ACIL sDoC Position Paper

The American Council of Independent Laboratories (ACIL) believes that third party certification procedures give assurance that a product, process or service conforms to specified requirements (see ACIL companion paper, "The Value of Third Party Certification," 2002); however, supplier's Declaration of Conformity[1] (sDoC), if designed appropriately, can be an effective method of assuring that products meet minimum technical requirements for market entry.

For sDoC to be considered, the following conditions must be met:

1. sufficient historical data exist that demonstrate that

    a. manufacturers understand the technical, regulatory and market requirements for conformity of their products in question,
    b. safety, health and/or environmental concerns of each product have been sufficiently addressed through technical, regulatory or market mechanisms, and
    c. confidence needs of acceptance interests (authorities having jurisdiction) have been satisfied

2. an operational, effective post-market surveillance system is in place that addresses the complexity and development changes to the product in question. Accordingly, the post-market surveillance system should consist of some or all of the following elements

    a. customer complaints,
    b. marketplace surveillance and testing,
    c. factory surveillance and testing,
    d. regular independent audits of individual manufacturer's declarations of conformity as required by acceptance interests to assure that:

        i. it accurately identifies and describes the supplier and product,
        ii. a conformity statement with referenced standards exist,
        iii. there is a date and place of issue of the declaration,
        iv. the signature, name and function of the person making the declaration exist,
        v. it is shipped individually with all products,
        vi. the declaration is kept for a minimum of ten years along with a copy of all test results, and
        vii. that a numbering and labeling scheme is in place so that customers can readily obtain the manufacturer's contact information if necessary;

[1] Supplier's Declaration of Conformity (sDoC) is a procedure by which a supplier gives written assurance that a product, process or service conforms to specified requirements.

e. penalties for noncompliance, which include but are not limited to

i. civil and criminal,
ii. product recall, and/or
iii. product bans.

Government regulatory authorities have the obligation of regulatory enforcement and must provide annual reports on effectiveness of the sDoC system and, if deemed necessary, make changes in conformity assessment requirements as appropriate. There are many options that regulators can use (both public and private sector) to assist them in carrying out these statutory responsibilities.

Conditions for these changes are discussed in further detail below.

Data Requirements

To move from a more well accepted form of product conformity assessment to sDoC, a sufficient body of test and/or certification data must exist and be analyzed. This data should come from acceptance interests, third party conformity assessment bodies, and manufacturers. The Challenger space shuttle disaster, the Firestone Tire product failures, and the Marine Corp's Osprey aircraft crashes are three examples of problems that have resulted from the supplier's declaration of conformity scheme.

Supplier generated data can help support the case for use of sDoC, but there is the potential of economic pressure on the manufacturer to market products as quickly as possible, which can cause difficulty with the objective nature of the data generated. Time to market issues need to be tempered with the safety, health and environmental concerns of each product. It is the responsibility of acceptance interests to determine what that balance should be, and to what level they must rely on independent third parties to provide the expertise in determining if products comply with the appropriate standards and requirements.

Compliant products generally are tested and certified by independent third party laboratories in less time than the manufacturer could complete their own evaluation of conformity. This is due to the third party's expertise, coupled with a variety of competitive third party schemes available in the marketplace.

A significant problem is non-compliant products. A majority of the products that are received by independent third parties for evaluation fail to comply with the requirements when initially evaluated. These failures often result in major product design changes to meet safety, health or environmental requirements, thereby causing delay in market introduction of the product.

The Post-Market Surveillance System

Once empirical data requirements have been met, the most critical element of an sDoC system is an operating post-market surveillance system that takes into account the complexity and potential for harm to health, safety and/or the environment.

The post-market surveillance system should be one that is designed in a consensus process with input from all stakeholders (manufacturers, third parties, customers, users, and acceptance interests) to generate acceptance and confidence in the system. It should consist of some or all of the elements listed earlier in this paper. It should be flexible enough so that, for example,

manufacturers could include an audit of their declarations of conformity during an ISO 9000 certification assessment. It should also be designed so that it does not create a competitive imbalance between the large and small manufacturers.

The Role of Laboratory Accreditation in sDoC

In virtually every industry sector worldwide, the critical role of laboratory accreditation in providing confidence that safe and reliable products enter the stream of commerce is well understood and accepted. Suppliers and acceptance interests expect third party laboratories and certifiers to be accredited so there is confidence in the results they produce and programs they operate. The supplier has an economic stake in the results coming from its own laboratory and should be held to standards comparable to the independent third party laboratory. The standard for laboratory competence should be equivalent for a laboratory that is operated by a supplier that develops data to support an sDoC as its means of demonstrating product conformity. ACIL believes that all laboratories that test products for the marketplace should be accredited.

The Future of sDoC in Global Markets

Only with data, an operating post-market surveillance system, and equality in laboratory accreditation requirements will sDoC be a credible method of product conformity worldwide. History has proven that it is irresponsible to believe that a competitive marketplace alone will result in suppliers manufacturing products that meet the safety, health and environmental requirements of nations and regions worldwide.

ACIL stands ready to help implement an sDoC system that can operate in global markets in support of the interests of all stakeholders, while providing the confidence in protection of health, safety and the environment necessary.

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