Developing a Risk-based Conformity Assessment System

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Innovation inherently creates risk
Services for today’s challenges

- TESTING
- INSPECTION
- CERTIFICATION
- AUDITING
- VALIDATION
- TRAINING
Conformity Assessment Defined

“demonstration that specified requirements relating to a product, process, system, person or body are fulfilled”

• Includes activities such as:
  • Testing
  • Inspection
  • Certification

Source: ISO/IEC 17000
Key Elements of Compliance

**Compliance Systems** *(Market Access)*
Rules and Regulations that define a market

**Conformity Assessment**
Available paths which compliance can be verified (design, production, documentation)

**Technical Requirements / Standards**
Minimum requirements used for evaluating compliance (may be mandatory or voluntary)

**Market Requirements** *(Market Acceptance)*
Additional requirements to those of the compliance system to establish confidence in the marketplace
A Balanced Approach to Conformity Assessment

Consensus Standards
- Industry
- Consumers
- Authorities
- Certifiers
- Interested Parties

Pre-Market Assessment and Certification
- Verification of Conformity to the Standard
- Factory Pre-Inspection & Approval

Ongoing Factory Surveillance
- Verification That Product “As Built” Conforms to the Approval

Post Market Surveillance
- Random Purchase at Retail and Verification Testing
- Anti-Counterfeiting
- Communications with Regulators

Threshold of Safety
- Ensuring Safety Entering the Market

Avoid Adulteration
- Monitor Real-Life Outcomes

Recipe for maintaining “Integrity & Trust” while balancing “Safety & Time-to-Market”
<table>
<thead>
<tr>
<th>Conformity assessment functions and activities&lt;sup&gt;a&lt;/sup&gt; within product certification schemes</th>
<th>Types of product certification schemes&lt;sup&gt;b&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>I</strong> Selection, including planning and preparation activities, specification of requirements, e.g. normative documents, and sampling, as applicable</td>
<td>1a 1b 2 3 4 5 6 N&lt;sup&gt;c,d&lt;/sup&gt;</td>
</tr>
<tr>
<td>II Determination of characteristics, as applicable, by:</td>
<td></td>
</tr>
<tr>
<td>a) testing</td>
<td>x x x x x x x x</td>
</tr>
<tr>
<td>b) inspection</td>
<td></td>
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<tr>
<td>c) design appraisal</td>
<td></td>
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<tr>
<td>d) assessment of services or processes</td>
<td></td>
</tr>
<tr>
<td>e) other determination activities, e.g. verification</td>
<td></td>
</tr>
<tr>
<td>III Review</td>
<td></td>
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<tr>
<td>Examining the evidence of conformity obtained during the determination stage to establish whether the specified requirements have been met</td>
<td>x x x x x x x x</td>
</tr>
<tr>
<td>IV Decision on certification</td>
<td></td>
</tr>
<tr>
<td>Granting, maintaining, extending, reducing, suspending, withdrawing certification</td>
<td>x x x x x x x x</td>
</tr>
<tr>
<td>V Attestation, licensing</td>
<td></td>
</tr>
<tr>
<td>a) issuing a certificate of conformity or other statement of conformity (attribution)</td>
<td>x x x x x x x x</td>
</tr>
<tr>
<td>b) granting the right to use certificates or other statements of conformity</td>
<td></td>
</tr>
<tr>
<td>c) issuing a certificate of conformity for a batch of products</td>
<td>x x x x x x x x</td>
</tr>
<tr>
<td>d) granting the right to use marks of conformity (licensing) is based on surveillance (VI) or certification of a batch.</td>
<td>x x x x x x x x</td>
</tr>
<tr>
<td>VI Surveillance, as applicable (see 5.3.4 to 5.3.8), by:</td>
<td></td>
</tr>
<tr>
<td>a) testing or inspection of samples from the open market</td>
<td>x x x</td>
</tr>
<tr>
<td>b) testing or inspection of samples from the factory</td>
<td>x x x</td>
</tr>
<tr>
<td>c) assessment of the production, the delivery of the service or the operation of the process</td>
<td>x x x</td>
</tr>
<tr>
<td>d) management system audits combined with random tests or inspections</td>
<td>x x</td>
</tr>
</tbody>
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<sup>a</sup> Where applicable, the activities can be coupled with initial audit and surveillance audit of the applicant's management system (an example is given in ISO/IEC Guide 53) or initial assessment of the production process. The order in which the assessments are performed may vary and will be defined within the scheme.

<sup>b</sup> An often used and well-tried model for a product certification scheme is described in ISO/IEC Guide 28; it is a product certification scheme corresponding to scheme type 5.

<sup>c</sup> A product certification scheme includes at least the activities I, II, III, IV and V a).

<sup>d</sup> The symbol N has been added to show an undefined number of possible other schemes, which can be based on different activities.
Technical Barriers to Trade (TBT) Agreement references various mechanisms for demonstrating a product’s compliance with requirements.

Third party Conformity Assessment and SDoC are listed as valid options, among others.

Stipulates that governments have the right to choose the method of conformity that meets their confidence needs.

Article 5 states that Members must ensure that conformity assessment measures do not create unnecessary barriers to trade.
3rd Party Conformity Assessment Value Chain

- CLIENT
  INTERACTIVE
  PROGRAMS

- SUPPLIER

- THIRD
  PARTY

- MARKET
  ACCESS

- CONFIDENCE
- VALUE

- ACCREDITATION

- ACCEPTANCE
  AUTHORITY #1
- ACCEPTANCE
  AUTHORITY #2
- ACCEPTANCE
  AUTHORITY #3
The NRTL Program and Benefits of Relying on Private Sector Organizations

OSHA’s Nationally Recognized Testing Laboratory (NTRL) Program recognizes private sector organizations as NRTLs to determine that specific products meet consensus-based safety standards to provide the assurance that these products are safe for use in the US workplace.

<table>
<thead>
<tr>
<th>How does OSHA benefit from reliance on private sector NRTLs?</th>
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<tbody>
<tr>
<td>• Recognition Process that Preserves Confidence</td>
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<tr>
<td>• Reduces Government Costs</td>
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<tr>
<td>• Lessens OSHA’s Market Surveillance Burdens</td>
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<tr>
<td>• Positively Affects the Development of Standards</td>
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<tr>
<td>• Promotes International Trade</td>
</tr>
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</table>
Purpose: To gauge the effectiveness of ensuring safety of consumer products, comparing self declaration system and 3rd party testing and certifications
IFIA Study: Methodology

Purchase products from the market and send to an independent laboratory not affiliated with IFIA.

- Electric Fans
- Toasters
- Heating Devices
- Luminaires
- Chargers for IT products
- Room heaters
- Hair dryers
- Hair curlers, straighteners
- Irons
- Small power tools
Of the 319 samples submitted, 77% were NOT in compliance with EU standards and regulations.

Safety-critical failures were found in 1 out of every 7 products tested were of (i.e. high risk of fire, permanent injury, etc) which were reported to local authorities (48 instances [15%])
Of the 139 samples submitted, there was only 1 instance (0.7%) of safety-critical failures, which was immediately reported to the certifier, and then to the manufacturer.
Of the 185 samples submitted, there were 2 instances (1%) of safety-critical failures, also immediately reported to the certifier, and then to the manufacturer.
IFIA Study: Other EU Data

- Online purchasing results (2015 survey) did not change in any significant manner from the past
- Percentage of products actually inspected by market surveillance authorities = 0.3%
- Percentage of domestic accidents due to faulty products that are reported by EU consumers = 1%
- Rate of success for first-time product submittals: 50%
- Percentage of periodic factory inspections that yield:
  - Safety-critical issues: 10%
  - Non-compliant findings: 15%
- Other directives (R&TTE): 69% of products 2014 not in compliance. Drones (remotely piloted aircraft systems): 92% not in compliance
- 13% of tablet PCs pulled from Germany and Netherlands’ markets in 2012 were ‘in compliance’.
- UK: 2011-2014 ~12,000 house fires were caused by faulty white good appliances. Recalls success < 20%.
Toy recalls/notifications in the EU and US

US Congress adopts CPSIA
Case Study: Impact of Third Party Testing on Toy Recalls in the US
Best Practices

- National Treatment
- Use of Independent Third Parties
- International Harmonization of Requirements
- Conformity Assessment Selection Based on Risk Level
- Public-Private Partnerships
- Private Sector, Consensus Based Standards
- Intellectual Property Protections
- Standards & Conformity Assessment in Government Procurement
- Science Based Risk Assessment
Asante Sana!
Transportable Conformity Assessment℠
Case: Flow of a CB Test Report (CBTR)/CB Test Certificate (CBTC)

Country A

Sector 1
NCB (I)
Conformity Assessment

SUPPLIER

Country B

Sector 1
NCB (R)
Product Certification

Acceptance of NCB (I) Conformity Assessment via G – 2 – G MRA

SDoC based on NCB (I) Conformity Assessment

Satisfaction of Market / Regulatory demands for Conformity Assessment: Market Acceptance

National Certification

CBTC