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Nanotechnologies — Nano-object-assembled layers for electrochemical bio-sensing applications — Specification of characteristics and measurement methods

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 229, *Nanotechnologies*.

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

Electrochemical electrodes can exhibit nano-enhanced performance after the deposition of nano-objects on the electrode surface. The increased surface area, orientation, the assembled density and ability to control the bio-receptor of the nano-object layer improves the performance of nano-biosensors. Nano-biosensor sensitivity, selectivity and reliability can be enhanced with specific nano-objects, e.g. gold nanoparticles[22][25][26], carbon nanotubes[24], CuS_2 nanorods[37] and silver[38] or palladium nanoplates[23].

Currently, most of the nano-enhanced electrochemical electrodes are fabricated by researchers in order to achieve predictable performance in their own programs without mass-production. However, the technology is maturing into a commercial phase. Fabricators are offering nano-enhanced electrodes to instrument manufacturers as a platform to add additional coatings for specific sensing applications. This document supports the development of material specifications for the transaction between electrode fabrications and instrument manufacturers to allow the purchase of electrodes with predictable performance.

This document is intended to help address this issue. It is also relevant to the process of qualification, specification and use of nano-object-modified electrodes. The standardization of protocols to specify various types of nano-object-modified electrodes related to electrochemical detection will be used by most manufacturers or business owners of electrochemical electrodes products. This document focuses on the nano-object-assembled layer on electrodes by means of a solution process for electrochemical applications.

In this document, the specifications for a nano-object constituting an assembled layer are provided, based on ISO/TS 12805, which describes the characteristics of manufactured nano-objects and their measurement methods (see Annex A). In addition, the characteristics of nano-object-assembled layer for enhanced electrochemical bio-sensing applications and their measurement methods are provided in detail.

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1 Scope

This document specifies the characteristics to be measured of nano-object-assembled layers on electrodes by means of a solution process and of nano-objects constituting the layers for electrochemical applications such as nano-biosensor or diagnosis applications. It also provides measurement methods for determining the characteristics.

It does not apply to:

— the requirements of nanostructures by top-down nanomanufacturing;

— the subsequent coating of materials such as biomaterials onto nano-object-assembled layers;

— specific health and safety requirements during manufacturing;

— the experimental conditions of electrochemical sensing;

— the packaging, labelling, expiratory dates and transport of nano-object-enhanced electrochemical electrodes.

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/TS 80004-2:2015, *Nanotechnologies — Vocabulary — Part 2: Nano-objects*

ISO/TS 80004-4:2011, *Nanotechnologies — Vocabulary — Part 4: Nanostructured materials*

ISO/TS 80004-8:2013, *Nanotechnologies — Vocabulary — Part 8: Nanomanufacturing processes*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/TS 80004-2, ISO/TS 80004-4, ISO/TS 80004-8 and the following apply.

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

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

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

3.1
nanoscale
size range from approximately 1 nm to 100 nm

Note 1 to entry: Properties that are not extrapolations from a larger size will typically, but not exclusively, be exhibited in this size range. For such properties the size limits are considered approximate.

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