GUIDE 7

Guidelines for drafting of standards suitable for use for conformity assessment

Second edition 1994

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Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work.

ISO/IEC Guide 7 was prepared by ISO/CASCO/WG 7, *Standards suitable for conformity assessment purposes.* A draft was circulated to CASCO members and IEC National Committees for comments. A final draft has subsequently been approved by ISO/CASCO and by IEC Council for publication as an ISO/IEC Guide.

This second edition cancels and replaces the first edition (ISO/IEC Guide 7:1982).

It should be noted that certain elements in the first edition have been omitted, as they are covered by the ISO/IEC Directives, parts 2 and 3. The Guide is intended to be read in conjunction with these parts of the Directives.

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Guidelines for drafting of standards suitable for use for conformity assessment

1 Scope

This Guide sets out guidelines to assist technical committees in drafting standards suitable for use for conformity assessment of products.

The guidelines contained herein may also be used as appropriate for the drafting of standards intended for conformity assessment of processes and services.

2 References

ISO/IEC Guide 2:1991, *General terms and their definitions concerning standardization and related activities.*

ISO/IEC Directives, Part 2: 1992, *Methodology for the development of International Standards.*

IEC/ISO Directives, Part 3: 1989, *Drafting and presentation of International Standards.*

3 Definitions

For the purposes of this Guide, the relevant definitions in ISO/IEC Guide 2:1991 and the following definition apply.

3.1 conformity assessment: Any activity concerned with determining directly or indirectly that relevant requirements are fulfilled.

NOTE 1 Examples of conformity-assessment activities are sampling, testing and inspection, evaluation, verification and assurance of conformity (supplier's declaration, certification), registration, accreditation and approval as well as their combinations.

4 General

4.1 For conformity-assessment purposes a number of aspects with which standards should normally comply, such as those covered by the ISO/IEC Directives, Part 2, including its annexes, require emphasis. These relate to the specific inclusion or exclusion of items in the standard so as to ensure its suitability for use for conformity assessment. For that reason, national member bodies should include, in their relevant national advisory groups and in their delegations to meetings of the relevant technical committees, persons with experience of conformity assessment.

4.2 Standards suitable for use for conformity assessment should be so written that they can be applied by any of the following:

— a manufacturer or supplier (first party);

— a user or purchaser (second party);

— an independent body (third party).

4.3 Each standard that the responsible technical committee considers suitable for use for conformity assessment should contain a clear statement to this effect in its scope.

4.4 Parties making use of a standard suitable for use for conformity assessment should be able to derive from the contents of the standard a common understanding of its meaning and intent. The standard should be so clear and precise that it results in accurate and uniform interpretation.

4.5 The standard should specify requirements or tests which should be designated as intended for one of the following purposes:

— type evaluation;

— routine production;

— surveillance.

4.6 Sample selection requirements relating to conformity assessment should appear in an annex or in a separate document, which should be referenced in the standard.

A clear statement regarding whether the sampling requirements are normative or informative should be given. A sample selection requirement may contain a specified statistically calculated sampling and compliance schedule.

4.7 The following items may be included in the standard in informative annexes or in the foreword; they should

not be normative unless the standard is identified for use in a quality assessment system such as the IECQ[1], in which case, one or more of these items may be normative:

a) matters relating to marks or labels of conformity, certificates of conformity or manufacturers' or suppliers' declarations of conformity;

b) dates of implementation or allocation of responsibilities to various parties making use of the standard;

c) requirements for manufacturing processes, unless it is impossible to specify adequately the product without doing so;

d) requirements for quality control during production.

5 Specification of requirements

5.1 Standards should always be written in such a way that they facilitate and do not retard the development of technology. Usually, this is accomplished by specifying performance requirements rather than product design requirements.

5.2 The requirements should be clearly specified, together with the required limiting values and tolerances, and the test methods to verify the specified characteristics.

The requirements should be free from subjective elements; the use of such phrases as "sufficiently strong to" or "of adequate strength" should be avoided.

5.3 It is often necessary to allow for more than one category, type or grade of a product within the same standard (or in separate standards, if necessary). Designers, users and consumers often need such variants for specific purposes or for economic reasons. Standards should therefore be written in such a way that these needs can be met.

It is important that variants are clearly defined and that identification of those which have been subject to conformity assessment can be made, either as a part of the marking, or on a label accompanying the product.

5.4 The standard should specify the sequence of tests when the sequence can influence the results.

5.5 Where the testing of a number of specimens is required to determine compliance with specific clauses in the standard, the number of required specimens should be given.

NOTE 2 It is recommended that the standard also include a statement about additional specimens which may be needed to reduce the time for completion of all tests.

6 Specification of test methods

6.1 Test methods should be clearly identified and be consistent with the purpose of the standard. They should be objective, concise and accurate, and produce unambiguous, repeatable and reproducible results, so that results of tests made under defined conditions are comparable.

NOTE 3 It is recommended that the description of test methods incorporate a statement as to their accuracy, reproducibility and repeatability.

6.2 To the extent practicable and consistent with their objective, the tests should provide results within a reasonable period of time and at a reasonable cost.

6.3 Non-destructive test methods should be chosen, whenever they can replace, within the same level of confidence, destructive test methods.

6.4 When choosing test methods, account should be taken of standards for general test methods and of related tests for similar characteristics in other standards. As regards the description of test methods, it is recommended that reference be made to other relevant standards, rather than quote the test methods in full in each standard.

6.5 Where test equipment is only available from one source or is not commercially available and has to be individually manufactured, the standard should include such specifications for the equipment as to ensure that comparable testing can be conducted by all involved parties.

1) IECQ is the IEC Quality assessment system for electronic components.

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Annex A

Bibliography

ISO/IEC Guide 51:1990, *Guidelines for the inclusion of safety aspects in standards.*

ISO/IEC *Compendium of conformity assessment documents,* 1991.

ISO 9000 Compendium, 2nd edition, 1992.

ISO/IEC book *Certification and related activities,* 1992.

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