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TECHNICAL SPECIFICATION

colour inside

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

FOREWORD

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- the subject is still under technical development or where, for any other reason, there is the future but no immediate possibility of an agreement on an International Standard.

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- withdrawn,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.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

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]

3.1.4
nanostructured material
material having internal nanostructure or surface nanostructure

[SOURCE: ISO/TS 80004-1:2015, 2.7]

3.1.5
nanoparticle
nano-object with all three external dimensions in the nanoscale

[SOURCE: ISO/TS 27687:2008, 4.1]

3.1.6
nanoplate
nano-object with one external dimension in the nanoscale and the two other external dimensions significantly larger

[SOURCE: ISO/TS 27687:2008, 4.2]

3.1.7
nanofibre
nano-object with two similar external dimensions in the nanoscale and the third dimension significantly larger

[SOURCE: ISO/TS 27687:2008, 4.3]

3.1.8
nano-enabled
exhibiting function or performance only possible with nanotechnology

[SOURCE: ISO/TS 80004-1:2015, 2.15]

3.1.9
nano-enhanced
exhibiting function or performance intensified or improved by nanotechnology

[SOURCE: ISO/TS 80004-1:2015, 2.16]

3.1.10
organization
person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its objectives

Note 1 to entry: The concept of organization includes, but is not limited to sole-trader, company, corporation, firm, enterprise, authority, partnership, charity or institution, or part or combination thereof, whether incorporated or not, public or private.

[SOURCE: ISO 14001:2015, 3.1.4]

3.1.11
environment
surroundings in which an organization operates, including air, water, land, natural resources, flora, fauna, humans, and their interrelationships

[SOURCE: ISO 14001:2015, 3.2.1]

3.1.12
environmental aspect
element of an organization's activities or products or services that interacts or can interact with the environment.

[SOURCE: ISO 14001:2015, 3.2.2]

3.1.13
environmental impact
change to the environment, whether adverse or beneficial, wholly or partially resulting from an organization's environmental aspects

[SOURCE: ISO 14001:2015, 3.2.4]

3.1.14
stakeholder
individual or group that has an interest in any decision or activity of an organization

[SOURCE: ISO 26000:2010 [4], 2.20]

3.1.15
reference model
conceptual framework for understanding significant relationships among the entities of some environment, and for the development of consistent standards or specifications supporting that environment

Note 1 to entry: As outlined in OASIS (Organization for the Advancement of Structured Information Standards). https://www.oasis-open.org/committees/soa-rm/faq.php.

3.2 Abbreviated terms

CNT	carbon nanotube
EHS	environment, health and safety
HOQ	House of Quality (method)
NE (product)	nano-enabled/nano-enhanced electrotechnical (product)
PRM	performance reference model
QFD	quality function deployment

4 Quality, and risk assessment

4.1 General requirement

Quality and risk assessments require an appropriate framework in order to offer some guidelines for selecting the most suitable and relevant functions and features of a particular nano-product to be developed. A reference model, a conceptual framework which provides high-level specification of a system architecture, is a suitable assessment model for the broad spectrum of the potential nano-products. The proposed conceptual quality and risk frameworks should be consistent with ISO 9001 [5] and ISO 31000. For specific product areas, it should also be consistent with any existing product standard category. Figure 1 shows an example of the conceptual model governing a nanomedical device. It indicates how a broader standard context of conceptual model can be used in order to satisfy quality, risk and performance requirements.