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TECHNICAL SPECIFICATION

colour inside

Guidelines for quality and risk assessment for nano-enabled electrotechnical products



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Guidelines for quality and risk assessment for nano-enabled electrotechnical products

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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GUIDELINES FOR QUALITY AND RISK ASSESSMENT FOR NANO-ENABLED ELECTROTECHNICAL PRODUCTS

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Technical Specifications are subject to review within three years of publication to decide whether they can be transformed into International Standards.

IEC TS 62844, which is a Technical Specification, has been prepared by IEC technical committee 113: Nanotechnology for electrotechnical products and systems.

The text of this Technical Specification is based on the following documents:

Enquiry draft	Report on voting
113/227/DTS	113/343/RVC

Full information on the voting for the approval of this Technical Specification can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- transformed into an International Standard,
- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

A bilingual version of this publication may be issued at a later date.

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INTRODUCTION

The nanoindustry is dealing with highly innovative technologies and products. For the purposes of assuring their performance and assessing the risks, a reliable quality, environmental, occupational health and safety management system for nanoindustrial companies and consumers is needed. The monitoring and measuring of all relevant parameters of nanomaterials and consequently identifying nonconformities in the products containing them and associated hazards are not straightforward. A systematic and practical assessment methodology for its implementation in industrial mass production is needed to simplify the monitoring processes and ensure both the quality of the products and the conformance of the products to health, occupational and environmental standards.

Quality needs to be defined firstly in terms of parameters or characteristics, relevant for the application, which vary from product to product. However, it is not trivial to identify the relevant characteristics and effectively apply these parameters for the application. The same is true for the identification of environmental and health and safety aspects, as demanded, for example, by ISO 14001 [1][1] for environmental aspects.

This document uses a reference model to provide a high level frame work, but not any details of EHS management aspects, for the identification and development of the stakeholders' needs, from the relationship of inputs such as technology measures, to outputs such as customer and business results. It is intended as a nanotechnology management guideline, not for details of EHS practices. However, it encourages users to adopt the necessary known EHS practices, and consider special requirements for nanotechnology. It also facilitates communication among all stakeholders. Further, it can be used to develop more specialized standards to support specific scenarios. The goal of this document is to specify general considerations and requirements for the assessment of quality and risk associated with nano-enabled electrotechnical products and serve as the basis for developing particular product specific standards.

1 Numbers in square brackets refer to the Bibliography.

GUIDELINES FOR QUALITY AND RISK ASSESSMENT FOR NANO-ENABLED ELECTROTECHNICAL PRODUCTS

1 Scope

This document provides a recommended methodology for identifying relevant parameters of nanomaterials as well as providing generic guidelines on implementation of quality assessment and environment/health/safety assessment for nano-enabled/nano-enhanced electrotechnical products.

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 31000:2009, *Risk management – Principles and guidelines on implementation*

3 Terms, definitions and abbreviated terms

3.1 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

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

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1.1
nanoscale
length range from approximately 1 nm to 100 nm

[SOURCE: ISO/TS 80004-1:2015 [2], 2.1]

3.1.2
nanomaterial
material with any external dimension in the nanoscale or having internal structure or surface structure in the nanoscale

[SOURCE: ISO/TS 80004-1:2015, 2.4]

3.1.3
nano-object
material with one, two or three external dimensions in the nanoscale

[SOURCE: ISO/TS 27687:2008 [7], 2.2]