IEC 60522-1

Edition 1.0 2020-12

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment – Diagnostic X-rays – Part 1: Determination of quality equivalent filtration and permanent filtration

Appareils électromedicaux – Rayonnements X de diagnostic – Partie 1: Détermination de la filtration de qualité équivalenteet de la filtration permanente

IEC 60522-1:2020-12(en-fr)

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Appareils électromedicaux – Rayonnements X de diagnostic – Partie 1: Détermination de la filtration de qualité équivalenteet de la filtration permanente

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ICS 11.040.50

ISBN 978-2-8322-9036-1

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MEDICAL ELECTRICAL EQUIPMENT – DIAGNOSTIC X-RAYS –

Part 1: Determination of quality equivalent filtration and permanent filtration

FOREWORD

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International Standard IEC 60522-1 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This first edition cancels and replaces the second edition of IEC 60522 published in 1999. This edition constitutes a technical revision. This edition includes the following significant technical changes with respect to the IEC 60522:1999:

The scope of the IEC 60522-1 has been changed with respect to second edition of the IEC 60522 as follows:

a) As radiotherapy standards do not reference IEC 60522, radiotherapy is no longer in the scope. Consequently, the HIGH VOLTAGE is limited to 150 kV, and copper is no longer used as reference material.

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b) While IEC 60522:1999 covers only PERMANENT FILTRATION, IEC 60522-1 also covers quite generally “material filtering the X-RAY BEAM incident on the PATIENT”. This concerns materials like ADDED FILTERS, table-tops, a breast COMPRESSION DEVICE, and materials in the BEAM LIMITING DEVICE. For these materials the defined term FILTERING MATERIAL has been introduced.

c) In order to provide technical and scientific background and rationale on the content of IEC 60522-1, IEC TR 60522-2 [2][1] was introduced.

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

FDIS	Report on voting
62B/1201/FDIS	62B/1213/RVD

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

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

A list of all parts in the IEC 60522 series, published under the general title *Medical electrical equipment – Diagnostic X-rays*, can be found on the IEC website.

In this document, the following print types are used:

– requirements and definitions: roman type;

– TERMS DEFINED IN CLAUSE 3 OF THIS DOCUMENT OR LISTED IN THE INDEX: SMALL CAPITALS.

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

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

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

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INTRODUCTION

The review of the second edition of IEC 60522 published in 1999 pointed to a number of technical issues. The analysis of these issues is laid down in the accompanying Technical Report, IEC TR 60522-2 [2]. This Technical Report identifies those items which are substantially modified in the first edition of IEC 60522-1 compared with the second edition of IEC 60522, and elucidates the analyses which led to the many new rationales and new approaches for the determination of the QUALITY EQUIVALENT FILTRATION.

While the second edition of IEC 60522 covers only PERMANENT FILTRATION, IEC 60522-1 also covers quite generally “material filtering the X-RAY BEAM incident on the PATIENT”. This concerns materials like ADDED FILTERS, a PATIENT table, a breast COMPRESSION DEVICE, and materials in the BEAM LIMITING DEVICE. For these materials the defined term FILTERING MATERIAL has been introduced.

With the extension by FILTERING MATERIAL, IEC 60522-1 now explicitly covers what IEC 60601-1-3:2008 requires in its Subclause 7.4 for irremovable materials, i.e. <Determine the represented FILTRATION by irremovable materials in an X-RAY SOURCE ASSEMBLY ……. If this information is not obtainable, determine the QUALITY EQUIVALENT FILTRATION in accordance with IEC 60522>.

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MEDICAL ELECTRICAL EQUIPMENT – DIAGNOSTIC X-RAYS –

Part 1: Determination of quality equivalent filtration and permanent filtration

1 Scope

This document applies to X-RAY TUBE ASSEMBLIES and to FILTERING MATERIAL, in medical diagnostic applications up to a HIGH VOLTAGE of 150 kV. For HIGH VOLTAGES greater than 50 kV, this document applies to X-RAY TUBE ASSEMBLIES with tungsten or tungsten-alloy TARGETS only.

NOTE 1 The FILTERING MATERIAL in the X-RAY BEAM can be removable or irremovable; it can be positioned in any orientation or can have any shape (e.g. tapering thickness) – although usually plane-parallel material, perpendicular to the REFERENCE AXIS is applied. Examples of FILTERING MATERIALS are ADDED FILTERS, a PATIENT table (in case of an under-table X-RAY TUBE ASSEMBLY), materials in the BEAM LIMITING DEVICE, or a breast COMPRESSION DEVICE.

NOTE 2 The methodology and statement of compliance given in this document is for flat FILTERS only, but the methodology can be used for any kind of non-flat FILTER. In that case further data are included in order to produce useful results, e.g. field size, geometry/position of FILTER, etc.

This document defines the concept of PERMANENT FILTRATION of X-RAY TUBE ASSEMBLIES, and it defines the term FILTERING MATERIAL.

Methods are given to determine the PERMANENT FILTRATION of an X-RAY TUBE ASSEMBLY and for determining the QUALITY EQUIVALENT FILTRATION of FILTERING MATERIALS.

It contains requirements for statements of compliance of X-RAY TUBE ASSEMBLIES in ACCOMPANYING DOCUMENTS and for markings on X-RAY TUBE ASSEMBLIES, and for indications and statements of compliance of FILTERING MATERIAL.

NOTE 3 This document does not contain requirements for any specific values of PERMANENT FILTRATION. For X-RAY EQUIPMENT used for diagnostic purposes, FILTRATION requirements are given in e.g. IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013 or in the applicable particular standard.

NOTE 4 The method of determination described in this document is suitable as a type test. It is not intended as a test to be applied by the USER.

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

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given 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 TR 60788:2004 and the following apply.

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

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1
FILTERING MATERIAL
material between the X-RAY TUBE ASSEMBLY and the PATIENT which causes FILTRATION of the X-RAY BEAM

3.2
PERMANENT FILTRATION
QUALITY EQUIVALENT FILTRATION effected in an X-RAY TUBE ASSEMBLY by permanently fixed materials intercepting the X-RAY BEAM, that are not intended to be removed for any application and are not provided with means for removal in NORMAL USE

3.3
QUALITY EQUIVALENT FILTRATION
quantitative indication of the FILTRATION effected by one or several layer(s) of reference material(s) which, if substituted in a beam of specified RADIATION QUALITY under NARROW BEAM CONDITION for the material under consideration, give(s) the same RADIATION QUALITY as for the material under consideration

Note 1 to entry: The QUALITY EQUIVALENT FILTRATION is expressed in suitable submultiples of the metre together with the reference material(s).

Note 2 to entry: In this document, RADIATION QUALITY is characterized by its first HALF-VALUE LAYER.

[SOURCE IEC 60601-1-3:2008, 3.52, modified – Addition of a new Note 2 to entry.]

4 Determination of QUALITY EQUIVALENT FILTRATION

4.1 Alignment of X-RAY TUBE ASSEMBLIES and of the FILTERS

If, apart from the X-RAY TUBE ASSEMBLY under test, a reference X-RAY TUBE ASSEMBLY is used, then their REFERENCE AXES shall be aligned.

NOTE The alignment of the REFERENCE AXES is important, as the HALF-VALUE LAYER depends strongly on the effective TARGET ANGLE. Simulations show, that at the typical mammographic HIGH VOLTAGE of 30 kV, the typical error in PERMANENT FILTRATION is of the order of 1,5 % per one-degree misalignment. At the typical radiographic HIGH VOLTAGE of 75 kV, it is of the order of 4 %.

Unless otherwise stated, the FILTERS are positioned perpendicular to the REFERENCE AXIS.

4.2 Generation of the X-RAY BEAM for the determination

The PERCENTAGE RIPPLE shall not be larger than 10 %.

It is recommended to limit the PERCENTAGE RIPPLE to 4 %, in order to maintain accuracy.

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– if the HIGH VOLTAGE is smaller than 50 kV, or
– if the HIGH VOLTAGE is larger than 50 kV and if the atomic number of the FILTERS is larger than 30, or
– if the HIGH VOLTAGE is larger than 50 kV and the atomic number of the FILTERS is not larger than 30, while the sum of the QUALITY EQUIVALENT FILTRATION of all materials with atomic number not larger than 26 is smaller than 0,5 mm Al.

The HIGH VOLTAGE shall be kept constant during all the steps in the determination.

NOTE Stability of the HIGH VOLTAGE during the determination is important, as the HALF-VALUE LAYER depends strongly on the HIGH VOLTAGE. HIGH VOLTAGE-shift of the order of 1 % in one of the steps of the determination can lead to an error in the determined value of the QUALITY EQUIVALENT FILTRATION of the order of 10 %.

Unless other standards prescribe the HIGH VOLTAGE, the following values of the HIGH VOLTAGE are recommended:

– for mammographic applications, 28 kV,
– for dental applications, 60 kV,
– for any other application, 75 kV,
– unless the application does not include 75 kV or is centred outside 75 kV; then it is recommended to apply a HIGH VOLTAGE in the range of the application.

4.3 Requirements for RADIATION DETECTOR

An AIR KERMA RATE RADIATION DETECTOR shall be used which complies with the requirements of IEC 61674:2012 for the beam qualities seen by the detector during the QUALITY EQUIVALENT FILTRATION-determination.

NOTE This requirement ensures that the detector used has a sufficiently flat AIR KERMA RATE response.

4.4 Composition of reference material

Values of HALF-VALUE LAYER and QUALITY EQUIVALENT FILTRATION determined in accordance with this document apply to the reference material aluminium with 99,9 % purity or higher and density 2,70 g/cm^3.

4.5 Determination of PERMANENT FILTRATION

4.5.1 Guideline

NOTE For guidance and overview, Table 1 serves to support selecting the appropriate method for determining the QUALITY EQUIVALENT FILTRATION. It does not replace the text of the paragraphs 4.5.2 to 4.5.4, which are to be referenced to take the final decision on the method to be applied.

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Table 1 – Overview for the selection of methods for the determination of PERMANENT FILTRATION

Object under test	Method for PERMANENT FILTRATION	X-ray source(s) required	HIGH VOLTAGE	Figure number
X-RAY TUBE ASSEMBLY with PERMANENT FILTRATION	direct	Original X-RAY TUBE ASSEMBLY with PERMANENT FILTRATION and X-RAY TUBE ASSEMBLY with minimal FILTRATION	≤150 kV	Figure 1
(Stack of) PERMANENT FILTRATION materials	indirect	X-RAY TUBE ASSEMBLY with minimal FILTRATION	≤150 kV	Figure 2
Separate individual FILTER(S) or stack(s) of FILTERS comprising the PERMANENT FILTRATION, the QEF-values of which can reliably be added	indirect	Reference X-RAY TUBE ASSEMBLY whose X-RAY BEAM is only filtered by materials with $Z \leq 26$, with a QEF of at least 0,5 mm Al	≥50 kV and ≤150 kV	Figure 3

4.5.2 Direct determination of PERMANENT FILTRATION

For the direct determination, i.e. while applying a reference X-RAY TUBE ASSEMBLY with minimal PERMANENT FILTRATION, the measurement arrangement indicated in Figure 1, is used.

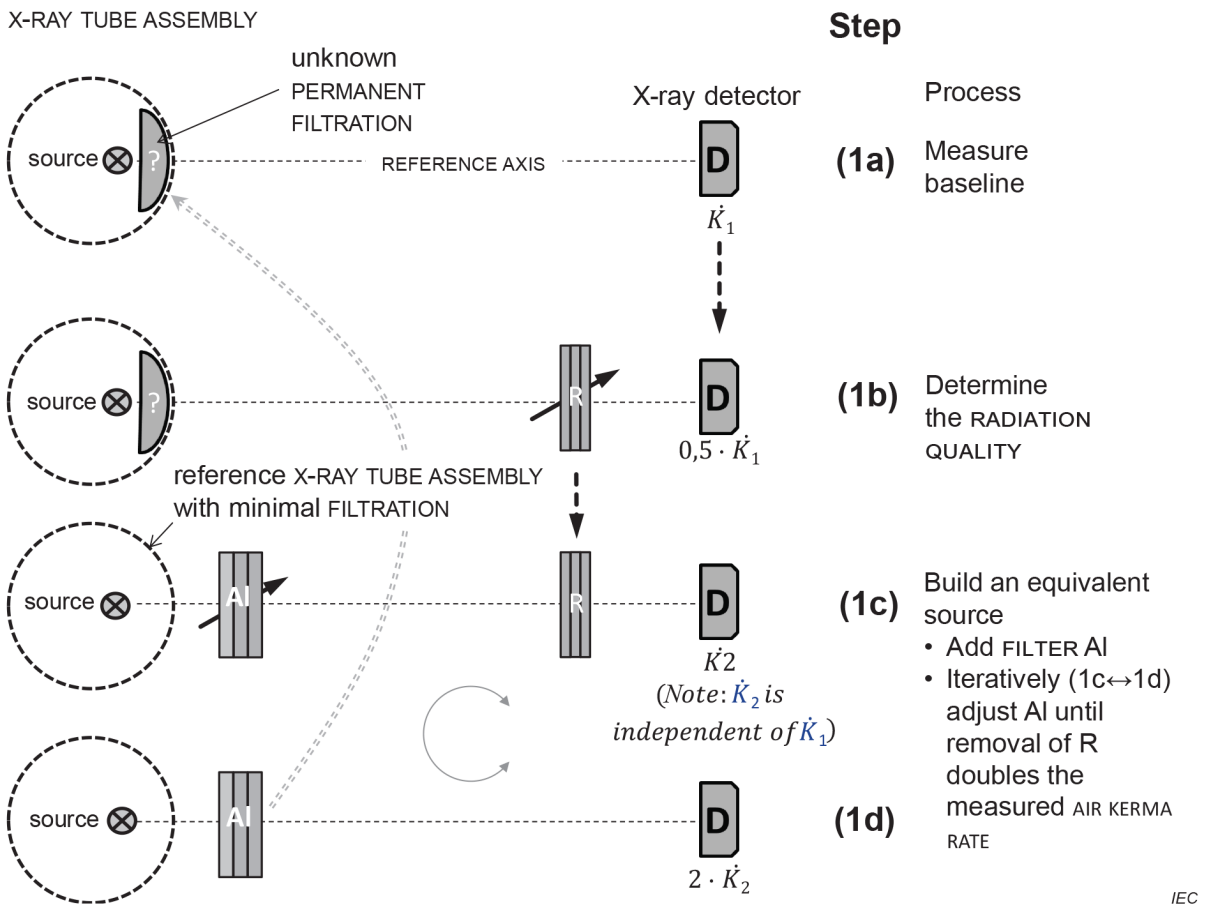

Figure 1 – Measurement steps for determining the PERMANENT FILTRATION of an X-RAY TUBE ASSEMBLY using a reference X-RAY TUBE ASSEMBLY

Steps for determining the PERMANENT FILTRATION:

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1a With the X-RAY TUBE ASSEMBLY under test, measure the AIR KERMA RATE $\dot{K}_1$ at a fixed reference HIGH VOLTAGE under the conditions stated in 4.2, using a suitable RADIATION DETECTOR (D) as described in 4.3.

1b Using an iterative measurement process, determine the HALF-VALUE LAYER referenced to aluminium of the X-RAY BEAM by adding aluminium reference FILTERS (R) into the beam until the AIR KERMA RATE is halved from the value determined in step 1a.

1c Substitute a reference X-RAY TUBE ASSEMBLY with minimal PERMANENT FILTRATION (e.g. a beryllium window X-RAY TUBE ASSEMBLY with all intervening layers of material in the X-RAY BEAM removed) in place of the X-RAY TUBE ASSEMBLY under test. The reference X-RAY TUBE ASSEMBLY shall have a TARGET with negligible roughness, and the TARGET shall be of the same material and have the same TARGET ANGLE as the TARGET of the X-RAY TUBE ASSEMBLY under test. While maintaining the reference FILTERS (R) determined from step 1b in the beam, place an aluminium FILTER (Al) into the beam and measure the resulting AIR KERMA RATE $\dot{K}_2$. Using an iterative measurement process, adjust the total thickness of the FILTER (Al) such that in step 1d the AIR KERMA RATE is doubled. The resulting thickness of the FILTER (Al) represents the PERMANENT FILTRATION of the X-RAY TUBE ASSEMBLY under test (indicated by the dashed arrow in Figure 1).

NOTE The intent of the term negligible roughness is to make sure the USER uses a tube with a non-damaged anode without major cracks, fissures, or signs of surface melting, e.g. a new tube after minimal seasoning.

1d Remove reference FILTERS (R) and compare the AIR KERMA RATE to the value determined in step 1c. The value at 1d shall be twice as large.

4.5.3 Indirect determination of PERMANENT FILTRATION – general case

The PERMANENT FILTRATION may also be determined in an indirect way, by determining the QUALITY EQUIVALENT FILTRATION of the individual material(s) of the PERMANENT FILTRATION. If the PERMANENT FILTRATION consists of one FILTER, then its QUALITY EQUIVALENT FILTRATION is the PERMANENT FILTRATION. For the determination in this case, the method indicated in Figure 2 shall be used for the FILTER itself (F1) or for a representative sample.

If the PERMANENT FILTRATION consists of a combination of materials, then the method indicated in Figure 2 may be used for the combination of materials or for a representative stack of materials.

First, the HALF-VALUE LAYER of the output from the source and the FILTER F1 is determined (steps 2a – 2b). Finally, the FILTER F1 is removed and a new FILTER Al is inserted and iteratively adjusted until the HALF-VALUE LAYER is the same as above (steps 2c – 2d).

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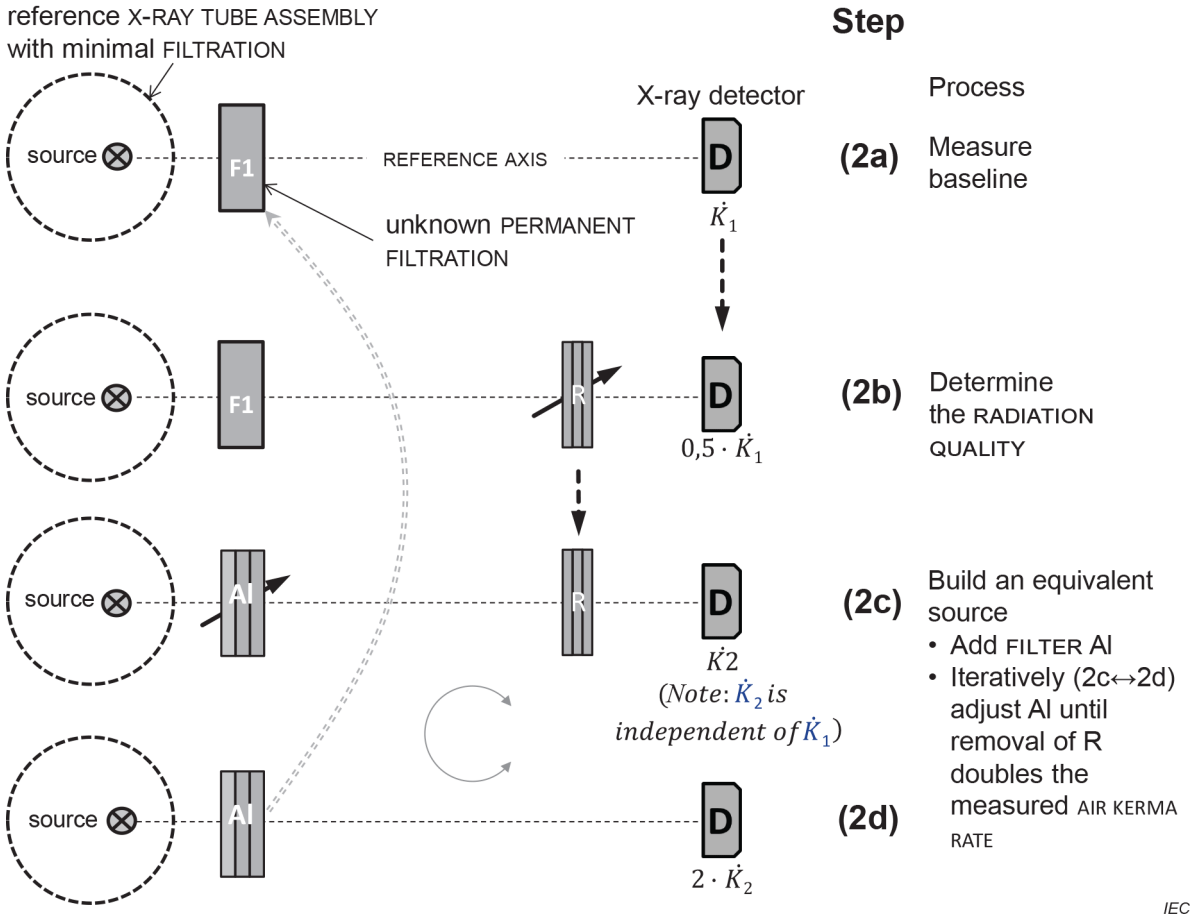

Figure 2 – Measurement steps for determining the QUALITY EQUIVALENT FILTRATION of a FILTER – general case

Steps for determining the QUALITY EQUIVALENT FILTRATION:

2a The X-RAY TUBE ASSEMBLY used for this test shall have minimal PERMANENT FILTRATION (e.g. a beryllium window X-RAY TUBE ASSEMBLY with all intervening layers of material in the X-RAY BEAM path removed) and shall have a TARGET with negligible roughness. The TARGET shall be of the same material and have the same TARGET ANGLE as the TARGET of the X-RAY TUBE ASSEMBLY under test. Place the FILTER (F1) to be measured in the X-RAY BEAM. Measure the AIR KERMA RATE $\dot{K}_1$ at a fixed reference HIGH VOLTAGE, under the conditions stated in 4.2, using a suitable RADIATION DETECTOR (D) as described in 4.3.

2b Using an iterative measurement process, determine the HALF-VALUE LAYER referenced to aluminium of the X-RAY BEAM by adding aluminium reference FILTERS (R) into the beam until the AIR KERMA RATE is one-half of the value determined in step 2a.

2c While maintaining the reference FILTERS (R) determined from step 2b in the beam, remove the FILTER (F1) and replace it with aluminium FILTER (Al) and measure the resulting AIR KERMA RATE $\dot{K}_2$. Using an iterative measurement process, adjust the total thickness of the FILTER (Al) such that the AIR KERMA RATE is doubled in step 2d. The resulting thickness of the FILTER (Al) represents the QUALITY EQUIVALENT FILTRATION of the FILTER (F1) under test (indicated by the dashed arrow in Figure 2).

2d Remove reference FILTERS (R) and compare the AIR KERMA RATE to the value determined in step 2c. The value at 2d shall be twice as large.

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