



**Guidance for writing standards
taking into account micro, small
and medium-sized enterprises' needs**

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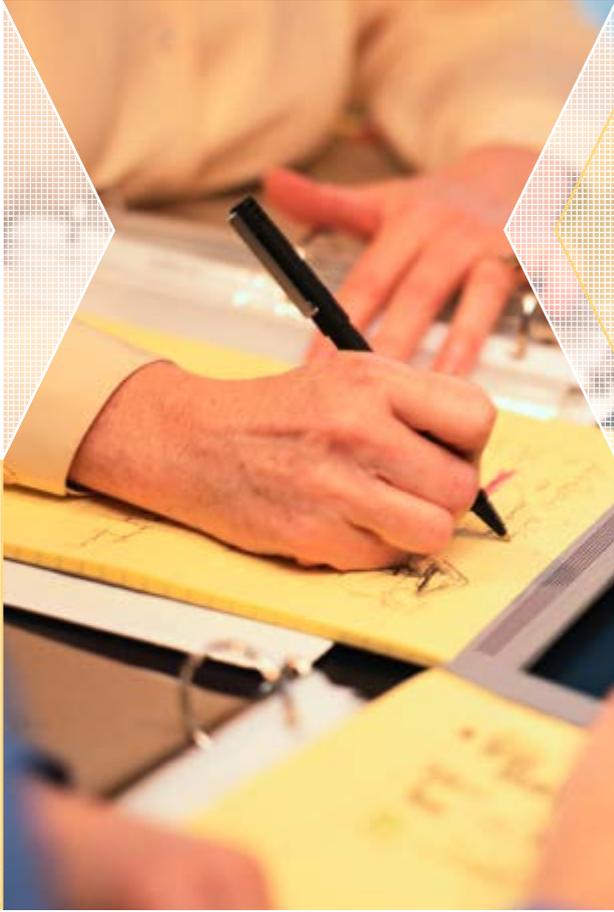


Why a squirrel to represent SMEs?

Why a squirrel? Squirrels are small yet enterprising animals whose cleverness and adaptability enables their success in the wild.

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Foreword

This Guidance document was prepared by a Task Force of the ISO Technical Management Board and 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>.

It 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 standards.

Introduction

Micro, small and medium-sized enterprises (SMEs) can sometimes be underrepresented in standards writing groups and their interests therefore not be sufficiently taken into account. In addition, the cost of implementing some standards can be relatively high ; in particular, standards aimed at large-scale or mass production may be too costly and complex for some smaller businesses to implement.

The aim of this Guidance document is to raise awareness on the issues that may be of importance to SMEs in the development of standards and to overcome possible non-representation of SMEs in standardization work.

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, they may have a weaker position in their product or service markets because of their dependency on larger competitors, suppliers or customers. They may also have to adapt to the existing solutions on the market.

Through addressing the needs of SMEs, the use of standards may be significantly increased. Furthermore, if standards were to take into consideration the SME perspective, considerable benefits would accrue to all the stakeholders involved in standardization.

1 Scope

This Guidance document provides advice 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 Guidance document is relevant to all stakeholders involved in standardization, i.e. standards writers in working groups (WGs) or technical committees (TCs) as well as members of national mirror committees. Not all principles presented in this Guidance document necessarily have to apply to all standards. Therefore, TCs and WGs are the best place to evaluate whether and how to address the specific needs of SMEs in their standards.

This Guidance document contains :

- a) considerations for the development of standards that are best adapted to the 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 guidance document checklist ;
- f) information on the impact that new standards can have on micro-enterprises.

NOTE: In this Guidance document, the term "standard" includes all ISO/IEC deliverables.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC Directives, Part 2, *Rules for the structure and drafting of International Standards*, 2011

3 Terms and definitions

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

NOTE: In this Guidance document, the expression "small and medium-sized enterprise" (SME) is used for micro, small and medium-sized enterprises, as defined by the recognized authority within the country or region as well as self-employed persons.

3.1 micro, small and medium-sized enterprise SME

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

3.2 standards writer

person responsible for the drafting of a standard.

4 General considerations

Standards writers should ensure that standards are understandable to those who are deemed to read them. The reality of standards users may be different depending on the use, sector and type of the standard.

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 need 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 below. 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 3:2008, *Guidelines to assist members of standards committees in preparing user-oriented European Standards*).

Since SMEs, and particularly micro-enterprises, often 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 shall 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, 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. It is important that standardization of a given item meets an identified need and is beneficial to the majority of enterprises that are liable to be influenced by the standard.

5.2.2 Stakeholders

Check if there are special SME needs among the stakeholders.

When preparing a new work item, all types of stakeholders shall be 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 shall 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 may not be cost-effective in all situations. Taking into account that the average number of employees of small manufactures is low, particular attention should be paid to micro-enterprises.

- Consequences of changes in technology
- Cost of buying new equipment
- Cost of training
- Cost of testing
- Cost of hiring consultants

Standards writers should always consider whether the requirements can be followed without putting disproportionate and/or unnecessary constraints on SMEs. A standard shouldn't 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 shall always reflect the most recent developments. However, all elements deemed necessary to meet a certain requirement shall be available on the market, namely in terms

of technology, products, testing equipment, testing laboratories, IPR, etc. Thus, the supply situation needs to 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 micro and small enterprises.

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.

On the subject of the performance approach, “[w]henver 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 world-wide (universal) acceptance. Where necessary, owing to differences in legislation, climate, environment, economies, social conditions, trade patterns, etc., several options may be indicated” (reference sentence from ISO/IEC Directives, Part 2, *Rules for the structure and drafting of International Standards*, 4.2).

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 small and micro-enterprises.

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 small and micro-enterprises that may 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.

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

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

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 need to analyze the relevant markets and verify whether other product categories could fall into the scope of a specific standard. Standards shall have clearly defined scopes and, within their limits, be as comprehensive as possible. This means that the standard should not cover issues that are not clearly defined in its scope, but should deal with all aspects of the items in the scope.

SMEs are often specialized in a narrow range of products and services. The scope needs to 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 small manufacturers. This includes the cost of measuring equipment, training staff, and time and resources necessary to perform the tests. Small enterprises 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.

It has to be noted that 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 small manufacturers 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 may 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 easy to follow as possible.

Standards should be readable by those who are deemed to read them. 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 small businesses may 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 may encourage small enterprises to use them more.

5.5.3 Presentation and figures

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

Standards writers shall 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 chapter on terminology.

HELP BOX Language

The writers shall 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 at first occurrence ;
- 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. When reproducing text, a reference to the source should always be clearly indicated.

All the normative documents necessary for applying the standard should 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.

Significant technical changes shall be specified and the reasons for the revision of a standard shall be given in the Foreword. According to ISO/IEC Directives, Part 2, 6.1.3,

“ The specific part (...) shall give a statement of significant technical changes from any previous edition of the document ”. This statement shall appear in the Foreword.

This is particularly important for the implementation of standards by SMEs as small enterprises 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 and set the transition period accordingly.

The amount 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 significantly prolonged. The need to buy new equipment, change the work organization and train staff has to be considered. It is especially difficult and expensive for small enterprises 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.

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.

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 Guidance document checklist

The table below presents the recommendations of this Guidance document 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 draft-

ing of a new standard or the revision of an existing one. The table reads from left to right. The questions in bullet points have been explained in detail in the corresponding sections of Clause 5 of this Guidance document.

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

ANNEX 1

Definitions of micro, small and medium-sized enterprises

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.

1) European Commission

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

1. number of employees and
2. either turnover or balance sheet total

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.

Refer to EU recommendation 2003/361 for more details : <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:124:0036:0041:en:PDF>

2) Organisation for Economic Cooperation and Development (OECD)

The OECD gives the following definition :

“Small and medium-sized enterprises (SMEs) are non-subsiary, 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.”

Source : <http://stats.oecd.org/glossary/detail.asp?ID=3123>

Source publication : OECD, OECD SME and Entrepreneurship Outlook : 2005, OECD Paris, page 17

3) 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.

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

Sources :

Meghana Ayyagari, Thorsten Beck, and Asli Demirgüç-Kunt

(2005), Small and Medium Enterprises across the Globe. Washington, D.C. : World Bank : http://siteresources.worldbank.org/DEC/Resources/84797-1114437274304/SME_globe.pdf

IFC, Verifying accuracy of IFC's SME measurement : http://www1.ifc.org/wps/wcm/connect/635f64804efbe2b18ef5cf3eac88a2f8/IFC_Factsheet_SME_Loan+Size+Proxy_Brief.pdf?MOD=AJPERES

4) The Brookings Institution

H. J. van der Vaart and Tom Gibson, Defining SMEs : A Less Imperfect Way of Defining Small and Medium Enterprises in Developing Countries, The Brookings Institution, 2008.

http://www.brookings.edu/~media/research/files/papers/2008/9/development%20gibson/09_development_gibson.pdf

Table 1 : SME Definitions Used by Multilateral Institutions

Institution	Maximum # employees	Max. 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 first by each country's rank in per capita gross national income (PC-GNI), and then by their rank relative to the maximum number of employees of an SME according to the national government.

Country by PC-GNI	Maximum # employees
Norway	100
Switzerland	250
Australia	200
Brazil	100
Belarus	250
Thailand	200
Peru	200
Moldova	250
Morocco	200
Egypt	50
Nicaragua	100
Pakistan	50
Vietnam	300
Bangladesh	100
Ghana	100
Tanzania	20
Malawi	50

Country by SME size	Maximum # employees
Vietnam	300
Belarus	250
Moldova	250
Switzerland	250
Australia	200
Morocco	200
Peru	200
Thailand	200
Bangladesh	100
Brazil	100
Ghana	100
Nicaragua	100
Norway	100
Egypt	50
Malawi	50
Pakistan	50
Tanzania	20

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[1] 2003/361/EC : Commission recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (Text with EEA relevance) (notified under document number C(2003) 1422), OJ L 124, 20.5.2003, pp. 36–41, available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:124:0036:0041:en:PDF>

[2] IFAN Guide 3:2008, *Guidelines to assist members of standards committees in preparing user-oriented European Standards*, First edition, 2008-04, available at http://www.ifan.org/ifanportal/livelink/fetch/2000/2035/36282/394607/publications/IFAN_Guide3-2008.pdf

[3] CEN Guidance Document – *Date of withdrawal*, Version 2, March 2010, available at <http://www.cen.eu/boss/supporting/Guidance%20documents/dow/Pages/default.aspx>

[4] ISO, *10 Good Things for SME*, First edition, 2011, available at <http://www.iso.org/iso/10goodthings.pdf>

