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# Nanotechnologies — Specification for developing representative test materials consisting of nano-objects in dry powder form

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# National foreword

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TECHNICAL SPECIFICATION

**ISO/TS 16195**

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# Nanotechnologies — Specification for developing representative test materials consisting of nano-objects in dry powder form

*Nanotechnologies — Spécifications relatives au développement de matériaux d'essai représentatifs constitués de nano-objets sous forme de poudre sèche*

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# Foreword

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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).

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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*.

This second edition cancels and replaces the first edition (ISO/TS 16195:2013), which has been technically revised.

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

As new manufactured nano-objects are developed and find a wider range of industrial applications, the roles of physico-chemical, performance, and safety testing of their powders (i.e. dry, unsuspended accumulations of such objects) have become more important than ever. However, many testing methods are still under development and have to be properly evaluated in terms of their reliability. Where possible, validation of new measurement methods is performed using certified reference materials, which have known and quantified properties. In the absence of certified reference materials, one often has to rely on non-certified reference materials, with assigned but not certified property values. However, in developing fields of measurement and testing, such as that of nanotechnology, even non-certified reference materials are scarce. In such cases, "test materials," which are evaluated for homogeneity and stability of one or several of their properties, will be helpful in efforts to improve the reproducibility of testing methods across testing laboratories and the comparability of test results across different test methods. This document specifies that for dry powders of nano-objects the following minimum information be gathered and provided in a verification report to qualify the material as a nanoscale representative test material:

— information describing the manufacturing process,

— information on the quality management of its manufacturing process,

— data from physico-chemical measurements representing the principal features of the representative test material, and

— data on the stability and homogeneity of the above parameters.

Conformity to this document, expressed in the form of a verification report, will provide a level of assurance that the representative test material is homogeneous, statistically representative of the manufacturing process, and has stability. This will increase the likelihood that measurements that are undertaken on the representative test material, whether for safety or function, are comparable across testing laboratories, even for properties for which methods are being developed and for which homogeneity and stability have not been quantitatively assessed.

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**TECHNICAL SPECIFICATION** **ISO/TS 16195:2018**

# Nanotechnologies — Specification for developing representative test materials consisting of nano-objects in dry powder form

## 1 Scope

This document specifies development of representative test materials consisting of nano-objects in dry powder form, to enable test method development and improve comparability of data for nanotechnology applications. It includes the physico-chemical properties (specifically, size and shape, specific surface area, crystal structure, and bulk chemical composition) that are required to be measured and reported with the representative test material.

## 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 Guide 31:2015, *Reference materials — Contents of certificates, labels and accompanying documentation*

ISO Guide 35, *Reference materials — Guidance for characterization and assessment of homogeneity and stability*

ISO 9276-1, *Representation of results of particle size analysis — Part 1: Graphical representation*

ISO/TS 80004-1, *Nanotechnologies — Vocabulary — Part 1: Core terms*

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

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/TS 80004-1 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**
**representative test material**
**RTM**
material, which is sufficiently homogenous and stable with respect to one or more specified properties, and is implicitly assumed to be fit for its intended use in the development of measurement and test methods that target properties other than those for which homogeneity and stability have been demonstrated

Note 1 to entry: An RTM may be a reference material for other properties (i.e. properties for which homogeneity and stability have been demonstrated), and a candidate reference material for the target property.

Note 2 to entry: An RTM can be a useful tool in inter- or intra-laboratory developments of test methods for which reference materials cannot (yet) be produced.

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