged to describe in their DICOM Conformance Statement additional details of how they implement specific DICOM-based transactions (e.g., the time frame in which an Acquisition Modality is able to store a Dose object relative to the completion of the irradiation event).

Annex C
(informative)

Glossary of DICOM data elements

The following table provides clarifications for some dose-related DICOM data elements.

Table C.1 – DICOM data elements

DICOM attribute or concept name	DICOM tag or template	Notes
Patient's Name	(0010,0010)	Patient's full name.
Patient ID	(0010,0020)	Primary hospital identification number or code for the patient.
Patient's Birth Date	(0010,0030)	Birth date of the patient.
Patient's Size	(0010,1020)	Length or size of the patient, in meters.
Patient's Weight	(0010,1030)	Weight of the Patient, in kilograms.
Device Serial Number	(0018,1000)	Manufacturer's serial number of the equipment that produced the composite instances. NOTE the underlying DICOM value representation allows the storage of an alpha-numeric identifier.
Manufacturer	(0008,0070)	Manufacturer of the equipment that produced the composite instances.
Manufacturer's Model Name	(0008,1090)	Manufacturer's model name of the equipment that produced the composite instances.
Software Versions	(0018,1020)	Manufacturer's designation of software version of the equipment that produced the composite instances.
Series Date Series Time	(0008,0021) (0008,0031)	Date the Series started. Time the Series started.
Institution Name	(0008,0080)	Institution where the equipment that produced the composite instances is located.
Calibration Factor	TID 10002	DICOM: Factor by which a measured or calculated value is multiplied to obtain the estimated real-world value. IEC: Average correction factor over the range of energies during NORMAL USE of the equipment This factor is greater than 1 if the actual dose or DAP exceeds the displayed (recorded) value.
Calibration Date	TID 10002	Last calibration date for the integrated dose meter or dose calculation.
Dose Measurement Device	TID 10002	Calibrated device to perform dose measurements.
Calibration Uncertainty	TID 10002	DICOM: Uncertainty of the 'actual' value. IEC: The percentage uncertainty of the displayed (recorded) dose value. This describes variation around the average value caused by variation in irradiation conditions. Expressed as the range containing the true value. The range may be asymmetrical.
Calibration Protocol	TID 10002	Describes the method used to derive the calibration factor.
Calibration Responsible Party	TID 10002	Individual or organization responsible for calibration.
Irradiation Event Type	TID 10003	The appropriate DICOM code among "Stationary Acquisition", "Stepping Acquisition" or "Rotational Acquisition" is used to indicate IRRADIATION for RADIOGRAPHY. The DICOM code "Fluoroscopy" is used to indicate IRRADIATION for RADIOSCOPY.
DateTime Started	TID 10003	The date and time of the first occurrence of an event. Provide DateTime the application of X-ray started. This shall correspond to the start of the first irradiation in the Irradiation Event, which defines the starting point for the calculation of "Irradiation Duration".
Acquisition Protocol	TID 10003	A type of clinical acquisition protocol for creating images or

DICOM attribute or concept name	DICOM tag or template	Notes
		image-derived measurements. Acquisition protocols may be specific to a manufacturer's product.
Acquisition Plane	TID 10003	Identification of acquisition plane with biplane systems.
Dose Area Product	TID 10003	DICOM: Radiation dose times area of exposure. IEC: Corresponds to DOSE AREA PRODUCT.
Dose (RP)	TID 10003	DICOM: Dose applied at the reference point (RP). IEC: Corresponds to REFERENCE AIR KERMA, which is the AIR KERMA expressed at the PATIENT ENTRANCE REFERENCE POINT. Refer to IEC 60601-2-43:2010 and IEC 60601-2-54:2009 for the location of the PATIENT ENTRANCE REFERENCE POINT
Distance Source to Detector	TID 10003	DICOM: Measured or calculated distance from the X-ray source to the detector plane in the center of the beam (see Figure E.7). IEC: Corresponds to FOCAL SPOT TO IMAGE RECEPTOR DISTANCE.
Distance Source to Isocenter	TID 10003	Distance from the X-ray source to the equipment C-arm Isocenter (center of rotation, see Figure E.7). NOTE the DICOM term "X-ray source" corresponds to EFFECTIVE FOCAL SPOT.
Table Longitudinal Position	TID 10003	Table Longitudinal Position with respect to an arbitrary chosen reference by the equipment (in mm). Table motion towards LAO is positive assuming that the patient is positioned supine and its head is in normal position (see Figure E.6).
Table Lateral Position	TID 10003	Table Lateral Position with respect to an arbitrary chosen reference by the equipment (in mm). Table motion towards CRA is positive assuming that the patient is positioned supine and its head is in normal position (see Figure E.6).
Table Height Position	TID 10003	Table Height Position with respect to an arbitrary chosen reference by the equipment (in mm). Table motion downwards is positive (see Figure E.6).
Table Longitudinal End Position	TID 10003	Table Longitudinal Position at the end of an irradiation event. For further definition see "Table Longitudinal Position".
Table Lateral End Position	TID 10003	Table Lateral Position at the end of an irradiation event. For further definition see "Table Lateral Position".
Table Height End Position	TID 10003	Table Height Position at the end of an irradiation event. For further definition see "Table Height Position".
Table Head Tilt Angle	TID 10003	Angle of the head-feet axis of the table in degrees relative to the horizontal plane. Positive values indicate that the head of the table is upwards.
Table Horizontal Rotation Angle	TID 10003	Rotation of the table in the horizontal plane (clockwise when looking from above the table).
Table Cradle Tilt Angle	TID 10003	Angle of the left-right axis of the table in degrees relative to the horizontal plane. Positive values indicate that the left of the table is upwards.
Positioner Primary Angle	TID 10003	Position of the X-ray beam about the patient from the RAO to LAO direction where movement from RAO to vertical is positive (see Figures E.2 to E.5).
Positioner Secondary Angle	TID 10003	Position of the X-ray beam about the patient from the caudal to cranial direction where movement from caudal to vertical is positive (see Figures E.2 to E.5).
Column Angulation	TID 10003	Angle of the X-ray beam in degree relative to an orthogonal axis to the detector plane.
Positioner Primary End Angle	TID 10003	Positioner Primary Angle at the end of an irradiation event. For further definition see "Positioner Primary Angle".
Positioner Secondary End Angle	TID 10003	Positioner Secondary Angle at the end of an irradiation event. For further definition see "Positioner Secondary Angle".
Patient Table Relationship	TID 10003	Orientation of the patient with respect to the head of the table (see Figure E.1).

DICOM attribute or concept name	DICOM tag or template	Notes
Patient Orientation	TID 10003	Orientation of the patient with respect to gravity (see Figure E.1).
Patient Orientation Modifier	TID 10003	Enhances or modifies the patient orientation specified in Patient Orientation (see Figure E.1).
Collimated Field Area	TID 10003	Collimated field area at image receptor. Area for compatibility with IEC 60601-2-43:2010. IEC: Corresponds to RADIATION FIELD at the IMAGE RECEPTION AREA.
X-Ray Filter Type	TID 10003	Type of filter(s) inserted into the X-ray beam (e.g. wedges). IEC: corresponds to (ADDED) FILTERS
X-Ray Filter Material	TID 10003	X-ray absorbing material used in the filter.
X-Ray Filter Thickness Maximum	TID 10003	The maximum thickness of the X-ray absorbing material used in the filters.
X-Ray Filter Thickness Minimum	TID 10003	The minimum thickness of the X-ray absorbing material used in the filters.
KVP	TID 10003	Applied X-ray Tube voltage at peak of X-ray generation, in kilovolts; Mean value if measured over multiple peaks (pulses). IEC: Peak value of X-RAY TUBE VOLTAGE.
X-Ray Tube Current	TID 10003	Mean value of applied tube current. IEC: Mean value of X-RAY TUBE CURRENT.
Pulse Width	TID 10003	(Average) X-ray pulse width. NOTE Either a set of individual values, one for each pulse within the irradiation event, or a total value summing up all individual pulses' widths to a single value.
Focal Spot Size	TID 10003	Nominal size of focal spot of X-ray tube
Number of Pulses	TID 10003	Number of pulses applied by X-Ray systems during an irradiation event (acquisition run or pulsed fluoro) IEC: The DICOM term "pulsed fluoro" corresponds to RADIOSCOPY and the term "acquisition run" corresponds to SERIAL RADIOGRAPHY.
Pulse Rate	TID 10003	Pulse rate applied by equipment during fluoroscopy IEC: The DICOM term "Fluoroscopy" corresponds to RADIOSCOPY.
Patient Equivalent Thickness	TID 10003	Value of the control variable used to parameterize the automatic exposure control (AEC) closed loop (e.g. "Water Value").
Collimated Field Height	TID 10003	Distance between the collimator blades in detector column direction as projected at the detector plane.
Collimated Field Width	TID 10003	Distance between the collimator blades in detector row direction as projected at the detector plane.
Dose Area Product Total	TID 10004	DICOM: Total calculated dose area product (in the scope of the including report) IEC: Sum of DOSE AREA PRODUCT values of all IRRADIATION-EVENTS in the RDSR.
Dose (RP) Total	TID 10004	DICOM: Total dose related to reference point (RP). (in the scope of the including report) IEC: Sum of REFERENCE AIR KERMA values of all IRRADIATION-EVENTS in the RDSR.
Distance Source to Reference Point	TID 10004 TID 10007	Distance to the reference point (RP) defined according to IEC 60601-2-43:2010 or equipment defined. IEC: Corresponds to distance from the EFFECTIVE FOCAL SPOT to the PATIENT ENTRANCE REFERENCE POINT.
Total Fluoro Time	TID 10004	DICOM: Total Radioscopy time IEC: Accumulated periods of LOADING TIME for all IRRADIATION

DICOM attribute or concept name	DICOM tag or template	Notes
		EVENTS performed in RADIOSCOPY.
Total Number of Radiographic Frames	TID 10004	Accumulated count of frames (single or multi-frame) created from irradiation events performed with high dose (acquisition).
Irradiation Duration	TID 10003	DICOM: Clock time from the start of the loading time of the first pulse until the loading time trailing edge of the final pulse in the same irradiation event. IEC: Corresponds to LOADING TIME

Annex D
(informative)

Coordinate systems and their applications

D.1 General

RDSRs compliant with the extended dose documentation requirements of this standard provide information describing the position and orientation of the X-RAY BEAM for each fixed IRRADIATION-EVENT. Information describing the position and orientation of the PATIENT SUPPORT is provided if the X-RAY EQUIPMENT is equipped with an integrated or connected PATIENT SUPPORT.

Extended geometric information (starting and stopping positions) is provided in the RDSR if the X-RAY BEAM and/or the PATIENT SUPPORT move during a single IRRADIATION-EVENT. This geometric information is usually expressed in terms of coordinates relative to the moving EFFECTIVE FOCAL SPOT.

The information supplied in the RDSR can be combined with X-RAY EQUIPMENT specific information describing the position and orientation of the EFFECTIVE FOCAL SPOT, the X-RAY IMAGE RECEPTOR and the PATIENT SUPPORT (if present) in terms of an absolute coordinate system defined to the outside world (the hospital room).

The information contained in this annex may be considered by the maintenance teams for International Standards IEC 60601-2-43:2010 and IEC 60601-2-54:2009.

D.2 Equipment-specific information

The following information related specifically to the X-RAY EQUIPMENT is relevant:

a) a reference point on the X-RAY EQUIPMENT that is always in a defineable location relative to room coordinates;

b) the spatial and angular coordinates of the EFFECTIVE FOCAL SPOT and the vector of the central ray of the X-RAY BEAM relative to the X-RAY EQUIPMENT reference point for at least one position and orientation of the X-RAY BEAM;

c) sufficient information to define the position of the dose reference point for each IRRADIATION-EVENT in absolute room coordinates. X-RAY EQUIPMENT specific constant values are combined with IRRADIATION-EVENT relative translation and rotation values to achieve this objective.

NOTE 1 Translation and rotation values displayed to the OPERATOR during a procedure can be modified to account for different PATIENT positions and orientations. The X-RAY EQUIPMENT specific constant values contain information describing the influence (if any) of such display changes on the values stored in the RDSR.

If a PATIENT SUPPORT forms part of the X-RAY EQUIPMENT, the following information is relevant:

a) a reference point on the PATIENT SUPPORT that is always in a defineable location relative to room coordinates;

b) the plane of the top of the PATIENT SUPPORT. A representative plane is used if the PATIENT SUPPORT is not planar;

c) the spatial and angular coordinates plane of the PATIENT SUPPORT and the visible PATIENT SUPPORT reference point relative to the PATIENT SUPPORT reference point for at least one orientation of the PATIENT SUPPORT;

d) sufficient information to define the position of the PATIENT SUPPORT reference point for each IRRADIATION-EVENT in absolute room coordinates. X-RAY EQUIPMENT-specific constant values are combined with IRRADIATION-EVENT relative translation and rotation values to achieve this objective.

NOTE 2 Translation and rotation values displayed to the OPERATOR during a procedure can be modified to account for different PATIENT positions and orientations. The PATIENT SUPPORT specific constant values contain information describing the influence (if any) of such display changes on the values stored in the RDSR.

Information might be provided in a system parameter sheet, which can be included in the ACCOMPANYING DOCUMENTS. Such a system parameter sheet can contain equipment specific parameters, which are not provided in the RDSR but which are useful during the interpretation of the RDSR contents.

The minimum contents of the system parameter sheet can be specified by the standard defining the requirement (e.g. IEC 60601-2-43 and/or IEC 60601-2-54) and can be published as part of the equipment's ACCOMPANYING DOCUMENTs. A copy of the information is a meaningful extension of the equipment's DICOM Conformance Statement.

D.3 Patient location and orientation

RDSRs complying with this standard do not supply sufficient information to describe the position of the patient relative to the X-RAY EQUIPMENT, the PATIENT SUPPORT or the room.

The RESPONSIBLE ORGANIZATION can provide policies and procedures that allow the OPERATOR to define the position and orientation of the patient relative to the equipment or room with an acceptable degree of accuracy.

General patient orientation information (e.g. head-first, supine) is included in the RDSR. This information may be either an X-RAY EQUIPMENT default value or a value entered by the OPERATOR. In all cases, the validity of these values is the responsibility of the OPERATOR.

D.4 Single procedure step patient dose estimates

PATIENTS can be represented by computational models for the purposes of estimating skin and organ dose distributions. The accuracy of such calculations depends on fixed uncertainties of the relationships between the X-RAY EQUIPMENT, PATIENT SUPPORT and room. Variable uncertainties include the influences of modelling parameters, uncertainties in the values reported by the RDSR, and patient position uncertainties.

Modelling uncertainty is related to differences between the computational model used to represent an actual patient and the details of the computation itself.

Uncertainties in the information contained in the RDSR are related to uncertainties in the reported dose information, the characterization of the x-ray field size and shape, the location of the EFFECTIVE FOCAL SPOT, and the direction of the central X-RAY BEAM.

The RDSR only provides start and stop information for moving X-RAY BEAMS and/or patients. Incorporating such data into a model includes additional considerations that are beyond the scope of this standard. Some of these additional considerations include how to apply time and/or position variation in the X-RAY BEAM during a moving IRRADIATION.

Patient position uncertainty is related to the spatial and angular orientation of the patient relative to the X-RAY BEAM. This uncertainty is lowered if an efficient protocol can be developed using the visible PATIENT SUPPORT reference point or perhaps a room-level reference point.

D.5 Multiple procedure step patient dose estimates

PATIENTS often undergo multiple procedure steps. These are often performed using different pieces of X-RAY EQUIPMENT and may be performed in different facilities. A clinical goal of

collecting RDSRs is to be able to assemble single procedure step dose estimates into a multiple procedure step cumulative dose estimate.

All of the uncertainties for a single procedure step are relevant for multiple procedure steps. PATIENT positioning uncertainty is likely to be of increased importance because of variability in PATIENT position relative to references from procedure step to procedure step.

D.6 Numeric and geometric expression of uncertainty

There is no generally accepted way to express uncertainty in either a numeric or geometric manner. The need for future research in this area is obvious.

The production of skin dose maps based on the RDSR data can be helpful in reducing skin injuries. These maps can be used to determine the location and intensity of skin IRRADIATION. Real-time skin-dose maps are intended provide information so that the OPERATOR can avoid or minimize radiation-induced skin injuries during a RADIOLOGICAL procedure. This objective is facilitated when the skin-dose map displayed at the start of a procedure step contains relevant data from previous procedure steps.

Avoiding or minimizing injuries to the PATIENT'S skin that is already at risk due to previous IRRADIATIONS, can be supported by such skin-dose maps in selecting locations on the skin that have received lower RADIATION doses.

Annex E
(informative)

Geometry and positions in DICOM

E.1 Patient positions

Figure E.1, taken from DICOM PS 3.3 [1] (section C.7.3.1.1.2), shows the various possible positions of the PATIENT (PATIENT orientation) relative to the PATIENT SUPPORT. The orientation of the PATIENT relative to gravity is always recumbent. The PATIENT can be positioned with head first or feet first and supine, prone or decubitus left or right.

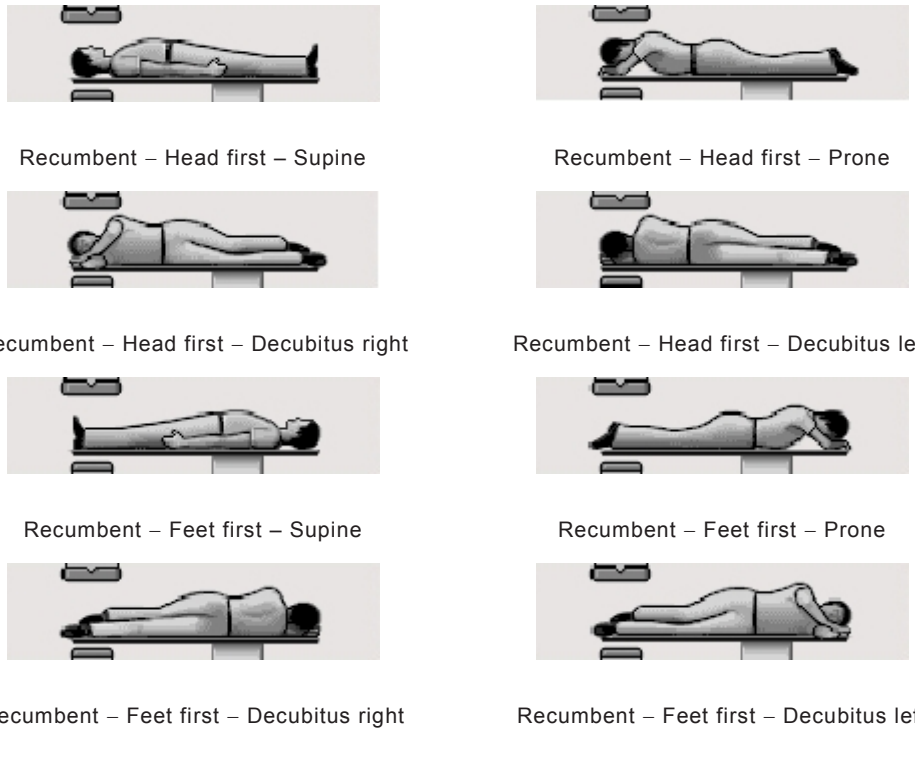


Figure E.1 – PATIENT positions for X-RAY EQUIPMENT with PATIENT SUPPORT such as in X-ray angiography.

E.2 Positioner primary and secondary angles

Figures E.2 and E.3, taken from DICOM PS 3.3 [1] (section C.8.7.5.1.2), illustrate the positioner primary angle and the positioner secondary angle and the axes of rotation. Figures E.4 and E.5 are adapted to illustrate other PATIENT positions. As a rule, the positioner primary angle and the positioner secondary angle are both equal to 0°, when the PATIENT faces the X-RAY IMAGE RECEPTOR. The directions for positive and negative angles are shown in the figures.

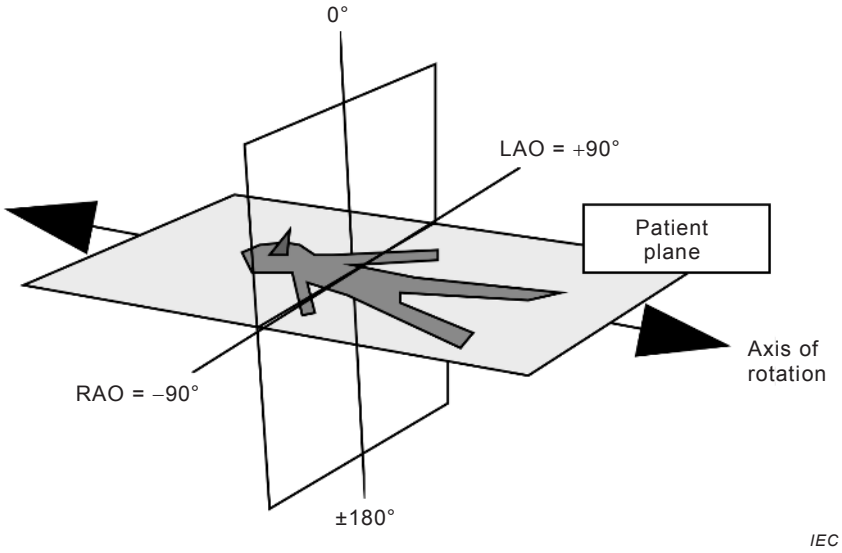


Figure E.2 – Positioner primary angle for patient position "recumbent – head first – supine"

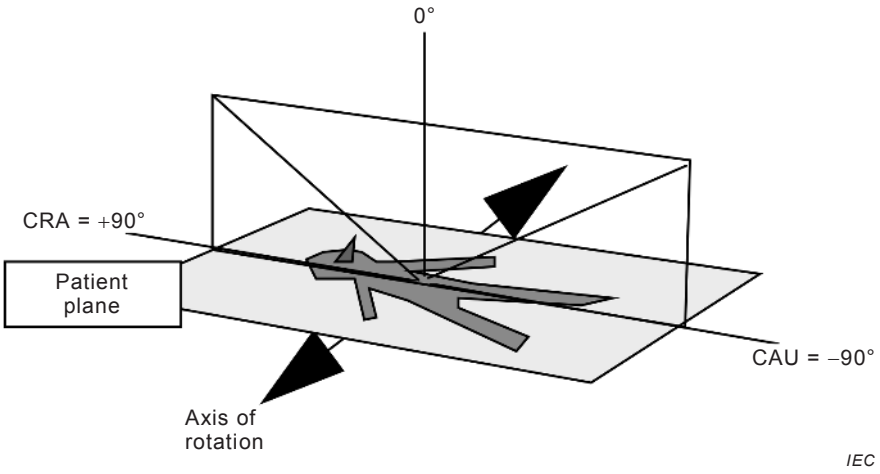


Figure E.3 – Positioner secondary angle for patient position "recumbent – head first – supine"

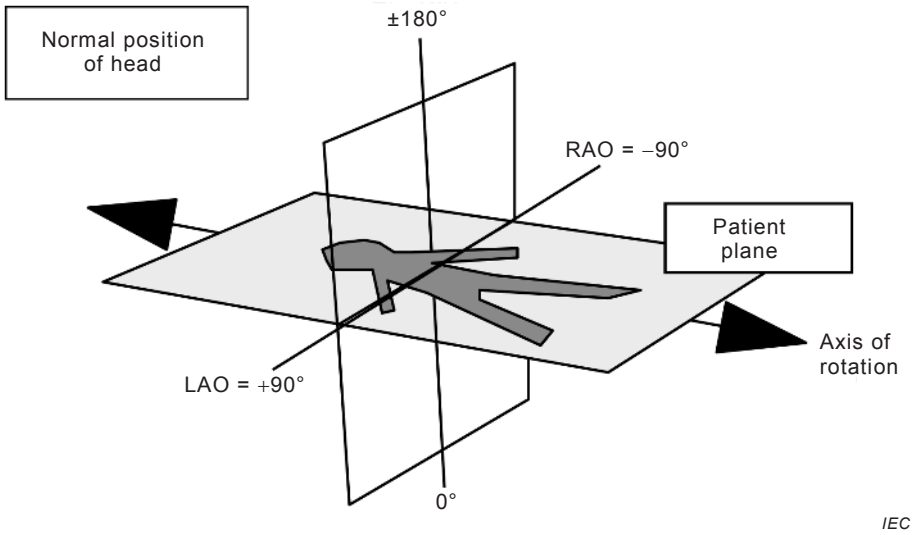


Figure E.4 – Positioner primary angle for patient position "recumbent – head first – prone"

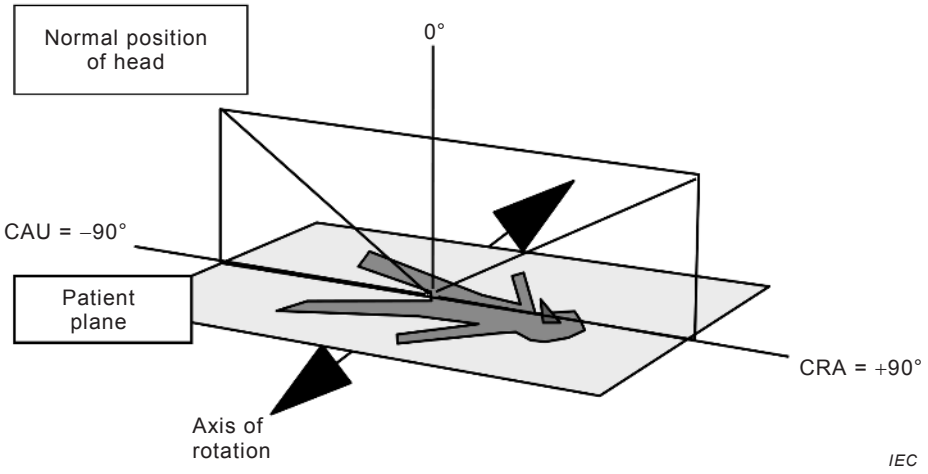


Figure E.5 – Positioner secondary angle for patient position "recumbent – feet first – supine"

E.3 PATIENT SUPPORT positions

Figure E.6 , taken from DICOM PS 3.3 (section C.8.19.6.11.1), shows the vectors defining the position of the PATIENT SUPPORT, which are the table lateral position, the table longitudinal position, and the table height position. The directions for positive and negative translations are shown in the figure.

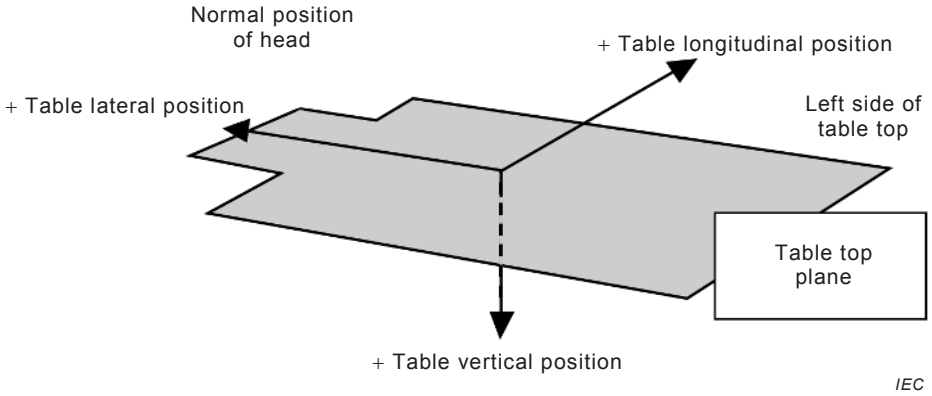
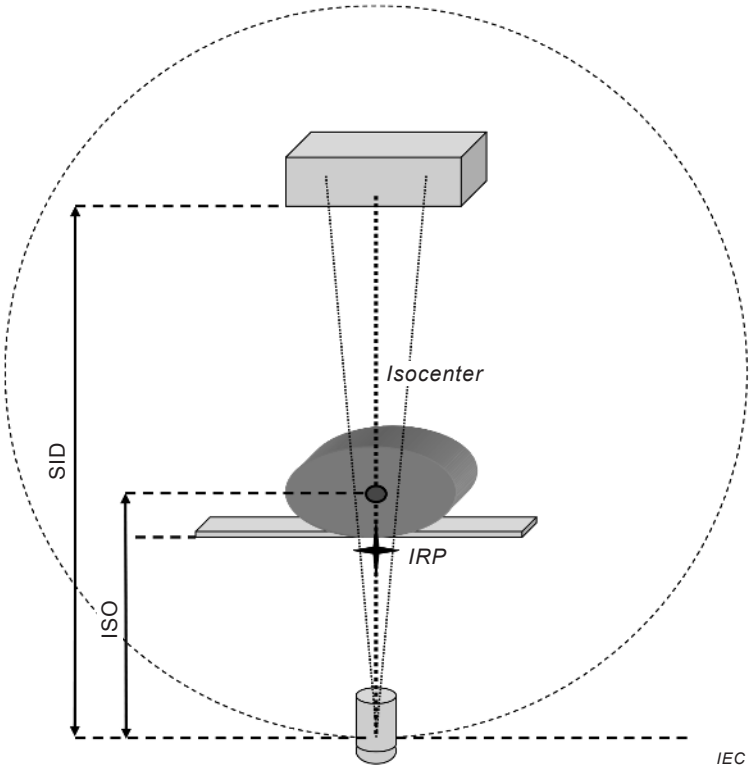


Figure E.6 – Position vectors defining the position of the PATIENT SUPPORT

E.4 Projection imaging geometries

Figure E.7, derived from DICOM PS 3.3 [1] (section C.8.19.6.9.1), illustrates the different distance-related DICOM attributes and their relationship when the X-RAY IMAGE RECEPTOR is in its normal position above the PATIENT SUPPORT. The distance source to isocenter (ISO) is the distance from the source (EFFECTIVE FOCAL SPOT) to the isocenter of the X-RAY EQUIPMENT with a C-arm. The Distance Source to Detector (SID) is the distance from the source to the entrance plane of the X-RAY IMAGE RECEPTOR and is equal to the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE defined in IEC 60601-1-3. The interventional reference point (IRP) is equal to the PATIENT ENTRANCE REFERENCE POINT defined in IEC 60601-1-3.



Key:

ISO: distance source to isocenter
SID: distance source to detector
IRP interventional reference point

Figure E.7 – Distance-related DICOM attributes for X-RAY EQUIPMENT with C-arm and PATIENT SUPPORT such as in X-ray angiography

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[1] DICOM PS 3:2013, *Digital Imaging and Communications in Medicine (DICOM). Published by National Electrical Manufacturers Association* (NEMA) [cited 2014-06-23]. Available at: <http://medical.nema.org/standard.html>

[2] IHE Radiology Technical Framework, Volume 1 (Revision 11.0 2012). *Integrating the Healthcare Enterprise (IHE),* [cited 2014-06-23]. *Available at:*http://www.ihe.net

[3] ICRP Publication 103:2007, *The 2007 Recommendations of the International Commission on Radiological Protection* – Annals of ICRP 37

Index of defined terms used in this particular standard

NOTE In the present document only terms defined either in IEC 60601-1:2005 + A1:2012, its collateral standards, IEC 60601-2-54:2009, IEC/TR 60788:2004 or in Clause 3 of this international standard were used. The definitions used in this international standard may be looked up at http://std.iec.ch/glossary.

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