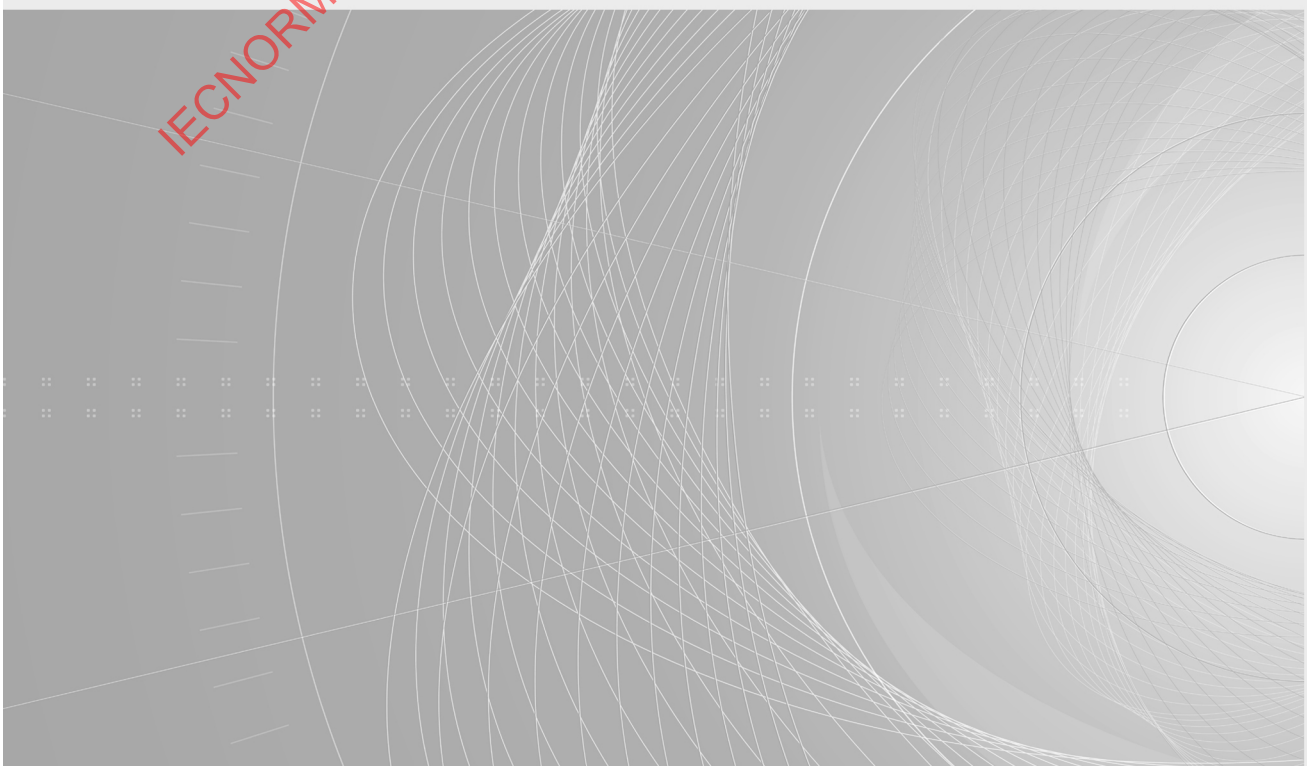
IEC TS 62844

Edition 1.0 2016-12

TECHNICAL SPECIFICATION

colour inside

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



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IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
Fax: +41 22 919 03 00
info@iec.ch
www.iec.ch

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

INTERNATIONAL
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COMMISSION

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CONTENTS

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- withdrawn,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.

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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]

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.

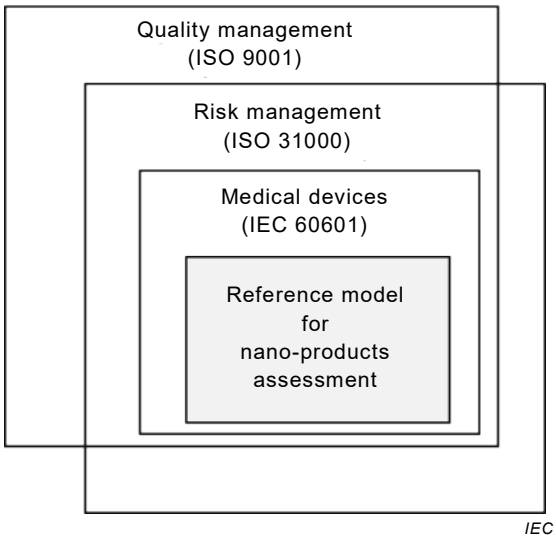


Figure 1 – The broader standard context of conceptual model governing a nanomedical device

4.2 Assessment model

4.2.1 General

The proposed reference model is a simplifed performance reference model (PRM) [6].The PRM is a framework for performance measurement providing common output measurements for nano-products. The PRM structure is designed to clearly express the cause-and-effect relationship between inputs and outputs. This PRM is articulated through the use of the measurement area, category, grouping and indicator hierarchy. It reflects how value is created as inputs (such as technology measures) and used to create outputs (such as customer and business results). Figure 2 shows the PRM structure. Figure 3 shows the PRM framework for NE products.

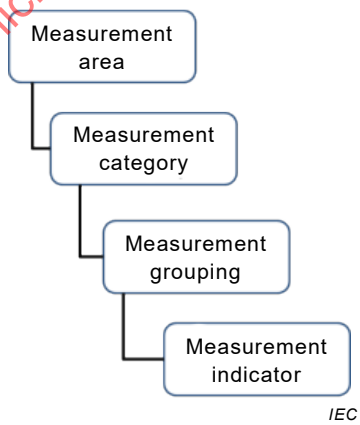


Figure 2 – Performance reference model (PRM) structure

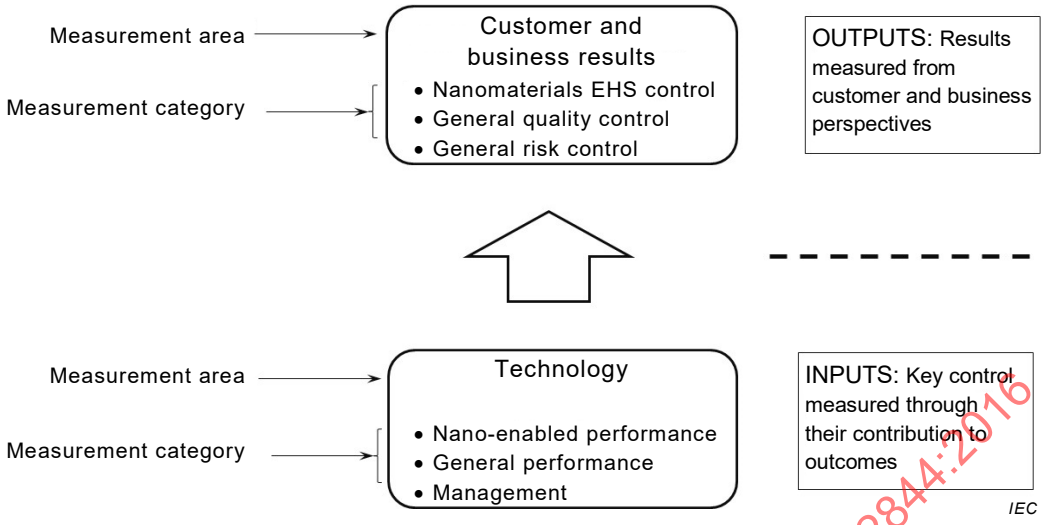


Figure 3 – PRM framework

The PRM in turn, is structured around measurement areas, measurement categories, measurement groupings and measurement indicators as shown in Figure 2.

- Measurement areas – The high-level organizing framework of the PRM capturing aspects of performance at the output levels. The PRM includes two measurement areas: customer and business results and technology measures.
- Measurement categories – Collections within each measurement area describing the attribute or characteristic to be measured. For example, the technology measurement area includes three measurement categories: nano-enabled performance, general performance, management.
- Measurement groupings – Further refinement of categories into specific types of measurement indicators: nano-characteristics, processes, etc. Figure 4 shows the measurement groups for measurement categories.
- Measurement indicators – The specific measures.

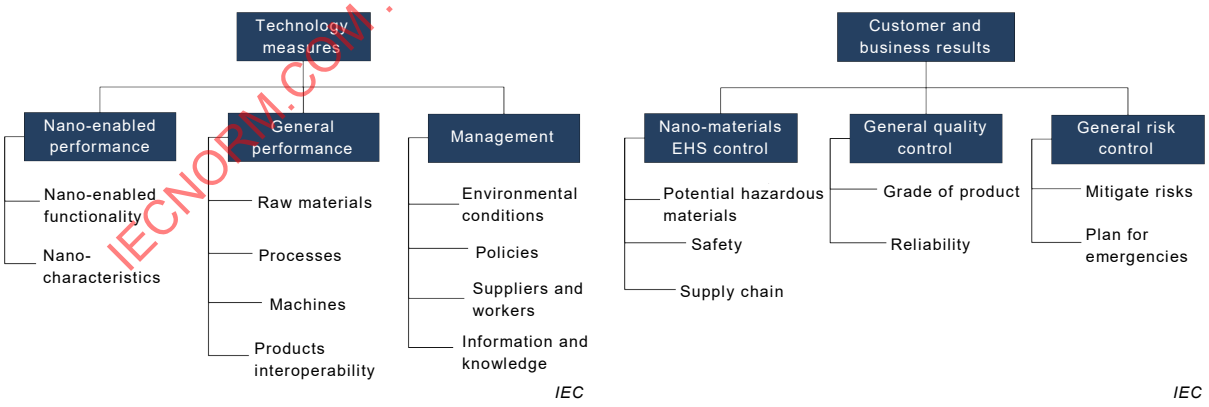


Figure 4 – Measurement groups for measurement categories

4.2.2 Customer and business results

The customer and business results measurement area of the PRM captures the outputs that stakeholders seek to achieve. These outputs are usually developed during the stakeholder strategic and long-term planning process prescribed under various objectives consideration. This measurement area identifies the extent to which those objectives are being achieved. The customer and business results measurement area is comprised of the following measurement categories:

- nanomaterials EHS control;
- general quality control;
- general risk control.

4.2.3 Technology measures

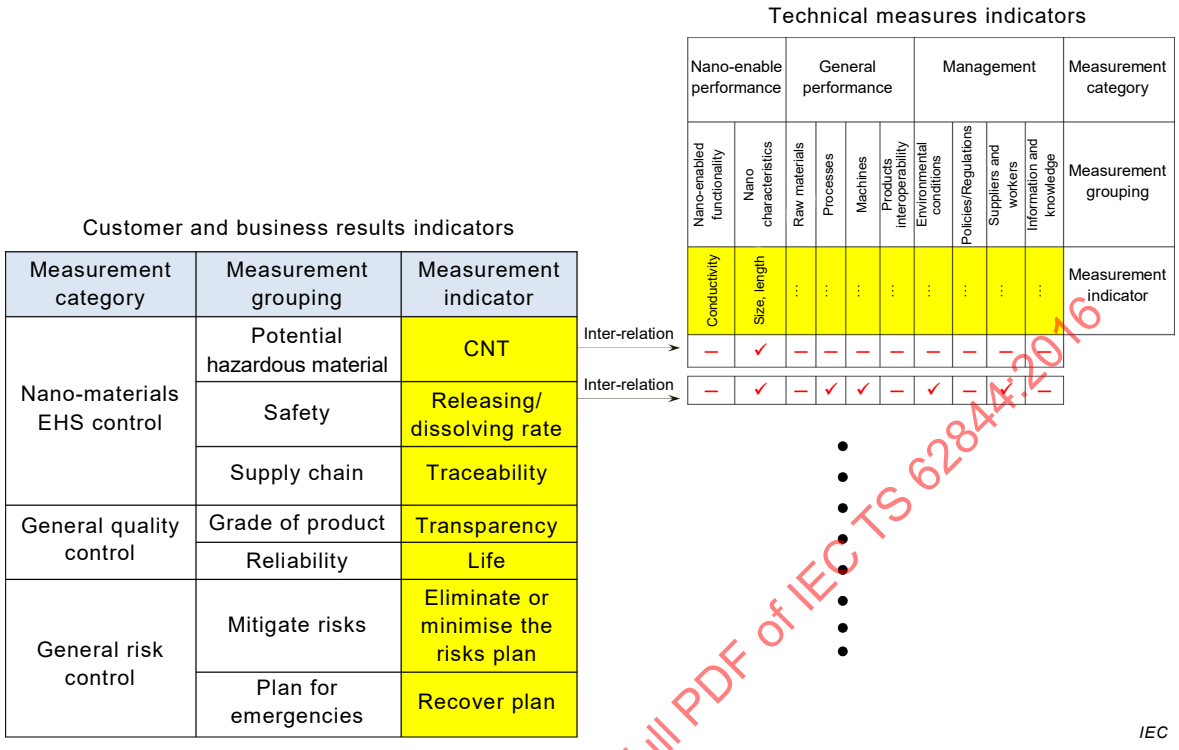
The technology measurement area captures key elements of performance directly relating to the NE products. The technology measurement categories and groupings will depend on the stakeholder's NE product and life-cycle development processes. However, the technology measurement area, in general, is comprised of the following basic measurement categories:

- nano-enabled performance;
- general performance;
- management.

4.2.4 Measurement indicators and inter-relation between indicators

Subclause 4.2.4 provides the measurement categories, groupings and indicators for the customer and business results measurement area. The organization's use of the table will determine the actual inventory of measurement indicators and the significance of the measurement indicators, i.e. specific measures for the technology and customer and business results and their inter-relationship. Table 1 shows a hypothetical relation between measurement indicators of customer and business results and technology indicators for a carbon nanotube (CNT)-enabled electrotechnical product. Each indicator should consider the inter-relation with technology measures indicators. For example, in "potential hazardous material" in Table 1, the measurement indicator is identified as CNT by stakeholders. However, not all CNTs are hazardous, the hazardous type of CNT should be discriminated from technical measures indicators. In this case, nano-characteristics (size, length) and CNT are highly correlative indicators, as highly correlative indicators are pairs of indicators that the dependent variable (e.g. an indicator of ouputs) will significantly change when the independent variable (e.g. an indicator of inputs) changes, and a "✓" is marked in the inter-relation matrix. The rest of the irrelevant inter-relation matrix is marked as "—". The same process applies to other customer and business results indicators. For "safety" in Table 1, the measurement indicator is identified from stakeholder as releasing and dissolving the rate of CNT, the indicators under nano-characteristics, manufacture process/machines, environmental conditions and suppliers and workers measurement grouping are the highly correlative indicators, and a "✓" is marked in the inter-relation matrix. The rest of the irrelevant inter-relation matrix is marked as "—". Two common methods for determining the inter-relation between indicators are listed in Annex B.

Table 1 – The relation between measurement indicators of customer and business results and technology indicators



The relationship between input and output indicators helps stakeholders to visualize the pattern of the relation between technical measures and stakeholder needs. The relation shows the impact of achieving the technical measures on achieving one or more of the stakeholder needs. The relation evaluations shall be based on expert experience, stakeholder responses and tabulated data from statistical studies or controlled experiments. Numbers and symbols can be used to establish the strengths of these relationships. The highly correlative indicators can be determined by the preferred methodology of the stakeholders.

4.3 Analysis methods

The interfunctional communication between input (technology measures) and output (customer and business results) measurement indicators can be analysed and fulfil the goal of quality and risk assessment. There are many analysis methods for such interfunctional communication relation. A simple method and a conceptual “House of Quality” method is provided in Clause C.3 for illustration purposes. In this document, it only provides a routine method for general step-by-step methodology to construct the measurement categories, groupings and indicators for the assessment model and the inter-relation between "technology measures" indicators and "customer and business results" indicators. The methodology selection should be based on stakeholders’ discretion and their technical preference.

5 General quality and risk assessment requirements for NE products

5.1 General

The procedures to assess the quality and risk requirements for NE products are depicted in Annex D. Detailed descriptions are given in Clauses 5 and 6.

5.2 Conditions for application to NE products

Unless otherwise specified, the requirements of this document shall apply in normal use and reasonably foreseeable misuse.

5.3 Risk management process for NE products

A risk management process complying with ISO 31000 shall be performed. Standard(s) governing other specific product category risk management processes will also be applicable, e.g. for medical device products ISO 14971 [7] also applies in addition to ISO 31000.

5.4 Essential performance

The manufacturer shall identify which functions of the NE products are essential performance. These functions shall be used and compliance shall be checked by inspection, or functional test. Compliance is checked by inspection of the quality management document.

5.5 Expected service life

The manufacturer shall state the expected service life of the NE products in the risk/quality management document.

5.6 Safety for NE products

The NE products shall comply with the safety requirements of the product category standard, e.g. if the NE product is a cell phone battery, the product safety shall conform to the battery standard.

5.7 NE product parts that contact person

The risk management process shall include an assessment of whether parts can come into contact with the person.

5.8 Components of NE products

All components shall be used in accordance with their specified ratings. The reliability of components shall comply with one of the following:

a) the applicable safety requirements of a relevant IEC or ISO standard;

b) where there is no relevant IEC or ISO standard, the requirements of this document.

5.9 General test requirement

The tests to be performed are determined taking into consideration the requirements of 5.2 to 5.8. The test results might necessitate a revision of the risk analysis.

6 Special assessment requirements for NE products

6.1 Nanomaterials environment, health and safety (EHS) control

a) Potential hazardous material

The manufacturers shall establish, implement and maintain a process to identify and document the relevant environmental aspects of nanomaterials across all life-cycle stages. Examples include: use of nano-objects, emissions to air, releases to surface water and ground water, waste, information about packaging/EHS impact for normal use/end of life management, etc. Compliance is checked by inspection of the relevant test documents or by giving a process description of the highly correlative indicators.

b) Safety

The manufacturers shall establish, implement and maintain a process to qualitatively or quantitatively determine and document the safety aspects that can have significant EHS impact during all life-cycle stages of the nanomaterials. Compliance is checked by inspection of the relevant design documents and by giving a process description of the highly correlative indicators.

c) Supply chain

The manufacturers as the key stakeholders shall establish, implement and maintain procedures to identify, access and use the information on the aspects of EHS of the nanomaterials intentionally added to their NE products. Such a process will identify all suppliers (including service providers). Compliance is checked by inspection of the relevant design documents and by giving a process description of the highly correlative indicators.

6.2 General quality control

a) Grade of product

The manufacturers shall establish, implement and maintain a process to identify and document the performance assigned to products or services having the same functional use but enabled by nanomaterials across all life-cycle stages. Compliance is checked by inspection of the relevant test documents or by giving a process description of the highly correlative indicators.

b) Reliability

The manufacturers shall establish, implement and maintain a process to qualitatively or quantitatively determine and document the ability of the NE products to perform its required functions under stated conditions for a specified period of time enabled by the nanomaterials. Compliance is checked by inspection of the relevant design documents and by giving a process description of the highly correlative indicators.

6.3 General risk control

a) Mitigate risks

The manufacturers shall establish, implement and maintain a process to identify and document the systematic reduction in the extent of exposure to a risk and/or the likelihood of its occurrence which is enabled by nanomaterials across all life-cycle stages. Compliance is checked by inspection of the relevant test documents or by giving a process description of the highly correlative indicators.

b) Plan for emergencies

The manufactures shall establish, implement and maintain a process to qualitatively or quantitatively determine and document targets for the significant EHS aspects of the nanomaterials to minimize as far as reasonable the adverse EHS impacts across all life-cycle stages. Compliance is checked by inspection of the relevant design documents and by giving a process description of the highly correlative indicators.

Annex A
(informative)

General approach and rationale

Nano-enabled electrotechnical products carry a particular risk of being detrimental to human health and the environment. Basic safety, essential performance and the environmental impact reduction of NE products are required for normal use and for reasonably foreseeable misuse as well as under normal conditions. For consistency with conventional practice, the basic safety, performance and risk management standards and ISO/IEC/ITU guides are considered. In addition, the special safety, performance and risk management standards associated specifically with nanotechnologies and products (ISO/TC 229 and IEC TC 113) are referred to for the purposes of developing a reference model for quality and risk assessment.

More specifically, Table A.1 provides the rationale for specific clauses in this document.

Table A.1 – Rationale related to specific clauses in this document

Clause No.	Title	Rationale
1	Scope	This document does not apply to any other electrical products unless it falls under the definition of NE products. This document recognizes that avoiding damage to the environment is part of basic safety and essential performance.
2	Normative references	This clause provides a list of documents indispensable for the application of this document. However, conformance with this list is required only to the extent of implementing the normative requirements of this document.
3	Terms, definitions and abbreviated terms	This clause contains definitions for terms that are necessary for the understanding of the requirements in this document. Many of these terms are inherited from the ISO/TC 229/IEC TC 113 JWG1 documents.
4	Quality, and risk assessment	The use of simplified PRM models is to provide a common methodology for improving strategic and daily decision-making, Improving the alignment of inputs to outputs and outcomes, Identify performance improvement opportunities, providing NE products' quality and risk information assessment from the stakeholders. The general requirements consideration example for a medical device containing nanomaterials is given in Figure 1. A hypothetical CNT product example is used to illustrate the measurement indicators relation in Table 1. General guidance examples for correlative indicators determination are illustrated in Annex C.
5	General quality and risk assessment requirements for NE product	5.2 The manufacturer identifies foreseeable misuse as part of the risk analysis. 5.3 The manufacturer is responsible for ensuring that the design and construction of the NE product renders it suitable for its intended purpose and that any risks associated with its use are acceptable. 5.5 The expected service life needs to be determined by the manufacturer, as part of the risk management process. 5.7 Since this document requires a risk management process to be followed, it is appropriate to use this process to establish whether such parts should be subject to the requirements.
6	Special assessment requirements for NE products	NE products are intended to have beneficial effects for the user; however, if the damage to the environment caused by the NE products outweighs the benefits, this is counterproductive to the intended function of the NE products. The special assessment requirements are to reduce the environmental impacts of the NE products taking into account all NE products life-cycle stages. An example of a special requirements declaration form for a CNT-coated touch panel is illustrated in Table B.1.

Annex B
(normative)

General guidance for stakeholder's declaration

The NE product example is a hypothetical CNT-coated touch panel. The general declaration items can follow Clause 5 using existing standards. The special requirements in Clause 6 for the CNT-coated touch panel can be described as in the example shown in Table B.1.

Table B.1 – Special requirements declaration form for the CNT-coated touch panel

Guidance and stakeholder's declaration – Special requirements for NE products		
CNT-coated touch panel		
Measurement category	**Measurement indicators**	**Tests or documents**
Nanomaterials EHS control	**Potential hazardous material** Type of CNT Nanomaterials label RoHS compliant	Internal documents EU directives
	Safety Workplace airborne/water concentration	Internal documents
	Supply chain Impurity of raw material	ISO/TS 13278 [8]
General quality control	**Grade of product** Conductivity	IEC TS 62607-2-1 [9] IEEE 1650 [10]
	Reliability Durability	Internal documents
General risk control	**Mitigate risks** Suppliers' performance products design	Internal documents ISO 31000
	Plan for emergencies Recycle plan	Internal documents

Annex C
(informative)

General guidance for correlative indicators determination

C.1 General

In Annex C, two methods are illustrated for general guidance to determine high correlated indicators:

– routine method;
– "House of Quality" method.

The methodology relies on stakeholders' discretion based on their technical preference.

C.2 Routine method

Each determined indicator in customer and business results is a column with all technical measures' indicators. The correlation between indicators is determined by stakeholders' methods. Table C.1 shows an indicators relation example for carbon nanotube (CNT).

Table C.1 – Indicators relation example for CNT

Measurement category	Measurement grouping	Measurement indicator	Potential hazardous material, e.g. CNT[a]
Nano-enabled performance	Nano-enabled functionality	Conductivity	–
	Nano-characteristics	Diameter, length	–
General performance	Raw materials	Impurity	–
	Processes	Uniformity (test by film)	✓
	Machines	repeatability	✓
	Products interoperability	conductivity	–
Management	Environmental conditions	Release to water	✓
	Policies/regulations	EU directives	✓
	Suppliers and workers	Air concentration	✓
	Information and knowledge	Packaging/normal use/end of life information	✓

[a] ✓= high correlated indicators; – = irrelevant indicators

C.3 House of Quality (HOQ)

House of Quality (HOQ) is a diagram, resembling a house, used for defining the relationship between customer/user desires/expectations and the product capabilities. It is a part of the

quality function deployment (QFD) [11]. HOQ is used for defining the relationship between customer desires and the product capabilities. User expectations include compliance with legal and other regulations concerning environment/health/safety (EHS) aspects. The house is a conceptual map that provides interfunctional communication. It utilizes a planning matrix to relate what the customer wants to how a firm (that produces the products) is going to meet those wants. It looks like a house with a "correlation matrix" as its roof, and customer needs versus product technical measures as the main part. The basic structure is a table with "Whats" as the labels on the left and "Hows" across the top. The roof is a diagonal matrix of "Hows vs. Hows" and the body of the house is a matrix of "Whats vs. Hows". Both of these matrices are filled with indicators of whether the interaction of the specific item is a strong positive, a strong negative, or somewhere in between. Additional annexes on the left side and bottom hold the "Rankings" (relative importance) and the "How muches". Relative importance and the correlations can be used to calculate priorities for the Hows. House of Quality analysis can also be cascaded, with "Hows" from one level becoming the "Whats" of a lower level; as this progresses the decisions get closer to the engineering/manufacturing details. (Based on *Wikipedia, House of Quality* [12]).

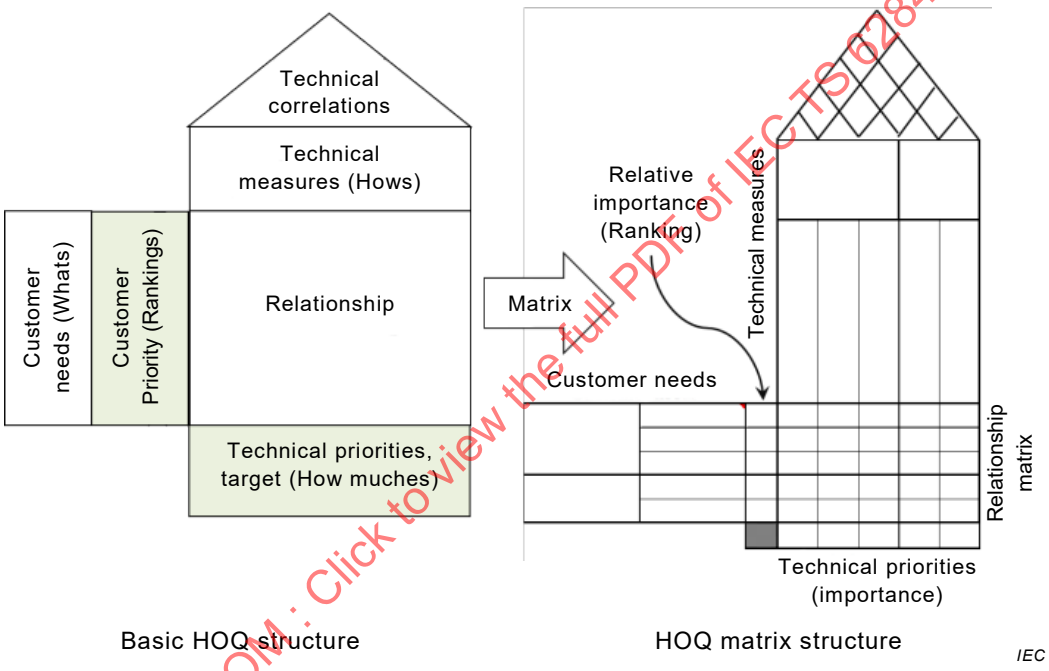


Figure C.1 – HOQ matrix structures

The next step is the transformation of technical measures (Hows) into requirements for the manufacturing process (see Figure C.2). In HOQ 2 the process becomes a translation of the technical measures into the parts characteristics. Then, in HOQ 3, the parts characteristics get translated into the key control characteristics. And finally, in HOQ 4, the key control characteristics are translated into the voice of production requirements.

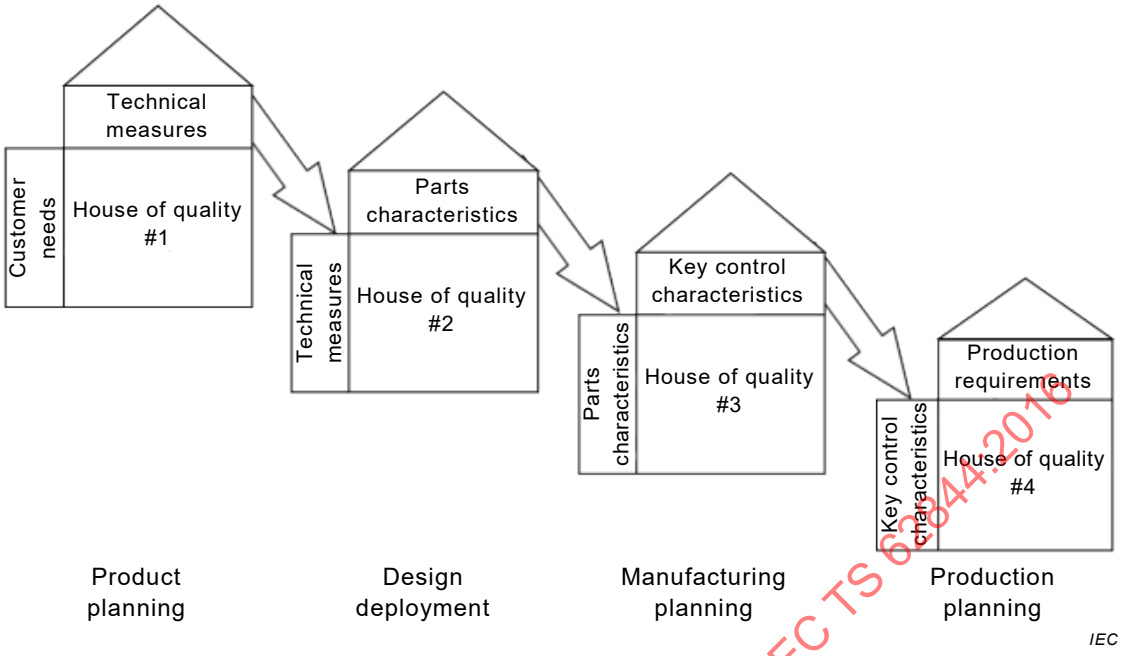


Figure C.2 – Cascaded HOQ

Figure C.3 depicts the HOQ structure based on the proposed PRM model. It highlights indicators inter-relation matrix for materials control (CNT) in comparion with the routine method in Clause C.2. The inter-relations are expressed as different numbers to represent the impact strength of the paired indicators.

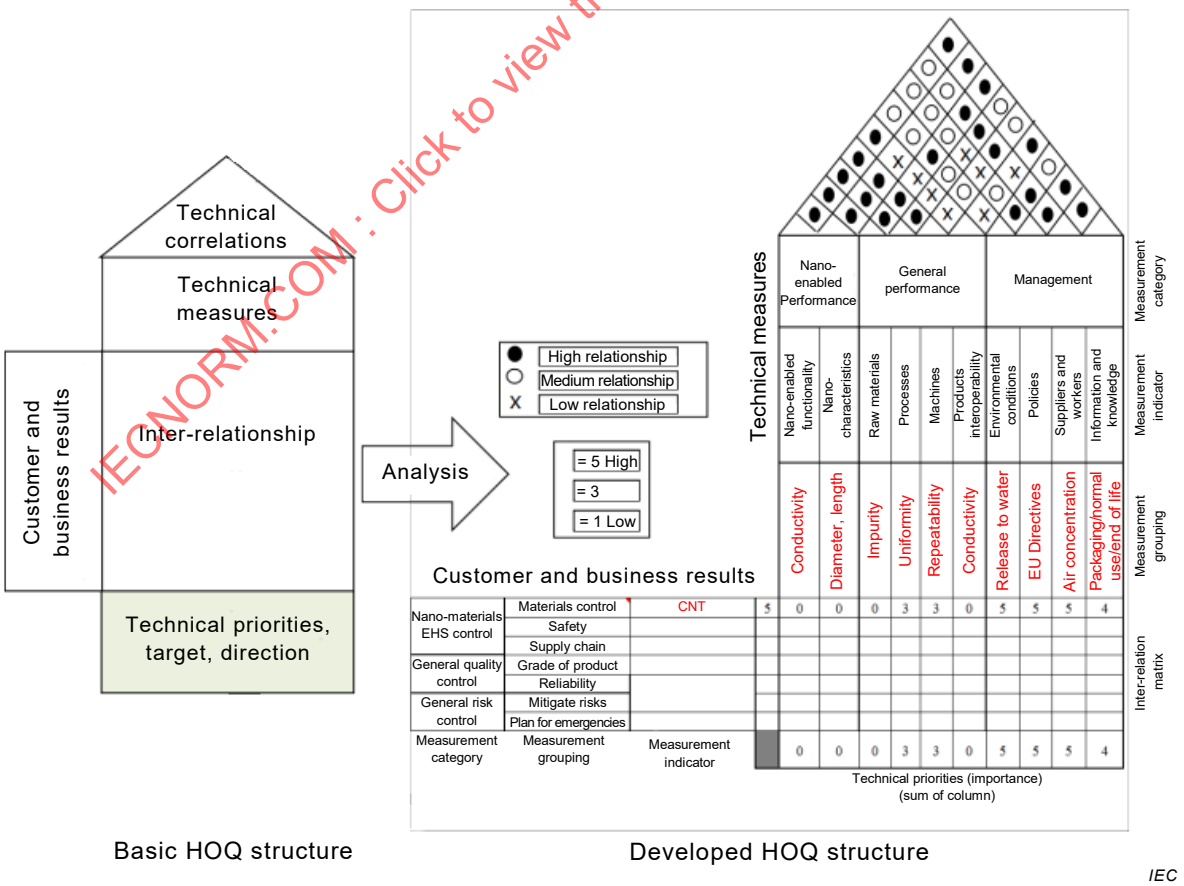


Figure C.3 – HOQ structure based on the proposed PRM model