Use of Conformity Assessment Procedures in Regulation

SESSION 4:
ANSI STANDARDS ALLIANCE / GCC GSO Workshop – Riyadh

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Conformity Assessment in support or enforcement of a regulation:

“A means to determine if a process, product, or service meets relevant requirements of standards or regulations and that relevant technical specifications is met in full.”

Conformity assessment activities may include: Testing, Surveillance, Inspection and Certification to meet compliance objectives”
Key factors for using Conformity Assessment (CA) in regulatory practice:

- Good regulatory practice
- Functional approach to conformity assessment
- Identifying controlled products and requirements
- Conformity assessment scheme design and ownership
- Investment and costs of conformity assessment options
- Conformity assessment and competition
- Risk management
- Access to competent resources
- Surveillance
Conformity Assessment: (CA)

Deciding Best Practice:

<table>
<thead>
<tr>
<th>Nature of risk involved</th>
<th>Complexity</th>
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<tbody>
<tr>
<td>Capability to access assessment options</td>
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<tr>
<td>Cost</td>
<td>options considered</td>
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<tr>
<td>Independence</td>
<td>Controls, Recognition</td>
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<td>Market acceptance of option selected</td>
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Conformity Assessment: (CA)

Functional approach to CA

- Selection
- Determination
- Review and attestation
- Surveillance

= System Type Decision

Object Specific

Selection

Determination

Surveillance

Review and Attestation

Nature and frequency of market surveillance

Decision, Declaration, Certification, Mark of Conformity

Audit Calibration Evaluation Examination Inspection Testing
Conformity Assessment: (CA)

Identifying controlled products and requirements:

- Evidence, trends of failure
- Statistics – Mortality / Injury
- Demographics – Who is at risk
- Prevalence – repeat failures
- Origin of supply chain
CA scheme design and ownership

01
Voluntary / Regulatory Schemes
Voluntary - are not legally binding, used as a market driver
Regulatory - Used to support regulation compliance

02
Scheme ownership
Responsibility for the scheme’s design, administration and maintenance.

03
Scheme – System Types: Schemes should be developed in accordance with ISO/IEC 17067:2013, declaring system Type approach.

04
Design
Ownership and responsibility of the scheme rules that govern the regulatory approach for CA.
Formally known as risk transfer:

Accreditation costs – CAB assessments

Business costs – CAB Skills / Recruitment / Training

In Summary:

Third party costs v Product Risk Balance
Conformity Assessment (CA)

Conformity assessment and competition

Maintaining quality and integrity levels of the scheme:

Antidote – Accreditation by peer assessment
Conformity  Assessment (CA)

Risk management:

- SDoC versus 3\textsuperscript{rd} Party
- Accreditation
- Statistical Analysis - Failures
- Market Complaints
- Standardisation approach
Conformity Assessment (CA)

Access to competent resources

- Training History
- Competency criteria
- Experience
- Technical Capability
- Appraisal / Authorisation
### Conformity Assessment (CA)

#### Market Surveillance (Who is watching who?)

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<tbody>
<tr>
<td><strong>Pre - Market</strong></td>
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<tr>
<td><strong>At Border</strong></td>
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<tr>
<td><strong>Post Market</strong></td>
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<tr>
<td><strong>SAMPLE INSPECTION / TESTING</strong></td>
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<tr>
<td><strong>PVOC (Pre Shipment Verification of Conformity)</strong></td>
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Conformity Assessment in support of Regulation: Case Study 1
Case Study 1 - USCG

Regulation 46 CFR - electrical equipment used offshore in hazardous locations.

Effective 02 April; 2018

Product CA scope - MODU & OSV (OCS)

Recognition – IECEx Certification / tested by accredited CABS to 46 CFR 110.15-1. (NRTL accredited)

Mandatory Conformity Marking – Type 5a

ATEX EU Type Certification alone under 2014/34/eu not accepted.

New build - detailed risk plan for all hazardous area classifications
Case Study 2:

GCC GSO  LV TR BD -142004-01 (RCAS)

Effective 01 Jul 2016

Type 1a program

IECEE CB scheme – presumption of conformity of ESR’s - Annex 1

Accreditation to ISO / IEC 17065 for Notification (GAC)

CAP for conformity specified in Annex 4, BD -142004-01

Mandatory Conformity Marking for specific products in scope