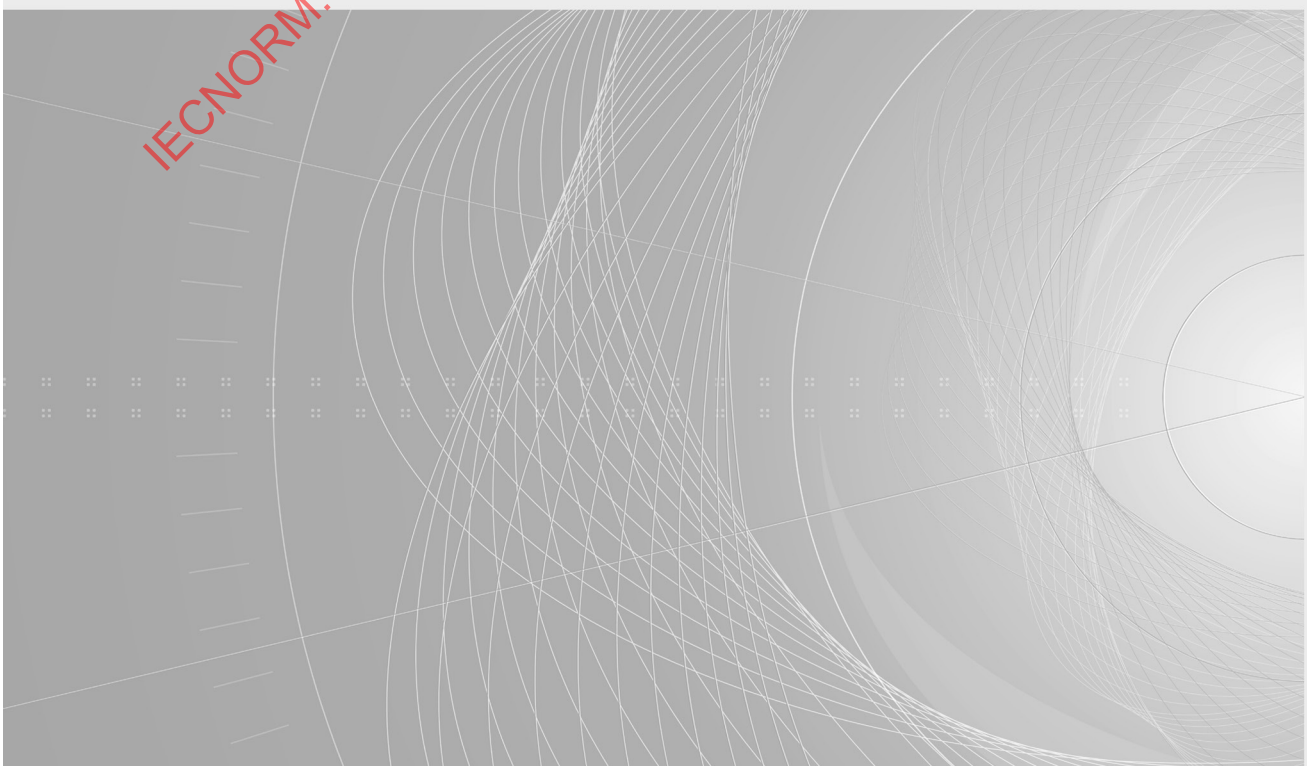
IEC TS 62565-1

Edition 1.0 2023-05

TECHNICAL SPECIFICATION

colour inside

Nanomanufacturing – Product specifications – Part 1: Basic concepts



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Part 1: Basic concepts

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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NANOMANUFACTURING – PRODUCT SPECIFICATIONS –

Part 1: Basic concepts

FOREWORD

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IEC TS 62565-1 has been prepared by IEC technical committee 113: Nanotechnology for electrotechnical products and systems. It is a Technical Specification.

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

Draft	Report on voting
113/697/DTS	113/723/RVDTS

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this Technical Specification is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

A list of all parts in the IEC 62565 series, published under the general title *Nanomanufacturing – Product specifications*, can be found on the IEC website.

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

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

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INTRODUCTION

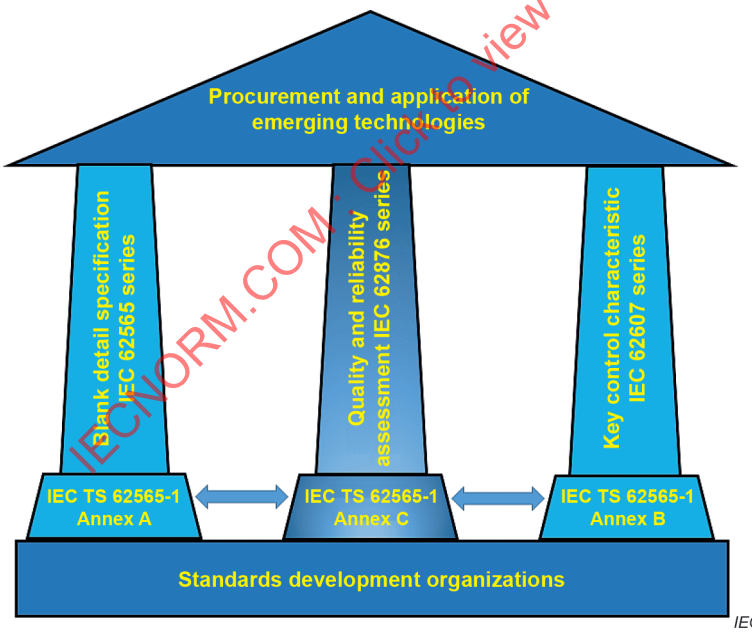
The mission of IEC technical committee 113 (IEC TC 113) is to develop IEC publications based on quality management (QM) principles in order to facilitate the transition of nano-enabled products from development to mass production.

The standardization strategy of IEC TC 113 covers the entire value chain from the production of nanomaterials and their use as independent products (in other words, the product is the raw material) to their use as raw materials for integration into subassemblies or end-user products. Since IEC TC 113 is an electrotechnical committee, the focus of standardization is on electrotechnical products without excluding the applicability to non-electrotechnical products. The development of IEC Publications for reliability and durability assessment is also in the scope of IEC TC 113.

This part of IEC 62565 provides the basic concept and guidelines on how to write the various types of blank detail specification (BDS) and detail specification (DS) in a standardized and harmonized manner and describes the systematics behind these documents.

The systematics is based on the "three pillar concept" and provides:

– standards for the specification of nanomaterials and nano-enabled products (left pillar: IEC TS 62565-x-y);
– standards for the measurement of key control characteristics (KCCs) for nanomaterials and nano-enabled products (right pillar: IEC TS 62607-x-y);
– standards for quality and reliability assessment. These include test methods for reliability and durability, but also general standards based on existing International Standards for quality management systems (QMS) adapted to the specific needs of nanotechnology (centre pillar: IEC TS 62876-x-y).



Blank detail specifications (BDSs) provide a list of all known product performance parameters, called key control characteristics (KCCs), of the nanomaterial or nano-subassembly which is part of the nano value chain.

Detail specifications (DSs) provide values and attributes (that had been left blank in BDS) for a specific application agreed between supplier and customer.

KCC measurement standards provide a detailed description how to measure a specific KCC and report the results. There can be several measurement methods for the same KCC, which can be selected based on the needs of the application.

Quality and reliability assessment standards describe the quality and reliability of nano-enabled products.

Figure 1 – Systematics of IEC TC 113 standards

In Figure 1, the logical connections in this comprehensive system of quality assurance for nanomaterials and nano-enabled products are visualized. Due to the interdependence of the three types of standards, it is important that standardization in IEC TC 113 covers all three columns in order to arrive at a consistent system of standards which can be operated in a "seamless" fashion.

This part of IEC 62565 provides the basic concept for the series of BDSs. Examples of other parts addressing specific technology areas are:

– IEC TS 62565-2-x: Carbon nanotube materials
– IEC TS 62565-3-x: Graphene-based materials
– IEC TS 62565-4-x: Luminescent nanomaterials
– IEC TS 62565-5-x: Nano-enabled energy storage materials

NOTE It is expected that additional BDS series will emerge as industrial uptakes of new materials or new applications occur.

An indispensable basis of the concept of BDS and DS are clear definitions of the product characteristics and detailed descriptions for measuring these characteristics. These characteristics are called key control characteristics (KCCs) because they represent key features of the products to be monitored in the framework of a quality management system. IEC 62607 consists of a series of KCC measurement Technical Specifications to be used for the BDS and DS:

– IEC TS 62607-2-x: KCCs for carbon nanotube materials
– IEC TS 62607-3-x: KCCs for luminescent nanomaterials
– IEC TS 62607-4-x: KCCs for nano-enabled electrical energy storage
– IEC TS 62607-5-x: KCCs for thin-film organic/nano electronic devices
– IEC TS 62607-6-x: KCCs for graphene-based material
– IEC TS 62607-7-x: KCCs for nano-enabled photovoltaics
– IEC TS 62607-8-x: KCCs for nano-enabled metal-oxide interfacial devices
– IEC TS 62607-9-x: KCCs for nano-scale stray magnetic field measurements

Each part of the IEC 62607 series of measurement Technical Specifications describes exactly one method for measuring a particular KCC. Measurement standards outside the IEC 62607 series can be used in IEC 62565 BDSs and DSs if their applications are clear in the context of the specification.

In addition to the specification of the nanomaterial characteristics (IEC 62565 series) and the standardized procedures for the measurement of the characteristics (IEC 62607 series), two additional aspects of quality management are relevant for complete quality assurance:

The performance of materials and products at the time of manufacture is one thing, but the reliability is an additional relevant quality assurance metric. Two examples in the IEC 62876 series are given below.

- IEC TS 62876-2-1:2018, *Nanotechnology – Reliability assessment – Part 2-1: Nano-enabled photovoltaic devices – Stability test*
- IEC TS 62876-3-1:2022, *Nanomanufacturing – Reliability assessment – Part 3-1: Graphene-based material – Stability: Temperature and humidity test*

To ensure that the sourcing of the nanomaterials and the manufacturing process are consistently managed according to the prescriptions of ISO 9001:2015, the first steps have been taken in the development of an IEC standard for a quality management system in nanoelectronics.

The reliability standards and the quality management system standard are represented by the centre pillar in Figure 1.

More background information can be found in Annex C.

NANOMANUFACTURING – PRODUCT SPECIFICATIONS –

Part 1: Basic concepts

1 Scope

This part of IEC 62565, which is a Technical Specification, defines the system of blank detail specifications for nanomaterials and nano-assemblies as well as final nano-enabled products addressed in the nanomanufacturing value chain.

It defines the concepts of blank detail specification (BDS), detail specification (DS) and key control characteristic (KCC). Furthermore, it provides guidelines how to develop and use product specifications, particularly the IEC 62565 series, in the field of nanotechnology.

This document also provides guidelines regarding the certification and reliability aspects for products specified by a DS and associated KCCs.

NOTE 1 The IEC 62565 series uses an open generic structure that can be flexibly adapted to technical developments. The double indexing of the individual parts allows grouping into technology areas without restriction due to an overly strict hierarchical structure.

NOTE 2 Key elements of the IEC 62565 series are a consensus-based set of key control characteristics (KCCs) with clear definitions and standardized measurement procedures to measure them.

2 Normative references

There are no normative references in this document.

3 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
key control characteristic
KCC
product characteristic which can affect safety or compliance with regulations, fit, function, performance, quality, reliability or subsequent processing of the final product

Note 1 to entry: The measurement of a key control characteristic is described in a standardized measurement procedure with known accuracy and precision.

Note 2 to entry: It is possible to define more than one measurement method for a key control characteristic if the correlation of the results is well-defined and known (3.2).

3.2
blank detail specification
BDS
structured generic specification providing a comprehensive set of key control characteristics which are needed to describe a specific product without assigning specific values or attributes

Note 1 to entry: Examples of nano-enabled products are: nanocomposites and nano-subassemblies.

Note 2 to entry: Blank detail specifications are intended to be used by industrial users to prepare their detail specifications used in bilateral procurement contracts. A blank detail specification facilitates the comparison and benchmarking of different materials. Furthermore, a standardized format makes procurement more efficient and more error robust.

3.3
detail specification
DS
specification based on a blank detail specification with assigned values and attributes

Note 1 to entry: The characteristics listed in the detail specification are usually a subset of the key control characteristics listed in the relevant blank detail specification. The industrial partners define only those characteristics which are required for the intended application.

Note 2 to entry: Detail specifications are defined by the industrial partners. Standards development organizations will be involved only if there is a general need for a detail specification in an industrial sector.

Note 3 to entry: The industrial partners may define additional key control characteristics if they are not listed in the blank detail specification.

3.4
good practice guide
GPG
informal document which is not necessarily peer reviewed but can be used as a working document to establish a measurement procedure

Note 1 to entry: A GPG serves as the first document based on initial scientific research which is intended to be the first step toward future standardization.

3.5
standard maturity level
SML
measure for estimating the maturity of a measurement procedure based on the consensus achieved in the stakeholder community

Note 1 to entry: SML 1 – No documented measurement procedure available.

Note 2 to entry: SML 2 – Good practice guide publicly available based on a reasonable consensus achieved in the stakeholder community, e.g. an industrial or academic consortium.

Note 3 to entry: SML 3 – IEC or ISO standard or Technical Specification available which can be applied with modification and adaption to the intended application and use case of the blank detail specification scope.

Note 4 to entry: SML 4 – IEC or ISO standard or Technical Specification available for the exact intended application and use case of the blank detail specification.

3.6
procurement information
information other than key control characteristics needed for the procurement process

3.7
measurand
quantity intended to be measured

Note 1 to entry: If the quantity is a key control characteristic, the measurement is an essential part of the quality management system.

[SOURCE: ISO/IEC Guide 99:2007, 2.1, modified – Notes to entry and examples have been deleted and a new Note 1 to entry has been added.]

3.8
measurement
process of experimentally obtaining one or more values that can reasonably be attributed to a quantity

Note 1 to entry: If the quantity is a key control characteristic, the measurement is an essential part of the quality management system.

[SOURCE: ISO/IEC Guide 99:2007, 2.1, modified – In the definition, "quantity values" has been replaced by "values". Notes to entry have been deleted and a new Note 1 to entry has been added.]

3.9
measurement accuracy
closeness of agreement between a measured quantity value and a true quantity value of a measurand

Note 1 to entry: The concept ‘measurement accuracy’ is not a quantity and is not given a numerical quantity value. A measurement is said to be more accurate when it offers a smaller measurement error.

[SOURCE: ISO/IEC Guide 99:2007, 2.13, modified – Notes 2 and 3 to entry have been deleted.]

3.10
measurement method
process of experimentally obtaining one or more values that can reasonably be attributed to a quantity

Note 1 to entry: If the quantity is a key control characteristic, the measurement is an essential part of the quality management system.

3.11
measurement principle
phenomenon serving as a basis of a measurement

EXAMPLE 1 Thermoelectric effect applied to the measurement of temperature.

EXAMPLE 2 Energy absorption applied to the measurement of amount-of-substance concentration.

EXAMPLE 3 Hall effect applied to the measurement of magnetic flux density.

Note 1 to entry: The phenomenon can be of a physical, chemical, or biological nature.

[SOURCE: ISO/IEC Guide 99:2007, 2.4, modified – EXAMPLE 3 has been replaced.]

3.12
measurement procedure
detailed description of a measurement according to one or more measurement principles and to a given measurement method, based on a measurement model and including any calculation to obtain a measurement result

Note 1 to entry: A measurement procedure is usually documented in sufficient detail to enable an operator to perform a measurement.

Note 2 to entry: A measurement procedure can include a statement concerning a target measurement uncertainty.

Note 3 to entry: A measurement procedure is sometimes called a standard operating procedure, abbreviated SOP.

[SOURCE: ISO/IEC Guide 99:2007, 2.6]

3.13
measurement result
set of quantity values being attributed to a measurand together with any other available relevant information

Note 1 to entry: A measurement result is generally expressed as a single measured quantity value and a measurement uncertainty. If the measurement uncertainty is considered to be negligible for some purpose, the measurement result may be expressed as a single measured quantity value. In many fields, this is the common way of expressing a measurement result.

[SOURCE: ISO/IEC Guide 99:2007, 2.9, modified – Notes 1 and 3 to entry have been deleted.]

3.14
measurement standard
standardized measurement procedure
normative document established by consensus and approved by a recognized body, that provides a measurement procedure, for common and repeated use, aimed at the achievement of the optimum degree of order in a given context

Note 1 to entry: Standards are in general based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits.

3.15
nano-enabled
exhibiting function or performance only possible with nanotechnology

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

3.16
nanomanufacturing
intentional synthesis, generation or control of nanomaterials, or fabrication steps in the nanoscale, for commercial purposes

[SOURCE: ISO/TS 80004-1:2015, 2.11]

3.17
product specification
structured document which describes all characteristics of a product known to be relevant for applications of that product

Note 1 to entry: A material specification is an example of a product specification

3.18
use case
specification of a generalized field of application, possibly entailing the following information about the system: one or several scenarios; the functional range; the desired behaviour; and the system boundaries

Note 1 to entry: The use case description typically does not include a detailed list of all relevant scenarios for this use case. Instead, a more abstract description of these scenarios is used.

4 General

4.1 Requirements for product specifications

The IEC 62565 series is intended to specify nanomanufactured products (materials, assemblies, end-user products) of stable quality under parametric control. Products produced to meet the specification, agreed between a customer and supplier, shall be qualified through routine process checks (routine process checks in mass production means that statistical process control (SPC) is applied), demonstrating that the process is in a state of control. More detailed information on the essential role of SPC can be found in [1][1] and [3].

The specification usually contains the following elements.

– Relevant information for product identification, such as a safety data sheet, which should be shared between customer and supplier during the purchasing process.

– Information about the fabrication process to address potentially relevant "hidden parameters".

– A list of key control characteristics of the product that are relevant for the intended application.

– For detailed specifications, include numerical values, value ranges, or non-numerical attributes (such as solid or liquid) of the key control characteristics. Leave these fields blank if no details are provided.

– Units of measurement for the key control characteristics.

– Reference to standardized measurement procedures for determining the key control characteristics or a standard measurement procedure if no standards exist.

NOTE With increasing maturity of the technology, formerly "hidden parameters" will appear as additional KCCs in the BDS: Standardization of the known will help to gain control of the unknown.

An example for the content structure of a blank detail specification is given in Annex A.

4.2 Generic systematics of specifications for nanomaterials and nano-enabled products

Given an ever-increasing number of materials used in the fabrication of nano-enabled electrotechnical products, the design of a classification system is essential to establish an easy-to-use suite of standards. The systematics defined support the users to find the most appropriate Technical Specification for their application, to incorporate new materials standards with ease, to define a way to develop a modified or new specification; and to facilitate the development of user-customer agreements if, for example, special final product characteristics make this necessary.

This system shall allow for the incorporation of new materials while maintaining the overall classification system.

[1] Numbers in square brackets refer to the Bibliography.

The systematics is reflected in the numbering system for specification documents: In order to fulfil the requirements described in the preceding paragraph, the parts of the IEC 62565 series have two indices, e.g. IEC 62565-x-y (x and y are natural numbers):

– The first index x is a number chosen by the technical committee to represent a product, system or more generally a technology or technical field, e.g. materials used for energy storage or for lighting applications; the second index y is a sequential number which is increased by one as each new specification is added.
– Furthermore, the parts of the IEC 62565 series differentiate between blank detail specifications (BDS) and detail specifications (DS), which have different roles as described in 4.3 and 4.4.

In this document, the general term "specification" is used if it is not necessary to differentiate between a BDS or DS, as all types of specification follow the same systematics.

4.3 Blank detail specification

A blank detail specification (BDS) for nanomanufactured products (materials, assemblies, end-user products) is a template which contains requirements for style, layout and content of a material specification. It lists the key control characteristics (KCCs) which are required to ensure the quality for material procurement and the use of the material in the manufacture of nano-enabled products. The BDS does not contain specific numerical values or attributes for those KCCs. Therefore, the BDS establishes the foundation for customers and suppliers of nanomaterials to develop their own specification. The relation of a BDS, KCCs and measurement methods is visualized in Figure 2 and Figure 3.

In more detail, a BDS has the following characteristics.

– It provides a predefined structure of the contents of a product description to identify the product, and defines general requirements in connection with the product.
– It contains a consensus-based list of KCCs which describe the nanomaterial or more generally the nano-enabled product. This list in the form of a table provides
  - name of the KCC, accompanied by a formal definition in the "Terms and definitions" clause,
  - name of the measurement method of the KCC, accompanied by a formal definition in the "Terms and definitions" clause,
  - format of the specified value and measurement unit, and
  - identification of the standard defining the measurement procedure for the key control characteristics. If there is no dedicated measurement standard for the KCC,
    i) other documented standards may be applied, if guidelines for their use are provided in Annex A of the BDS, or if no applicable standard exists,
    ii) good practice guides or bilateral supply agreements may fill the gap. This shall be addressed in Annex B, because no KCC shall be listed without providing a guideline to verify conformity with the specification.

  The document maturity is indicated by the SRL value.
– Each KCC listed in the specification is voluntary. Supplier and customer may add or remove items in the KCC list or agree on other methods than those in the BDS to verify the specified KCCs.

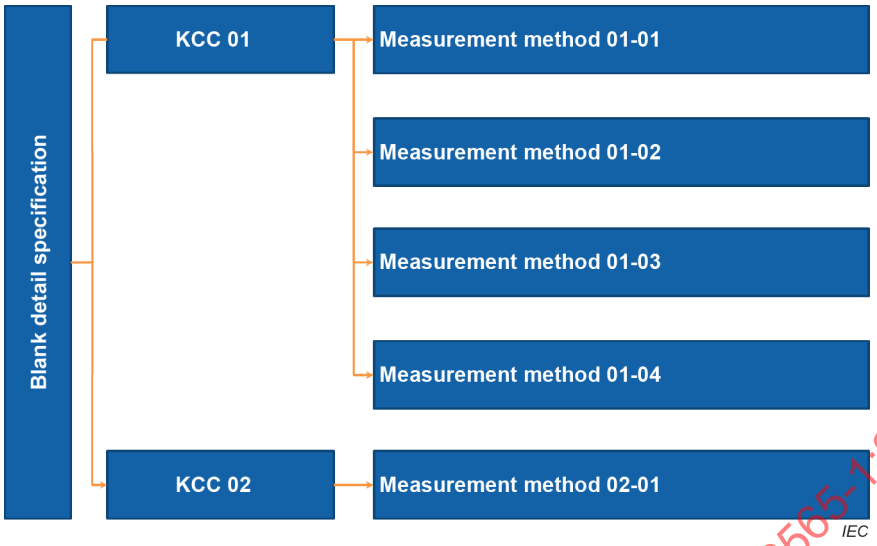


Figure 2 – KCCs and their relation to the BDS: general scheme

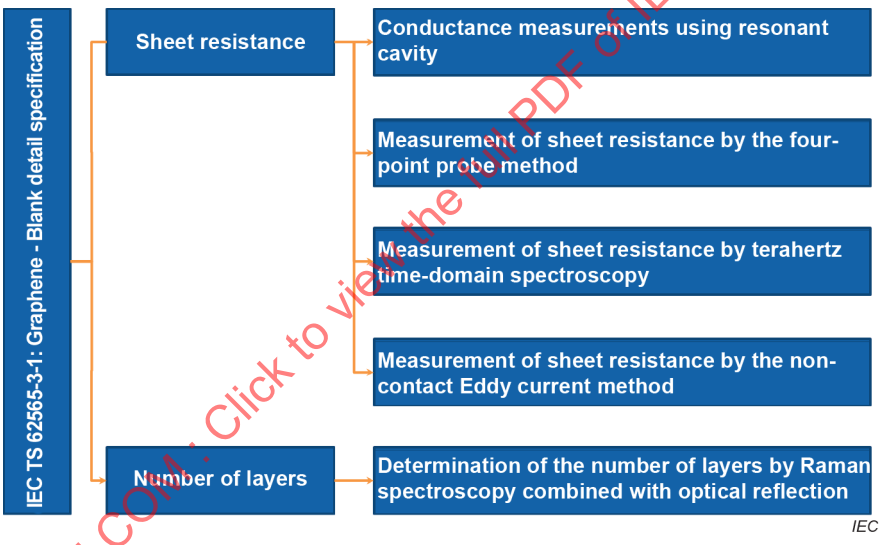


Figure 3 – KCCs and their relation to the BDS: example

NOTE In special cases for a particular application it can be useful to establish a document containing only a subgroup of the KCCs listed in the BDS. This document is called a sectional blank detail specification.

4.4 Detail specification

A detail specification (DS) for nanomanufactured products, including materials, assemblies, and end-user products, serves as a template which is based on a BDS. In contrast to the BDS the DS contains specific numerical values or attributes for the key control characteristics (KCCs) of the product. The KCC list of the DS is typically a subset of the list in the BDS. If required by the application additional KCCs may be added. The BDS shall be referenced in the DS as a normative reference. The DS shall include all the elements of the product specification necessary to ensure the reliability of the numerical values. While alternative measurement methods may be accepted in the BDS, this is typically not the case in the DS. The measurement method and procedure shall be included in the detail specification.

A DS is often used in supplier–customer relations to define the quality of products and serves as a basis to accept or reject a delivery. If required, a technical committee can issue a DS to provide guidance to stakeholders.

5 Structure of a blank detail specification

5.1 General

The recommended structure of a BDS is shown in Annex A. Although the introduction is not normative in nature, it does provide the user with important information regarding the commercial relevance of the BDS as well as its relationship to other product specifications in the same technology area. Annex A also provides a generic format of title and scope as well as a suggested table of contents.

The core elements of the BDS are the tables listing the information to specify the product. This includes a general product description and procurement information as well as the list of the KCCs.

5.2 General product description and procurement information

Table 1 contains information needed for the procurement of the specified material, component or sub-assembly generally referred to as product. The information shall be suitable to track it back to the particular fabrication process at the supplier and it is assumed that this information allows the supplier to verify the complete set of fabrication conditions for the production batch in question. In addition, the information shall be suitable to order the identical product again.

Table 1 – General product description and procurement information

Item No	Item		Information
1.1	Supplier		
1.2	Trade name		
1.3	ID number		
1.4	Typical batch quantity	☐ Number of pieces	
		☐ Mass [kg]	
		☐ Volume [l]	
1.5	Traceability requirements	☐ Batch number ☐ Serial number ☐ Others, specify ……	
		Manufacturing date	
1.6	Specification	Number	
		Revision level	
		Date of issue	
1.7	Packaging requirements		
1.8	Factory name and location		

5.3 Specification of key control characteristics

This part of the BDS lists the identified KCCs for the product. In general, it is recommended to provide it in table form similar to that of Table 2, but as every product is different this can be only a guideline. For a BDS that contains many KCCs, it is recommended to structure the list by dividing it into categories. This makes the specification clearer and easier to use in practice.

NOTE Example for the category structure of nanomaterials: chemical KCCs, electrical KCCs, thermal KCCs, optical KCCs, mechanical KCCs, dimensional and structural KCCs.

Table 2 – Format for specification of key control characteristics

KCC No.	KCC	SPECIFICATION	UNIT	MEASUREMENT METHOD	SML	MEASUREMENT PROCEDURE
3.1	key control characteristic	Nominal [ ] ± Tolerance [ ] or larger than [ ], smaller than [ ]				
3.2	sheet resistance	Nominal [ ] ± Tolerance [ ] or larger than [ ], smaller than [ ]	Ω/□	Terahertz time-domain spectroscopy	4	IEC TS 62607-6-10
3.3	specific surface area	Nominal [ ] ± Tolerance [ ] or larger than [ ], smaller than [ ]	m^2/g	BET method	3	ISO 9277 (Annex A.n)
3.4					2	(Annex B.n)
3.5					1	NA

Description of the entries in Table 2:

– KCC contains the term used for the KCC. This term should be defined in the "terms and definitions" clause of the BDS with a reference to the source if the definition was taken from another standard. Whenever possible the definitions shall be consistent with definitions in the terminological databases maintained by IEC and ISO (IEC Electropedia and ISO Online Browsing Platform) preferably the definitions in the IEC 62565, IEC 62607, IEC 62876 and ISO 80004 series.

– SPECIFICATION is described as the nominal value of the KCC with its tolerance or the limiting values such as larger than or smaller than a specified value.

– UNIT is the physical unit of the measurand.

– MEASUREMENT METHOD is the generally used name of measurement according to a given principle, e.g. Raman spectroscopy, atomic force microscopy, van der Pauw method.

– SML describes the maturity of measurement procedure based on the consensus achieved in the stakeholder community.

– MEASUREMENT PROCEDURE ideally refers to the measurement standard for the KCC. Depending on the degree of maturity of the measurement standard, additional information is given in Annex A.

6 Measurement procedures for key control characteristics

6.1 General

According to the philosophy in IEC TC 113, all KCCs and the measurement procedures listed in the BDS are defined in Clause 3 "Terms and definitions". In some cases, there are several measurement methods that are suitable for measuring a specific KCC. Although it is recommended to specify exactly one combination of KCC and measurement method, there can be good reasons to specify multiple combinations.

For each combination of KCC and measurement method there shall be a reference in Table 2 to a document describing the measurement procedure. The referenced measurement procedures should be International Standards from the IEC 62607 series because they are focused on providing exactly the information in the KCC table. Nevertheless, for emerging technologies like nanotechnology this is not always possible.

In general, there are four scenarios regarding the availability of standardized measurement methods. These are outlined in 6.2 to 6.5.

6.2 SML 4: Standardized measurement procedure for the KCC available

SML 4 describes the situation where a standardized measurement procedure is available and can be used exactly for the use case under consideration. In this case it is suitable just to list the standard in Table 2.

The advantage of SML 4 is that the standard can directly be applied to the intended use case including sample preparation, description of the measurement procedure, data analysis and reporting of the results.

6.3 SML 3: Adoption and adaptation of an existing standardized measurement procedure

A standardized measurement procedure is available which is intended to be used for another use case – for example, other materials or other applications – but can be adapted for the desired use case. The measurement procedure may not yet be validated for the use case in the BDS. In this case the method shall be listed in Annex A of the BDS. It is requested to review the adopted measurement standard paragraph by paragraph and describe the modifications needed in detail. It shall be checked whether additional measurement errors can occur because the standard is used outside its scope.

A reference to the annex paragraph with the description of the modifications shall be given in Table 2. It is recommended to transform the measurement procedure into a documented standard as soon as the procedure is mature enough for standardization.

6.4 SML 2: Guidance for measurement procedures in the absence of a standard

A standardized measurement method is not yet available but the technical community has consensus about the need to specify the KCC. In this case, guidance on how to perform the measurement procedure shall be added for each combination of the KCC and measurement methods as a paragraph in Annex B. If a GPG was developed by a group of stakeholders or a consortium and is publicly available, this may be referenced instead together with an introduction of its use.

The level of detail of the guidelines inevitably depends on the state of the art of the technology and ranges from a rough description of the measurement procedure to a precise work instruction analogous to a KCC measurement standard (See Annex B of this document). It is recommended to transform the guideline into a documented standard as soon as the procedure is mature enough for standardization.

6.5 SML 1: No documented measurement procedure available

There is no documented measurement method available, neither as a standard or adaptable standard nor as a GPG. Nevertheless, the technical community achieved consensus about the need to specify the KCC. This is the lowest level of common understanding in the community, and it is left to the parties involved in the delivery process to define a way of dealing with the situation if they write a detail specification.

6.6 Overview of measurement methods and SML of the related measurement procedures

To support an easy use of a BDS, there should be a paragraph providing an overview of the test procedures (see also example table of contents in Annex A of this document) including a table (see example Table 3 below) containing the combinations of KCCs and measurement standards as well the SML number to support easy use of the BDSs.

If there is more than one combination of KCC and measurement standard listed in Table 2, in this case a comment is requested to support supplier and customer in selecting the best one for their use case giving due consideration to the following:

– accuracy and precision of the method;

– experience they have in performing different methods;

– availability of equipment;

– spatial restrictions, for example, due to restrictions accessing the sample in the fabrication line;

– measurement speed.

For the entry SML under "measurement procedure" in the KCC tables, there are four scenarios regarding the availability of documented measurement procedures which are summarized in the overview Table 3 for each combination of KCC and measurement method.

SML1: A standardized measurement procedure is not yet available, but the technical community has consensus about the need to specify the KCC. Also, a GPG is not available. This is the lowest level of common understanding in the community, and it is left to the parties involved in the delivery process to define a way of dealing with the situation, for example by adding an agreed standard operation procedure (SOP) to the specification. That shall be mentioned in Annex A also.

SML2: A standardized measurement procedure is not yet available, but the technical community has consensus about the need to specify the KCC. In this case, a GPG developed by a group of stakeholders or a consortium may serve as the basis for the measurement. The GPGs shall be attached to the BDS as clauses in Annex B with an introduction of their use and a comment of their scientific validation. If the GPG is publicly available, it can be referenced instead.

SML3: A standardized measurement procedure is available which is intended to be used for another use case but can be adapted for the desired use case, for example, other materials or other applications. They may not yet be validated for the use case in the BDS. In this case the method shall be listed in Annex A with a description of how the standard shall be adopted. Reference to the Annex A clause shall be given in the KCC tables.

SML4: A standardized measurement procedure is available and can be used exactly for the use case under consideration. In this case it is suitable just to list the standard in the column "measurement procedure" of the KCC tables.

In the cases 2 and 3 it is recommended to transform the measurement procedure into a documented standard and to perform all necessary steps to prepare submission of a New Work Item Proposal to the IEC through the appropriate National Committee.

Table 3 – Overview of measurement methods (Example)

KCC		Measurement											
		IEC 62xxx-xx-yy	ISO 22xxx-xx-yy	GPG B.1.1	none	IEC 62xxx-xx-yy	none	IEC 62xxx-xx-yy	ISO 22xxx-xx-yy	GPG B.2.1	IEC 62607-6-10	IEC 62607-6-9	IEC 62607-6-87
		Method 1	Method 2	Method 3	Method 4	Method 5	Method 6	Method 7	Method 8	Method 9	THz-TDS	Eddy current method	Van der Pauw method
Category 1	KCC 1,1	1	1										
	KCC 1,2			2									
	KCC 1,3				1	1							
Category 2	KCC 2,1						1	1					
	KCC 2.2							1					
	KCC 2,3								1	2			
Category 3	Sheet resistance										4		
	Sheet resistance											4	
	Carrier mobility												4

7 Certification aspects

7.1 General remarks

To achieve the objective to create trust in the quality of nanomaterials, both the quality of the material and the quality of the manufacturing process shall be demonstrated to potential customers.

The confirmation of the quality of the materials is demonstrated with the reference to the standardized materials specifications (DSs) and the associated characterization methods for the key control characteristics (KCCs). The practical implementation of this confirmation procedure, in other words, a product audit, is described in general terms in 7.2 and guidance on details is provided in Annex C.

The confirmation that the material in question fulfils the materials specification on a sample basis shall be underpinned by a confirmation that the manufacturing process can produce consistent quality, in other words the quality of the manufacturing process shall be ascertained. This procedure, which is commonly called a factory audit, confirms that the manufacturing process can produce the required material quality consistently. The factory audit is described in general terms in 7.3 and guidance on details is provided in Annex C.

7.2 Product audit

To certify a certain product, a product audit shall be performed. To this end, a random sample of the material shall be drawn by the certification personnel on site in the stores of the manufacturer location from the stored finished products.

In this procedure, the lot number(s) of the material sample(s) shall be recorded, and the material sample(s) shall be packed in a way that an unauthorized opening of the package is prevented. The sample(s) shall be analysed by an independent accredited laboratory. The result of the evaluations shall be documented.

Guidance on practical details can be found in Annex C.

7.3 Factory audit

As described in 7.1, the confirmation of the capability of the manufacturing process to consistently manufacture products of the quality specified in the materials specification is performed in a factory audit.

The audit process shall be carried out by an independent organization by qualified auditors that are employed by the organization or hired by the organization.

During the factory audit, the quality management system, the standardized operating procedures and the quality records shall be checked for consistency and adequateness to assure the necessary process quality. In addition, the auditors shall confirm that the prescriptions of the quality management system are implemented for every process step in the manufacturing process and that the quality records are adequate.

Guidance on practical details can be found in Annex C.

8 Process steps for the development of nanomaterial or nano-enabled product detail specification

8.1 General

As explained in the Introduction, this document is embedded in a general systematics for the development of standards which are anticipative for processes and documents needed in a quality management system for the manufacturing of nano-enabled electrotechnical products.

For more detailed information on this, see Annex C.

8.2 Defining the scope of the specification

The scope of the DS shall be defined as a starting point of the development. Depending on the complexity of the field, it can be a good strategy to initially concentrate on the more mature part of the technology and accept that the list of KCCs is incomplete. Hidden parameters, in other words parameters unknown at the time of development, may occur and which therefore cannot be addressed at that particular point in time. Nevertheless, a clear definition of KCCs for the maturer part of the technology will help to identify those hidden parameters over time and improve later editions of the document. To make those special circumstances clear to the user of the specification, the situation should be described in the "Introduction" of the document.

8.3 Defining the list of key control characteristics

During the development of a BDS or DS, all interested stakeholders shall be consulted to collect the relevant KCCs and measurement methods to measure them. If there are no specific measurement standards available, action shall be taken to initiate their development.

Documents listing KCCs and the related measurement methods shall be revised frequently. In the future, it is expected that digital representations of standards will even better serve the community than printed versions since their frequent revision is implemented more easily.

Some guidance and how to define measurement methods and procedures for key control characteristics in the absence of standards can be found in Annex C.

Annex A
(informative)

Structure of standards for blank detail specifications

A.1 Title and scope of standards for blank detail specifications

A.1.1 Generic format of the title

NANOMANUFACTURING – PRODUCT SPECIFICATION –

Part X-Y: <Product> – <BDS>: <Application>

NOTE <Product> includes material, groups of materials, components and subassemblies. <BDS> is the term describing the type of specification: blank detail specification, sectional blank detail specification, or detail specification. <Product> and <Application> are repeated in the scope together with additional information regarding the applicability of the standard.

A.1.2 Generic format of the scope

This part of IEC 62565 establishes a standardized method to determine a blank detail specification for

- <product>

used for

- <application>.

<Additional details regarding the application>

– <use case 1>
– <use case 2>
– <use case n>

NOTE The scope lists the key control characteristic to measure, the measurement method and short description of the measurement principle and use cases describing criteria for the application of the standard.

A.2 Content of standards for blank detail specifications

This table of contents provides a generic structure of standards for blank detail specifications. Subdivisions may be added or removed without changing the basic concept, if there is a good technical reason to do so.

FOREWORD
INTRODUCTION
1 Scope
2 Normative references
3 Terms and definitions
3.1 General terms
3.2 General product description and procurement information
3.3 Category 1 key control characteristics
3.4 Category n key control characteristics
3.5 Measurement methods
4 General introduction regarding measurement methods

Annex B
(informative)

Structure of measurement standards for key control characteristics

B.1 Title and scope of measurement standards for key control characteristics

B.1.1 Generic format of the title

NANOMANUFACTURING – KEY CONTROL CHARACTERISTICS –

Part X-Y: <Product> – <KCC>: <Measurement method>

NOTE <Product> includes material, groups of materials, components and subassemblies. <KCC> is the term describing the key control characteristic and <Measurement method> the term for the measurement method. <KCC> and <Measurement method> are repeated in the scope together with additional information regarding the applicability of the standard

B.1.2 Generic format of the scope

This part of IEC 62607 establishes a standardized method to determine the key control characteristic

- <key control characteristic>

for <product> by

- <measurement method>.

<short description of the measurement principle>

– <use case 1>
– <use case 2>
– <use case n>

NOTE The scope explicitly lists the key control characteristic to measure, the measurement method and short description of the measurement principle and use cases describing criteria for the application of the standard.

B.2 Content of measurement standards for key control characteristics

This table of contents provides a generic structure of measurement standards for key control characteristics. Subdivisions may be added or removed without changing the basic concept, if there is a good technical reason to do so.

FOREWORD
INTRODUCTION
1 Scope
2 Normative references
3 Terms and definitions
4 General
4.1 Measurement principle
4.2 Sample preparation method
4.3 Description of measurement equipment and apparatus
4.4 Supporting materials
4.5 Calibration standards
4.6 Ambient conditions during measurement