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**NATIONAL  
CONFORMITY ASSESSMENT  
PRINCIPLES  
FOR THE  
UNITED STATES**

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

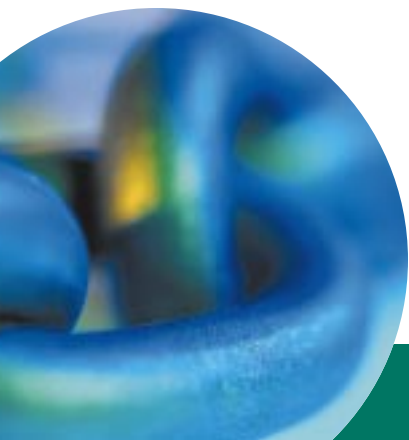




## **AMERICAN NATIONAL STANDARDS INSTITUTE**

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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.





## PURPOSE

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The “*National Conformity Assessment Principles for the United States*” 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.

We base these principles on the conformity assessment language in the Agreement on Technical Barriers To Trade, one of the agreements within the World Trade Organization (WTO).<sup>1</sup> These principles supplement the language of the agreement to give additional clarity and focus to conformity assessment in the United States.

We intend the concise and clear presentation of these principles for the United States to promote national and international understanding and recognition of competently conducted U.S. conformity assessment processes resulting in increased acceptance of U.S. products<sup>2</sup> within national and international markets. National and international 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 “*National Standards Strategy for the United States*.” These two sets of principles should be considered together in the evaluation of standards and conformity assessment activities and related issues.

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

<sup>2</sup> For purposes of this document, the term “product” includes products, services, processes, systems, personnel qualifications and organizations.



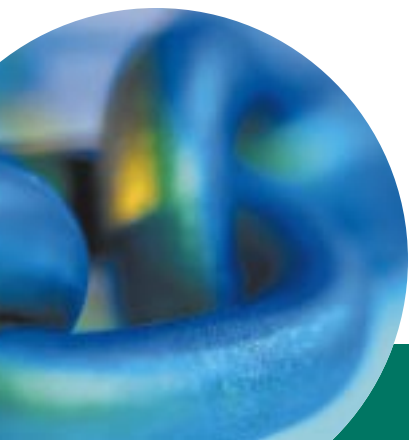
## CONFORMITY ASSESSMENT

ISO/IEC Guide 2: 1996, *Standardization and related activities — General vocabulary*, defines Conformity Assessment as “any activity concerned with determining directly or indirectly that relevant requirements 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 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 and can provide explicit or implicit information about its 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 regarding 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.





## APPLICABILITY OF PRINCIPLES

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The principles in this document may be beneficial to either first, second or third parties or to government users of conformity assessment, as well as 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 supplier and acceptance authorities in a cost-effective manner. Consideration should be given to approaches that facilitate trade, provide regulatory confidence and protect public safety.

The definitions in this document are based on ISO/IEC Guide 2: 1996.<sup>3</sup> Some variances, noted in italics, occur where the term is not in Guide 2 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 mean very different types of activities.

**Accreditation** Procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks. (*These tasks include sampling and testing, inspection, certification and registration.*)

**Certification** Procedure by which a third party gives written assurance that a product, process, service or person conforms to specified requirements.

**Conformity Assessment** Any activity concerned with determining directly or indirectly that relevant requirements are fulfilled.

**First, Second and Third Party** The first party is usually the supplier. The second party is usually the customer. The third party is that person or body that is recognized as being independent of the parties involved, as concerns the issue in question.

**Inspection** Conformity evaluation by observation and judgment accompanied as appropriate by measurement, testing or gauging.

**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** *Procedure used to give written assurance that a system conforms to specified requirements. Such systems include those established for the management of product, process or service quality and environmental performance.*

**Sampling** *The selection of one or more specimens of a product, process or service for the purpose of evaluating the conformity of the product, process or service to specified requirements.*

**Supplier's Declaration** Procedure by which a supplier gives written assurance that a product, process or service conforms to 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** Action of carrying out one or more tests.

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

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<sup>3</sup> ISO/IEC Guide 2, *Standardization and related activities — General vocabulary*. Conformity Assessment terms in this Guide are subject to revision in the forthcoming draft standard ISO/IEC 17000, *Conformity assessment — General vocabulary and functional approach*.



## CONFORMITY ASSESSMENT PRINCIPLES

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1. Conformity Assessment requirements and procedures do not create unnecessary obstacles to national/international trade.<sup>4</sup>
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.

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 conducting conformity assessment 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.

*(continued)*

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<sup>4</sup> “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 introduction of products globally. 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.

## PRINCIPLES (CONTINUED)

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6. Conformity assessment procedures are completed promptly and efficiently. Accurate and timely information on the status of ongoing conformity assessments are provided to applicants on request.<sup>5</sup>
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.<sup>6</sup>
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.<sup>7</sup>

*(continued)*

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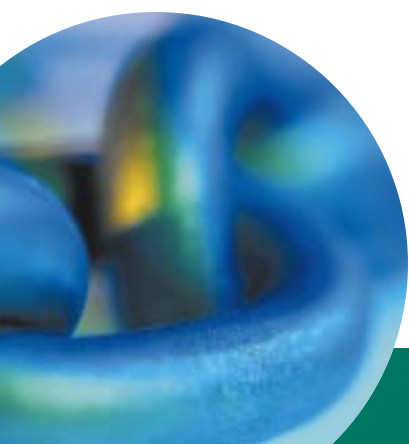
<sup>5</sup> Unnecessary delays in the performance of conformity assessment activities or the failure to keep applicants apprised of the status of ongoing conformity assessment work can impede product entry into the marketplace. As a result, such delays can cause economic injury to the affected companies, 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.

<sup>6</sup> 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.

<sup>7</sup> "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.





## PRINCIPLES (CONTINUED)

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**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.

## SUGGESTED READING

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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; and

Article 9: International and Regional Systems)

Breitenberg, Maureen A., The ABC's of the U.S. Conformity Assessment System,

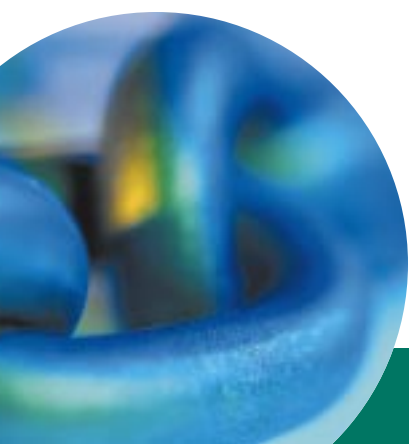
U.S. Department of Commerce, Technology Administration, National Institute of

Standards and Technology (NIST), April 1997

ISO/IEC Guide 2, International Organization for Standardization, Switzerland, 1996

ISO/IEC Compendium Conformity Assessment Guides and Standards, 4th Edition,

International Organization for Standardization, Switzerland, 1999



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