GHWP/GL/WG8-SEC/P002/2024

GHWP

Global Harmonization Working Party

Towards Medical Device Harmonization

PROPOSED DOCUMENT

Title:	Guidelines on Development of GHWP Documents - Part 2: Structure and Drafting
Authoring Group:	Work Group 8 – Standards and GHWP Secretariat
Date:	9th Sep 2024

Working Group 8

GHWP Secretariat

38
39
40 ## Acknowledgements
41
42 This GHWP document was prepared by Global Harmonization Working Party (GHWP), Working
43 Group 8 on Standards and GHWP Secretariat. We wish to acknowledge the contributions of working
44 group members:
45

Salbiah Bt Yaakop†	Medical Device Authority, Malaysia
Tony Low	Commissioning Agents International Malaysia
Muhammad Marwan Bin Anoor	Medical Device Authority, Malaysia
Abdullah Mohammed Alghuraibi	Saudi Food and Drugs Authority
Osamah Al-Barikan	Saudi Food and Drugs Authority
Sameer A. Al-Hamdan	Saudi Food and Drugs Authority
Christopher Chan	Industrial Technology Research Institute, Taiwan
Raghavan Nair Asok Kumar	Abbott Healthcare Private Limited, India
Gite Sadanand	Abbott Healthcare Private Limited, US
Zhang Yidong	Medtronic, China
Scott A. Colburn	US Food & Drug Administration
Vats Aaditya	Abbott Healthcare Private Limited, India
Bryan So	GHWP Secretariat
Elizabeth Chan	GHWP Secretariat

† In Memoriam of late Mrs Sabiah Binti Yaakop, for her great contributions on leading the team in preparation of this guideline.

46

47
48 ## Contents

49 **Page**

50 *Contents* *1*
51 *Foreword* *3*
52 *1 Scope* *4*
53 *2 Normative references* *4*
54 *3 Terms and definitions* *4*
55 *A. GENERAL PRINCIPLES* *7*
56 *5 Principles* *8*
57 *6 Organisation and subdivision of the subject matter* *9*
58 *7 Organisation and subdivision of the subject matter* *9*
59 *9 Numbers, quantities, units and values* *12*
60 *10 Referencing* *14*
61 *B. SUBDIVISIONS OF THE DOCUMENT* *19*
62 *11 Title* *20*
63 *12 Acknowledgments* *21*
64 *13 Contents* *21*
65 *14 Foreword* *22*
66 *15 Introduction* *22*
67 *16 Scope* *22*
68 *17 Normative references* *24*
69 *18 Terms and definitions* *25*
70 *19 Symbols and abbreviated terms* *29*
71 *20 Annexes* *30*
72 *21 Bibliography* *31*
73 *C. COMPONENTS OF THE TEXT* *33*
74 *22 Clauses and subclauses* *34*
75 *23 Internal section and subsection* *36*
76 *24 Lists* *36*
77 *26 Notes* *38*
78 *27 Examples* *38*
79 *28 Footnotes* *39*
80 *29 Mathematical formulae* *39*
81 *30 Figures* *40*
82 *31 Tables* *42*
83 *ANNEXES* *44*
84 *Annex A* *45*
85 *Annex B* *48*
86 *Annex C* *49*
87 *Annex D* *50*
88

Annex E *52*
Bibliography *65*

Foreword

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

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

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

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

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 given in Table 2.

Table 2. Names of divisions and subdivision

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

6.2 Subdivision of the subject matter within an individual document

The arrangement of GHWP document is given in Table 3.

Table 3. Overview of the major subdivisions of a document and their arrangement in the text

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.

7 Organisation and subdivision of the subject matter

7.1 General

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

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

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

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

7.2 Requirement

See the definition given in 3.3.3.

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 (×) 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 (·) 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.

EXAMPLE1 80 mm × 25 mm × 50 mm (**not** 80 × 25 × 50 mm)

EXAMPLE 2 80 µF ± 2 µF or (80 ± 2) µF

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

EXAMPLE 4 $80\ ^{+2}_{0}$ (not $80\ ^{+2}_{-0}$)

EXAMPLE 5 $80\ \mathrm{mm}^{+50}_{-25}$ 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)

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 %)

The degree should be divided decimally.

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

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.

9.3 Quantities, units, symbols and signs

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_f, D_i for i = 1, 2, 3, …..

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.

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*

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

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.

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), *Household and similar electrical appliances - Safety*	Reference to **all parts**
IEC 60335-1, *Household and similar electrical appliances - Safety – Part 1: General requirements*	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, *High-voltage switchgear and controlgear - Part 1: Common specifications*	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.

609

610 For an individual document, the form “this GHWP document” shall be used.
611
612 Such undated references are understood to include all amendments and revisions to the
613 referenced document.

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 andclassification*

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:

a) “Vocabulary” if both terms and definitions are included; or

b) “List of equivalent terms” if only equivalent terms in different languages are given.

12 Acknowledgments

12.1 Purpose or rationale

The acknowledgement provides listing of members in the relevant committee, that have contributed to the preparation of the documents.

12.2 Normative or informative?

The acknowledgement is an informative element.

12.3 Mandatory, conditional or optional?

The acknowledgement is a mandatory element.

12.4 Numbering and subdivision

The acknowledgement shall not have a clause number.

13 Contents

13.1 Purpose or rationale

The contents makes the document easier to consult.

13.2 Normative or informative?

The contents is an informative element.

13.3 Mandatory, conditional or optional?

The contents is a mandatory element.

13.4 Numbering and subdivision

The contents shall not have a clause number.

13.5 Specific principles and rules

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

14 Foreword

14.1 Purpose or rationale

The Foreword provides information on:

a) the committee under GHWP responsible to develop the document;

b) a revised document stating:

this document cancels and replaces [the document(s) from the previous edition of the GHWP document]; and

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.

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 …"
  - the characteristics of …"
- describes
  - a method of …"
  - the way in which …"
  - recommendations for …"
  - guidance on …"
- establishes
  - 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. Referenced documents listed are not numbered.

17.5 Specific principles and rules

17.5.1 General

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

a) documents that are not referenced or cited in the GHWP document;

b) documents to which only informative reference is made; and

c) documents which have merely served as bibliographic or background material in the preparation of the standard.

17.5.2 Introductory wording

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.

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

> There are no normative references in this document.

17.5.3 Referencing

Only references cited in the text in such a way that some or all of their content constitutes

requirements of the document shall be listed in the normative references clause.

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.

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

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

EXAMPLE 2

In the following case, the reference is informative.

– For additional information on communication, see ISO 14063.

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

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.

EXAMPLE 2

3 Terms and definitions

[…]

3.2 Optical properties

[…]

3.2.1
colour retention
degree of permanence of a colour

NOTE. Colour retention can be influenced by weathering.

3.5 Surface properties

3.5.1
abrasion
loss of material from a surface due to frictional forces

[…]

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

943
944 **18.5.1 General**
945
946 The terms and definitions clause shall only appear once in each document.
947
948 **18.5.2 Introductory wording**
949
950 If all the specific terms and definitions are provided in Clause 3, use the following introductory
951 text:
952

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

953 If reference is given to an external document, use the following introductory text:
954

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

955 If terms and definitions are provided in Clause 3, in addition to a reference to an external
956 document, use the following introductory text:
957

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

958 If there are no terms and definitions provided, use the following introductory text:
959

No terms and definitions are listed in this document.

960
961 **18.5.3 Permitted content**
962
963 Only terms which are used in the document shall be listed in the terms and definitions clause.
964 This rule does not apply to terminology standards, whose terms are intended for wider use.
965
966 **18.5.4 Terms**
967
968 Terms shall be written in lower case characters and shall be listed in alphabetical order. Upper
969 case characters, mathematical symbols, typographical signs and syntactic signs (e.g.
970 punctuation marks, hyphens, parentheses, square brackets and other connectors or delimiters)
971 as well as their character styles (i.e. fonts and bold) shall be used in a term only if they constitute
972 part of the normal written form of the term. Terms shall in general be presented in their basic
973 grammatical form, i.e. nouns in the singular, verbs in the infinitive.
974

EXAMPLE 1	
Correct use of parentheses:	
bis(dimethylthiocarbamyl) disulphide	The parentheses and the content therein are part of the term.
Incorrect use of parentheses:	
integrity (of system)	The words in parentheses are not part of the term.

EXAMPLE 2 Correct expression of equivalent terms: **live working** **live work** Incorrect expression of equivalent terms: **live working (work)**	 The preferred term and any synonyms are written on separate lines. It is incorrect to indicate a synonymous term using parentheses.

EXAMPLE 3 Correct use of capitalisation: **Reynolds number** Incorrect use of capitalisation: **Planned outage**	 “Reynolds” is a proper noun. It is capitalised. “Planned” is not a proper noun. Do not capitalise this.

18.5.5 Definitions

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

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

EXAMPLE

2.1.17
die
<extrusion> metal block with a shaped orifice through which plastic material is extruded

2.1.18
die
<moulding> assembly of parts enclosing the cavity from which the moulding takes its form

18.5.6 Examples

Examples provide information that illustrates the concept. 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.

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

18.5.7 Non-verbal representations

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

18.5.8 Note

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

a) provisions (statements, instructions, recommendations or requirements) relating to the use of a term;

b) information regarding the units applicable to a quantity; or

c) an explanation of the reasons for selecting an abbreviated form as the preferred term.

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

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

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.

18.5.9 Footnotes

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

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

19 Symbols and abbreviated terms

19.1 Purpose or rationale

The symbols and abbreviated terms clause or subclause provides a list of the symbols and abbreviated terms used in the document, along with their definitions.

19.2 Normative or informative?

The symbols and abbreviated terms clause is a informative element.

19.3 Mandatory, conditional or optional?

The symbols and abbreviated terms clause is a conditional element.

19.4 Numbering and subdivision

The symbols do not need to be numbered. 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".

19.5 Specific principles and rules

Only symbols used in the text shall be listed.

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

a) upper case Latin letter followed by lower case Latin letter (A, a, B, b, etc.);

b) letters without indices preceding letters with indices, and with letter indices preceding numerical ones (B, b, C, C_{m}, C_2, c, d, d_{ext}, d_{int}, d_1, etc.);

c) Greek letters following Latin letters (Z, z, A, α, B, β, …, Λ, λ, etc.); and

d) any other special symbols.

20 Annexes

20.1 Purpose or rationale

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

a) when the information or table is very long and including it in the main body of the document would distract the user;

b) to set apart special types of information (e.g. software, example forms, results of interlaboratory tests, alternative test methods, tables, lists, data); and

c) to present information regarding a particular application of the document.

Requirements for annexes is also applicable to national annexes.

20.2 Normative or informative?

Annexes can be normative or informative elements.

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

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

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.

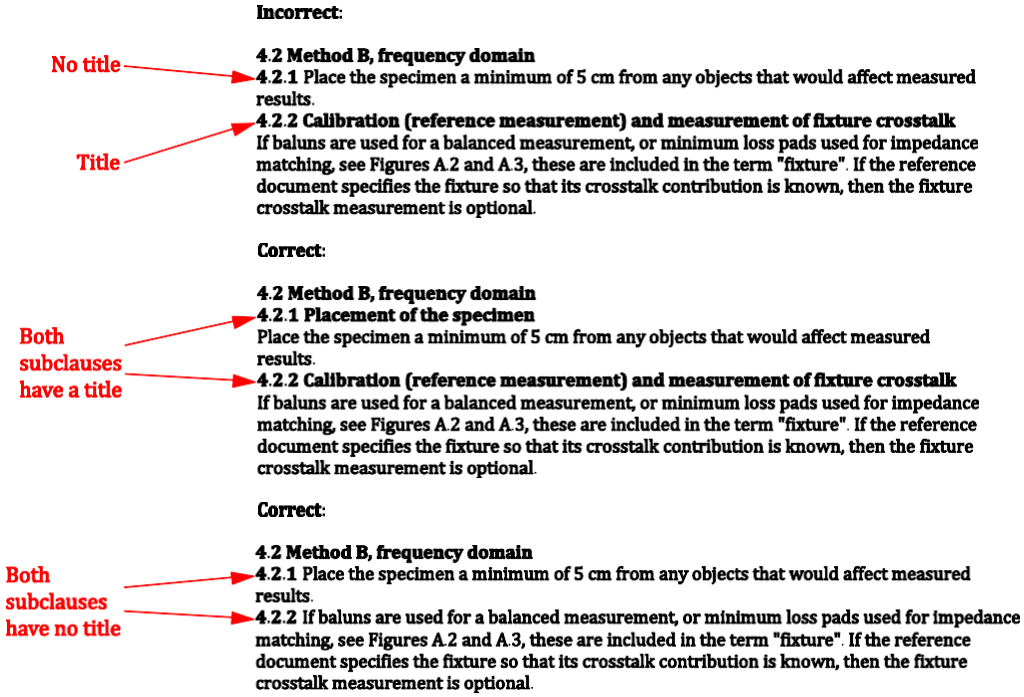

Figure 2. Correct and incorrect use of subclause titles

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).

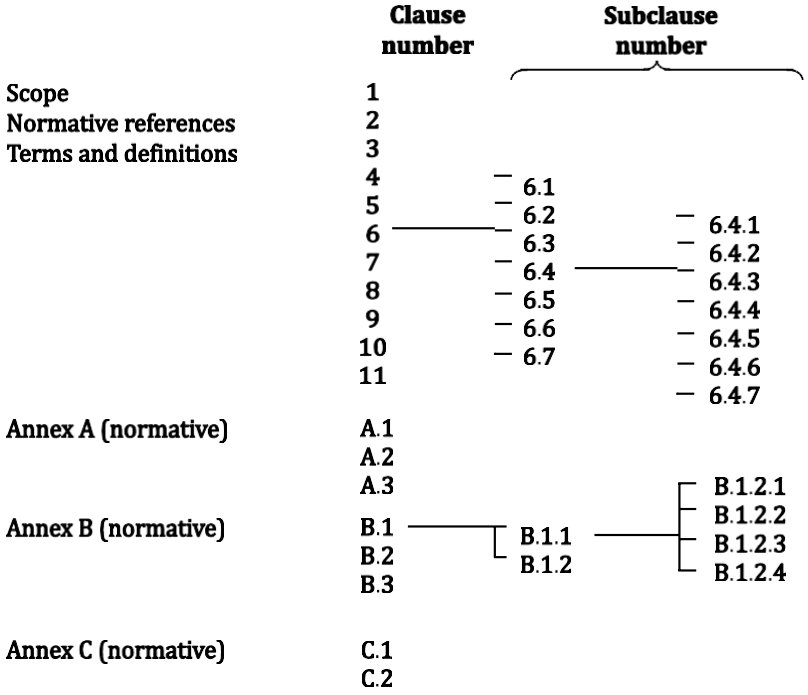

Figure 3. Example of numbering of divisions and subdivisions

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
5 Uncertainty of the certified value **5.1 General** The combined expanded uncertainty of the measurement is calculated. **5.2 Budget of uncertainty** […]	**5 Uncertainty of the certified value** The combined expanded uncertainty of the measurement is calculated. **5.1 Budget of uncertainty** […]

Hanging Paragraph

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

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.

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.

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.

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.

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.

1370

1371 **Table 7. Use of notes and footnotes within documents**

1372

	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)

1373

Table 7. Use of notes and footnotes within documents *(continued)*

	Element	Rule	Numbering	Designation	Provisions allowed
Figures *(continued)*	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

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

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

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

$\frac{V}{km/h}$ *or* $V/(\mathrm{km/h})$

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

$x^2 + y^2 < z^2$ (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

$x^2 + y^2 < z^2$ (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

30.3.1 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.

EXAMPLE

Drawing or illustration

Figure #. Title

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)*”.

EXAMPLE

Drawing or illustration

Figure #. Title *(continued)*

30.3.2 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.

EXAMPLE

Statement concerning units

a) Subtitle **b) Subtitle**

Key

Figure #. Title

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 2”. 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 *(continued)*

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 / Dimension	A	B	C

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 C.1.

Table C.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 *(continued)*
		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 *(continued)*
		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 (*Italic*)	Sentence case	Justify	Text (listing)
13	Header	Size 10	-	Top right	GD project number
14	Footer	Size 10	-	Center	Page number

Annex B
(informative)

Layout

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

Table D.1. Layout requirements

No.	Items	Size (cm)	Remarks
1	Page size	8¼ × 11¾	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

Annex C
(normative)

GHWP Commenting Template

Comments on GHWP Proposed Document

Document number_____**& Title:**_____

Submitted by (name):_____**Affiliated to:**_____**Date:** _____**dd/mm/yyyy**

Comment Number	Affiliation (if more than one affiliation)	Page / Section / Line	Editorial or Technical	Comment and rationale	Proposed revised text	WG Decision (& date)

Page 1
GHWP Operating Procedure – Comments Feedback Form
Ver 03/2022

Annex D
(normative)

New Work Item Proposal Form

Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

New Document Request/ New Work Item Proposal Form

Please submit to GHWP Secretariat by email to secretariat@ghwp.info

Please choose one of the following:
☐ New Document Request
☐ New Work Item Proposal
☐ New Work Item Modification/ Extension Proposal

For GHWP and TC Leaders consideration

Proposed Project Title		
Initiator		
Purpose and Rationale (Including a reference to one or more of the goals or objectives of the GHWP)	Purpose	
	Rationale	
	Alignment with goals or objectives	
Scope	Summary of issues need to be addressed	
	Impact for regulatory convergence	
General Work Plan and Timelines		
Project Leader		
Proposed Work Group		
Work Group teams and experts if needed		
Relevant reference documents at IMDRF or GHTF and national level, ISO, as well as in international bodies		

Page 1
GHWP- New Document Request/ New Work Item Proposal Form
January 2022

Annex E
(informative)

GHWP/WG8/F0XX:202X

Global Harmonization Working Party

Towards Medical Device Harmonization

DRAFT / PROPOSED/ PROPOSED FINAL/ FINAL DOCUMENT

Title: [Guidance Document/ Whitepaper on ……]

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:]
[Position, Name of WG Chair, Working Group 8]

Acknowledgements

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]

[Name 1]	[Organisation 1]
[Name 2]	[Organisation 2]
[Name 3]	[Organisation 3]
[Name 4]	[Organisation 4]
[Name 5]	[Organisation 5]
[Name 6]	[Organisation 6]
[Name 7]	[Organisation 7]
……	……

Contents

Page

Foreword IV
Introduction 1
1 Scope 1
2 Normative References 1
3 Terms And Definitions 1
4 [Clause Title] 1
4.1 [SUBCLAUSE TITLE] 1
5 [Clause Title] 1
Annex A 4
[TITLE OF ANNEX] 4
Annex B 5
[TITLE OF ANNEX] 5
Bibliography 6

GHWP/WG8/F0XX:202X

Foreword

This Guidance 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.

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

In this Guidance 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*].

GHWP/WG8/F0XX:202X

Introduction

[Paragraph]

1 Scope

[Paragraph]

2 Normative references

[Paragraph]

3 Terms and definitions

[Paragraph]

4 [Clause title]

[Paragraph]

4.1 [Subclause title]

[Paragraph]

5 [Clause title]

[Paragraph]

GHWP/WG8/F0XX:202X

Annex A

(normative/informative)

[Title of Annex]

[Introductory paragraph]

[Table/ Figure/ Details/ etc]

GHWP/WG8/F0XX:202X

Annex B

(normative/informative)

[Title of Annex]

[Introductory paragraph]

.

[Table/ Figure/ Details/ etc]

GHWP/WG8/F0XX:202X

Bibliography (for template purposes)

[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*

[3] *Example: ISO 10961, Gas cylinders — Cylinder bundles — Design, manufacture, testing and inspection*

END OF DOCUMENT

Bibliography

[1] *ISO/IEC Directives, Part 1, Consolidated ISO supplement*

[2] *ISO/IEC Directives, Part 2, Principles and rules for the structure and drafting of ISO and IEC documents*