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Nanotechnologies — Performance characteristics of nanosensors for chemical and biomolecule detection

Part 1: Detection performance

bsi.

National foreword

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

Nanostructured materials possess fascinating properties such as high reactivity, excellent electrical conductivity, quantum-scaled confinement, great degree of biocompatibility, versatile optical transmission, outstanding electromagnetic properties and substantial surface area-to-volume ratio. Physical and chemical behaviour of nanomaterials are tunable by morphological variation as well as surface modification. It is these unique properties and functionalities that enable nanomaterials to be a novel solution for the development of advanced high-performance sensing devices.

Applications of advanced nanomaterials in the detection of chemicals or biomolecules have been widely studied to cater to variety of demands from innovative healthcare practice to industrial process improvement to potent environmental surveillance. By introducing nanotechnology in sample preparations, biomolecule reactions and chemical sensing procedures, the performance of traditional sensor technologies has been enhanced, brand-new nanosensors have been commercialized, and related markets have achieved remarkable growth.

There are several standards that specify the performance characteristics and the performance evaluation of a specific sensing or metrological device/equipment, especially in in vitro diagnosis, food safety management and environmental monitoring. Existing standards describe the performance of conventional sensors, however, there is not any standard document which generally addresses the enhanced sensing performance of a nanosensor. Moreover, the enhancement of sensing performance by nanotechnologies is not yet reflected in the existing relevant standards for conventional sensor technologies. As a result, there is a growing need for standardization to accurately describe the performance characteristics of nanosensors for chemical and biomolecule detection. This document standardizes performance characteristics of nanosensors which are utilized for performance evaluation in medical diagnosis, personal healthcare, environment monitoring, food quality and safety monitoring and biohazard defence.

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Nanotechnologies — Performance characteristics of nanosensors for chemical and biomolecule detection —

Part 1: Detection performance

1 Scope

This document describes the performance characteristics necessary to evaluate the detection performance of nanosensors for chemical and biomolecule detection. This document does not cover the analytical performance characteristics or the performance evaluation procedure of a specific sensor.

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.

ISO/IEC Guide 99:2007, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

ISO 16604:2004, *Clothing for protection against contact with blood and body fluids — Determination of resistance of protective clothing materials to penetration by blood-borne pathogens — Test method using Phi-X 174 bacteriophage*

ISO 17511:2020, *In vitro diagnostic medical devices — Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples*

ISO 18113-1:2022, *In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions, and general requirements*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC Guide 99:2007, ISO 16604:2004, ISO 17511:2020, ISO 18113-1 and the following apply.

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

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
analyte
component represented in the name of a measurable quantity

EXAMPLE In the type of quantity "mass of protein in 24-hour urine", "protein" is the analyte. In "amount of substance of glucose in plasma", "glucose" is the analyte. In both cases the long phrase represents the *measurand* (3.9).

[SOURCE: ISO 17511:2020, 3.1]

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