Developing a risk-based conformity assessment system (CAS)

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TOPICS:

01. CAS – Where is the risk?
02. Factors To Consider
03. Risk Assessment – planning / evaluation
04. Conformity Assessment System Design
05. Case Studies – US / AFRICAN CAS
CAS – Where is the risk?
Here:
Scotland, 1988 Piper Alpha
Loss of life -167
Cost – $ 2 Billion
Here:
Australia, Apr 2016.
28 year old woman from NSW electrocuted by faulty USB phone charger.
And here....

2016 - ESFI Extract
From Spring
Electrical Safety

Table 1. Electrocutions Related to Consumer Products and Death Rates Based on U.S. Po
Risk mitigation of product conformity is a global commitment, recognised by:

- World Trade Organisation (WTO)
- Standards Organisations
- National Government Authorities
- Manufacturers
- Trade organisations
- Testing, Inspection, Certification Industry (TIC)
- Retailers
- Consumers

Implementing a Conformity Assessment System using threat levels, reduces risk
CAS - Factors To be considered
What is a Conformity Assessment System? Ref: ISO / IEC 17000: 2004

1. Rules, procedures and management for carrying out conformity assessment. Can be operated at international, regional, national or sub-national level.

2. Relates to specified objects of conformity assessment, to which the same specified requirements, specific rules and procedures apply, can be operated at international, regional, national or sub-national level.

3. Conformity Assessment Gives:

   Confidence in connection with products, services, processes and personnel. The confidence connection facilitates both trade with arguably as much impact as standards, therefore when combined affect virtually all commerce.
### CAS: Factors To Consider:

#### Good Practice:
- Risk levels involved
- Complexity of CAS
- Practicality – Market levels
- Costs - All functions
- Degree of independence and Market acceptance

#### Functional approach to CAS:
- Selection
- Determination
- Review and attestation
- Surveillance

#### Identify controlled products and requirements:
- Empirical evidence
- Injury rates,
- Demographics
- Prevalence
- Supply Chain

#### CAS – scheme design:
- Voluntary and regulatory
- Scheme ownership
- Scheme types
  - ISO/IEC 17067:2013
  - ISO/IEC 17026

#### Costs of conformity assessment options:
- Investment Levels
- The “customer” impacts
- Accreditation
- 3 Party Bodies

#### Conformity assessment and competition:
- Provides choice
- Lines of resistance
- Accreditation
- Peer assessment
Risk management approach should be:
- Relevant
- Sector specific
- Object uncertainties
- Key players

Competent Authorities:
- Competency levels
- Sector specific
- Transition periods
- Accreditation, Peer assessment

Surveillance:
- Pre-market
- At-the-border
- Or post-market
- PVOC

All the above factors can be applied as a risk approach to determine a process or system by mitigation of risk, each key factor can be applied independently or by interrelation more than once within the Conformity Assessment System Design.
## 02: CAS: Factors To Consider

**Conformity Assessment – By 3 tier mitigation of risk:**
1st Party, 2nd Party and 3rd Party, ISO / IEC 17000: 2004 Definitions:

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
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<tbody>
<tr>
<td>1</td>
<td>First-party conformity assessment activity that is performed by the person or organization that provides the object. (Self Declaration)</td>
</tr>
<tr>
<td>2</td>
<td>Second-party conformity assessment activity that is performed by a person or organization that has a user interest in the object. (Code of practice / Trade organisation, Retailer needs)</td>
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<tr>
<td>3</td>
<td>Third-Party conformity assessment activity that is performed by a person or body that is independent of the person or organization that provides the object, and of user interests in that object. (Testing, Inspection, Certification or authoritative body)</td>
</tr>
</tbody>
</table>
### Two trains of thought?

| 01 | Object failure presents low risk - do nothing / 1<sup>st</sup> party CAS? Perceived high level of compliance? |
| 02 | Object failure presents high risk – 2<sup>nd</sup> / 3<sup>rd</sup> party CAS to be considered? |
| 03 | 1<sup>st</sup> party - conscientious manufacturer/ can result in better conformity than independent third-party assessment? |
| 04 | 3<sup>rd</sup> Party considered less frequent with time constraints, thus levels of compliance versus risk questioned? |
| 05 | However, 1<sup>st</sup> party do use 3<sup>rd</sup> party results / data to verify conformity - CE Marking? |

**Conformity Scheme Matrix**

- **High Level of Compliance**
  - DO NOTHING
  - SUPPIERS OWN DECLARATION
- **Low Level of Compliance**
  - Market / Media Drivers
  - 2<sup>nd</sup> or 3<sup>rd</sup> Party Conformity

**Level of Risk**

- Low
- High
02: CAS: Factors To Consider

- **01** 3rd Party intervention gives confidence to regulators and market drivers.

- **02** 1st Party CAS can deliver high % of non-conforming objects (CE marking surveillance).

- **03** Globally market/media drivers are demanding higher integrity and quality lean towards 3rd Party CAS.

- **04** 3rd Party is peer assessed by the regulators and or by appointed National Accreditation Bodies.

- **05** Mandatory and even voluntary CAS reduced risk and increase levels of object compliance.

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But in practice / experience:

**Conformity Scheme Matrix**

- **2nd or 3rd Party Conformity**
- **Market / Media Drivers**
- **Suppliers Own Declaration**
- **Do Nothing**

**Level of risk**

- **Low**
- **High**

**Level of compliance**

- **Low**
- **High**
02: CAS: Factors To Consider

Risk versus Independence / Integrity

- 1st Party Supplier / Manufacturer
- Specific Oversight 2nd Party
- 3rd Party Certification
- 3rd Party Certification / Accreditation

Independence / Quality & Integrity of Conformity Assessment
Risk Assessment – planning / evaluation
Risk Assessment / Analysis

- Identification of risk in a selected domain of interest (Market / Industry sector)
- Planning the process (Selection of program or system applicable)

Project Planning

- Mapping out the following:
  - The scope of risk management
  - The identity and objectives of stakeholders
  - The basis upon which risks will be evaluated, any constraints.

Implementation

- Defining a framework for the activity and an agenda for identification
- Developing an analysis of risks involved in the process
- Mitigation or solution of risks using available technological, human and organizational resources.
03: CAS: Risk Assessment – planning / evaluation

- Risk Assessment
- Project Planning
- Implementation
Conformity Assessment - System Design
The perceived risks associated with non-conformity

The practical means of evaluating the characteristics of interest.

The scale and type of production operation or delivery in the case of a service;
The effectiveness of marketplace mechanisms to remove non-conforming products from the market;

The effectiveness of penalties for placing non-conforming regulated products in the market; and

The effectiveness of systems to recall non-conforming regulated products from the market.
04. CAS: Conformity Assessment System Design

- Meets Market Needs – Manufacturers / Importers / Retailers / Consumers / Regulators
- Regulator Controlled – Deploys Transference of Risk
- Scaled Risk - 1st and 3rd Party Involvement
- Surveillance – Cross Border / Product Recall System
- National Accreditation Bodies / Peer Assessment
Case Studies – US / AFRICAN CAS
Case Study 1, USA approach to risk mitigation (HAZLOC)
CASE STUDY 1 - Further Standardization (HAZLOC)

Industry Sector Specific: HAZLOC
Exporting Countries: Global Market
Economic Players: USA & EU (Manufacturing / imports)
CAS deployment: Mandatory, 3rd Party, Peer assessed
Global Recognition / Acceptance: IECEx Scheme – Country Member Bodies
USA – Regulatory Scheme: OSHA Regulations & NRTL program
EU – Regulatory Scheme: EU Directives – Gov appointed Bodies
Market Acceptance: Program correlation – plus national deviations

…Greater flexibility, reduction of individual market requirements
CASE STUDY 2: PVoC (Pre-Export Verification of Conformity) for Exports to Kenya

Industry Sector: All imports to Kenya
Exporting Countries: Global Market
Economic Players: Global manufacturing base
CAS deployment: Mandatory, 3rd Party, Accreditation.
Scheme owner: KNEBS (Kenya Bureau of Standards)
Scheme Type: Type 1a – pre export inspection (PVoc)
Defined product list: Example, Pharmacy, Toxins, KEBS Diamond marked products,
Developing a risk-based conformity assessment system (CAS)

Thank you

Any Questions?