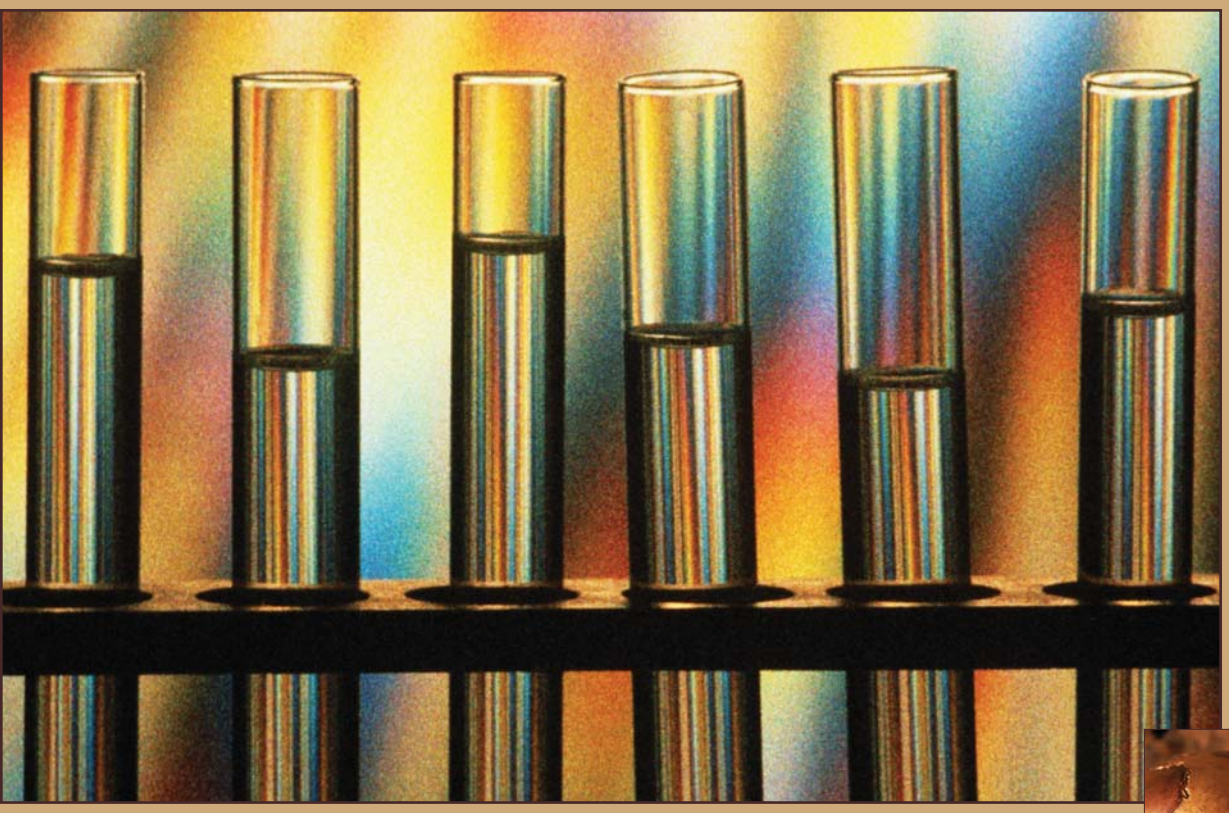
National Conformity Assessment Principles
for the United States



Conformity assessment activities form a vital link between standards and products, services, processes, systems, personnel qualifications and organizations.

I Purpose

The *National Conformity Assessment Principles for the United States* (second edition) articulates the principles for U.S. conformity assessment activities that will allow consumers, buyers, sellers, regulators and other interested parties to have confidence in the processes of providing conformity assessment, while avoiding the creation of unnecessary barriers to trade.

These principles are based on the conformity assessment language in the Agreement on Technical Barriers to Trade, one of the agreements within the World Trade Organization (WTO).[1] These principles supplement the language of the agreement to give additional clarity and focus to conformity assessment in the United States.

The concise and clear presentation of these principles is intended to promote national and international understanding and recognition of competently conducted conformity assessment processes resulting in increased acceptance of U.S. products[2] within national and international markets. Global acceptance is vital to the continued economic health of the United States, as well as to the protection of human health, safety and the environment.

Because standards underlie all conformity assessment activities, this document is intended to be a companion to the principles of the U.S. standards system as described in the *United States Standards Strategy*. These two documents should be considered together in the evaluation of standards and conformity assessment activities and related issues.

1. Also referred to as the Final Act of the 1986-1994 Uruguay Round of trade negotiations.

2. For purposes of this document, the term "product" includes products, services, processes, systems, personnel qualifications and organizations.

II Conformity assessment

ISO/IEC 17000:2004, *Conformity assessment—Vocabulary and general principles*, defines conformity assessment as "demonstration that specified requirements relating to a product, process, system, person or body are fulfilled."

Conformity assessment includes sampling and testing, inspection, supplier's declaration of conformity, certification, and management system assessment and registration. It also includes accreditation of the competence of those activities by a third party and recognition (usually by a government agency) of an accreditation program's capability.

While each of these activities is a distinct operation, they are closely interrelated. The choice of the most appropriate assessment processes, as well as the quality with which any one of them is performed, can have a significant effect on the confidence in and reliance that can be placed on the results of the entire conformity assessment.

The evolution of the global marketplace has made buyers and regulators increasingly dependent not only on standards but also on the methods used to ensure that products comply with the requirements of those standards. Conformity assessment activities therefore form a vital link between standards (which define the necessary characteristics or requirements) and the products themselves. Conformity assessment can verify that a particular product meets a given level of quality or safety. It can provide explicit or implicit information about the product's characteristics, the consistency of those characteristics and/or the performance of the product. Conformity assessment can also increase a buyer's confidence in a product, furnish useful information to a buyer and help to substantiate advertising and labeling claims. Information on conformance (or nonconformance) to a particular standard can provide an efficient method of conveying information needed by regulators or buyers on the product's safety and suitability.

Because conformity assessment forms a vital link between standards that define product characteristics or requirements and the products themselves, stakeholders in conformity assessment must better understand these conformity assessment principles to use and benefit from conformity assessment effectively. As the global marketplace continues to evolve, buyers, regulators and suppliers will depend increasingly on standards and conformity assessment to assure that products fulfill specified requirements. Understanding these conformity assessment principles will aid stakeholders in their decision-making with regard to conformity assessment usage. In addition, such understanding will encourage stakeholders in conformity assessment to work towards harmonization of requirements and the global acceptance of all competently performed conformity assessments.

III Applicability of principles

The principles in this document may be beneficial to first, second or third parties, or to government users of conformity assessment. The principles can be applied to any of the different types of conformity assessment activities (accreditation, certification, inspection, registration, supplier's declaration of conformity, and testing). There is no one-size-fits-all solution. Industry, government, consumers and other users rely on the results of the conformity assessment to meet the needs of suppliers and acceptance authorities in a cost-effective manner. Consideration should be given to approaches that facilitate trade, provide regulatory confidence and protect public safety.

IV Definitions

The definitions in this document are based on ISO/IEC 17000:2004, *Conformity assessment — Vocabulary and general principles*. Some variances, noted in italics, occur where the term is not in ISO/IEC 17000 or has another specific meaning in the United States. Definitions are included in this document to preclude confusion and to make it more understandable. In different contexts, the same term can signify different types of activities.

- **Accreditation**
  Third party attestation related to a conformity assessment body conveying a formal demonstration of its competence to carry out specific conformity assessment tasks. (*These tasks include sampling and testing, inspection, certification and registration.*)

- **Certification**
  Third party attestation related to products, processes, or persons *that conveys assurance that specified requirements have been demonstrated.*

- **Conformity Assessment**
  Demonstration that specified requirements relating to a product, process, system, person or body are fulfilled. (*This may include any activity concerned with determining directly or indirectly that relevant requirements are fulfilled.*)

- **First, Second and Third Party**
  The first party is generally the person or organization that provides the object, such as the supplier. The second party is usually a person or organization that has a user interest in the product, such as the customer. The third party is a person or body that is recognized as being independent of the person or organization that provides the object, as well as the user or customer of the object.

- **Inspection**
  Examination of a product design, product, process or installation and determination of its conformity with specific requirements or, on the basis of professional judgement, with general requirements.

- **Recognition**
  Procedure used to provide formal notice that an accreditation body is competent to carry out specific tasks. These tasks include accreditation of testing laboratories and inspection, certification and registration bodies. A governmental recognition system is a set of one or more procedures used by a Federal agency to provide recognition.

- **Registration**
  Third party attestation related to systems that convey assurance that specified requirements have been demonstrated. Such systems include those established for the management of product, process or service quality and environmental performance.

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IV Definitions (continued)

- **Sampling**
  Provision of a sample of the object of conformity assessment according to a procedure.

- **Supplier's Declaration**
  Procedure by which a first party or supplier conveys assurance that the object of conformity fulfills specified requirements.

- **Test**
  Technical operation that consists of the determination of one or more characteristics of a given product, material, equipment, organism, person's qualification, physical phenomenon, process or service according to a specified technical procedure (test method).

- **Testing**
  Determination of one or more characteristics of an object of conformity according to a *specified technical* procedure (*test method*). *Action of carrying out one or more tests.*

- **Test Method**
  Specified technical procedure for performing a test.

V Conformity assessment principles

1. Conformity assessment requirements and procedures do not create unnecessary obstacles to national/international trade.[3]

2. Conformity assessment requirements and procedures are open and transparent to all applicants and provide them with equal treatment.

   All parties desiring to have their products, processes, services or personnel assessed for compliance with relevant requirements are allowed to make application to any conformity assessment body and have their applications accepted and processed in a reasonable time period.

3. Conformity assessments are competently conducted and based on appropriate standards requirements and procedures. Conformity assessment requirements and procedures are based on international guides and standards to the extent feasible.

   Organizations are encouraged to demonstrate their competency to conduct conformity assessment activities using accepted standards and requirements for conformity assessment, either through formal recognition or accreditation activities or by maintaining adequate records and documentation that are available for public review.

4. The characteristics of a sector and the associated risks of the product drive the conformity assessment requirements and procedures.

5. Information on all conformity assessment requirements and procedures for obtaining conformity assessments are publicly available. Information on costs and processing times are available at any time to all applicants.

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3. "Unnecessary obstacles to trade," as used in this Principle, is understood to be within the context of the use and meaning of the WTO TBT Agreement. Information on a product's conformance to a particular standard can provide an efficient method of conveying information needed by regulators, customers, or society on the product's safety and suitability. Efficient, competently conducted, market-relevant conformity assessment programs can often satisfy both regulatory and market confidence needs with a single assessment to common or multiple requirements. Such programs can facilitate simultaneous global introduction of products. National Treatment of Conformity Assessment Bodies (each country shall accord to the bodies of other countries treatment no less favorable than that it accords to its own bodies) is one of the most effective means of facilitating these kinds of programs.

V Conformity assessment principles (continued)

6. Conformity assessment procedures are completed promptly and efficiently. Accurate and timely information on the status of ongoing conformity assessments is provided to applicants on request.[4]

7. Information requirements are limited to what is necessary to assess conformity and determine fees. Protective measures are taken so that confidential or proprietary information is not communicated to any person or organization not having legal right to such information.[5]

8. All applicants who apply for conformity assessment are treated equally with respect to the imposition of any fees charged. When fees are imposed, they are comparable for all applicants, taking into account communication, transportation and other costs arising from differences between location of facilities of the applicants and the conformity assessment bodies. Fees are not imposed in a manner that restricts marketplace competition or creates unnecessary obstacles to trade.

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4. Unnecessary delays in the performance of conformity assessment activities or the failure to keep applicants apprised of the status of ongoing conformity assessment work can impede product entry into the marketplace. Such delays can cause economic injury to the affected companies, restrict marketplace competition and create unnecessary and unacceptable barriers to trade.

Failure to provide timely information on programmatic changes in a conformity assessment scheme can cause significant economic injury to stakeholders. Inadequate transition periods can also restrict marketplace competition and create barriers to trade. Conformity assessment bodies should allow applicants adequate time to make any necessary changes whenever possible. However, in establishing the transition period, conformity assessment bodies need to take into account any significant risks to health, safety or the environment associated with noncompliance of the product to the new requirements.

Where relevant, any certification mark, number or other identification that will be required on the product's label or on the product's manual/accompanying documentation/packaging/carton should be provided to the applicant at the time of application rather than after completion of the assessment. Approval for its use on the product will of course be dependent on the applicant's successful fulfillment of all conformity assessment requirements. If the certification mark, number or other identification is only provided after completion of the assessment, the applicant cannot begin to prepare for product distribution. This will delay time-to-market for the product. If, on the other hand, the mark, number or other identification is provided up-front, the applicant can proceed with preparation for distribution if the applicant is willing to assume the risks associated with cancellation of packaging in the event that the product fails the assessment.

5. All companies and personnel have the right to have any proprietary information that they provide to conformity assessment bodies protected. Conformity assessment bodies should restrict access to such information to persons or organizations that have a legal right to such records. Protective measures should be taken so that such information is not provided or accidentally released to any person or organization (not having legal right to such information) thereby decreasing the value of the information to the company. Failure by conformity assessment bodies to adequately protect such information can cause serious and unacceptable economic injury to the affected companies.

9. The location, timing and sample selection process for the conformity assessment work are chosen in a manner that enables competent conformity assessment and minimizes inconvenience and costs to applicants.

10. When requirements and procedures change, stakeholders are notified expeditiously. Transition periods allow applicants adequate time to make necessary changes. However, the transition period takes into account any significant risks to health, safety or the environment associated with noncompliance of the product to the new requirements.

11. Organizations conducting conformity assessment have effective procedures for reviewing complaints, and such procedures are open to all stakeholders. Organizations take appropriate corrective action whenever they justify a complaint.

12. As appropriate, conformity assessment bodies undertake reasonable surveillance procedures to ensure continued product conformity and protection of their mark.

13. Bilateral or multilateral agreements (MLAs) among conformity assessment bodies or their accreditors should:

(a) be sound, credible, open and transparent;
(b) provide confidence in the competence and comparability of the conformity assessment results;
(c) provide significant marketplace benefits;
(d) be developed only where standards, test methods, and other conformity assessment processes are essentially equivalent;
(e) be supported by rigorous processes that ensure the equivalency of conformity assessment bodies and effectively address issues of potential marketplace misunderstanding and/or deception;
(f) include a process that ensures the continued competency of all bilateral or MLA participants;
(g) encourage the development of metrics that document the agreement's benefits; and
(h) incorporate the use of the least burdensome, time consuming, and costly form of conformity assessment that is recognized and accepted as meeting the needs of all stakeholders.

VI Suggested reading

The World Trade Organization (WTO) Agreements

(also known as)

Final Act of the 1986-1994 Uruguay Round of trade negotiations

AGREEMENT ON TECHNICAL BARRIERS TO TRADE
Article 5: Procedures for Assessment of Conformity by Central Government Bodies
Article 6: Recognition of Conformity Assessment by Central Government Bodies
Article 7: Procedures for Assessment of Conformity by Local Government Bodies
Article 8: Procedures for Assessment of Conformity by Non-Governmental Bodies
Article 9: International and Regional Systems

Breitenberg, Maureen A., The ABC's of the U.S. Conformity Assessment System, U.S. Department of Commerce, Technology Administration, National Institute of Standards and Technology (NIST), April 1997.

ISO/IEC 17000, *Conformity assessment — Vocabulary and general principles*, International Organization for Standardization, Switzerland, 2004.

American National Standards Institute

The American National Standards Institute (ANSI) is a private non-profit organization that administers and coordinates U.S. voluntary standardization and conformity assessment activities. Its mission is to enhance U.S. global competitiveness and the American quality of life by promoting, facilitating and safeguarding the integrity of the voluntary standardization system.

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