BS EN IEC 61223-3-8:2024

BSI Standards Publication

Evaluation and routine testing in medical imaging departments

Part 3-8: Acceptance and constancy tests — Imaging performance of X-ray equipment for radiography and radioscopy

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National foreword

This British Standard is the UK implementation of EN IEC 61223-3-8:2024. It is identical to IEC 61223-3-8:2024.

The UK participation in its preparation was entrusted to Technical Committee CH/62/2, Diagnostic imaging equipment.

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EUROPÄISCHE NORM

EN IEC 61223-3-8

May 2024

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Evaluation and routine testing in medical imaging departments - Part 3-8: Acceptance and constancy tests - Imaging performance of X-ray equipment for radiography and radioscopy (IEC 61223-3-8:2024)

Essais d'évaluation et de routine dans les services d'imagerie médicale - Partie 3-8: Essais d'acceptation et de constance - Performance d'imagerie des appareils à rayonnement X pour la radiographie et la radioscopie (IEC 61223-3-8:2024)

Bewertung und routinemäßige Prüfung in Abteilungen für medizinische Bildgebung - Teil 3-8: Abnahme- und Konstanzprüfungen - Leistungsmerkmale zur Bildgebung von Röntgeneinrichtungen für Radiographie und Radioskopie (IEC 61223-3-8:2024)

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European foreword

The text of document 62B/1347/FDIS, future edition 1 of IEC 61223-3-8, prepared by SC 62B "Diagnostic imaging equipment" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 61223-3-8:2024.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2025-01-30
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IEC 60627:2013	NOTE	Approved as EN 60627:2015 (not modified)
IEC 61223-3-6:2020	NOTE	Approved as EN IEC 61223-3-6:2020 (not modified)
IEC 62220-1-1:2015	NOTE	Approved as EN 62220-1-1:2015 (not modified)
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IEC 62563-1:2009/A1:2016	NOTE	Approved as EN 62563-1:2010/A1:2016 (not modified)
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IEC 62563-2:2021	NOTE	Approved as EN IEC 62563-2:2021 (not modified)

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Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cencenelec.eu.

Publication	Year	Title	EN/HD	Year
IEC 60336	2020	Medical electrical equipment - X-ray tube assemblies for medical diagnosis - Focal spot dimensions and related characteristics	EN IEC 60336	2021
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
-	-		+ corrigendum Mar.	2010
+ A1	2012		+ A1	2013
-	-		+ A12	2014
+ A2	2020		+ A2	2021
-	-		+ A13	2024
IEC 60601-1-3	2008	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment	EN 60601-1-3	2008
-	-		+ corrigendum Mar.	2010
+ A1	2013		+ A1	2013
-	-		+ AC	2014
-	-		+ A11	2016
+ A2	2021		+ A2	2021
IEC 60601-2-43	2022	Medical electrical equipment - Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures	EN IEC 60601-2-43	2023
IEC 60601-2-54	2022	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy	-	-

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IEC 61267	2005	Medical diagnostic X-ray equipment - Radiation conditions for use in the determination of characteristics	EN 61267	2006
IEC 61674	2012	Medical electrical equipment - Dosimeters with ionization chambers and/or semiconductor detectors as used in X-ray diagnostic imaging	EN 61674	2013
IEC 61676	2023	Medical electrical equipment - Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology	EN IEC 61676	2023
IEC 62494-1	2008	Medical electrical equipment - Exposure index of digital X-ray imaging systems - Part 1: Definitions and requirements for general radiography	EN 62494-1	2008

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EVALUATION AND ROUTINE TESTING IN MEDICAL IMAGING DEPARTMENTS –

Part 3-8: Acceptance and constancy tests – Imaging performance of X-ray equipment for radiography and radioscopy

FOREWORD

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

Draft	Report on voting
62B/1347/FDIS	62B/1351/RVD

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

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The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

In this document, the following print types are used:

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– *test specifications: in italic type.*
– TERMS USED THROUGHOUT THIS DOCUMENT THAT HAVE BEEN LISTED IN THE INDEX OF DEFINED TERMS AND DEFINED IN CLAUSE 3, OR IN OTHER STANDARDS: IN SMALL CAPITALS.

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

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A list of all parts of the IEC 61223 series, published under the general title *Evaluation and routine testing in medical imaging departments,* can be found on the IEC website.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn, or
- revised.

NOTE The attention of the users of this document is drawn to the fact that equipment MANUFACTURERS and testing organizations might need a transitional period following publication of a new, amended or revised IEC publication in order to develop contractual specifications in accordance with the new test procedures and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

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INTRODUCTION

The IEC 61223 series gives methods for ACCEPTANCE TESTS and CONSTANCY TESTS for diagnostic X-RAY EQUIPMENT.

IEC 60601-2-54:2022 and IEC 60601-2-43:2022 state that the MANUFACTURER provides ACCOMPANYING DOCUMENTS with instructions for MANUFACTURER-recommended QUALITY CONTROL PROCEDURES and tests to be performed on the X-RAY EQUIPMENT by the RESPONSIBLE ORGANIZATION. In this document, these instructions are referred to as a QUALITY CONTROL manual.

This part of IEC 61223 provides guidance on the content to be considered for inclusion in the QUALITY CONTROL manual for X-RAY EQUIPMENT for RADIOGRAPHY and RADIOSCOPY, including INTERVENTIONAL X-RAY EQUIPMENT. The QUALITY CONTROL manual is intended to be used independently by the RESPONSIBLE ORGANIZATION to ensure safe and effective equipment performance during its EXPECTED SERVICE LIFE, without the need to consult IEC standards.

This document provides parameters to be evaluated, examples of test methods, recommended minimum frequencies of evaluation and tools intended to be used by the RESPONSIBLE ORGANIZATION on installed X-RAY EQUIPMENT within the scope of this document. For the parameters applicable to the specific X-RAY EQUIPMENT to be tested, specific acceptance criteria are supplied by MANUFACTURERS, which can be superseded with contractual criteria with the RESPONSIBLE ORGANIZATION and further superseded with locally applicable regulatory criteria.

A major purpose of this document is that of facilitating technical communication between stakeholders in the areas of ACCEPTANCE and CONSTANCY TESTING. The three major stakeholders responsible for assuring the safety and efficacy of X-RAY EQUIPMENT are the MANUFACTURER, the RESPONSIBLE ORGANIZATION and the regulatory authorities.

Generally, equipment installed in accordance with the MANUFACTURER'S QUALITY CONTROL PROCESS will comply with applicable IEC standards as well as meeting both local regulatory requirements and the MANUFACTURER'S general specifications and contractual specifications by the RESPONSIBLE ORGANIZATION.

The performance of installed equipment that is tested is assessed by the RESPONSIBLE ORGANIZATION and regulators using a wide variety of PROCESSES and tools. Acceptability criteria and PROCESSES can differ from those of equipment MANUFACTURERS.

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EVALUATION AND ROUTINE TESTING IN MEDICAL IMAGING DEPARTMENTS –

Part 3-8: Acceptance and constancy tests – Imaging performance of X-ray equipment for radiography and radioscopy

1 Scope and object

This part of IEC 61223 applies to evaluation of the imaging performance and related QUALITY CONTROL parameters of X-RAY EQUIPMENT for RADIOGRAPHY and RADIOSCOPY that conform to IEC 60601-2-54:2022 or IEC 60601-2-43:2022.

NOTE Cone-beam CT is a MODE OF OPERATION in INTERVENTIONAL X-RAY EQUIPMENT. This document discusses such MODE OF OPERATION in the informative Annex F.

This document applies to the evaluation of the imaging performance of the entire imaging chain from image acquisition, image processing and image display.

This document applies to ACCEPTANCE TESTS and CONSTANCY TESTS, which are part of the QUALITY ASSURANCE PROGRAM in medical imaging departments and are intended to be performed by or under the responsibility of the RESPONSIBLE ORGANIZATION. A detailed discussion of the position of these tests within the medical radiological equipment lifecycle is provided in Clause A.2. The methods included rely mainly on non-invasive measurements that use appropriate test equipment and are performed after the installation is completed in accordance with the MANUFACTURER'S installation instructions.

IEC 60601-2-54:2022 and IEC 60601-2-43:2022 require information to be provided to the RESPONSIBLE ORGANIZATION with respect to QUALITY CONTROL. This document provides guidance to MANUFACTURERS regarding the ACCEPTANCE and CONSTANCY TESTS for the X-RAY EQUIPMENT in a MANUFACTURER supplied QUALITY CONTROL manual. Annex G provides guidance for such a manual.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60336:2020, *Medical electrical equipment – X-ray tube assemblies for medical diagnosis – Focal spot dimensions and related characteristics*

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

IEC 60601-1-3:2008, *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral standard: Radiation protection in diagnostic X-ray equipment*
IEC 60601-1-3:2008/AMD1:2013
IEC 60601-1-3:2008/AMD2:2021

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IEC 60601-2-43:2022, *Medical electrical equipment – Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures*

IEC 60601-2-54:2022, *Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy*

IEC 61267:2005, *Medical diagnostic X-ray equipment – Radiation conditions for use in the determination of characteristics*

IEC 61674:2012, *Medical electrical equipment – Dosimeters with ionization chambers and/or semi-conductor detectors as used in X-ray diagnostic imaging*

IEC 61676:2023, *Medical electrical equipment – Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology*

IEC 62494-1:2008, *Medical electrical equipment – Exposure index of digital X-ray imaging systems – Part 1: Definitions and requirements for general radiography*

3 Terms, definitions, symbols and abbreviated terms

3.1 Terms and definitions

For the purposes of this document, the terms and definitions in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020, IEC 60601-1-3:2008, IEC 60601-1-3:2008/AMD1:2013, IEC 60601-1-3:2008/AMD2:2021, IEC 60601-2-54:2022, IEC 60601-2-43:2022 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- IEC Electropedia: available at https://www.electropedia.org/
- IEC Glossary; available at http://std.iec.ch/glossary
- ISO Online browsing platform: available at https://www.iso.org/obp

3.1.1
ACCEPTANCE TEST
ACCEPTANCE TESTING
test carried out after new equipment has been installed, or major modifications have been made to existing equipment, in order to verify compliance with specifications

Note 1 to entry: The specifications could include contractual specifications, requirements enforced by legislation, the MANUFACTURER's specifications or requirements from standards, for example in the IEC 60601 series.

[SOURCE: IEC 61223-1:1993, 3.2.4, modified – Words "contractual specifications" replaced with "specifications" and Note 1 to entry added.]

3.1.2
ACTUAL FOCAL SPOT
area on the surface of the anode that intercepts the beam of accelerated particles

[SOURCE: IEC 60336:2020, 3.1, modified – Word "target" replaced with "anode" and Note 1 to entry removed.]

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3.1.3
ANTI-SCATTER GRID
device to be placed before the IMAGE RECEPTION AREA in order to reduce the incidence of SCATTERED RADIATION upon that area and thus increase the contrast in the X-RAY PATTERN

[SOURCE: IEC 60627:2013, 3.1.1]

3.1.4
ARTEFACT
apparent structure visible in the image, which does not represent a structure within the object and which cannot be explained by noise or the MODULATION TRANSFER FUNCTION of the system

[SOURCE: IEC 61223-3-3:1996, 3.3.1, modified – Term "artifact" changed to "ARTEFACT".]

3.1.5
ASSOCIATED EQUIPMENT
ME EQUIPMENT, in a RADIOLOGICAL INSTALLATION, other than those for the production and control of IONIZING RADIATION, but essential for its application

[SOURCE: IEC TR 60788:2004, rm-30-01, modified – Word "equipment" replaced with "ME EQUIPMENT" and definition rephrased.]

3.1.6
BASELINE VALUE
reference value of functional parameter, which is either:

– the value obtained for this parameter in the initial CONSTANCY TEST immediately following an ACCEPTANCE TEST, or
– where described in a corresponding particular standard, the mean value of values obtained in a series of initial CONSTANCY TESTS, immediately following an ACCEPTANCE TEST

Note 1 to entry: The CONSTANCY TEST method can be different from the ACCEPTANCE TEST method. In case the methods are the same, the value obtained in the ACCEPTANCE TEST can be used.

[SOURCE: IEC 61223-3-6:2020, 3.1.5, modified – Term "status test" replaced with "ACCEPTANCE TEST" and Note 1 to entry added.]

3.1.7
CONSTANCY TEST
CONSTANCY TESTING
each of a series of tests, carried out following ACCEPTANCE TESTING, to ensure that the functional performance of the equipment continues to meet ESTABLISHED CRITERIA

Note 1 to entry: For each CONSTANCY TEST, the ACCEPTANCE TEST method or an alternative test method can be used.

3.1.8
DIGITAL DRIVING LEVEL
DDL
digital value given as input to an IMAGE DISPLAY SYSTEM producing a LUMINANCE

[SOURCE: IEC 62563-1:2009, 3.1.7]

3.1.9
DIGITAL SUBTRACTION ANGIOGRAPHY
DSA
SUBTRACTION IMAGING to visualize vessels using RADIOGRAPHY or SERIAL RADIOGRAPHY

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3.1.10
DIGITAL X-RAY IMAGING DEVICE
device consisting of a digital X-ray detector including the protective layers installed for use in practice, the amplifying and digitizing electronics, and a computer providing the original data of the image

Note 1 to entry: A DIGITAL X-RAY IMAGING DEVICE can include protecting parts, such as ANTI-SCATTER GRIDS and components for AUTOMATIC EXPOSURE CONTROL.

[SOURCE: IEC 62220-1-1:2015, 3.6]

3.1.11
DOSIMETER
equipment which uses IONIZATION CHAMBERS and/or semiconductor detectors for the measurement of AIR KERMA, AIR KERMA length product and/or AIR KERMA RATE in the beam of an X-RAY EQUIPMENT used for medical radiological procedures

Note 1 to entry: A DOSIMETER contains the following components:

- one or more detector assemblies which can or cannot be an integral part of the measuring assembly; and/or
- a measuring assembly.

[SOURCE: IEC 61674:2012, 3.1, modified – Word "diagnostic" deleted twice from the definition and third item of Note 1 to entry deleted.]

3.1.12
DYNAMIC RANGE
range between the highest and lowest value of the thickness of a specified material, which can be differentiated by an X-RAY IMAGE RECEPTOR and displayed artefact-free on an IMAGE DISPLAY DEVICE

3.1.13
ENTRANCE PLANE
plane, for an X-RAY IMAGE RECEPTOR, perpendicular to its axis of symmetry and grazing the part which protrudes most in the direction of the FOCAL SPOT of the X-RAY TUBE

[SOURCE: IEC TR 60788:2004, rm-32-42, modified – Words "electro-optical X-ray image intensifier" changed to "X-RAY IMAGE RECEPTOR" and "radiation source" changed to "FOCAL SPOT of the X-RAY TUBE" and definition rephrased.]

3.1.14
ESTABLISHED CRITERIA
limits, in a QUALITY ASSURANCE PROGRAMME, to acceptable variation in the results of a CONSTANCY TEST

Note 1 to entry: Values within ESTABLISHED CRITERIA are consistent with satisfactory functional performance of the equipment tested.

Note 2 to entry: ESTABLISHED CRITERIA can include target values.

[SOURCE: IEC 61223-3-6:2020, 3.1.8, modified – Definition rephrased and notes to entry added.]

3.1.15
FOCAL SPOT
EFFECTIVE FOCAL SPOT
perpendicular PROJECTION of the ACTUAL FOCAL SPOT on the REFERENCE PLANE

[SOURCE: IEC 60336:2020, 3.4]

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3.1.16
FOCAL SPOT PINHOLE RADIOGRAM
RADIOGRAM obtained by means of a PINHOLE CAMERA, showing the shape and orientation of an EFFECTIVE FOCAL SPOT, and the spatial distribution of intensity of RADIATION across it

[SOURCE: IEC 60336:2020, 3.5]

3.1.17
FOCAL SPOT SLIT RADIOGRAM
RADIOGRAM obtained by means of a SLIT CAMERA, showing the distribution, across an EFFECTIVE FOCAL SPOT, in the direction normal to the length of the slit, of the intensity of the RADIATION emitted

[SOURCE: IEC 60336:2020, 3.6]

3.1.18
GREYSCALE STANDARD DISPLAY FUNCTION
GSDF
mathematically defined mapping of input, DIGITAL DRIVING LEVEL (DDL) to LUMINANCE values based on the Barten model

[SOURCE: IEC 62563-1:2009, 3.1.11]

3.1.19
HIGH-VOLTAGE GENERATOR
combination of all components, in an X-RAY GENERATOR, for control and production of the electrical energy to be supplied to an X-RAY TUBE, usually consisting of a high-voltage transformer assembly and a control assembly

[SOURCE: IEC TR 60788:2004, rm-21-01, modified – Definition rephrased]

3.1.20
IMAGE DISPLAY DEVICE
specific hardware/medium used to display images presented through an analogue or digital interface

[SOURCE: IEC 62563-1:2009, 3.1.13]

3.1.21
IMAGE DISPLAY SYSTEM
workstation consisting of an IMAGE DISPLAY DEVICE, display controller and computer hardware and software, capable of displaying images

[SOURCE: IEC 62563-1:2009, 3.1.14]

3.1.22
IMAGE RECEPTION PLANE
plane containing the greatest dimensions of the IMAGE RECEPTION AREA

[SOURCE: IEC TR 60788:2004, rm-37-15]

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3.1.23
INTENSIFYING SCREEN
layer of material used in DIRECT RADIOGRAPHY to convert the incident X-RADIATION or gamma RADIATION into RADIATION more suitable for the RADIATION-sensitive emulsion of the RADIOGRAPHIC FILM

[SOURCE: IEC TR 60788:2004, rm-32-38]

3.1.24
IONIZATION CHAMBER
IONIZING RADIATION detector consisting of a chamber filled with air, in which an electric field insufficient to produce gas multiplication is provided for the collection at the electrodes of charges associated with the ions and the electrons produced in the measuring volume of the detector by IONIZING RADIATION

[SOURCE: IEC 61674:2012, 3.1.1.1.1, modified – Notes to entry deleted.]

3.1.25
ISOCENTRE
centre of the smallest sphere through which the RADIATION BEAM AXIS passes, in X-RAY EQUIPMENT with several modes of movement of the REFERENCE AXIS around a common centre

[SOURCE: IEC TR 60788:2004, rm 37-32, modified – Words "radiological equipment" replaced with "X-RAY EQUIPMENT" and definition rephrased.]

3.1.26
LIGHT FIELD
area illuminated by light, being the locus of points at which the illumination exceeds a specific or specified level, simulating the RADIATION FIELD, in X-RAY EQUIPMENT

[SOURCE: IEC TR 60788:2004, rm-37-09, modified – Word "equipment" replaced with "X-RAY EQUIPMENT" and definition rephrased.]

3.1.27
LIGHT FIELD-INDICATOR
device, in X-RAY EQUIPMENT, to delineate by means of visible light the extent of the field to be irradiated

[SOURCE: IEC TR 60788:2004, rm 37-31, modified – Words "radiological equipment" replaced with "X-RAY EQUIPMENT" and definition rephrased.]

3.1.28
LINE PAIR RESOLUTION
highest SPATIAL FREQUENCY of the specified line-group TEST PATTERN imaged under specified conditions which is distinguishable in the image

Note 1 to entry: The unit is lp/mm.

Note 2 to entry: Generally, SPATIAL RESOLUTION is used for the system property, whereas the term LINE PAIR RESOLUTION is often used in relation to test methods and TEST DEVICES.

[SOURCE: IEC 61223-3-1:1999, 3.3.2, modified – Unit information moved to a new note to entry, and details given in the existing note.]

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3.1.29
LOW CONTRAST RESOLUTION
lowest contrast detail object of a specified shape and area that can be resolved from an uniform background under defined IRRADIATION conditions

[SOURCE: IEC TR 60788:2004, rm-32-56, modified – Words "under defined IRRADIATION conditions" added.]

3.1.30
LUMINANCE
ratio of luminous flux penetrating (impinging on) a surface area in a specified direction to the product of the irradiated solid angle and the PROJECTION of the surface area onto a plane perpendicular to the viewing direction

Note 1 to entry: The unit is candela per square meter (cd/m^2)

[SOURCE: IEC 62563-1:2009, 3.1.15, modified – Note 1 to entry replaced with unit information which was in the definition.]

3.1.31
MEASUREMENT UNCERTAINTY
non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used

[SOURCE: ISO/IEC Guide 99:2007, 2.26, modified – Notes to entry deleted.]

3.1.32
MODULATION TRANSFER FUNCTION
MTF(*u*,*v*)
modulus of the generally complex optical transfer function, expressed as a function of SPATIAL FREQUENCIES *u* and *v*

[SOURCE: IEC 62220-1-1:2015, 3.10]

3.1.33
NOMINAL FOCAL SPOT VALUE
dimensionless numerical value having a specific relation to the dimensions of the EFFECTIVE FOCAL SPOT of an X-RAY TUBE, measured under specific conditions

[SOURCE: IEC 60336:2020, 3.8]

3.1.34
PATIENT SUPPORT
component such as a table top or arm rest, in X-RAY EQUIPMENT, serving to support the PATIENT in order to allow the part of his/her body which is to be irradiated to be positioned or to be displaced

[SOURCE: IEC TR 60788:2004, rm-30-02, modified – Words "radiological equipment" replaced with "X-RAY EQUIPMENT" and definition rephrased.]

3.1.35
PINHOLE CAMERA
assembly of equipment used to obtain a FOCAL SPOT PINHOLE RADIOGRAM

[SOURCE: IEC 60336:2020, 3.9]

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3.1.36
PROJECTION
transformation of a three-dimensional object into its two-dimensional image or of a two-dimensional object into its one-dimensional image, by integrating the physical property which determines the image along the direction of the projection beam

[SOURCE: IEC TR 60788:2004, rm-32-61, modified – Note deleted.]

3.1.37
QUALITY ASSURANCE
planned and systematic actions necessary to provide adequate confidence by ensuring that a product or service will satisfy given requirements for quality

[SOURCE: IEC TR 60788:2004, rm-70-05]

3.1.38
QUALITY ASSURANCE PROGRAMME
detailed instruction for carrying out actions of QUALITY ASSURANCE for individual items of equipment, systems of equipment or facilities, including quality administrative elements and QUALITY CONTROL techniques

Note 1 to entry: The QUALITY ASSURANCE PROGRAMME is broader than the QUALITY CONTROL of the X-RAY EQUIPMENT and includes for example QUALITY CONTROL of the facility and training of the personnel. The IEC 61223 series focusses only on the QUALITY CONTROL of the X-RAY EQUIPMENT.

[SOURCE: IEC 61223-3-6:2020, 3.1.14, modified – Note 1 to entry added.]

3.1.39
QUALITY CONTROL
part of the QUALITY ASSURANCE, including tests of instruments with appropriate test methods

Note 1 to entry: Includes both ACCEPTANCE TEST and CONSTANCY TEST.

[SOURCE: IEC TR 61948-3:2018, 3.11, modified – Domain <nuclear medicine> removed and “routine test” replaced with “constancy test” in Note 1 to entry.]

3.1.40
RADIOGRAM
RECORD, in RADIOLOGY, of an X-RAY PATTERN

[SOURCE: IEC TR 60788:2004, rm-32-02, Modified – definition rephrased.]

3.1.41
RADIOGRAPHIC CASSETTE
light-tight receptacle with a RADIATION-transparent front cover, intended to house one or more stationary RADIOGRAPHIC FILMS, usually with one or more INTENSIFYING SCREENS

[SOURCE: IEC TR 60788:2004, rm-35-14]

3.1.42
RADIOGRAPHIC FILM
sheet or roll material consisting of a transparent carrier covered with RADIATION-sensitive emulsion on one or usually both sides and designed for use in DIRECT RADIOGRAPHY

[SOURCE: IEC TR 60788:2004, rm-32-32]

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3.1.43
READY STATE
state of equipment in which all conditions, such as carrying out of confirming operations and any other satisfaction of interlocks are prevailing so that the intended operation of such equipment can be initiated by a single action

[SOURCE: IEC TR 60788:2004, rm-84-05]

3.1.44
REFERENCE AXIS
<RADIATION SOURCE> line in the REFERENCE DIRECTION through the centre of the RADIATION SOURCE

[SOURCE: IEC 60336:2020, 3.10]

3.1.45
REFERENCE DIRECTION
<RADIATION SOURCE> specified direction to which characteristics such as TARGET ANGLE, RADIATION FIELD and specifications with respect to the imaging quality of the RADIATION SOURCE are referenced

[SOURCE: IEC 60336:2020, 3.11]

3.1.46
REFERENCE PLANE
<diagnostic X-RAY EQUIPMENT for an EFFECTIVE FOCAL SPOT> plane perpendicular to the REFERENCE DIRECTION containing the point at which the REFERENCE AXIS intersects with the ACTUAL FOCAL SPOT

Note 1 to entry: By convention, the point of intersection forms the centre of the EFFECTIVE FOCAL SPOT.

[SOURCE: IEC 60336:2020, 3.12]

3.1.47
SIMPLE CHECK
test that can be performed routinely and uses simple means and methods to enable the early detection of changes in the functional performance of equipment

Note 1 to entry: SIMPLE CHECKS are intended to be performed by the RESPONSIBLE ORGANIZATION frequently and without any measurement instruments (e.g., DOSIMETER, LUMINANCE meter).

3.1.48
SLIT CAMERA
assembly of equipment used to obtain a FOCAL SPOT SLIT RADIOGRAM

[SOURCE: IEC 60336:2020, 3.13]

3.1.49
SPATIAL FREQUENCY
u* or *v
inverse of the period of a repetitive spatial phenomenon

Note 1 to entry: The dimension of the SPATIAL FREQUENCY is inverse length.

[SOURCE: IEC 62220-1-1:2015, 3.17]

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3.1.50
SPATIAL RESOLUTION
ability of the system to display small structures of high contrast

Note 1 to entry: SPATIAL RESOLUTION depends both on technical and observer performance.

3.1.51
SPOTFILM DEVICE
device for taking one or more RADIOGRAMS for which the choice of object and moment is made during RADIOSCOPY

Note 1 to entry: A RADIOGRAPHIC CASSETTE holder attached to a radioscopic device is not considered as a SPOTFILM DEVICE.

[SOURCE: IEC TR 60788:2004, rm-31-05]

3.1.52
SUBTRACTION IMAGING
MODE OF OPERATION to visualize differences between images or image series

Note 1 to entry: SUBTRACTION IMAGING includes DIGITAL SUBTRACTION ANGIOGRAPHY (see 3.1.9) which is a RADIOGRAPHY MODE OF OPERATION, but also includes a RADIOSCOPY MODE OF OPERATION.

3.1.53
TARGET ANGLE
acute angle between the plane of the ACTUAL FOCAL SPOT and the REFERENCE AXIS

[SOURCE: IEC TR 60788:2004, rm-20-11]

3.1.54
TEST DEVICE
specific structure, for tests requiring an X-RAY PATTERN, of one or more suitable materials to be placed in a RADIATION BEAM in order to produce such a pattern

[SOURCE: IEC TR 60788:2004, rm-71-04]

3.1.55
TEST PATTERN
image for testing or verifying the IMAGE DISPLAY SYSTEMS

[SOURCE: IEC 62563-1:2009, 3.1.21]

3.1.56
X-RAY BEAM AXIS
RADIATION BEAM AXIS
line through the centre of the RADIATION SOURCE, for a symmetrical RADIATION BEAM, and half way between the effective edges of the BEAM LIMITING DEVICE

Note 1 to entry: Usually, the RADIATION BEAM AXIS coincides within required tolerances with the REFERENCE AXIS of the RADIATION SOURCE

[SOURCE: IEC TR 60788:2004, rm-37-06, modified – Second sentence of the definition moved to a note to entry, and examples of beam axis removed as are not relevant in this document.]

3.1.57
TISSUE EQUIVALENT MATERIAL
material which absorbs and scatters a specified IONIZING RADIATION to the same degree as a particular biological tissue

[SOURCE: IEC TR 60788:2004, rm-35-16]

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3.2 Symbols and abbreviated terms

Physical quantity/description	Symbol/abbreviated term	Typical unit
(REFERENCE) AIR KERMA	K	mGy
(REFERENCE) AIR KERMA RATE	$\dot{K}$	mGy/min mGy/s
AUTOMATIC EXPOSURE CONTROL	AEC	-
computed RADIOGRAPHY	CR	-
CURRENT TIME PRODUCT	Q	mAs
DIGITAL DRIVING LEVEL	DDL	-
digital RADIOGRAPHY	DR	-
DIGITAL SUBTRACTION ANGIOGRAPHY	DSA	-
DOSE AREA PRODUCT[a]	DAP/KAP/P_{KA}	Gy·cm^2 µGy·m^2 cGy·cm^2 mGy·cm^2
GREYSCALE STANDARD DISPLAY FUNCTION	GSDF	-
HALF-VALUE LAYER	HVL	mm Al
LINE PAIR RESOLUTION	R	lp/mm
LOADING TIME	t	s, ms
LOW CONTRAST RESOLUTION	C	%
MODULATION TRANSFER FUNCTION	MTF	-
polymethylmethacrylate	PMMA	-
X-RAY IMAGE RECEPTOR AIR KERMA (RATE)	K_B $\dot{K}_B$	mGy mGy/s
X-RAY TUBE VOLTAGE	U	kV
X-RAY TUBE CURRENT	I	mA

[a] The quantity (AIR) KERMA-area product (KAP) is historically known as DOSE AREA PRODUCT (DAP). The symbol recommended in ICRU report 74 [1][1] is P_{KA}

4 General aspects of ACCEPTANCE TESTING

4.1 General

Clause 4 focuses on general aspects of ACCEPTANCE TESTING. A detailed discussion on the relation between ACCEPTANCE TESTING and CONSTANCY TESTING, as part of the QUALITY ASSURANCE PROGRAM in medical imaging departments is provided in Annex A.

ACCEPTANCE TESTING shall be performed after installation of new X-RAY EQUIPMENT. Consideration shall be given to performing ACCEPTANCE TESTING upon change or after repair of the X-RAY EQUIPMENT, depending on the nature of the change or repair.

[1] Numbers in square brackets refer to the Bibliography.

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4.2 Levels of requirements

4.2.1 General

The ACCEPTANCE TESTS described in this document cover a range of X-RAY EQUIPMENT. Only those test PROCEDURES relevant for the equipment under test and provided with acceptance criteria determined from 4.2.2, 4.2.3 and 4.2.4 shall be applicable.

4.2.2 Local regulatory requirements

For the RESPONSIBLE ORGANIZATION, local regulatory requirements, including test PROCEDURES and acceptance values, can apply.

4.2.3 Contractual requirements

Individual contractual requirements with the RESPONSIBLE ORGANIZATION can specify more stringent test PROCEDURES and acceptance values than items in this document.

Tests needed to verify the contractual requirements should be included in these requirements.

4.2.4 MANUFACTURER specifications

The RESPONSIBLE ORGANIZATION shall apply the acceptance values and tolerances that are provided by the MANUFACTURER in the ACCOMPANYING DOCUMENTS. Local regulatory requirements or contractual requirements can apply.

4.3 General conditions in test procedures

Prior to the ACCEPTANCE TEST, an inventory of the delivered X-RAY EQUIPMENT shall be established by the RESPONSIBLE ORGANIZATION.

The X-RAY EQUIPMENT and its components shall be unambiguously identified by the RESPONSIBLE ORGANIZATION, for example with respect to type and serial number, and checked against the order contract. The check shall also encompass ascertaining that the delivery is complete, that the ACCOMPANYING DOCUMENTS are included and that these documents relate to the equipment delivered.

Testing of IMAGE DISPLAY DEVICES that are a part of the X-RAY EQUIPMENT, used in ACCEPTANCE and CONSTANCY TESTS, is a prerequisite to perform any image quality related test specified in this document. It shall be assured that the IMAGE DISPLAY DEVICES perform as specified, for example with respect to contrast, brightness and absence of ARTEFACTS.

Non-invasive measurements are preferred for the ACCEPTANCE TEST. Whenever invasive tests are part of the programme, the equipment shall be restored to its original condition and safety confirmed after the invasive test has been completed.

Before the ACCEPTANCE TEST, the X-RAY EQUIPMENT shall be completely installed and calibrated according to the MANUFACTURER'S specifications.

4.4 Documents and data for the tests

Together with the X-RAY EQUIPMENT used for RADIOGRAPHY or RADIOSCOPY, the following documentation is required to complete the ACCEPTANCE TEST:

– list of equipment/parts of equipment ordered and actual delivery list;
– list of applicable tests and acceptance criteria according to this document as agreed upon between the RESPONSIBLE ORGANIZATION and the supplier of the equipment;

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– results supplied by the MANUFACTURER from tests performed at the MANUFACTURER'S site or during installation covering items of importance to quality, such as the X-RAY TUBE CURRENT or CURRENT TIME PRODUCT and the confirmation of the FOCAL SPOT dimensions;
– ACCOMPANYING DOCUMENTS;
– reports on previous tests on the equipment where applicable;
– documentation of technical changes performed on the equipment since previous testing;
– list of agreed technical modifications between the order contract and the ACCEPTANCE TEST, if applicable.

4.5 Test conditions

Different categories of tests can be identified:

– visual inspection;
– functional tests;
– system performance tests.

The measuring arrangements which can be used for performing tests are illustrated in Figure 1 and Figure 2.

Figure 1 includes the measuring arrangement for the AIR KERMA (RATE) at the IMAGE RECEPTION PLANE and the test parameters derived from them.

Figure 2 includes the measuring arrangement to test geometry and image quality, for example LOW CONTRAST RESOLUTION, DYNAMIC RANGE or SPATIAL RESOLUTION.

The arrangements in Figure 1 and Figure 2 are indicative only. The test can be carried out in the vertical or the horizontal position according to the MODE OF OPERATION of the equipment. The figures show an under-table X-RAY TUBE configuration by default. The PATIENT SUPPORT and PHANTOM are interchanged in an over-table configuration. Not every component in the figures is needed in every test. The QUALITY CONTROL manual of the specific equipment can provide actual details for the equipment under test, as required by IEC 60601-2-54:2022, 201.7.9.1, and IEC 60601-2-43:2022, 201.7.9.1. See also Annex G.

In the actual measuring arrangements, the effects of SCATTERED RADIATION should be considered (see also 4.7.6 c) for general aspects and the applicable subclauses in Clause 7 for specific details on the test methods).

The tests should yield information sufficient for a demonstration of performance over the range of OPERATOR accessible variables corresponding to the INTENDED USE of the equipment.

All relevant data, such as the identification of the X-RAY EQUIPMENT under test, identification of the test equipment used, geometrical set-up, operating characteristics (e.g., MODE OF OPERATION), correction factors and test results of the ASSOCIATED EQUIPMENT shall be recorded with the test results. The RECORD shall include the identification of the location, the date and the names of the persons performing the tests.

For testing purposes, a MANUFACTURER supplied QUALITY CONTROL mode can be used, as mentioned in IEC 60601-2-54:2022, 203.6.5.

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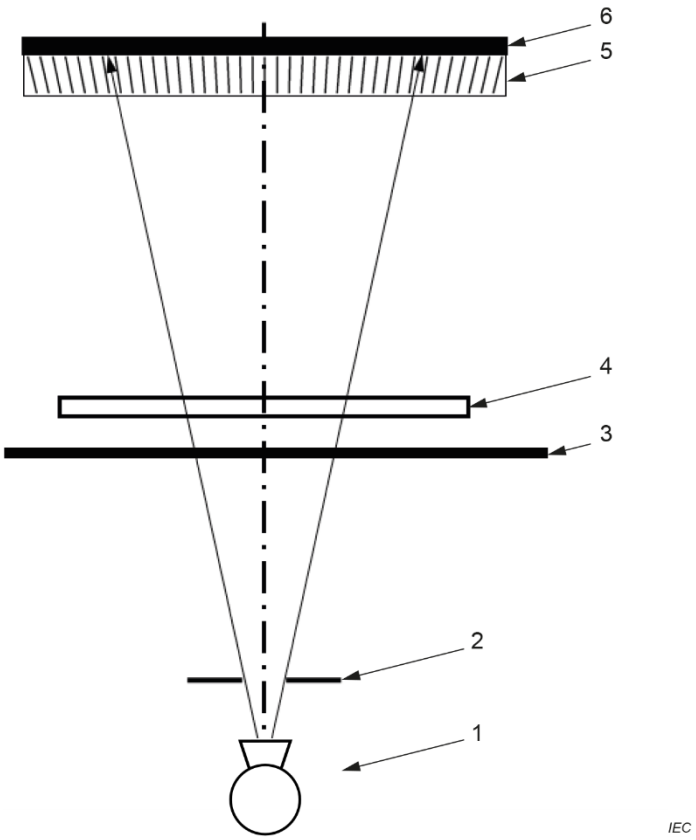

Key

1 X-RAY TUBE

2 DIAPHRAGM (BEAM LIMITING DEVICE)

3 PATIENT SUPPORT

4 additional ATTENUATION layer / PHANTOM

5 ANTI-SCATTER GRID

6 IMAGE RECEPTION PLANE (of X-RAY IMAGE RECEPTOR)

NOTE 1 The position of the detector of the DOSIMETER is not indicated in the figure, since it can be placed in multiple positions depending on the actual tests defined in Clause 7.

NOTE 2 The exact measuring arrangement can be adapted to the specific configuration under test.

Figure 1 – Indicative measuring arrangement for RADIOGRAPHY and RADIOSCOPY equipment for AIR KERMA measurements

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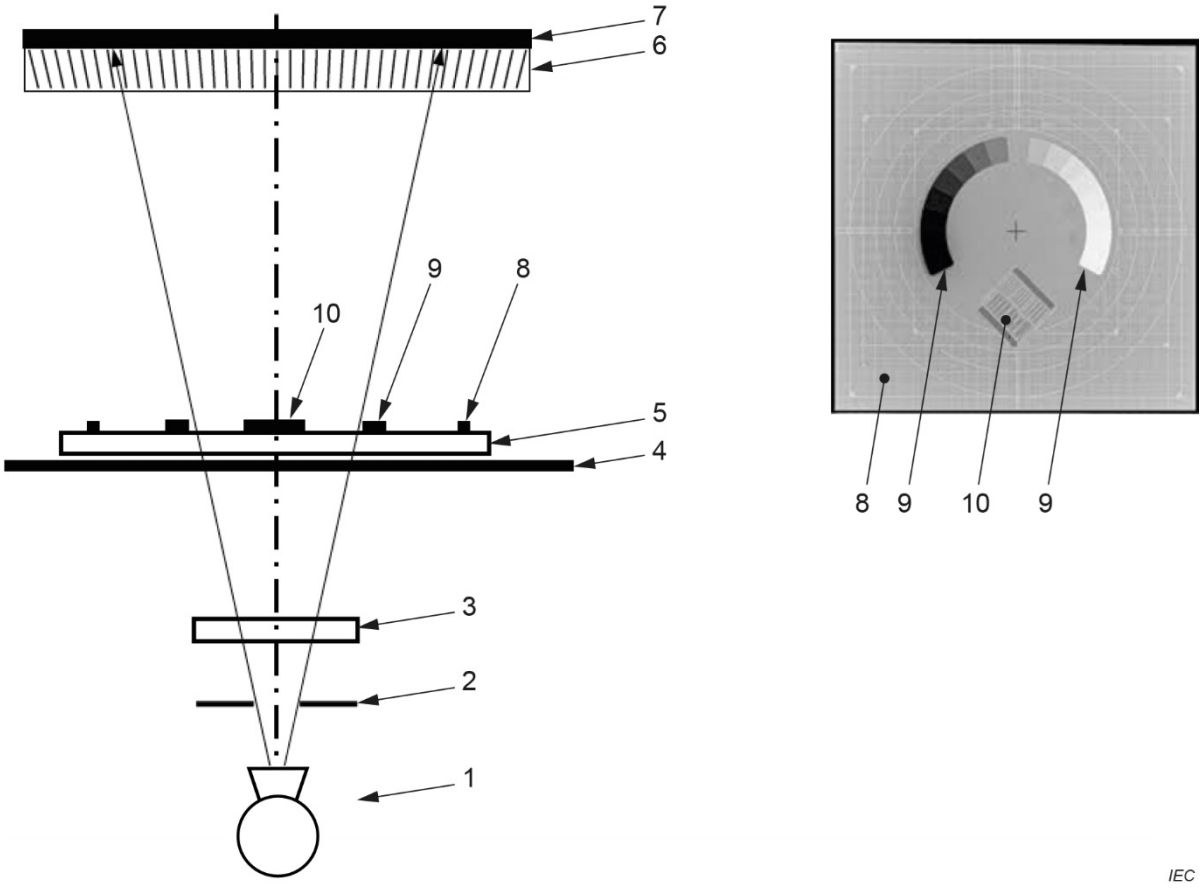

Key

1 X-RAY TUBE

2 DIAPHRAGM (BEAM LIMITING DEVICE)

3 additional ATTENUATION layer / PHANTOM (e.g., 25 mm Al)

4 PATIENT SUPPORT

5 TEST DEVICE

6 ANTI-SCATTER GRID

7 IMAGE RECEPTION PLANE (of X-RAY IMAGE RECEPTOR)

8 markings for field geometry (LIGHT FIELD – structural elements)

9 contrast details (DYNAMIC RANGE and LOW CONTRAST RESOLUTION)

10 LINE PAIR RESOLUTION TEST DEVICE (under 45° of the X-RAY IMAGE RECEPTOR axes)

Figure 2 – Indicative measuring arrangement for RADIOGRAPHY and RADIOSCOPY equipment to test geometry and resolutions

4.6 Scope of tests

An overview of tests possible for X-RAY EQUIPMENT is given in Table 1. Tests shall be performed for each imaging chain available, where relevant. Only tests applicable to the system under test shall be performed.

If equipment can be configured by the MANUFACTURER to enable or disable specific functionality, only those functions enabled in the normal MODE OF OPERATION shall be tested. However, if changes are made to enable additional functionality, then additional tests can be necessary at that time.

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4.7 Test equipment including PHANTOMS and TEST DEVICES

4.7.1 General

The measurement equipment used shall be certified as calibrated against a national or international standard where such a standard exists. The uncertainty of measuring instruments shall be suitable for the measurement. Additional discussion on uncertainty is provided in Annex H. Details on test conditions, test equipment, PHANTOMS and TEST DEVICES are discussed below.

4.7.2 Analysis software

The use of validated automated analysis software can facilitate the test PROCEDURES. For establishment of BASELINE VALUES and CONSTANCY TESTING, the same software type and version should be used consistently.

NOTE The validation of the software can be verified by the inspection of the documentation and test RECORDS provided by the supplier of this software.

4.7.3 Viewing conditions

The ambient lighting in the room shall be maintained at clinically used conditions unless permitted otherwise in the QUALITY CONTROL manual. Room lights, windows, viewing devices etc. shall not cause any disturbing reflections on the IMAGE DISPLAY DEVICE. If, due to visual impairment, the tester shall to use optical devices, then the appropriate devices shall be used, particularly for evaluating of images on the IMAGE DISPLAY DEVICE.

The IMAGE DISPLAY DEVICE controls that can be modified by the OPERATOR (e.g. brightness, contrast, window width and window levels), shall be set according to the instructions in the ACCOMPANYING DOCUMENTS.

4.7.4 High-voltage measuring instrument

The high-voltage measuring instrument shall determine the X-RAY TUBE VOLTAGE within the specified range. Instruments complying with IEC 61676:2023 shall be used. The overall MEASUREMENT UNCERTAINTY for non-invasive measurement instruments shall be less than ±2 % or ±1 kV, whichever is larger. Additional discussion on uncertainty is provided in Annex H.

4.7.5 DOSIMETER

The DOSIMETER used to test the equipment according to this document shall have a range sufficient to measure the AIR KERMA (RATE) within the required accuracy for the system under test and shall be calibrated for the applied RADIATION QUALITY. The DOSIMETER shall conform to IEC 61674:2012. Additional discussion on uncertainty is provided in Annex H.

Legal regulations requiring the use of other dosimetric quantities can apply.

If the DOSIMETER does not have a negligible ATTENUATION, the DOSIMETER should be placed outside the sensitive area of the imaging surface used for the AUTOMATIC CONTROL SYSTEM. For systems where the whole imaging area is used as a sensitive area, the DOSIMETER can influence the results. Always follow the MANUFACTURER guidance, if available.

4.7.6 PHANTOMS, TEST DEVICES and their application

PHANTOMS and TEST DEVICES can consist of attenuating material (PHANTOM part of the object) and/or structural elements (TEST DEVICE part of the object) that can be arranged in combination or separately.

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