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**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY/T 0062.1-2024

Replacing YY/T 0062-2004

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

医用电气设备 诊断X射线 第1部分：等效滤过和固有滤过的测定
(English Translation)

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part 1: Structure and drafting rules for standardization documents" Drafting.

This document is part 1 of YY/T 0062 "Medical electrical equipment for diagnostic X-rays". YY/T 0062 has been published for the following part.

--- Part 1: Determination of equivalent filtration and intrinsic filtration.

This document replaces YY/T 0062-2004 "Determination of inherent filtration of X-ray tubes". Compared with YY/T 0062-2004, except for the structural adjustment in addition to

the integration and editorial changes, the main technical changes are as follows.

- a) The scope has been changed (see Chapter 1, Chapter 1 of the 2004 edition);
- b) The normative references in the terms and definitions have been changed (see Chapter 3, Chapter 3 of the 2004 edition);
- c) Added the terms and definitions of "filtration material" and "mass equivalent filtration" (see 3.1 and 3.3);
- d) "Overview" was deleted (see 4.1 of the 2004 edition);
- e) Added "Alignment of X-ray tube assembly and filter plate" (see 4.1);
- f) "Test sample" has been deleted (see 4.2 of the 2004 edition);
- g) "Measurement X-ray beam" has been changed (see 4.2, 4.3 of the 2004 edition);
- h) The "Requirements for Radiation Detectors" were modified (see 4.3, 4.4 of the 2004 edition);
- i) The "composition of reference materials" has been changed (see 4.4, 4.5 of the 2004 edition);
- j) "Determination of inherent filtration" was changed (see 4.5, 4.6 of the 2004 edition);
- k) Added "Determination of the equivalent filtration mass of filter material or stacked filter material" (see 4.6);
- l) Added "Simulated X-ray" (see 4.7);
- m) "Compliance test" has been changed (see 4.8, 4.6 of the 2004 edition);
- n) The "Indication and Declaration of Equivalent Filtration Quality" has been changed (see Chapter 5, Chapter 5 of the 2004 edition).

This document is modified to adopt IEC 60522-1:2020 "Medical electrical equipment for diagnostic X-rays - Part 1: Equivalent filtration and inherent filtration Determination of the past.

The technical differences between this document and IEC 60522-1:2020 and their reasons are as follows.

--- IEC 60601-1 (see Chapter 3) is replaced by the normative reference GB 9706.1 to adapt to my country's technical conditions;

--- IEC 60601-3 (see Chapter 3) is replaced by the normative reference GB 9706.103 to adapt to my country's technical conditions;

--- Added GB/T 10149 (see Chapter 3) to adapt to my country's technical conditions.

The following editorial changes were made to this document.

--- Deleted the notes in IEC 60522-1:2020.

Introduction

YY/T 0062 "Medical Electrical Equipment for Diagnostic X-ray" is intended to consist of two parts.

--- Part 1: Determination of equivalent filtration and intrinsic filtration. Part 1 replaces YY/T 0062-2004.

--- Part 2: Guidance and rationale for quality equivalent filtration and permanent filtration. Part 2 provides the technical background of Part 1.

Scenery and basic principles.

The scope of application of this document has undergone significant adjustments compared to YY/T 0062-2004.

For medical diagnosis and radiotherapy X-ray tube assemblies, the scope of application of this document no longer includes radiotherapy X-ray tube assemblies.

The range is adjusted to X-ray tube components and filter materials below 150kV in medical diagnostic applications, and the equivalent filtration related information of the filter materials is increased.

YY/T 0062-2004 only covers inherent filtration, this document also covers filtering the X-ray beam on the patient.

Materials, this refers to materials in additional filter plates, beds, breast compression devices and restraining devices. For these materials, the term "filter material" is introduced.

The historical background of this document is shown in Appendix A.

Medical electrical equipment diagnostic X-ray Part 1: Determination of equivalent filtration and intrinsic filtration

1 Scope

This document describes the method for determining the inherent filtration of X-ray tube assemblies and the equivalent filtration of the filter material mass.

Requirements for the declaration of conformity of the components in the accompanying documents and the marking of the X-ray tube assembly, as well as the indication and declaration of conformity of the filter material Require.

This document applies to X-ray tube assemblies and filter materials for medical diagnostic applications with high voltages up to 150 kV.

50kV, This document applies only to X-ray tube assemblies with tungsten or tungsten alloy

targets.

NOTE 1 The filter material in the X-ray beam may be removable or non-removable; it may be mounted in any position or have any shape (e.g., tapered thickness).

Although usually plane-parallel material, it is perpendicular to the reference axis. Examples of filter materials include additional filters, patient beds (such as under-bed X-ray tube sets) Materials in breast restraints, breast compression devices, or breast compression devices.

NOTE 2 The methods and declarations of conformity given in this document apply only to flat plate filter plates, but the methods are applicable to any type of non-flat plate filter plates.

In some cases, further data such as field size, filter geometry/position, etc. are included in order to produce useful results.

Note 3: This document does not contain requirements for any specific values of inherent filtration. For X-ray equipment used for diagnostic purposes, the filtration requirements are given in GB 9706.103-2020 or applicable specific standards.

NOTE 4 The determination method described in this document is intended for type testing. It is not intended for user testing.

2 Normative references

The contents of the following documents constitute the essential clauses of this document through normative references in this document.

For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to this document.

GB 9706.1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance (GB 9706.1-2020, IEC 60601-1:2012,MOD) GB 9706.103 Medical electrical equipment Part 1-3.General requirements for basic safety and essential performance Collateral standard. Diagnostic X Radiation protection of radiation equipment (GB 9706.103-2020, IEC 60601-1-3:2013, MOD) GB/T 10149 Terminology and symbols for medical X-ray equipment IEC 61674:2012 Medical electrical equipment Ionization chambers and/or semiconductor detector dosimeters for use in X-ray diagnostic imaging

Note 3: GB/T 19629-2005 Medical electrical equipment Ionization chambers and (or) semiconductor detector dosimeters used in X-ray diagnostic imaging (IEC 61674:1997,IDT)

3 Terms and definitions

The terms and definitions defined in GB/T 10149, GB 9706.1, GB 9706.103 and the following apply to this document.

Filtering material