IEC TR 60522-2

Edition 1.0 2020-10

TECHNICAL REPORT

colour inside

Medical electrical equipment – Diagnostic X-rays – Part 2: Guidance and rationale on quality equivalent filtration and permanent filtration

IEC TR 60522-2:2020-10 (en)

IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

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Medical electrical equipment – Diagnostic X-rays – Part 2: Guidance and rationale on quality equivalent filtration and permanent filtration

INTERNATIONAL ELECTROTECHNICAL COMMISSION

ICS 11.040.50 ISBN 978-2-8322-8880-1

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Part 2: Guidance and rationale on quality equivalent filtration and permanent filtration

FOREWORD

IEC TR 60522-2 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice. It is a Technical Report.

The text of this Technical Report is based on the following documents:

Draft	Report on voting
62B/1136/DTR	62B/1159/RVDTR

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

The language used for the development of this Technical Report is English.

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

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;

– 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 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- withdrawn,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.

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INTRODUCTION

This document supports IEC 60522-1.

The purpose of this document is to identify those items which are substantially modified in IEC 60522-1 versus the 2nd Edition of IEC 60522, published in 1999, as well as to elucidate the technical analyses which led to the many new rationales and new approaches for the determination of the QUALITY EQUIVALENT FILTRATION (abbreviated, where appropriate, like in figures and tables, by "QEF").

The review of IEC 60522:1999 pointed to several technical issues, as discussed in Clause 4. These issues have been investigated with the help of a RADIATION BEAM HALF-VALUE LAYER simulation tool, based on the SRS-78 code (see [2][1]) and the NIST X-ray mass ATTENUATION COEFFICIENTS [4]. On this basis, HALF-VALUE LAYER values can reliably be obtained (see [3]). (For further confirmation of the tool's accuracy, the tool has been validated against laboratory measurements, with good results – see 9.2).

With this tool, the properties of the RADIATION BEAM can be analysed as a function of the TARGET material, TARGET ANGLE, HIGH VOLTAGE and FILTER material.

It appears then that the following statements in the IEC 60522:1999 are not always true:

1) on the concept of adding individual values of QEF to obtain the total QEF value, i.e. the concept of "additivity" (see 5.5 for details);
2) on the relevance of the K-edge for RADIOGRAPHY, and
3) on the method for determining the PERMANENT FILTRATION on the basis of a composite sample of the materials.

Further, it appears that the method of choice for the determination depends on the class of FILTER material and HIGH VOLTAGE. Two ranges of HIGH VOLTAGE are discerned:

1) up to 50 kV;
2) from 50 to 150 kV.

In this document, for ease of use, the term "RADIOGRAPHY" is used for applications within the HIGH VOLTAGE range 50 kV to 150 kV, although strictly speaking the defined term "RADIOGRAPHY" does not limit the HIGH VOLTAGE. So "RADIOGRAPHY", i.e. if it is *not* written in small capitals in order to discern it from the IEC defined term, thus covers applications in the scope of [6] IEC 60601-2-43 (INTERVENTIONAL PROCEDURES), [7] IEC 60601-2-44 (CT), [9] IEC 60601-2-54 (RADIOGRAPHY and RADIOSCOPY), [10] IEC 60601-2-63 and [11] IEC 60601-2-65 (dental applications).

For RADIOGRAPHY, three groups of FILTER materials are discerned, see a) to c).

The term "mammography" is used in this document, for applications up to 50 kV HIGH VOLTAGE. (If mammographic applications go beyond 50 kV, then these are considered to fall within RADIOGRAPHY).

For RADIOGRAPHY, three groups of FILTER materials are discerned, see a) to c).

a) atomic number not larger than 26 e.g. the materials Cr (Z=22), Ti (Z=24) and Fe (Z=26); these materials may FILTER like aluminium, so they are designated in this document as "Al-like";

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

b) atomic number larger than 26, but not larger than 30; in *combination with* the materials of the former group, i.e. “atomic number not larger than 26”, these materials may also act “Al-like”. An important example in this group of materials is copper (Z=29);

c) atomic number larger than 30.

Due attention is given to relatively new FILTERS (Au, W, Ta, Ag, Sn) as applied in RADIOGRAPHY and in mammography.

Recommendations are given for the HIGH VOLTAGE to be used per type of application, HIGH VOLTAGE stability, VOLTAGE RIPPLE; for the alignment of the X-RAY TUBE ASSEMBLIES for the determination of the PERMANENT FILTRATION and for the choice of a representative TARGET ANGLE for the determination of the QUALITY EQUIVALENT FILTRATION of FILTERING MATERIAL.

The results of this document are based on the analyses of error-propagation of many parameters (see e.g. Clauses 6, 7, 8 and Table 1; see also 10.1). In general, the prediction of the total error of a QEF determination is beyond the scope of this document – as each measurement system will be designed with its own balance in parameters and their accuracy. It is thus left up to the manufacturers to analyse the total error of their measurement system, while using, where appropriate, the error-propagation as analysed in this document.

MEDICAL ELECTRICAL EQUIPMENT – DIAGNOSTIC X-RAYS –

Part 2: Guidance and rationale on quality equivalent filtration and permanent filtration

1 Scope

This document provides guidance on quality equivalent filtration and permanent filtration with regards to the requirements of IEC 60522-1 and its modifications versus IEC 60522:1999.

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 60522:1999, *Determination of the permanent filtration of X-ray tube assemblies*

IEC 60522-1:2020, *Medical electrical equipment – Diagnostic X-rays – Part 1: Determination of quality equivalent filtration and permanent filtration*

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 60613:2010, *Electrical and loading characteristics of X-ray tube assemblies for medical diagnosis*

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

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 and IEC 60601-1:2005/AMD2:2020, IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013, IEC 60613:2010, IEC 60522-1:2020, and IEC TR 60788:2004 apply.

4 Technical issues in IEC 60522:1999

4.1 General

While reviewing the processes described in IEC 60522:1999, several technical issues appear to require further analysis:

4.2 Subclause 4.1, second dash, of IEC 60522:1999

Text:
<the RADIATION QUALITY of the X-RAY BEAM used for the determination is adjusted to compensate for the absence of any components of the PERMANENT FILTRATION missing from the sample and normally located between the sample and the FOCAL SPOT>.

Issue: At this stage it is not clear how the "adjustment" should be obtained. It might be explained in IEC 60522:1999 as discussed in 4.6.

4.3 Subclause 4.3, first paragraph, of IEC 60522:1999

Text:
<To generate the X-RAY BEAM for measurement, use an X-RAY TUBE with a TARGET of the same material as the X-RAY TUBE ASSEMBLY under test at an X-RAY TUBE VOLTAGE with a PERCENTAGE RIPPLE not exceeding 10 ...>.

Issue: A ripple of up to 10 % seems quite lenient – it might not be valid for all situations.

4.4 Subclause 4.3, item a) of IEC 60522:1999

Text:
<… for X-RAY TUBE ASSEMBLIES in which the PERMANENT FILTRATION contains a material with a K-edge absorption energy at 19 keV or above, use an X-RAY TUBE VOLTAGE corresponding to the K-edge energy of the material, for example 20 kV for molybdenum with a K-edge at 19,99 keV; otherwise …>

Issues: A HIGH VOLTAGE of 20 kV is less relevant for newer mammography systems, which operate over a wider X-RAY TUBE VOLTAGE range than was typical in the past. Further, the determination is performed at the K-edge energy, whereas 4.5 of IEC 60522:1999 suggests the contrary. <It is desirable to avoid testing close to the absorption edge of tungsten …>.

4.5 Subclause 4.3, item d), last phrase, of IEC 60522:1999

Text:
<… for X-RAY TUBE ASSEMBLIES with a NOMINAL X-RAY TUBE VOLTAGE exceeding 65 kV, 75 kV or approximately half the NOMINAL X-RAY TUBE VOLTAGE, whichever is the greater. It is desirable to avoid testing close to the absorption edge of tungsten …>.

Issue: It is unclear why testing close to the absorption edge of tungsten is "not desirable", particularly so because in this situation there is very limited flux at the "absorption edge of tungsten".

4.6 Subclause 4.3, last paragraph, of IEC 60522:1999

Text:
<For testing with a composite sample, use an X-RAY BEAM with negligible TOTAL FILTRATION (e.g. a beryllium window). For testing with a sample of a single material, add an appropriate thickness of the reference material between the material under test and the FOCAL SPOT. This is to compensate for the effect on the RADIATION QUALITY at the ENTRANCE SURFACE of the sample of omitting any layers of material forming part of the actual PERMANENT FILTRATION.>.

Issues: It is unclear how the "thickness of reference material" is determined. It might be that the "actual layer forming part of the actual PERMANENT FILTRATION" shall be placed between the sample and the FOCAL SPOT.

4.7 Subclause 4.6, second paragraph, second phrase of IEC 60522:1999

As to the addition of the values of the QUALITY EQUIVALENT FILTRATION (QEF), the following text: <If the sample is a composite one, representing all the materials comprising the PERMANENT FILTRATION, the result is also the value of the PERMANENT FILTRATION for the X-RAY TUBE ASSEMBLY concerned. Alternatively, add the values obtained (with the same reference material and primary beam conditions) for the QUALITY EQUIVALENT FILTRATION of samples representing all the different single materials forming part of the PERMANENT FILTRATION.>.

In view of the various dependencies of the QEF on HIGH VOLTAGE for many of the practical materials, there is doubt whether "addition" is a valid concept.

5 Influence of HIGH VOLTAGE and of atomic number of FILTER MATERIAL

5.1 General

IEC 60601-1-3 focusses on "classical" RADIOGRAPHY, i.e. the 50 kV to 150 kV HIGH VOLTAGE range – see Table 3 of IEC 60601-1-3:2008, which covers this range (and in a Note indicates <HALF-VALUE LAYERS for other voltages shall be obtained by linear interpolation or extrapolation.>). Consequently, this analysis starts with the 50 kV to 150 kV HIGH VOLTAGE range, in 5.2 and 5.3 of this document. Mammography is treated in 5.4 of this document.

The typical FILTER materials for these two applications are indicated in Figure 1.

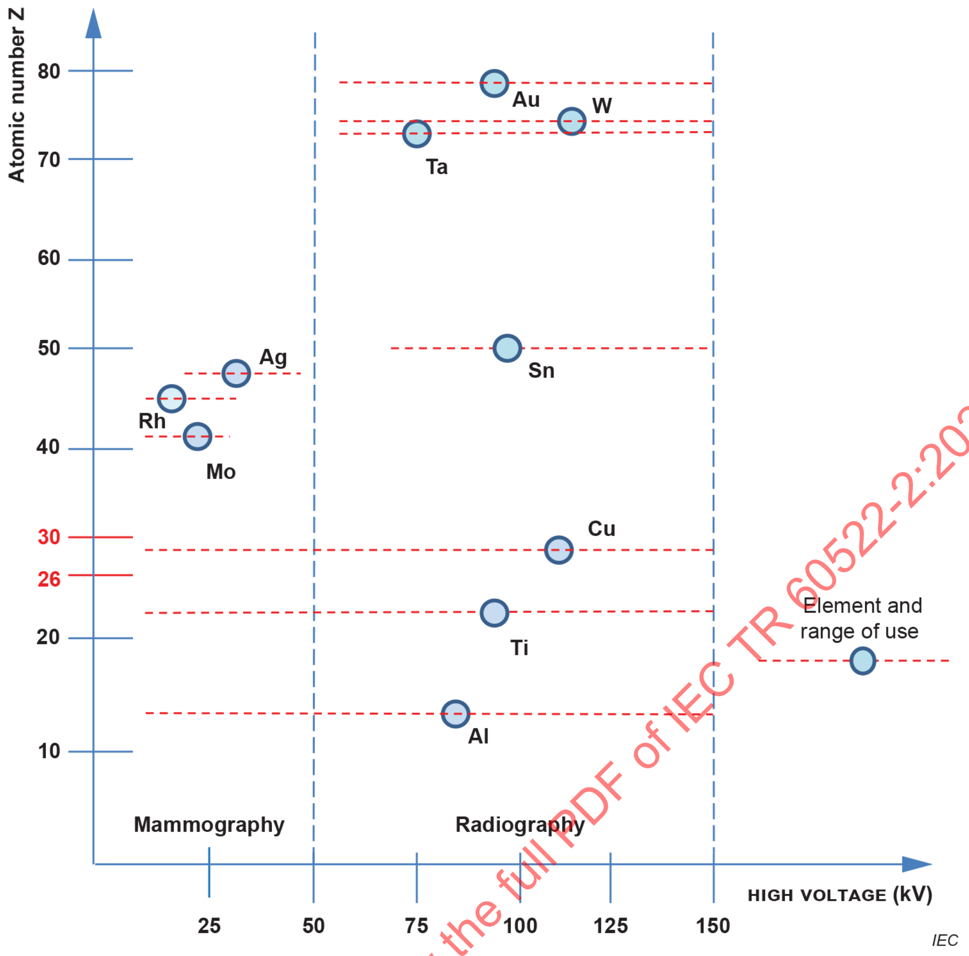


Figure 1 – Typical FILTER materials for mammography and RADIOGRAPHY

5.2 RADIOGRAPHY – Atomic number of FILTERS ≤30

Except for the reference material aluminium (aluminum, Al), the QEF depends on HIGH VOLTAGE. To illustrate this dependency, the method of determination "according to IEC 60522:1999", i.e. an X-RAY TUBE ASSEMBLY with minimal PERMANENT FILTRATION (Be-window) is used to draw Figure 2. The materials indicated could represent the PERMANENT FILTRATION of an X-RAY TUBE ASSEMBLY, or the QUALITY EQUIVALENT FILTRATION of an ADDED FILTER.

Regular FILTER materials in the radiographic range are Al, Ti and Cu. Figure 2 depicts the QUALITY EQUIVALENT FILTRATION for these and other materials with intermediate and higher atomic number as a function of the HIGH VOLTAGE. For this example X-RAYS are generated from a tungsten TARGET with TARGET ANGLE 10°. No pre-FILTRATION is applied. The thicknesses of the FILTERS are normalized at 125 kV and chosen such that the individual FILTERS have the same QUALITY EQUIVALENT FILTRATION at the reference HIGH VOLTAGE 125 kV. In this case, for example, the Cu FILTER shall have a thickness of 0,1 mm.

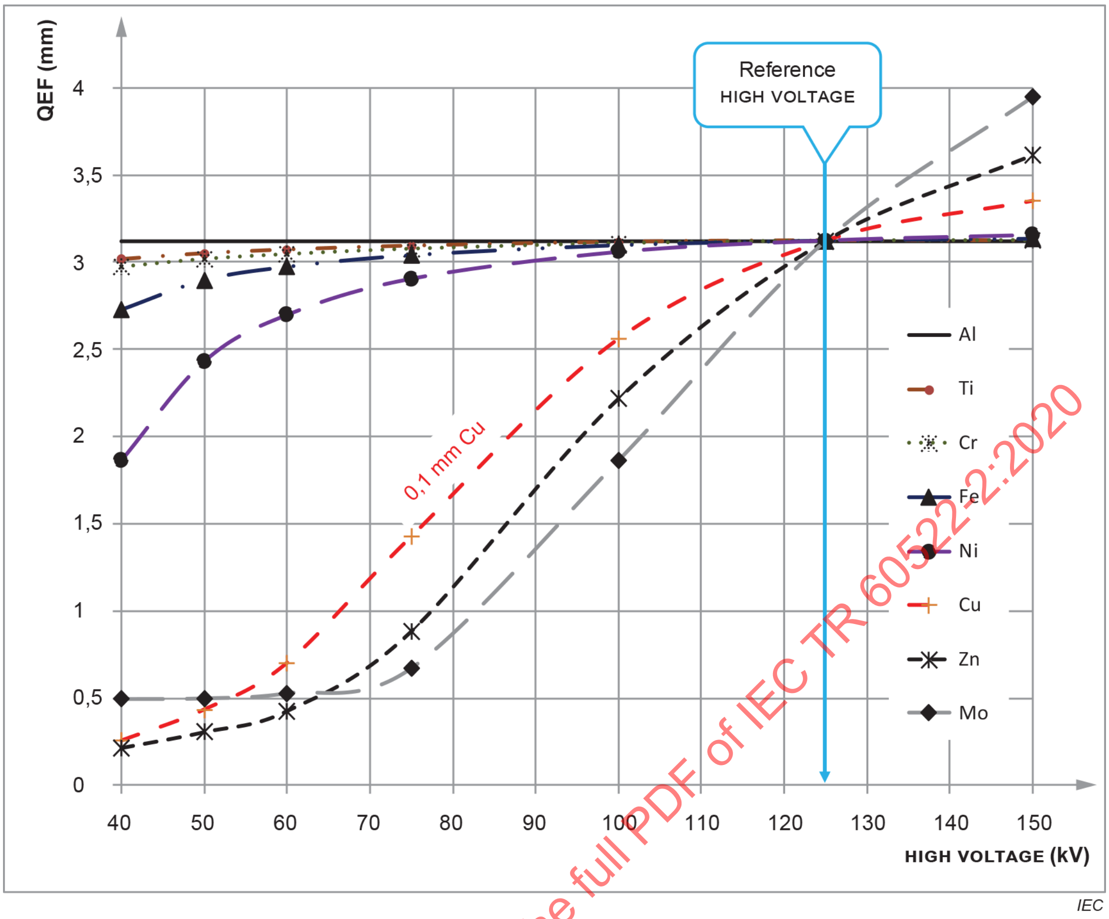
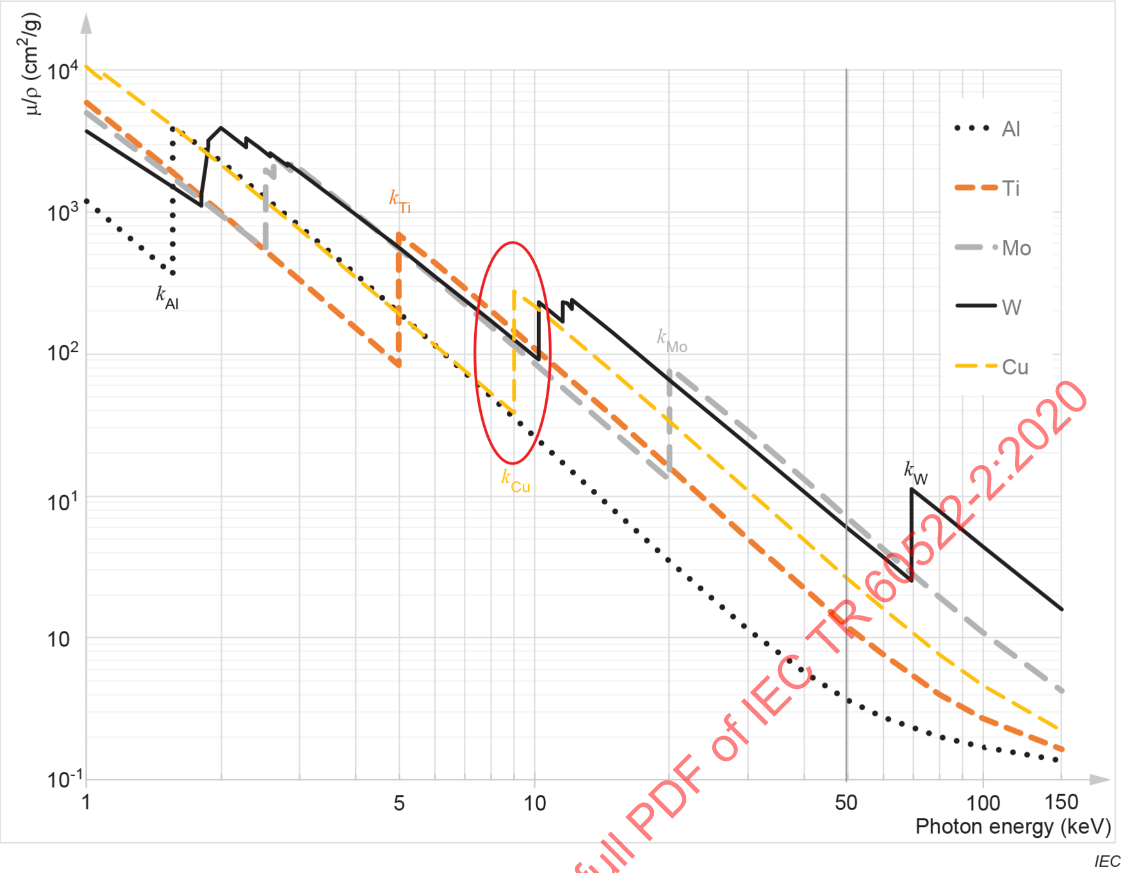


Figure 2 – QUALITY EQUIVALENT FILTRATION of elements as a function of HIGH VOLTAGE

Figure 2 shows how, under realistic conditions, the QUALITY EQUIVALENT FILTRATION depends on the HIGH VOLTAGE, except for the reference Al (Z=13). The discrepancy is relatively small for atomic numbers Z up to 26 (Fe). But, the effect is large and growing with Z for Ni (Z=28), Cu (Z=29), Zn (Z=30) and Mo (Z=42). The reason for this is the discontinuity of the ATTENUATION COEFFICIENTS of these materials at their K-edges. Those discontinuities appear within or close to the relevant range of photon energies, which has a significant influence, see Figure 3.

NOTE 1 Mo is normally not used in RADIOGRAPHY – it has been added here because Mo is a telling example of a FILTER material with considerably higher atomic number than 30.

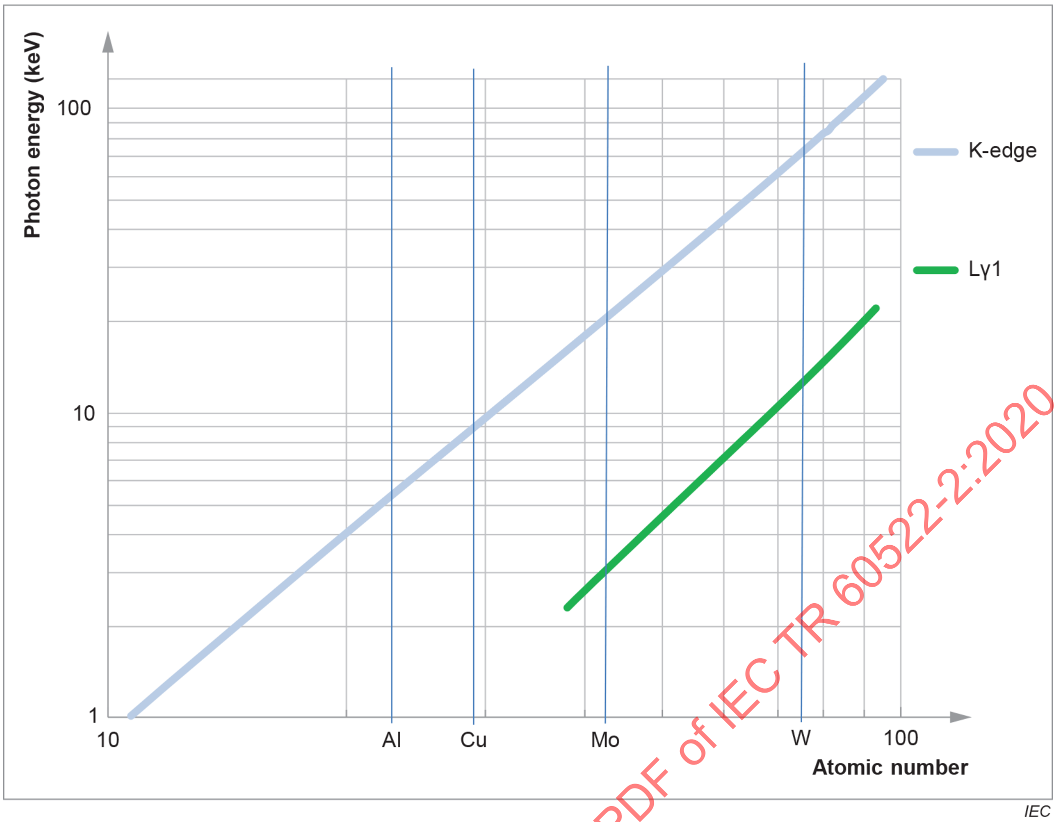
Given the fact that the reference material is aluminium, the effect of HIGH VOLTAGE on QEF of a different material will be small if the ATTENUATION COEFFICIENT, which is a function of the of photon energy of the other material in question, has a similar slope in a double logarithmic plot as that of aluminium for the relevant range of HIGH VOLTAGE. Such materials are called “Al-like” in this document. Figure 3 depicts the dependency of mass ATTENUATION (μ/ρ) on photon energy for typical materials. Data were adapted from reference [4]. μ denotes the ATTENUATION COEFFICIENT per unity length in the Lambert-Beer law and ρ the mass density of the attenuating material. The functions for “Al-like” materials can be sufficiently well transformed into each other by vertical shift in the double logarithmic graph, which means, by multiplication with a constant factor. In the monotonous low energy portions of the functions, where photoelectric absorption dominates over scattering, and for Z<30, the attenuation coefficient (μ/ρ) scales with about $1/Z^3$.



Data adapted from reference [4]. Axes logarithmic

Figure 3 – Mass X-ray attenuation coefficients (μ/ρ) vs. photon energy

A material can only behave “Al-like”, if its K-edge does not fall into the relevant range of photon energies, (and, of course, lack other discontinuities like L-edges) see Figure 3 and Figure 4. Figure 3 depicts K-edges and attenuation coefficients of the reference material Al, and Ti, Mo, W and Cu. Observe the K-edge of Cu at 8,993 keV (encircled), which is close to the lower end of the spectrum relevant for diagnostic medical imaging.



SOURCE: Data adapted from Figure 2.13 of reference [5].

Figure 4 – Energetic location of discontinuities of the absorption coefficients (vertical axis) of elements vs. their atomic number, characteristic lines, L- and K-edge energies

Cu, Mo, and W do not behave "Al-like".

NOTE 2 Other than for Al and Ti, the ATTENUATION COEFFICIENT of Cu comprises its K-edge at 8,993 keV, see above. Such low energy photons can become important for non-diagnostic X-RAY sources with very little ADDITIONAL FILTRATION.

NOTE 3 Typically, the Cu K-edge low energy radiation is irrelevant for medical diagnostic image generation. Moreover, as such low energy photons are potentially hazardous as they tend to enhance the patient skin dose, X-RAY sources comprising Cu as a FILTER are usually also equipped with an Al-FILTER in addition.

The dependency on HIGH VOLTAGE appears to be the larger the higher Z is. In other words, using the IEC 60522:1999 method of determination, an unambiguous scalar QUALITY EQUIVALENT FILTRATION of a FILTER does not exist. Rather, the resulting value should be described as a function of the HIGH VOLTAGE, especially for the practical material Cu and for material with higher Z.

However, in a practical radiographic system, there will often be additional low-Z material in the beam. This may be glass, oil or Al in the X-RAY port of an X-RAY TUBE ASSEMBLY. This additional FILTER material may delimit the output spectrum such that the effect, which the K-edge of Cu imprints, becomes irrelevant, see explanations to Figure 8 and Figure 9 below. If the beam also passes such additional low-Z material, then the peculiarities of the ATTENUATION COEFFICIENT for low HIGH VOLTAGES are considerably damped. The result can be that in such a case the QUALITY EQUIVALENT FILTRATION of such higher Z materials, including Zn (Z=30), then also hardly depends on HIGH VOLTAGE. Similarly, the QUALITY EQUIVALENT FILTRATION of such material will then hardly change if more Al is added.

For illustration, Figure 5 shows a simulation of the QEF of a 0,1 mm Cu FILTER combined with an additional Al FILTER with varying thickness of up to 2,5 mm.

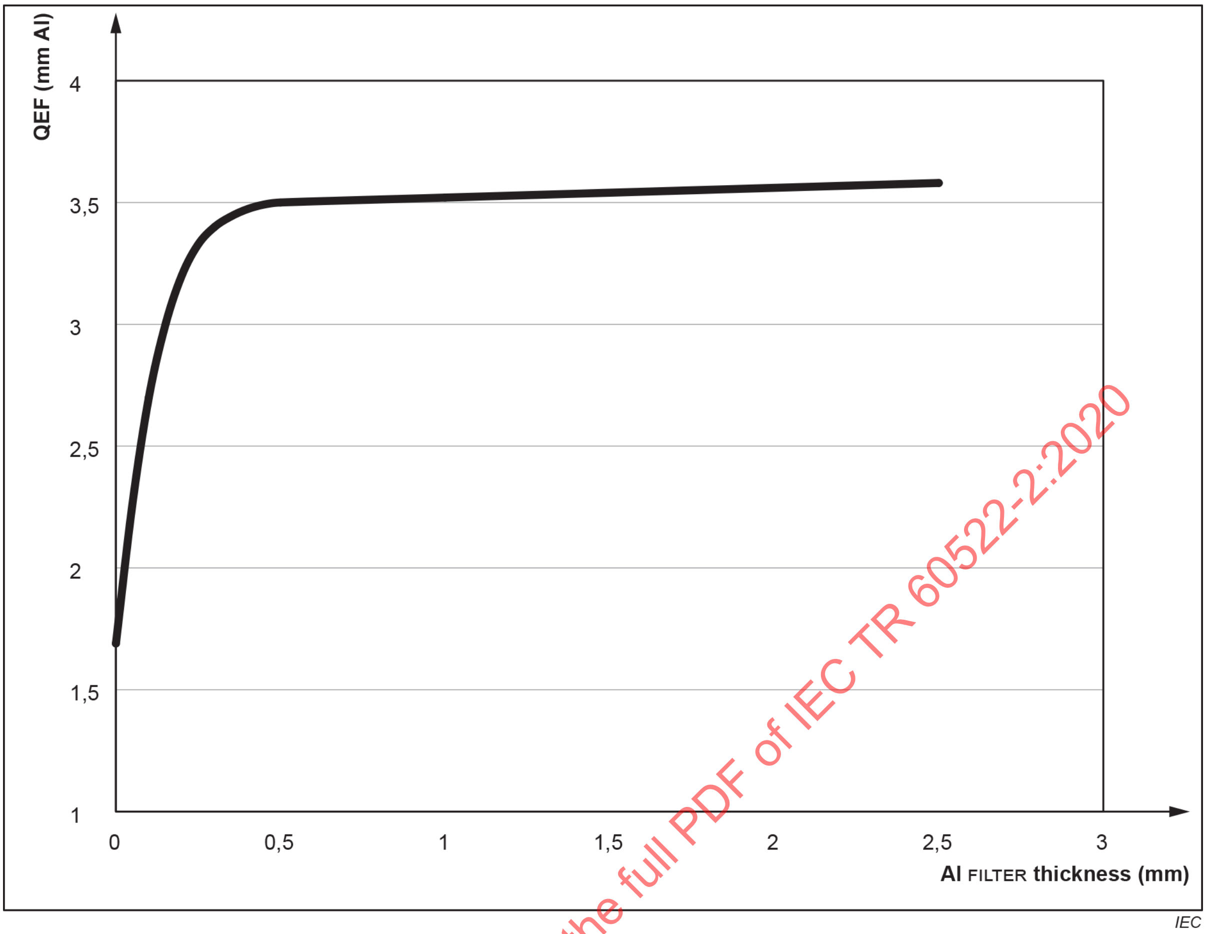


Figure 5 – QEF of 0,1 mm Cu FILTER vs. thickness of an additional Al FILTER (at HIGH VOLTAGE of 75 kV)

Remarks:

a) The QUALITY EQUIVALENT FILTRATION of a Cu FILTER depends indeed on the existence of other FILTERS in the beam, notably the presence of an Al FILTER. This effect has consequences for the suitability of the concept of additivity, and for the determination of the QUALITY EQUIVALENT FILTRATION, which is further discussed in 5.5.

b) For thickness 0,3 mm Al and higher, the QUALITY EQUIVALENT FILTRATION of the Cu FILTER approaches to the asymptotic value of 3,5 mm Al. This value is indeed close to the first order approximate value (i.e. ATTENUATION is proportional to thickness, to Z^3 and to density; so for Cu relative to Al: 0,1 multiplied by $[29/13]^3$, multiplied by [8,94/2,7], equals 3,68).

The dependency on HIGH VOLTAGE for the cases in Figure 2, with an additional 1,0 mm Al FILTER, is given in Figure 6. As expected, the dependence on HIGH VOLTAGE is small.

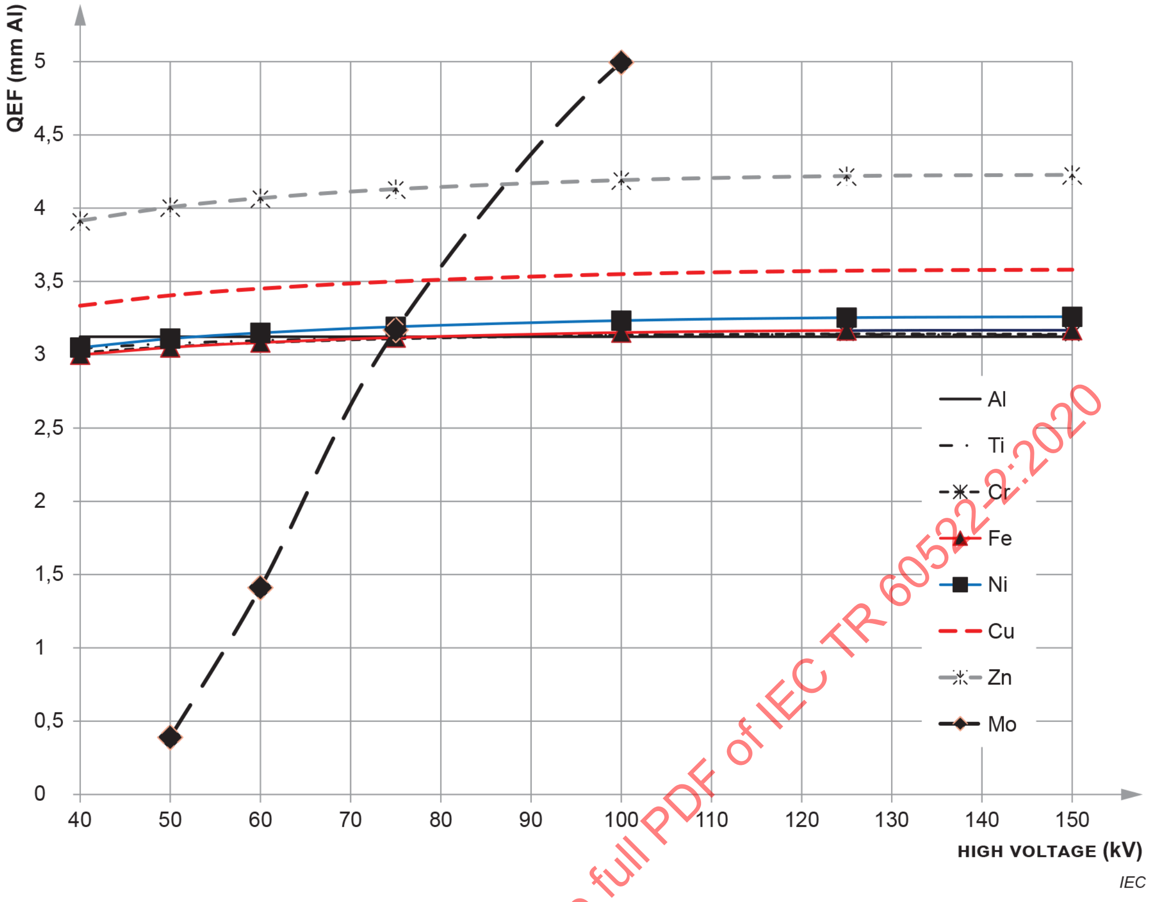


Figure 6 – QUALITY EQUIVALENT FILTRATION of elements with 1,0 mm Al pre-FILTRATION as a function of HIGH VOLTAGE (W TARGET with TARGET ANGLE 10°, thickness according to Figure 2)

NOTE 4 Considerable dependence on the HIGH VOLTAGE remains for the Mo FILTER, normally used in mammography. Other than for Cu, additional Al-FILTRATION does not render materials like Mo and W to behave "Al-like".

A similar, but larger, dependency is found for a thinner (0,5 mm Al) FILTER. Using a 0,3 mm Al FILTER, the dependency is considerably greater (13,5 % change between 50 kV and 150 kV).

Data on the influence of pre-FILTRATION by Al are summarized in Table 1. The lower limit for FILTRATION by Al, which for practical purposes makes the QUALITY EQUIVALENT FILTRATION of Cu practically independent of the HIGH VOLTAGE, is set at 0,5 mm Al.

Table 1 – QEF-variation of 0,1 mm Cu FILTER with Al pre-FILTRATION

Al thickness mm	QEF-variation of 0,1 mm Cu over range 50 kV to 150 kV %
0,3	13,5
0,5	6,0
1,0	4,3
2,5	2,8

In view of the relatively small dependence on HIGH VOLTAGE in Figure 2 for materials Ti (*Z*=22), Cr (*Z*=24), and Fe (*Z*=26), it is expected that these materials have a similar effect as Al, i.e. they behave "Al-like". This is indeed the case, see Figure 7, which shows the effect of FILTRATION by these materials (each having a thickness corresponding to 0,5 mm Al QUALITY EQUIVALENT FILTRATION) on the QUALITY EQUIVALENT FILTRATION of an 0,1 mm Cu FILTER: again only a small dependence on HIGH VOLTAGE results. The graphs coincide, except for the unfiltered case.

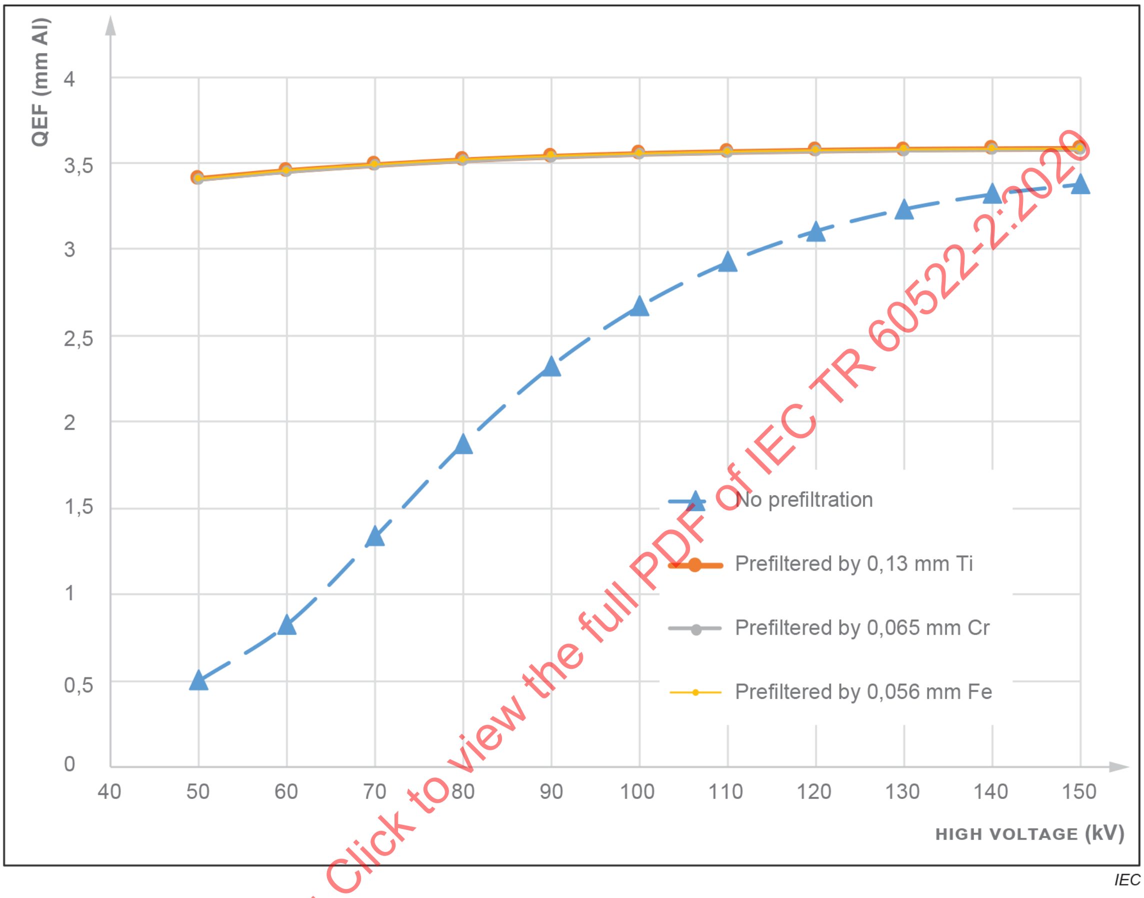


Figure 7 – QEF of 0,1 mm Cu as determined with various pre-FILTRATION materials as a function of HIGH VOLTAGE

Remarks:

a) The statement, that the lower limit of FILTRATION by Al, which for practical purposes makes the QUALITY EQUIVALENT FILTRATION of Cu practically independent of the HIGH VOLTAGE, is set at 0,5 mm Al, is related to Table 1. It can thus be more generally formulated as: The lower limit of the FILTRATION which for practical purposes makes the QUALITY EQUIVALENT FILTRATION of Cu and Zn practically independent of the HIGH VOLTAGE, is set at a QUALITY EQUIVALENT FILTRATION of 0,5 mm Al produced by materials with $Z \leq 26$ in the beam.

b) With "Al-like" FILTRATION for the cases above, the QUALITY EQUIVALENT FILTRATION will also hardly depend on the TARGET ANGLE, see 8.2.

c) For those cases above, for which the QUALITY EQUIVALENT FILTRATION hardly depends on the HIGH VOLTAGE, there is in principle no need to indicate the HIGH VOLTAGE in the statement of PERMANENT FILTRATION, see IEC 60522-1; see also 10.2.

The effect of additional "Al-like" FILTRATION can also be understood by its effect on the RADIATION BEAM spectrum. This is illustrated in Figure 8, which compares X-RAY spectra from a 12° W TARGET without pre-FILTRATION for FILTER materials which have the same QEF at HIGH VOLTAGE 100 kV, (i.e. 0,1 mm Cu vs. 2,5 mm Al). The pronounced intensity peak right below the K-edge of Cu at about 9 keV results in significant discrepancy between the intensity-normalized spectra, if no Al FILTRATION is applied. The figure compares the spectrum after passing through its quality equivalent thickness of Al for 100 kV HIGH VOLTAGE, in this case 2,5 mm Al, and a spectrum normalized to equal total intensity. The normalized Al-spectrum does not match the Cu-spectrum.

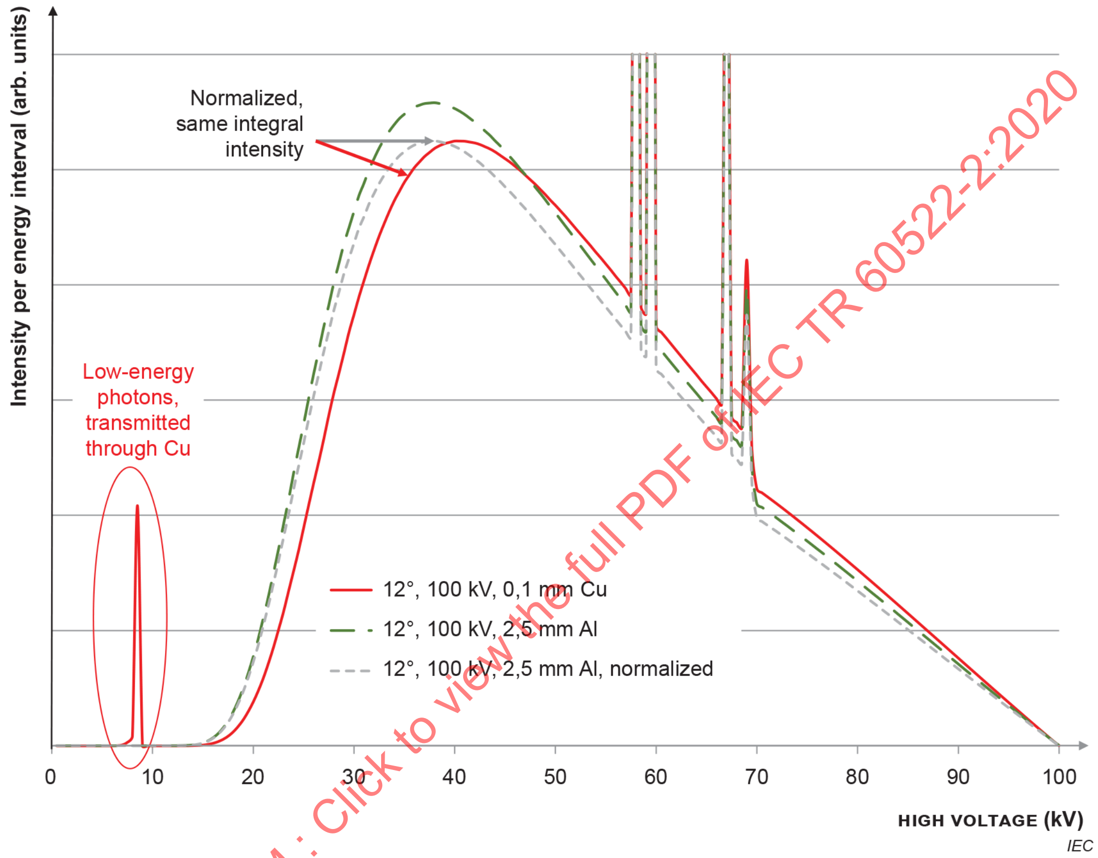


Figure 8 – X-RAY spectra (12 ° W TARGET, 100 kV HIGH VOLTAGE) for FILTER materials Cu and Al with the same QEF

ADDITIONAL FILTRATION with 1,0 mm Al from a 12° W TARGET without pre-FILTRATION is simulated for the comparison in Figure 9. It shows spectra behind 0,1 mm Cu resp. 3,5 mm Al with additional 1,0 mm Al FILTRATION. There is an almost perfect match between the normalized Cu- and the Al-spectra. So, one can indeed state in this case that "the QUALITY EQUIVALENT FILTRATION of 0,1 mm Cu is effectively 3,5 mm Al – for the range of 50 kV to 150 kV".

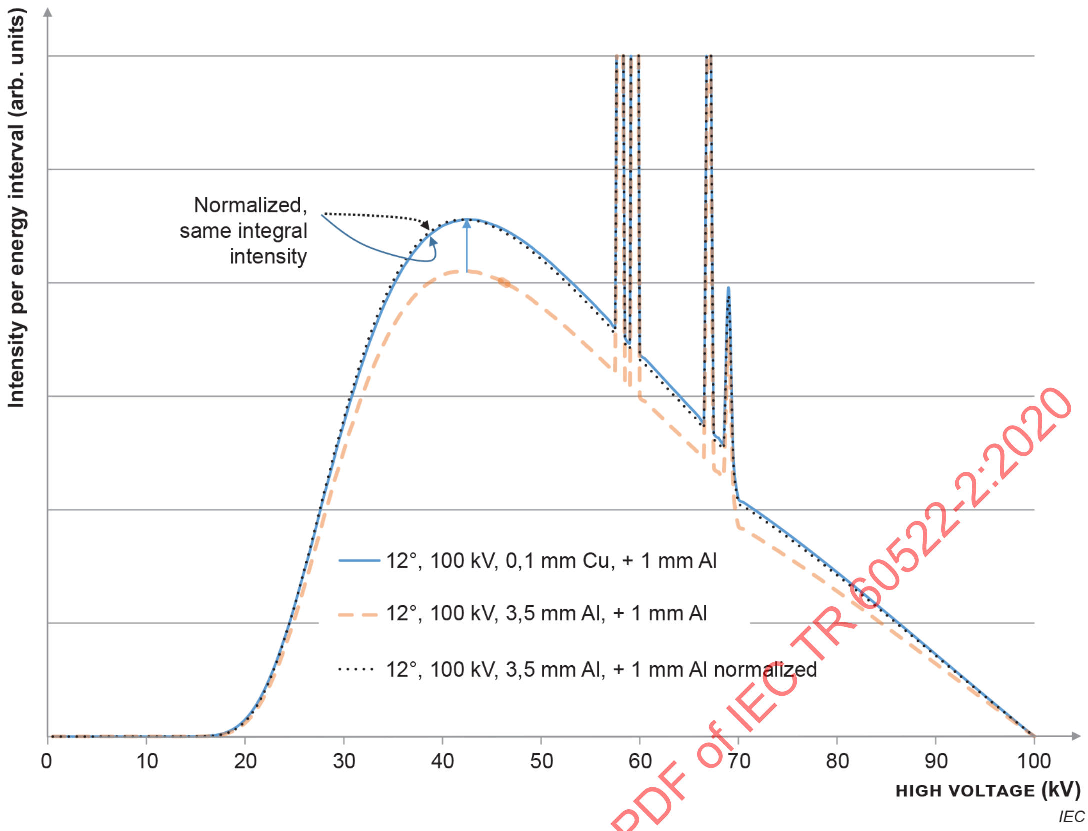
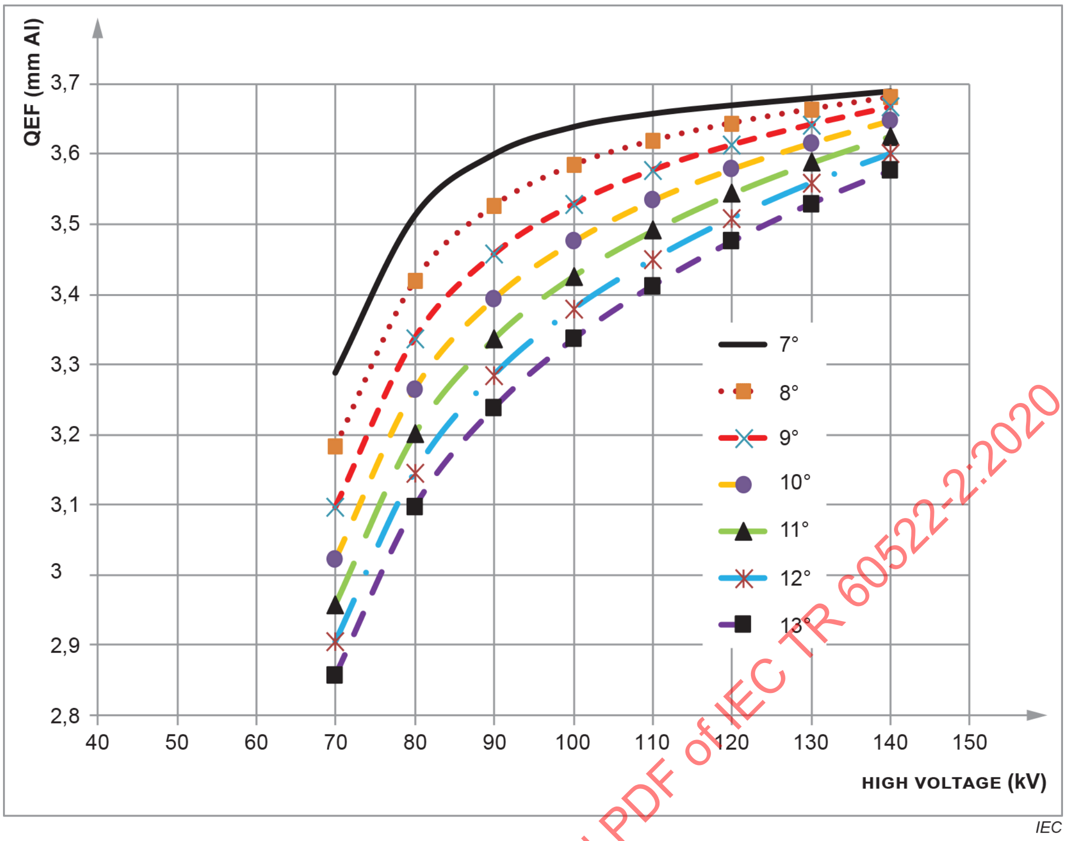


Figure 9 – X-RAY spectra from a 12° W TARGET with 1,0 mm additional FILTRATION

5.3 RADIOGRAPHY – Atomic number of FILTERS >30

For special purposes, higher *Z* FILTERS like Sn-, Ta-, W- and Au FILTERS are applied (Figure 1). As an example, for the QUALITY EQUIVALENT FILTRATION for this class of FILTERS, the QUALITY EQUIVALENT FILTRATION of a 0,025 mm W FILTER has been calculated as a function of HIGH VOLTAGE, for various TARGET ANGLES – see Figure 10. (The influence of TARGET ANGLE is further analysed in 8.3).



Parameter: target angle

Figure 10 – QEF of a 0,025 mm W FILTER as a function of HIGH VOLTAGE

Conclusion: The QUALITY EQUIVALENT FILTRATION depends considerably on RADIATION QUALITY, hence on HIGH VOLTAGE *and* on TARGET ANGLE.

5.4 Mammography

The HIGH VOLTAGE in mammography ranges from about 25 kV up to 50 kV. Typically, Mo and Rh TARGETS are used in combination with Mo and Rh FILTERS. For digital imaging also W TARGETS, and Ag, Ti, and Al FILTERS are employed. With a W TARGET, generally a greater HIGH VOLTAGE is applied. See Table 2 for the practical configurations which have been analysed,

Table 2 – Representative combinations of mammography TARGETS and FILTERS

TARGET material	Mo	W	W	W	W	Mo	Rh	Rh
FILTER 1 material	Mo	Ag	Ag	Ag	Ti	Cu	Cu	Rh
FILTER 1 thickness (mm)	0,030	0,050	0,025	0,025	1,00	0,30	0,30	0,025
FILTER 2 material				Al		Al	Al	
FILTER 2 thickness (mm)				0,35		0,30	0,30	

The PERMANENT FILTRATION has been determined as a function of HIGH VOLTAGE for the appropriate range of HIGH VOLTAGE. For the results, see four typical examples in Figure 11. The labels at the arrows indicate the maximum change of the QUALITY EQUIVALENT FILTRATION and its sensitivity per kV. These data are used in 7.4.

Conclusion: For mammography the QUALITY EQUIVALENT FILTRATION depends considerably on HIGH VOLTAGE, see also Table 12.

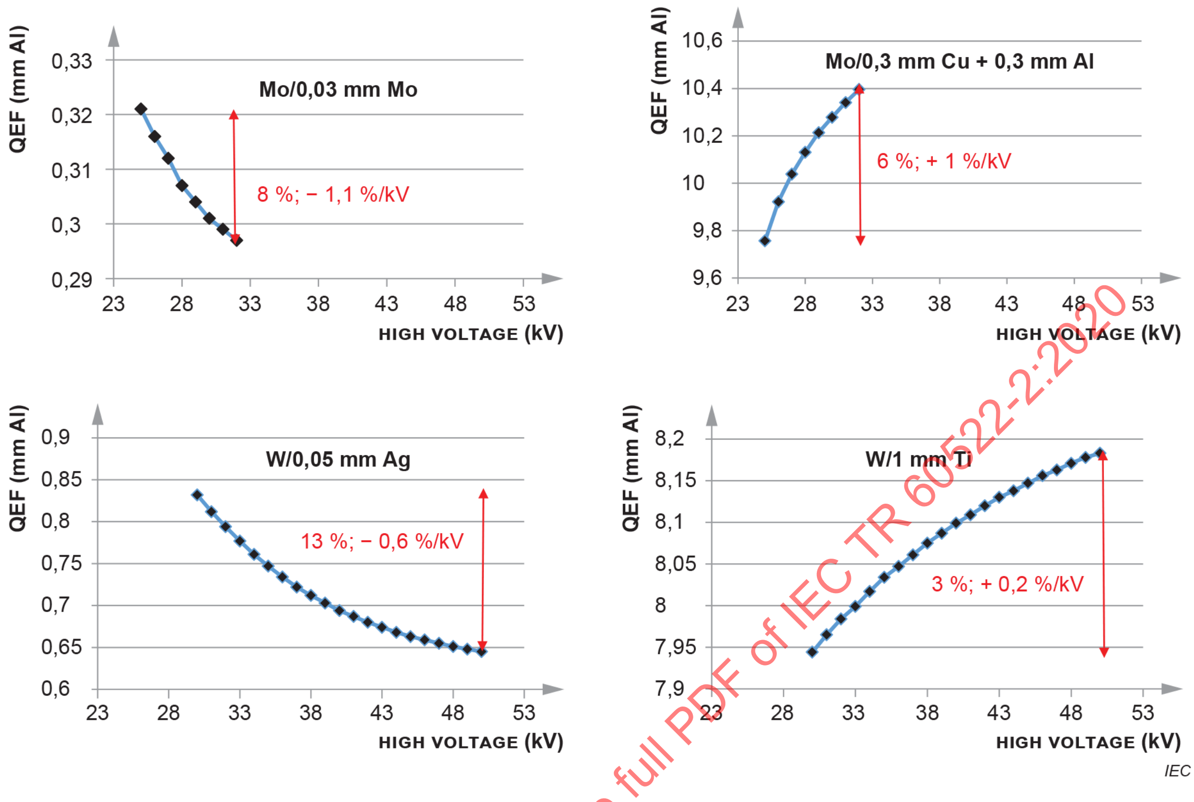


Figure 11 – Four typical examples of PERMANENT FILTRATION of mammographic X-RAY TUBE ASSEMBLIES as a function of HIGH VOLTAGE

5.5 Additivity

5.5.1 General

For a stack of materials, IEC 60522:1999 instructs to sum the QUALITY EQUIVALENT FILTRATION of the individual materials of the stack (see 4.7). Also, 7.4 of IEC 60601-1-3:2008 instructs such an addition: < … *by adding the values of QUALITY EQUIVALENT FILTRATION from each irremovable layer* … >. However, below is shown that such addition does not always yield the right result.

5.5.2 RADIOGRAPHY

For analysis, the QUALITY EQUIVALENT FILTRATION of a stack of materials is considered consisting of Fe, Ni, and Cu. Table 3, produced with the method of straight-forward addition, shows that the addition of the QUALITY EQUIVALENT FILTRATIONS gives a wrong result (7,4 mm Al), i.e. a result which is 26 % lower than the QUALITY EQUIVALENT FILTRATION of the stack (10,1 mm Al).

Table 3 – Sample comparison of concepts of addition: IEC 60522:1999

HIGH VOLTAGE 75 kV; QEF according to IEC 60522:1999			
Material	**Fe**	**Ni**	**Cu**
Z	26	28	29
Thickness (mm)	0,13	0,10	0,10
QEF	3,04	2,90	1,43
Sum of QEFS of individual materials			7,4 mm Al
QEF of the stack of materials			10,1 mm Al

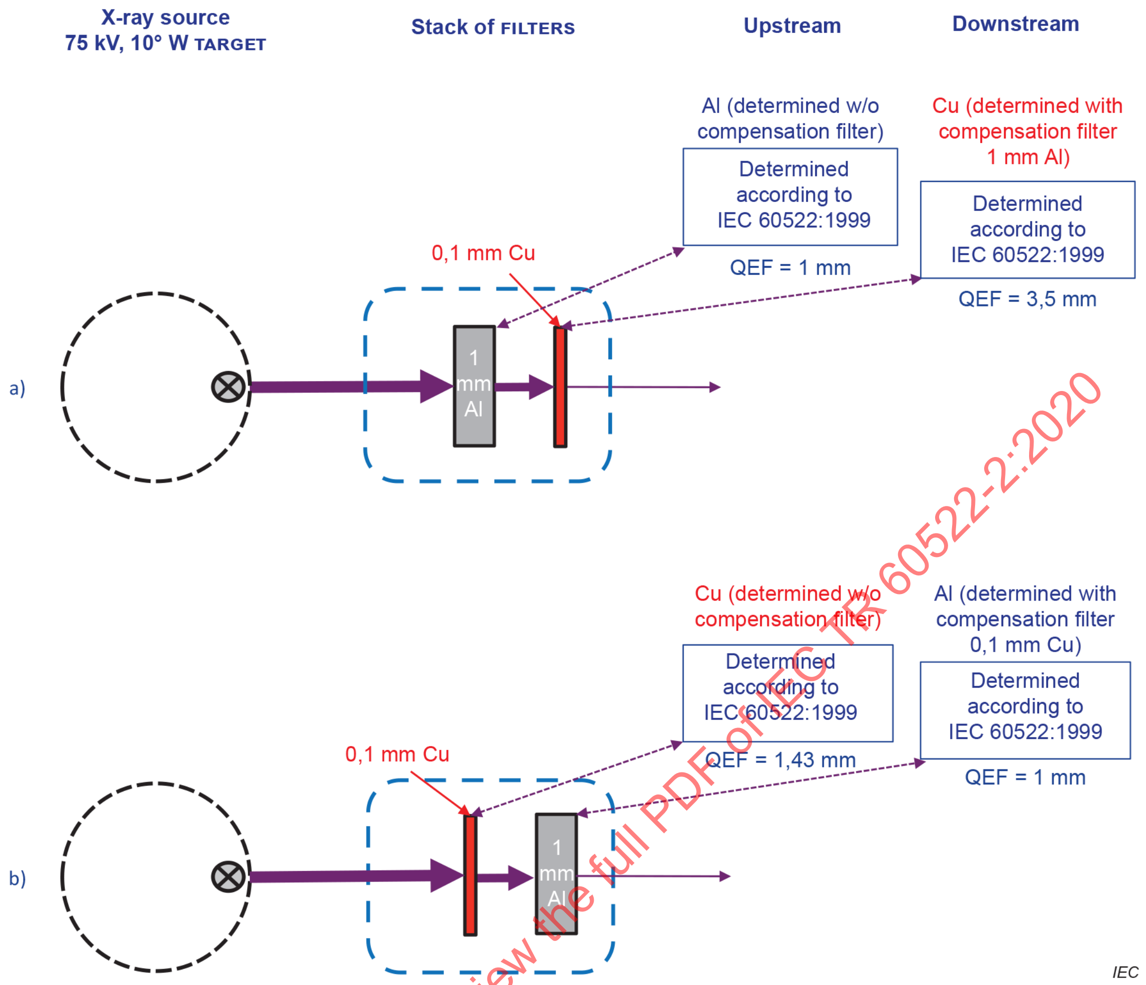
Summing up the individual QEFS is wrong, because in this case the determination of the QUALITY EQUIVALENT FILTRATION of Cu in the stack differs considerably from the value determined for an isolated Cu FILTER (compare Figure 2 and Figure 6). This effect is caused by the presence of a sufficient amount of “Al-like” material with low-Z (Fe) in the stack.

The method of determination in IEC 60522-1 prevents such error. In this case a reference X-RAY TUBE ASSEMBLY with sufficient low-Z filtering is employed. If the method of determination in IEC 60522-1:2020, Figure 3, is thus applied then the addition gives the correct result within 3 %, see Table 4.

Table 4 – Sample comparison of concepts of addition: IEC 60522-1

HIGH VOLTAGE 75 kV; QEF according to IEC 60522-1			
Material	**Fe**	**Ni**	**Cu**
Z	26	28	29
Thickness (mm)	0,13	0,10	0,10
QEF (mm Al)	3,12	3,19	3,50
Sum of QEFS of individual materials			9,8 mm Al
QEF of the stack of materials			10,1 mm Al

IEC 60522:1999 also describes situations in which not just “addition” is prescribed. Adjustment of the RADIATION BEAM is namely also applied to < *..compensate for the absence of any components of the* PERMANENT FILTRATION *missing from the sample and normally located between the sample and the* FOCAL SPOT > (4.1 of IEC 60522:1999). See also 4.6 of IEC 60522:1999, where a similar approach is described. However, with such compensation, additivity still does not always hold. Prescribed insertion respectively non-insertion of compensation FILTERS causes the discrepancy. As an example, illustrated in Figure 12, consider a PERMANENT FILTRATION consisting of a stack of two FILTERS, 1,0 mm Al and 0,1 mm Cu. The FILTER which is positioned closest to the FOCAL SPOT is designated “upstream” FILTER, the FILTER complementing the stack is designated “downstream” FILTER. Two configurations are considered: a) Al FILTER upstream, no compensation FILTER for the determination; Cu FILTER downstream, 1 mm Al compensation FILTER used for the determination. b) Cu FILTER upstream, no compensation FILTER for the determination; Al FILTER downstream, Cu compensation FILTER.



a) Al filter upstream. b) Cu filter upstream

Figure 12 – Inconsistent results from addition of the qefs according to IEC 60522:1999.

With the method of determination of IEC 60522:1999 including "compensation", the resulting two values for PERMANENT FILTRATION after addition differ considerably, see Table 5. Moreover, the result of the addition depends on the order in which the FILTERS are positioned. This contradicts the physical reasoning. The main cause of discrepancy is "leaking" low energy photons behind the copper FILTER, see Figure 8, if it is positioned close to a non-filtered source upstream of the Al FILTER. IEC 60522-1 renders consistent values of the PERMANENT FILTRATION whatever the order of the FILTERS would be, see Table 5.

Table 5 – PERMANENT FILTRATION per order of the FILTERS – comparison of concepts

75 kV, 10 ° W TARGET			
Upstream FILTER	**Downstream FILTER**	**PERMANENT FILTRATION according to IEC 60522:1999**	**PERMANENT FILTRATION according to IEC 60522-1:2020**
1,0 mm Al	0,1 mm Cu	4,50 mm Al	4,50 mm Al
0,1 mm Cu	1,0 mm Al	2,43 mm Al	4,50 mm Al

In conclusion, the addition of QUALITY EQUIVALENT FILTRATIONS gives the correct result only if all materials act Al-like, i.e. the following boundary conditions should be met:

The HIGH VOLTAGE is not less than 50 kV, and

– all materials have an atomic number not larger than 26, or
– none of the materials has an atomic number larger than 30, and the sum of the QUALITY EQUIVALENT FILTRATION of all materials in the X-RAY beam with atomic number 26 or smaller is at least 0,5 mm Al.

5.5.3 Mammography

For mammography, addition does not give the correct results either. As an example (see Table 2, 4th combination), a typical modern X-RAY TUBE ASSEMBLY with a W TARGET and 0,025 mm Ag FILTER is taken as starting point. A 0,35 mm Al FILTER is added, and subsequently the PERMANENT FILTRATION of this FILTER stack is determined. Alternatively, assuming additivity holds, the PERMANENT FILTRATION with only the Ag FILTER is determined, and that of 0,35 mm Al is added. The results are given in Figure 13. It depicts a comparison of a simulated W/Ag FILTER with added 0,35 mm Al FILTER by two concepts of determination. The top data points show the result of a determination of the PERMANENT FILTRATION with application of the addition concept. The result of the determination for a stack is shown as bottom data points. The discrepancy amounts to up to 13 % in this sample case.

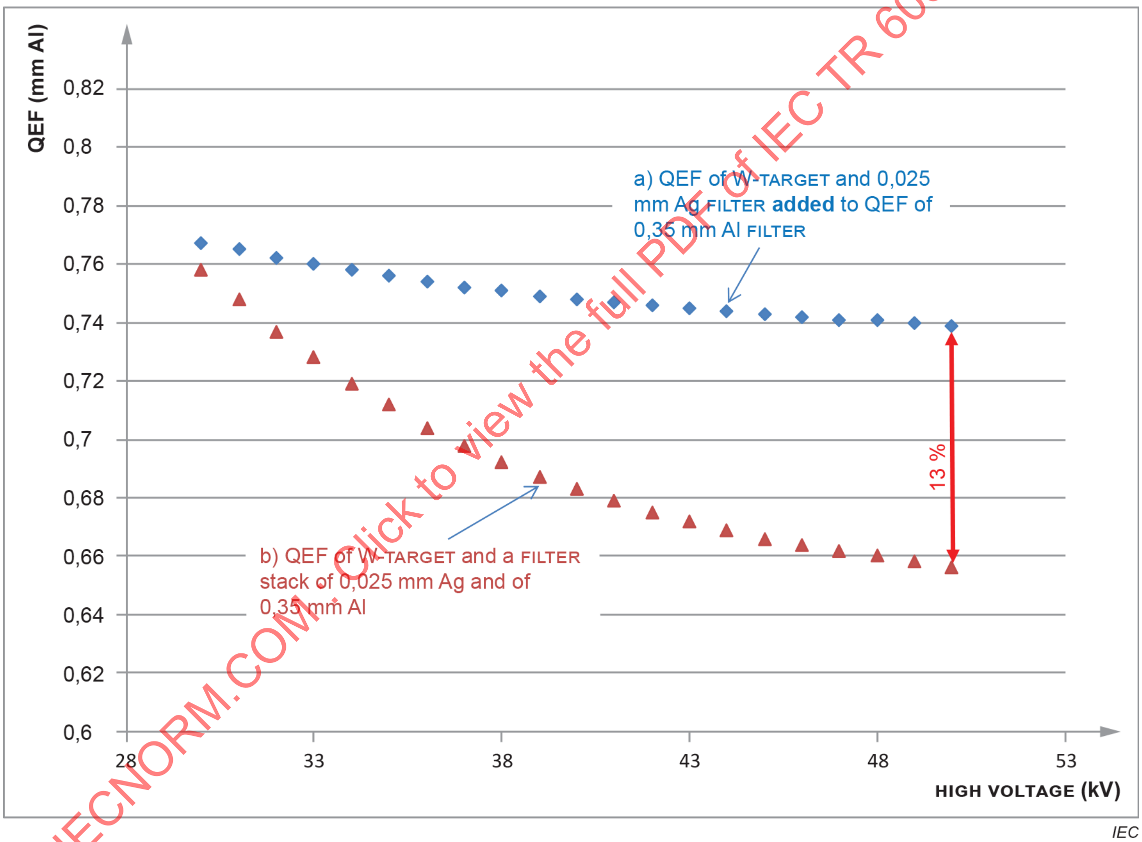


Figure 13 – Example of failing additivity concept of IEC 60522:1999 in mammography

5.5.4 Decision process for the indirect determination of the permanent FILTRATION

If the PERMANENT FILTRATION should be determined by the indirect determination, i.e. by analysing the materials or the stack of materials or substack(s) of materials, then the choice of the method of determination is, thus, guided by the decision process depicted in Figure 14. The indicated numbers of figures in this graphic refer to IEC 60522-1. Determination for HIGH VOLTAGE ≤ 50 kV applies to mammography;

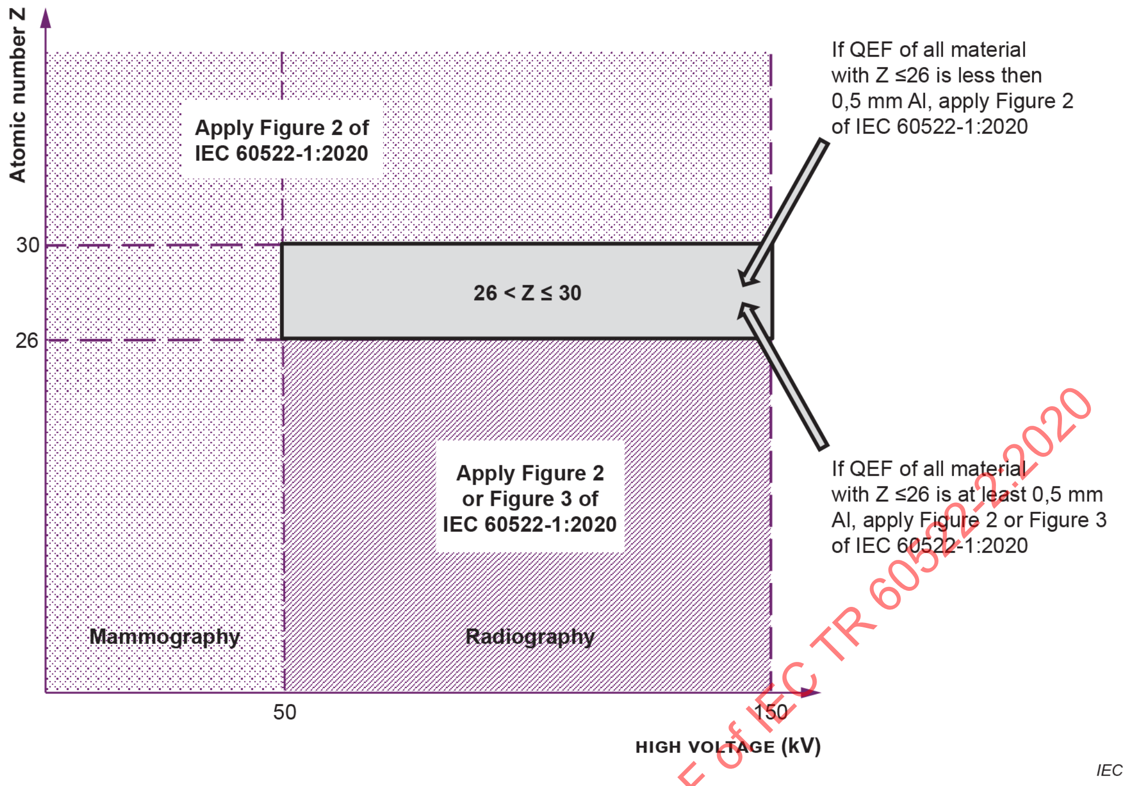


Figure 14 – Indirect determination of PERMANENT FILTRATION

6 Alignment of the REFERENCE AXES

6.1 General

For the direct determination of the PERMANENT FILTRATION while using a reference X-RAY TUBE ASSEMBLY, in 4.5.2 of IEC 60522-1:2020, the alignment of the REFERENCE AXES of the X-RAY TUBE ASSEMBLY under test and of the reference X-RAY TUBE ASSEMBLY is important. The determined HALF-VALUE LAYER value depends namely on the RADIATION QUALITY, which in turn depends on the effective TARGET ANGLE as seen from the RADIATION DETECTOR. The analyses for misalignment of the axes are given in 6.2, 6.3, and 6.4 for representative configurations.

6.2 RADIOGRAPHY – Atomic number ≤30

The method of determination is given in Figure 1 of IEC 60522-1:2020. The X-RAY TUBE ASSEMBLY under test is applied in steps 1a and 1b. The reference X-RAY TUBE ASSEMBLY is applied in steps 1c and 1d. For the analysis below the REFERENCE AXIS of the reference X-RAY TUBE ASSEMBLY will be misaligned on purpose, to quantify the effect on the determined PERMANENT FILTRATION.

As an example, a typical X-RAY TUBE ASSEMBLY comprising a glass tube is used with a 12° W TARGET at 75 kV with the following FILTER materials: 1,75 mm Pyrex glass of the tube; 0,5 mm oil; 1,5 mm Al. Its REFERENCE AXIS is initially perfectly aligned, then subsequently misaligned by 1° or by 2°. The resulting PERMANENT FILTRATIONS are given in Table 6.

Table 6 – Impact of angular misalignment on PERMANENT FILTRATION

Alignment of reference X-RAY TUBE ASSEMBLY	PERMANENT FILTRATION	Difference
Perfect	2,55 mm Al	±0
Misaligned +1°	2,64 mm Al	+3,8 %
Misaligned −1°	2,44 mm Al	−4,0 %
Misaligned +2°	2,73 mm Al	+7,2 %

Remarks:

a) Misalignment has a strong effect. With 1° misalignment, the error is of the order of 4 %.

b) The error in the PERMANENT FILTRATION is roughly linearly related to the error of misalignment.

6.3 RADIOGRAPHY – Atomic number >30

The example for *Z*>30 is a 0,025 mm W FILTER in combination with an 1,0 mm Al FILTER, a tungsten 10° TARGET and a HIGH VOLTAGE of 100 kV. The simulation cycle is identical to the one in 6.2. The results are given in Table 7.

Table 7 – Impact of angular misalignment on PERMANENT FILTRATION

Alignment of reference X-RAY TUBE ASSEMBLY	PERMANENT FILTRATION	Difference
Perfect	4,50 mm Al	±0 %
Misaligned +1°	4,69 mm Al	+4,2 %
Misaligned −1°	4,28 mm Al	−5,0 %

Remark:
Misalignment has a strong effect. With 1° misalignment the error is up to 5 %.

6.4 Mammography

As an example, a typical mammographic X-RAY TUBE ASSEMBLY is investigated with a 12° Mo TARGET, with the following FILTER materials: 1,0 mm Be and 0,030 mm Mo. The simulation cycle is identical to the one 6.2. The HIGH VOLTAGE is 30 kV, a typical value for mammography. The resulting PERMANENT FILTRATIONS are given in Table 8.

Table 8 – Impact of angular misalignment on PERMANENT FILTRATION

Alignment of reference X-RAY TUBE ASSEMBLY	PERMANENT FILTRATION	Difference
Perfect	0,301 5 mm Al	±0 %
Misaligned +1°	0,305 5 mm Al	+1,3 %
Misaligned −1°	0,296 8 mm Al	−1,6 %
Misaligned +2°	0,308 8 mm Al	+2,4 %

Remarks:

a) Misalignment in mammography has a smaller effect than for RADIOGRAPHY. With 1° misalignment, the error is of the order of 1,5 %.

b) The error in the PERMANENT FILTRATION is roughly linearly related to the misalignment-error.

7 Requirements on the HIGH VOLTAGE

7.1 General

Subclause 4.3 of IEC 60522:1999 indicates which HIGH VOLTAGE shall be chosen per application; further it is stated that the maximum PERCENTAGE RIPPLE shall not be larger than 10 %. There is no requirement on the stability of the HIGH VOLTAGE. These and other requirements will be reviewed in the following paragraphs.

7.2 RADIOGRAPHY – Determination at the K-edge – Requirement on constancy

IEC 60522:1999 requires that the determination should not be made with a HIGH VOLTAGE "... *close to the absorption edge of tungsten*" (4.3 of IEC 60522:1999). However, a rationale is not given. Further, the curves for QUALITY EQUIVALENT FILTRATION as a function of HIGH VOLTAGE (Figure 2 and Figure 6) do not show any singularity at the K-edge (see Figure 3 and Figure 4), so this does not make the K-edge suspect. The reason for the requirement in IEC 60522:1999 might be that the sensitivity for VOLTAGE RIPPLE or for shifts of the HIGH VOLTAGE during the determination is particularly large at such a specific value of HIGH VOLTAGE.

To analyse this further, simulations similar to those in Clause 6 have been performed, but in this case not the REFERENCE AXIS is misaligned, but the HIGH VOLTAGE is changed 1 kV or 2 kV in step (1b) in Figure 1 of IEC 60522-1:2020, to simulate the HIGH VOLTAGE shift during the determination. Initially, the HIGH VOLTAGE in step (1a) is 70,0 kV, i.e. indeed "*close to the absorption edge of W (at 69,5 kV)*", the K-edge. The results are given in Table 9.

Table 9 – Impact of HIGH VOLTAGE shift (close to K-edge) on PERMANENT FILTRATION

HIGH VOLTAGE shift (at 70 kV)	PERMANENT FILTRATION	Difference
None	2,55 mm Al	±0
HIGH VOLTAGE + 1 kV	3,00 mm Al	+18 %
HIGH VOLTAGE − 1 kV	2,14 mm Al	−19 %
HIGH VOLTAGE + 2 kV	3,50 mm Al	+37 %
HIGH VOLTAGE − 2 kV	1,76 mm Al	−31 %

Remarks:

a) The influence of a HIGH VOLTAGE shift on QEF in just one of the steps of the determination is large – about 18 %/kV. The influence is large because the HALF VALUE LAYER depends strongly on the HIGH VOLTAGE.

b) The error in the PERMANENT FILTRATION is roughly linearly related to the HIGH VOLTAGE shift.

This analysis is repeated for a starting HIGH VOLTAGE "*away from the absorption edge of W*", i.e. at 75 kV, which is the regular HIGH VOLTAGE for many determinations in IEC 60522:1999.

The results for a 1 kV shift are given in Table 10.

Table 10 – Impact of HIGH VOLTAGE shift (distant from K-edge) on PERMANENT FILTRATION

HIGH VOLTAGE shift (at 75 kV)	PERMANENT FILTRATION	Difference
None	2,55 mm Al	– – -
HIGH VOLTAGE + 1 kV	2,98 mm Al	+17 %
HIGH VOLTAGE − 1 kV	2,15 mm Al	−16 %

Remarks:
The sensitivity for a HIGH VOLTAGE shift at 75 kV is almost identical with the sensitivity in the 70 kV case. This can be explained by the fact that the relative intensity due to “K-edge photons” with energies close to the Duane-Hunt limit, i.e. the portion of the spectrum very close to the maximal photon energy for a given HIGH VOLTAGE, is very small in relation to the rest of the continuum portion of the spectrum. Thus, varying the HIGH VOLTAGE around the K-edge causes only a minor change of the measured AIR KERMA RATE.

Conclusion: There is no need to “stay away from the absorption edge of tungsten”.

As to the requirement on constancy of the HIGH VOLTAGE: On the basis of the results above, one can conclude that a HIGH VOLTAGE shift of the order of 1 % in just a single step of the determination will already result in an error of the PERMANENT FILTRATION of the order of 10 %. Errors in other steps would add.

7.3 Mammography – Requirement on constancy

A simulation similar to those in 7.2 has been performed, but the initial HIGH VOLTAGE is 30,0 kV, typical for mammographic applications.

The results for a 1 kV shift are given in Table 11.

Table 11 – Impact of shift of HIGH VOLTAGE on PERMANENT FILTRATION

Influence of HIGH VOLTAGE shift (at 30 kV)	PERMANENT FILTRATION	Difference
None	0,30 mm Al	±0
HIGH VOLTAGE + 1 kV	0,38 mm Al	+27 %
HIGH VOLTAGE −1 kV	0,22 mm Al	−27 %

Similar to 7.2, the conclusion is that a HIGH VOLTAGE shift during the determination of the order of 1 % will lead to an error of the PERMANENT FILTRATION of the order of 10 %.

7.4 Ripple

VOLTAGE RIPPLE leads to the averaging of the QUALITY EQUIVALENT FILTRATION over the voltage-swing. So, the determination of QUALITY EQUIVALENT FILTRATION becomes unprecise in terms of the HIGH VOLTAGE working point. That is not problematic if the dependency of the QUALITY EQUIVALENT FILTRATION on HIGH VOLTAGE is small, e.g. in case of radiology with FILTERS with atomic numbers $Z \leq 30$ when sufficient “Al-like” FILTRATION is present (Figure 5 and Figure 6).

IEC 60522:1999, 4.3, requires a PERCENTAGE RIPPLE not exceeding 10. However, for mammography, and for RADIOGRAPHY with FILTERS with $Z>30$, the dependency on HIGH VOLTAGE will be relatively large. As discussed in the first paragraph, the PERCENTAGE RIPPLE should be smaller in order to obtain a similar accuracy.

The dependency on HIGH VOLTAGE for RADIOGRAPHY with $Z>30$ (for a W FILTER) is given in Figure 10. For this W FILTER, the dependency for the HIGH VOLTAGE range 70 kV to 100 kV is considerable, for higher voltages the dependency is smaller. The sensitivity of the QUALITY EQUIVALENT FILTRATION has thus been analysed for the critical range 70 kV to 100 kV.

The dependency on HIGH VOLTAGE for mammography is given in Figure 11. The voltage ranges are stated in this figure.

The results on the sensitivity for VOLTAGE RIPPLE i.e. the change of QUALITY EQUIVALENT FILTRATION per kV, are summarized in Table 12.

Table 12 – Sensitivity for VOLTAGE RIPPLE

	TARGET/FILTER	Change of QEF over practical range of HIGH VOLTAGE	Sensitivity of QEF per kV
Mammography	W/1,0 mm Ti	3 %	+0,2 %/kV
	Mo/(0,3 mm Cu + 0,3 mm Al)	6 %	+1,0 %/kV
	Mo/0,03 mm Mo	8 %	−1,1 %/kV
	Mo/0,05 mm Ag	13 %	−0,6 %/kV
RADIOGRAPHY (*Z*≤30 and sufficient low-*Z* FILTRATION)	W/0,33 mm Ti	2 %	+0,03 %/kV
	W/0,1 mm Cu	5 %	+0,05 %/kV
RADIOGRAPHY (*Z*>30)	W/0,025 mm W	16 %	+0,5 %/kV

Remarks:

a) For mammography and for RADIOGRAPHY with FILTERS with *Z*>30, the HIGH VOLTAGE sensitivity is always (much) larger (5 times to 25 times) than for RADIOGRAPHY with FILTERS with *Z*≤30 and at least 0,5 mm Al equivalent low-*Z* FILTRATION.

b) If in the IEC 60522:1999 a VOLTAGE RIPPLE of 10 % is acceptable for RADIOGRAPHY with FILTERS with *Z*≤30 and sufficient low-*Z* FILTRATION, then the VOLTAGE RIPPLE for mammography and for RADIOGRAPHY with FILTERS with *Z*>30 should thus be much smaller, of the order of 1 %, in order to obtain a similar accuracy in terms of HIGH VOLTAGE. As this is often impractically small, the upper value for the VOLTAGE RIPPLE in these cases has thus been put at the practical low value of 4 % in IEC 60522-1.

c) It is advisable to apply this minimum VOLTAGE RIPPLE, too, for RADIOGRAPHY with FILTERS with *Z*≤30, in cases *without* sufficient low-*Z* FILTRATION.

7.5 Choice of HIGH VOLTAGE

In many radiographic applications the influence of the HIGH VOLTAGE on the QUALITY EQUIVALENT FILTRATION is small, so there is then no need to enforce the use of a particular value of HIGH VOLTAGE for the determination. However, there are many situations in which the choice of THE HIGH VOLTAGE *does* matter. As further other standards rarely specify the HIGH VOLTAGE, it is of practical value to give a recommendation for the HIGH VOLTAGE to be applied. For continuity reasons with IEC 60522:1999, the recommendations below are as much as possible in line with the requirements in IEC 60522:1999, whilst taking into account the findings reported in this document. So, for the HIGH VOltage to be applied, the following is recommended:

Unless other standards prescribe the HIGH VOLTAGE to be applied

– for mammography X-RAY TUBE ASSEMBLIES, apply 28 kV;
– for dental X-RAY TUBE ASSEMBLIES, apply 60 kV;
– for any other application, apply 75 kV;
– unless the application does not include 75 kV or is centred outside 75 kV; then use a HIGH VOLTAGE in the range of the application.

Remarks:

– for mammography X-RAY TUBE ASSEMBLIES, 28 kV is chosen in line with [8] IEC 60601-2-45:2011, 203.6.7.104.1, on “AIR KERMA RATE at 28 kV”.
– for dental X-RAY TUBE ASSEMBLIES, 60 kV is chosen in line with [11] IEC 60601-2-65:2012 (intra-oral), 203.7.101, and [10] IEC 60601-2-63:2012 (extra-oral), 203.7.101.

8 FILTERING MATERIAL – Representative TARGET ANGLE

8.1 General

Usually, the QUALITY EQUIVALENT FILTRATION of FILTERING MATERIAL depends on RADIATION QUALITY, hence it depends on TARGET ANGLE. Preferably, the TARGET ANGLE should correspond with the X-RAY TUBE ASSEMBLY the FILTERING MATERIAL is combined with in the diagnostic system. If that is not known, a representative TARGET ANGLE should be chosen within the practical range of TARGET ANGLES, which minimizes the maximum error in practice – see 8.2, 8.3 and 8.4.

8.2 RADIOGRAPHY – Atomic number ≤30

It is expected that the FILTRATION by low-*Z* material like 1,0 mm Al not only leads to a small dependency of the QUALITY EQUIVALENT FILTRATION on HIGH VOLTAGE, but also to a small dependency on TARGET ANGLE. Although TARGET ANGLE influences RADIATION QUALITY, the low-Z FILTRATION dampens such effect.

This has been studied for the critical case of a 0,1 mm Cu FILTER, for three levels of Al-FILTRATION (0,1 mm Al; 0,5 mm Al and 1,0 mm Al), and for a typical range of TARGET ANGLES (6 °, 10 ° and 16 °). The results for the representative HIGH VOLTAGE of 75 kV are given in Table 13.

Table 13 – Influence on QEF of low-Z FILTRATION and of TARGET ANGLE

QUALITY EQUIVALENT FILTRATION, TARGET ANGLE and FILTRATION of 0,1 mm Cu at 75 kV				
TARGET ANGLE (°)	0,1 mm Al FILTRATION	0,5 mm Al FILTRATION	1,0 mm FILTRATION	Diff. w.r.t.1,0 mm Al FILTRATION at 10 °
6	3,14	3,50	3,52	+0,5 %
10	2,70	3,47	3,50	0 %
16	2,31	3,44	3,48	−0,5 %

Remarks:

a) As expected, the variation of the QUALITY EQUIVALENT FILTRATION with TARGET ANGLE decreases as Al-FILTRATION increases, down to 0,1 %/°.

b) A representative TARGET ANGLE may be 10 °. Then the percentage errors with respect to the smallest and the largest TARGET ANGLE are minimal.

8.3 RADIOGRAPHY – Atomic number >30

The influence of TARGET ANGLE has been analysed for a W TARGET and a typical 0,025 mm W FILTER (see Figure 10), for the range of practical TARGET ANGLES 7° to 13°. The QUALITY EQUIVALENT FILTRATION is given for three representative HIGH VOLTAGES in Figure 15.