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Part 1: Radiation dose structured reports for radiography and radioscopy

Please notify the secretary if you are aware of any keywords that might assist in classifying or identifying the standard or if the content of this standard

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Introduction

This draft standard is based on European discussions in which the UK took an active part. Your comments on this draft are welcome and will assist in the preparation of the consequent British Standard. Comment is particularly welcome on national legislative or similar deviations that may be necessary.

Even if this draft standard is not approved by the UK, if it receives the necessary support in Europe, the UK will be obliged to publish the official English Language text unchanged as a British Standard and to withdraw any conflicting standard.

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Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	(7)
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/ Table/Note	Type of comment	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



62B/906/CDV

COMMITTEE DRAFT FOR VOTE (CDV) PROJET DE COMITÉ POUR VOTE (CDV)

Project number Numéro de projet		IEC 61910-1 Ed. 1.0	
IEC/TC or SC: SC 62B CEI/CE ou SC:		Secretariat / Secrétariat Germany	
<input checked="" type="checkbox"/> Submitted for parallel voting in CENELEC <input type="checkbox"/> Soumis au vote parallèle au CENELEC	Date of circulation Date de diffusion 2013-03-22	Closing date for voting (Voting mandatory for P-members) Date de clôture du vote (Vote obligatoire pour les membres (P)) 2013-06-28	
Also of interest to the following committees Intéresse également les comités suivants SC 62C		Supersedes document Remplace le document 62B/882/CD & 62B/903/CC	
Proposed horizontal standard Norme horizontale suggérée <input type="checkbox"/> Other TC/SCs are requested to indicate their interest, if any, in this CDV to the TC/SC secretary Les autres CE/SC sont requis d'indiquer leur intérêt, si nécessaire, dans ce CDV à l'intention du secrétaire du CE/SC			
Functions concerned Fonctions concernées <input type="checkbox"/> Safety <input type="checkbox"/> EMC <input type="checkbox"/> Environment <input type="checkbox"/> Quality assurance Sécurité CEM Environnement Assurance qualité			

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

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

<p style="text-align: center;">ATTENTION VOTE PARALLÈLE CEI – CENELEC</p> <p>L'attention des Comités nationaux de la CEI, membres du CENELEC, est attirée sur le fait que ce projet de comité pour vote (CDV) de Norme internationale est soumis au vote parallèle. Les membres du CENELEC sont invités à voter via le système de vote en ligne du CENELEC</p>	<p style="text-align: center;">ATTENTION IEC – CENELEC PARALLEL VOTING</p> <p>The attention of IEC National Committees, members of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) for an International Standard is submitted for parallel voting. The CENELEC members are invited to vote through the CENELEC online voting system.</p>
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CONTENTS

INTRODUCTION	5
1 Scope	6
2 Normative references	6
3 Terms and definitions	7
4 Units and their DICOM storage formats	7
5 General requirements	8
5.1 * Conformance levels	8
5.1.1 Basic dose documentation	8
5.1.2 Extended dose documentation	9
5.2 Data flow	10
5.2.1 General	10
5.2.2 RDSR STREAMING TRANSMISSION	10
5.2.3 RDSR END OF PROCEDURE TRANSMISSION	11
Annex A (informative) General guidance and rationale	12
A.1 General guidance	12
A.2 Rationale for specific clauses and subclauses	12
Annex B (informative) Notes and explanations	15
B.1 DICOM Objects	15
B.2 IHE Profiles	16
B.3 The IHE Radiation Exposure Monitoring Profile	16
Annex C (informative) Glossary of DICOM Data Elements	18
Annex D (informative) Biological background	22
Annex E (informative) Coordinate Systems and their Applications	23
E.1 General	23
E.2 Equipment-specific Information	23
E.3 Patient location and orientation	24
E.4 Single procedure step patient dose estimates	24
E.5 Multiple procedure step patient dose estimates	25
E.6 Numeric and geometric expression of uncertainty	25
Annex F (informative) Drawings and Figures	26
F.1 Patient Positions	26
F.2 Positioner Primary and Secondary Angles	26
F.3 PATIENT SUPPORT Positions	29
F.4 Projection imaging geometries	29
Bibliography	31
Index of defined terms	32

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –**Radiation dose documentation - Part 1: Radiation dose structured reports for radiography and radioscopia**

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 the PAS 61910-1.

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

FDIS	Report on voting
62B/xxx/FDIS	62B/xxx/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 date¹ 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.

¹ The National Committees are requested to note that for this publication the stability date is 2018.

INTRODUCTION

Documentation of the amount of IONIZING RADIATION used during an 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.

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 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 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 into 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. 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 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 data-set 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 referenced documents are indispensable for the application of this International Standard. 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*
Amendment 1 (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 60601-2-43:2010, *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*

74 3 Terms and definitions

75 For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 + A1 (2012),
76 IEC 60601-1-3:2008, IEC 60601-2-43:2010, IEC 60601-2-54:2009, IEC TR 60788:2004 and the
77 following apply.

78 3.1

79 * IRRADIATION-EVENT

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

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

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

87 Note 3 to entry: Corresponding statement in the DICOM standard PS3.16-2011, Annex D: An IRRADIATION-EVENT is the
88 occurrence of radiation being applied to a patient in a single continuous time-frame between the start (release) and the stop
89 (cease) of the irradiation. Any on-off switching of the irradiation source during the event shall not be treated as separate events,
90 rather the event includes the time between start and stop of irradiation as triggered by the user. E.g., a pulsed fluoro X-Ray
91 acquisition shall be treated as a single IRRADIATION-EVENT.

92 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.

93 3.2

94 ACTOR

95 Information system or component of information system that produces, manages, or acts on categories
96 of information required by operational activities in the RESPONSIBLE ORGANIZATION.

97 [Source: IHE Radiology Technical Framework:2011, Volume 1, Section 1.6.1]

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

99 3.3

100 RADIATION DOSE STRUCTURED REPORT

101 RDSR

102 structured digital record of RADIATION dose delivered to a PATIENT during a RADIOLOGICAL procedure,
103 encoded as DICOM Dose Structured Report object.

104 3.4

105 * RDSR STREAMING TRANSMISSION

106 Process of sending the current partial RDSR after completion of each IRRADIATION-EVENT.

107 3.5

108 RDSR END OF PROCEDURE TRANSMISSION

109 Process of sending a final RDSR after completion or discontinuation of a RADIOLOGICAL procedure.

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

111 4 Units and their DICOM storage formats

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

114 5 General requirements

115 5.1 * Conformance levels

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

118 NOTE 1 Extended dose documentation is intended for X-RAY EQUIPMENT capable of producing cumulative REFERENCE AIR KERMA
119 exceeding 5 Gy during any single procedure within the scope of its INTENDED USE.

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

122 5.1.1 Basic dose documentation

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

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

- 127 • Dose (RP) Total
 - 128 • Dose Area Product Total
 - 129 • Distance Source to Reference Point
- 130 If the equipment is providing this information:

- 131 • Total Number of Radiographic Frames
- 132 If there was RADIOSCOPY:
- 133 • Total Fluoro Time

134

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

- 136 • Total Number of Radiographic Frames

137

138 In TID 10007 (Accumulated Integrated Projection Radiography Dose)

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

142

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

- 144 • Acquisition Protocol
- 145 • DateTime Started
- 146 • Irradiation Event Type

147

148 In the RDSR Header:

- 149 • Station Name
- 150 • Software Versions
- 151 • Date, Time for the Series

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

154 In the RDSR Header:

- 155 • Institution Name
- 156 • Patient Size
- 157 • Patient Weight
- 158 • Patient Name
- 159 • Patient ID
- 160 • Patient's Birth Date

- 161 • Performing Physician's Name
- 162 • Operators' Name
- 163 • Referenced Request Sequence (with Requested Procedure Description or Requested Procedure
- 164 Code Sequence)
- 165 • Performed Procedure Code Sequence

166

167 In TID 10002 (Accumulated X-Ray Dose):

- 168 • Calibration Factor(s)
- 169 • Calibration Date
- 170 • Calibration Responsible Party
- 171 • Calibration Protocol

172

173 NOTE 1 New software versions may infer modifications of hardware.

174 NOTE 2 Dose Measurement Device is an independent device with a traceable calibration.

175 NOTE 3 The Calibration Responsible Party element in the Calibration data contains the information about the party responsible
176 for the most recent calibration service.

177 NOTE 4 The RDSR contains the values displayed at the equipment, no Calibration Factor delivered in TID 10002 is applied.

178 **5.1.2 Extended dose documentation**179 The RDSR conforming to extended dose documentation shall comply with 5.1.1 and shall contain, in
180 addition, the following elements (Type 2 and 3):

181 In TID 10002 (Accumulated X-Ray Dose):

- 182 • Calibration Factor(s)
- 183 • Calibration Date
- 184 • Calibration Responsible Party
- 185 • Calibration Protocol

186

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

- 188 • Dose Related Distance Measurements ("Distance Source to Reference Point")
- 189 • Dose Related Distance Measurements ("Distance Source to Detector")
- 190 • if the equipment is Isocentric:
 - 191 ○ Dose Related Distance Measurements ("Distance Source to ISOCENTER")
- 192 • if the equipment has a PATIENT SUPPORT and means to determine one or more of the following:
 - 193 ○ Dose Related Distance Measurements ("Table Longitudinal Position")
 - 194 ○ Dose Related Distance Measurements ("Table Lateral Position")
 - 195 ○ Dose Related Distance Measurements ("Table Height Position")
 - 196 ○ Table Head Tilt Angle
 - 197 ○ Table Horizontal Rotation Angle
 - 198 ○ Table Cradle Tilt Angle
 - 199 ○ if the PATIENT SUPPORT moved during the IRRADIATION-EVENT:
 - 200 ▪ Dose Related Distance Measurements ("Table Longitudinal End Position")
 - 201 ▪ Dose Related Distance Measurements ("Table Lateral End Position")
 - 202 ▪ Dose Related Distance Measurements ("Table Height End Position")
- 203 • either Column Angulation or (Positioner Primary Angle and Positioner Secondary Angle)
- 204 • if the Positioner moved during the IRRADIATION-EVENT:
 - 205 ○ Positioner Primary End Angle
 - 206 ○ Positioner Secondary End Angle
- 207 • Patient Table Relationship
- 208 • Patient Orientation
- 209 • Patient Orientation Modifier
- 210 • Collimated Field Area

- 211 • Collimated Field Height
- 212 • Collimated Field Width
- 213 • Collimated Field Rotation
- 214 • X-Ray Filter Type
- 215 • X-Ray Filter Material
- 216 • X-Ray Filter Thickness Minimum
- 217 • X-Ray Filter Thickness Maximum
- 218 • KVP
- 219 • X-Ray Tube Current
- 220 • Pulse Width
- 221 • Focal Spot Size
- 222 • Number of Pulses
- 223 • Acquisition Plane
- 224 • Dose (RP)
- 225 • Dose Area Product
- 226 • Irradiation Duration

227
228 In TID 10004 (Accumulated Projection X-Ray Data):

- 229 • Total Number of Radiographic Frames

230 The RDSR conforming to extended dose documentation should contain, in addition, the following
231 elements (Type 2 and 3):

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

- 233 • if Pulsed Fluoroscopy is used:
 - 234 ○ Pulse Rate

235 The RDSR conforming to extended dose documentation may contain, in addition, the following elements
236 (Type 3):

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

- 238 • "Patient Equivalent Thickness" value on which Automatic Exposure Control AEC is based.

239

240 **5.2 Data flow**

241 **5.2.1 General**

242 A RDSR shall be created and exported for each RADIOLOGICAL procedure.

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

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

247 **5.2.2 RDSR STREAMING TRANSMISSION**

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

- 249 • The value of Completion Flag (0040,A491) DICOM attribute shall be "Partial".
- 250 • The IRRADIATION-EVENT X-Ray Data shall include all IRRADIATION-EVENTS in the current procedure
251 step, up to and including the IRRADIATION-EVENT that triggered this transmission.

- 252 • The “Scope of Accumulation” RDSR element shall be set to “Procedure Step To This Point”.

253 **5.2.3 RDSR END OF PROCEDURE TRANSMISSION**

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

- 256 • The value of Completion Flag (0040,A491) DICOM attribute shall be “Complete”.
- 257 • The IRRADIATION-EVENT X-Ray Data shall include all IRRADIATION-EVENTS in the current procedure
258 step.
- 259 • The “Scope of Accumulation” RDSR element shall be set to “Performed Procedure Step”.

260
261
262
263

Annex A (informative)

General guidance and rationale

A.1 General guidance

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

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

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

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

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

282 See Annex B for more details on DICOM Objects, IHE Profiles and the IHE REM Profile.

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

286 Information describing each of the IRRADIATION-EVENTS associated with a RADIOLOGICAL procedure may
287 be grouped together and encoded as a DICOM structured report dataset. This dataset plus an
288 appropriate header constitute a DICOM X-Ray Radiation Dose Structured Report object. Such a
289 DICOM Dose object is an example of a RADIATION DOSE STRUCTURED REPORT (RDSR).

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

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

A.2 Rationale for specific clauses and subclauses

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

298 Subclause 3.1 – IRRADIATION-EVENT

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

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

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

307 Subclause 3.4 - RDSR STREAMING TRANSMISSION

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

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

315 Subclause 5.1 – Conformance levels

316 The radiation risks to which patients are exposed are a function of radiation levels. Therefore, the data
317 needed from equipment corresponds to the radiation level associated with NORMAL USE of that X-RAY
318 EQUIPMENT.

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

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

322 The basic dose documentation conformance level is intended to supply:

- 323 – basic dose information;
- 324 – general patient and physician information;
- 325 – basic tools for quality management;
- 326 – educational information.

327 The extended dose documentation conformance level is intended to supply:

- 328 – dose information for managing potential tissue reactions;
- 329 – specific patient and procedure information;
- 330 – quality management;

331 – educational information.

Annex B (informative)

Notes and explanations

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336 **B.1 DICOM Objects**

337 The major part of the following description is a condensed copy quoted from DICOM Standard PS 3.1.

338 PS 3.3 of the DICOM Standard specifies a number of Information Object Classes which provide an
339 abstract definition of real-world entities applicable to communication of digital medical images and
340 related information (e.g., waveforms, structured reports, radiation dose structured reports, etc.). Each
341 Information Object Class definition consists of a description of its purpose and the Attributes which
342 define it. An Information Object Class does not include the values for the Attributes which comprise its
343 definition.

344 Two types of Information Object Classes are defined: normalized and composite.

345 Normalized Information Object Classes include only those Attributes inherent to the real-world entity.
346 For example the study Information Object Class, which is defined as normalized, contains study date
347 and study time Attributes because they are inherent in an actual study. Patient name, however, is not
348 an Attribute of the study Information Object Class because it is inherent to the patient on whom the
349 study was performed and not the study itself.

350 Composite Information Object Classes may additionally include Attributes which are related to but not
351 inherent to the real-world entity. For example, the Computed Tomography Image Information Object
352 Class, which is defined as composite, contains both Attributes which are inherent in the image (e.g.
353 image date) and Attributes which are related to but not inherent in the image (e.g. patient name).

354 Composite Information Object Classes provide a structured framework for expressing the
355 communication requirements of images where image data and related data needs to be closely
356 associated.

357 To simplify the Information Object Class definitions, the Attributes of each Information Object Class are
358 partitioned with similar Attributes being grouped together. These groupings of Attributes are specified as
359 independent modules and may be reused by other Composite Information Object Classes.

360 DICOM PS 3.3 defines a model of the Real World along with the corresponding Information Model that
361 is reflected in the Information Object Definitions. Future editions of the DICOM Standard may extend
362 this set of Information Objects to support new functionality.

363 To represent an occurrence of a real-world entity, an Information Object Instance is created, which
364 includes values for the Attributes of the Information Object Class. The Attribute values of this
365 Information Object Instance may change over time to accurately reflect the changing state of the entity
366 which it represents. This is accomplished by performing different basic operations upon the Information
367 Object Instance to render a specific set of services defined as a Service Class. These Service Classes
368 are defined in DICOM PS 3.4.

369 Sending RDSR involves the Storage Service Class. An RDSR is the real world instance of the X-Ray
370 Radiation Dose SR IOD encoded with the TID 10001 "Projection X-Ray Radiation Dose Report"
371 exported as file or sent over a DICOM network.

372 B.2 IHE Profiles

373 The major part of the following description is a condensed copy quoted from IHE Technical Framework
374 Part I.

375 Integrating the Healthcare Enterprise (IHE) is an initiative designed to stimulate the integration of the
376 information systems that support modern healthcare institutions. Its fundamental objective is to ensure
377 that in the care of patients all required information for medical decisions is both correct and available to
378 healthcare professionals. The IHE initiative is both a process and a forum for encouraging integration
379 efforts. It defines a technical framework for the implementation of established messaging standards to
380 achieve specific clinical goals. It includes a rigorous testing process for the implementation of this
381 framework. And it organizes educational sessions and exhibits at major meetings of medical
382 professionals to demonstrate the benefits of this framework and encourage its adoption by industry and
383 users.

384 The approach employed in the IHE initiative is not to define new integration standards, but rather to
385 support the use of existing standards, HL7, DICOM, IETF, and others, as appropriate in their respective
386 domains in an integrated manner, defining configuration choices when necessary. IHE maintains formal
387 relationships with several standards bodies including HL7, DICOM and refers recommendations to them
388 when clarifications or extensions to existing standards are necessary.

389 The IHE Technical Frameworks for the various domains (IT Infrastructure, Cardiology, Laboratory,
390 Radiology, etc.) defines specific implementations of established standards to achieve integration goals
391 that promote appropriate sharing of medical information to support optimal patient care. It is expanded
392 annually, after a period of public review, and maintained regularly through the identification and
393 correction of errata. The current version for these Technical Frameworks may be found at
394 http://www.ihe.net/Technical_Framework/

395 The IHE Technical Framework identifies a subset of the functional components of the healthcare
396 enterprise, called IHE Actors, and specifies their interactions in terms of a set of coordinated,
397 standards-based transactions. It describes this body of transactions in progressively greater depth.
398 Volume 1 provides a high-level view of IHE functionality, showing the transactions organized into
399 functional units called Integration Profiles that highlight their capacity to address specific clinical needs.
400 The subsequent volumes provide detailed technical descriptions of each IHE transaction.

401 B.3 The IHE Radiation Exposure Monitoring Profile

402 This Integration Profile specifies how details of radiation exposure resulting from imaging procedures
403 are exchanged among the imaging systems, local dose information management systems and cross-
404 institutional systems such as dose registries. The data flow in the profile is intended to facilitate
405 recording individual procedure step dose information, collecting dose data related to specific patients,
406 and performing population analysis.

407 Use of the relevant DICOM objects (CT Dose SR, Projection X-Ray Dose SR) is clarified and
408 constrained.

409 The Profile focuses on conveying the details of individual irradiation events. A proper radiation
410 exposure management program at an imaging facility would involve a medical physicist and define such
411 things as local policies, local reporting requirements, annual reviews, etc. Although this Profile is
412 intended to facilitate such activities, it does not define such policies, reports or processing, or in itself
413 constitute a radiation exposure management program.

- 414 The Profile addresses dose reporting for imaging procedures performed on CT and projection X-ray
415 systems, including mammography. It does not currently address procedures such as nuclear medicine
416 (PET or SPECT), radiotherapy, or implanted seeds.
- 417 Typically, irradiation events occur on X-ray based imaging modalities, which record them in Dose
418 objects that are part of the same study as the images and stored to the Image Manager/Archive.
- 419 In many organizations, a Dose Information Reporter will collect Dose objects covering a particular
420 period (e.g., today, this week or last month), analyze them, compare to site policy and generate
421 summary reports.
- 422 All, or a sampled subset of the Dose objects might be submitted to a National Registry to facilitate
423 composing population statistics and other research. Such Dose objects will generally undergo a
424 configurable de-identification process prior to submission.
- 425 By profiling automated methods of distribution, dose information can be collected and evaluated without
426 imposing a significant administrative burden on staff otherwise occupied with caring for patients.
- 427 MANUFACTURERS are encouraged to describe in their DICOM Conformance Statement additional details
428 of how they implement specific DICOM-based transactions (e.g., the time frame in which an Acquisition
429 Modality is able to store a Dose object relative to the completion of the irradiation event).
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Annex C (informative)

Glossary of DICOM Data Elements

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

DICOM Attribute or Concept Name	DICOM Tag or Template	Notes
Patient 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.
Station Name	(0008,1010)	User defined name identifying the machine that produced the composite instances. NOTE Typically this is the X-RAY EQUIPMENT that creates the RDSR.
Software Versions	(0018,1020)	Manufacturer's designation of software version of the equipment that produced the composite instances.
Series Date	(0008,0021)	Date the Series started.
Series Time	(0008,0031)	Time the Series started.
Performing Physician's Name	(0008,1050)	Name of the physician(s) administering the Series.
Operators' Name	(0008,1070)	Name(s) of the operator(s) supporting the Series
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 Method	TID 10002	Describes the method used to derive a calibration factor.
Calibration Setup	TID 10002	Describes the setup of the calibration equipment and the equipment calibrated while determining a calibration factor.
Calibration Conditions	TID 10002	Describes conditions existing and to be observed while determining a 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.
Acquisition Protocol	TID 10003	A type of clinical acquisition protocol for creating images or 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 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. IEC: Corresponds to FOCAL SPOT TO IMAGE RECEPTOR DISTANCE.
Distance Source to Isocenter	TIS 10003	Distance from the X-Ray source to the Equipment C-arm Isocenter (Center of rotation). 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. Table motion towards LAO is positive assuming that the patient is positioned supine and its head is in normal position.
Table Lateral Position	TID 10003	Table Lateral Position with respect to an arbitrary chosen reference by the equipment. Table motion towards CRA is positive assuming that the patient is positioned supine and its head is in normal position.
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.
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.
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.
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	TID 10003	Positioner Secondary Angle at the end of an irradiation event.

Angle		For further definition see "Positioner Secondary Angle".
Patient Table Relationship	TID 10003	Orientation of the Patient with respect to the Head of the Table.
Patient Orientation	TID 10003	Orientation of the Patient with respect to Gravity.
Patient Orientation Modifier	TID 10003	Enhances or modifies the Patient orientation specified in Patient Orientation
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 "fluoro" corresponds to RADIOSCOPY.
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 (e.g. "Water Value") used to parameterize the Automatic Exposure Control (AEC) closed loop.
Collimated Field Height	TID 10003	Distance of the "A Blades" in the collimated field plane.
Collimated Field Width	TID 10003	Distance of the "B Blades" in the collimated field plane.
Collimated Field Rotation	TID 10003	Rotation of the collimated field with respect to the patient's foot to head axis. Positive angle is CCW.
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 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

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Annex D **(informative)**

Biological background

442 Medical uses of ionizing radiation have associated risks. These risks can be reduced by minimizing the
443 use of radiation for diagnostic purposes or for the visual guidance of therapeutic interventions. However,
444 the quality of an X-ray image will decrease if too little radiation is used to create it. The lack of sufficient
445 radiation for the intended purpose is almost always immediately visible to a radiologist. In the era of
446 digital images, the use of too much radiation is much less apparent. Documenting radiation usage is of
447 increasing importance in this environment.

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

449 Stochastic injuries occur when a radiation event damages the DNA in a single cell beyond its ability to
450 repair itself. Depending on the type of cell, this causes cellular death, genetic mutation, or malignant
451 transformation. There is a very small chance that this will occur after any single RADIOLOGICAL procedure.
452 However, the dose-response model used by the International Commission on Radiation Protection
453 (ICRP) predicts that a number of events will occur in an irradiated population. Dose documentation of all
454 procedure steps provides the information needed to assess this risk as well as information that can be
455 used to manage radiation usage for particular examinations in individual institutions.

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

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Annex E (informative)

Coordinate Systems and their Applications

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466 E.1 General

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

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

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

478 The information contained in this Annex may be considered by the Maintenance Teams for the
479 international standards IEC 60601-2-43:2010 and 606601-2-54:2009.

480 E.2 Equipment-specific Information

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

- 482 a) a reference point on the X-RAY EQUIPMENT that is always in a defineable location relative to room
483 coordinates.
- 484 b) the spatial and angular coordinates of the EFFECTIVE FOCAL SPOT and the vector of the central ray of
485 the X-RAY BEAM relative to the X-RAY EQUIPMENT reference point for at least one position and
486 orientation of the X-RAY BEAM.
- 487 c) sufficient information to define the position of the dose reference point for each IRRADIATION-EVENT in
488 absolute room coordinates. X-RAY EQUIPMENT specific constant values are combined with
489 IRRADIATION-EVENT relative translation and rotation values to achieve this objective.

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

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

- 494 a) a reference point on the PATIENT SUPPORT that is always in a defineable location relative to room
495 coordinates.
- 496 b) the plane of the top of the PATIENT SUPPORT. A representative plane is used if the PATIENT SUPPORT is
497 not planar.
- 498 c) the spatial and angular coordinates plane of the PATIENT SUPPORT and the visible PATIENT SUPPORT
499 reference point relative to the PATIENT SUPPORT reference point for at least one orientation of the
500 PATIENT SUPPORT.

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

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

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

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

514 **E.3 Patient location and orientation**

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

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

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

523 **E.4 Single procedure step patient dose estimates**

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

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

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

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

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

541 E.5 Multiple procedure step patient dose estimates

542 Patients often undergo multiple procedure steps. These are often performed using different pieces of X-
543 RAY EQUIPMENT and may be performed in different facilities. A clinical goal of collecting RDSRs is to be
544 able to assemble single procedure step dose estimates into a multiple procedure step cumulative dose
545 estimate.

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

549 E.6 Numeric and geometric expression of uncertainty

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

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

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

560

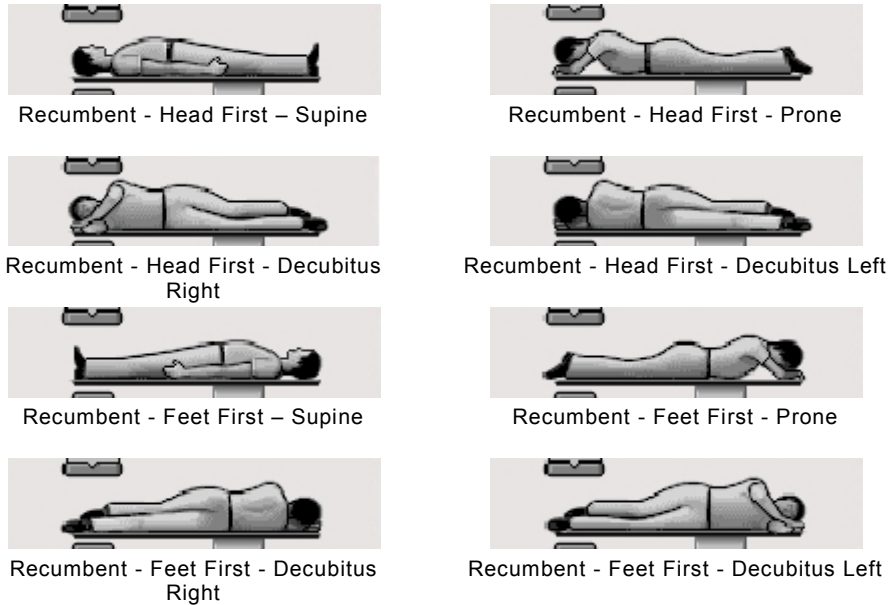
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Annex F (informative)

Drawings and Figures

565 F.1 Patient Positions

566 The following figure is from DICOM PS 3.17 and shows the Position relative to the PATIENT SUPPORT.

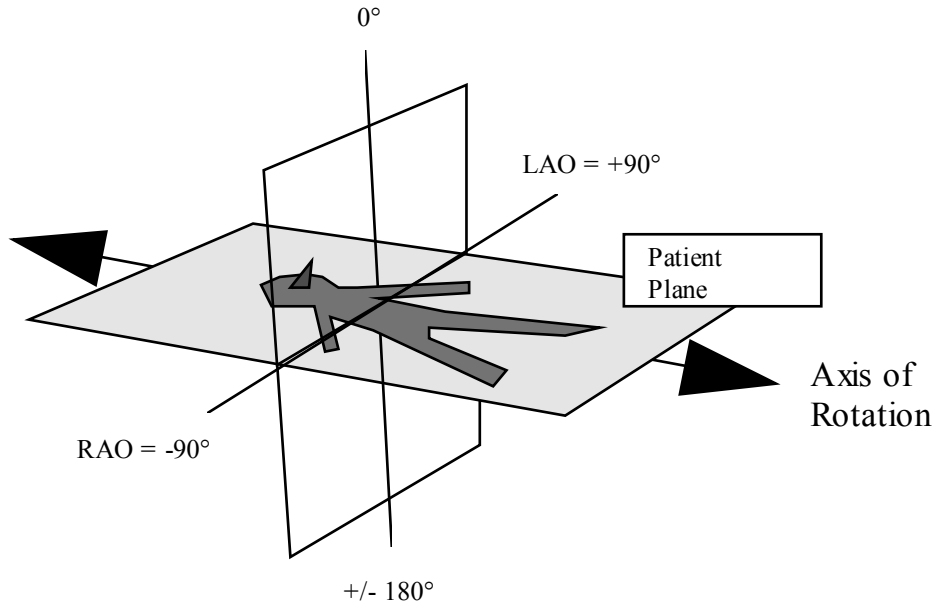


567 Figure 1 - The Figure illustrates these defined terms for X-RAY EQUIPMENT with a PATIENT SUPPORT, such
568 as in X-Ray Angiography. The orientation of the PATIENT related to gravity is always recumbent.

569 F.2 Positioner Primary and Secondary Angles

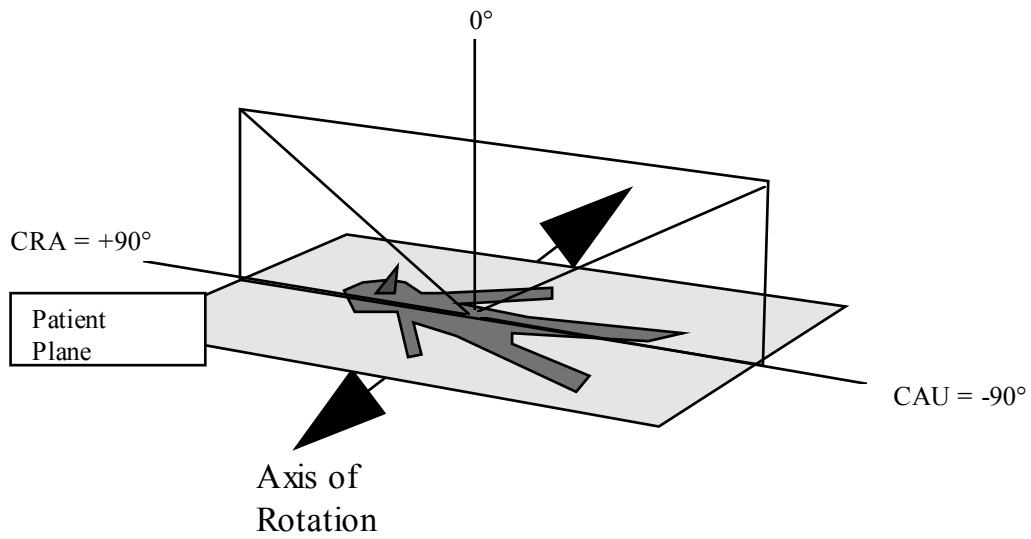
570 The following figure is from DICOM PS 3.3.

571 At a 0 degree angle for both the Positioner Primary Angle and the Positioner Secondary Angle, the
572 PATIENT faces the X-RAY IMAGE RECEPTOR.



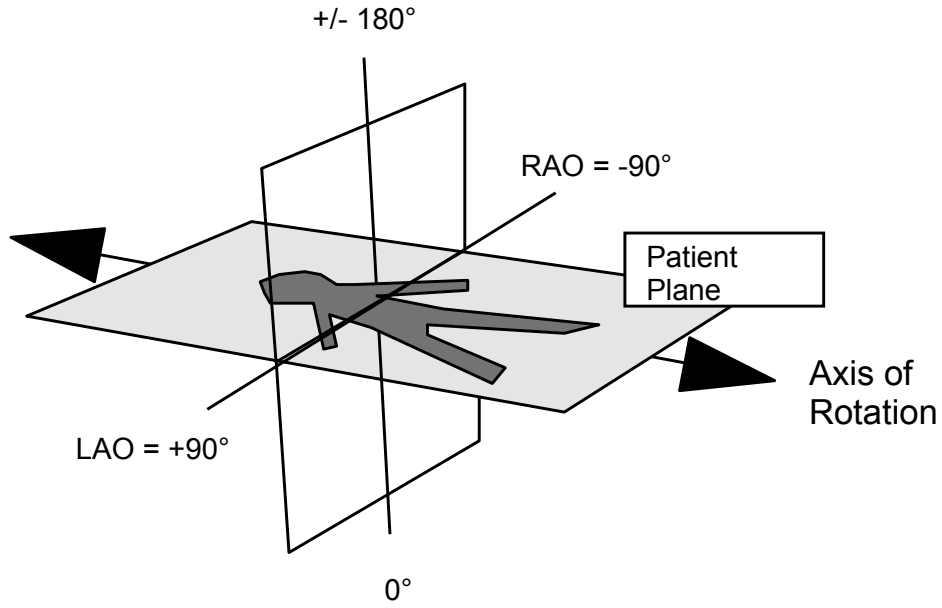
573

574 Figure 2 - Illustration for Positioner Primary Angle with "Recumbent - Head First - Supine" Patient
575 Position..



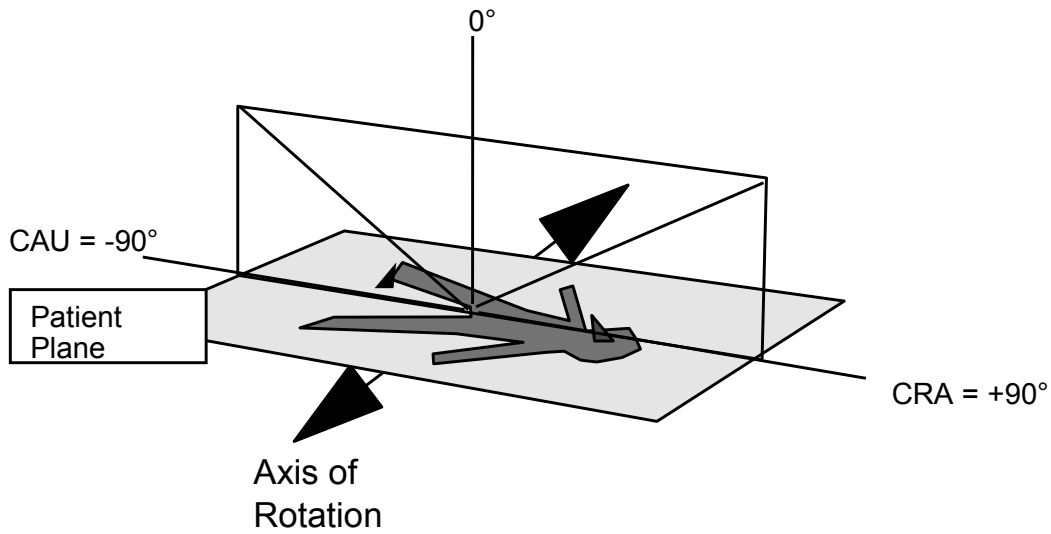
576

577 Figure 3 - Illustration for Positioner Secondary Angle with "Recumbent - Head First - Supine" Patient
578 Position.



579

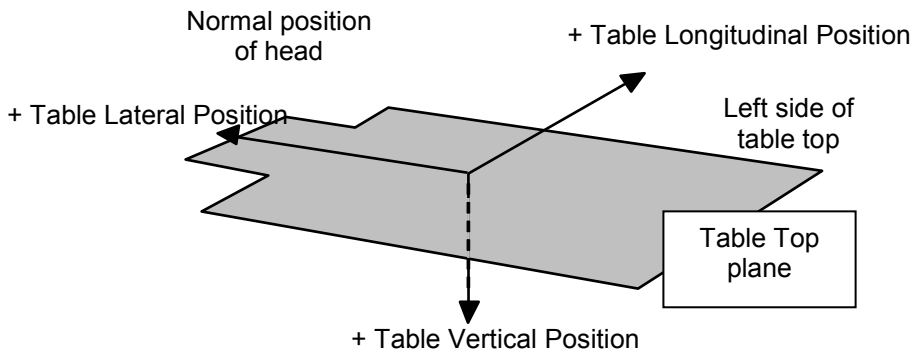
580 Figure 4 - Illustration for Positioner Primary Angle with "Recumbent - Head First - Prone" Patient
581 Position..



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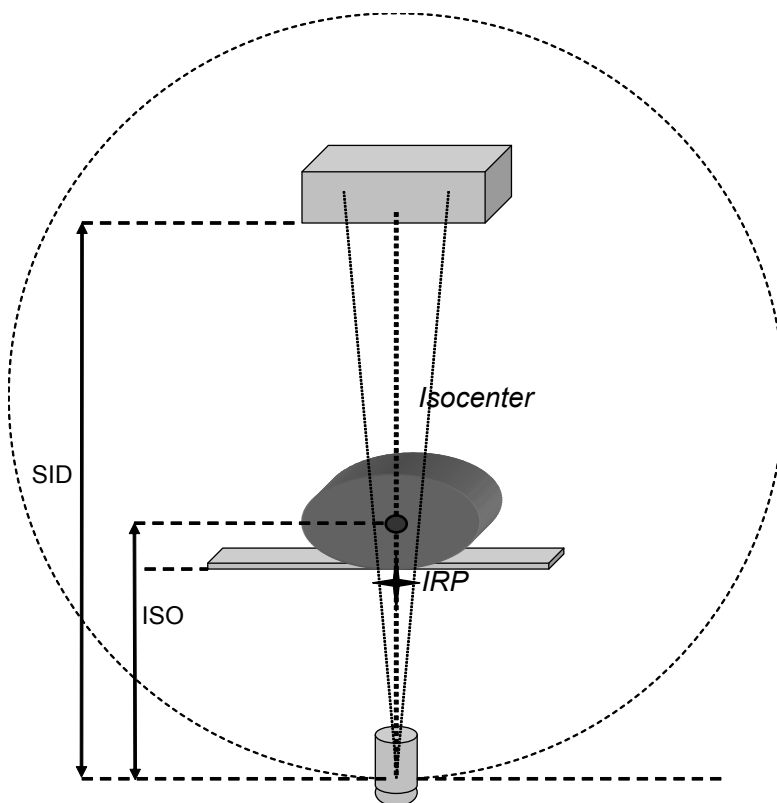
583 Figure 5 - Illustration for Positioner Secondary Angle with "Recumbent - Feet First - Supine" Patient
584 Position.

585

586 **F.3 PATIENT SUPPORT Positions**

587

588 Figure 6 - The following figure is from DICOM PS 3.3 and shows the PATIENT SUPPORT position vectors.

589 **F.4 Projection imaging geometries**

590

591 Figure 7 - The following figure is derived from DICOM PS 3.3 and illustrates the different distance-
592 related attributes and their relationship in normal position of the X-RAY IMAGE RECEPTOR.

593 The following definitions apply:

594	ISO :	Distance Source to Isocenter
595	SID :	Distance Source to Detector
596	IRP	Interventional Reference Point

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598

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600

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602 [2] DICOM PS 3:2011, *Digital Imaging and Communications in Medicine. Published*
603 *by National Electrical Manufacturers Association (NEMA)* [viewed 2012-11-23].
604 <<http://dicom.nema.org>> including Correction proposals 1077, 1223 and ??
605 (Expected to be published 2013)

606 [3] *IHE Radiology Technical Framework 2011. Integrating the Healthcare Enterprise (IHE)*, (c) 2011
607 [viewed 2012-11-23]. <<http://www.ihe.net>>

608

Index of defined terms used in this particular standard

609

610 NOTE 1 In the present document only terms defined either in this international standad, IEC 60601-1:2005, its collateral
611 standards, in IEC/TR 60788:2004 or in Clause 3 of this particular standard were used.

612	ACCOMPANYING DOCUMENTS	IEC 60601-1:2005, 3.4
613	ACTOR.....	3.2
614	AIR KERMA	IEC 60601-1-3:2008, 3.4
615	DOSE AREA PRODUCT.....	IEC 60601-2-54:2009, 201.3.203
616	EFFECTIVE FOCAL SPOT.....	IEC 60788:2004, 3.105
617	FOCAL SPOT TO IMAGE RECEPTOR DISTANCE	IEC 60601-1-3:2008, 3.25
618	IMAGE RECEPTION AREA	IEC 60601-1-3:2008, 3.28
619	INTENDED USE.....	IEC 60601-1:2005, 3.44
620	IONIZING RADIATION	IEC 60601-1-3:2008, 3.29
621	IRRADIATION	IEC 60601-1-3:2008, 3.30
622	IRRADIATION SWITCH.....	IEC 60601-1-3:2008, 3.31
623	IRRADIATION-EVENT	3.1
624	LOADING	IEC 60601-1-3:2008, 3.34
625	LOADING TIME	IEC 60601-1-3:2008, 3.37
626	MANUFACTURER	IEC 60601-1:2005, 3.55
627	NORMAL USE	IEC 60601-1:2005, 3.71
628	OPERATOR.....	IEC 60601-1:2005, 3.73
629	PATIENT	IEC 60601-1:2005, 3.76
630	PATIENT ENTRANCE REFERENCE POINT	IEC 60601-1-3:2008, 3.43
631	PATIENT SUPPORT	IEC 60788:2004, 3.239
632	RADIATION	IEC 60601-1-3:2008, 3.53
633	RADIATION DOSE STRUCTURED REPORT (RDSR)	3.3
634	RADIOGRAPHY	IEC 60601-1-3:2008, 3.64
635	RADIOLOGICAL	IEC 60601-1-3:2008, 3.65
636	RADIOLOGICAL IMAGE.....	IEC 60601-1-3:2008, 3.66
637	RADIOSCOPY	IEC 60601-1-3:2008, 3.69
638	RDSR END OF PROCEDURE TRANSMISSION	3.5
639	RDSR STREAMING TRANSMISSION	3.4
640	REFERENCE AIR KERMA	IEC 60601-1-3:2008, 3.70
641	RESPONSIBLE ORGANIZATION.....	IEC 60601-1:2005, 3.101
642	X-RAY EQUIPMENT	IEC 60601-1-3:2008, 3.78
643	X-RAY BEAM.....	IEC 60601-1-3:2008, 3.55
644	X-RAY IMAGE RECEPTOR.....	IEC 60601-1-3:2008, 3.81
645	X-RAY TUBE CURRENT	IEC 60601-1-3:2008, 3.85
646	X-RAY TUBE VOLTAGE	IEC 60601-1-3:2008, 3.88

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