QUALITY COUNCIL OF INDIA

ACCREDITATION CRITERIA

FOR

STANDARDS DEVELOPMENT ORGANIZATIONS

Effective from 1 June 2008
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0. Foreword

0.1 The Government of India and the Indian Industry came together to establish an accreditation system in response to the need of the industry and the certification bodies of Management Systems (QMS, EMS, and other Management Systems) which were largely dependent on the accreditation systems of Europe and US.

0.2 A council with representation from the Government, Industry, Certification Bodies, Non government organizations (NGOs), Bureau of Indian Standards, etc was formed as Quality Council of India (QCI). The Council was entrusted the task of establishing the accreditation system in India.

0.3 QCI has already initiated and is operating schemes for accreditation in the areas of Conformity Assessment through the National Accreditation Board for Certification Bodies (NABCB) which includes Management Systems certification such as QMS, EMS, and FSMS, Product certification and Inspection Bodies ), Hospitals and Healthcare through the National Accreditation Board for Hospitals and Healthcare Providers (NABH), and Schools through the National Accreditation Board for Education and Training (NABET). At the request of the Petroleum and Natural Gas Regulatory Board (PNGRB), a new regulator set up by the Govt. of India for the Oil & Gas sector, QCI is now launching a scheme for accreditation of Standards Development Organizations (SDOs) to support PNGRB in establishing a regulatory framework.

1. Introduction

1.1 Standards play an important role in facilitating trade and commerce within and between all countries of the world. They advance the national economy, benefit the health, safety and welfare of the public, and assist and protect consumers. These standards are developed by many bodies, at the sub-national, national, regional and international levels, usually by consensus processes. Alongside the growth of international trade and technological cooperation, standards development organizations have developed procedures and modes of cooperation which are commonly considered to constitute good practices for standards development at all levels. These practices are set out here in the form of a code applicable to governmental and non-governmental consensus bodies.

1.2 The accreditation of standards development organizations includes their activities leading to publication of standards well as other documents prepared using the consensus process, which may be used and accepted by those concerned on a national or regional basis.

1.3 This document has been prepared in consultation with a number of stakeholders having a broad cross-section of interest in standards, including
representatives of government, standards development organizations, conformity assessment bodies, non government organizations. Quality Council of India recognizes the need to move towards internationally accepted methods of accrediting standards development organizations.

1.4 This document is based on

a. WTO Agreement on Technical Barriers to Trade (TBT Agreement) Annex 3 "Code of good practice for the preparation, adoption and application of standards".
d. Accreditation of Standards Development Organizations CAN-P-1E, December 2006, Standards Council of Canada

1.5 Adoption of this document by SDOs is voluntary and is intended to ensure openness and transparency, together with an optimum degree of order, coherence and effectiveness in the standardization processes.

1.6 This document provides the basis for accreditation of standards developing organizations operating in India by the QCI. This document is intended for use by any SDO, whether governmental or non governmental, seeking accreditation from QCI.

1.7 Provisions which are of a binding nature are given in the form of requirements, using the modal auxiliary "shall".

2 Definitions

For the purposes of this document, the definitions as given below shall apply besides those given in ISO/IEC Guide 2:1991:

2.1 Consensus

General agreement, characterized by the absence of sustained opposition to substantial issues by any important part of the concerned interests and by a process seeking to take into account the views of all parties concerned and to reconcile any conflicting arguments.

NOTE - Consensus need not imply unanimity

2.2 Standard

Document, approved by a recognized body, that provides, for common and repeated use, rules, guidelines, or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.
NOTE - Standards should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits.

2.3 Standardization

Activity of establishing, with regard to actual or potential problems, provisions for common and repeated use, aimed at the achievement of the optimum degree of order in a given context.

NOTE 1 - In particular, the activity consists of the processes of formulating, issuing and implementing standards.

NOTE 2 - Important benefits of standardization are improvement of the suitability of products, processes and services for their intended purposes, prevention of barriers to trade and facilitation of technological cooperation.

2.4 National standardization

Standardization that takes place at the level of one specific country

NOTE - Within a country or a territorial division of a country, standardization may also take place on a branch or sectoral basis (e.g. ministries), at local levels, at association and company levels in industry and in individual factories, workshops and offices.

2.5 National standard

Standard that is adopted by a national standards body and made available to the public

3. General Requirements

3.1 The standards development organization shall be a legal entity in India.

3.2 The standards development organization shall be so constituted as to provide a reasonable assurance of continuity of operation in the production and maintenance of standards.

3.3 The standards development organization shall be national in character, with standards interests of relevance of concern on a broad geographical basis. The standards development organization shall identify the characteristics or procedures which demonstrate that it is national in character and that its area of standards interests has relevance to a broad geographic area of India.

3.4 The standards development organization shall identify the manner in which national interests are reflected in arriving at decisions throughout the stages in the evolution of a standard, ranging from the decision to prepare the standard to the decision for its approval and promulgation.
3.5 The SDO shall afford sympathetic consideration to, and adequate opportunity for, consultation regarding representations made with respect to compliance to this document by other SDOs who have accepted this document.

3.6 SDOs shall use the International Classification for Standards (ICS).

Note - The International Classification for Standards (ICS) provides, through the use of numeric codes, the facility for language-independent communication between standards users and developers throughout the world. The ICS also provides a model structure for standards catalogues and standing order systems. The ICS will also be useful as the basis for a more structured system of accessing information on standards development activities. Many ISO members have already committed themselves to implement the ICS at the national level, and it is anticipated that others will follow.

4 Documentation Requirements

4.1 The SDO shall have written procedures to govern the methods used for development, review, publication and distribution of standards. These procedures shall be generally be based on the consensus principle. Copies of the procedures of the SDO shall be available to interested parties in a reasonable and timely manner upon request.

4.1.1 Written procedures employed in establishing the standards shall be designed as to afford all interested parties the opportunity to communicate their view through a committee structure and shall cover various stages of establishment of standards as prescribed in Clause 7.

4.2 Such written procedures shall contain an identifiable, realistic and readily available mechanism for the impartial handling of any substantive and procedural complaints and appeals.

4.3 At the inception of the standard development process, public notification shall be given in a suitable media for new, current and completed standards development activities. Status changes shall also be reported on as appropriate.

4.4 At least once every six months, the SDO shall publish a Work Programme containing its name and address, the standards it is currently preparing and the standards it has adopted in the preceding period. A standard is under preparation from the moment a decision has been taken to develop a standard until that standard has been adopted. A notice of the existence of the Work Programme shall be publicly available. On the request of any interested party, the SDO shall promptly provide or arrange to provide a copy of its most recent Work Programme.

5. Structural Requirements

5.1 The standards development organization shall provide assurance, by a copy of its
organizational structure or its established procedures that concerned interests directly or materially affected are afforded the opportunity for equal access and effective participation in the development of standards in those areas in which the standards development organization intends to develop standards. National interest shall be considered at all stages of development of the standards.

5.2 The standards development organization, if involved in certification, quality system registration or similar activities shall demonstrate a clear separation of the managing and policymaking functions of such activities from those of standards preparation. If applicable, the standards development organization shall demonstrate compliance by reference to policy, organizational or procedural documents.

6. Resource Requirements

6.1 The standards development organization shall have staff knowledgeable about standardization, including related matters of philosophy, policies and techniques together with appropriate facilities for the development of standards. The standards development organization shall:

a) Identify the number of staff members directly involved in the preparation of standards and the functions they perform within the organization;

b) Provide a biography of the senior members of the staff involved in the preparation of standards;

c) Describe the physical resources for the development and maintenance of standards.

6.2 The standards development organization shall have the ability to provide adequate secretariat support. The standards development organization shall describe current or proposed capability for providing secretariat support, identifying administrative and technical expertise.

7. Process Requirements

7.1 The standards development organization shall have well-defined procedures for preparation, review, publication and distribution of standards including user notification procedures when a standard is withdrawn, abandoned, or significantly altered. This procedure shall identify at least one level of review and approval beyond the technical development level.

7.2 Technical Committees

7.2.1 The SDO shall constitute a committee of experts to oversee the standards development work, howsoever named.
7.2.2 For the purpose of formulation of standards within any technical area, technical committees of experts may be constituted which may include Subcommittees and Panels and ad hoc expert groups, howsoever named. The formally constituted committees shall be reconstituted once every three years while the ad hoc groups may have tenure as decided by the committees that set them up.

7.2.3 The Committees shall have defined scopes of work.

7.2.4 The Committees shall have a chairman and a member secretary besides members representing all interested parties. It shall be ensured that balance of interest is maintained and no single interest predominates. The Committees may co-opt experts to assist them in their work.

7.2.5 The standards development organization shall ensure that membership on voluntary standards preparation committees will be open to all concerned interests, subject to maintenance of a reasonable balance and size of committee and shall identify the organization's procedures which support this criterion.

7.2.6 The standards development organization shall be prepared, and shall confirm willingness to make provision for public examination of committee membership rosters on request.

7.3 Procedure for Establishment of Standards

7.3.1 Any interested party may submit proposals for establishing a standard or for revising, amending, or cancelling an established standard by making such request in writing.

7.3.2 Proposals for the development of new or revised standards, when submitted according to appropriate procedures by any materially and directly interested person or organization, wherever located, shall be given prompt consideration.

7.3.3 The work of formulation of standards on any specific subject shall be undertaken when the technical committee concerned is satisfied as a result of its own deliberations or on investigation and consultation with concerned interests that the necessity for standardization has been established.

7.3.4 When request for establishing a standard for any specific subject has not been accepted after its due consideration, the proposer shall be informed of the decision.

7.3.5 A draft standard prepared and duly approved by a Committee shall be issued in draft form and publicly circulated for a period of not less than two months amongst the various interests concerned for critical review and suggestions for improvement both outside as well as within India. The public comment period may be reduced or waived if so decided by the Committee where the matter is urgent or non-controversial and in cases where urgent problems of safety, health or environment arise or threaten to arise.

7.3.6 No later than at the start of the comment period, the SDO shall publish a notice announcing the period for commenting in the publication referred to in clause 4.3. Such notification shall include, as far as practicable, whether the draft standard deviates from relevant international standards, if available.
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7.3.7 On the request of any interested party within or outside of India, the SDO shall promptly provide, or arrange to provide, a copy of a draft standard which it has submitted for comments.

7.3.8 The appropriate Committee shall thereafter finalize the draft standard giving due consideration to the comments that may be received. Comments received shall, if so requested, be replied to as promptly as possible. The reply shall include an explanation why a deviation from relevant international standards, if in existence, is necessary.

7.3.9 The draft standard after it has been approved by the Committee may be submitted to a designated person or committee for adoption.

7.3.10 Formal approval of standards shall generally be based on evidence of consensus. In exceptional cases, when consensus is not the basis, reasons for the same shall be recorded.

7.3.11 All approved standards shall be published promptly. Copies shall be made available under reasonable terms and conditions to any person, wherever located.

7.3.12 All established standards shall be reviewed periodically, at least once in five years, to determine the need for revision or withdrawal. Standards which in the opinion of the Technical Committee need no revision or amendment shall be reaffirmed by the Committee.

7.3.13 Proposals for revising or amending published standards shall be considered by the appropriate Committee in a manner similar to proposals for new standards.

7.3.14 Proper records of standards development activity shall be prepared and maintained.

8. Advancement of Trade

8.1 Standards should be developed to meet the needs of the market-place and should contribute to advancing free trade in the broadest possible geographic and economic contexts. The SDO shall ensure that standards are not prepared, adopted or applied with a view to, or with the effect of, creating unnecessary obstacles to international or inter-provincial trade, or both.

8.2 It is not possible for persons developing standards to predict all possible outcomes, including the possibility that a standard inadvertently results in the impedance or inhibition of trade. It is possible, and it is required of persons participating in the process of SDOs, to develop standards with the intent to not inhibit or impede trade.

8.3 The SDOs shall take action to resolve an unjustified impediment or inhibition to trade.

8.4 Standards shall not be developed as a means to fix prices, nor to exclude competition or other wise inhibit commerce beyond that necessary to meet requirements of relevant technical regulations or other legitimate sectoral or local requirements for compatibility, environmental protection, health and safety.
8.5 When international standards exist or their completion is imminent, they, or their relevant parts, should be used as the basis for corresponding standards, except where such international standards or relevant parts would be ineffective or inappropriate. This includes for instance, an insufficient level of protection, fundamental climatic, geographical factors or fundamental technological problems.

8.6 Standards should not be developed so as to allow them to be used to mislead consumers and other users of a product, process or service addressed by the standard. SDOs shall take action to resolve identified instances of standards being used to mislead.

8.7 Standards shall neither be developed nor adopted so as to discriminate among products on the basis of the place of origin. SDOs shall take action to resolve identified instances of unjustified discrimination, and remove the potential for future instances.

8.8 Whenever possible, in order to leave maximum freedom for technical development, the requirements of standards shall be expressed in terms of performance rather than design or descriptive characteristics.

8.9 Administrative requirements relating to conformity assessment, marks of conformity or other, non-technical issues should be presented separately from technical and/or performance requirements.

8.10 Standards should not be drafted in terms that include the use of a patented item unless the use of such an item is justifiable for technical reasons and the rights holder agrees to negotiate licenses with interested applicants, wherever located, on reasonable terms and conditions.

9. Participation in the Standards Development Process

9.1 Participation in standardization processes at all levels shall be accessible to materially and directly interested persons and organizations within a coherent process as described in this clause.

9.2 With a view to harmonizing standards on as wide a basis as possible, the SDO shall, in an appropriate way, give priority to playing a full part, within the limits of its resources, in the preparation, by relevant international standardizing bodies, of international standards regarding subject matter for which it either has developed or adopted, or expects to develop or adopt standards.

10. Coordination and Information
10.1 An SDO shall make every effort to avoid duplication of, or overlap with the work of other SDOs in India or with the work of relevant international or regional standardizing bodies. They shall also make every effort to achieve a national consensus on the standards they develop.

11. Complaints

11.1 Complaints concerning the contents of a standard (proposed, draft, or published) shall be handled by:

a) The established committee structure, when it exists in a viable form; or
b) An ad-hoc group of experts convened by the top management of SDO.

11.1.1 At the time of making a complaint, the complainant shall be provided with a copy of the particular SDO’s procedures for the development of standards.

11.1.2 The time to respond to a complaint shall not exceed 60 calendar days for any step.

11.1.3 Any decision on a technical matter may be appealed against to the next higher committee level.

11.2 Complaints concerning the procedures used to prepare a standard (proposed, draft, or published) shall be made to an officer of the SDO involved with the administration of the SDO’s highest committee.

11.2.1 At the time of making a complaint, the complainant shall be provided with a copy of the particular SDO’s procedures for the development of standards.

11.2.2 The officer of the SDO shall attempt to resolve the complaint within 15 calendar days through discussions with concerned parties.

11.2.3 Failing resolution as above, the SDO shall render a written decision within a further 15 calendar days.

11.2.4 This decision may be appealed against to the SDO’s highest standards governance body within one month.

11.2.5 The SDO shall provide a final written decision within 60 days of the appeal.

11.3 The SDO shall apprise the complainants of any further avenues of appeal.

11.4 The SDO shall keep records of all complaints received as well as their handling, and disposition.

12. Records
12.1 The standards development organization shall maintain adequate records of committee meetings and other relevant deliberations, decisions and actions to permit inspection by identified stakeholders like the regulator, accreditation body etc. as well as for reference use by officers, staff and members.

12.2 The standards developing organization shall identify the type of information related to developing a standard which is retained in its records and indicate the length of time data is normally kept standard.