NIST Special Publication 2000-01

ABC's of Conformity Assessment

Lisa Carnahan
Amy Phelps

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National Institute of
Standards and Technology
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September 2018

U.S. Department of Commerce
Wilbur L. Ross, Jr., Secretary

National Institute of Standards and Technology
Walter Copan, NIST Director and Undersecretary of Commerce for Standards and Technology

Publications in the SP 2000 subseries provide detailed descriptions of important activities and features related to the use and harmonization of standards and conformity assessment in the United States and globally. The publications include reports, guidelines, and other information resources on key concepts, activities, features, and other specific topics regarding coordination of standards and use of conformity assessment impacting both international and U.S. trade.

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Foreword

The Standards Coordination Office at NIST serves as the focal point for federal government standards and conformity assessment coordination, operates the United States Inquiry Point for the World Trade Organization's Technical Barriers to Trade Agreement, and is a key information source for United States industry on standards-related market access issues.

The Standards Coordination Office periodically publishes information related to standards and conformity assessment as a service to producers and users of such systems – both in the public and private sector.

The authors recognize the late Maureen Breitenberg, whose work and efforts led to the first edition of this document and other frequently referenced NIST standards and conformity assessment-related documents. The "ABC's of Standards Activities" and "ABC's of the U.S. Conformity Assessment System" are well-recognized in the standard-setting and conformity assessment communities as the primers for anyone entering those fields.

Abstract

This publication is designed to provide the reader with an introduction to conformity assessment and information on how the various conformity assessment activities are interlinked. It serves as background for using available conformity assessment resources. The interested reader may wish to take advantage of other available publications and services provided by the Standards Coordination Office.

Key words

Certification; conformance; conformity assessment; inspection; standards; testing.

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1. Introduction

The purpose of this publication is to provide an overview of the topic of conformity assessment to facilitate better understanding of its impact on the marketplace. The publication describes conformity assessment terminology and concepts, identifies some of the interrelationships among conformity assessment activities, and discusses possible impacts on trade.

The United States (U.S.) operates in a global marketplace where a vast array of goods and services produced in and offered by the U.S. as well as foreign countries are available for purchase. Buyers have become increasingly dependent on formal methods and procedures for ensuring that the products, services, and systems they purchase, whether domestic or foreign, consistently meet their needs. Such characteristics need to be determined and assessed to provide confidence to the buyer (or other interested party) that the product conforms to requirements and that conformance is consistent from product to product.

Conformity assessment is defined in ISO/IEC 17000[1] as the "demonstration that specified requirements relating to a product, process, system, person or body are fulfilled". While the term 'product' is frequently used within this publication, the statements apply equally to processes, services, systems, persons or bodies.

Conformity assessment procedures provide a means of assuring that the products, services, or systems produced or operated have the required characteristics, and that these characteristics are consistent from product to product, service to service, or system to system. Conformity assessment includes testing, inspection, as well as certification of products, management systems, and personnel. It also includes accreditation of the competence of the organizations performing conformity assessment activities. The collection of all activities that are repeatedly applied to a specified group of products, processes, services, systems, persons or bodies is referred to as a 'conformity assessment scheme' or 'scheme'.

While each of the conformity assessment activities are operated independently, they are closely interrelated. The inclusion or absence of any of these activities, as well as the competence, consistency and impartiality 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 process. In addition, standards, which underlie each of these activities, can also have a major impact on the outcome of each specific conformity assessment activity as well as a cumulative effect on the outcome of the entire process. Conformity assessment activities form a vital link between standards (which define necessary characteristics or requirements for products) and the products, processes, services, systems, person or bodies themselves.

Conformity assessment can assure that a particular product, service, or system meets a given level of quality or safety, and provide explicit or implicit information about its characteristics, the consistency of those characteristics, performance, and/or adherence to regulatory requirements. Conformity assessment can also increase confidence, furnish useful information, and help to substantiate a company's advertising and labeling claims. Therefore,

[1] ISO/IEC 17000 "*Conformity Assessment – vocabulary and general principles*" provides terms and definitions applicable to conformity assessment.

conformity assessment is an important marketplace communication mechanism providing a means of information exchange. It is vital for interested parties to understand the conformity assessment process to competently judge the value of a conformity assessment program and to use the information resulting from that program to make intelligent choices that can achieve the desired goals. For example, a state-of-the-art computer is of no use without compatible software. A technologically superior electrical appliance is useless if its plug does not fit the outlet or appears to fit but increases the potential for fire or electrical shock.

The quality of the conformity assessment information conveyed depends on the impartiality, consistency, and competence of the body that assesses conformity, the types of assessment activities included in the program, as well as the adequacy and appropriateness of the standards against which the object of assessment is evaluated. Improperly conducted conformity assessment activities may result in widespread dishonesty and potential negative consequences to health, safety, or the environment.

1.1. Conformity Assessment Concepts

Those who rely on conformity assessment results need to know and understand which types of conformity assessment activities are included in the conformity assessment program. Figure 1 illustrates a conceptual view of conformity assessment activities. Conformity assessment examines an object of conformity (such as a product, process, system, person, or body) and determines whether the object meets specified requirements. A decision whether fulfillment of requirements has been demonstrated is made based on evidence of conformity (such as a test report, inspection report, or audit report). An attestation that fulfillment has been demonstrated is issued based on the decision. Support for on-going validity of the attestation may be accomplished through surveillance. Accreditation provides confidence by assessing an organization's competence, conformity assessment process, infrastructure and results to ensure that conformity assessment bodies meet requirements. This section explores each of these concepts in more detail.

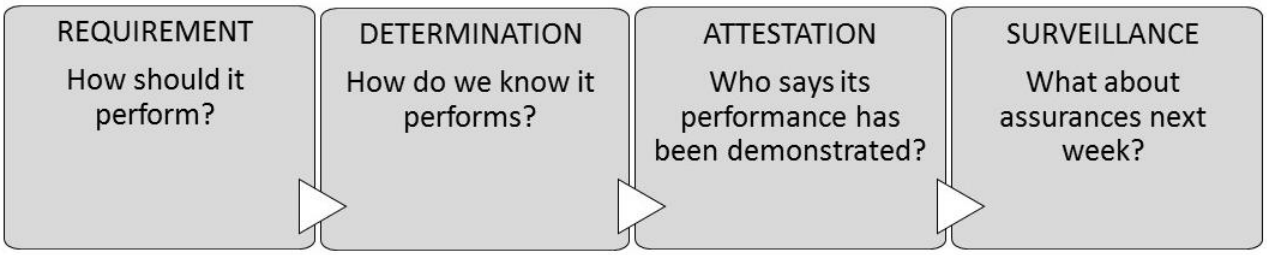

Figure 1. A conceptual view of conformity assessment

Within ISO, standards related to conformity assessment are developed and published by the ISO Committee on Conformity Assessment (CASCO)[2]. The conformity assessment standards are commonly known as the CASCO toolbox. These conformity assessment standards are developed and published jointly by the International Organization for Standardization (ISO)[3] and the International Electrotechnical Commission (IEC)[4]. The

[2] ISO Committee on Conformity Assessment (CASCO) and the CASCO toolbox (accessed September 2018).
[3] International Organization for Standardization (ISO) (accessed September 2018).
[4] International Electrotechnical Commission (IEC) (accessed September 2018).

combination of geographical reach and a multi-stakeholder development approach creates wide support and use of the CASCO toolbox.

The remainder of this document explores the topics of conformity assessment in detail including the role of standards within conformity assessment processes, conformity assessment concepts, as well as trade-related principles. The conformity assessment terms used throughout this document are based on the International Organization for Standardization (ISO)/ International Electrotechnical Commission (IEC) standards related to conformity assessment topics and terminology as defined in ISO/IEC 17000 "*Conformity Assessment - Vocabulary and General Principles*."

2. Conformity Assessment Concepts

This section provides detailed information into the concepts and activities within the conceptual view of conformity assessment (Figure 1). The following sections discuss the parties involved in conformity assessment activities, the role of standards as well as the different types of conformity assessment activities from requirements, to determination, attestation, and surveillance.

2.1. Conformity Assessment Parties

Many organizations and individuals can perform conformity assessment activities. Figure 2[5] illustrates the different types of parties that may be involved.

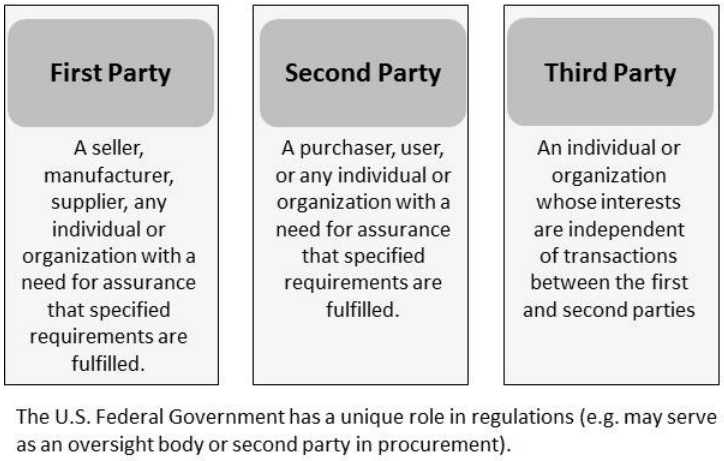

Figure 2. Types of parties involved in conformity assessment

2.2. Standards

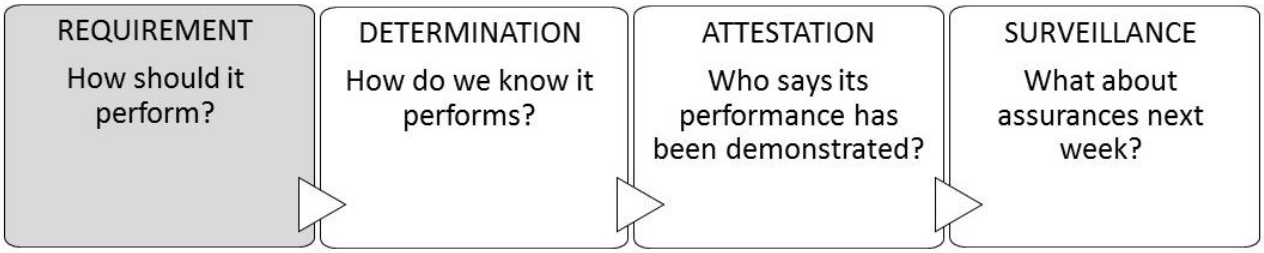

Figure 3. A conceptual view of conformity assessment

The standards used in conformity assessment have significant impact on the validity of the procedures, the value of the information conveyed, and the cost. ISO/IEC Guide 2[6] defines the term *standard* as a "document, established by consensus and 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.

[5] ISO/IEC 17000 "*Conformity Assessment – vocabulary and general principles*" provides terms and definitions applicable to conformity assessment.
[6] ISO/IEC Guide 2 "*Standardization and related activities - General vocabulary"*.

- NOTE Standards should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits.
- NOTE By virtue of their status as standards, their public availability and their amendment or revision as necessary to keep pace with the state of the art, international, regional, national, and provincial standards are presumed to constitute acknowledged rules of technology."

In addition, according to U.S. Office of Management and Budget (OMB) Revision of Circular A-119,[7] the term *standard*, as defined in the U.S. Public Law 104 - 113 - National Technology Transfer and Advancement Act (NTTAA) of 1995,[8] includes the following:

- common and repeated use of rules, conditions, guidelines or characteristics for products or related processes and production methods, and related management systems practices;
- the definition of terms; classification of components; delineation of procedures; specification of dimensions, materials, performance, designs, or operations; measurement of quality and quantity in describing materials, processes, products, systems, services, or practices; test methods and sampling procedures; formats for information and communication exchange; or descriptions of fit and measurements of size or strength; and
- terminology, symbols, packaging, marking, or labeling requirements as they apply to a product, process, or production method.

Standards are a vital tool of industry and commerce promoting market understanding, for example, between buyers, and sellers thus enabling mutually beneficial commercial transactions. Information on a product's conformance (or nonconformance) to a particular standard can provide an efficient method of conveying information needed by a buyer and other interested parties on the product's safety and suitability.

Example

A performance standard for a water pipe might set requirements for the pressure per unit area that a pipe must withstand, along with a test method to determine if a pipe sample meets the requirement. Manufacturers are free to choose any product design, material, and manufacturing process as long as the pipe can perform in the specified manner. On the other hand, a standard that requires that a pipe be made of a given gauge of copper and have a given diameter is a design standard. Manufacturers trying to comply with such a standard are not free to make the pipe out of stainless steel, for example, or to vary the size of the diameter no matter how such changes impact the pipe's performance.

Standards can cover many aspects of the conformity assessment process. They can describe characteristics of the product for which conformity is sought; the methodology (e.g., test, inspection or other assessment methods) used to assess that conformity; or even the conformity assessment process itself (e.g., how a certification program should be operated). Standards used in

[7] U.S. Office of Management and Budget (OMB) Revision of Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities" (OMB, 2016).
[8] U.S. Public Law 104 - 113 - National Technology Transfer and Advancement Act (NTTAA) of 1995 (Public Law 104-113, 1996).

conformity assessment should be clearly and concisely written, readily understood, precise, and technically credible, as well as contain requirements for objective verification. The use of well-written standards in a conformity assessment process lends credibility and validity to the process, increasing its usefulness.

Standards used in conformity assessment should not impede innovation. When possible, standards should be performance based, describing how a product is supposed to function, rather than how the product is to be designed.

Standards used in conformity assessment should also be chosen so that they specify all essential characteristics of a product necessary for achieving the objective of the conformity assessment activity. For example, if confidence in the electrical safety of a coffee pot is the objective, a standard that covers only the electrical safety of the coffee pot's cord and does not cover the pot's heating element would not meet the objective.

Knowing what aspects of the product will be evaluated in a conformity assessment process and whether there are other aspects that might impact quality, safety, or performance allows the user of the conformity assessment data to evaluate the data's significance.

2.3. Determination

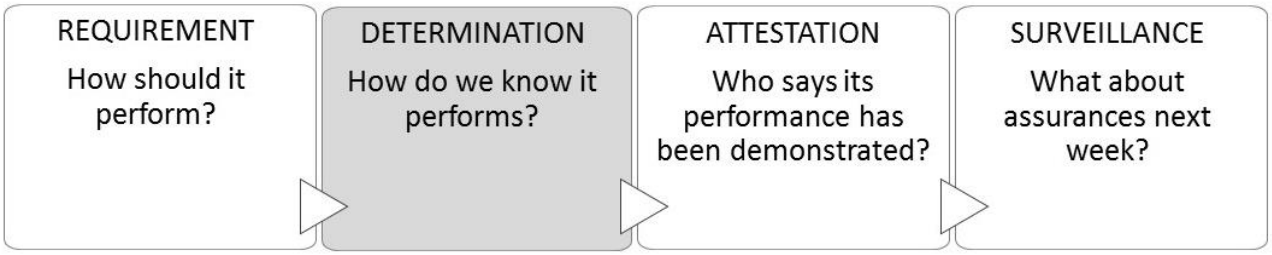

Figure 4. A conceptual view of conformity assessment

This section describes determination activities that may be used to examine an object of conformity to specified requirements. The following conformity assessment activities may be used to provide evidence of conformity as a basis for an attestation. Although each conformity assessment activity is separate, they are closely interrelated.

2.3.1. Testing

According to ISO/IEC 17000, testing is defined as "the determination of one or more characteristics of an object of assessment, according to a specified way to carry out an activity." Per ISO/IEC 17000, testing is an activity to develop information about the object's fulfillment of requirements. It does not include an attestation. Rather, testing can be used as a basis for an attestation.

ISO/IEC 17025[9] defines the general requirements for the competence of testing laboratories to conduct tests and/or calibrations as well as how each is performed using standard or non-standard methods. ISO/IEC 17025 is used to demonstrate that testing and calibration laboratories are competent and capable of generating valid results. This helps to promote confidence in the work of laboratories.

[9] ISO/IEC 17025 *"General requirements for the competence of testing and calibration laboratories"*.

In the testing activity, testing laboratories use a test method (often a set of procedures) to conduct tests on received samples and report data. The test data developed is used to determine whether tested items demonstrate conformity with specified requirements. Testing can be performed by first, second, or third-party laboratories. They may be private sector laboratories, laboratories affiliated with or owned by industrial firms or industry associations, or manufacturers' in-house laboratories. Testing laboratories differ widely in size, legal status, purpose, range of testing services offered and accredited scope.

Test reports issued by testing laboratories may be used for evidence of conformance in support of other conformity assessment activities. For example, test results may be used in

- a supplier's declaration of conformity when an organization, such as a manufacturer or supplier, conducts the necessary activities to determine that one or more characteristics of the object of assessment conforms to the appropriate standards
- providing a higher level of confidence is needed in the results of the object under assessment
- determining that one or more characteristics of an object meet the appropriate standards
- certification programs to assist in determining if products conform to requirements

Example

The U.S. Consumer Product Safety Commission testing requirements for children's products[10] call for independent third-party testing to ensure that products comply with the requirements and are safe. It is used in combination with other non-compliance deterrence measures, such as civil and criminal penalties, market and import surveillance, education of the supply chain on CPSC requirements and a recall system.

2.3.2. Inspection

Inspection is defined in ISO/IEC 17000 as the "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." Inspection is an activity to develop information about the object's fulfillment of requirements. It does not include an attestation. Rather, inspection can be used as a basis for an attestation. ISO/IEC 17020[11] defines requirements for the operation of various types of bodies performing inspection. The broad definition of inspection in the standard allows greater flexibility in application from systems to services and raw material to finished products.

In the inspection activity, an inspection body uses an inspection method (often a set of procedures) to examine a product design, product, or installation to determine conformity with requirements and produce an inspection report. Inspection can be performed by first, second, or third parties. Generally, inspection activities only demonstrate conformity of the actual products inspected or of the lot from which the inspected samples are drawn. Often

[10] https://www.cpsc.gov/Business--Manufacturing/Testing-Certification/Third-Party-Testing.
[11] ISO/IEC 17020 "*Conformity Assessment – Requirements for the operation of various types of bodies performing inspections*".

professional judgement is used making inspection a more subjective determination based on expertise. Sometimes, testing is used in support of inspection.

Inspection applies to many sectors and characteristics being inspected. It is well-suited to product characteristics that can be readily measured and where production occurs in batches. The supplier can arrange for the inspection of a production batch when needed. Inspection is also well-suited to determine that component parts and materials have been installed correctly.

Example
Inspection may be applied to building and infrastructure code enforcement to meet regulatory requirements based on a determination of items such as quantity, quality, safety, etc., and compliance of plants, installations, operating systems, and design suitability.

Inspection may also be applied to structures that must meet regulatory requirements or be embedded in a larger conformity assessment process. For example, the U.S. Department of Agriculture inspects meat and poultry products to determine whether they meet labeling and packaging requirements. Inspection may be used within surveillance activities of certification programs.

2.3.3. Audit

Audit activities use an organized, predictable process for assessing records and other information to determine whether requirements have been fulfilled. ISO/IEC 17000 defines an audit as a "systematic, independent, documented process for obtaining records, statements of fact or other relevant information and assessing them objectively to determine the extent to which specified requirements are fulfilled". ISO/IEC 17021[12] outlines requirements for certification bodies to ensure that management system certifications are performed in a consistent, competent, and impartial manner. The audit activity may provide assurance of a credible management system certification.

[12] ISO/IEC 17021 "*Conformity assessment -- Requirements for bodies providing audit and certification of management systems -- Part 1: Requirements*".

2.4. Attestation

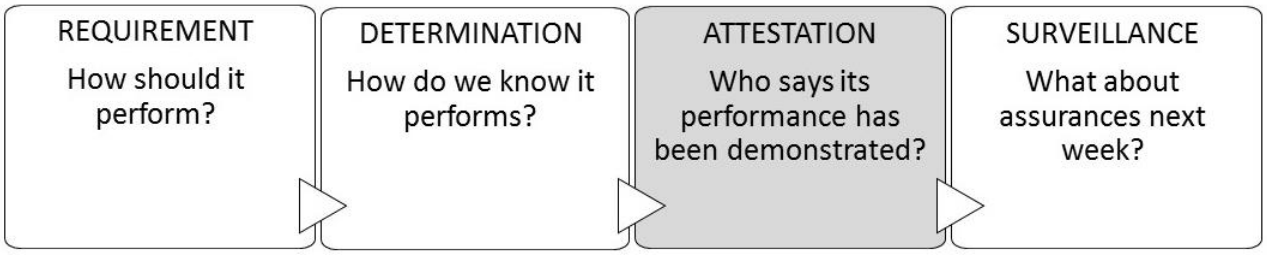

Figure 5. A conceptual view of conformity assessment

Information obtained from a conformity assessment activity about the object's fulfillment of requirements is used as the basis of an attestation. As defined in ISO/IEC 17000, attestation is "an issue of a statement, based on a decision following review, that fulfilment of specified requirements has been demonstrated". The attestation intends to convey assurance about the conformity of the object to consumers, regulators, buyers, or other interested parties. An attestation issued by a manufacturer (i.e. the organization that provides the product or service) is called a Supplier Declaration of Conformity. An attestation issued by an organization independent of the manufacturer and the user is called a certification.

2.4.1. Suppliers Declaration of Conformity

One way to attest that an object of conformity conforms to specific requirements is through a supplier's declaration of conformity (SDOC). As defined in ISO/IEC 17000, SDOC is a "declaration where the conformity assessment activity is performed by the person or organization that provides the 'object' (such as product, process, management system, person or body) and the supplier provides written confidence of conformity." The supplier makes a declaration that requirements have been met based on the results of testing, inspection, or audits undertaken by the manufacturer or other parties on its behalf.

ISO/IEC 17050-1[13] and ISO/IEC 17050-2[14] define the requirements for suppliers to meet when a formal claim that a product, service, system, or persons conform to specified requirements. Part 1 specifies the general requirements for an SDOC. Part 2 contains requirements for supporting documentation to substantiate the SDOC, such as reports of testing carried out by the supplier or independent third-party. A declaration is generally used when the consequences (accounting for risk) associated with nonconformity are low, there are suitable penalties for placing nonconforming products on the market, and/or there are suitable mechanisms in place to remove nonconforming products from the market.

2.4.2. Product Certification

Certification is defined in ISO/IEC 17000 as "third-party attestation related to products, processes, systems or persons." ISO/IEC 17065[15] identifies the general requirements for certification bodies to ensure they are competent, apply consistent processes, and operate in an impartial manner in order to facilitate national and international trade of certified

[13] ISO/IEC 17050-1 "*Conformity assessment – suppliers declaration of conformity – Part 1: General Requirements*".
[14] ISO/IEC 17050-2 "*Conformity assessment – suppliers declaration of conformity – Part 2: Supporting Documentation*".
[15] ISO/IEC 17065 *"Conformity assessment – Requirements for bodies certifying products, processes and services"*.

products, processes and services. The goal of certification is to provide confidence to interested parties that objects of assessment meet specified requirements.

Certification may provide a higher level of confidence since the third-party's certification decision is required to be impartial and free of commercial, financial or other pressures that may compromise impartiality. Activities on which certification is based include the following:

- Evaluation of evidence of conformity
- Determination of conformity
- Attestation of conformity granted (i.e. certificate issued)
- Surveillance and/or ongoing renewal process (may be optional based on the certification program)

Example

The Environmental Protection Agency (EPA) ENERGY STAR[16] program is a voluntary public-private partnership that relies on independent third-party certification to ensure ongoing compliance and the integrity of the ENERGY STAR label. Reliance on third-party certification helps maintain consumer trust and improve oversight of the program while allowing the agency to utilize the private sector to conduct evaluation and additional market surveillance activities.

Certification programs are usually designed for mass-produced products to provide assurance of continued conformity to applicable standards throughout the manufacturer's production process. Corrective actions may be deemed necessary if nonconformities or issues are identified during the certification process. Continued conformity may be driven by user needs or changes to the object of assessment that affect continuing fulfillment of specified requirements. The attestation may be based on multiple conformity assessment activities.

There are many organizations that operate third-party certification programs. The following provide examples of different types of organizations, including:

- Conformity assessment bodies
- Other organizations, such as nonprofit organizations
- Professional or technical societies
- Trade associations

The Federal government as well as State and Local governments also administer certification programs that cover a diversity of products from meat inspection to ensuring the health and safety of amusement rides on its population. Federal government certification programs can be classified into several general categories:

- Programs to certify products directly affecting the health or safety of the user or the public
- Programs to provide a uniform basis for trade by assessing the quality and condition of products offered for sale

[16] The Environmental Protection Agency EnergyStar program is a voluntary program to help businesses and individuals save money and protect the climate through energy efficiency. https://www.energystar.gov/.

2.4.3. Management System Certification

Management system certification is third-party attestation related to systems within an organization. A management system is the way in which an organization manages the inter-related parts of its business to achieve its objectives. These objectives can relate to product or service quality, operational efficiency, environmental performance, health and safety in the workplace, and many more.

Certification of management systems is generally used as a demonstration of fulfillment of quality, security, and environmental management system standards. Some of the most commonly used management system standards include:

- ISO 9001 "*Quality management systems – requirements with guidance for use"*
- ISO 14001 "*Environmental management systems - requirements with guidance for use"*
- ISO 22000 "*Food safety management systems - requirements for any organization in the food chain"*
- ISO 27001 "*Information technology - security techniques - information security management systems – requirements"*
- *ISO 50001 "Energy management systems – requirements with guidance for use"*

ISO/IEC 17021-1[17] contains principles and requirements for the competence, consistency, and impartiality of bodies providing audit and certification of all types of management systems. The management system certification process involves assessment of the compliance of documented policies and procedures with management system requirements according to a specific scope. An audit of the implementation of the system requirements to the scope is conducted on a continuing basis. Certification bodies issue certificates and publish lists of certified organizations and their scopes of certification.

2.4.4. Personnel Certification

Personnel certification has become an important component of ensuring competency to an increasingly globalized workforce due to technological innovation and the need for specialized credentials. Personnel certification provides confidence that individuals have skills needed to perform their work competently. ISO/IEC 17024[19] specifies requirements to ensure certification bodies for persons operate personnel certification schemes with competence, consistency, and impartiality.

Example
The National Registry of Food Safety Professionals[18] develops and maintains an accredited certification examination program in the areas of food safety as well as Hazard Analysis Critical Control Point (HACCP) for workers in food manufacturing facilities, plants, packaging facilities, and warehouses.

[17] ISO/IEC 17021-1 *Conformity assessment — Requirements for bodies providing audit and certification of management systems*.
[18] The National Registry of Food Safety Professionals Hazard Analysis Critical Control Point program for food safety.
[19] ISO/IEC 17024 *Conformity assessment – General requirements for bodies operating certification of persons*.

2.4.5. Surveillance

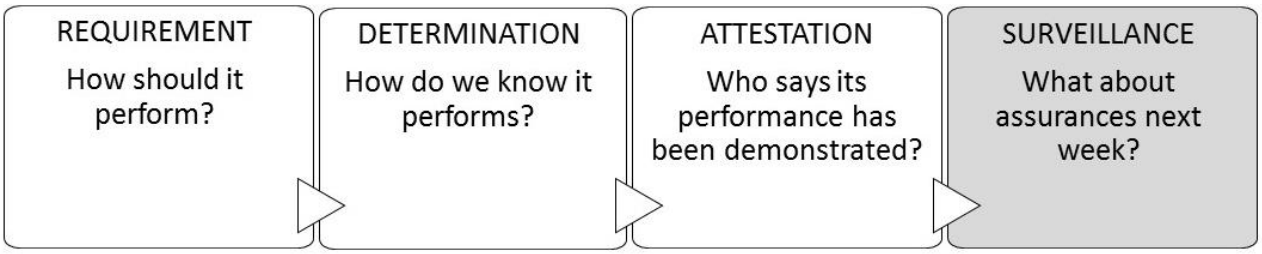

Figure 6. A conceptual view of conformity assessment

Conformity assessment programs may require assurance on an on-going basis. Surveillance comprises a group of activities conducted to maintain the validity of the attestation. Per ISO/IEC 17000, surveillance is defined as "systematic iteration of conformity assessment activities as a basis for maintaining the validity of the statement of conformity." Post-market surveillance involves the evaluation of certified products taken from the marketplace to determine if product requirements continue to be met. Pre-market surveillance is the checking of products before they reach the market and may include audits of the supplier's process control systems and/or inspection of the production.

In some conformity assessment programs, surveillance is accomplished by requiring all or some significant part of the activities used initially to determine conformance to be re-conducted on a periodic basis. This recertification (or reissue of an SDOC) process can take the form of retesting or re-assessing the characteristics of interest at prescribed intervals.

Example
Radio Frequency Devices with an intentional radiator (transmitter) are required to be certified by a U.S. Federal Communications Commission (FCC)-approved Telecommunications Certification Body (TCB). TCBs are private sector certification organizations. The FCC requires the TCBs to perform surveillance and meet specific requirements that address the way surveillance is conducted[20]. These requirements include: determining sample sizes based on product type and other attributes; obtaining samples from the supplier or marketplace; determining conformity to requirements; submitting an annual surveillance report to the FCC capturing all surveillance audits performed and follow-up action (in the case of non-conforming products, for example).

2.4.6. Accreditation

According to ISO/IEC 17000, accreditation is defined as "third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks." Accreditation provides confidence, through an independent evaluation of conformity assessment bodies against standards to carry out specific activities, that conformity assessment organizations meet requirements and operate

[20] TCB Post-Market Surveillance. U.S. Federal Communications Commission. [Online] Available: https://apps.fcc.gov/kdb/GetAttachment.html?id=AWhYotapku%2FSkvVA1wkMAw==&desc=610077 D01 TCB Post Market Surveillance v06r01&tracking_number=20540 [Accessed Dec. 20, 2017].

with independence, impartiality, and competence. There are accreditation programs for testing laboratories, and inspection bodies, as well as certifiers.

ISO/IEC 17011[21] specifies requirements for accreditation bodies that provide services for accrediting conformity assessment bodies. Accreditation bodies provide a first-party attestation that they comply with the requirements of ISO/IEC 17011. Accreditation applies to bodies performing activities such as testing, calibration, inspection, reference materials, proficiency testing, certification, management systems, persons, products, processes and services, and validation and verification. Many accreditation bodies use the ISO/IEC standards plus additional technical and specific program requirements to assess conformity of a conformity assessment body. One important attribute of accreditation is the use of competent assessors to perform assessments of conformity assessment bodies.

The requirements used in accreditation of conformity assessment bodies create a type of hierarchy as depicted in Figure 7.

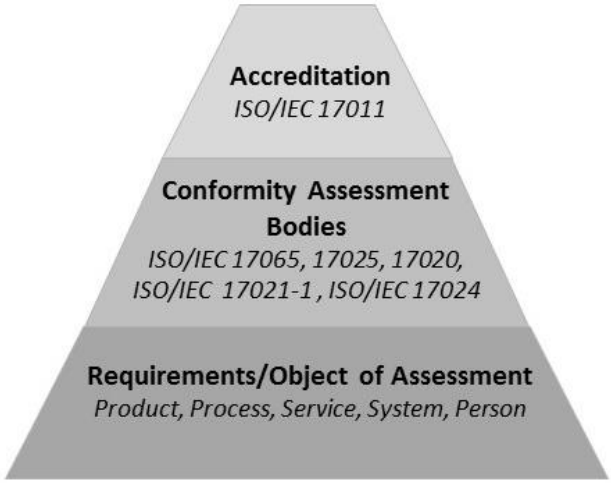

Figure 7. Conformity assessment hierarchy

There are other approaches used to provide confidence about the fulfillment of requirements by conformity assessment organizations. Peer assessment is an organized system used at regional and international levels to provide increased confidence that accreditation bodies or conformity assessment bodies meet competence requirements. Staff from one or more conformity assessment bodies evaluate the competence of other bodies that perform similar conformity assessment functions. This approach is used by accreditors, certifiers, and testing laboratories with the goal of facilitating recognition or the acceptance of each other's conformity assessment systems and results. Peer assessment systems may assist in promoting the acceptance of products and services without the need for additional testing, inspection, certification, or accreditation in different countries in which the object of assessment is sold.

[21] ISO/IEC 17011[21] "*Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies*".

3. Scheme Ownership

A conformity assessment scheme specifies how conformity assessment activities are structured and managed. According to ISO/IEC 17000, a conformity assessment scheme is a "…system related to specified objects of conformity assessment, to which the same specified requirements, specific rules and procedure apply". The organization that develops and maintains the conformity assessment program policies and procedures is called the conformity assessment scheme owner.

Many different organizations can act as a conformity assessment scheme owner such as:

- Certification bodies
- Consumer organizations
- Government or regulators
- Purchasing agencies
- Standards organizations
- Trade associations

Scheme owners may develop a conformity assessment scheme to ensure conformance to specific regulatory or legal requirements. As a conformity assessment scheme owner, organizations define the policies and procedures to operate and maintain the program based on the organization's goals and/or regulatory requirements of the conformity assessment object(s) as well as the desired level of risk and confidence. Factors to be considered include the type of conformity assessment activities and specific requirements to be met.

Example
The Occupational Safety and Health Administration (OSHA) requires that products used in the workplace meet safety requirements.[22] OSHA recognizes private-sector conformity assessment bodies as Nationally Recognized Testing Laboratories (NRTLs) and conducts ongoing evaluation activities, including audits, to ensure compliance with the policies and continued conformity with requirements. For recognition, OSHA requires organizations to comply with ISO/IEC 17025 and ISO/IEC 17065 as well as OSHA-specific policies that supplement the general provisions in each of the standards, as defined in the OSHA Directive.

[22] OSHA Nationally Recognized Testing Laboratory program, https://www.osha.gov/dts/otpca/nrtl/index.html.

4. Trade Related Concepts

Conformity assessment procedures are a key aspect for global trade. Statutory and international obligations exist governing standard-related activities including conformity assessment. The World Trade Organization (WTO) Technical Barriers to Trade (TBT) Agreement contains obligations regarding conformity assessment procedures and their use in international trade. In addition, the United States has 20 Free Trade Agreements in force, and many of them have additional provisions with respect to conformity assessment procedures. For example, some Free Trade Agreements enforce the commitment to provide national treatment to conformity assessment bodies.[23] The TBT Agreement requires, among other things, that conformity assessment procedures not be "prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade". This means "conformity assessment procedures shall not be applied more strictly than is necessary to give the importing Member adequate confidence that products conform with the applicable technical regulations or standards, taking account of the risks non-conformity would create.[24]"

The U.S. OMB Circular A-119 includes international trade-related guidance for Federal Agencies: "Agencies should use voluntary consensus standards and international guides and recommendations issued by international standardizing bodies in conformity assessment procedures… including where such standards, guides and recommendations are used by a trading partner." In addition, Article 6.1[25] of the WTO TBT Agreement encourages, whenever possible, WTO Members, including the United States, to accept the results of conformity assessment procedures in other WTO member countries, provided the Member is satisfied that those procedures offer an assurance of conformity equivalent to its own procedures. U.S. free trade agreements may also have obligations with respect to recognition of trading partners' conformity assessment procedures.

Different principles apply with respect to the acceptance of results of conformity assessment such as national treatment, mutual recognition, and international systems. [26]

4.1. National Treatment

When similar, or comparable, conformity assessment situations occur, the use of national treatment is one approach that can be utilized to facilitate the acceptance of results. According to Article 5.1.1[27] of the WTO TBT Agreement, national treatment with respect to conformity assessment is when procedures are "prepared, adopted and applied so as to grant access for suppliers of like products originating in the territories of other Members under conditions no less favorable than those accorded to suppliers of like products of national origin or originating in any other country, in a comparable situation; access entails suppliers' right to an assessment of conformity under the rules of the procedure, including, when foreseen by this procedure, the possibility to have conformity assessment activities undertaken at the site of facilities and to receive the mark of the system."

[23] List of U.S. Free Trade Agreements in force. https://ustr.gov/trade-agreements/free-trade-agreements.
[24] World Trade Organization (WTO) Technical Barriers to Trade (TBT) Agreement.
[25] WTO TBT Agreement Article 6, *Recognition of Conformity Assessment by Central Government Bodies.*
[26] In addition, the WTO agreed to the Indicative List of Approaches to Facilitate Acceptance of Results of Conformity Assessment.
[27] WTO TBT Agreement Article 5, *Procedures for Assessment of Conformity by Central Government Bodies.*

4.2. Mutual Recognition[28]

Mutual recognition agreements and mutual recognition arrangements are two mechanisms used to facilitate the acceptance of conformity assessment results between two or more parties). These agreements on conformity assessment can provide several benefits such as:

- recognition of conformity assessment body competence to conduct activities to specific regulatory or non-regulatory requirements;
- improved transparency of conformity assessment requirements across markets; and
- reduced diversity of procedures and methods for conformity to requirements.

A mutual recognition ***agreement*** is an intergovernmental agreement that results in the acceptance of the results of conformity assessment originating in the territory of either party that demonstrate fulfillment of requirements. These agreements may be used where conformity assessment programs involve regulatory requirements.

Mutual recognition agreements provide for the acceptance of conformity assessment results generated by recognized conformity assessment bodies in the other economy. This may reduce unnecessary duplication of services. A mutual recognition agreement usually requires the regulator to have direct involvement in the program as the legal entity responsible for the technical regulatory requirements. For example, the regulator may serve in the official capacity of the Regulatory Authority that "recognizes" the conformity assessment bodies of the mutual recognition agreement partner.

A mutual recognition ***arrangement*** or a multilateral recognition arrangement is an international or regional arrangement among parties to the arrangement recognizing the results of each other's conformity assessment. This approach may be used by accreditation bodies to accept the results of each other's accredited conformity assessment bodies or by conformity assessment bodies to recognize the results of conformity assessment.

Unlike mutual recognition ***agreements***, operational processes for mutual recognition ***arrangement*** are generally developed and approved by representatives from the organizations involved, whether governmental or private sector.

4.3. International Systems

Accreditation bodies from around the world have formed international and regional "cooperations" and established "multilateral agreements or arrangements" to recognize and accept results of conformity assessment. The evaluation process of the accreditation cooperation is conducted by member accreditation bodies based on peer evaluation of each other. The use of mutual recognition arrangements or multilateral agreement may provide a global network of accreditation bodies to assist in improving acceptance of reliable conformity assessment results. Parties, in this case the accreditation bodies, to the arrangement agree to accept each other's results rather than each other's accreditation. This may result in the acceptance of:

[28] The purpose of this section is to explain the concept of mutual recognition. Some stakeholders, such as the Federal Government, may use other terminology for these concepts.

- the conformity assessment bodies that have been accredited by one member of the agreement to also be accepted as competent by another signatory to the agreement;
- conformity assessment results prepared by a conformity assessment body, that has been accredited by an accreditation body participating in the mutual recognition agreement; or
- The accreditation body that has been recognized by the regulatory authority in a jurisdiction, also be accepted in other participating jurisdictions for the purpose of meeting regulatory conformity assessment requirements imported products.

Other types of approaches can be established between two or more organizations to accept each other's conformity assessment data and/or conformity assessment results.

Example
The IEC System for Conformity Testing to Standards for Safety of Electrical Products[29] (the IECEE CB scheme) is an international system for mutual acceptance of test reports and certificates dealing with the safety of electrical and electronic components, equipment and products. It is a multilateral agreement among participating certification organizations worldwide.

The concepts of national treatment, recognition, and use of international systems may help reduce technical barriers to trade, quicken the circulation of goods and services entering the markets, eliminate the need for retesting and/or recertification and thus reduce the costs incurred, and ensure that regulatory conformity assessment requirements are met.

[29] https://www.iecee.org/about/cb-scheme/.

5. Glossary

Term	Definition	Source
conformity assessment	demonstration that specified requirements relating to a product, process, system, person or body are fulfilled	ISO/IEC 17000
conformity assessment body	body that performs conformity assessment services	ISO/IEC 17000
first-party conformity assessment activity	conformity assessment activity that is performed by the person or organization that provides the object	ISO/IEC 17000
second-party conformity assessment activity	conformity assessment activity that is performed by a person or organization that has a user interest in the object	ISO/IEC 17000
third-party conformity assessment activity	conformity assessment activity that is performed by a person or body that is independent of the person or organization that provides the object, and of user interests in that object	ISO/IEC 17000
impartiality	presence of objectivity Note 1 to entry: Objectivity means that conflicts of interest do not exist or are resolved so as not to adversely influence subsequent activities of the [conformity assessment body]. Note 2 to entry: Other terms that are useful in conveying the element of impartiality include "freedom from conflict of interests", "freedom from bias", "lack of prejudice", "neutrality", "fairness", "open-mindedness", "even-handedness", "detachment", "balance."	ISO/IEC 17025
specified requirement	need or expectation that is stated	ISO/IEC 17000
certification requirement	specified requirement, including product requirements, that is fulfilled by the client as a condition of establishing or maintaining certification	ISO/IEC 17065 See also: ISO/IEC 17021-1 ISO/IEC 17024
audit	systematic, independent, documented process for obtaining records, statements of fact or other relevant information and assessing them objectively to determine the extent to which specified requirements are fulfilled NOTE Whilst "audit" applies to management systems, "assessment" applies to conformity assessment bodies as well as more generally.	ISO/IEC 17000

Term	Definition	Source
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	ISO/IEC 17000
testing	determination of one or more characteristics of an object of conformity assessment, according to a procedure	ISO/IEC 17000
attestation	issue of a statement, based on a decision following review, that fulfilment of specified requirements has been demonstrated NOTE 1 The resulting statement, referred to in this International Standard as a "statement of conformity", conveys the assurance that the specified requirements have been fulfilled. NOTE 2 First-party and third-party attestation activities are distinguished by the terms declaration [first-party] and certification [third-party]. For second-party attestation, no special term is available	ISO/IEC 17000
declaration	first-party attestation	ISO/IEC 17000
supplier declaration of conformity (SDoC)	first-party attestation NOTE 1 "Supplier's declaration of conformity" is a "declaration" as defined in ISO/IEC 17000, i.e. first-party attestation.	ISO/IEC 17050
certification	third-party attestation related to products, processes, systems or persons	ISO/IEC 17000
credential	recognition of qualification or competence issued to a person by an organization	ISO/IEC 17027
credentialing	process by which an organization issues a credential	ISO/IEC 17027
surveillance	systematic iteration of conformity assessment activities as a basis for maintaining the validity of the statement of conformity	ISO/IEC 17000
accreditation	third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks	ISO/IEC 17000
recognition of conformity assessment results	acknowledgement of the validity of a conformity assessment result provided by another person or body	ISO/IEC 17000
acceptance of conformity assessment results	use of a conformity assessment result provided by another person or body	ISO/IEC 17000
accreditation body	authoritative body that performs accreditation	ISO/IEC 17000

Term	Definition	Source
laboratory	body that performs one or more of the following activities: — testing; — calibration; — sampling, associated with subsequent testing or calibration	ISO/IEC 17025
inspection body	conformity assessment body that performs inspection	ISO/IEC 17020
certification body	third-party conformity assessment body operating a certification scheme [program]	ISO/IEC 17065
scheme owner [program owner]	person or organization responsible for developing and maintaining a specific product certification scheme	ISO/IEC 17067

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