Conformity Assessment in Practice

Fundamentals of Standards and Conformity Assessment for Government Agencies

Hosted by NIST Standards Coordination Office

June 23, 2016

About ITI

- The Information Technology Industry Council (ITI) is the premier policy and advocacy organization for the world's leading innovation companies.
- We advocate for global policies that advance industry leadership, open access to new and emerging markets, promote e-commerce expansion, drive sustainability and efficiency, protect consumer choice, and enhance worldwide competitiveness of our member companies.


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How & Where We Work

- ITI engages in domestic and global policy discussions through four teams of experts:
  - Environment & Sustainability
  - Global Policy
  - Government Affairs
  - Public Sector (ITAPS)
- Our primary areas of focus include:
  - Accessibility, broadband, conflict minerals, cybersecurity, encryption, energy efficiency, procurement policy, IoT, privacy, Smart Cities, tax policy, trade and market access, work force
- Our primary areas of engagement include:
  - U.S. (federal, state and some local); Latin America; Europe; Asia (particularly China, India and South Korea)
- We also host INCITS: The International Committee for Information Technology Standards

SECTION I

Why Conformity Assessment is Important to the Global Information & Communications Technology (ICT) Sector

Conformity Assessment: Impact on Trade in ICT

- We are a global industry and we sell our products in virtually every market in the world. Our primary objectives revolve around consistency (see also: “alignment”, “standardization” & “uniformity”)
- Consistency provides certainty and predictability to manufacturers and our suppliers, and generates broad benefits for our customers (including government):
  - Cost advantages
  - Interoperability and reliability
  - Availability of products and parts

Conformity Assessment: Impact on Trade in ICT

- Trade in ICT products is especially affected by standards and conformity assessment requirements, because ICT products typically -
  - Are designed for the global market
  - Have a large number of components and rely on complex global supply chains
  - Are constantly evolving in response to user demands and technological advances
  - Are deployed in a wide and varied array of scenarios and sectors
  - Are highly configurable. (One product family can have hundreds of different configurations.)

Conformity Assessment: Tech Sector Objectives

- Consistent Requirements: International standards help drive certainty and uniformity on product design and performance across all markets
- Consistent Application: Uniform interpretation and application of standards accelerates time to market, saves costs and benefits customers
- Consistent Testing: The ability to test a given product one time against one standard and then sell that product in global markets benefits everyone
- Consistent Verification: Standard approaches to post-market surveillance, verification and enforcement are essential to the integrity of the system

Conformity Assessment: Our Dreams & Aspirations

Manufacture a single product for the global market

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Test one time against a globally recognized standard

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Meet conformity assessment requirements that are risk-based and least trade restrictive to meet legitimate regulatory objectives

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Conformity Assessment: A Complex Reality

- Over 80 countries have regulations for ICT products
  - Most countries reference international standards/specifications. Some have national standards with significant deviations.
  - Many accept test results from any competent (e.g., accredited) lab. Others require testing be performed by local designated labs.
  - Many accept Supplier's Declaration of Conformity (SDoC). Others require third-party certification by designated bodies.
  - Some require factory audits and accept results from other certification bodies. Others require that they conduct the audits themselves.
  - Many conduct market surveillance. Many others do not.
- The resulting patchwork of regulations (duplicating, conflicting, diverging) works counter to an efficient and effective program that maximizes global leverage and minimizes cost

Conformity Assessment: The Stakes

- Costs to industry (and therefore to our customers) include:
  - Redundant, often unnecessary testing and/or certification procedures
  - Additional administrative 'paperwork' burdens
  - Back-up of products at the border, at test labs, or within the supply chain cause delays to market
  - In some cases, manufacturers/importers may need to reconsider costs of market entry
- Actual Financial impacts are significant:
  - Depending on the market, initial (fixed) costs for a single country can be $10,000,000s
  - Longer term losses (e.g., from delays to market to the complete stoppage of imports) may be $100,000,000s - $1,000,000,000s.
- These translate into higher in-country costs and reduced availability of the latest technologies needed to compete in the global economy

SECTION II

How the ICT Sector Manages Conformity Assessment in Our Global Supply Chains

Conformity Assessment: Tech Sector Practices

- Before we can design, manufacture, market and distribute the latest innovation, we must have rigorous systems in place throughout our global supply chains to ensure our products satisfy all applicable requirements.
- Most manufacturers use a Conformity Assurance Process (or System)
  - While no two companies do it exactly the same way, the basic elements are consistent
- The process is based on the assessment of relative risk
  - Not “risk” as in hazard + exposure
  - Established supplier relationship with simpler parts or products = low risk
  - New suppler, supplier with prior issues, or very complex process = higher risk

Conformity Assessment: Tech Sector Practices

- Risk rating and type of product will determine what evidence is collected
  - Negative declarations ("substance X is not in this part")
  - Positive or "inventory" declarations (part contains substances X, Y and Z and concentration levels)
  - Testing by supplier showing how they arrived at declaration
  - Testing by manufacturer to verify supplier declaration and testing results
    - Manufacturers will very often sample and perform "spot check" of products
    - Most analytical testing is destructive, so will never have test data for "that" specific device
  - Third-party certifications and/or conformity marking (UL or CE marks)

Conformity Assessment: Tech Sector Practices

- Manufacturers will evaluate all evidence collected for quality and accuracy
  - Ensure that the data is reliable, relevant and complete
- Have a plan in place for identifying and correcting adverse findings ("negative results")
  - Need to determine issues before the product is on shelves
- Institute corrective action plan to:
  - Identify the specific source of the non-conformance
  - Ensure the availability of conforming replacement parts
  - Review relationship with supplier
- Establish a process of continuous improvement

Conformity Assessment: Tech Sector Practices

- The ICT sector relies on complex software systems and tracking to advance conformity assessment
  - Extremely data-intensive process
  - Involves a system (usually computerized) to manage, track, analyze, store and report data across numerous metrics
- There are a number of off-the-shelf software systems in the marketplace
  - Companies will customize these platforms to meet their unique needs

Conformity Assessment: Tech Sector Practices

- These systems track:
  - Parts and subassemblies
  - Supplier declarations and materials data
  - Supplier relations and “trustworthiness of the supplier” (actual term used in EU RoHS Directive)
  - Analytical testing data – mathematical data from lab test (e.g., a metal contains 500 ppm lead)
    - From both supplier and manufacturer
  - Empirical data – process and engineering knowledge (e.g., you don’t need to test metals for halogen content; recycled plastics will likely contain flame retardants, etc.)

Section III

Challenges & Recommendations in Conformity Assessment Processes

Common Challenges

- Lack of consistent application:
  - Different labs/verifiers may hold varying interpretations of what “conformance” means and what data and documentation is required to establish it
    - Verifiers have required far more extensive documentation of conformance than that required by regulatory agencies to satisfy their own government requirements
- Unique national approaches:
  - Some countries recognize international standards but mandate in-country testing as a price of market access
    - This often involves national labs and can lead to additional costs, market access delays, and favoritism being shown to native manufacturers
  - Some countries also require companies to periodically “re-validate” their products

Overall Recommendations

- Determine need for voluntary or mandatory requirements
- Seek global alignment of requirements
- Solicit input from industry and other stakeholders
- Understand and factor in the global nature of the ICT industry and its products
- Consider timelines for adoption, implementation, and transitions
- Follow a risk-based conformity assessment model
- Leverage existing international resources and agreements
- Set minimal marking/labeling requirements

Bottom Line: Industry, economies and consumers have much to gain or lose

Recommendations for ICT Products

- Generally low-risk products built to meet or exceed globally recognized standards (e.g,. RoHS, product safety and EMC)
- Long history of product compliance with minimal issues in the field
- SDoC recognized as preferred conformity assessment for EMC for ICT products
    - See ITA Guidelines for EMC/EMI Conformity Assessment Procedures, 2005
- ITI supports this position and encourages governments globally to consider it
- We also look to multilateral solutions including discussions in APEC and are actively working on it in the TPP.

Contact Information

Rick Goss
Senior Vice President of Environment and Sustainability
Information Technology Industry Council

202-626-5724
Email: rgoss@itic.org
Website: www.itic.org

Additional Information

"Worldwide, the ICT industry has a proven track record in providing safe, high quality, state-of the-art products. The industry has worked closely with government groups and other formal standards setting bodies to develop internationally recognized standards in areas such as product safety and electromagnetic interference for a wide range of products (e.g., computers, monitors, storage devices, and telecommunications equipment). Nearly all governments that regulate in these areas have adopted some form of these international standards, and this alignment has greatly facilitated global trade."

- Joint ITI-DigitalEurope comments on the Transatlantic Trade and Investment Partnership (TTIP) (February 2015)

Conformity Assessment: Tech Sector Objectives

"However, the proliferation of unique regulations in the areas of testing and certification requirements to show conformance with such international standards is now seriously diminishing their benefits. Many of these national conformity assessment requirements cause repetition of tests that have already been performed and thus provide no additional benefit to customers or to societies. Redundant testing and certification increases customer costs, limits choice, and delays market entry—in many cases, by weeks or months, which is significant given the rapidly development and marketing/sales cycle of ICT products."

- Joint ITI-DigitalEurope comments on TTIP (February 2015)

Conformity Assessment: Tech Sector Objectives

"A successful model for overcoming these regulatory hurdles is reliance upon a declaration of conformity by suppliers and effective post-market regimes (including surveillance and enforcement) which together offer a more flexible, trade-friendly method to meet regulatory objectives. The Supplier's Declaration of Conformity (SDoC) model has been used for a wide variety of products in the US, EU, and in many other countries."

- Joint ITI-DigitalEurope comments on TTIP (February 2015)