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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 18988.1-2025

Replacing GB/T 18988.1-2013

**Radionuclides imaging devices - Characteristics and test
conditions - Part 1: Positron emission tomographs**

放射性核素成像设备 性能和试验规则 第1部分：正电子发射断层成像装置

(English Translation)

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part 1: Structure and Drafting Rules of Standardization Documents".

Drafting.

This document is Part 1 of GB/T 18988, "Performance and Test Rules for Radionuclide Imaging Equipment". GB/T 18988 has been...

The following sections were published.

---Part 1: Positron Emission Tomography Apparatus;

---Part 2: Planar, Whole-body, Tomographic Gamma Cameras this document replaces GB/T 18988.1-2013 "Performance and Test Rules for Radionuclide Imaging Equipment - Part 1: Positron Emissions".

Compared with GB/T 18988.1-2013, the main technical changes in "Radio Tomography Imaging Devices" are as follows, except for structural adjustments and editorial modifications.

- a) Some content in the "Terms and Definitions" section has been changed (see Chapter 3, Chapter 2 of the 2013 edition);
- b) The methodology, analysis, and reporting of "spatial resolution" have been changed (see 4.2, 3.1 in the 2013 edition);
- c) The methodology, analysis, and reporting of "Tomographic Sensitivity" have been modified (see 4.3, 3.3 in the 2013 edition);
- d) The methodology, analysis, and reporting of the "scattering fraction" have been changed (see 4.4, 3.6 of the 2013 edition);
- e) The methodology, analysis, and reporting of "PET count rate characteristics" have been changed (see 4.5, 3.5 in the 2013 edition);
- f) Added "time-of-flight resolution" (see 4.6);
- g) Combine "Restoration Factor" (see 3.2 in the 2013 edition) and "Attenuation Correction" (see 3.7 in the 2013 edition) into "Image Quality and Magnification".

The accuracy of quantitative determination of source activity concentration was improved (see 4.7), and the methods, analysis, and reporting were modified.

h) "Uniformity" has been removed (see 3.4 in the 2013 edition);

i) The contents of "Supplementary Documents" have been changed (see Chapter 5, Chapter 4 of the 2013 edition).

This document is modified to adopt IEC 61675-1:2022 "Radionoid Imaging Apparatus - Performance and Test Rules - Part 1: Positron Emissions".

"Radio-tomographic imaging device".

This document has undergone the following structural adjustments compared to IEC 61675-1:2022.

---Appendix A has been added;

---Versions 4.7.4.2 and 4.7.5.5 have been deleted, and 4.7.4.1 has been changed to 4.7.4 in this file.

The technical differences between this document and IEC 61675-1:2022, and the reasons therefor, are as follows.

---The content regarding PET/CT image registration (see 4.7.4.2 and 4.7.5.5 of IEC 61675-1:2022) has been removed to align with the standard.

Use range.

The following editorial changes have been made to this document.

---To facilitate users' understanding and use of the IEC and NEMA series standards for positron emission tomography (PET) devices the document includes an informative appendix, Appendix A, which contains NEMANU2-2018, "Performance of Positron Emission Tomography (PET) Devices".

test".

Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents.

This document was proposed by the National Medical Products Administration.

This document is under the jurisdiction of the National Technical Committee on Standardization of Medical Electrical Appliances (SAC/TC10).

Introduction

GB/T 18988, "Performance and Test Rules for Radionuclide Imaging Equipment", is divided into two parts.

---Part 1: Positron Emission Tomography (PET) Apparatus. The purpose is to describe the experimental methods for evaluating the performance of PET systems.

Law and accompanying documents.

---Part 2: Planar, Whole-Body, Tomographic Gamma Cameras. The purpose is to describe gamma cameras and single-photon emission computed tomography (SEP) imaging

techniques.

Test methods and accompanying documentation for SPECT (Spectral Parametric Electron Device) performance.

This document is Part 1, describing how positron emission tomography (PET) devices detect the annihilation of positron-emitting radionuclides using coincidence detection.

radiation.

This document modifies and adopts IEC 61675-1:2022, and incorporates NEMA standard publication NU2-2018 "Positron Emission Tomography Apparatus".

Performance testing is included as Appendix A. Due to differences in testing requirements and methods between IEC and NEMA standards, it is recommended that the standard be...

Prospective users should use either method in its entirety, without crossing them over.

Performance and testing rules for radionuclide imaging equipment Part 1: Positron Emission Tomography Apparatus

1 Scope

This document specifies the test methods and accompanying documentation for the performance of positron emission tomography (PET) devices.

This document applies to positron emission tomography (PET) devices.

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are not included.

For references to documents, only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies.

This document.

(defined terms)

Note: GB/T 17857-1999 Medical Radiology Terminology (IEC 60788:1984, eqv)

3 Terms and Definitions

The terms and definitions defined in IEC TR60788:2004 and the following terms and definitions apply to this document.

Tomography

X-ray imaging of one or more layers inside an object.