



GHWP

Global Harmonization Working Party

Towards Medical Device Harmonization

PROPOSED FINAL DOCUMENT

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Foreword

92 This document was prepared by Global Harmonization Working Party (GHWP), Working Group
93 8 (Standards) together with GHWP Secretariat, and endorsed by the GHWP.

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95 This guideline indicates the general procedures by which Global Harmonization Working Party
96 (GHWP) Documents are developed in order to ensure that they are clear, precise and
97 unambiguous.

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99 This guideline is intended to ensure that any GHWP Documents produced by the committees
100 under GHWP is presented in a uniform manner.

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102 Any statements or references from external sources are used under appropriate citations as
103 specified in the normative references and bibliography.

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105 This guideline is subject to review and users are advised to confirm that the version used is
106 current.

1 Scope

This guideline provides the principles and rules for the structure and drafting of GHWP Documents to ensure that such documents, prepared by the committees are drafted in as uniform manner as practicable, irrespective of the technical content.

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.

3.1 Elements of a document

3.1.1

normative element

element that describes the scope of the document or sets out provisions

[Source: ISO/IEC Directives, Part 2, 2021, 3.2.1]

3.1.2

informative element

element intended to assist the understanding or use of the document or that provides contextual information about its content, background or relationship with other documents

[Source: ISO/IEC Directives, Part 2, 2021, 3.2.1]

3.1.3

mandatory element

element that has to be present in a document.

EXAMPLE The Scope is an example of a mandatory element.

[Source: ISO/IEC Directives, Part 2, 2021, 3.2.1]

3.1.4

conditional element

element that is present depending on the provisions of the particular document.

EXAMPLE

The symbols and abbreviated terms clause are the examples of a conditional element.

[Source: ISO/IEC Directives, Part 2, 2021, 3.2.1]

3.1.5

optional element

element that the writer of a document may choose to include or not

EXAMPLE The Introduction is an example of an optional element.

[Source: ISO/IEC Directives, Part 2, 2021, 3.2.1]

3.2

GHWP Document

consensus document, whitepaper, guidance document (GD) or guideline (GL) developed by committees under GHWP for publication.

3.3 Provisions

3.3.1

provision

expression in the content of a normative document that takes the form of a statement, an instruction, a recommendation or a requirement.

NOTE. These forms of provision are distinguished by the form of wording they employ; e.g. instructions are expressed in the imperative mood, recommendations by the use of the auxiliary “should” and requirements by the use of the auxiliary “shall”.

[SOURCE: ISO/IEC Guide 2:2004, 7.1].

3.3.2

statement

expression, in the content of a document, that conveys information

[Source: ISO/IEC Directives, Part 2, 2021, 3.3.2, modified, deleted Note 1 to entry]

3.3.3

requirement

expression, in the content of a document, that conveys objectively verifiable criteria to be fulfilled and from which no deviation is permitted if conformance with the document is to be claimed

[Source: ISO/IEC Directives, Part 2, 2021, 3.3.3, modified, deleted Note 1 to entry]

3.3.4

recommendation

expression, in the content of a document, that conveys a suggested possible choice or course of action deemed to be particularly suitable without necessarily mentioning or excluding others

Note 1 to entry: In the negative form, a recommendation is the expression that a suggested possible choice or course of action is not preferred but it is not prohibited.

[Source: ISO/IEC Directives, Part 2, 2021, 3.3.4, modified, deleted Note 1 to entry].

3.3.5

permission

expression, in the content of a document, that conveys consent or liberty (or opportunity) to do something

[Source: ISO/IEC Directives, Part 2, 2021, 3.3.5, modified, deleted Note 1 to entry].

3.3.6

possibility

expression, in the content of a document, that conveys expected or conceivable material, physical or causal outcome

[Source: ISO/IEC Directives, Part 2, 2021, 3.3.6, modified, deleted Note 1 to entry].

3.3.7

capability

expression, in the content of a document, that conveys the ability, fitness, or quality necessary to do or achieve a specified thing

[Source: ISO/IEC Directives, Part 2, 2021, 3.3.7, modified, deleted Note 1 to entry].

3.4

state of the art

developed stage of technical capability at a given time as regards products, processes and services, based on the relevant consolidated findings of science, technology and experience.

[SOURCE:ISO/IEC Guide 2:2004, 1.4].

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A. GENERAL PRINCIPLES

4 Objective of GHWP Document

The objective of documents is to specify clear and unambiguous provisions in order to facilitate the usage of the documents. To achieve this objective, the GD shall:

a) be complete within the limits specified by their scope;

NOTE. When a document provides requirements or recommendations, these are either written explicitly, or made by reference to other documents.

b) be consistent, clear and accurate;

c) be written using all available knowledge about the state of the art;

d) be comprehensible to qualified people who have not participated in their preparation; and

e) consideration to comply with GD.

5 Principles

5.1 Planning and preparation

The rules given in this guideline shall be applied throughout all stages of drafting to avoid delay. In order to ensure the timely publication of a document, the following shall be determined before drafting begins:

a) the intended structure;

b) any interrelationships; and

c) the organisation and subdivision of the subject matter.

EXAMPLE

Different approaches are possible in the specification of requirements concerning a table.

Design requirements: The table shall have four wooden legs.

Performance requirements: The table shall be constructed such that when subjected to ... [stability and strength criteria].

5.2 Performance principle

Whenever possible, requirements shall be expressed in terms of performance rather than design or descriptive characteristics. When the performance principle is adopted, care shall be taken to ensure that important features are not inadvertently omitted from the performance requirements.

5.3 Consistency

Consistency should be maintained within each GHWP document.

a) Identical wording should be used to express identical provisions.

b) The same terminology should be used throughout. The use of synonyms should be avoided.

Consistency is particularly important to help the user understand documents or series of associated documents. It is also important when using automated text processing techniques and computer-aided translation.

6 Organisation and subdivision of the subject matter

6.1 Names of the main subdivisions

The terms that shall be used to designate the divisions and subdivisions of subject matter are

311 given in Table 1.

312 **Table 1. Names of divisions and subdivision**
313

Term	Example of numbering
Clause	1
Subclause	1.1, 1.1.1, 1.1.1.1
Paragraph	no number
Annex	A

314 **6.2 Subdivision of the subject matter within an individual document**
315
316

317 The arrangement of GHWP document is given in Table 2.
318

319 **Table 2. Overview of the major subdivisions of a document and their arrangement in the**
320 **text**
321

Major subdivision	Mandatory/optional/conditional element
Title	Mandatory
Acknowledgement	Mandatory
Contents	Mandatory
Foreword	Mandatory
Introduction	Optional
Scope	Mandatory
Normative references	Mandatory*
Terms and definitions	Mandatory*
Requirements	Conditional
Symbols and abbreviated terms	Conditional
Technical content: For example: test methods	Conditional
Annexes	Conditional
Bibliography	Conditional
*When no normative references or terms are listed, use the introductory texts provided in 17.5.2, and condition as in 18.5.3.	
Note: Any other subdivision may be added as necessary.	

322 **7 Verbal forms for expressions of provisions**
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324 **7.1 General**
325

326 The user of the document needs to be able to identify the requirements he/she is obliged to
327 satisfy in order to claim compliance with a document. The user also needs to be able to
328 distinguish these requirements from other types of provision where there is a choice (i.e.
329 recommendations, permissions, possibilities and capabilities).
330

331 It is essential to follow rules for the use of verbal forms so that a clear distinction can be made
332 between requirements, recommendations, permissions, possibilities and capabilities.
333

334 The first column in Table 4 to Table 7 shows the preferred verbal form to be used to express
335 each type of provision. The equivalent expressions given in the second column shall be used
336 only in certain cases when the form given in the first column cannot be used for linguistic
337 reasons.
338

339 Only singular forms are shown in Tables 3 to Table 7.
340

341 **7.2 Requirement**
342

343 See the definition given in 3.3.3.
344

The verbal forms shown in Table 4 shall be used to express requirements.

Table 4. Requirement

Preferred verbal form	Equivalent phrases or expressions for use in certain cases
shall	is to is required to it is required that has to only ... is permitted it is necessary
should	is not allowed [permitted] [acceptable] [permissible] is required to be not is required that ... be not is not to be do not
EXAMPLE 1	
Implants shall conform to the biocompatibility requirements specified by ISO 10993-1.	
Do not use "must" as an alternative for "shall".	
Do not use "may not" instead of "shall not" to express a prohibition	

7.3 Recommendation

See the definition given in 3.3.4.

The verbal forms shown in Table 5 shall be used to express recommendations.

Table 5. Recommendation

Preferred verbal form	Equivalent phrases or expressions for use in certain cases
should	it is recommended that ought to
should not	it is not recommended that ought not to
EXAMPLE	
In carrying out risk management manufacturers should estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse.	

7.4 Permission

See the definition given in 3.3.5.

The verbal forms shown in Table 6 shall be used to express permission.

Table 6. Permission

Preferred verbal form	Equivalent phrases or expressions for use in certain cases
may	is permitted is allowed is permissible
may not	it is not required that no ... is required
EXAMPLE 1	
In some countries, medical device gases may be regulated as a medical device, a drug or not subject to regulation.	

Do not use “possible” or “impossible” in this context.

Do not use “can” instead of “may” in this context. “May” signifies permission expressed by the document, whereas “can” refers to the ability of a user of the document or to a possibility open to him/her.

Do not use “might” instead of “may” in this context.

7.5 Possibility and capability

See the definitions given in 3.3.6 and 3.3.7.

The verbal forms shown in Table 7 shall be used to express possibility and capability.

Table 7. Possibility and capability

Preferred verbal form	Equivalent phrases or expressions for use in certain cases
can	be able to there is a possibility of it is possible to
cannot	be unable to there is no possibility of it is not possible to
EXAMPLE 1	
...IVD medical device is subjected to the stresses which can occur during normal conditions of use...	
Do not use “may” instead of “can” in this context.	
“May” signifies permission expressed by the document, whereas “can” refers to the ability of a user of the document or to a possibility open to him/her.	

8 Language, spelling, abbreviated terms, style and basic reference works

8.1 Language and spelling

The following English reference works for language and spelling are suggested:

- a) The Shorter Oxford English Dictionary,
- b) The Concise Oxford Dictionary; or
- c) Chambers Concise Dictionary

8.2 Spelling of names of organisations

The names of organisations shall be formal as confirmed by the representatives of the organisations.

8.3 Abbreviated terms

The use of abbreviated terms shall be consistent throughout the document.

If a list of abbreviated terms is not given in the document (see Clause 19), then the first time that an abbreviated term is used, the full term shall be given with the abbreviated term following in brackets.

EXAMPLE 1

the weighted root mean square (RMS) width of the active output interface optical spectrum ...

Any abbreviated term should be in upper case letters, without a full stop after each letter.

EXAMPLE 2

“RH” for “relative humidity”.

“WG” for “Working Group”

9 Numbers, quantities, units and values

9.1 Representation of numbers and numerical values

The decimal sign shall be a point.

- a) To express values of physical quantities, Arabic numerals (0-9) followed by the international symbol for the unit shall be used.

EXAMPLE 1 1 kg 1 L 2 mm 5 min

- b) Each group of three digits shall be separated by a small space from the preceding digits. This also applies to digits following the decimal sign. This does not apply to binary and hexadecimal numbers, numbers designating years or the numbering of standards.

EXAMPLE 2 23 456 2 345 2.345 2.345 6 2.345 67 year 2011

- c) The multiplication cross (\times) shall be used to indicate the multiplication of numbers and numerical values written in decimal form, in vector products and in cartesian products.

EXAMPLE 3 $A = 80 \text{ mm} \times 25 \text{ mm}$

EXAMPLE 4 $l = 2.5 \times 10^3 \text{ m}$

EXAMPLE 5 $I_G = I_1 \times I_2$

- d) The half-high dot (\cdot) shall be used to indicate a scalar product of vectors and comparable cases, and may also be used to indicate a product of scalars and in compound units.

EXAMPLE 6 $U = R \cdot I$

EXAMPLE 7 $\text{rad} \cdot \text{m}^2/\text{kg}$

- e) In some cases, the multiplication sign may be omitted.

EXAMPLE 8 $4c - 5d$ $6ab$ $7(a + b)$ $3 \ln 2$

9.2 Values, dimensions and tolerances

9.2.1 General

Values and dimensions shall be indicated as being minimum or maximum. Their tolerances (if applicable) shall be specified in an unambiguous manner.

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EXAMPLE 1 80 mm × 25 mm × 50 mm (**not** 80 × 25 × 50 mm)

EXAMPLE 2 80 μF ± 2 μF or (80 ± 2) μF

EXAMPLE 3 $\lambda = 220 \times (1 \pm 0.002) \text{ W}/(\text{m} \cdot \text{K})$

EXAMPLE 4 80 $^{+2}_0$ (not 80 $^{+2}_0$)

EXAMPLE 5 80 mm $^{+50}_{-2}$ μm

EXAMPLE 6 10 kPa to 12 kPa (**not** 10 to 12 kPa or 10 – 12 kPa)

EXAMPLE 7 0 °C to 10 °C (**not** 0 to 10 °C or 0 – 10 °C)

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In order to avoid misunderstanding, tolerances on values expressed in percent shall be expressed in a mathematically correct form.

EXAMPLE 8 Write “from 63 % to 67 %” to express a range. (**Not** 63 to 67 % or 63 – 67 %)

EXAMPLE 9 Write “(65 ± 2) %” to express a centre value with tolerance. (**Not** 65 ± 2 %)

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The degree should be divided decimally.

EXAMPLE 10 Write 17.25° rather than 17°15'.

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Any value or dimension that is mentioned for information only shall be clearly distinguishable from requirements.

9.2.2 Limiting values

For some purposes, it is necessary to specify limiting values (maximum, minimum). Usually one limiting value is specified for each characteristic. In the case of several widely used categories or levels, several limiting values are required.

Limiting values for maximum can be written as max. or minimum can be written as min. in the table.

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9.3 Quantities, units, symbols and signs

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- a) The International System of units (SI) as shall be used.
- b) The units in which any values are expressed shall be indicated.
- c) The unit symbols for degree, minute and second for plane angle shall immediately follow the numerical value; all other unit symbols shall be preceded by a space.
- d) Language-specific abbreviated terms such as ppm should not be used, if possible. If it is necessary to use language-specific abbreviated terms such as ppm, their meaning shall be explained.
- e) Symbols in formula and text shall use the defaulted font, size 10 pt. using Microsoft Words Equation function.
- f) Symbols in note shall use the defaulted font, size 9 pt. using Microsoft Words symbol function.

Do not italicise subscripts for symbols unless they are also variables.

EXAMPLE 1 m_i, D_i for $i = 1, 2, 3, \dots$

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Use Annex A as a checklist of the quantities and units which shall be used.

10 Referencing

10.1 Purpose or rationale

As a general rule, references to particular pieces of text should be used instead of repetition of the original source material. Repetition introduces the risk of error or inconsistency and increases the length of the document. However, if it is considered necessary to repeat such material, its source shall be referenced precisely.

Imprecise references such as “the following clause” or “the figure above” shall not be used.

References can be made:

- a) to other parts of the document [e.g. a clause, table or figure (see 10.6)]; or
- b) to other documents or publications (see 10.2).

References can be:

- a) informative (see Clause 23); or
- b) normative (see Clause 17).

References can be:

- a) dated (see 10.5); or
- b) undated (see 10.4).

10.2 Permitted referenced documents

Normatively referenced documents shall be documents published under GHWP. In the absence of appropriate GHWP Documents, those published by other bodies may be listed as normative references provided that:

- a) the referenced document is recognised by the GHWP as having wide acceptance and authoritative status as well as being publicly available (e.g. IMDRF, ISO, IEC, WHO documents); and
- b) the document is available under commercial terms which are fair, reasonable and non-discriminatory.

Informative reference may be made to any other type of document. Informative references shall be listed in the bibliography.

The GHWP shall validate all referenced documents when a GHWP document is revised. The normative references list shall not include the following:

- a) referenced documents which are not publicly available (in this context, “publicly available” means published documents which are available free of charge, or available commercially under reasonable and non-discriminatory terms to any user); and
- b) referenced documents which are cited only informatively as bibliographic or background material.

10.3 Presentation of references

Documents shall be referred to by their number, and if applicable, date of publication and title.

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EXAMPLE 1

ISO 1161:2000, *Series 1 freight containers - Corner fittings – Specification*

EN 10025 (all parts), *Hot rolled products of structural steels*

IEC 61175-1, *Industrial systems, installations and equipment and industrial products - Designation of signals - Part 1: Basic rules*

GHWP/WG8/F001:2023, *Medical Gas System (MGS) – Essential Principles of Safety and Performance (EPSP) – Standards for Demonstrating Compliance*

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For other referenced documents and information resources (printed, electronic or otherwise), the following styles apply:

EXAMPLE 2

a) Printed book or monograph:

- GREAT BRITAIN. Data Protection Act 1984. Schedule 1, c35, Part 1, Clause 7. London: HMSO

b) Electronic book or monograph:

- INTERNET ENGINEERING TASK FORCE (IETF). RFC 3979: *Intellectual Property Rights in IETF Technology* [online]. Edited by S. Bradner. March 2005 [viewed 2015-12-21]. Available at <http://www.ietf.org/rfc/rfc3979.txt>

c) Contribution to printed serial publication:

- AMAJOR, L.C. The Cenomanian hiatus in the Southern Benue Trough, Nigeria. *Geological Magazine*. 1985, 122(1), 39-50. ISSN 0016-7568

d) Contribution to online serial publication:

- STRINGER, John A., et al. Reduction of RF-induced sample heating with a scroll coil resonator structure for solid-state NMR probes. *Journal of Magnetic Resonance* [online]. Elsevier. March 2005, 173(1), 40-48 [viewed 2018-04-17]. Available at: <http://dx.doi.org/10.1016/j.jmr.2004.11.015>

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For online referenced documents, information sufficient to identify and locate the source shall be provided. Preferably, the primary source of the referenced document should be cited, in order to ensure traceability.

The information shall include the method of access to the referenced document and the full network address, with the same punctuation and use of upper case and lower case letters as given in the source.

Furthermore, the referenced document should be expected to remain valid for the expected life of the referring document.

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EXAMPLE 3

i) ISO/IEC Directives, IEC Supplement. International Electrotechnical Commission. Available at http://www.iec.ch/members_experts/refdocs/

ii) Statutes and directives. International Electrotechnical Commission, ©2004-2010 [viewed 2011-02-09]. Available at http://www.iec.ch/members_experts/refdocs/

iii) Statutes and directives. International Electrotechnical Commission, ©2004-2010 [viewed 2011-02-09]. Available at http://www.iec.ch/members_experts/refdocs/

iv) ISO 7000/IEC 60417 [online database], Graphical symbols for use on equipment [viewed 2016-04-18]. Available at <http://www.graphical-symbols.info/>

10.4 Undated references

Undated references may be made:

- a) only to a complete document;
- b) if it will be possible to use all future changes of the referenced document for the purposes of the referring document; and
- c) when it is understood that the reference will include all amendments to and revisions of the referenced document.

The date of publication or dash (see 10.5) shall not be given for undated references. When an undated reference is to all parts of a document, the standard identifier shall be followed by “(all parts)”.

In the normative reference clause or in the bibliography, use the following forms to list undated references.

EXAMPLE 1

IEC 60335 (all parts), <i>Household and similar electrical appliances - Safety</i>	Reference to all parts
IEC 60335-1, <i>Household and similar electrical appliances - Safety - Part 1: General requirements</i>	Reference to a single part

In the text, use the following forms to make undated references to a document.

EXAMPLE 2

- i) “... use the methods specified in ISO 1399-1 ...”; and
- ii) “... ISO 1399-1 shall be used...”.

10.5 Dated references

Dated references are references to:

- a) a specific edition, indicated by the date of publication; or
- b) a specific enquiry or final draft, indicated by a dash.

For dated references, each shall be given with its year of publication, or, in the case of final drafts, with a dash together with a footnote, such as “Under preparation” and full title.

If the referenced document is amended or revised, the dated references to it will need to be reviewed to assess whether they should be updated or not.

In this context, a part is regarded as a separate document.

Within the text, references to specific elements (e.g. clauses or subclauses, tables and figures) of a referenced document shall always be dated, because subsequent editions could result in the renumbering of such elements within the referenced document.

In the normative reference clause or in the bibliography, use the following forms to list dated references.

EXAMPLE 1

IEC 62271-1:2007, <i>High-voltage switchgear and controlgear - Part 1: Common specifications</i>	Dated reference to a standard / document
--------------------------------------------------------------------------------------------------	------------------------------------------

The titles are usually only written out in full in the normative references clause and in the bibliography.

In the text, use the following forms to make dated references to a document.

EXAMPLE 2	
... as specified in Table 1 of ISO 5070-3:1988...	Dated reference to a specific table in another published document
...in accordance with Clause 3 of ISO 1234:1984 ...	Dated reference to a specific clause in another published document
...according to Annex C of ISO 5170-3:2019...	Dated reference to a specific annex in another published document
... perform the tests given in ISO 1398-1:1988...	Dated reference to a published document
... according to ISO 3874:2000, AMD. 1:2009...	Dated reference to an amendment

For dated versus undated references.

EXAMPLE 3	
The test methods of IEC 61300-2-2 shall be used.	This is a reference to a complete document and it is therefore undated
The dimensions shall be in accordance with Table B.1 of IEC 60793-2-50:2012.	This is a reference to a specific element in the referenced document and it is therefore dated

10.6 References in a document to itself

References shall not be made to page numbers, since pagination can change if the referenced document is published in different formats, or if the document is revised.

For an individual document, the form “this GHWP document” shall be used.

Such undated references are understood to include all amendments and revisions to the referenced document.

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B. SUBDIVISIONS OF THE DOCUMENT

11 Title

11.1 Purpose or rationale

The title is a clear, concise description of the subject matter covered by the document. It is drafted so as to distinguish the subject matter from that of other documents, without going into unnecessary detail. Any necessary additional details are given in the Scope.

11.2 Normative or informative?

The title is a normative element.

11.3 Mandatory, conditional or optional?

The title is a mandatory element.

11.4 Numbering and subdivision

The title is composed of separate elements, each as short as possible, proceeding from the general to the particular, for example:

- a) an *introductory element* indicating the general field to which the document belongs;
- c) a *main element* indicating the principal subject treated within that general field; and
- d) a *complementary element* indicating the particular aspect of the principal subject or giving details that distinguish the document from other documents, or other parts of the same document.

No more than three elements shall be used. The main element shall always be included.

EXAMPLE 1 The introductory element is necessary to indicate the field of application.

i) Correct: *Raw optical glass - Grindability with diamond pellets - Test method and classification*

Incorrect: *Grindability with diamond pellets - Test method and classification*

ii) Correct: *Fork-lift trucks - Hook-on type fork arms - Vocabulary*

Incorrect: *Hook-on type fork arms - Vocabulary*

The title of a part shall be composed in the same way. All the individual titles in a series of parts shall contain the same introductory element (if present) and main element, while the complementary element shall be different in each case in order to distinguish the parts from one another. The complementary element shall be preceded in each case by the designation "Part ...":

EXAMPLE 2

Low-voltage switchgear and controlgear - Part 1: General rules

Low-voltage switchgear and controlgear - Part 2: Circuit-breakers

11.5 Specific principles and rules

11.5.1 Wording

The terminology used in the titles of documents shall be consistent.

For documents dealing exclusively with terminology, the following expressions shall be used:

- 681 a) “Vocabulary” if both terms and definitions are included; or
 682
 683 b) “List of equivalent terms” if only equivalent terms in different languages are given.
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685 **12 Acknowledgments**

686 **12.1 Purpose or rationale**

687
 688 The acknowledgement provides listing of members in the relevant committee, that have
 689 contributed to the preparation of the documents.
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691 **12.2 Normative or informative?**

692
 693 The acknowledgement is an informative element.
 694

695 **12.3 Mandatory, conditional or optional?**

696
 697 The acknowledgement is a mandatory element.
 698

699 **12.4 Numbering and subdivision**

700
 701 The acknowledgement shall not have a clause number.
 702
 703
 704

705 **13 Contents**

706 **13.1 Purpose or rationale**

707
 708 The contents makes the document easier to consult.
 709

710 **13.2 Normative or informative?**

711
 712 The contents is an informative element.
 713

714 **13.3 Mandatory, conditional or optional?**

715
 716 The contents is a mandatory element.
 717

718 **13.4 Numbering and subdivision**

719
 720 The contents shall not have a clause number.
 721

722 **13.5 Specific principles and rules**

723
 724 The contents shall be entitled “Contents” and shall list clauses and if appropriate, subclauses
 725 with titles, annexes, bibliography, figures and tables. All the elements listed shall be cited with
 726 their full titles.
 727

728 **14 Foreword**

729 **14.1 Purpose or rationale**

730
 731 The Foreword provides information on:
 732

- 733 a) the committee under GHWP responsible to develop the document;
 734
 735 b) a revised document stating:
 736
 737 this document cancels and replaces [the document(s) from the previous edition of the GHWP
 738 document]; and
 739
 740 c) legal disclaimers.

14.2 Normative or informative?

The foreword is an informative element. It shall not contain requirements, permissions or recommendations.

14.3 Mandatory, conditional or optional?

The foreword is a mandatory element.

14.4 Numbering and subdivision

The foreword shall not have a clause number and shall not be subdivided.

15 Introduction**15.1 Purpose or rationale**

The Introduction provides specific information or commentary about the technical content of the document, and about the reasons prompting its preparation.

15.2 Normative or informative?

The Introduction is an informative element. It shall not contain requirements.

15.3 Mandatory, conditional or optional?

The Introduction is an optional element.

15.4 Numbering and subdivision

The Introduction may not have a clause number.

15.5 Specific principles and rules

The introduction shall be on a designated page after foreword.

16 Scope**16.1 Purpose or rationale**

The scope clearly defines the subject of the document and the aspects covered, thereby indicating the limits of applicability of the document or particular parts of it.

If necessary, the scope should indicate subjects that might be reasonably inferred to be covered but actually excluded from the document.

EXAMPLE

This document excludes

The scope shall be succinct so that it can be used as a summary for bibliographic purposes, for example, as an abstract. If further details and background information are necessary, these shall be included in either the Introduction or in an annex.

16.2 Normative or informative?

The scope is a normative element. It shall not contain requirements, permissions or recommendations.

16.3 Mandatory, conditional or optional?

The scope is a mandatory element.

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16.4 Numbering and subdivision

The scope shall be numbered as Clause 1. It may be subdivided; however, this is not normally necessary as it is meant to be succinct.

16.5 Specific principles and rules

The scope shall only appear once in each document and shall be worded as a series of statements of fact.

Forms of expression such as the following can be used:

“This GHWP Document...

- | | | |
|-----------------------------|---|------------------------------------------------------------------------------------------------------|
| - specifies | } | requirements for ...”
the dimensions of ...”
a method of ...” |
| - describes | } | the characteristics of ...”
a method of ...”
the way in which ...”
recommendations for ...” |
| - establishes | } | guidance on ...”
a system for ...”
general principles for ...”
the nomenclature for ...” |
| - gives guidelines for ...” | | |
| - defines terms ...” | | |

Statements of applicability of the document shall be introduced by wording such as:

- a) “This document is applicable to ...”; or
- b) “This document does not apply to ...”.

17 Normative references

17.1 Purpose or rationale

The normative references clause lists, for information, those documents which are cited in the text in such a way that some or all of their content constitutes requirements of the document.

Information on how these references apply is found in the place where they are cited in the document, and not in the normative references clause.

17.2 Normative or informative?

The normative references clause is an informative element.

The list of references it contains is given for the convenience of the user, who can then consult the place where they are cited in the document to understand and assess how they apply.

17.3 Mandatory, conditional or optional?

The normative references clause is a mandatory element, even if it contains no normative references.

17.4 Numbering and subdivision

The normative references clause shall be numbered as Clause 2. It shall not be subdivided.

857 Referenced documents listed are not numbered.

858 17.5 Specific principles and rules

860 17.5.1 General

861 The normative references clause shall only appear once in each document. The list shall not
862 include the following:

- 863 a) documents that are not referenced or cited in the GHWP document;
- 864 b) documents to which only informative reference is made; and
- 865 c) documents which have merely served as bibliographic or background material in the
866 preparation of the standard.

867 17.5.2 Introductory wording

868 The list of normative references shall be introduced by the following wording:

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.

871 The above wording is also applicable to a part of a multipart document. If no references exist,
872 include the following phrase below the clause title:

There are no normative references in this document.

873 17.5.3 Referencing

874 Only references cited in the text in such a way that some or all of their content constitutes
875 requirements of the document shall be listed in the normative references clause.

876 EXAMPLE 1

In the following case, the citation is normative and the document shall be listed in the normative references clause:

- Connectors shall conform to the electrical characteristics specified by IEC 60603-7-1.

In the following case, the citation does not express a requirement so the document cited is not a normative reference. Instead, the document cited shall be listed in the bibliography:

- Wiring of these connectors should take into account the wire and cable diameter of the cables defined in IEC 61156.

877 Table 4 provides the verbal forms and expressions that make a citation normative.

878 When citing other documents, avoid using potentially ambiguous expressions, where it is
879 unclear whether a requirement or a recommendation is being expressed. For example, the
880 expressions “see ...” and “refer to ...” should only be used informatively and listed in the
881 Bibliography.

882 EXAMPLE 2

In the following case, the reference is informative.

- For additional information on communication, see ISO 14063.

883 The types of document which may be referenced are given in 10.2.

884 References listed may be dated or undated. See 10.4 and 10.5.

18 Terms and definitions

18.1 Purpose or rationale

The terms and definitions clause provides definitions necessary for the understanding of certain terms used in the document.

If necessary, terminological entries can be supplemented by information (including requirements) given in the note.

EXAMPLE

3.19

gas for medicinal use

gas or mixture of gases having properties for treating or preventing disease in human beings which may be used in or administered either with a view to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action, or to make a medical diagnosis

Note 1 to entry: This is also sometimes referred to as medicinal gas.

Note 2 to entry: In Europe this is classified as a medicinal product in accordance with Directive 2001/83/EC.

Terminology may take the form of an independent terminology standard (a vocabulary or nomenclature) or be included in a terms and definitions clause in a document that also deals with other aspects.

18.2 Normative or informative?

The terms and definitions clause is a normative element. It defines the way in which the listed terms shall be interpreted.

18.3 Mandatory, conditional or optional?

The terms and definitions clause is a mandatory element, even if it contains no terminological entries.

18.4 Numbering and subdivision

The Terms and definitions clause shall be numbered as Clause 3. It may be subdivided. Terminological entries shall be numbered.

NOTE. These numbers are not considered as subclause numbers.

EXAMPLE 1

3 Terms and definitions

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

3.1

management performance indicator

MPI

environmental performance indicator that provides information about the management efforts to influence an organisation's environmental performance

Terms and definitions shall be listed according to alphabetical order.

926

<p>EXAMPLE 2</p> <p>3 Terms and definitions</p> <p>[...]</p> <p>3.2 Optical properties</p> <p>[...]</p> <p>3.2.1 colour retention degree of permanence of a colour</p> <p>NOTE. Colour retention can be influenced by weathering.</p> <p>3.5 Surface properties</p> <p>3.5.1 abrasion loss of material from a surface due to frictional forces</p> <p>[...]</p>

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For convenience, the symbols and abbreviated terms may be combined with the terms and definitions in order to bring together terms and their definitions, symbols and abbreviated terms under an appropriate composite title, for example “Terms, definitions, symbols and abbreviated terms”.

18.5 Specific principles and rules

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18.5.1 General

The terms and definitions clause shall only appear once in each document.

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18.5.2 Introductory wording

If all the specific terms and definitions are provided in Clause 3, use the following introductory text:

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942

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

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944

If reference is given to an external document, use the following introductory text:

For the purposes of this document, the terms and definitions given in [external document reference xxx] apply.

945
946
947

If terms and definitions are provided in Clause 3, in addition to a reference to an external document, use the following introductory text:

For the purposes of this document, the terms and definitions given in [external document reference xxx] and the following apply.

948
949

If there are no terms and definitions provided, use the following introductory text:

No terms and definitions are listed in this document.

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18.5.3 Permitted content

Only terms which are used in the document shall be listed in the terms and definitions clause. This rule does not apply to terminology standards, whose terms are intended for wider use.

957 **18.5.4 Terms**

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959 Terms shall be written in lower case characters and shall be listed in alphabetical order. Upper
960 case characters, mathematical symbols, typographical signs and syntactic signs (e.g.
961 punctuation marks, hyphens, parentheses, square brackets and other connectors or delimiters)
962 as well as their character styles (i.e. fonts and bold) shall be used in a term only if they constitute
963 part of the normal written form of the term. Terms shall in general be presented in their basic
964 grammatical form, i.e. nouns in the singular, verbs in the infinitive.

<p>EXAMPLE 1</p> <p>Correct use of parentheses:</p> <p>bis(dimethylthiocarbamyl) disulphide</p> <p>Incorrect use of parentheses:</p> <p>integrity (of system)</p>	<p>The parentheses and the content therein are part of the term.</p> <p>The words in parentheses are not part of the term.</p>
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<p>EXAMPLE 2</p> <p>Correct expression of equivalent terms:</p> <p>live working live work</p> <p>Incorrect expression of equivalent terms:</p> <p>live working (work)</p>	<p>The preferred term and any synonyms are written on separate lines.</p> <p>It is incorrect to indicate a synonymous term using parentheses.</p>
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<p>EXAMPLE 3</p> <p>Correct use of capitalisation:</p> <p>Reynolds number</p> <p>Incorrect use of capitalisation:</p> <p>Planned outage</p>	<p>“Reynolds” is a proper noun. It is capitalised.</p> <p>“Planned” is not a proper noun. Do not capitalise this.</p>
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968 **18.5.5 Definitions**

969
970 The definition shall be written in such a form that it can replace the term in its context. It shall
971 not start with an article (“the”, “a”) nor end with a full stop. A definition shall not take the form
972 of, or contain, a requirement.

973
974 Only one definition per terminological entry is allowed. If a term is used to define more than one
975 concept, a separate terminological entry shall be created for each concept and the domain shall
976 be included in angle brackets before the definition.
977
978

<p>EXAMPLE</p> <p>2.1.17 die <extrusion> metal block with a shaped orifice through which plastic material is extruded</p> <p>2.1.18 die <moulding> assembly of parts enclosing the cavity from which the moulding takes its form</p>

979 **18.5.6 Examples**

980
981 Examples provide information that illustrates the concept. Examples shall not contain
982 requirements (use of “shall”) or any information considered indispensable for the use of the
983 document, for example instructions (imperative mood), recommendations (use of “should”) or

984 permission (use of “may”). Examples should be written as a statement of fact.

985
986 A single example in a terminological entry shall be preceded by “EXAMPLE”. When several
987 examples appear within the same terminological entries, they shall be numbered starting with
988 “1.” within each terminological entry. For multiple examples, they shall be designated
989 “EXAMPLE 1”, “EXAMPLE 2”, “EXAMPLE 3”, etc.

991 18.5.7 Non-verbal representations

992
993 Figures and formulae may be included within a terminological entry. The definition may take
994 the form of a formula.

996 18.5.8 Note

997
998 A note provides additional information that supplements the terminological data, e.g.:

- 999
1000 a) provisions (statements, instructions, recommendations or requirements) relating to the use
1001 of a term;
1002
1003 b) information regarding the units applicable to a quantity; or
1004
1005 c) an explanation of the reasons for selecting an abbreviated form as the preferred term.
1006

1007 A single note in a clause or subclause shall be preceded by “NOTE.”. When several notes
1008 appear within the same clause or subclause, they shall be designed “NOTES:” followed by
1009 number 1., 2., 3., etc.
1010

1011 Table 7 summarises how to use notes and footnotes within documents.
1012

EXAMPLE 1

3.1.4

continuous scale

scale with a continuum of possible values

EXAMPLE. Interval scale and ratio scale.

NOTES:

1. A continuous scale can be transformed into a discrete scale, by grouping “values”. This inevitably leads to some loss of information. Often the resulting discrete scale will be ordinal.
2. Scale resolution can be adversely affected by measurement system limitations. Such measurement limitations can, sometimes, give rise to measurements being represented on a discrete, ordinal, scale.

EXAMPLE 2

3.6

moisture content mass by volume

mass of evaporable water divided by volume of dry material

NOTE. The method of evaporating water from a moist material shall be stated when this term is used.

1014 18.5.9 Footnotes

1015
1016 Footnotes to any part of a terminological entry are not allowed.

1017
1018 Table 7 summarises how to use notes and footnotes within documents.

1021 19 Symbols and abbreviated terms

1022 19.1 Purpose or rationale

1023
1024 The symbols and abbreviated terms clause or subclause provides a list of the symbols and

1025 abbreviated terms used in the document, along with their definitions.

1026 **19.2 Normative or informative?**

1027 The symbols and abbreviated terms clause is a informative element.

1028 **19.3 Mandatory, conditional or optional?**

1029 The symbols and abbreviated terms clause is a conditional element.

1030 **19.4 Numbering and subdivision**

1031 The symbols do not need to be numbered. For convenience, the symbols and abbreviated
1032 terms may be combined with the terms and definitions in order to bring together terms and their
1033 definitions, symbols and abbreviated terms under an appropriate composite title, for example
1034 "Terms, definitions, symbols and abbreviated terms".

1035 **19.5 Specific principles and rules**

1036 Only symbols used in the text shall be listed.

1037 Unless there is a need to list symbols in a specific order to reflect technical criteria, all symbols
1038 should be listed in alphabetical order in the following sequence:

- 1039 a) upper case Latin letter followed by lower case Latin letter (*A, a, B, b*, etc.);
- 1040 b) letters without indices preceding letters with indices, and with letter indices preceding
1041 numerical ones (*B, b, C, C_m, C₂, c, d, d_{ext}, d_{int}, d₁*, etc.);
- 1042 c) Greek letters following Latin letters (*Z, z, A, α, B, β, ..., Λ, λ*, etc.); and
- 1043 d) any other special symbols.

1044 **20 Annexes**

1045 **20.1 Purpose or rationale**

1046 Annexes are used to provide additional information to the main body of the document and are
1047 developed for several reasons, for example:

- 1048 a) when the information or table is very long and including it in the main body of the document
1049 would distract the user;
- 1050 b) to set apart special types of information (e.g. software, example forms, results of
1051 interlaboratory tests, alternative test methods, tables, lists, data); and
- 1052 c) to present information regarding a particular application of the document.

1053 Requirements for annexes is also applicable to national annexes.

1054 **20.2 Normative or informative?**

1055 Annexes can be normative or informative elements.

1056 Normative annexes provide additional normative text to the main body of the document.

1057 Informative annexes provide additional information intended to assist the understanding or use
1058 of the document. Informative annexes may contain optional requirements. For example, a test
1059 method that is optional may contain requirements but there is no need to comply with these
1060 requirements to claim compliance with the document. The status of the annex (informative or
1061 normative) shall be made clear by the way in which it is referred to in the text and shall be stated
1062 under the heading of the annex.

EXAMPLE

[...] see Annex A for additional information [...]

The status of Annex A is informative.

[...] the test method shall be carried out as specified in Annex B [...]

The status of Annex B is normative.

20.3 Mandatory, conditional or optional?

Annexes are optional elements.

20.4 Numbering and subdivision

Each annex shall be designated by a heading comprising the word "Annex" followed by a capital letter, starting with "A", for example "Annex A". The annex heading shall be followed by the indication "(*normative*)" or "(*informative*)", and by the title, each on a separate line. A single annex shall be designated "Annex A".

EXAMPLE 1

Annex A
(*informative*)

Example form

Annexes may be subdivided into clauses, subclauses, paragraphs and lists.

Numbers given to the clauses, subclauses, tables, figures and mathematical formulae of an annex shall be preceded by the letter designating that annex followed by a full stop. The numbering shall start afresh with each annex.

EXAMPLE 3

In the case of Annex A, the first clause would be numbered A.1, the first figure would be Figure A.1, the first table would be Table A.1 and the first formula would be Formula (A.1).

20.5 Specific principles and rules

Each annex shall be explicitly referred to within the text.

EXAMPLE

- a) "Annex B provides further information...";
- b) "Use the methods described in Annex C";
- c) "See Figure A.6";
- d) "Clause A.2 describes..."; and
- e) "...as specified in C.2.5."

21 Bibliography

21.1 Purpose or rationale

The bibliography lists, for information, those documents which are cited informatively in the document, as well as other information resources.

21.2 Normative or informative?

The bibliography is an informative element. It shall not contain requirements, permissions or recommendations. Preferably, the primary source of the referenced document should be cited, in order to ensure traceability.

21.3 Mandatory, conditional or optional?

The bibliography is a conditional element. Its inclusion is dependent on whether informative references are present in the document.

21.4 Numbering and subdivision

The bibliography shall not have a clause number. It may be subdivided in order to group the referenced documents under descriptive headings. Such headings shall not be numbered.

Referenced documents and information resources listed may be numbered.

21.5 Specific principles and rules

The bibliography, if present, shall appear after the last annex.

Referenced documents and information resources listed can be dated or undated. See 10.4 and 10.5.

EXAMPLE

In the following case, the citation is not normative but informative. The document cited shall be listed not in the normative references clause but in the bibliography:

- Wiring of these connectors should take into account the wire and cable diameter of the cables defined in IEC 61156.

In the following case, the citation is normative and the document shall be listed in the normative references clause:

- Connectors shall conform to the electrical characteristics specified by IEC 60603-7-1.

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C. COMPONENTS OF THE TEXT

22 Clauses and subclauses

22.1 Purpose or rationale

Clauses and subclauses serve as the basic components in the subdivision of the content of a document.

22.2 Title

Each clause shall have a title.

Each first level subclause (e.g. 5.1, 5.2) should preferably be given a title. Within a clause or subclause, the use of titles shall be uniform for subclauses at the same level, for example if 10.1 has a title, 10.2 shall also have a title. Figure 2 shows examples of correct and incorrect use of subclause titles.

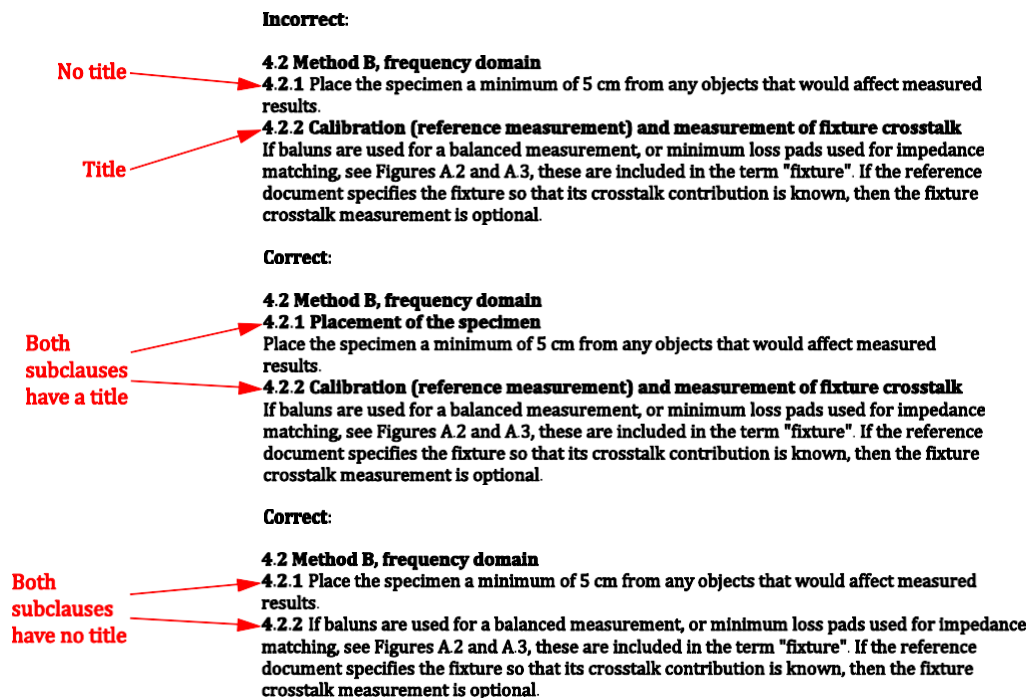


Figure 2. Correct and incorrect use of subclause titles

22.3 Numbering, subdivision and hanging paragraphs

22.3.1 Numbering

The clauses in each document or part shall be numbered with Arabic numerals, starting with 1 for the scope (see Figure 3).

The numbering shall be continuous up to but excluding any annexes (see Clause 22).

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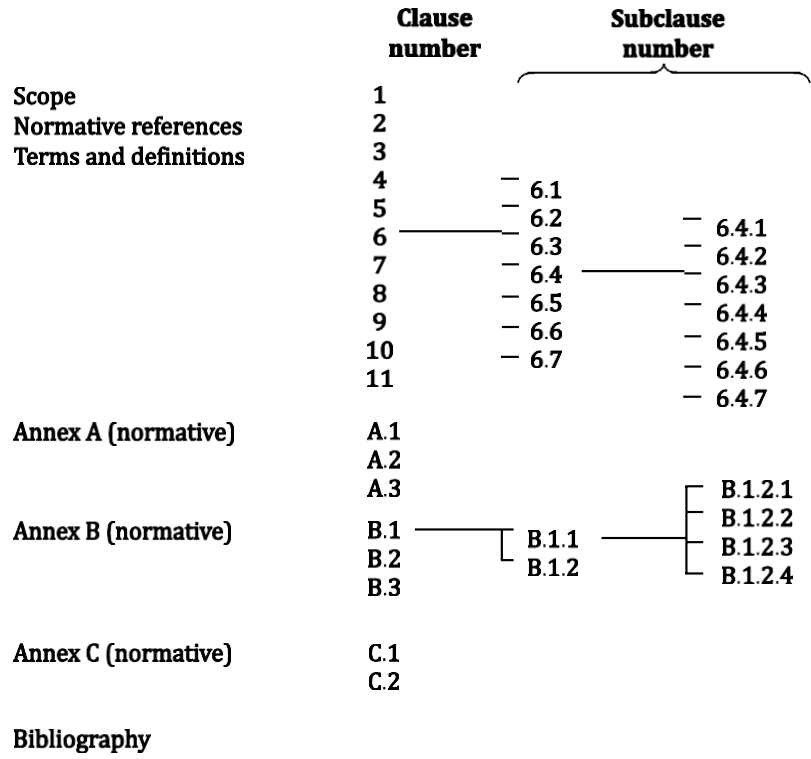


Figure 3. Example of numbering of divisions and subdivisions

22.3.2 Subdivision

A subclause is a numbered subdivision of a clause. A clause may be subdivided into subclauses as far as the third level (e.g. 6.1.1, 6.1.1.1).

Too many levels of subdivision should be avoided, as this can make it hard for the user to understand the document.

Figure 3 provides an example of numbering of divisions and subdivisions.

A subclause shall not be created unless there is at least one further subclause at the same level. For example, text in Clause 10 shall not be designated subclause “10.1” unless there is also a subclause “10.2”.

22.3.3 Hanging paragraphs

“Hanging paragraphs” shall be avoided since reference to them is ambiguous.

In the example given in Figure 4, the hanging paragraph indicated cannot be uniquely identified as being in “Clause 5” since the paragraphs in 5.1 and 5.2 also form part of Clause 5. To avoid this problem, it is necessary to identify the hanging paragraph as subclause “5.1 General” (or other suitable title) and to renumber the existing 5.1 and 5.2 accordingly (as shown), or to move the hanging paragraph elsewhere, or to delete it.

Correct	Incorrect
<p>5 Uncertainty of the certified value</p> <p>5.1 General</p> <p>The combined expanded uncertainty of the measurement is calculated.</p> <p>5.2 Budget of uncertainty</p> <p>[...]</p>	<p>5 Uncertainty of the certified value</p> <p>The combined expanded uncertainty of the measurement is calculated. Hanging Paragraph</p> <p>5.1 Budget of uncertainty</p> <p>[...]</p>

Figure 4. Example of a hanging paragraph (right) and one way to avoid it (left)

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22.4 Referencing

Clauses and subclauses do not need to be specifically referred to in the text.

Use, for example, the following forms for references to clauses and subclauses:

- a) "in accordance with Clause 4";
- b) "details as given in 4.1.1";
- c) "the requirements given in B.2"; or
- d) "the methods described in 5.3 provide further information on...".

It is unnecessary to use the term "subclause".

23 Internal section and subsection

23.1 Purpose or rationale

Internal sections and subsections are usually an internal subdivision of a publication, used to group a series of related clauses. The use of sections is of particular value to simplify the structure of lengthy complex documents. Annex B provide the illustration of format for contents with internal subdivision.

23.2 Title

The corresponding internal subdivision is a separately published section is designated "subsection". Each section or subsection has a title.

23.3 Numbering and subdivision

The numbering of sections is sequential, using Arabic numerals. Section 1 of a publication, frequently entitled "General, groups the clause that include scope, references, definitions and other clauses that relate to the publication as a whole. Subsections are point-numbered.

24 Lists

24.1 Purpose or rationale

A list serves to subdivide information to aid understanding.

24.2 Title

Lists do not have a title. They may, however, be preceded by a title or introductory phrase.

24.3 Numbering and subdivision

Lists can be numbered or unnumbered. Lists can be subdivided.

See the examples below.

- a) A lower-case letter followed by a single parenthesis (round bracket) is used to introduce each item in the list i.e. 'a), b), c),' etc. If it is necessary to further subdivide an item in such a list, Roman numerals followed by the single parenthesis i.e. 'i), ii), iii),' etc. are used. In exceptional cases, further subdivision is indicated by the use of Arabic numerals followed by a single parenthesis, i.e. '1), 2), 3)' etc.

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EXAMPLE 1

The following basic principles shall apply to the drafting of definitions.

- a) The definition shall have the same grammatical form as the term:
 - i) to define a verb, a verbal phrase shall be used; or
 - ii) to define a singular noun, the singular shall be used.

The preferred structure of a definition is a basic part stating the class to which the concept belongs, and another part enumerating the characteristics that distinguish the concept from other members of the class.

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If more than one list of items appears within the same clause or subclause, items in the first list are identified by lower case letters and the second list by Roman numerals. In such circumstances, care has to be taken not to subdivide items so that similar identifiers are used in several lists. If more than three lists appear within the same clause or subclause, redrafting should be considered to avoid the complications of identification and referencing.

- b) A dash may also be used to introduce each item in the list.

EXAMPLE 2

No switch is required for any of the following categories of apparatus:

- apparatus having a power consumption not exceeding 10 W under normal operating conditions;
- apparatus having a power consumption not exceeding 50 W, measured 2 min after the application of any of the fault conditions; or
- apparatus intended for continuous operation.

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EXAMPLE 3

Vibrations in the apparatus can be caused by:

- unbalance in the rotating elements;
- slight deformations in the frame;
- the rolling bearings; and
- aerodynamic loads.

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24.4 Specific principles and rules

Lists generally fall into one of the following two types:

- a) Some lists comprise grammatically incomplete elements that do not form complete sentences. These are introduced by a statement ending with a colon. Each item in the list starts with a lower-case letter and ends with a semicolon, except the last item which ends with a full point.
- b) Other lists consist of items comprising one or more sentences each, but in which the items are not sufficiently independent or self-contained to become subclauses. These are introduced by a complete sentence ending with a full point and each item in the list starts with a capital letter and ends with a full point.

Type a) and type b) styles are not to be mixed within a single list.

24.5 Referencing

The purpose of a list should be made clear by its context. For example, an introductory

proposition or a subclause title can serve to introduce the list. Lists do not need to be specifically referred to in the text.

If cross-references to list items are necessary, a numbered list shall be used. Within a subdivision, each list item in a numbered list shall have a unique identifier. Numbering restarts at each new clause or subclause.

Use, for example, the following forms for references to lists:

- a) “as specified in 3.1 b)”; and
- b) “the requirements given in B.2 c)”.

25 Notes

25.1 Purpose or rationale

Notes are used for giving additional information intended to assist the understanding or use of the text of the document. The document shall be usable without the notes.

Notes in terminological entries follow slightly different rules from those for notes, see 18.5.8. Table 7 summarises how to use notes and footnotes within documents.

Table 7. Use of notes and footnotes within documents

	Element	Rule	Numbering	Designation	Provisions allowed
In terminology	Note	18.5.8	Numbered if more than one; numbering restarts for each new clause or subclause	NOTE. NOTES: 1. 2.	May contain provisions (shall, should or may) related to the use of the term
	Footnotes to terminological entries are not allowed	18.5.9			
In the text	Note	28.1	Numbered if more than one; numbering restarts for each new clause or subclause	NOTE. NOTES: 1. 2.	No requirements (shall) or any information considered indispensable for the use of the document, recommendations (should) or permissions (may)
	Footnote	30.1	Sequential throughout the document	Normally with superscript Arabic numerals, starting with “1”, followed by parenthesis, e.g.: ¹⁾ (superscript) In certain cases, *, **, ***, etc.; †, ‡, etc. may be used.	No requirements (shall) or any information considered indispensable for the use of the document, recommendations (should) or permissions (may)

Figures	Notes to figures	32.5.4	Numbered if more than one; numbered independently from the notes to the text; numbering restarts for each new figure	NOTE. NOTES: 1. 2.	No requirements (shall) or any information considered indispensable for the use of the document, recommendations (should) or permissions (may)
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Table 7. Use of notes and footnotes within documents (*continued*)

	Element	Rule	Numbering	Designation	Provisions allowed
Figures (<i>continued</i>)	Footnotes to figures	32.5.5	Numbered if more than one; numbered independently from the footnotes to the text; numbering restarts for each new figure	Normally superscript lower-case letters, starting with "a", e.g.: ^a	May contain requirements
Tables	Notes to tables	33.5.2	Numbered if more than one; numbered independently from the notes to the text; numbering restarts for each new table	NOTE. NOTES: 1. 2.	No requirements (shall) or any information considered indispensable for the use of the document, recommendations (should) or permissions (may)
	Footnotes to tables	33.5.3	Numbered if more than one; numbered independently from the footnotes to the text; numbering restarts for each new table	Normally superscript lower-case letters, starting with "a", e.g.: ^a	May contain requirements

25.2 Title

Notes do not have a title.

25.3 Numbering and subdivision

Within a given clause or subclause, notes shall be numbered sequentially. The numbering restarts at each new subdivision. A single note in a subdivision does not need to be numbered.

25.4 Referencing

Notes do not need to be specifically referred to in the text.

If notes are referred to, use for example, the following forms for references:

- a) "an explanation is provided in 7.1, Note 2"; and
- b) "see 8.6, Note 3".

25.5 Specific principles and rules

Notes shall not contain requirements (e.g. use of "shall", see Table 4) or any information considered indispensable for the use of the document, for example instructions (imperative mood), recommendations (e.g. use of "should", see Table 5) or permission (e.g. use of "may",

see Table 6). Notes should be written as a statement of fact.

Table 7 summarises how to use notes and footnotes within documents.

25.6 Examples

<p>EXAMPLE 1</p> <p>Correct example of the use of a note:</p> <p>Each label shall have a length of between 25 mm and 40 mm and a width of between 10 mm and 15 mm.</p> <p>NOTE. The size of the label was chosen so that it will fit most sizes of syringe without obscuring the graduation marks</p>

<p>EXAMPLE 2</p> <p>Incorrect examples of the use of a note:</p> <p>NOTE. In this context a part shall be regarded as a separate document...</p> <p>NOTE. Alternatively, test at a load of ...</p> <p>NOTE. Where a laboratory is part of a larger organisation, the organisational arrangements <i>should</i> be such that departments having conflicting interests ...</p> <p>NOTE. Individuals may have more than one function ...</p>	<p><i>"shall"</i> constitutes a requirement</p> <p><i>"test"</i> constitutes a requirement, expressed here in the form of an instruction using the imperative</p> <p><i>"should"</i> constitutes a recommendation</p> <p><i>"may"</i> constitutes a permission</p>
--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

26 Examples

26.1 Purpose or rationale

Examples illustrate concepts presented in the document. The document shall be usable without the examples.

26.2 Title

Examples do not need to have a title, but they can, if necessary, be grouped into a clause or subclause entitled "EXAMPLE" or "EXAMPLE 1", "EXAMPLE 1", "EXAMPLE 2", "EXAMPLE 3", etc. (see 29.6, which is titled "Examples").

26.3 Numbering and subdivision

Within a given clause or subclause, examples shall be numbered sequentially. The numbering restarts at each new subdivision. A single example in a subdivision does not need to be numbered.

26.4 Referencing

Examples do not need to be specifically referred to in the text.

If examples are referred to, use for example, the following forms for references:

- a) "see 6.6.3, Example 5"; and
- b) "Clause 4, Example 2 lists ...".

26.5 Specific principles and rules

Examples shall not contain requirements (use of "shall") or any information considered indispensable for the use of the document, for example instructions (imperative mood),

recommendations (use of “should”) or permission (use of “may”). Examples should be written as a statement of fact.

An example can cite text to illustrate a point. If the cited text contains requirements, recommendations and permissions, this is acceptable.

26.6 Examples

EXAMPLE

The generic model can be applicable to other possible manufacturing operations categories or for other operations areas within the enterprise.

EXAMPLE A company could apply the model to receiving operations management and associated services.

27 Footnotes

27.1 Purpose or rationale

Footnotes to the text of a document are used to give additional contextual information to a specific item in the text. The document shall be usable without the footnotes.

27.2 Title

Footnotes do not have a title.

27.3 Numbering and subdivision

Normally, footnote references are indicated using Arabic numerals, beginning with 1, followed by parenthesis. Footnotes shall be numbered sequentially throughout the document: 1), 2), 3), etc. Exceptionally, other systems (*, **, ***, etc.; †, ‡, etc.) can be used, for example when there is the possibility of confusing them with superscript numbers.

27.4 Referencing

Footnotes shall be referenced in the text.

Use, for example, the following form for references to footnotes:

- ISO 1234:–¹⁾ lists the requirement of...

¹⁾ Under preparation. *Vegetable shortening - Specification.*

28 Mathematical formulae

28.1 Purpose or rationale

A mathematical formula uses symbols to express the relationship between quantities.

NOTE. Notations such as

1478 $V/(km/h)$
~~1479~~ km/h or $V/(km/h)$

for numerical values are not mathematical formulae. They are particularly useful on the axes of graphs and in the headings of columns in tables.

28.2 Title

Mathematical formulae do not have a title.

28.3 Numbering and subdivision

If needed for cross-referencing purposes, mathematical formulae can be numbered in a document. Arabic numbers in parentheses shall be used, starting with 1.

EXAMPLE 1

$$x^2 + y^2 < z^2 \quad (1)$$

The numbering shall be continuous and independent of the numbering of clauses, tables and figures. Subdivision of mathematical formulae [for example (2a), (2b), etc.] is not permitted.

When mathematical formulae in annexes are numbered, the numbering restarts and is preceded by the annex letter.

EXAMPLE 2

$$x^2 + y^2 < z^2 \quad (A.1)$$

28.4 Referencing

If a formula is numbered, it should be referred to in the text. The purpose of a formula should be made clear by its context, for example, with an introductory proposition.

Use, for example, the following forms for references to mathematical formulae:

- a) "see 10.1, Formula (3)"; and
- b) "see A.2, Formula (A.5)".

29 Figures

29.1 Purpose or rationale

Figures are a graphical means of representation used when they are the most efficient means of presenting information in an easily comprehensible form.

Photographs and other media may be used if it is not possible to represent the concept as a line drawing.

29.2 Title

It is recommended to provide a concise figure title.

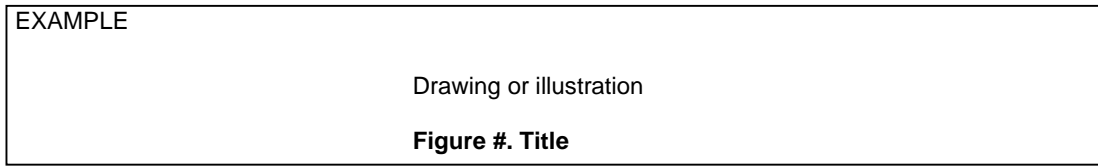
29.3 Numbering and subdivision

29.3.1 Figure designation

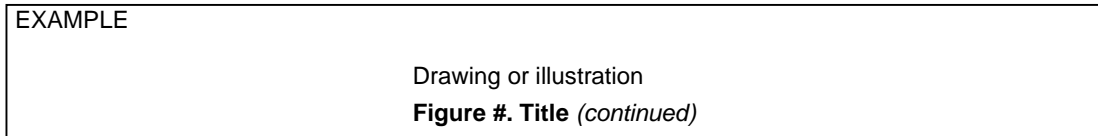
Figures shall be designated "Figure" and numbered with Arabic numerals, beginning with 1. A single figure shall be designated "Figure 1". This numbering shall be independent of the numbering of the clauses and of any tables.

In annexes, the figure numbering restarts and the number is preceded by the annex letter (e.g. Figure A.1, etc.).

The figure designation and title (if present) shall be centred horizontally below the figure.



When a figure is continued over several pages, it can be useful to repeat the figure designation, followed by the title and by the wording of “(continued)”.

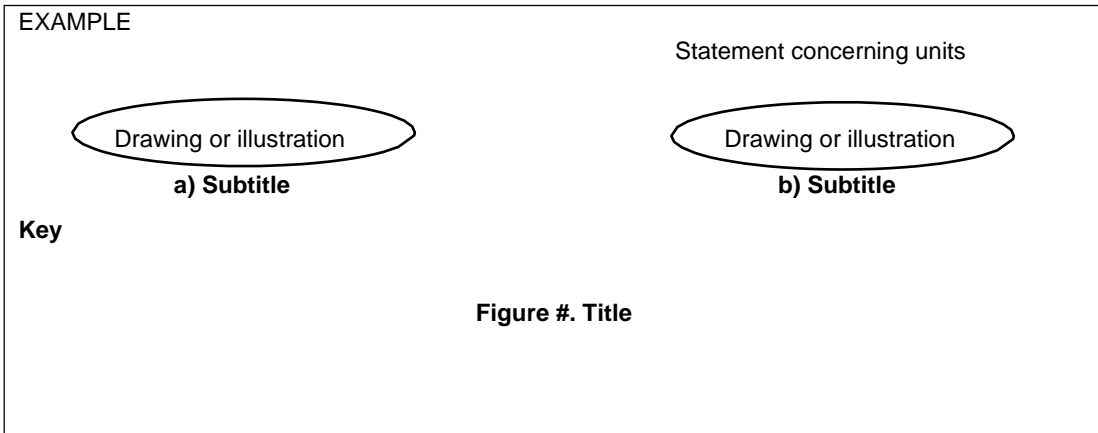


29.3.2 Subfigures

In general, the use of subfigures should be avoided whenever possible since it complicates document layout and management.

Only one level of subdivision of a figure is permitted. Subfigures shall be identified by a lower-case letter [e.g. Figure 1 may comprise subfigures a), b), c), ...]. Other forms of identification of the subfigures such as 1.1, 1.2, ..., 1-1, 1-2, ..., etc. shall not be used.

Separate keys, notes and footnotes for subfigures are not permitted.



29.4 Referencing

Each figure shall be explicitly referred to within the text.

Use, for example, the following forms for references to figures and subfigures:

- a) “Figure 3 illustrates...”; and
- b) “See Figure 6 b)”.

30 Tables

30.1 Purpose or rationale

Tables are used when they are the most efficient means of presenting information in an easily comprehensible form.

30.2 Title

It is recommended to provide a concise table title.

30.3 Numbering and subdivision

Tables shall be designated "Table" and numbered with Arabic numerals, beginning with 1. A single table shall be designated "Table 1". This numbering shall be independent of the numbering of the clauses and of any figures.

Further subdivision [e.g. Table 2 a)] is not permitted. A table within a table is not permitted. Subdivision of a table into subsidiary sections with new column headings is not permitted.

It is often better to create several tables rather than trying to consolidate too much information into one table. The simpler the presentation, the better.

In annexes, the table numbering restarts and the number is preceded by the annex letter (e.g. Table A.1).

The table designation and title (if present) shall be centred horizontally above the table.

EXAMPLE

Table #. Title	

When a table is continued over several pages, it can be useful to indicate the continuation.

EXAMPLE

Table #. Title <i>(continued)</i>	

The column headings together with any statement concerning units can be repeated on all pages after the first.

30.4 Referencing

Each table shall be explicitly referred to within the text.

Use, for example, the following forms for references to tables:

- a) "Table 4 lists..."; and
- b) "See Table B.1".

30.5 Examples

EXAMPLE 1

The layout of the different elements that can appear in a table

Dimensions in millimetres

Type	Length	Inside diameter	Outside diameter
	^a l_1	d_1	
	l_2	$d_2^{b,c}$	

A paragraph containing a requirement.

NOTES:

1. Table note.
2. Table note.

- ^a Table footnote.
^b Table footnote.
^c Table footnote.

EXAMPLE 2

When there are several different units:

Type	Linear density (kg/m)	Inside diameter (mm)	Outside diameter (mm)

EXAMPLE 3

When all the units are the same:

Dimensions in millimetres

Type	Length	Inside diameter	Outside diameter

EXAMPLE 4

Correct and incorrect table headers. Table cells shall not be split diagonally.

Correct:

Dimension	Type		
	A	B	C

Incorrect:

Type	A	B	C
<div style="display: flex; align-items: center; justify-content: center;"> <div style="writing-mode: vertical-rl; transform: rotate(180deg);">Dimension</div> <div style="border: 1px solid black; width: 100%; height: 100%; position: relative;"> <div style="position: absolute; top: 0; left: 0; right: 0; bottom: 0; border-left: 1px solid black; border-right: 1px solid black; border-bottom: 1px solid black;"></div> </div> </div>			

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ANNEXES

Annex A
(informative)

Guidelines on font size and style, and alignment

All fonts using Arial except for symbol or formula (use the default setting of Microsoft Word) and cover page (Times New Roman). The font size and style, and alignment for drafting the document, refer to Table A.1.

Table A.1. Font size and style, and alignment

No.	Description	Font		Alignment	Remarks
		Size	Style		
1	Cover page	Size 20 (Bold)	Upper case	Center	Status of document
		Size 14	Sentence case	Justify	GHWP Document title
		Size 14	Sentence case	Justify	Authoring Group
		Size 14	Sentence case	Justify	Date of endorsement
		Size 14	Sentence case	Right	Name of Chair & Committee In Charge
		Size 11.5	Sentence case	Center	Copyright
2	Acknowledgements	Size 12 (Bold)	Sentence case	Center	Acknowledgements
		Size 11	Sentence case	Justify	Paragraph
		Size 10	Sentence case	Justify	Table containing list of WG members
3	Content page	Size 12 (Bold)	Sentence case	Left	Contents
		Size 12 (Bold)	Sentence case	Right	Page
		Size 11	Sentence case	Left	Listing of clauses
4	Foreword	Size 12 (Bold)	Sentence case	Left	Foreword
		Size 11	Sentence case	Justify	Text (paragraph, listing)
5	Introduction	Size 12 (Bold)	Sentence case	Left	Introduction
		Size 11	Sentence case	Justify	Text (paragraph, listing)
6	Clause	Size 12 (Bold)	Sentence case	Left	Title
		Size 11	Sentence case	Justify	Text (paragraph, listing)

No.	Description	Font		Alignment	Remarks
		Size	Style		
8	Subclauses	Size 11 (Bold)	Sentence case (except: terminologically entries which is lower case)	Left	Title
		Size 11	Sentence case	Justify	Text (paragraph, listing)
9	Table	Size 10 (Bold)	Sentence case	Centre	Title (should be placed above the table)
		Size 10 (Bold)	Sentence case	Centre	Continuation tables: Table X. Title (<i>continued</i>)
		Size depends on the table size (Bold)	Sentence case	Depends on the table	Heading of table
		Size 10	Sentence case	Right-hand corner of the table	When all units for a quantity are the same, a suitable statement (e.g. Dimensions in millimetres" or "Units in percentage", etc.
		Size 9	Upper case	Left	NOTE. or NOTES: 1. , 2.
		Size 9	Lower case with superscript	Left	Footnote: ^a , ^b , ^c
10	Figure	Size 10 (Bold)	Sentence case	Centre	Title (should be placed below the figure)
		Size 10 (Bold)	Sentence case	Centre	Continuation figures: Figure X. Title (<i>continued</i>)
		Size 10	Sentence case	Right-hand corner of the figure	When all units for a quantity are the same, a suitable statement (e.g. Dimensions in millimetres" or "Units in percentage", etc.
		Size 10 (Bold)	Sentence case	Left	Key
		Size 9	Upper case	Left	NOTE. or NOTES: 1. , 2.
		Size 9	Lower case with superscript	Left	Footnote: ^a , ^b , ^c
		Size 12 (Bold)	Sentence case	Centre	Annex A, Annex B,
		Size 12	Lower case	Centre	(normative) or (informative)
11	Annexes	Size 12 (Bold)	Sentence case	Centre	Title
		Size 11	Sentence case	Justify	Text (paragraph, listing)
12	Bibliography	Size 12 (Bold)	Sentence case	Centre	

No.	Description	Font		Alignment	Remarks
		Size	Style		
		Size 11 (<i>Italic</i>)	Sentence case		
13	Header	Size 10	-	Top right	GD project number
14	Footer	Size 10	-	Center	Page number

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Annex B
(informative)

Layout

The layout requirements for drafting the document, refer to Table B.1.

Table B.1. Layout requirements

No.	Items	Size (cm)	Remarks
1	Page size	8¼ × 11¼	A4 size paper
2	Margins of the cover page	2.54	Top
		2.54	Bottom
		2.54	Left
		2.25	Right
4	Margins of the text (Portrait)	2.54	Top
		2.54	Bottom
		2.54	Left
		2.25	Right
5	Margins of the text (Landscape)	1.25	Top
		1.25	Bottom
		1.00	Left
		2.00	Right
6	Header (Portrait)	1.25	Header from top
7	Header (Landscape)	1.25	Header from right
8	Footer (Portrait)	0.50	Footer from bottom
9	Footer (Landscape)	0.50	Footer from left

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Annex G
(informative)

GHWP/WG8/F0XX:202X



GHWP

Global Harmonization Working Party

Towards Medical Device Harmonization

DRAFT / PROPOSED/ PROPOSED FINAL/ **FINAL DOCUMENT**

Title: [.....]

Authoring Group: [Name of Relevant Working Group / Joint Working Group: etc. Work Group 8 (Standards) / Joint Working Groups of Working Group 8 (Standards) and 9 (UDI)]

Date: [Date of endorsement: etc. 16 February]

[Name of Chair: etc. Ms. Salbiah Yaakop]
[Position, Name of WG Chair, Working Group 8]

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Acknowledgements

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This GHWP document was prepared by Global Harmonization Working Party (GHWP),
[Name of relevant working group / Joint Working Group: etc. Work Group 8 (Standards) /
Joint Working Groups of Working Group 8 (Standards) and 9 (UDI)]. We wish to
acknowledge the contributions of working group members: [List of members, who
contribute in preparation of the document, including the co-opted members]

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[Name 1]

[Organisation 1]

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[Name 2]

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Foreword

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This GHWP Document was developed by Global Harmonization Working Party (GHWP), [Name of working group / Joint Working Group: etc. Work Group 8 (Standards) / Joint Working Groups of Working Group 8 (Standards) and 9 (UDI)]. GHWP is a voluntary group of representatives from medical device regulatory authorities and the regulated industry. The document is intended to provide non-binding guidance for use in the regulation of medical devices, and subject to consultation throughout its development process.

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This GHWP Document shall be read in conjunction with the current laws and regulations used in member economies.

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Any statements or references from external sources are used under appropriate citations as specified in the normative references and bibliography.

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There are no restrictions on the reproduction, distribution, translation or use of this document. However, incorporation of this document, in part or in whole, into any other document does not convey or represent an endorsement of any kind by the Global Harmonization Working Party.

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In this GHWP Document, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission; and

— “can” indicates a possibility or a capability.

This document cancels and replaces GHWP/WG8/F001:2001, [Title].

1826
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1828 **Introduction**
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[Paragraph]

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1832 **1 Scope**
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[Paragraph]

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1836 **2 Normative references**
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[Paragraph]

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1840 **3 Terms and definitions**
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[Paragraph]

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1844 **4 [Clause title]**
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[Paragraph]

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1847 **4.1 [Subclause title]**
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[Paragraph]

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1851 **5 [Clause title]**
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[Paragraph]

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Annex A
(normative/informative)

[Title of Annex]

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[Table/ Figure/ Details/ etc]

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Annex B
(normative/informative)

[Title of Annex]

[Introductory paragraph]

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[Table/ Figure/ Details/ etc]

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Bibliography (for template purposes)

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[1] *Example: ISO 10079-1, Medical suction equipment — Part 1: Electrically powered suction equipment*

[2] *Example: ISO 10524 (all parts), Pressure regulators for use with medical gases*

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END OF DOCUMENT

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