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

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



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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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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 (hereinafter “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[9]. This document specifies that for dry powders of nano-objects the following minimum information can 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.

Compliance with 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.