SELECTING METHODS OF CONFORMITY FOR REGULATORY SCHEMES

Conformity assessment (CA) is a valuable tool used to support regulatory frameworks and industry oversight programs. CA includes testing, inspection, and certification among others and can involve pre and post market surveillance. The level of CA used can depend on several factors; this document offers suggestions and recommendations to assist scheme owners in selecting the right level of CA for their use. The suggestions provided below will not fit with every oversight program but represents what is generally the case for each method of conformity.

1. Questions for agencies to consider when deciding on a method of conformity that best meet their confidence needs

When a decision has been made to regulate (or recognize/reference standards) to address a specific hazard or risk, how to choose the appropriate method of conformity? How does the role of government change under each method?

In general, the requirement for a particular level of rigor in the conformity assessment process is determined by the risks associated with the product, process, or service and its scope of use. The appropriate conformity assessment mechanism is also determined by other market factors, such as the legal system and the general philosophy of pre-market conformity assessment versus a fully funded post-market surveillance system. The confidence level needed is based on the risk of non-compliance and what market-driven mechanisms exist as mitigation tools for non-compliance. Part of a full analysis would include the pre-market and post-market structure that would be required. The choice of that structure has implications for costs of related government infrastructure, socio-economic costs, costs of establishing and sustaining technical competency levels, and capacity of those providing the service.

Below is a table that summarizes a few questions that agencies should consider when deciding on a method of conformity that best meet their confidence needs with the answers depending on the method of conformity. The answers below are not always this clear cut but represents what is generally the case for each method of conformity.

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QUESTIONS:	FIRST-PARTY	THIRD-PARTY
1. Is a high level of confidence required?	No	Yes
2. Is the perceived risk high?	No	Yes
3. Are products regulated primarily manufactured in countries with a history of risk factors and other issues?	No	Yes
4. Are products manufactured in complex and fragmented supply chains?	No	Yes
5. Is there a documented history of industry compliance?	Yes	No
6. Is there a documented history of industry non-compliance?	No	Yes
7. Is there evidence that product liability is an effective deterrent?	Yes	No
8. Do regulatory authorizing/statutory provisions provide severe penalties and an effective deterrent?	Yes	No
9. How strong is the need for impartiality and independence?	Low	High
10. Are there voluntary, market driven schemes that address confidence needs?	Yes	No
11. Are there relied upon accepted international schemes that can be leveraged?	Yes, and sufficient to meet confidence needs	Yes, but insufficient
12. What are the societal risks of non-compliant products?	Low	High
13. Who bears the costs of market surveillance?	Primarily governments	Private sector
14. How likely is the need for recall or corrective action?	More likely	Less likely

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2. Methods of conformity agencies can choose to satisfy their confidence needs

In general, there are three approaches to conformity assessment: **First-Party** (manufacturer), **Second-Party** (purchaser or user) and **Third-Party** (independent entity).

First-Party Conformity Assessment: "Performed by the person or organization that provides the object" [1], that is, the **supplier or manufacturer demonstrates that a product or service fulfils specified requirements,** and it is typically used when there is a lower level of risk associated with non-compliance and with the product. In First Party Conformity Assessment, the resulting statement of conformity is commonly referred to as the Supplier's Declaration of Conformity (SDoC).

For a First-Party conformity assessment model to work:[2]

- The risk of noncompliance must be low;
- The risk of the product must be low;
- There is confidence that manufacturers understand the technical, regulatory and market requirements and has satisfactory control over their supply chain;
- There are adequate penalties for placing noncompliant products in the market, which include - but are not limited - to:
    - civil and criminal penalties
    - product recall, and/or
    - product bans; and
- There is a **fully-funded** post market surveillance system in place that quickly and effectively removes noncompliant products from the market in order to avoid injury and societal costs. A post market surveillance system should consist of:
    - mechanism for customer complaints,

[1] https://www.iso.org/standard/29316.html
[2] ACIL: https://c.ymcdn.com/sites/www.acil.org/resource/resmgr/imported/ACILsDoCPositionPaper.pdf

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- marketplace surveillance and testing,
- factory surveillance and testing, and
- regular independent audits of individual manufacturers' declarations of conformity.

A **fully-funded** post market surveillance system is a key requirement for a first-party conformity assessment model to be successful and avoid a high incidence of non-compliant products on the market that can contribute to health and safety issues and other socio-economic costs.

Second-Party Conformity Assessment

"Performed by a person or organization that has a user interest in the object" [3], that is, the end user or entity acting in the interests of the end user, or an individual or group whose primary interest is in fulfilment of requirements demonstrates for itself that specified requirements are fulfilled.

Second parties may not always have business models that allow them to maintain the infrastructure, processes and technical competence to cost-effectively take advantage of this approach. Also, costs of goods and services can increase if suppliers face a high number of demands from individual second parties each carrying out their own conformity assessment. Therefore, second parties often rely on third-party conformity assessment to fulfil their confidence needs in a cost-effective manner.

Third-Party Conformity Assessment

Performed "by a person or body whose interests in the product are independent from those of first parties and whose interests in fulfilment of requirements are independent from those of second parties."[4]

Independent third-party conformity assessment bodies (CABs) may be accredited and regularly assessed by accreditation bodies as proof of qualification (competence) to provide services as a result of accreditation to international ISO/CASCO standards such as: ISO/IEC 17025 for testing, ISO/IEC 17020 for inspection and ISO/IEC 17065 for certification. This

[3] https://www.iso.org/standard/29316.html
[4] https://www.iso.org/standard/29316.html

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accreditation also includes an in-depth review of their documented management systems used to assure ongoing compliance with these international standards. The accreditation bodies may be either government bodies, recognized accreditation bodies operating under international guides, or a combination of both.

Third-party is widely relied upon in many markets when[5]:

- There may be a **higher risk associated with non-compliance;**
- There may be a **higher risk from products;**
- There is need for an **independent** demonstration to the supply and demand chain such as consumers, manufacturers and regulators that a product fulfils specified requirements;
- There is need for **higher levels of confidence and assurance of compliance** with safety, health or environmental requirements;
- Manufacturers seek to **reduce in-house compliance costs** or apply third-party as an added value to their own quality and conformity assessment procedures to gain global market access and protect their brands and reputation; and/or
- There are **limited government resources to fully fund market surveillance systems.**

3. Third-party conformity assessment – Testing and Certification options

Within third-party there are various options; in some cases, there will be a need for a full certification and others third-party testing only. Sometimes the agency may need only facility audits or inspections or a combination of different procedures. Again, it will depend on various factors and the levels of confidence needed will drive the decision. For instance, if the agency has no resources for funding post-market surveillance and the risks associated with the product and with non-compliance are high, the agency might consider full certification. If the risks of non-compliance are low, there are liability laws and penalties that function as effective deterrents, and there is adequate post-market surveillance, then the agency might consider

[5] ACIL: http://c.ymcdn.com/sites/www.acil.org/resource/resmgr/imported/The%20Value%20of%20Third%20Party%20Certification.pdf

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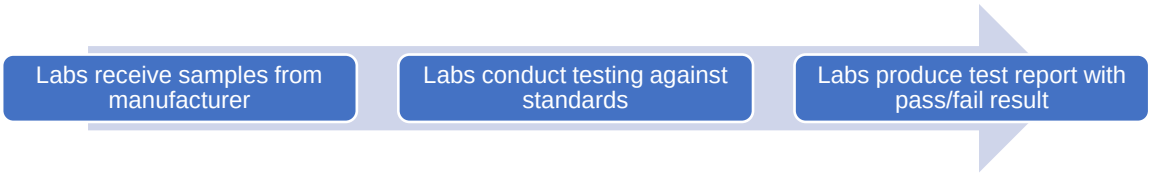
SDoC. If the situation is somewhere in between, perhaps third-party testing requirements might be an effective tool.

Below are a few examples to illustrate third-party testing and third-party certification:

Third-party Testing:



When conducting testing only, the laboratory role is limited to receiving samples, testing against standards and reporting pass/fail results. Labs have no control of, nor information about:

a. Whether manufacturers are testing "golden samples";

b. Any material changes by the manufacturers when receiving a request from manufacturers to transfer data from old test reports or from reports issued by other labs;

c. Whether the sample is representative of the entire production;

d. Whether manufacturers have reasonable testing programs in place;

e. Whether labs meet the applicable accreditation requirements when receiving test results from reports issued by other labs;

f. Whether manufacturers' supply chains ensure traceability and there are documentation controls in place; and

g. Whether there is a system to offer testing to maintain continuing compliance

The U.S. Consumer Product Safety Commission (CPSC) third-party testing requirements for children's products is an example of the use of third-party testing as one of the tools in the regulator's toolbox to ensure products are safe. It is used in combination with other non-compliance deterrence measures, such as civil and criminal penalties, market and import

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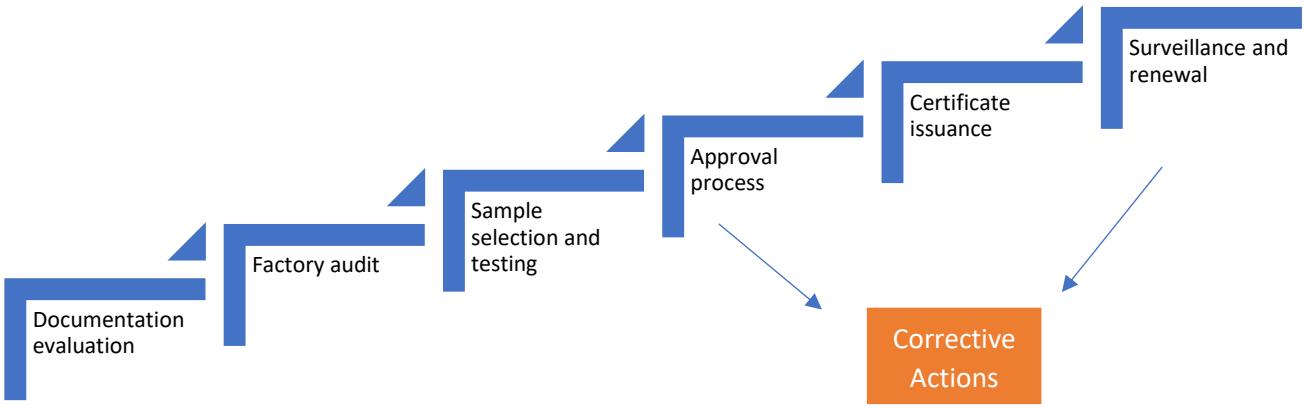
surveillance, education of the supply chain on CPSC requirements, and a product recall system. Other market-driven aspects such as product liability and retailers' programs also provide further incentive for compliance.

Third-party Certification:

Certification bodies conduct extensive review of a product's manufacturing process and make a determination that the product (or system, process, person) complies with applicable standards. The certification process includes periodic testing, inspection and factory auditing. It provides higher levels of assurance of ongoing compliance throughout the entire production process with corrective actions in place if non-conformities or issues are identified during the process.

The Environmental Protection Agency (EPA) Energy Star program is an example of a voluntary public-private partnership that relies on independent third-party certification to help ensure ongoing compliance and the integrity of the Energy Star label. Third-party requirements were introduced after high levels of non-compliance were identified by an investigation from the Government Accountability Office (GAO). Reliance on third-party certification helps maintain consumer trust in the Energy Star designation and improve oversight of the program while allowing the agency to save scarce resources since evaluation and market surveillance is performed by the private sector.

Below is an overview of the certification process:



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About TIC Council

TIC Council is the global trade federation representing the independent third-party Testing, Inspection and Certification (TIC) industry which brings together more than 90-member companies and organizations from around the world to speak with one voice. Its members provide services across a wide range of sectors: consumer products, medical devices, petroleum, mining and metals, food, and agriculture among others. Through provision of these services, TIC Council members assure that not only regulatory requirements are met, but also that reliability, economic value, and sustainability are enhanced. TIC Council's members are present in more than 160 countries and employ more than 300,000 people across the globe.

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