CEN/CENELEC Guide 17

Guidance for writing standards taking into account micro, small and medium-sized enterprises (SMEs) needs

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Foreword

This document (CEN/CLC Guide 17) has been prepared by the Technical Board CEN/CLC BT WG 208 "Guidance on SME needs", the secretariat of which was held by Normapme.

This Guide provides orientation, advice and recommendations to standard writers on how to take into account SMEs needs. This document addresses the issues to be considered during the development process of standards.

Introduction

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

The aim of this Guide 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 standardisation work.

SMEs are present in the majority of sectors. As the other users do, SMEs benefit from the technical expertise of the 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 as well as to the European Standards. That is why special attention is required to address the interests of SMEs and in particular micro enterprises as potential users of standards.

SMEs constitute over 99% of enterprises in Europe. 92% of enterprises have less than 10 employees and limited resources. Through addressing their needs, the use of standards may be significantly increased. Furthermore, if standards take more account of the SME perspective, considerable benefits would accrue to all stakeholders in standardization.

1   Scope

This Guide provides guidance to writers of European 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 involved in standardisation, i.e. standard writers in Working Groups or Technical Committees as well as members of national mirror committees. Not all principles presented in this guide necessarily have to apply to all standards. Therefore, TCs and WGs are the best place to evaluate if and how to address specific needs of SMEs in their standards.

This Guide 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)   Guide checklist;

f)   Information on how to make a micro enterprise impact of new standards.

NOTE   In this Guide "standard" includes all CEN/CENELEC 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.

CEN/CENELEC Internal Regulations — Part 3: Rules for the structure and drafting of CEN/CENELEC Publications (ISO/IEC Directives – Part 2, modified) – 2009-08 corrected version

3   Terms and definitions

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

NOTE   In this Guide the term "small and medium-sized enterprises" (SMEs) is used for micro, small and medium-sized enterprises as defined by the EU as well as self-employed persons.

3.1
Micro, small and medium-sized enterprises
SMEs
enterprises which employ fewer than 250 persons and which have an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million

[2003/361/EC: Commission recommendation C(2003) 1422]

3.2
small enterprise
enterprise which employs fewer than 50 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 10 million

[2003/361/EC: Commission recommendation C(2003) 1422]

3.3
microenterprise
enterprise which employs fewer than 10 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 2 million

[2003/361/EC: Commission recommendation C(2003) 1422]

3.4
standard writer
person taking part in the development of standards

3.5
guide
document published by CEN or CENELEC giving rules, orientation, advice or recommendations relating to European standardization

4   General considerations

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

SMEs have similar but sometimes also very different business models from other potential target groups of standards. Due to the fact that SMEs are present in almost all sectors, special attention is required to address the interests of SMEs and in particular micro enterprises as potential users of standards. For instance, it should be noted that consultants, certifiers, testing or research laboratories may have divergent interests than 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 for SMEs are presented below. This is not exhaustive and may be supported by more general or specific principles relevant to the needs of users of standards 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*).

As SMEs, and even more micro enterprises, in many cases find it difficult to contribute directly to the process, consultations on SME needs and/or interests should in priority be undertaken through their associations and/or sectoral associations.

5.2   Preparation of a New Work Item

5.2.1   Market relevance

Check the relevance of the standard for European SMEs.

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

For new work item proposals the market needs shall be clearly specified reflecting also the SME relevance. For CEN see CEN form A and N respectively. For CLC in the TC request towards BT for starting new work (New Work Item proposal).

It is important that European Standards are market-relevant and reflect the needs of all stakeholders including SMEs. It is important that European standardisation of a given item is necessary and beneficial for the majority of enterprises that could be influenced by the standard.

5.2.2 Stakeholders

Check if there are special SMEs needs among the stakeholders.

When preparing a new work item all types of stakeholders shall be identified and consulted in order to give also SMEs or their representatives the opportunity to become involved in the standardisation work.

Particular SME needs shall be considered in the development and the drafting process as well as the needs of all target groups for the finished standard.

5.3 Issues to be considered during the course of 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 costs for 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 European enterprises is six, particular attention should be paid for 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. No standard should introduce any hindrance to the promotion of innovation on products, services or processes.

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

5.3.2 Availability of elements

Consider the availability of elements required.

Standards shall always reflect the most recent developments (see *CEN/CENELEC Internal Regulations, — Part 3*). However all elements necessary to meet a certain requirement shall be available on the market, as for instance in regard 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.

About the performance approach, "[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" (reference sentence from *CEN/CENELEC Internal Regulations — Part 3: Rules for the structure and drafting of CEN/CENELEC Publications*, 4.2).

The performance approach gives enterprises flexibility and room for innovation. Standards should also play the role of transfer of basic know-how. The performance approach however 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 by 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 difficulties in transposing pure performance requirements into practical solutions (*CEN/CENELEC Internal Regulations — Part 3*).

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 explanations of the reasons of 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 are not always aware of which standards apply to their businesses; 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 analyse 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 it should deal with all aspects of the items in the scope of the standard.

SMEs are often specialised in a narrow range of products and services. The scope needs to be defined in a way that it is clear what products and services are covered.

5.4.4   Testing

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

The required tests for compliance with standards are often a significant financial burden for small manufacturers. This includes the costs of measuring equipment, staff training, time and resources necessary to perform the tests. Small enterprises usually do not produce on 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, a presumption should be made that, in the event of doubt based on the adequacy and necessity of a given test method, it should not be added to the existing test regime.

The standard writers should check who can perform any given test and avoid as far as 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 in verification of requirements, alternative methods including calculations and tabular methods for the assessment should be taken into account whenever possible.

In addition, standard 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 tend to be too voluminous, try to divide it into parts, for a more narrow range of products, processes or services.

In case of a longer standard, the writers should assess whether it would be useful to divide it into a number of shorter standards more specific to a narrow range of products, processes or services. In this case, the standard writer should ensure that all necessary information to aid greater understanding of the standard is given and that cross-references to other parts of the standard is avoided if not limited. 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 it is difficult to find the relevant information. 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, the target groups need to be identified in order to adapt the standard to the needs of its potential users.

Consequently, standards should be designed in a user friendly way. Important provisions should be highlighted and explained so far as possible, but at the same time these explanatory parts should not complicate the structure of the document. The layout of the text should be adapted, so far as possible, to the purpose of the standard and the needs of its target audience.

Many entrepreneurs from small business may not have the time or the resources to study the standard thoroughly. They need to be able to easily find the information relevant to them. Making the operational part of standards more visible may encourage small enterprises to use them more often.

5.5.3 Presentation and figures

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

Standard writers shall write so that the standards are as easy to read and understand 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, while 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.

Users of the standard having different 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 a simple and clear language so that they are comprehensible by standard users who have not been directly involved in their preparation.

Standards should be easily readable by their users. SMEs should be given particular attention as potential users and therefore 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 simple language when translating standards into national languages.

Furthermore, all abbreviations and acronyms should be always explained and, if some wording seems to be complicated or ambiguous, it is recommended to define them in the chapter on terminology.

HELP BOX Language

The writer shall use a style that is clear, direct, and unambiguous. For example,

– use the verbs in the active voice rather than the passive;

– use simple, meaningful and intelligible words;

– be assertive by using commands rather than weaker forms;

– use action verbs rather than abstract nouns;

– speak directly to users rather than saying what they might do;

– use lists where appropriate;

– define technical terms and abbreviations at first occurrence;

– use 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. In cases of reproductions of texts a reference to the source should always be clearly indicated.

All the normative documents necessary for applying the standard should be publicly available when the standard is published.

Normative references in standards are useful as they prevent duplication of work and allow for the maintenance of 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 on the changes made to a previous version is provided in the new and revised standards.

Significant technical changes shall be specified and the reasons for the revision of a standard shall be given in the Foreword. According to *CEN/CENELEC Internal Regulations — Part 3*, 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 changes resulting from new and revised standards and set the transition period accordingly.

The amount and complexity of technical modifications should be reflected in extensions of the transition periods Any transition period should take into account the implementation needs of SMEs. For CEN, see CEN Guidance Document - *Date of withdrawal*. For CLC, the date of withdrawal forms part of the formal approval procedure by BT.

In case a European Standard introduces a completely new requirement or solution in some countries, the co-existence period should be significantly prolonged. The necessity to buy new equipment, to change the organization of work and to train the 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 before. Therefore they need assistance and have to assess the profitability of staying on the market. This however may require an extended period of co-existence.

5.6.2 Supportive implementation assistance

Investigate if assistance in implementation is necessary for standards that cannot be simplified.

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

Standard writers may participate in the creation of any additional implementation guidance, but their main role is to assure that the standards are as easily applicable as possible. An intention to produce implementation assistance should not be used as a justification for developing complex standards.

6 Guide checklist

The table below presents the recommendations of this Guide in form of a checklist. Standard writers may find the table useful in ensuring that needs of SMEs have been considered during the drafting 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 Guide.

Guide checklist

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

Bibliography

[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/Notice.do?val=284986:cs&lang=en&list=284986:cs,284128:cs,&pos=1&page=1&nbl=2&pgs=10&hwords=&checktexte=checkbox&visu=#texte

[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