



# UNITED STATES CONFORMITY ASSESSMENT PRINCIPLES

4<sup>TH</sup> EDITION

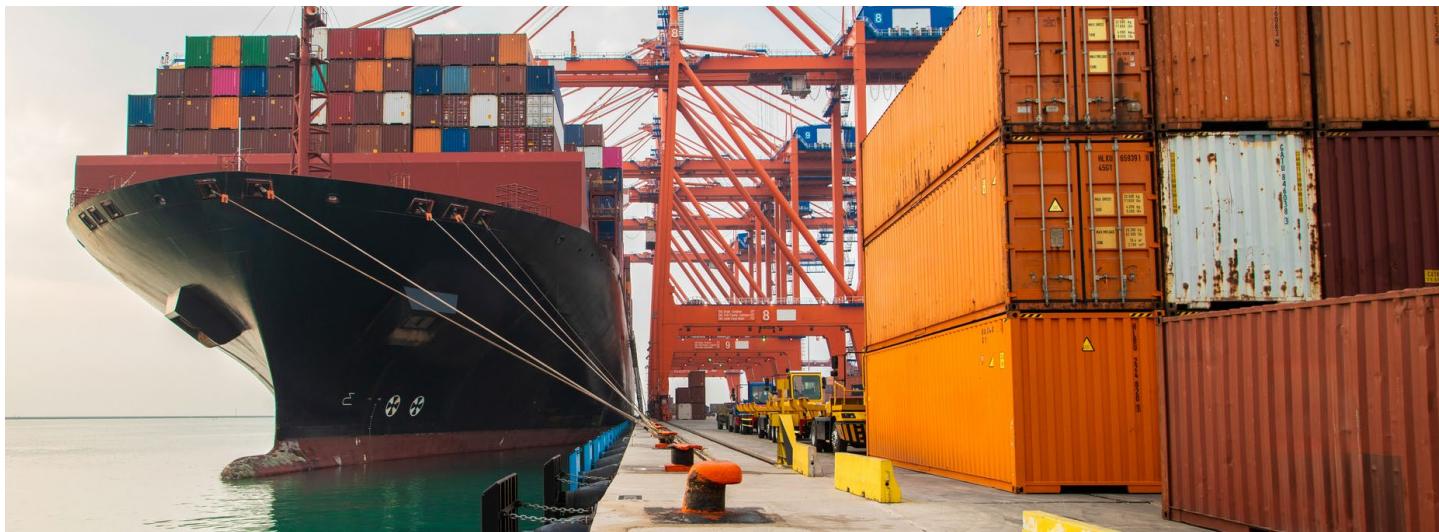
# PURPOSE

The *United States Conformity Assessment Principles* document (fourth edition) articulates the principles for U.S. conformity assessment activities that allow consumers, buyers, sellers, regulators, and other interested parties to have confidence, or be assured, that the benefits expected from fulfillment of requirements will be realized while avoiding unnecessary costs and burdens, including barriers to trade.

These principles are based on the conformity assessment terminology in ISO/IEC 17000:2020 and are consistent with the World Trade Organization (WTO) Agreement on Technical Barriers to Trade.<sup>1</sup> These principles 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 and services 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 health, safety, and the environment.

Standards are often the primary technical requirements used in 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.



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<sup>1</sup> See [https://www.wto.org/english/tratop\\_e/tbt\\_e/tbt\\_e.htm](https://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm)

# CONFORMITY ASSESSMENT

ISO/IEC 17000:2020, *Conformity assessment—Vocabulary and general principles*, defines conformity assessment as “demonstration that specified requirements are fulfilled.”

Conformity assessment can demonstrate that requirements for a given level of quality or safety are fulfilled. For example, it can provide confidence in or assurance of a product's<sup>2</sup> characteristics, the consistency of those characteristics, the performance of the product, and help to substantiate advertising and labeling claims.

Conformity assessment includes activities such as sampling and testing; inspection; supplier's declaration of conformity; auditing; certification; and validation and verification; among others. It also includes demonstrations that the bodies performing conformity assessment activities fulfill requirements for competence, consistency, and impartiality. These demonstrations include activities such as self-assessment, peer assessment, and accreditation.

The individual activities within a demonstration are distinct operations and are closely interrelated. The choice of the most appropriate activities, as well as the competence, consistency, and impartiality with which any one of them is performed, nearly always impacts the level of assurance from, 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 assure fulfilment of the requirements of those standards. Conformity assessment activities therefore are a vital means for the demonstration of compliance to standards, as are market facing conformity assessment schemes and programs. The expanded use and participation in international conformity assessment schemes has the potential to reduce the burden on industry related to challenges of market access.

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.

The use of digital technologies and solutions is becoming more prevalent in the conformity assessment space. These tools can help improve the transparency of conformity assessment procedures and enhance

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2 Note: although the term “product” is used throughout this document, it is assumed that “product” includes both tangible and intangible products, such as digital services. In today's digital world, digital products and services such as cloud computing and artificial intelligence systems will require conformity assessment as both stand-alone “products” and as part of other systems and even components of tangible products.

supply chain integrity. For example, they may support acceptance and recognition of conformity assessment results, by providing real time access to conformity data, and facilitating post-market activities.

As the global marketplace continues to evolve, consumers, retailers, and other buyers; regulators; and other acceptance interests will depend increasingly on conformity assessment for assurance that specified requirements are fulfilled. 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.



Working from the principles upon which our system is built, the U.S. private-sector-led conformity assessment community is committed to:

## **An International Conformity Assessment Framework Where:**

- Conformity assessment schemes/programs and associated technical requirements and procedures do not create unnecessary barriers to national/international trade
- The characteristics of a sector and associated risks of the product, process, or system being evaluated drive conformity assessment schemes/programs
- Conformity assessment approaches foster openness by recognizing all conformity assessment body applicants that can fulfill requirements for qualification and recognition
- Accreditation operated according to international standards may serve to promote confidence in the competence, consistency, and impartiality of conformity assessment bodies and reinforce the acceptance of conformity assessment results.
- Arrangements between domestic and foreign conformity assessment bodies, where relevant, may also help facilitate acceptance of results
- Conformity assessment activities are competently conducted in accordance with, where possible, requirements and procedures specified in standards. Such requirements and procedures are based on international standards to the extent feasible

## **A U.S. Conformity Assessment Framework Where Conformity Assessment Programs:**

- Serve the needs of the market in an open, flexible, and efficient manner that maintains the highest technical rigor and upholds the highest level of integrity
- Operate in a competitive market environment that presents customers with a choice of qualified service providers
- Serve the needs of government agencies to enhance recognition and use of private sector conformity assessment processes for domestic and non-domestic needs
- Operate in conformance with relevant international standards, where appropriate
- Support mutual recognition programs where such recognition promotes the interests and competitiveness of U.S. industry

The definitions in this document are based on ISO/IEC 17000:2020, *Conformity assessment – Vocabulary and general principles*. Definitions are included in this document to preclude confusion and to make it more understandable. Text in italics is provided to convey additional context for specific terms. In different contexts, the same term can signify different types of activities.

### **Conformity Assessment**

Demonstration that specified requirements are fulfilled.

*Conformity assessment is a solution to a need, demand, or expectation for assurance, confidence, or trust that specified requirements are fulfilled. A particular combination of objects of conformity assessment, specified requirements, and conformity assessment activities performed by conformity assessment bodies as appropriate in accordance with established rules and procedures form conformity assessment solutions.*

### **Conformity Assessment Scheme/Conformity Assessment Program**

Set of rules and procedures that describes the object of conformity assessment, identifies the specified requirements, and provides the methodology for performing conformity assessment.

*The set of rules and procedures can be captured in a single document or collection of documents. It can be in the form of a contract, regulation, standard, or stand-alone document. A scheme/program provides consistency for conformity assessment performed in accordance with the scheme/program.*

### **Recognition**

Recognition of a Conformity Assessment Result

Acknowledgement of the validity of a conformity assessment result provided by another person or organization.

The expression “conformity assessment result” signifies the output of any conformity assessment activity (e.g., a report or certificate) and can include a finding of nonconformity.

### **Attestation**

Issue of a statement based on a decision that fulfillment of specified requirements has been demonstrated.

*An attestation is an activity taken not something that is issued. A statement issued as a result of attestation can be conveyed via a mark, certificate, letter, report, internet listing, database entry, or other.*

## **First, Second, and Third Party**

Conformity assessment activities can be characterized as “first-party,” “second-party,” or “third-party.”

See ISO/IEC 17000:2020 4.3, 4.4, and 4.5

### **Declaration**

First-party attestation.

As a *first-party activity, declaration (also known as supplier's declaration of conformity) is performed by the provider of the object of conformity.*

### **Certification**

Third-party attestation related to an object of conformity assessment.

An object of conformity is what fulfills specified requirements, is subjected to conformity assessment activities to demonstrate that fulfillment, and can be for example a product, process, service, system (including a management system), installation, project, data, design, material, claim, person, or any combination thereof. See ISO/IEC 17000:2020 4.2.

As a third-party activity, certification is performed by a person or organization who is independent of the provider of the object of conformity assessment and has no user interest in the object of conformity assessment. See ISO/IEC 17000 4.5.

### **Accreditation**

Third-party attestation related to a conformity assessment body conveying formal demonstration of its competence, impartiality, and consistent operation in performing specific conformity assessment activities.

As a *third-party activity, accreditation is performed by a person or organization who is independent of the conformity assessment body and has no user interest in the conformity assessment body's fulfillment of requirements for competence, consistency, and impartiality.*

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## SUGGESTED READING

- The WTO Agreements Series Technical Barriers to Trade
- Committee on Technical Barriers to Trade Guidelines on Conformity Assessment Procedures, Non-Prescriptive Practical Guidelines to Support Regulators in the Choice and Design of Appropriate and Proportionate Conformity Assessment Procedures
- NIST SP 2000-01: [ABCs of Conformity Assessment](#) (2018)
- NIST SP 2000-02: [Conformity Assessment Considerations for Federal Agencies](#) (2018)
- ISO/IEC 17000, *Conformity assessment – Vocabulary and general principles*, International Organization for Standardization, Switzerland, 2020.
- ISO CASCO Toolbox
- *United States Standards Strategy 2025*