

SELF-CERTIFICATION:
Supplier's declarations and Conformity Assessment

CMGT 564 RESEARCH PAPER

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July 24, 2006

Executive Summary

ISO/IEC 17050-1:2004, Conformity Assessment—Suppliers Declaration of Conformity—Part 1:General Requirements is the current standard recognized by the international standards community as the basis for the general requirements of a supplier's declaration of conformity to specified requirements for a product, process, system or body. The standard was published in 2004 as a replacement to ISO/IEC Guide 22:1996, General Criteria for Supplier's Declaration of Conformity.

Objectives of the Standard

The objective of any standard, first and foremost is to provide an agreed-upon, consistent set of rules that apply to a particular product or process. Specifically, in the case of manufactured products there is a need for a system that establishes whether the performance and other characteristics of a product are representative of what a consumer expects and suitable for the intended use. Such a system, and the information it produces, also increases a buyer's confidence in a product.

How do I know it works?

However unreliable, the earliest testament to the suitability of a product was the craftsman's claim that a product would do what he said it would do. This was a system that could obviously be improved upon, beginning with a system of

standards that established what the critical characteristics or properties of the product are. The relationship of the standards discussed herein with standards that specify product requirements is that they form a basis of information that could “certify” or assure a buyer that a product conforms to one or more applicable standards and is therefore fit, and usually safe, for his use.

As in the earlier case of the seller’s promise, the current procedure of self-certification, also known as a *manufacturer’s- or supplier’s declaration*, is the manufacturer’s assertion that his product meets the required standards.

The Bigger Picture

Supplier’s declarations, as well as sampling, testing, certification, registration, accreditation and the standards that establish performance or other requirements for a product are all part of a group of activities, referred to in whole as “conformity assessment.” In short, conformity assessment includes any activity concerned with ensuring that requirements for a product are fulfilled. Therefore, supplier’s declarations of conformity and the self-certification process are tools that help provide consumers with the information they need, thus encouraging trade and opening markets.

Background

The original intent of the author was to have as the subject of this paper the American National Standard, ANSI Z34.2, “Self-Certification by Producer or Supplier,” published in 1987. However, severely limited amounts of information during early research suggested that this standard had been subsequently replaced or was no longer active. As the scope of ISO/IEC 17050:2004 is similar and because the author believes that part of their histories are shared, much of the remaining discussion will be from a national (U.S.) perspective despite its application to an international standard.

History

In the United States, self-certification has historically been the primary method for establishing conformity to product requirements. To meet the need for consistency in the process, in 1987 the American Nation Standards Institute (ANSI) published ANSI Z34.2, “Self-Certification by Producer or Supplier,” which set forth generic criteria and procedures for a producer, on its own authority, to declare that a product or service is in conformity with specific standards or specifications. ANSI Z34.2 included requirements for a quality assurance system as well as for testing and inspection. This standard was adopted on March 8, 1988 for use by the Department of Defense. ANSI withdrew the standard on March 19, 1996.

In 1992 ANSI's certification program policies and procedures were revised to be consistent both with the international expectations for standards and guides for conformity assessment programs. Therefore, although documentation could not be found, the author suspects that the withdrawal of ANSI Z34.2 in 1996 was a result of the publication of ISO/IEC Guide 22, General Criteria for Supplier's Declaration of Conformity.

ISO/IEC Guide 22 was developed by the International Organization for Standardization (ISO) to standardize the use of supplier's declarations of conformity (SDoC). Originally, applicability of the standard was limited to manufactured products. As the international standards community came to accept SDoC, the increased use of Guide 22 exposed the limitations of its scope. Consequently, the standard was revised to include processes and services as well as management systems such as ISO 9000.

When Guide 22 came up for its five-year review, the conformity assessment community felt that additional information was needed within SDoC's for them to gain even greater acceptance. This led to a proposal to convert Guide 22 to an ISO standard and add a companion standard that described the supporting the documentation that should accompany an SDoC. The conversion of Guide 22 to a

standard was intended to make the requirements clearer and make its provisions more acceptable to government and regulatory institutions. In 2004, ISO/IEC Guide 22 was replaced by ISO/IEC 17050-1, Conformity assessment — Supplier's declaration of conformity — Part 1: General requirements.

Development

ISO 17050-1 was developed within the Committee for conformity assessment (CASCO) of ISO. This committee is responsible for ensuring that regulators, suppliers and consumers have confidence that products (as well as processes, services and management systems) meet their specified requirements. This is important to the international standards community because this confidence is an essential part of worldwide commerce.

The activities of CASCO are related to: studying methods of conformity assessment; preparing international guides and standards on testing, inspection and certification, testing laboratories, inspection bodies, certification bodies, accreditation bodies and their operation and acceptance; and promoting mutual recognition national and regional conformity assessment systems.

One-hundred and one countries (about two-thirds of ISO's membership), including the United States through ANSI, participate in the activities of CASCO, which is a policy development committee. These special committees are not as specialized as technical committees and provide strategic guidance on standards development work that involves multiple sectors to ensure that it aligns with broad market and stakeholder interests. This advisory committee, established by the General Assembly, reports to the ISO council. Although CASCO is not a technical committee, where most of ISO's standards are developed, ISO 17050-1 was developed in a working group, specifically *WG 24, Supplier's Declaration of conformity and its supporting documentation*. CASCO membership is open to all ISO member bodies.

The Information Technology Industry Council, was a great promoter of SDoC for the IT industry, and developed a draft standard that became the foundation for ISO 17050-2, *Requirements for supporting documentation to a supplier's declaration of conformity*, the companion standard to ISO 17050. CASCO also receives input from 12 international governmental and non-governmental standards-related organizations that are liaison members.

Procedures

ISO standards are developed within an “open,” consensus- based committee process, which requires resolution of substantial objections, with input from all interested parties. Each of these parties does not get a vote in ISO, but are represented with one vote from their national member body, who must act on a unified position of the interest it represents. Publication as an International Standard requires approval by at least 75 % of the national bodies casting a vote. ISO 17050-1 was circulated for voting to the national bodies of both ISO and IEC, and was approved by both organizations. Any member body of ISO may appeal a decision or action at the technical committee, technical management board or council board level within three months of the decision in question.

Adherence to ISO standards is voluntary, although regulatory bodies may make their requirements enforceable. The author could find no evidence that ISO 17050-1 has been adopted as an American National Standard. Interestingly, ANSI Z-34.2 is still used by the Department of Defense, having been adopted in 1988.

Structure

Conformity Assessment – Supplier’s declaration of conformity – Part 1: General requirements, contains ten sections, the first of which is its scope. Sections 2 and 3 contain references and terms and definitions, for both of which the user is directed

to *ISO/IEC 17000:2004, Conformity assessment — Vocabulary and general principles*. A note in Section 3 discourages the use of the term “self-certification,” so as to avoid confusion with the process of attestation by certification bodies.

After stating the purpose of declarations for conformity in Section 4, the requirements of the standard begin in Section 5, **General Requirements**. This section includes general responsibilities of the states that the issuer of an SDoC is responsible for its maintenance including issuing, reducing, suspending or withdrawing it. The declaration can be based on any conformity assessment activities (testing, measurement, inspection, et. al.) and can be carried out by first, second or third parties or a combination. This section requires the declaration to cover each individual product in a group and recommends that the person reviewing the conformity assessment results be independent from the issuer.

Section 6 describes the contents of the declaration, a list of items that as a minimum, the declaration must include. Some of these are contact address of the issuer of the declaration, name or identifier of the object of declaration (product, type, production date, process description, etc.), the statement of conformity, a list of applicable standards and requirements, and any limitations on the validity of the declaration, among others.

Additional supporting information for the declaration may include the name and address of any conformity assessment body involved (laboratories, certification or inspection bodies, conformity assessment reports, accreditation documents, or certificates or registrations attained.

Section 7 of ISO/IEC 17050-1 identifies a standard form, an example of which is included in an Annex. Sections 8 and 9, “Accessibility” and “Product marking,” state that a copy of the declaration can be used in manufacturer’s documentation such as catalogs, websites, but any marking placed on the product itself cannot be in a form that may be confused with any certification mark.

The final section of the standard requires the issuer to ensure the continued conformity of the object of the declaration. The validity of the declaration should be re-evaluated upon changes in the object, ownership or management of the producer, relevant standards, or any information indicates that the object may no longer conform to specified requirements.

Value

Assurance that a manufacturer adheres to the requirements of a voluntary consensus standard provides increased confidence in a product or service.

Standards that provide a consistent format for documents attesting conformity assessment ease verification of conformity assessment procedures, particularly SDoC's, and help the U.S. succeed in a world marketplace that was initially reluctant to accept SDoC's. The requirements of ISO 17050 reduce the risks associated with supplier self-assessment and build trust between suppliers and consumers.

When SDoC's are presented in an accepted and consistent form, they often eliminate duplicative testing procedures and are a simpler alternative to complex regulatory administrative requirements. This is particularly important when there is no formal certification program for a particular product or process. This clear presentation of product information and its supporting documentation eases the use of first party attestation for procurement in government or quasi-governmental agencies, without the need for regulatory requirements. The resulting cost and time savings provide benefits to suppliers and their customers. Accuracy and relevancy of the declaration is ensured by the standards requirements for continued conformity and re-evaluation. Consumers may also use other conformity

assessment activities, including certification and accreditation in addition to, or in support of the declaration to further enhance its value.

Conclusion

The adoption of an international standard covering requirements for supplier's declarations of conformity is a significant aid to the growth of world trade. The global marketplace is not only dependent on standards but also on the methods used to ensure that products comply with the requirements of those standards. International acceptance of suppliers declarations allow suppliers much greater flexibility in choosing their conformity assessment procedures and can significantly reduce costs associated with ensuring conformance. ISO 17050 allows this, while improving transparency.

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