BS EN 61331-1:2014

BSI Standards Publication

Protective devices against diagnostic medical X-radiation

Part 1: Determination of attenuation properties of materials

National foreword

This British Standard is the UK implementation of EN 61331-1:2014. It is identical to IEC 61331-1:2014. It supersedes BS EN 61331-1:2002, which will be withdrawn on 11 June 2017.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electrical Equipment in Medical Practice, to Subcommittee CH/62/2, Diagnostic imaging equipment.

A list of organizations represented on this committee can be obtained on request to its secretary.

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English Version

Protective devices against diagnostic medical X-radiation - Part 1: Determination of attenuation properties of materials (IEC 61331-1:2014)

Dispositifs de protection radiologique contre les rayonnements X pour diagnostic médical - Partie 1: Détermination des propriétés d'atténuation des matériaux (CEI 61331-1:2014)

Strahlenschutz in der medizinischen Röntgendiagnostik - Teil 1: Bestimmung von Schwächungseigenschaften von Materialien (IEC 61331-1:2014)

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CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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Foreword

The text of document 62B/936/FDIS, future edition 2 of IEC 61331-1, 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 61331-1:2014.

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)	2015-04-24
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2017-06-11

This document supersedes EN 61331-1:2002.

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Endorsement notice

The text of the International Standard IEC 61331-1:2014 was approved by CENELEC as a European Standard without any modification.

IEC 61331-3	NOTE	Harmonised as EN 61331-3.

Annex ZA
(normative)
Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 When 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.cenelec.eu.

Publication	Year	Title	EN/HD	Year
IEC 60601-1	2005	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
			+EN 60601-1:2006/corrigendum Mar. 2010	2010
			+AC	2014
			+A11	2011
+A1	2012		+A1	2013
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
			+EN 60601-1-3:2008/corrigendum Mar. 2010	2010
+A1	2013		+A1	2013
			+AC	2014
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-

CONTENTS

PROTECTIVE DEVICES AGAINST DIAGNOSTIC MEDICAL X-RADIATION –

Part 1: Determination of attenuation properties of materials

1 Scope

This part of IEC 61331 applies to materials in sheet form used for the manufacturing of PROTECTIVE DEVICES against X-RADIATION of RADIATION QUALITIES generated with X-RAY TUBE VOLTAGES up to 400 kV and gamma radiation emitted by radionuclides with photon energies up to 1,3 MeV.

This Part 1 is not intended to be applied to PROTECTIVE DEVICES when these are to be checked for the presence of their ATTENUATION properties before and after periods of use.

This Part 1 specifies the methods of determining and indicating the ATTENUATION properties of the materials.

The ATTENUATION properties are given in terms of:

– ATTENUATION RATIO;
– BUILD-UP FACTOR;
– ATTENUATION EQUIVALENT;

together with, as appropriate, an indication of homogeneity and mass per unit area.

Ways of stating values of ATTENUATION properties in compliance with this part of the International Standard are included.

Excluded from the scope of this International Standard are:

– methods for periodical checks of PROTECTIVE DEVICES, particularly of PROTECTIVE CLOTHING,
– methods of determining ATTENUATION by layers in the RADIATION BEAM, and
– methods of determining ATTENUATION for purposes of protection against IONIZING RADIATION provided by walls and other parts of an installation.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 60601-1:2005/AMD1:2012

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

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

Monographie BIPM-5:2013, *Table of Radionuclides*[1]

NISTIR 5632:2004, *Tables of X-Ray Mass Attenuation Coefficients and Mass Energy-Absorption Coefficients (version 1.4)* [on-line, cited 2014-01-30] Available at http://www.nist.gov/pml/data/xraycoef/][2]

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC/TR 60788:2004, IEC 60601-1:2005 and IEC 60601-1:2005/AMD 1:2012, IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013 and the following apply.

3.1
ATTENUATION RATIO
ratio of the value of a SPECIFIED RADIATION QUANTITY in the centre of a SPECIFIED RADIATION BEAM of SPECIFIED RADIATION QUALITY, with the attenuating material under consideration outside the beam, to the value at the same position and under the same conditions with this attenuating material placed in the beam

4 Methods to determine the ATTENUATION RATIO

4.1 General

There are four different conditions described in this standard to determine ATTENUATION RATIOS, F:

F_N	ATTENUATION RATIO measured with a NARROW BEAM CONDITION	(4.2)
F_B	ATTENUATION RATIO measured with a BROAD BEAM CONDITION	(4.3)
F_{IB}	ATTENUATION RATIO measured with an inverse BROAD BEAM CONDITION	(4.4)
$F_{N,R}$	ATTENUATION RATIO calculated for a photon-emitting radionuclide, R	(4.5)

4.2 NARROW BEAM CONDITION

4.2.1 General description

The ATTENUATION RATIO F_N for a given test material (or test object) shall be measured according to the arrangement for NARROW BEAM CONDITION as shown in Figure 1. This arrangement is designed to measure the ATTENUATION of the X-RAY BEAM only due to primary photons. The probability that secondary photons such as fluorescence photons or Compton scattered photons from the test object reach the RADIATION DETECTOR is minimized. The aperture in the DIAPHRAGM shall be just large enough to produce the smallest beam covering the radiation detector. An additional DIAPHRAGM (number 5 in Figure 1) shall be used to shield the RADIATION DETECTOR from SCATTERED RADIATION produced in the test object. The distance a from the test object to the reference point of the RADIATION DETECTOR on the beam axis shall be at least ten times the diameter d of the detector or ten times the diameter t of the RADIATION BEAM at the distal surface of the test object , whatever is larger, i.e. $a \geq 10 \max(d,t)$. The minimal distance of the wall or the floor from the detector (position 6 in the Figure 1) in the direction of the beam shall be 700 mm.

4.2.2 AIR KERMA RATE measurements

The AIR KERMA RATE shall be measured under three different conditions with the same RADIATION DETECTOR at the same position, where

[1] Bureau International de Poids et Mesures, Pavillon de Breteeuil, F-92310 Sèvres, ISBN 92-822-2204-7 (set).

[2] National Institute of Standards and Technology (NIST), U.S.Department of Commerce.

$\dot{K}_0$ denotes the AIR KERMA RATE without the test object in the RADIATION BEAM;

$\dot{K}_1$ the AIR KERMA RATE with the test object in the RADIATION BEAM;

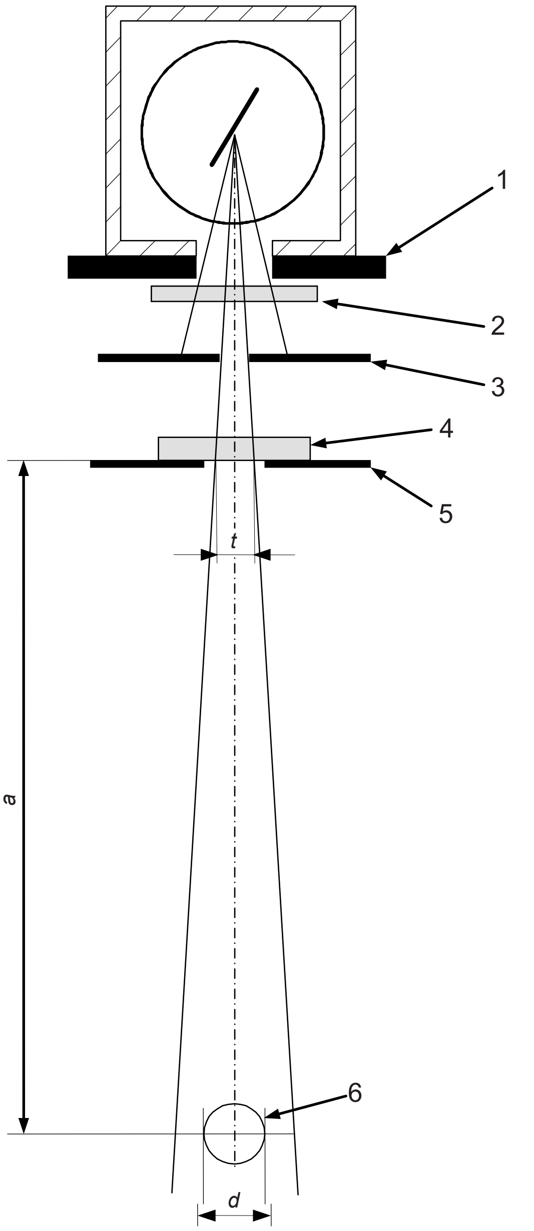
$\dot{K}_B$ the AIR KERMA RATE with the test object in the beam replaced by a sheet of material of the same shape with an ATTENUATION RATIO greater than 10^5.

The same constant dose rate of the primary beam shall be used for the three measurements. If the mean dose rate of the primary beam varies by more than 0,2 % during the measurements, a monitor shall be used to normalize the three measurements to the same primary beam dose rate.

4.2.3 RADIATION QUALITIES and RADIATION DETECTOR

The RADIATION QUALITIES used for the measurements shall be selected from Table 1 . The RADIATION DETECTOR shall be calibrated in terms of AIR KERMA. The quotient $\dot{K}_0$ divided by $\dot{K}_1$ shall be known with a relative standard uncertainty not more than 2 %.

NOTE The AIR KERMA RESPONSE of the RADIATION DETECTOR can be measured with e.g. NARROW BEAM qualities and the RESPONSE can be plotted as a function of Al or Cu HALF-VALUE LAYERS (HVL). Tables A.4 and A.5 of this standard can be used to look up the approximate Al or Cu HVL of the non-attenuated and attenuated beams. The AIR KERMA RESPONSE in the actual beam can then be evaluated from the plot.



1 DIAPHRAGM

2 Beam filtration

3 Beam-limiting DIAPHRAGM

4 Test object

5 DIAPHRAGM

6 Radiation detector

Condition: $a \geq 10 \max(d,t)$

Figure 1 – NARROW BEAM CONDITION

4.2.4 Signal to noise condition

The following condition shall be fulfilled:

$$\dot{K}_1 \geq 10\,\dot{K}_B$$

4.2.5 ATTENUATION RATIO evaluation

The ATTENUATION RATIO F_N shall be evaluated as:

$$F_N = \frac{\dot{K}_0 - \dot{K}_B}{\dot{K}_1 - \dot{K}_B}$$

4.3 BROAD BEAM CONDITION

4.3.1 General description

The ATTENUATION RATIO F_B for a given test material (or test object) shall be measured according to the arrangement for BROAD BEAM CONDITION as shown in Figure 2. This arrangement is designed to measure the ATTENUATION of the x-ray beam if secondary photons emitted by the material sample are included in the detection of the attenuated beam. The probability that secondary photons such as fluorescence photons or Compton scattered photons from the test object reach the RADIATION DETECTOR is maximized. The distance a, from the focal spot to the radiation exit plane of the test object shall be at least three times the diameter d, of the beam limiting aperture, i.e. $a \geq 3d$. The aperture diameter d shall be at least 10 times greater than the distance b, of the reference point of the RADIATION DETECTOR from the surface of the test object, i.e. $d \geq 10b$. b shall be chosen as small as possible in order to minimize the ATTENUATION of secondary photons by the amount of air between the reference point of the RADIATION DETECTOR and the point of emission of the secondary photons from the test object. The distance between the outer wall of the chamber and the surface of the test object shall not exceed 10 mm. The minimal distance of the wall or the floor from the detector (position 6 in Figure 2) in the direction of the beam shall be 700 mm.

4.3.2 AIR KERMA RATE measurements

The AIR KERMA RATE shall be measured under three different conditions with the same RADIATION DETECTOR at the same position, where:

$\dot{K}_0$ denotes the AIR KERMA RATE without the test object in the RADIATION BEAM;

$\dot{K}_1$ the AIR KERMA RATE with the test object in the RADIATION BEAM;

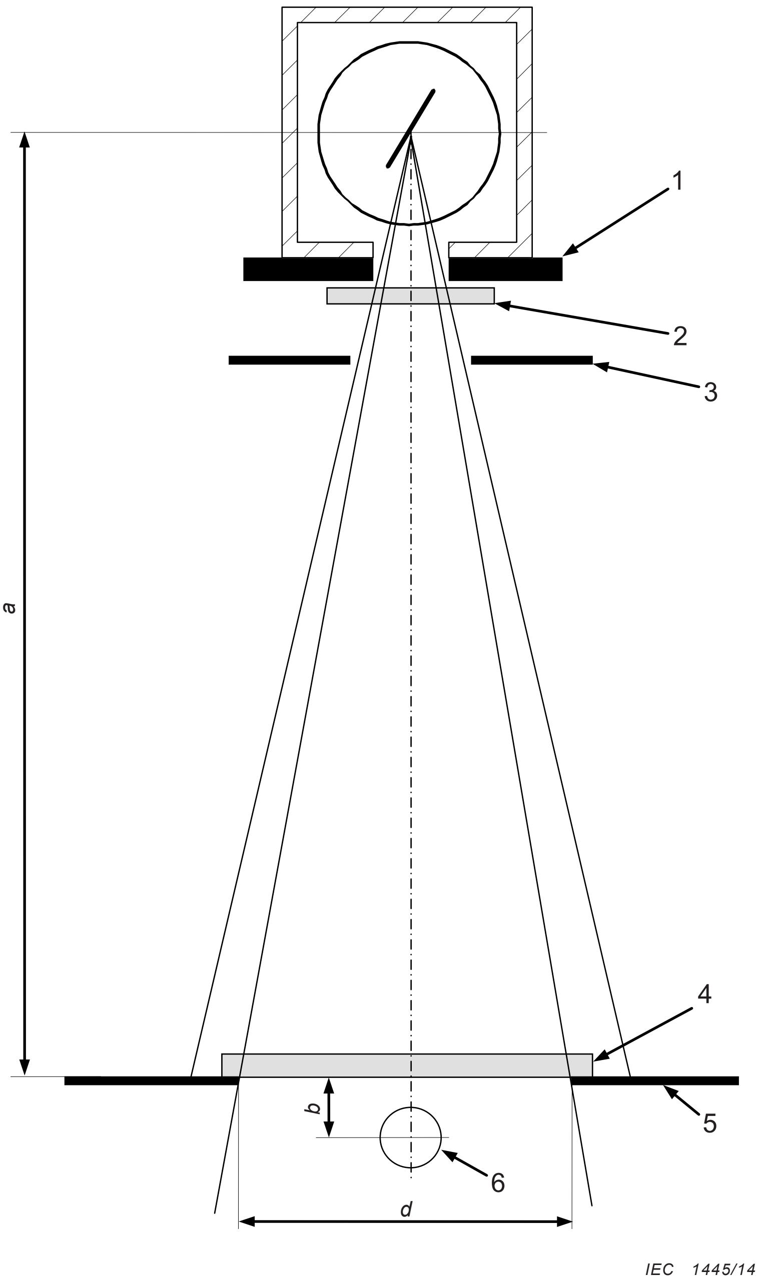
$\dot{K}_B$ the AIR KERMA RATE with the test object in the beam replaced by a sheet of material of the same shape with an ATTENUATION RATIO greater than 10^5.

The same constant dose rate of the primary beam shall be used for the three measurements. If the mean dose rate of the primary beam varies by more than 0,2 % during the measurements a monitor shall be used to normalize the three measurements to the same primary beam dose rate. The dose rate of the primary beam at any point in the plane of the beam-limiting aperture shall not vary by more than 2 %.

4.3.3 RADIATION QUALITIES and RADIATION DETECTOR

The RADIATION QUALITIES given in Table 1 shall be used for the measurements. The RADIATION DETECTOR shall be calibrated in terms of AIR KERMA. The quotient $\dot{K}_0$ divided by $\dot{K}_1$ shall be known with a relative standard uncertainty not more than 2 %. The dependence of the response of the RADIATION DETECTOR upon the direction of incidence shall be negligibly small over a hemisphere. It is recommended to use a spherical ionisation chamber.

NOTE The AIR KERMA RESPONSE of the RADIATION DETECTOR can be measured with e.g. NARROW BEAM qualities and the RESPONSE can be plotted as a function of Al or Cu HALF-VALUE LAYERS (HVL). Tables A.4 and A.5 of this standard can be used to look up the approximate Al or Cu HVL of the non-attenuated and attenuated beams. The AIR KERMA RESPONSE in the actual beam can then be evaluated from the plot.



1 DIAPHRAGM

2 Beam filtration

3 DIAPHRAGM

4 Test object

5 Beam-limiting DIAPHRAGM

6 Radiation detector

Conditions: a ≥ 3 *d*, *d* ≥ 10 *b*

Figure 2 – BROAD BEAM CONDITION

4.3.4 Signal to noise condition

The following condition shall be fulfilled:

$$\dot{K}_1 \geq 10\,\dot{K}_B$$

4.3.5 ATTENUATION RATIO evaluation

The ATTENUATION RATIO F_B shall be evaluated as:

$$F_B = \frac{\dot{K}_0 - \dot{K}_B}{\dot{K}_1 - \dot{K}_B}$$

4.4 Inverse BROAD BEAM CONDITION

4.4.1 General description

The geometry of the inverse BROAD BEAM shown in Figure 3 is an alternative method to measure the ATTENUATION RATIO F_B. In order to distinguish from the conventional method, it is designated as F_{IB}. In contrast to the conventional method described in 4.2 where a BROAD BEAM impinges on a large area piece of the test object and a small RADIATION DETECTOR closely behind the test object is used, the inverse method is characterized by a NARROW BEAM impinging on a small area piece of the test object and a large area flat RADIATION DETECTOR immediately behind the test object. A flat ionisation chamber shall be used for this purpose. This method has some advantages because it is easy to use, has low measuring uncertainties, need only small field sizes and small sheets of material. It shall be used for the determination of the ATTENUATION properties of materials used for PROTECTIVE CLOTHING and PROTECTIVE DEVICES for gonads in medical x-ray diagnostic described in IEC 61331-3. The method as described here shall not be used for RADIATION QUALITIES with X-RAY TUBE VOLTAGES above 150 kV. The distance *a*, from the focal spot to the entrance plane of the measuring DIAPHRAGM shall not be less than 5 times the diameter of the DIAPHRAGM aperture, *d*, i.e. $a \geq 5\ d$. The test object can be fixed to the exit plane of the measuring DIAPHRAGM. The distance *b*, between the radiation exit plane of the test object and the flat ionisation chamber shall be chosen to be as close as possible. The following condition shall be fulfilled: $D - d \geq 10\ b$. The distance *b* shall not exceed 5 mm. The minimal distance of the wall or the floor from the detector (position 6 in the Figure 3) in the direction of the beam shall be 700 mm.

4.4.2 AIR KERMA RATE measurements

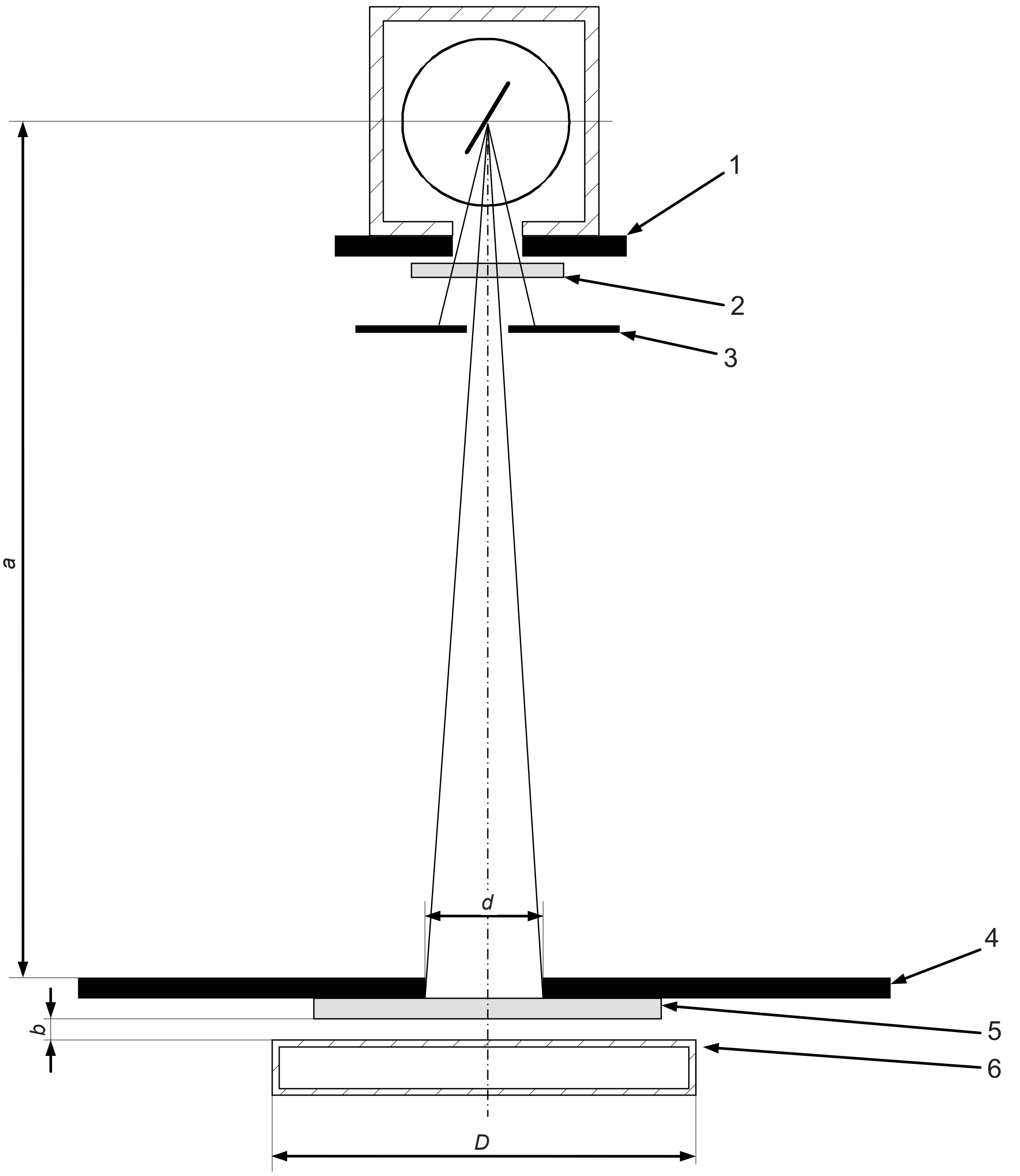
The AIR KERMA RATE shall be measured under three different conditions with the same RADIATION DETECTOR at the same position, where:

$\dot{K}_0$ denotes the AIR KERMA RATE without the test object in the RADIATION BEAM;

$\dot{K}_1$ the AIR KERMA RATE with the test object in the RADIATION BEAM;

$\dot{K}_B$ the AIR KERMA RATE with the test object in the beam replaced by a sheet of material of the same shape with an ATTENUATION RATIO greater than 10^5.

The same constant dose rate of the primary beam shall be used for the three measurements. If the mean dose rate of the primary beam varies by more than 0,2 % during the measurements, a monitor shall be used to normalize the three measurements to the same primary beam dose rate.



1 DIAPHRAGM

2 Beam filtration

3 DIAPHRAGM

4 Measuring DIAPHRAGM

5 Test object

6 Flat measuring chamber

Conditions: a ≥ 5 *d*, *D* – *d* ≥ 10 *b*, b ≤ 5 mm

Figure 3 – Inverse BROAD BEAM CONDITION

4.4.3 RADIATION QUALITIES and RADIATION DETECTOR

The RADIATION QUALITIES given in Table 1 shall be used for the measurements. The flat ionisation chamber shall be calibrated in terms of AIR KERMA under the same irradiation conditions as used in the measurements. The quotient $\dot{K}_0$ divided by $\dot{K}_1$ shall be known with a relative standard uncertainty not more than 2%.

NOTE The AIR KERMA RESPONSE of the RADIATION DETECTOR can be measured with e.g. NARROW BEAM qualities and the RESPONSE can be plotted as a function of Al HALF-VALUE LAYERS (HVL). Table A.4 of this standard can be used to look up the approximate Al HVL of the non-attenuated and attenuated beams. The AIR KERMA RESPONSE in the actual beam can then be evaluated from the plot.

4.4.4 Signal to noise condition

The following condition shall be fulfilled:

$$\dot{K}_1 \geq 10\,\dot{K}_B$$

4.4.5 ATTENUATION RATIO evaluation

The ATTENUATION RATIO F_{IB} shall be evaluated as:

$$F_{IB} = \frac{\dot{K}_0 - \dot{K}_B}{\dot{K}_1 - \dot{K}_B}$$

4.5 Calculation of the ATTENUATION RATIO for photon-emitting radionuclides

4.5.1 Equation

The ATTENUATION RATIO $F_{N,R}$ for a given test material to protect against the photon-emitting radionuclide R shall be calculated according to the following equation:

$$F_{N,R} = \frac{\sum_i \left(\frac{\mu_{en}(E_i)}{\rho}\right)_{air} p(E_i)E_i}{\sum_i \left(\frac{\mu_{en}(E_i)}{\rho}\right)_{air} p(E_i)E_i e^{-\left(\frac{\mu(E_i)}{\rho}\right)_m d\rho}} \ , \ E_i \geq 20 \text{ keV}$$

where

E_i	is the energy of the i-th photon emitted per decay
$p(E_i)$	is the photon emission probability per decay event for photons with energy E_i
$\left(\frac{\mu_{en}(E_i)}{\rho}\right)_{air}$	is the mass energy-absorption coefficient of air for photons with energy E_i
$\left(\frac{\mu(E_i)}{\rho}\right)_m$	is the mass ATTENUATION COEFFICIENT of the test material for photons with energy E_i
d	is the thickness of the test material
ρ	is the density of the test material

4.5.2 Decay data

Photon energies E_i and photon emission probabilities $p(E_i)$ shall be taken from the Monographie BIPM-5: Table of Radionuclides.

4.5.3 Mass ATTENUATION and mass energy-absorption coefficients

Mass ATTENUATION and mass energy-absorption coefficients shall be taken from NISTIR 5632: Tables of X-Ray Mass Attenuation Coefficients and Mass Energy-Absorption Coefficients.

4.5.4 Verification of the mass- ATTENUATION COEFFICIENTS of the test material

The test material's mass ATTENUATION COEFFICIENTS used in 4.5.1 shall be verified by comparison of measured values of F_N according to 4.2 with calculated values $F_{N,C}$ according to the procedure described in the following. A set of standard RADIATION QUALITIES of Tables 1 and 2 shall be used which covers approximately the energy range of the photons emitted by the radionuclide. Measurements for the standard gamma RADIATION QUALITIES listed in Table 2 shall be done with a NARROW BEAM CONDITION similar to that shown in Figure 1. The distribution of the photon fluence with respect to the photon energies of the standard RADIATION QUALITIES shall be known for this purpose. The value of F_N of the photon fluence spectra shall be evaluated according to the following formula:

$$F_{N,C} = \frac{\sum_i \left(\frac{\mu_{en}(E_i)}{\rho}\right)_{air} \phi(E_i)E_i}{\sum_i \left(\frac{\mu_{en}(E_i)}{\rho}\right)_{air} \phi(E_i)E_i e^{-\left(\frac{\mu(E_i)}{\rho}\right)_m d\rho}}$$

where

E_i is the energy attributed to the channel i containing all photons with energies between $E_i - \frac{\Delta}{2}$ and $E_i + \frac{\Delta}{2}$

$\phi(E_i)$ is the number of photons contained in channel i

and the other symbols have the same meaning as in the equation of 4.5.1.

The condition $|1 - F_N / F_{N,C}| \leq 0,2$ shall be fulfilled for the chosen set of qualities.

Table 1 – Standard RADIATION QUALITIES for X-RAY BEAMS

Tube voltage (nominal) kV	TOTAL FILTRATION (nominal)		1st HVL (nominal)		AIR KERMA RATE 1 m, 10 mA (approximately)
	mm Al	mm Cu	mm Al	mm Cu	mGy/s
30	2,5		0,99		0,1
40	2,5		1,44		0,2
50	2,5		1,81		0,3
60	2,5		2,14		0,4
70	2,5		2,44		0,5
80	2,5		2,77		0,6
90	2,5		3,10		0,8
100	2,5		3,44		0,9
110	2,5		3,79		1,0
120	2,5		4,13		1,2
130	2,5		4,48		1,4
140	2,5		4,82		1,6
150	2,5		5,17		2
200		1,2	14,6	1,63	1
250		1,8	16,8	2,53	1,5
300		2,5	18,6	3,37	2
400		3,5	20,8	4,51	3

The X-RAY TUBE VOLTAGE shall not differ from the nominal values by more than 2 % or 2 kV, whatever is less. The aluminium filter shall be of 99,9 % purity or higher and density 2,70 g cm^{-3}. The copper filter shall be of 99,9 % purity or higher and density 8,90 g cm^{-3} The thickness of the aluminium and copper filters shall not differ from the nominal values by more than 0,1 mm. The first Al and Cu HALF-VALUE LAYERS and the approximate AIR KERMA RATES are given for information only.

Table 2 – Standard gamma RADIATION QUALITIES according to ISO 4037-1

Gamma sources	Code ISO 4037	RADIATION ENERGY keV	Half life days	AIR KERMA RATE constant of the pure source μGy h^{-1} m^2 MBq^{-1}
Cs-137	S-Cs	661,6	11 050	0,079
Co-60	S-Co	1 173,3; 1 332,5	1 925,5	0,31

5 Determination of ATTENUATION properties

5.1 ATTENUATION RATIO

5.1.1 Determination

The ATTENUATION RATIOS F_N, F_B, F_{IB} and $F_{N,R}$ shall be determined according to 4.2, 4.3, 4.4 and 4.5, respectively.

5.1.2 Indication

The ATTENUATION RATIOS F_N, F_B, F_{IB} and $F_{N,R}$ shall be indicated by its numerical value together with the method of determination (NARROW BEAM, BROAD BEAM, inverse BROAD BEAM, or calculated) and the RADIATION QUALITY in terms of the beam code, the X-RAY TUBE VOLTAGE and HALF-VALUE LAYER or the code of the radionuclide (see Clause 6).

5.2 BUILD-UP FACTOR

5.2.1 Determination

The BUILD-UP FACTOR B shall be determined according to the equations

$$B = \frac{F_N}{F_B} \text{ or } B = \frac{F_N}{F_{IB}}$$

depending on the method used for the BROAD BEAM measurement, where F_N, F_B and F_{IB} refer to the numbers obtained by measurements according to 4.2, 4.3 and 4.4, respectively. F_N and F_B or F_N and F_{IB}, respectively, shall be done in the beam of the same x-ray facility.

5.2.2 Indication

The BUILD-UP FACTOR shall be indicated by its numerical value together with the RADIATION QUALITY in terms of the beam code, the X-RAY TUBE VOLTAGE and HALF-VALUE LAYER (see Clause 6).

5.3 ATTENUATION EQUIVALENT

5.3.1 Determination

The ATTENUATION EQUIVALENTS δ_N, δ_B, δ_{IB} and , $\delta_{N,R}$ shall be determined by measurements of F_N, F_B and F_{IB} according to 4.2, 4.3 and 4.4, or calculations of $F_{N,R}$ according to 4.5, respectively, for the material under test and by comparison with the thickness of a layer of the reference material resulting within given tolerances in the same values of F_N, F_B, F_{IB} and

$F_{N,R}$, respectively. The measurements for the material and the reference material shall be done in the same beam of the same x-ray facility.

5.3.2 Indication

The ATTENUATION EQUIVALENT shall be indicated in thickness of the reference material in mm together with the method used for the determination (NARROW BEAM, BROAD BEAM, inverse BROAD BEAM or calculated), the chemical symbol or other identification of the reference material and the RADIATION QUALITY in terms of the beam code, the X-RAY TUBE VOLTAGE and HALF-VALUE LAYER or the code of the radionuclide (see Clause 6).

5.4 LEAD EQUIVALENT

5.4.1 Determination

The LEAD EQUIVALENT shall be determined as ATTENUATION EQUIVALENT, but with (a) layer(s) of lead as reference material.

NOTE LEAD EQUIVALENT values of a test material can be obtained by interpolation from measured ATTENUATION RATIOS of lead sheets of different thicknesses covering the range of interest.

5.4.2 Indication

The LEAD EQUIVALENT shall be indicated in thickness of lead in mm together with the chemical symbol for lead and the method used for the determination (NARROW BEAM, BROAD BEAM, inverse BROAD BEAM, calculated) and the RADIATION QUALITY in terms of the X-RAY TUBE VOLTAGE and HALF-VALUE LAYER or the code of the radionuclide (see Clause 6).

5.5 LEAD EQUIVALENT class for a SPECIFIED range of RADIATION QUALITIES

5.5.1 Materials

Some materials used for PROTECTIVE CLOTHING and protective patient shields in medical x-ray diagnostic as described in IEC 61331-3 need the definition of the LEAD EQUIVALENT value for a SPECIFIED range of RADIATION QUALITIES. The conditions for the assignment of such a value are described in the following subclauses.

5.5.2 Standard thicknesses

The LEAD EQUIVALENT value shall be assigned to a material for one of the following classes of lead thickness: 0,25 mm, 0,35 mm, 0,5 mm and 1 mm.

5.5.3 Conditions for assignment to a LEAD EQUIVALENT class

The LEAD EQUIVALENT class shall be assigned to a material if at least one of the following two conditions is fulfilled for a SPECIFIED range of RADIATION QUALITIES selected from the full range 30 kV – 150 kV, see Table 1:

1) The ATTENUATION RATIO F_{IB} of a material for a special RADIATION QUALITY is greater than 250.
2) The LEAD EQUIVALENT δ_{IB}, by definition determined with the inverse BROAD BEAM method according to 4.4, is equal or greater than a standard thickness of lead SPECIFIED in 5.5.2. A relative standard uncertainty of 7 % in the determination of the LEAD EQUIVALENT shall be taken into account in the decision of conformity, thus, if t_{Pb} is the standard lead thickness and δ_{IB} is the LEAD EQUIVALENT of the test material, the condition can be written as:

   $\delta_{IB} \geq 0,93\, t_{PB}$

5.5.4 Indication

The LEAD EQUIVALENT range shall be indicated in the standard thickness of lead in mm together with the chemical symbol for lead followed by the specification of the X-RAY TUBE VOLTAGE range in kV (see Clause 6).

5.6 Homogeneity

5.6.1 Determination

The homogeneity of a protective material shall be determined from measured values of F_N obtained over the area of the test object under the conditions of 4.2 and the corresponding values of ATTENUATION EQUIVALENT $\delta_{N,i}$.

These values $\delta_{N,i}$ shall be determined

– for 5 to 10 representative places, or
– continuously in representative directions over the area of the test object.

The deviation from homogeneity V of the protective material shall be determined as the greatest deviation of a single value of ATTENUATION EQUIVALENT $\delta_{N,i}$ from the mean value of ATTENUATION EQUIVALENT $\overline{\delta}_N$:

$$\overline{\delta}_N = \frac{1}{n}\sum_{i=1}^{n} \delta_{N,i}$$

$$V = \left|\overline{\delta}_N - \delta_{N,i}\right|_{max}$$

5.6.2 Indication

The inhomogeneity shall be indicated together with the ATTENUATION EQUIVALENT as tolerance in the same units, e.g.:

3 mm ± 0,2 mm Pb, NARROW BEAM, 100 kV, HVL = 3,44 mm Al (see Clause 6).

6 Statement of compliance

If for SPECIFIED ATTENUATION properties compliance with this part of IEC 61331 shall be stated, this shall be indicated as follows, e.g.:

– attenuation ratio 2×10^2: narrow beam 200 kV HVL = 1,64 mm Cu IEC 61331-1:2014;
– attenuation ratio 20: narrow beam Cs-137 IEC 61331-1:2014;
– attenuation ratio 15: calculated Ir-192 IEC 61331-1: 2014;
– build-up factor 1,4: 150 kV HVL = 5,17 mm Al IEC 61331-1:2014;
– attenuation equivalent 2 mm Fe: narrow beam 100 kV HVL = 3,44 mm Al IEC 61331-1:2014;
– attenuation equivalent 2 mm ± 0,1 mm Fe: narrow beam 100 kV HVL = 3,44 mm Al IEC 61331-1:2014;
– lead equivalent 1 mm Pb: narrow beam 300 kV HVL = 3,37 mm Cu IEC 61331-1:2014;
– lead equivalent 1 mm Pb: broad beam 300 kV HVL = 3,37 mm Cu IEC 61331-1:2014;
– lead equivalent 0,25 mm Pb: inverse broad beam 60 – 120 kV IEC 61331-1:2014.

Annex A
(informative)

Tables of ATTENUATION RATIOS, BUILD-UP FACTORS and first HALF-VALUE LAYERS

Tables A.1 to A.5 contain calculated values of ATTENUATION RATIOS, BUILD-UP FACTORS and first HALF-VALUE LAYERS of the RADIATION QUALITIES of Table 1 when filtered with additional layers of the reference material lead. Calculations are based on primary photon fluence spectra measured at the Physikalisch-Technische Bundesanstalt (PTB), Braunschweig, Germany. The values serve as guidance for testing laboratories to confirm their results. Actual values measured at testing laboratories may differ from these values by several percent due to differences in the photon fluence spectra and RADIATION DETECTORS used in measurements.

Table A.1 – ATTENUATION RATIOS F_N of lead thicknesses from 0,125 mm to 2 mm calculated for RADIATION QUALITIES of Table 1 according to the formula given in 4.5.4

mm Pb	30 kV	40 kV	50 kV	60 kV	70 kV	80 kV	90 kV	100 kV	110 kV	120 kV	130 kV	140 kV	150 kV
0	1,00E+00	1,00E+00	1,00E+00	1,00E+00	1,00E+00	1,00E+00	1,00E+00	1,00E+00	1,00E+00	1,00E+00	1,00E+00	1,00E+00	1,00E+00
0,125	8,65E+02	7,84E+01	2,70E+01	1,49E+01	1,01E+01	7,41E+00	5,88E+00	5,06E+00	4,53E+00	4,14E+00	3,83E+00	3,57E+00	3,36E+00
0,25	1,64E+05	1,50E+03	1,98E+02	6,63E+01	3,31E+01	1,97E+01	1,37E+01	1,11E+01	9,67E+00	8,67E+00	7,87E+00	7,19E+00	6,61E+00
0,35		1,24E+04	7,78E+02	1,79E+02	7,12E+01	3,68E+01	2,33E+01	1,84E+01	1,59E+01	1,42E+01	1,28E+01	1,16E+01	1,05E+01
0,5			5,08E+03	6,74E+02	1,95E+02	8,29E+01	4,64E+01	3,54E+01	3,04E+01	2,71E+01	2,44E+01	2,20E+01	1,96E+01
1				3,14E+04	3,34E+03	7,89E+02	3,04E+02	2,10E+02	1,78E+02	1,61E+02	1,47E+02	1,32E+02	1,14E+02
1,5					4,09E+04	5,53E+03	1,48E+03	9,42E+02	7,82E+02	7,10E+02	6,58E+02	5,97E+02	5,15E+02
2						3,35E+04	6,24E+03	3,72E+03	3,03E+03	2,75E+03	2,57E+03	2,37E+03	2,04E+03

Table A.2 – BUILD-UP FACTOR *B* measured for RADIATION QUALITIES of Table 1 according to the formula given in 5.2.1 for lead thicknesses 0,25 mm, 0,35 mm and 0,50 mm

mm Pb	50 kV	60 kV	70 kV	80 kV	90 kV	100kV	110 kV	120 kV	130 kV	140 kV	150 kV
0,25	1,29	1,26	1,23	1,20	1,19	1,21	1,23	1,25	1,27	1,28	1,28
0,35	1,37	1,31	1,27	1,24	1,22	1,24	1,27	1,30	1,32	1,33	1,33
0,50	1,47	1,35	1,32	1,28	1,26	1,29	1,33	1,38	1,41	1,43	1,44

NOTE Values were obtained from the measured ratio $B = \frac{F_\mathrm{N}}{F_\mathrm{IB}}$ (see 5.2.1).

Table A.3 – ATTENUATION RATIOS F_N of lead thicknesses from 0,125 mm to 7 mm calculated for RADIATION QUALITIES of Tables 1 and 2 according to the formula given in 4.5.4

mm Pb	200 kV	250 kV	300 kV	400 kV	662 keV	1 325 keV
0	1,00E+00	1,00E+00	1,00E+00	1,00E+00	1,00E+00	1,00E+00
0,125	1,62E+00	1,44E+00	1,32E+00	1,20E+00	1,02E+00	1,01E+00
0,25	2,49E+00	1,97E+00	1,68E+00	1,41E+00	1,03E+00	1,02E+00
0,35	3,41E+00	2,48E+00	1,99E+00	1,58E+00	1,04E+00	1,02E+00
0,5	5,27E+00	3,38E+00	2,51E+00	1,85E+00	1,06E+00	1,03E+00
1	1,81E+01	7,95E+00	4,78E+00	2,84E+00	1,13E+00	1,07E+00
1,5	5,11E+01	1,61E+01	8,12E+00	4,06E+00	1,21E+00	1,10E+00
2	1,30E+02	3,02E+01	1,30E+01	5,57E+00	1,28E+00	1,14E+00
2,5	3,11E+02	5,37E+01	2,00E+01	7,46E+00	1,37E+00	1,18E+00
3	7,06E+02	9,26E+01	3,01E+01	9,79E+00	1,46E+00	1,22E+00
3,5	1,55E+03	1,56E+02	4,44E+01	1,27E+01	1,55E+00	1,26E+00
4	3,31E+03	2,57E+02	6,44E+01	1,63E+01	1,65E+00	1,31E+00
4,5	6,94E+03	4,17E+02	9,23E+01	2,06E+01	1,75E+00	1,35E+00
5	1,43E+04	6,71E+02	1,31E+02	2,60E+01	1,87E+00	1,40E+00
5,5	2,91E+04	1,07E+03	1,85E+02	3,26E+01	1,99E+00	1,44E+00
6	5,84E+04	1,68E+03	2,58E+02	4,06E+01	2,12E+00	1,49E+00
6,5	1,16E+05	2,63E+03	3,58E+02	5,03E+01	2,25E+00	1,54E+00
7	2,30E+05	4,09E+03	4,95E+02	6,22E+01	2,40E+00	1,59E+00

Table A.4 – First HALF-VALUE LAYERS in mm Al of RADIATION QUALITIES of Table 1 as a function of additional lead filters of different thicknesses in the range from 0,125 mm to 2 mm

mm Pb	30 kV	40 kV	50 kV	60 kV	70 kV	80 kV	90 kV	100 kV	110 kV	120 kV	130 kV	140 kV	150 kV
0	1,0	1,4	1,8	2,1	2,4	2,8	3,1	3,4	3,8	4,1	4,5	4,8	5,2
0,125	1,8	3,0	4,2	5,3	6,3	7,2	7,9	8,4	8,9	9,2	9,6	10,0	10,3
0,25	2,0	3,5	5,1	6,4	7,6	8,6	9,4	9,9	10,2	10,5	10,8	11,1	11,5
0,35	2,0	3,7	5,4	6,9	8,2	9,3	10,1	10,5	10,7	11,0	11,3	11,6	12,0
0,5	2,1	3,9	5,8	7,4	8,8	9,9	10,7	11,1	11,3	11,5	11,7	12,1	12,5
1	2,4	4,2	6,3	8,1	9,7	10,9	11,8	12,1	12,2	12,3	12,5	12,8	13,3
1,5	2,5	4,4	6,5	8,4	10,1	11,3	12,4	12,6	12,7	12,7	12,8	13,1	13,6
2	2,6	4,5	6,6	8,6	10,3	11,6	12,7	12,9	12,9	13,0	13,0	13,2	13,8

Table A.5 – First HALF-VALUE LAYERS in mm Cu of RADIATION QUALITIES of Table 1 as a function of additional lead filters of different thicknesses in the range from 0,125 mm to 4 mm

mm Pb	200 kV	250 kV	300 kV	400 kV
0	1,6	2,5	3,4	4,5
0,125	1,8	2,8	3,7	4,9
0,25	2,0	3,1	4,0	5,1
0,35	2,2	3,3	4,2	5,3
0,5	2,4	3,6	4,5	5,5
1	3,0	4,2	5,0	6,0
1,5	3,4	4,6	5,3	6,3
2	3,7	4,9	5,5	6,5
2,5	3,9	5,0	5,7	6,6
3	4,1	5,1	5,8	6,7
3,5	4,2	5,2	5,9	6,8
4	4,3	5,3	5,9	6,9

Bibliography

IEC 61331-3, *Protective devices against diagnostic medical X-radiation – Part 3: Protective clothing and protective devices for gonads*

ISO 4037-1, *X and gamma reference radiation for calibrating dosemeters and doserate meters and for determining their response as a function of photon energy – Part 1: Radiation characteristics and production methods*

Index of defined terms used in this International Standard

NOTE In the present document terms defined either in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013, in IEC/TR 60788:2004 or in this International Standard have been used. These defined terms can be looked up at the IEC website http://std.iec.ch/glossary .

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