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Guide for writing standards taking into account the needs of micro, small and medium-sized enterprises

Guide de rédaction des normes pour la prise en compte des besoins des micro, petites et moyennes entreprises

Contents

Page

Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) are worldwide federations of national standards bodies (ISO member bodies and IEC national committees). The work of preparing International Standards is normally carried out through ISO and IEC technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non- governmental, in liaison with ISO or IEC, also take part in the work. ISO collaborates closely with IEC on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO and IEC shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

ISO/IEC Guide 17 was prepared jointly by ISO/TMB and IEC/SMB.

ISO/IEC Guide 17 is based on CEN/CENELEC Guide 17, *Guidance for writing standards taking into account micro, small and medium-sized enterprises (SMEs) needs*, which can be accessed through http://www.cencenelec.eu/sme/smenews/Pages/guide17.aspx

Introduction

It is important that the views of micro, small and medium-sized enterprises (SMEs) are sufficiently considered during the development of standards and that standards aimed at large-scale or mass production are not too costly and complex for SMEs to implement.

SMEs benefit from standards, however they may have a weaker position in their market because of their dependency on larger competitors, suppliers or customers or they may have to adapt to existing solutions on the market.

SMEs are present in the majority of sectors. As do other users, SMEs benefit from the technical expertise of standards in the elaboration of which they may not have been present. Nevertheless, there are also sometimes advantages to being small as they can adapt quickly, can be more flexible and can have smaller overhead.

Furthermore, if standards were to take into consideration the SME perspective, considerable benefits would accrue to all the stakeholders involved in standardization.

The aim of this Guide is to raise awareness on the issues that may be of importance to SMEs. By addressing the needs of SMEs, the use of standards may be significantly increased and SMEs will be able to gain the full benefit of utilizing standards.

This Guide provides guidance, advice and recommendations to standards writers on how to take into account the needs of SMEs and addresses the issues to be considered during the development process of ISO or IEC standards.

Guide for writing standards taking into account the needs of micro, small and medium-sized enterprises

1 Scope

This Guide provides guidance and recommendations to writers of standards on the needs of micro, small and medium- sized enterprises (SMEs) in order to avoid the exclusion of SMEs from the market and the distortion of fair competition.

This Guide is relevant to all stakeholders involved in standardization, i.e. standards writers in working groups (WGs), technical committees (TCs), project committees (PCs), or subcommittees (SCs) as well as members of national mirror committees. Not all principles presented in this Guide necessarily have to apply to all standards. Furthermore, sector-specific questions might not be covered. TCs, PCs, SCs and WGs are best placed to evaluate how to address the specific needs of SMEs in their standards.

This Guide contains:

a) considerations for the development of standards that are best adapted to SMEs' needs;

b) techniques for identifying and assessing provisions in standards that may especially impact SMEs;

c) ways to reduce negative impacts on SMEs resulting from some provisions in standards;

d) guidelines for writing SME-friendly standards;

e) a checklist;

f) information on the impact that new standards can have on micro-enterprises.

NOTE   In this Guide, the term "standard" includes all ISO/IEC deliverables.

2 Normative references

There are no normative references.

3 Terms and definitions

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

3.1
micro, small and medium-sized enterprise
SME
micro, small and medium-sized enterprises, as defined by the recognized authority within the country or region, as well as self-employed persons

Note 1 to entry: There is currently no universal definition of what constitutes an SME. Annex A contains examples of definitions from various sources.

3.2
standards writer
person(s), group or organization responsible for the drafting of a standard

4   General considerations

Standards writers should ensure that standards are understandable to those who are meant to use and apply them. The context in which standards users operate within their own organization may be different depending on the use, sector and type of the standard. Therefore, in drafting standards, care should be given to the use of terminology and language which is understandable by all qualified users.

SMEs can have similar, but sometimes also very different, business models from other potential target groups of standards. Given the fact that SMEs are present in almost all sectors, special attention is required in order to address their interests – and in particular those of micro- enterprises – as potential users of standards. For instance, it should be noted that consultants, certifiers, and testing or research laboratories may have different interests from enterprises involved in manufacturing or distribution of specific products or services. Hence, the interests of each of these stakeholders needs to be considered carefully.

5   Issues to consider during the standards development process

5.1   General

Several aspects of standardization of specific importance to SMEs are presented in 5.2 to 5.6. This is not exhaustive and may be supported by more general or specific principles relevant to the needs of standard users as laid down in other documents (e.g. IFAN Guide 3[2]).

Since SMEs, and particularly micro-enterprises, might find it difficult to contribute directly to the process, consultations of SME needs and/or interests through their associations and/or sectoral associations should be undertaken as a priority.

5.2   Preparation of a new work item

5.2.1   Market relevance

Check the relevance of the standard for SMEs.

Before proposing a new work item, the originator of the proposal should assess the need for a standard. All possible stakeholders should be consulted in order to assess their need for, or interest in, the proposed standard.

For new work item proposals, the market needs should be clearly specified, reflecting also the relevance for SMEs. For ISO, see forms 1 and 4; for IEC, see forms NTC and NP. Reference should also be made to the ISO/IEC Directives, Part 1[4], Annex C, *Justification of proposals for the establishment of standards.* It is important for standards to be market-relevant and reflect the needs of all stakeholders, including SMEs, meeting identified needs and benefitting the majority of enterprises that are likely to be influenced by the standard.

5.2.2   Stakeholders

Check whether there are special requirements for SME stakeholders.

When preparing a new work item, all reasonable efforts should be made such that all types of stakeholders are identified and consulted in order to give SMEs or their representatives the opportunity to become involved in the standardization work.

The needs of all target groups affected by the finished standard should be considered in the development and the drafting process, including those of SMEs.

5.3 Issues to be considered during the preparation of a standard

5.3.1 Implementation cost-effectiveness of standards for SMEs

Consider the costs of investment and training required for the implementation of a standard.

The cost of implementing the standard should be considered before introducing provisions or requirements that might not be cost-effective in all situations. Taking into account that SMEs will have fewer employees, particular attention should be paid to:

— consequences of changes in technology;

— cost of buying new equipment;

— cost of training;

— cost of testing;

— cost of reporting;

— cost of hiring consultants;

— cost of compliance to regulations that refer to the new standard;

— specific competencies of SMEs.

Standards writers should always consider whether the requirements can be followed without putting disproportionate and/or unnecessary constraints on SMEs. A standard should not hinder the promotion or innovation of new products, services or processes.

Furthermore, special attention should be paid to situations involving a lesser volume of production or activities. Standards should not hamper the flexibility and versatility that often characterize SME business models.

5.3.2 Availability of elements

Consider the availability of elements required.

Standards should reflect the most recent developments. However, all elements deemed necessary to meet a certain requirement should be available on the market, namely in terms of technology, products, testing equipment, testing laboratories, intellectual property rights (IPR), etc. Thus, the supply situation should be verified while a new or revised standard is produced. These considerations should include the availability in the national markets which are more important for SMEs.

5.4 Developing the content of the standard

5.4.1 Performance approach

Improve understanding and use of the standard by adding examples and explanations.

According to ISO/IEC Directives, Part 2[5], 4.2, "[w]henever possible, requirements shall be expressed in terms of performance rather than design or descriptive characteristics. This approach leaves maximum freedom to technical development. Primarily those characteristics shall be included that are suitable for worldwide (universal) acceptance. Where necessary, owing to differences in legislation, climate, environment, economies, social conditions, trade patterns, etc., several options may be indicated."

The performance approach gives enterprises flexibility and room for innovation. Standards should also play the role of purveyor of basic know-how. However, the performance approach sometimes needs to be accompanied by examples and explanations in order for the standard to be easily understood and implemented by SMEs.

This can be done in an informative manner, for example through texts, illustrations, graphs or tables that focus on simple implementation methods.

Such information would facilitate and increase the implementation of standards by SMEs that might have difficulty transposing pure performance requirements into practical solutions.

5.4.2 Introduction

Provide an introduction with supportive information.

The information below should be included in the introduction and, if an abstract is available, it should be repeated in the abstract.

a) Every standard should contain an explanation of the reasons for its creation and/or the motivation for all modifications or revisions.

b) The type of business and/or activities covered by the standard should be specified.

c) If the standard may be applicable to a wide range of products or services, these should, as far as possible, be mentioned in the scope.

SMEs do not always know which standards apply to their business; thus the document should detail the target groups as far as possible, especially with regard to SMEs.

5.4.3 Scope

Make standards precise and complete within their scope.

Writers of standards should analyse the relevant markets and verify whether other product categories could fall into the scope of a specific standard. A standard should have a clearly defined scope and should comprehensively cover all issues within this; conversely a standard should not cover issues beyond its scope.

SMEs are often specialized in a narrow range of products and services, therefore the scope of a standard should be defined in a way that clearly states what products and services are covered.

5.4.4 Testing

Avoid imposing costly and complex testing regimes and consider the frequency of testing.

The tests required for compliance with standards often present a significant financial burden for SMEs. This includes the cost of measuring equipment, training staff, and time and resources necessary to perform the tests. SMEs do not usually produce on a mass scale and their products may have specific characteristics. Imposing a high number of tests significantly increases the price of their products.

When considering which tests should be included, good regulatory practice should be followed. Prior to a test being introduced, the principle of proportionality should be followed, taking into account, such factors as the type of products, services covered, the nature of the risks involved and the economic impact of the choices made. Ultimately, the choice made should be commensurate with the risk while minimizing the potential negative impact for all stakeholders, especially SMEs.

Standards should not introduce any unnecessary tests. That is to say, if in doubt about the adequacy and necessity of a given test method, it should not be added to the existing test regime.

Standards writers should check who can perform a given test and avoid, where possible, favouring a test that leads to, or reinforces, monopolistic or dominant positions.

5.4.5 Verification methods

Identify simple and cost-effective ways of verifying conformity with the requirements.

In order to allow flexibility when verifying requirements, alternative methods including calculations and tables should be taken into account in the assessment whenever possible.

In addition, standards writers need to ensure that the results of the tests described in standards are unambiguous. It is vital for SMEs that standards refer to methods which cannot be undermined by parties with partial interests.

5.5 Structure and presentation of the content

5.5.1 Length

Standards should be as short as feasible.

If a standard becomes too lengthy, it should be divided into parts that cover a narrower range of products, processes or services.

In the case of longer standards, writers should assess whether it might be useful to divide it into a number of shorter standards that are more specific to a narrow range of products, processes or services. In this case, the standards writer should ensure that all information is given that helps gain better understanding of the standard and that cross-references to other parts of the standard are avoided or kept to a minimum. Alternatively, a very clear structure of the standard (clauses, subclauses and annexes to the specific technical aspects) could facilitate reading and comprehension.

The length of a standard can depend on its purpose and the subject concerned. Nonetheless, long standards may discourage potential users from reading them, especially if the relevant information is difficult to find. Long paragraphs and lists may impede understanding of the important provisions.

5.5.2 Structure

Standards should be as clear, logical and as easy to follow as possible.

Standards should be readable by their intended audience. Therefore, when writing a standard, target groups of potential users need to be identified in order to adapt the standard to their needs.

Consequently, standards should be designed in a user-friendly way. Important provisions should be highlighted and explained as clearly as possible, although these explanatory sections should not complicate the structure of the document. The layout of the text should be adapted, as far as possible, to the purpose of the standard and the needs of its target audience.

Many entrepreneurs from SMEs might not have the time or the resources to study the standard thoroughly. They need to be able to find easily the information relevant to them.

Making the operational part of the standard more visible might encourage SMEs to use them more.

5.5.3 Presentation and figures

Include supportive charts, graphs, drawings and representative examples of applications whenever possible.

Standards writers should draft standards to be as easy to read and as understandable as possible. Charts, graphs, drawings and clarifying examples of application may significantly facilitate the understanding of a standard. The examples could be part of the main text or added in an annex. However, when giving examples, endorsement of a particular product or service should be avoided.

5.5.4 Clear language

Use language simple enough to be understood by all the expected standard users, not only experts.

Standard users with differing qualifications, knowledge and education should be able to understand the parts of the standard relevant to them. Even if standards are directed at personnel with knowledge of specific products, processes or services, they still need to be written in simple, clear language so that they are comprehensible by standards users who have not been directly involved in their preparation.

Standards should be easy to read. SMEs should be given particular attention as potential users and the language should be adapted to their way of functioning if they constitute the main target group of the standard. Attention should be paid to keeping language simple when translating standards into national languages.

Furthermore, all abbreviations and acronyms should always be explained and, if some wording seems complicated or ambiguous, it is recommended that it be defined in the Clause on terminology.

TIPS on clear language

The writers should use a style that is clear, direct and unambiguous, for example

— using verbs in the active voice rather than the passive;

— using simple, meaningful and intelligible words;

— being assertive by using commands rather than weaker forms;

— using action verbs rather than abstract nouns;

— speaking directly to users rather than saying what they might do;

— using lists where appropriate;

— defining technical terms and abbreviations;

— using terms consistently throughout the text.

5.5.5   References

Reduce the need to acquire referenced standards.

To increase their operability, repeat short excerpts from other standards instead of merely referring to them. Clause 2.13 of the ISO/IEC Directives, Part 1[4] applies when reproducing text.

According to the ISO/IEC Directives, Part 2[5], all the normative documents necessary for applying the standard shall be publicly available at the time the standard is published.

Normative references in standards are useful as they prevent duplication of work and help to maintain consistency when one of the standards is revised. However, numerous references make the operability of standards more complex.

5.5.6   Revision

Ensure that clear information about the changes made to a previous version is provided in the new and revised standard.

According to ISO/IEC Directives, Part 2[5], 6.1.3, "The specific part (...) shall give a statement of significant technical changes from any previous edition of the document". This statement appears in the Foreword.

This is particularly important for the implementation of standards by SMEs as they do not have the time or the resources to study new editions of standards in detail.

5.6 Final review

5.6.1 Transition period

Assess the implications of the changes in new and revised standards in setting the transition period.

The number and complexity of technical modifications should be reflected in an extension of the transition period. Any transition period should take into account the implementation needs of all stakeholders, including SMEs.

In cases where a standard introduces a completely new requirement or solution in some countries, the coexistence period should be considered. The need to buy new equipment, change the work organization and train staff should be considered. It is especially difficult and expensive for SMEs to change their business model, particularly if it was functioning well beforehand. Therefore, they need assistance and have to assess the profitability of staying on the market. This may, however, require an extended period of coexistence.

SME associations and/or sectoral associations can help identify SME transition needs and help establish the correct transition period length.

5.6.2 Supportive implementation assistance

Investigate whether assistance will be necessary for the implementation of standards that cannot be simplified.

In some complex areas of standardization, particularly in the application of complex legislation, it might be difficult to simplify standards. In such cases, standards writers should express their opinion as to the need for supportive implementation assistance for SMEs, e.g. an implementation manual.

Implementation assistance can also be identified and collaborated on with SME associations and/or sectoral associations.

Standards writers may participate in the creation of any additional implementation guidance, but their main role is to ensure that the standards are as easy to apply as possible. The intention to provide implementation assistance should not be used as a justification for developing complex standards.

6 Checklist

Table 1 presents the recommendations of this Guide in the form of a checklist. Standards writers may find the table useful in ensuring that the needs of SMEs have been considered during the drafting of a new standard or the revision of an existing one. Table 1 reads from left to right. The questions in bullet points have been explained in detail in the corresponding sections of Clause 5 of this Guide.

Table 1 — Checklist for standards writers

Preparation of new work item	Preparation of standard	Development of content	Structure and presentation of content	Final review
☐ (5.2.1) Did you check the relevance of the standard for SMEs?	☐ (5.3.1) Did you evaluate the cost of investment (technology, equipment, testing)?	☐ (5.4.1) If the performance approach is used, is it understandable?	☐ (5.5.1) Is the standard as short as possible?	☐ (5.6.1) Did you suggest a transition period reflecting the implications of the changes?
☐ (5.2.2) Did you check with all the stakeholders if there are special needs for SMEs?	☐ (5.3.1) Did you evaluate the cost of training (staff)?	☐ (5.4.2) Have you used descriptive explanations?	☐ (5.5.1) If the standard is long, did you evaluate the possibility of dividing it into shorter standards?	☐ (5.6.2) Did you evaluate the need for an implementation manual?
☐ (5.2.2) Did you evaluate whether there are SMEs among the target groups?	☐ (5.3.1) Did you evaluate the cost of implementation?	☐ (5.4.3) Is the scope of the standard precise and complete?	☐ (5.5.2) Is the structure of the standard easy to follow?	
	☐ (5.3.2) Did you verify that all elements are available?	☐ (5.4.4) Did you avoid strict testing regimes?	☐ (5.5.3) Have you included supportive graphs, charts, etc. (when possible)?	
		☐ (5.4.4) Did you evaluate testing costs?	☐ (5.5.4) Have you used clear language understandable by all expected standards users?	
		☐ (5.4.5) Did you identify simple, cost-effective ways of checking conformity to the requirements?	☐ (5.5.5) Did you minimize the number of referenced standards? ☐ (5.5.6) Did you provide clear information on the changes from the previous versions of the standard?	

Annex A
(informative)

Definitions of micro, small and medium-sized enterprises

A.1 General

There is currently no widely accepted, universal definition of what constitutes a micro, small or medium-sized enterprise. Many national and regional institutions, as well as intergovernmental and non-governmental organizations, have their own definitions. Criteria such as the number of employees, total net assets, sales and investment level are all commonly used as part of the definition of an SME, but the number of employees is perhaps the most common basis.

This annex gives some examples of definitions for SMEs from a variety of sources (updated in May 2014).

A.2 European Commission

The main factors determining whether a company is an SME are:

a) **number of employees** and

b) either **turnover** or **balance sheet total**

See Table A.1.

Table A.1 — European Commission definitions

Company category	Employees	Turnover EUR	and/or	Balance sheet total EUR
Medium-sized	< 250	≤ 50 million		≤ 43 million
Small	< 50	≤ 10 million		≤ 10 million
Micro	< 10	≤ 2 million		≤ 2 million

These ceilings apply to the figures of individual firms only. A firm which is part of larger grouping may need to include employee/turnover/balance sheet data from that grouping too.

More information is available in References [1],[6].

A.3 Organization for Economic Cooperation and Development (OECD)

The OECD gives the following definition[7][8].

Small and medium-sized enterprises (SMEs) are non-subsidiary, independent firms which employ fewer than a given number of employees. This number varies across countries. The most frequent upper limit designating an SME is 250 employees, as in the European Union. However, some countries set the limit at 200 employees, while the United States considers SMEs to include firms with fewer than 500 employees.

Small firms are generally those with fewer than 50 employees, while micro-enterprises have at most 10, or in some cases 5, workers.

Financial assets are also used to define SMEs. In the European Union, a new definition came into force on 1 January 2005 applying to all Community acts and funding programmes as well as in the

field of State aid where SMEs can be granted a higher national and regional aid intensity than large companies. The new definition raises the financial ceilings: the turnover of medium- sized enterprises (50-249 employees) should not exceed EUR 50 million; that of small enterprises (10-49 employees) should not exceed EUR 10 million while that of micro-firms (less than 10 employees) should not exceed EUR 2 million. Alternatively, balance sheets for medium, small and micro-enterprises should not exceed EUR 43 million, EUR 10 million and EUR 2 million, respectively.

A.4 World Bank and the International Finance Corporation (World Bank Group)

The World Bank and the International Finance Corporation's definition of an SME is based on three indicators: number of employees, total assets and annual sales. To be classified as an SME, enterprises need to meet two of these three criteria. See Table A.2.

Table A.2 — World Bank and International Finance Corporation definitions

Firm size	Employees	Assets USD	Annual sales USD
Micro	< 10	< 100 000	< 100 000
Small	< 50	< 3 million	< 3 million
Medium	< 300	< 15 million	< 15 million

See References [9],[10].

A.5 The Brookings Institution

See Reference [11] and Table A.3.

Table A.3 — SME definitions used by multilateral institutions

Institution	Maximum number of employees	Maximum revenues or turnover USD	Maximum assets USD
World Bank	300	15 000 000	15 000 000
MIF – IADB	100	3 000 000	(none)
African Development Bank	50	(none)	(none)
Asian Development Bank	No official definition. Uses only definitions of individual national governments.		
UNDP	200	(none)	(none)

The following group of countries is listed in Table A.4 by each country's rank in per capita gross national income (PC-GNI), and in Table A.5 by their rank relative to the maximum number of employees of an SME according to the national government.

Table A.4 — Countries ranged by PC-GNI

Country by PC-GNI	Maximum number of employees
Norway	100
Switzerland	250
Australia	200
Brazil	100
Belarus	250
Thailand	200
Peru	200
Moldova	250