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Date: 15 August 2023

Origin: International

Latest date for receipt of comments: 4 October 2023

Project No. 2020/02373

Responsible committee: CH/62/3 Equipment for radiotherapy, nuclear medicine and radiation dosimetry

Interested committees:

Title: BS EN IEC 61267 Medical diagnostic X-ray equipment - Radiation conditions for use in the determination of characteristics

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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

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Template for comments and secretariat observations

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



PROJECT NUMBER:

IEC 61267 ED3

DATE OF CIRCULATION:

2023-08-11

CLOSING DATE FOR COMMENTS:

2023-11-03

SUPERSEDES DOCUMENTS:

62C/782/RR

IEC SC 62C : EQUIPMENT FOR RADIOTHERAPY, NUCLEAR MEDICINE AND RADIATION DOSIMETRY

SECRETARIAT:

Germany

SECRETARY:

Ms Regina Geierhofer

OF INTEREST TO THE FOLLOWING COMMITTEES:

SC 62B

PROPOSED HORIZONTAL STANDARD:

☐

Other TC/SCs are requested to indicate their interest, if any, in this CD to the secretary.

FUNCTIONS CONCERNED:

☐ EMC

☐ ENVIRONMENT

☒ QUALITY ASSURANCE

☐ SAFETY

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TITLE:

Medical diagnostic X-ray equipment - Radiation conditions for use in the determination of characteristics

NOTE FROM TC/SC OFFICERS:

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

**MEDICAL DIAGNOSTIC X-RAY EQUIPMENT –
RADIATION CONDITIONS FOR USE IN THE
DETERMINATION OF CHARACTERISTICS**

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International Standard IEC 61267 has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Medical equipment, software, and systems.

This third edition cancels and replaces the second edition published in 2005. The main changes of the second edition of this standard include:

- a) removing former Annex C “Measurement of the practical peak voltage”;
- b) inserting of an informative Annex B “Tabulated values for the squared signal-to-noise ratio per air kerma (SNR_{in}^2)” and a normative Annex C “Additional X-RAY RADIATION CONDITIONS as used in mammography and determination of the corresponding nominal first and second aluminium half-value-layers”;
- c) revision of X-RAY RADIATION CONDITIONS;
- d) change of term definitions.

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

FDIS	Report on voting

109
110 Full information on the voting for the approval of this standard can be found in the report on
111 voting indicated in the above table.

112 This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

113 In this standard, the following print types are used:

- 114 – requirements proper: roman type;
115 – *test specifications: italic type*;
116 – notes and explanatory matter: small roman type;
117 – TERMS USED THROUGHOUT THIS PARTICULAR STANDARD THAT ARE DEFINED IN CLAUSE 3, OR IN
118 OTHER STANDARDS: SMALL CAPITALS.

119 The committee has decided that the contents of this publication will remain unchanged until the
120 maintenance result date indicated on the IEC web site under "<http://webstore.iec.ch>" in the data
121 related to the specific publication. At this date, the publication will be

- 122 • reconfirmed;
123 • withdrawn;
124 • replaced by a revised edition, or
125 • amended.

126

INTRODUCTION

To establish characteristics, aspects or properties of ASSOCIATED EQUIPMENT or to have available RADIATION BEAMS for physical and medical investigations, sets of well-defined X-RAY RADIATION CONDITIONS can offer an important tool in many situations.

From a regulation and standardization point of view there is a need:

- to have available well-defined X-RAY RADIATION CONDITIONS that can be used internationally to specify standards of operation of X-RAY EQUIPMENT;
- to provide a basis for the harmonization of existing national standards;
- to provide uniform sets of X-RAY RADIATION CONDITIONS (a dictionary of X-RAY RADIATION CONDITIONS) to describe and judge the performance of X-RAY EQUIPMENT for the benefit of MANUFACTURERS, USERS, PATIENTS and health protection authorities;
- to solve communication problems between MANUFACTURERS, USERS and regulatory authorities, stemming from a lack of internationally accepted definitions and test methods.

From an application point of view, commonly accepted sets of X-RAY RADIATION CONDITIONS would in general find use in:

- QUALITY CONTROL tests by MANUFACTURERS;
- installation and ACCEPTANCE TESTS;
- calibration of test instrumentation;
- type approval tests (where required);
- inspection and tests by regulatory authorities and testing institutes;
- physical and medical studies in physical laboratories and medical facilities;
- determination of characteristics of ASSOCIATED EQUIPMENT.

Standard X-RAY RADIATION CONDITIONS can benefit a range of potential users, such as:

- MANUFACTURERS of X-RAY EQUIPMENT;
- MANUFACTURERS of X-ray test instrumentation;
- research laboratories;
- testing institutes;
- USERS;
- government regulatory authorities;
- service organizations;
- standardization organizations.

In this standard the X-RAY TUBE VOLTAGE is measured as the PRACTICAL PEAK VOLTAGE according to the description in IEC 61676.

In the development of the second edition of this standard, efforts were made to set up procedures that give a high degree of equivalence of standard X-RAY RADIATION CONDITIONS realized on different X-ray machines. The procedure by which the X-RAY RADIATION CONDITIONS are realized consists of setting the X-RAY TUBE VOLTAGE to the prescribed value and determining the amount of ADDITIONAL FILTRATION needed to produce the required HALF-VALUE LAYER. The nature of this process implies that there is a certain maximum INHERENT FILTRATION beyond which a given X-RAY TUBE ASSEMBLY may no longer be used to produce a given X-RAY RADIATION CONDITION. In order not to exclude what are considered as standard X-RAY TUBE ASSEMBLIES, the HALF-VALUE LAYERS have been chosen in such a way that it is possible to establish all X-RAY RADIATION CONDITIONS in this standard with an X-RAY TUBE ASSEMBLY with a PERMANENT FILTRATION OF 2,5 mm Al and with ANODE ANGLES down to 9°.

171 The procedure to be followed for producing the X-RAY RADIATION CONDITIONS of the RQR series
172 does require a certain amount of additional effort. In contrast to this, the procedure for the
173 heavily filtered X-RAY RADIATION CONDITIONS was simplified. The great advantage of the method
174 lies in a much higher degree of equivalence of a given X-RAY RADIATION CONDITIONS with X-RAY
175 TUBE ASSEMBLIES having different INHERENT FILTRATIONS.

176 The second edition of this standard included the X-RAY RADIATION CONDITIONS RQR-M and RQA-
177 M which were considered as being representative for mammography beams. However, since
178 the publication of the second edition in 2005 many additional X-RAY RADIATION CONDITIONS have
179 emerged. Due to the large number of this X-RAY RADIATION CONDITIONS, it is impractical to list
180 their nominal first aluminium half-value-layers. This third edition of this standard introduces a
181 systematic procedure for the characterization and description of X-RAY RADIATION CONDITIONS
182 for these additional X-RAY RADIATION CONDITIONS, as well as a method for the validation of the
183 associated half-value-layers.
184

MEDICAL DIAGNOSTIC X-RAY EQUIPMENT – RADIATION CONDITIONS FOR USE IN THE DETERMINATION OF CHARACTERISTICS

1 Scope and object

This International Standard applies to test procedures which, for the determination of characteristics of systems or components of medical diagnostic X-RAY EQUIPMENT, require well-defined X-RAY RADIATION CONDITIONS.

Except for mammography, this standard does not apply to conditions where discontinuities in radiation absorption of elements are deliberately used to modify properties of the RADIATION BEAM (for example by rare earth filters).

X-RAY RADIATION CONDITIONS as used for screen-film sensitometry are not covered in this standard.

NOTE Screen-film sensitometry is the subject of the ISO 9236 series.

This standard deals with methods for generating X-ray beams characterized by X-RAY RADIATION CONDITIONS which can be used under test conditions typically found in test laboratories or in manufacturing facilities for the determination of characteristics of medical diagnostic X-RAY EQUIPMENT.

Examples of such X-RAY RADIATION CONDITIONS are X-ray beams emerging through the filtration from an X-RAY SOURCE ASSEMBLY whereby the RADIATION FIELD includes only an insignificant amount of SCATTERED RADIATION. X-RAY RADIATION CONDITIONS can also represent the more general case, where SCATTERED RADIATION emerges from an EXIT SURFACE of a PATIENT or a PHANTOM.

The attempt to define a X-RAY RADIATION CONDITION just by means of the X-RAY TUBE VOLTAGE, the first and possibly the second HALF-VALUE LAYER is a compromise between the mutually conflicting requirements of avoiding excessive efforts for establishing a X-RAY RADIATION CONDITION and of the complete absence of any ambiguity in the definition of a X-RAY RADIATION CONDITION. Due to differences in the design and the age of X-RAY TUBES in terms of anode angle, anode roughening and INHERENT FILTRATION, two X-RAY RADIATION CONDITIONS produced at a given X-RAY TUBE VOLTAGE having the same first HALF-VALUE LAYER can still have quite different spectral distributions. Given the inherent ambiguity in the characterization of X-RAY RADIATION CONDITIONS, it is essential that further tolerances introduced by allowing certain ranges of values, e.g. for X-RAY TUBE VOLTAGE and first HALF-VALUE LAYER, must be sufficiently small not to jeopardise the underlying objective of this standard. This standard is to ensure that measurements of the properties of medical diagnostic equipment should produce consistent results if X-RAY RADIATION CONDITIONS in compliance with this standard are used.

To achieve this objective, certain degrees of freedom in the way in which a X-RAY RADIATION CONDITION could be established in the framework of the first edition of this standard had been removed in the second edition. The essential restriction introduced in the second edition was that the X-RAY TUBE VOLTAGE is measured and set to its prescribed value. The second step was to attempt to establish the prescribed first HALF-VALUE LAYER by adding into the beam the necessary amount of ADDITIONAL FILTRATION. If the INHERENT FILTRATION provided by the X-RAY TUBE ASSEMBLY alone is so strong that the HALF-VALUE LAYER of the RADIATION BEAM emerging from the X-RAY TUBE ASSEMBLY as such is larger than that to be established, the X-RAY TUBE ASSEMBLY used is not suited for producing the desired X-RAY RADIATION CONDITIONS. This may occur if the anode angle of the X-RAY TUBE ASSEMBLY is too small and/or in the case of excessive anode roughening due to tube ageing. In the framework of what is physically feasible,

233 differences in tube design and ageing are considered by adding or removing the appropriate
234 amount of ADDITIONAL FILTRATION.

235 In the approach outlined in the two preceding paragraphs the X-RAY TUBE VOLTAGE plays a
236 decisive role. It is therefore essential that the prescribed X-ray tube voltage is chosen
237 irrespective of the type of high voltage generator connected to the X-RAY TUBE. The way in which
238 this is realized in this standard is by measuring the X-RAY TUBE VOLTAGE in terms of the
239 PRACTICAL PEAK VOLTAGE. This quantity is a weighted mean of all values of the X-RAY TUBE
240 VOLTAGE occurring during an exposure. The weighting is done in such a way that identical values
241 of the PRACTICAL PEAK VOLTAGE give identical values of the low-level contrast on a radiograph
242 irrespective of the waveform supplied by the generator.

243 This standard describes both primary X-RAY RADIATION CONDITIONS, which to a good
244 approximation are free of SCATTERED RADIATION (RQR, RQA, RQC, RQT, RQR-M and RQA-M)
245 and, for PATIENT simulation, X-RAY RADIATION CONDITIONS containing SCATTERED RADIATION (RQN,
246 RQB, RQN-M and RQB-M). It is crucial to be aware that in the presence of SCATTERED RADIATION
247 the characteristics of X-radiation in terms of fractions of AIR KERMA associated with the PRIMARY
248 RADIATION and the SCATTERED RADIATION depend on the position and nature of any ADDED FILTER
249 or PHANTOM. It is therefore obvious that AIR KERMA measurements in such RADIATION BEAMS need
250 careful consideration.

251 Clauses 5 to 9 deal with primary X-RAY RADIATION CONDITIONS which are essentially free of
252 SCATTERED RADIATION. Due to the spatial homogeneity of the corresponding X-RAY RADIATION
253 CONDITIONS, the APPLICATION DISTANCE does not influence the linked X-RAY RADIATION
254 CONDITIONS to a significant extent.

- 255 • Clause 5 deals with X-RAY RADIATION CONDITIONS for the RADIATION BEAM emerging from the
256 X-RAY SOURCE ASSEMBLY. Such X-RAY RADIATION CONDITIONS can be used for determining
257 ATTENUATION properties of ASSOCIATED EQUIPMENT.
- 258 • Clause 6 deals with X-RAY RADIATION CONDITIONS for the RADIATION BEAM emerging from an
259 irradiated object that simulates a PATIENT under the conditions that:
 - 260 – the contribution of SCATTERED RADIATION in the RADIATION BEAM is not significant;
 - 261 – exact simulation of the spectral distribution of the RADIATION BEAM emerging from the
262 PATIENT is not a prerequisite.
- 263 • Clauses 7 and 8 deal with X-RAY RADIATION CONDITIONS from those dealt with in Clause 6 in
264 view of special applications like automatic exposure and automatic exposure rate control
265 systems and computed tomography. The radiation transmitted through the irradiated object
266 has properties similar to those of the radiation transmitted through a PATIENT under the
267 conditions that:
 - 268 – the contribution of SCATTERED RADIATION in the RADIATION BEAM is not significant;
 - 269 – exact simulation of the spectral distribution of the RADIATION BEAM emerging from the
270 PATIENT is not a prerequisite.
- 271 • Clauses 9 and 10 deal with X-RAY RADIATION CONDITIONS where SCATTERED RADIATION is taken
272 into account. This is done either by limiting the amount of SCATTERED RADIATION by
273 appropriate means and/or providing specific additional information.
- 274 • Clause 9 deals with measuring arrangements primarily intended in combination with X-RAY
275 RADIATION CONDITIONS RQB of Clause 10 to be used for those measurements where the
276 contribution of SCATTERED RADIATION to the detected signal is minimal and is known as
277 NARROW BEAM CONDITION.
- 278 • Clause 10 deals with X-RAY RADIATION CONDITIONS to be used for measurements where the
279 contribution of SCATTERED RADIATION to the detected signal is significant and is known as
280 BROAD BEAM CONDITION.

281 For the X-RAY RADIATION CONDITIONS specified in Clauses 5 to 10 it is assumed that an X-RAY
282 TUBE is available with an anode angle of not less than about 9°. For X-ray tubes with smaller
283 anode angles it may not be possible to realize some or all X-RAY RADIATION CONDITIONS of Clause
284 5. If some or all X-RAY RADIATION CONDITIONS of the RQR series cannot be realized with a given

285 X-RAY TUBE due to a too strong INHERENT FILTRATION, some special provisions have been made
286 to establish nevertheless the more heavily filtered X-RAY RADIATION CONDITIONS in Clauses 6 to
287 10 which are in principle based on the X-RAY RADIATION CONDITIONS of the RQR series.

288 In order to make allowance for the use of X-RAY TUBES with ANODE ANGLES down to 9°, the HALF-
289 VALUE LAYERS of X-RAY RADIATION CONDITIONS RQR 4 to RQR 10 have been increased with
290 respect to the values specified in the first edition of this standard (1994).

291 Clauses 11 to 14 deal with X-RAY RADIATION CONDITIONS applicable to mammography.

- 292 • Clause 11 deals with X-RAY RADIATION CONDITIONS for the RADIATION BEAM emerging from
293 the X-RAY TUBE ASSEMBLY. Such X-RAY RADIATION CONDITIONS can be used for determining
294 ATTENUATION properties of ASSOCIATED EQUIPMENT.
- 295 • Clause 12 deals with X-RAY RADIATION CONDITIONS transmitted through an irradiated object
296 that simulates a PATIENT under the conditions that:
 - 297 – the contribution of SCATTERED RADIATION in the RADIATION BEAM is not significant;
 - 298 – exact simulation of the spectral distribution of the RADIATION BEAM emerging from the
299 PATIENT is not a prerequisite.
- 300 • CLAUSE 13 deals with X-RAY RADIATION CONDITIONS to be used for studies in mammography
301 under NARROW BEAM CONDITION. These X-RAY RADIATION CONDITIONS are achieved by
302 applying a special tissue-equivalent PHANTOM.
- 303 • CLAUSE 14 deals with X-RAY RADIATION CONDITIONS to be used for studies in mammography
304 under BROAD BEAM CONDITION. These X-RAY RADIATION CONDITIONS are achieved by applying
305 a special tissue-equivalent PHANTOM.

306 The test instrumentation as required in this standard partly comprises SPECIFIC components or
307 a series of equivalent components out of which the most suitable should be chosen in order to
308 provide test conditions required to achieve prescribed test parameters. However, these
309 provisions in terms of hardware may not be available at USER facilities. As an example, clinical
310 mammography units are not suited for producing the X-RAY RADIATION CONDITIONS in Clauses
311 11 to 14 without modification. In order to adapt them the PATIENT SUPPORT needs to be removed
312 to allow for the measurement geometry required by this standard.

313 2 Normative references

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

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

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

322 3 Terms and definitions

323 For the purposes of this document, the terms and definitions given in IEC 61674 and IEC 61676
324 and the following definitions apply.

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

- 327 • IEC Electropedia: available at <https://www.electropedia.org/>

- ISO Online browsing platform: available at <https://www.iso.org/obp>

3.1**application distance**

distance from the EFFECTIVE FOCAL SPOT to the APPLICATION PLANE

3.2**application plane**

plane perpendicular to the CENTRAL BEAM AXIS, where the standard X-RAY RADIATION CONDITION is defined

3.3**central beam axis**

line from the FOCAL SPOT through the centre of the DIAPHRAGM

3.4**exit surface**

<RADIOLOGY> plane or curved surface through which the RADIATION BEAM emerges from an irradiated object

3.5**half-value layer test device**

device, normally shaped as foil or plate, which, when applied under NARROW BEAM CONDITIONS, attenuates AIR KERMA RATE to one half of the value that is measured without the device

3.6**homogeneity coefficient**

ratio of first to second HALF-VALUE LAYER

NOTE 1 to entry: The first HVL gives the thickness of a SPECIFIED material which reduces the AIR KERMA RATE to half the value without this material; the second HVL gives the additional thickness to reduce the AIR KERMA RATE to a quarter.

3.7**X-ray radiation condition**

selection of the following parameters to achieve specific X-ray beam characteristics:

- the material of the emitting TARGET;
- the X-RAY TUBE VOLTAGE;
- a specific TOTAL FILTRATION consisting of that of
 - the X-RAY TUBE ASSEMBLY, and
 - an ADDED FILTER or PHANTOM of specific material and thickness;
- the first HALF-VALUE LAYER;
- HOMOGENEITY COEFFICIENT;
- APPLICATION DISTANCE;
- field size;
- PHANTOM.

3.8**reference point**

point of a RADIATION DETECTOR which, during the calibration of the DETECTOR, is brought to coincidence with the point at which the CONVENTIONAL TRUE VALUE is specified

[IEC 61674:1997, 3.17, modified]

3.9**X-ray tube voltage**

potential difference applied to an X-RAY TUBE between the anode and the cathode. The unit of this quantity is the volt (V)

[IEC 61676:2002, 3.25]

NOTE 1 to entry: The X-RAY TUBE VOLTAGE may vary as a function of time. The PRACTICAL PEAK VOLTAGE is a weighted value of the X-RAY TUBE VOLTAGE over a time period.

3.10**reference direction**

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

4 Common aspects – Adjustment procedures**4.1 Radiation detector**

The RADIATION DETECTOR to be used for measurements of AIR KERMA or AIR KERMA RATE to determine the attenuation curve shall comply with IEC 61674. Additionally,

- its energy dependence of response shall not exceed ± 3 % over the range of X-RAY RADIATION CONDITIONS encountered during the determination of the attenuation curve.
- the dimensions of the entrance surface of its SENSITIVE VOLUME shall be such that it will be fully covered by the RADIATION BEAM;
- its sensitivity shall be such that measurements can (still) be carried out, when applying ADDED FILTERS or PHANTOMS described in this standard;
- the RADIATION DETECTOR shall be applicable for the AIR KERMA RATES involved (with and without application of ADDED FILTERS or PHANTOMS).

4.2 Percentage ripple of the X-ray tube voltage

PERCENTAGE RIPPLE of the X-RAY TUBE VOLTAGE shall not exceed 10 %, apart from the case of mammography, where a limit of 4 % shall not be exceeded.

4.3 Anode material

Requiring tungsten as target material does not refer to pure tungsten but to a “tungsten-rich” target material. For technological reasons, for example, alloys are used containing up to 10 % of rhenium.

5 RQR – X-RAY RADIATION CONDITIONS**5.1 Object**

This clause deals with X-RAY RADIATION CONDITIONS, which are used for measurements in the RADIATION BEAM as emerging from the X-RAY SOURCE ASSEMBLY under low-scatter condition. Such X-RAY RADIATION CONDITIONS are, for example, applied for determining characteristics of PATIENT SUPPORTS in case the PATIENT SUPPORT is situated in between the X-RAY SOURCE ASSEMBLY and the PATIENT.

5.2 Characterization

The standard X-RAY RADIATION CONDITIONS, characterized by the letter code given in the first column of Table 1, are referred to as follows:

RQR x IEC 61267:y,