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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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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT – RADIATION DOSE DOCUMENTATION –

Part 1: Equipment for radiography and radioscopy

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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A PAS is a technical specification not fulfilling the requirements for a standard, but made available to the public.

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.