IEC 61331-1

Edition 2.0 2014-05

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Protective devices against diagnostic medical X-radiation –
Part 1: Determination of attenuation properties of materials

Dispositifs de protection radiologique contre les rayonnements X pour diagnostic médical –
Partie 1: Détermination des propriétés d'atténuation des matériaux

IEC 61331-1:2014-05(en-fr)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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PROTECTIVE DEVICES AGAINST DIAGNOSTIC MEDICAL X-RADIATION –

Part 1: Determination of attenuation properties of materials

FOREWORD

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International Standard IEC 61331-1 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition of IEC 61331-1, published in 1994. It constitutes a technical revision. This second edition has been adapted to apply to the present technology. In particular, this second edition is consistently applicable to lead- and non-lead-containing materials. The essential changes and extensions are:

– extension of the scope to cover photon-emitting radionuclides;
– improved methods to determine the ATTENUATION RATIO;
– addition of the so-called inverse BROAD BEAM CONDITION;
– addition of a method to calculate the ATTENUATION RATIO of photon-emitting radionuclides;
– definition of new standard X- and gamma RADIATION QUALITIES used for testing;
– addition of the so-called LEAD EQUIVALENT class;

– tables of ATTENUATION RATIOS, BUILD-UP FACTORS and first HALF-VALUE LAYERS for the standard RADIATION QUALITIES filtered with different thicknesses of lead.

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

FDIS	Report on voting
62B/936/FDIS	62B/942/RVD

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

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

In this standard, the following print types are used:

– requirements and definitions: roman type;.
– informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;
– TERMS DEFINED IN CLAUSE 3 OF THIS STANDARD OR AS NOTED: SMALL CAPS.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;
– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
– "may" is used to describe a permissible way to achieve compliance with a requirement or test.

A list of all parts of the IEC 61331 series, published under the general title *Protective devices against diagnostic medical X-radiation,* can be found on the IEC website.

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

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

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;

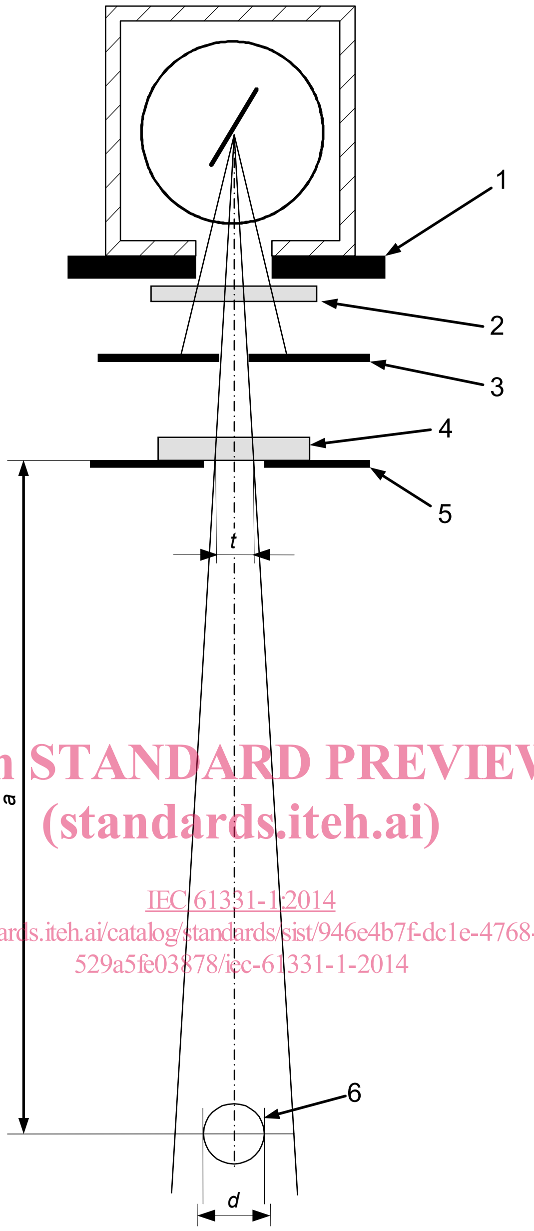
$\dot{K}_B$ the AIR KERMA RATE with the test object in the beam replaced by a sheet of material of the same shape with an ATTENUATION RATIO greater than 10^5.

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;

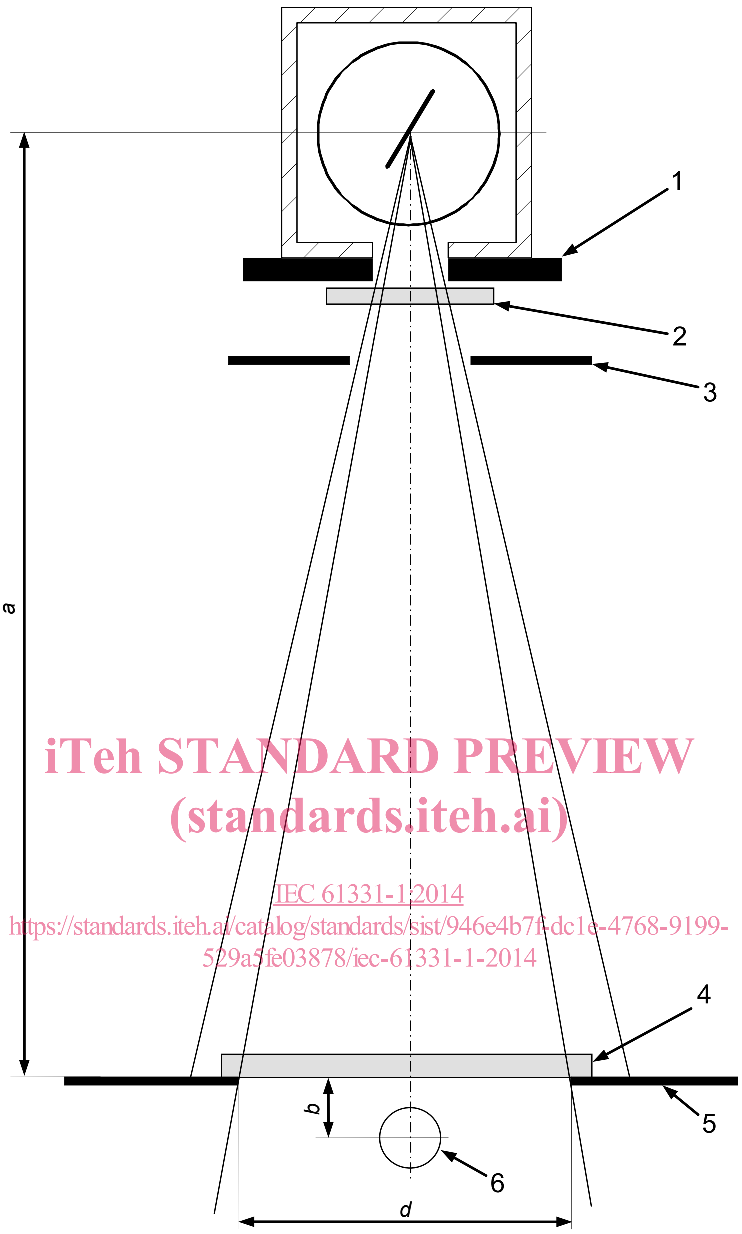
$\dot{K}_B$ the AIR KERMA RATE with the test object in the beam replaced by a sheet of material of the same shape with an ATTENUATION RATIO greater than 10^5.

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.



IEC 1445/14

1 DIAPHRAGM

2 Beam filtration

3 DIAPHRAGM

4 Test object

5 Beam-limiting DIAPHRAGM

6 Radiation detector

Conditions: $a \geq 3\,d$, $d \geq 10\,b$

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

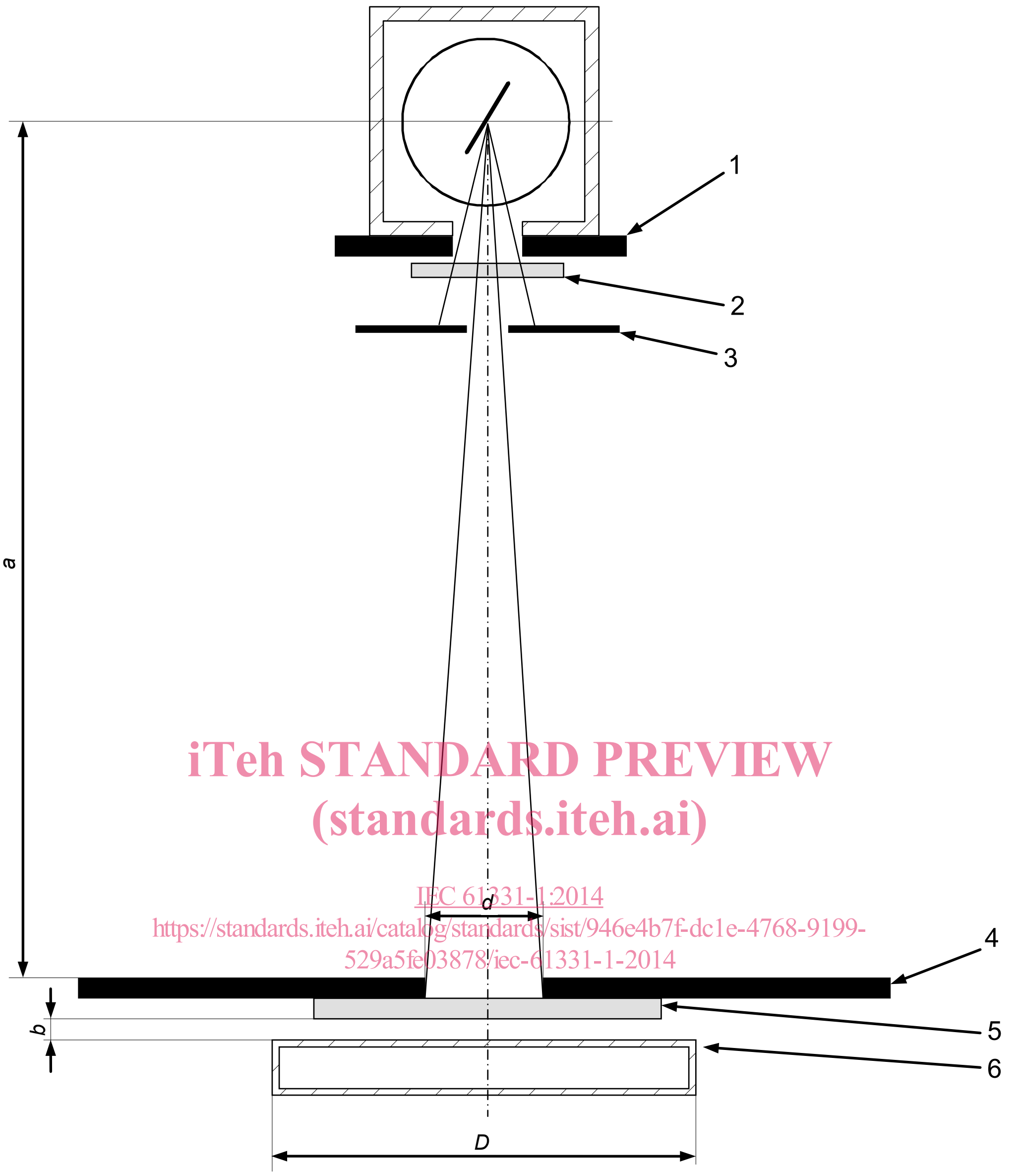
The AIR KERMA RATE shall be measured under three different conditions with the same RADIATION DETECTOR at the same position, where:

$\dot{K}_0$ 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