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Pre-Standard

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Medical electrical equipment – Radiation dose documentation –

Part 1: Equipment for radiography and radioscopy

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CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT – RADIATION DOSE DOCUMENTATION –

Part 1: Equipment for radiography and radioscopy

FOREWORD

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IEC-PAS 61910-1 has been prepared by maintenance team 38 of IEC subcommittee 62B of IEC technical committee 62: Electrical equipment in medical practice.

The text of this PAS is based on the following document:	This PAS was approved for publication by the P-members of the committee concerned as indicated in the following document

Draft PAS	Report on voting
62B/645/PAS	62B/653/RVN

Following publication of this PAS, which is a pre-standard publication, the technical committee or subcommittee concerned will transform it into an International Standard. Its structure will then be adapted to the IEC rules.

This PAS shall remain valid for an initial maximum period of three years starting from 2007-07. The validity may be extended for a single three-year period, following which it shall be revised to become another type of normative document or shall be withdrawn.

In this publicly available specification, 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: in smaller type. Normative text of tables is also in a smaller type.

– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PAS OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, the term

– "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

– "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this PAS are preceded by the term "Clause" followed by the clause number. References to subclauses within this collateral standard are by number only.

In this document, 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 document conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this PAS, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this PAS;

– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this PAS;

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

Clauses, subclauses and definitions for which a rationale is provided in informative Annex A are marked with an asterisk (*).

INTRODUCTION

Documentation of the amount of radiation used during an imaging 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 deterministic injuries.

The transition of imaging from film to stored digital images opened the possibility of automatically recording dose and other data with the images. The DICOM structure traditionally provides some relevant facilities for doing this in image headers. This system 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 data was stored if the images were not stored.

Improving dose documentation was addressed jointly by the International Electrotechnical Commission (IEC) and the DICOM Committee. The supplement 94 to the DICOM standard was approved in 2005. This supplement provides the technical format needed to store the entire description of the dose used to perform a single imaging procedure. The companion IEC publicly available specification defines the relevant radiation quantities and establishes equipment compliance levels. These represent a combination of increasing patient risk and an increasing interest in quality assurance. Compliance level one is intended for equipment that produces dose levels below significant deterministic thresholds for all intended uses. Compliance level two is intended for equipment used for procedures that could cause significant deterministic injuries. Compliance level three, while not described in this document, will eventually contain specifications for advanced dose modelling on individual patients.

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 PACS system, in a medical informatics system, in a freestanding dose management workstation, or in the imaging equipment itself. The data structure permits the transfer of entire studies at once or the streaming of individual irradiations.

At present, the scope of DICOM DOSE is limited to aspects of projection radiography and radioscopy. Expansion of DICOM DOSE to all X-ray imaging modalities is planned.

MEDICAL ELECTRICAL EQUIPMENT – RADIATION DOSE DOCUMENTATION –

Part 1: Equipment for radiography and radioscopy

1 Scope, object and related standards

1.1 Scope

This Publicly Available Specification (PAS) applies to MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS, hereafter referred to as ME EQUIPMENT and ME SYSTEMS.

The scope of this document encompasses all forms of projection radiographic equipment incorporating means for measuring or calculating dose related quantities and capable of producing DICOM compatible images and/or reports.

This document provides specific units and quantities. It does not apply for:

– dental radiography and radioscopy;

– mammography;

– computed tomography.

NOTE A system that uses a film-screen image receptor may conform to this PAS if it can produce reports confirming to a level of this document.

The intent is to develop and publish similar documents for all X-ray imaging modalities capable of producing DICOM compatible images and/or reports.

Parallel documents are currently under development for mammography and computed tomography.

This document defines data storage formats. It does not put specific requirements on the accuracy of the data.

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

This document does not present any requirements on the form of display of such information to operators or other individuals.

1.2 Object

The object of this PAS, and associated DICOM standard, is to provide a standard public data structure intended for recording dosimetric and related information associated with the production of projection radiographic and radioscopic images.

NOTE The data fields and reporting structure are intended to facilitate the collection of dosimetric data useful for; management of procedures requiring significant dose, facility quality programs, establishment of reference levels, teaching, and similar purposes.

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 PAS. 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 60601-2-43:2000, *Medical electrical equipment – Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures*

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

Digital Imaging and Communications in Medicine (DICOM)

IHE Technical Framework, Volume I, Integration Profiles, Revision 7.0 - Final Text, May 15, 2006

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC TR 60788, the DICOM standard, and the following terms and definitions apply.

NOTE The term "electrical equipment" is used to mean ME EQUIPMENT or other electrical equipment. This document also uses the term "equipment" to mean ME EQUIPMENT or other electrical or non-electrical equipment in the context of an ME SYSTEM.

The Radiation Dose Structured Report (RDSR) is an essential part of this document. Its formal definition appears in the DICOM standard. Please see Clause B.2 for further discussions.

An index of defined terms is found at the end of this document.

3.1
IRRADIATION-EVENT

LOADING of equipment caused by a single continuous actuation of the equipment's irradiation control device

NOTE 1 An IRRADIATION-EVENT might produce a single image (e.g. chest-radiograph), a defined series of images (e.g. DSA acquisition), or an indefinite series of images (e.g. radioscopy).

NOTE 2 The images resulting from an IRRADIATION-EVENT may or may not be stored in the imaging device or in an image archive.

NOTE 3 Corresponding statement in the DICOM standard: An IRRADIATION-EVENT is the occurrence of radiation being applied to a patient in 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.

3.2
DOSE AREA PRODUCT

DAP

product of the area of the cross-section of an X-RAY BEAM and the averaged AIR KERMA over that cross-section

[IEC 60601-2-43:2000, definition 2.105]

NOTE 1 The unit is the Gray square metre (Gym^2).

NOTE 2 DOSE AREA PRODUCT is measured under low scatter conditions.

NOTE 3 If the X-ray beam can be oriented such that it does not always pass through the PATIENT SUPPORT (including ACCESSORIES) before entering the PATIENT, then DOSE AREA PRODUCT is measured without the beam passing through the PATIENT SUPPORT (and ACCESSORIES).

3.3
AIR KERMA

K

quotient of dE_{tr} by dm, where dE_{tr} is the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles in air of mass dm

[IEC 60731:1997: definition 3.27]

NOTE 1 The unit of AIR KERMA is Gy (where 1 Gy = 1 J · kg-1), (see C.6 of ICRU 33).

NOTE 2 AIR KERMA is measured under low scatter conditions.

NOTE 3 If the X-ray beam can be oriented such that it does not always pass through the patient support (including accessories) before entering the patient, then AIR KERMA is measured without the beam passing through the patient support (and accessories).

3.4
ESTIMATED MAXIMUM ENTRANCE SKIN AIR KERMA
maximum AIR KERMA (excluding scatter) delivered to any point on the patient's skin during a single procedure

NOTE This is a potentially calculated value. The location of this point is highly dependent on many factors including the patient's size, location relative to the gantry, and procedural details.

3.5
ACTOR
information systems or components of information systems that produce, manage, or act on information associated with operational activities in the enterprise

[IHE Technical Framework:2006, 1.6.1]

4 Units and their DICOM storage formats

All quantities not specifically defined in this section shall use the units given in the DICOM standard.

The numerical values of all quantities shall be stored in a format such that storage uncertainty introduces less than 0,5 % total additional uncertainty in to the statement of value.

5 General requirements

5.1 DICOM elements and conformance levels

An equipment claiming a level of conformance with this document shall generate and export a Radiation Dose Structured Report (RDSR) for each examination (study) containing at least the DICOM elements listed in Annex C for that conformance level.

Equipment providing radiography only may not supply information for radioscopy elements.

Equipment providing radioscopy only may not supply information for radiography elements.

Equipment may conform to a higher level than that indicated by the maximum estimated entrance skin AIR KERMA for normal use.

NOTE The Radiation Dose Structured Report (RDSR) is defined in the DICOM standard. Conformance with a higher level provides information that can be of use for public health purposes. Conforming to the highest level for which an equipment has the necessary measurement means is suggested. Level 2 conformance is recommended for dedicated paediatric equipment.

Conformance with a higher level shall include conformance with all lower levels.

Equipment with different modes of operation conforming to different levels should report RDSRs for all procedures at the highest level claimed for the equipment.

5.1.1 Level 0 limited conformance

Equipment not conforming to a higher level but capable of generating a RDSR with some information.

DICOM elements that are stored are defined by the MANUFACTURER.

NOTE 1 Most of the equipment within the scope of this PAS is expected to conform to class 1 or class 2.

NOTE 2 Level 0 is intended to provide a structural method for reporting any available data from simple or special purpose equipment using the DICOM-DOSE framework. An example is a simple radiographic machine used with a third-party digital detector. The detector associated with such a system might only be able to report the AIR KERMA at the detector used to form the image.

DICOM elements that are unique to level 0 may not be stored by equipment conforming to a higher level.

5.1.2 Level 1 limited dose monitoring

Equipment where the ESTIMATED MAXIMUM ENTRANCE SKIN AIR KERMA for any examination (study) is expected to be less than two gray (Gy) for all normal uses.

The defining dose is the cumulative dose for a complete examination at the interventional reference point defined in IEC 60601-2-43 (for equipment capable of measuring AIR KERMA at this point

or

the equipment manufacturers estimate of the cumulative dose for a complete examination at the closest point to the X-ray source where the patient's skin might be placed.

NOTE The defining dose resets the maximum AIR KERMA delivered to the patient's skin (measured under low scatter conditions). The safe assumption is made that the entire procedure is performed with one beam/patient orientation. The purpose is to supply:

– Basic dose information
– General patient and physician information
– Basic tools for quality management
– Teaching information

5.1.3 Level 2 general dose monitoring

Equipment where the ESTIMATED MAXIMUM ENTRANCE SKIN AIR KERMA for any examination (study) may exceed two Gray (Gy) for any normal use.

The defining dose is the cumulative dose for a complete examination at the interventional reference point defined in IEC 60601-2-43:2000 (for equipment capable of measuring AIR KERMA at this point)

or

the equipment manufacturers estimate of the cumulative dose for a complete examination at the closest point to the X-ray source where the patient's skin might be placed.

NOTE The defining dose resets the maximum AIR KERMA delivered to the patient's skin (measured under low scatter conditions). The safe assumption is made that the entire procedure is performed with one beam/patient orientation.

The purpose is to supply:

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

5.1.4 Level 3 RESERVED

NOTE This level will be used to define compliance for equipment recommended for use in performing procedures where the cumulative dose at the interventional reference point is likely to exceed 5 Gy for any single procedure. Major fluoroscopically guided interventional equipment is an example.

5.2 Data flow

5.2.1 General

Data flow describing an IRRADIATION-EVENT between imaging equipment and a compatible ACTOR may occur either after each IRRADIATION-EVENT or at the end of an examination. An ACTOR is meant in its IHE sense.

5.2.2 IRRADIATION-EVENT by IRRADIATION-EVENT transmission

After each IRRADIATION-EVENT, the imaging equipment shall send a full RSDR to the ACTOR.

The completion Flag (0040,A491) shall be set to “Partial”.

The header(s) shall be complete and contain summary data updated to include the results of the most current irradiation.

The body of the RDSR shall include each set of IRRADIATION-EVENT entries.

When an examination is marked as complete, or a new PATIENT is registered on the imaging equipment, a final RDSR shall be sent with the completion Flag (0040,A491) set to “Complete”.

NOTE 1 The IRRADIATION-EVENT by IRRADIATION-EVENT work-flow enables near-real time dose analysis and feedback to the operator.

NOTE 2 Sending a RSDR with an updated header and a list of all the IRRADIATION-EVENT data after each IRRADIATION-EVENT will assure that the ACTOR receives the most complete available data on a particular procedure. It is assumed that the ACTOR will discard earlier partial reports when it receives a later partial report or a complete report.

NOTE 3 Sending a RDSR flagged as complete at the end of the examination maximizes data integrity. It is presumed that each partial RSDR is discarded when the “complete” or next “partial RDSR is received.

NOTE 4 An ACTOR is allowed to append value-added computations to the RDSR.

5.2.3 End of procedure transmission

When an examination is marked as complete, or a new patient is registered on the imaging equipment, a single RDSR shall be sent to the ACTOR with the completion tag (0400,A491) set to “Complete”.

5.2.4 Storage of RDSRs in the imaging equipment

The imaging equipment shall store a minimum of 500 RDSRs internally and independent of storage of the associated images.

RSDRs shall be internally stored in the equipment as long as the associated images are stored internally in the equipment.

Facilities shall be provided to locally transfer RDSRs to compatible storage media without the aid of special tools.

Provisions shall be made to optionally de-identify RSDRs when they are transferred.

NOTE 1 Storing RDSRs in the equipment will facilitate their retrieval in those situations where data connections are not available (such as digital imaging equipment with only hard-copy output.) This will also provide backup if there are difficulties with a connected informatics structure.

NOTE 2 Compatible digital transfer media include (but are not limited to) CD-R, DVD-R, and memory stick.

NOTE 3 It is recommended that the equipment be able to store at least one week’s worth of studies.

NOTE 4 The transfer of RDSRs from the equipment to the storage media is regarded as a normal operator function of the equipment.

NOTE 5 Examples of transfer media include: Floppy Disks, CD/DVD, and USB based memory devices.

NOTE 6 Both identified and deidentified transfers are important. Identified RDSRs are medical records. Appropriately deidentified RDSRs are useful for public health, research, teaching, and other purposes.

5.3 Data to be recorded and stored

All of the data elements corresponding to a conformance level claimed for the equipment shall be stored in the RDSR.

All of the data elements corresponding to all lower conformance levels shall be stored in the RDSR.

NOTE 1 Equipment claiming level 2 conformance is expected to store all of the data elements required for both level 1 and level 2.

Other data elements described in the DICOM standard, compatible with the capabilities of the equipment, may be recorded and stored.

The format and range of relevant units are specified in the DICOM standard.

Data elements specified in this PAS shall not be stored in private fields.

Data elements stored both in the RDSR and in the header of an associated DICOM image shall be identical.

NOTE 2 This requirement is expected to avoid data mismatches between these locations.

All recorded and stored data elements in the RDSR and corresponding fields of an associated DICOM Image Object Header shall be public fields conforming to the DICOM standard.

NOTE 3 The fields that will be populated by any given imaging system should include, at a minimum, all dosimetric data required by the local regulatory authorities.

NOTE 4 It is recognized that regulatory requirements may change over time. It is presumed that the equipment will be reconfigured as required to retain compliance.

NOTE 5 Different fields may be required in different localities. A manufacturer may elect Level 0 conformance as a means of reporting only regulatory required information.

NOTE 6 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. The original RDSR should maintain links to the associated stored images.

A particular piece of equipment producing a particular type of examination should always generate and export RDSRs with the same elements.

NOTE 7 The exported data is in the special RDSR format (not MPPS). The DICOM standard permits defines "actors" as software objects capable of accepting and managing RDSRs in an informatics, PACS, or stand-alone environment. An ACTOR resident on a stand-alone system is envisioned as either receiving complete RDDRs for stand-alone dose recording or individual IRRADIATION-EVENTs in near real-time. The latter function could enable real-time dose mapping.

NOTE 8 As a minimum all similar examinations produced on the same piece of equipment should provide the same dose data in the RDSR. Wherever possible, the same data elements should be produced for the same examination for all examinations of the same type in a facility, geographic region, or world-wide.

5.4 Data to be displayed by the equipment

This document does not impose any mandatory requirements for data display by the equipment.

The RSDR may be displayed on the equipment.

NOTE Specific requirements may be specified in other standards.

Annex A
(informative)

General guidance and rationale

A.1 General guidance

The standards for improved dose reporting were jointly developed by IEC SC 62B/ MT 38 and DICOM (Committees 2 and 6). This project, and its proposed extensions, is called DICOM DOSE. This document is the IEC portion of this project.

In this document, the concept of a digital imaging system is constrained to X-RAY EQUIPMENT capable of transmitting one or more of the images produced by that system to an external receiver in DICOM format. This document is limited to DICOM objects that can be generated by a single (digital) imaging system as the result of a single patient study (examination).

Image production involves irradiating the PATIENT. A single irradiation (called an IRRADIATION-EVENT) may produce a single image or a series of images (e.g. chest radiograph, kidney DSA run, cardiac radiography, GI radioscopy). These images may or may not be archived.

Technical information is usually available (in the imaging system) for each IRRADIATION-EVENT. This information may include system configuration and settings, imaging geometry, electrical values, dosimetric information, and other data. This information can be collected into an 'irradiation object'. It is customary to place some elements of the IRRADIATION-EVENT into the DICOM image object header when images are stored (an image object may contain of a single frame or a series of frames (multi frame)).

Information describing each of the IRRADIATION-EVENTs associated with a study (examination) may be grouped into a structured report. This collected information plus an appropriate header constitutes a "Radiation Dose Structured Report" (RDSR).

Supplement 94 to the DICOM standard provides the technical framework needed to implement DICOM DOSE. The DICOM standard was partially based the parallel development of this document.

Working drafts prepared by IEC SC 62B/MT 38 defined the data fields found in irradiation objects and IRRADIATION-EVENTs. All of these elements are 'public fields' in the DICOM sense. Imaging equipment complying with this document is only required to provide data for only those fields for which it is equipped. The accuracy of the reported data is outside the scope of this document. Existing standards or regulations may have applicable requirements for accuracy and precision.

Supplement 94 states that an "irradiation object "be stored for each IRRADIATION-EVENT, irrespective of the storage of the images produced by that irradiation. The irradiation objects, along with other information, are stored in a 'Radiation Dose Structured Report'. In addition, information from the IRRADIATION-EVENT is stored in the DICOM header of stored images from that irradiation. The detailed format for storing the set of IRRADIATION-EVENTs is specified by the DICOM committee.

This IEC PAS provides the framework for implementing DICOM DOSE in compliant X-ray imaging systems. Four compliance levels are defined in this document. These represent a combination of increasing patient risk and an increasing interest in quality assurance. A system claiming compliance with a level must provide information in at least all of the relevant specified fields.

A.2 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclause in this document, with clause and subclause numbers parallel to those in the body of the document.

Subclause 1.1 – Scope

The scope of DICOM DOSE was limited to aspects of projection radiography and radioscopy so that working standards could be completed in a reasonable period of time. Expansion of DICOM DOSE to all digital X-ray imaging modalities is planned. The present documents are expected to provide the framework for such expansions.

Subclause 1.2 – Objective

The object of the DICOM DOSE project is to provide means for clearly reporting dose and dose related quantities.

Definition 3.1 – IRRADIATION-EVENT

This term is introduced to break a study (examination) into a series of elements small enough to permit dose analysis and reconstruction. Many IRRADIATION-EVENTS, such as RADIOSCOPY, that occur during an examination 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 examination.

The discussion of an IRRADIATION-EVENT stated in the DICOM standard is:

"An IRRADIATION-EVENT is the occurrence of radiation being applied to a patient in single continuous time-frame between the start (release) and the stop (cease) of the irradiation. The IRRADIATION-EVENT is the "smallest" information entity to be recorded in the realm of Radiation Dose reporting. Individual IRRADIATION-EVENTS are described by a set of accompanying physical parameters that are sufficient to understand the "quality" of irradiation that is being applied. This set of parameters may be different for the various types of equipment that are able to create IRRADIATION-EVENTS. 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.

Each release of irradiation will create an IRRADIATION-EVENT that includes dose related values. In order to understand the nature of these values a sufficient amount of "additional data" to describe the physical context of the irradiation exposure has to be recorded along with the dose values. An event resulting in creation of a DICOM Image SOP Instance must include the reference to it. There are definitely IRRADIATION-EVENTs that will not result in any image storage but will create dose relevant data stored in the Radiation Dose Reporting Object."

Subclause 4.1 – Conformance levels

The radiation risks to which patients are exposed are a function of radiation levels. These in turn are related to the normal use of the equipment. Therefore, the data needed for each conformance level increases as risk increases.

Level 3 is planned to record the information needed for detailed skin dose evaluation of individual patients. No commercially available implementation is currently available. However several implementations are under development by manufacturers and by the user community. Standards are therefore inappropriate at this time.

Annex B
(informative)

Notes and explanations

B.1 RADIATION DOSE STRUCTURED REPORT

NOTE This annex is informative in this document because it has a formal normative definition within the DICOM standard.

The RADIATION DOSE STRUCTURED REPORT (RDSR) is comprised of a header containing general and summary data and a series of elements describing each IRRADIATION-EVENT.

IRRADIATION-EVENT data is stored in the RDSR, and included in the summary even if the images produced by that irradiation are not stored.

B.2 Preliminary definition of Level 3 advanced dose monitoring equipment where the expected maximum skin dose for any examination (study) may exceed seven gray (Gy) for any normal use

Cumulative doses at the IEC interventional reference point exceeding 7 Gy are occasionally seen in complex interventional procedures performed by highly skilled operators. The intention of level 3 is to supply information needed by operators in balancing risk-benefit for individual patients.

In the United States, the Joint Commission on Accreditation of Health Care Organizations established 15 Gy maximum skin dose as a sentinel event (comparable to the accidental leaving of a foreign body inside a patient). The 7 Gy specification in this document provides an adequate safety margin.

Development in this area is presently too rapid to impose standards.

Level 3 will eventually provide additional information for documenting procedures and managing potential tissue reactions. Major interventional equipment should be at this level when the state-of-the-art permits.

B.3 External data management

Systems compliant with the DICOM standard send Radiation Dose Structured Reports to ACTORS residing on the information network. These ACTORS are software entities that may reside on image management elements (e.g. PACS); information management elements (e.g. RIS, MIS); or on free-standing devices.

RDSR's generated by systems compliant with this PAS include all of the data elements required for the claimed level of compliance plus additional public data fields defined in the DICOM standard.

The systems that host the ACTORS may produce value-added processing such as computing skin dose maps by analyzing the data contained in the RDSR. The DICOM standard allows the addition of such added value elements to the RDSR.

Annex C
(normative)

Levels of compliance

C.1 Common header elements (for all levels of compliance)

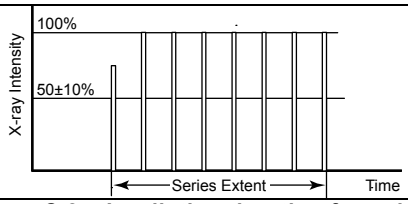
Organization of the following tables		
Item	Field content	DICOM TAG if available
	Comments and notes	

Level 1 RDSR (Common header elements)		
NOTE RADIOGRAPHY only systems do not need to supply specific data for radioscopic elements. RADIOSCOPY only systems do not need to supply specific data for radiographic elements.		
Template identifier (of RDSR Root Container)	10001 (“X-Ray Radiation Dose Report”)	**(0040,DB00)**
	Fixed field	
Completion Flag	“Partial” or “Complete”	(0040,A491)
	Facilitates separation of these two classes of reports	
Patient Name	Per DICOM	(0010,0010)
	Removable	
Patient ID	Per DICOM	(0010,0020)
	Removable	
Patient’s Birth date	Per DICOM	(0010,0030)
	Removable	
Patient’s Size	Per DICOM	(0010,1020)
	Patient's height	
Patient’s Weight	Per DICOM	(0010,1030)
Procedure Type	Per DICOM	(0040,0254)
	Performed Procedure Step Description	
Procedure Date	Per DICOM	(0040,0244)
	Performed Procedure Step Start Date	
Procedure Time	Per DICOM	(0040,0245)
	Performed Procedure Step Start Time	
Facility ID	Per DICOM	(0008,0080)
	Institution Name	

Manufacturer	Per DICOM	(0008,0070)
	Manufacturer	
Model	Per DICOM	(0008,1090)
	Manufacturer's Model Name	
Serial	Per DICOM	(0018,1000)
	Device Serial Number	

C.2 Level 1 limited dose monitoring

Level 1 RDSR (plane header elements) Separate set of plane header elements for each plane		
Plane AIR KERMA Area product Total	The total DAP delivered during a complete study. It is equal to the sum of the radioscopy and acquisition total DAPs	
	Current DICOM terminology calls this "DOSE AREA PRODUCT" Required if equipment has this capability.	
Plane Dose (RP) Total	The total AIR KERMA delivered to a defined reference point during a complete study. It is equal to the sum of the doses for all IRRADIATION-EVENTS that comprise the complete study.	
	Required if equipment has this capability.	
Calibration Date	Date for the most recent calibration service of the dose-measuring equipment.	Within the RDSR Container
	DATE mm/yyyy	
Correction Factor	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.	Within the RDSR Container
	Current DICOM terminology calls this "Calibration Factor"	
"Calibration Uncertainty"	The percentage uncertainty of the displayed (recorded) dose value. This describes variation around the average value caused by variation in irradiation conditions.	Within the RDSR Container
	Expressed as the range containing the true value. The range may be asymmetrical.	
"Calibration Responsible Organization"	Text containing the name of the responsible institution or service company for the most recent calibration service.	Within the RDSR Container
	Not the name of an individual	

Level 1 RDSR (IRRADIATION-EVENT elements)		
All items are part of the RDSR IRRADIATION-EVENT container; some also have the indicated tags when used in image headers.		
Irradiation Plane	Per DICOM	(0008,0008) Image Type (4th value)
	The imaging plane producing this irradiation	
IRRADIATION-EVENT Type	RADIOGRAPHY or RADIOSCOPY	NA
	The IRRADIATION-EVENT type is determined prior to the irradiation.	
Irradiation Protocol	Per DICOM	(0008,1030)
	Protocol Name	
Irradiation Kerma Area Product	The DAP delivered during this single IRRADIATION-EVENT	(0018,115E)
	Required if equipment has this capability.	
Irradiation Dose	The AIR KERMA delivered to the reference point during this single IRRADIATION-EVENT	Refer to 60601-2-43
	Required if equipment has this capability.	
Number of Images	Number of Frames	(0028,0008)
	The total number of radiographic or radioscopic frames produced during this IRRADIATION-EVENT. Required except for continuous RADIOSCOPY.	
IRRADIATION TIME	DICOM: The time interval between the first time the X-ray intensity exceeds approximately 50% of maximum and the last time the X-ray intensity exceeds approximately 50% of maximum during a single irradiation (see drawing)	NA
	Required for continuous or pulsed radioscopy Please refer to the figures for an operational definition.	
		
Figure C.1 – Irradiation duration for continuous irradiation, defined from the time that the irradiation intensity is above the average peak value		**Figure C.2 – Irradiation duration for pulsed irradiation, defined as the time between the first upward and last downward crossing of 50% of the average peak value**
"Stored Image"	SOP Instance UID	(0008,0018)
	Only if images are stored	

C.3 Level 2 general dose monitoring

Level 2 RDSR (Additional Plane Header Elements) Separate set of plane header elements for each plane		
NOTE RADIOGRAPHY only systems do not need to supply specific data for radioscopic elements. RADIOSCOPY only systems do not need to supply specific data for radiographic elements.		
RADIOSCOPY: AIR KERMA Area product Total	The total DAP for the complete study delivered by the identified plane during the radioscopy portion of the study.	(0018,115E)
	Includes contribution to DAP from all radioscopy IRRADIATION-EVENTS	
Radiography: AIR KERMA Area product Total	The total DAP for the complete study delivered by the identified plane during the radiography portion of the study.	(0018,115E)
	Includes contribution to KAP from all radiography IRRADIATION-EVENTS	
RADIOSCOPY: AIR KERMA (RP) Total	The total AIR KERMA for the complete study delivered by the identified plane during the radioscopy portion of the study.	Refer to 60601-2-43 for the location of the reference point
	Includes contribution to dose from all radioscopy IRRADIATION-EVENTS	
RADIOGRAPHY: AIR KERMA (RP) Total	The total AIR KERMA for the complete study delivered by the identified plane during the radiography portion of the study.	Refer to 60601-2-43 for the location of the reference point
	Includes contribution to dose from all radiography IRRADIATION-EVENTS	
Total number of radiographic frames	The total number of frames acquired during complete study by all radiographic IRRADIATION-EVENTS. Delivered by the identified plane.	(0028,0008)
Total radioscopy time	The sum of radioscopic times during complete study by all radioscopic IRRADIATION-EVENTS. Delivered by the identified plane.	NA
Distance Source to ISOCENTER	The distance from the focal spot of the X-ray tube to the isocenter of an isocentric system.	Required for isocentric systems.
	The unit of the distance is mm.	
Distance Source to Reference Point	The distance from the focal spot of the X-ray tube to the dose reference point (RP).	The definition of the reference point is found in 60601-2-43
	The unit of the distance is mm.	

Level 2 RDSR (Additional IRRADIATION-EVENT elements) One entry for each IRRADIATION-EVENT		
Distance "Source to Detector"	Per DICOM	(0018,1110)
	The unit of the distance is mm.	
Distance Source to Patient Support	Distance along the central ray from the source to the intersection of the central ray and the portion of the patient support closest to the patient. NOTE In X-Ray Angiography, the value "Distance Source to Table Plane" shall be used to indicate the "Distance Source to Patient Support". In other modalities that do not have an integrated table as patient support, the value "Distance Source to Detector" shall be used.	
NEW FIELD	Adding this field (if at all possible) was strongly recommended by almost all FDA and AAPM members who reviewed the previous draft. The entry surface of the image receptor is the default patient support if there is no other explicit patient support. This definition is equally applicable if the beam passes through the patient support first or if it passes through the patient first.	
"Positioner Primary Angle" (stationary or starting)		(0018,1510)
"Positioner Secondary Angle" (stationary or starting)		(0018,1511)
"Positioner Primary End Angle"	When the positioner moves during an irradiation, this field reports the primary angle at the end of the irradiation.	NA
"Positioner Secondary End Angle"	When the positioner moves during an irradiation, this field reports the secondary angle at the end of the irradiation.	NA
Patient Position	Per DICOM	(0018,5100)
	Required for irradiations where the positioner angles are specified relative to the patient. Example: Head-first, prone.	
Patient Orientation		(0020,0020)
	Required for all other irradiations.	

Collimated Field Area	Per DICOM	(0018,1147) Field of View Shape (0018,1149) Field of View Dimension(s)
"X-Ray Filter Type"	Per DICOM	(0018,1161)
	Describes the composition and thickness of any removable filters in position for this irradiation. NOTE There will be more details in the RDSR than in image header.	
"KVP"	Per DICOM	(0018,0060)
	According to current reporting practice if a series is recorded.	
"X-Ray Tube Current"	Per DICOM	(0018,1151)
	According to current reporting practice if a series is recorded.	
"Pulse Width"	Nominal Pulse Width	(0018,1154)
	According to current practice if a series is recorded.	
"Pulse Rate"	Number of individual radioscopic images produced per second during this irradiation. Not applicable for continuous radioscopy.	NA
Focal Spot Size”	Nominal IEC Size	(0018,1190)
“Radioscopy Mode”	Radiation Mode	(0018,115A)
	Pulsed or continuous	