



Quality Certification Alliance

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Measuring and Defining Safe Product Manufacturing Compliance

“Compliance” is alternatively defined as the “act or process of complying to a desire, demand or proposal or to coercion,” “the act of conforming, acquiescing or yielding,” and “the act of cooperation or obedience.”

As “compliance” is used in relation to the standards advocated by QCA, it is complying to regulatory and legal standards, best practice standards and other applicable voluntary standards as appropriate. Companies’ practices that have been accredited under the auspices of QCA are deemed to MEET OR EXCEED requirements, whether those requirements are regulatory (legal) in nature or best practices.

Product Safety Systems Compliance

QCA measures and evaluates the management practices – a company’s policies, procedures and protocols – that provide for the predictable output of safe product continuously manufactured and shipped under the company’s name. Management practices must at minimum assure conformance with all applicable regulatory (legal) requirements related to design and construction of the company’s product line.

All accredited companies must have:

- A documented protocol for assuring continuous updates to information impacting applicable legal requirements related to the company’s product line
- A documented format for communicating product requirements
- A documented means for communicating banned and restricted substances to those manufacturing products on the company’s behalf
- A documented protocol for validating product prior to the commencement of manufacture, whether new product or new manufacturing facility
- A documented protocol for validating conformance of finished product with approved product and legal requirements that, at minimum, include annual testing of all products
- A documented protocol to validate all regulatory requirements are adhered to
- A documented supplier selection program
- A documented protocol for implementing an effective and efficient recall system that includes traceability down to all components and raw materials, as applicable
- Product safety compliance-related accountabilities assigned to a senior position

Product Safety Systems Best Practices

Best practices are those activities implemented by individual companies that assist in achieving compliance over a set of processes. Not all accredited companies will adopt identical best practices. Companies frequently have different methodologies for achieving the same outcome. Arguably, best practices are considered to be strategic decisions on the part of a company given their internal structure, size and product line.

Best practices advocated for the predictability they offer in manufacturing safer product include, but are not limited to:

- Development checklists including a review of applicable regulatory requirements
- Pre-production approval processes that include testing of approval samples
- Supplier scorecards incorporating onsite evaluation
- In-line sampling and inspection of manufactured products
- In-house testing of a representative sample size of all lots or batches of finished product received
- Documented supplier corrective actions
- Product safety compliance training provided to all members of a company, as appropriate to their level of interaction with the product and the end user
- Appointment of a compliance officer

Product Safety Testing

Testing has always been considered a valuable tool in measuring compliance. Testing may be administered in-house or through an approved third party. Some finished product must be evaluated by an approved and certified third-party laboratory. Other product may be tested in-house. The legal guidelines regarding the applicable testing that must be conducted for a product may be found in the regulations related to that product.

In-house testing is distinct from a third-party test in that the testing procedures are conducted by a party with interests in the supply chain for the product. A raw material supplier may test the product and, unless the testing is conducted through a third party, cannot certify the raw material. A manufacturer may test the product and, again, unless the testing is conducted through a third party, cannot certify the finished product. Testing conducted by an agent, a consolidator or a forwarder is also considered to be in-house. Testing, no matter how sophisticated in these examples, is considered to lack the credibility of a third-party test.

In-house testing labs frequently do not have the equipment and investment that are required to achieve ISO 17025, the ILAC (International Laboratory Accreditation Cooperation) standard recognized for qualifying third party laboratories. Frequently, In-house labs include scales, calibration tools and other performance testing tools. Many companies have testing tools such as XRF equipment they actively use, allowing them to screen for issues. While these are recognized best practices and they may meet the requirements for “testing” in a voluntary environment depending on the legal requirement, they do not meet the requirement of third party if the regulation expressly states third party testing is required for demonstrating compliance.

Determining the Applicable Regulatory Testing Standard

The nature and the use of the product may be two of many factors used to determine the classification of the item and, therefore, the applicable testing required for demonstrating compliance with regulatory standards. Adult standards may not apply to children's

product and, conversely, children's standards may not – and frequently do not – apply to adult product. Material content standards may vary between the item and its components, which may include surface coatings and inaccessible parts. A different standard may apply to a box intended to hold paper clips than the same box that holds breath mints. The precision of the description of the product and its intended use and potential user are imperative to determining the applicable performance standard, the appropriate tests and the nature of acceptable testing.

QCA accredited companies have policies, procedures and protocols that assure product safety through manufacturing practices that provide for the clear definition and classification of product, what materials may be used in the manufacture of that product, an approval and evaluative process for the product and an effective process for retrieving noncompliant and unsafe product from the market when all other product safety checks fail.