PD IEC TR 60522-2:2020

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Medical electrical equipment — Diagnostic X-rays

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

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TECHNICAL REPORT

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT – DIAGNOSTIC X-RAYS –

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

FOREWORD

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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.

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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.

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- withdrawn,
- replaced by a revised edition, or
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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";

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

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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.

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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.

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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.>.

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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.

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