

DRAFT ISO/IEC GUIDE

ISO/IEC GUIDE 17.2

ISO/TMBG

Secretariat: ISO

Voting begins on:
2015-07-01

Voting terminates on:
2015-09-01

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 (PME)

ICS: 01.120

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Reference number
ISO/IEC GUIDE 17.2:2015(E)

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Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 General considerations	1
5 Issues to consider during the standards development process	2
5.1 General.....	2
5.2 Preparation of a new work item.....	2
5.2.1 Market relevance.....	2
5.2.2 Stakeholders.....	2
5.3 Issues to be considered during the preparation of a standard.....	2
5.3.1 Implementation cost-effectiveness of standards for SMEs.....	2
5.3.2 Availability of elements.....	3
5.4 Developing the content of the standard.....	3
5.4.1 Performance approach.....	3
5.4.2 Introduction.....	4
5.4.3 Scope.....	4
5.4.4 Testing.....	4
5.4.5 Verification methods.....	4
5.5 Structure and presentation of the content.....	5
5.5.1 Length.....	5
5.5.2 Structure.....	5
5.5.3 Presentation and figures.....	5
5.5.4 Clear language.....	5
5.5.5 References.....	6
5.5.6 Revision.....	6
5.6 Final review.....	6
5.6.1 Transition period.....	6
5.6.2 Supportive implementation assistance.....	7
6 Checklist	7
Annex A (informative) Definitions of micro, small and medium-sized enterprises	9
Bibliography	12

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).

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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>

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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.

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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 may 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 responsible for the drafting of a standard

4 General considerations

Standards writers should ensure that standards are understandable to those who are meant to read them. The context in which standards users operate 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 to all 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 3:2008^[2]).

Since SMEs, and particularly micro-enterprises, may 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, 2014^[5], 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 may 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 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 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 2:2011^[6], 4.2, “[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 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 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 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.