

Use of Conformity Assessment Procedures in Regulation

SESSION 4:

ANSI STANDARDS ALLIANCE /
GCC GSO Workshop – Riyadh

Bruce McGill

Vice President – Global Certification

Date 22/04/2017



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:

Nature of risk involved - Complexity

Capability to access assessment options

Cost - options considered

Independence - Controls, Recognition

Market acceptance of option selected

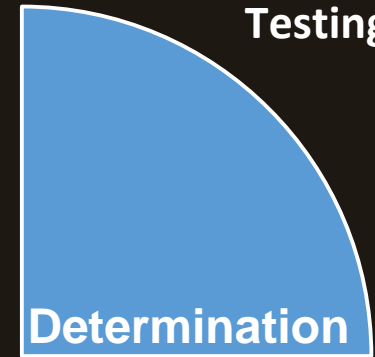


Conformity Assessment: (CA)

Functional approach to CA



Object
Specific t



Audit
Calibration
Evaluation
Examination
Inspection
Testing

Nature and
frequency of
market
surveillance

Decision,
Declaration,
Certification,
Mark of Conformity

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

Responsibility for the scheme's design, administration and maintenance.

Scheme ownership

03

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

04

Ownership and responsibility of the scheme rules that govern the regulatory approach for CA.

Design

Investment and costs of CA options

Complexity

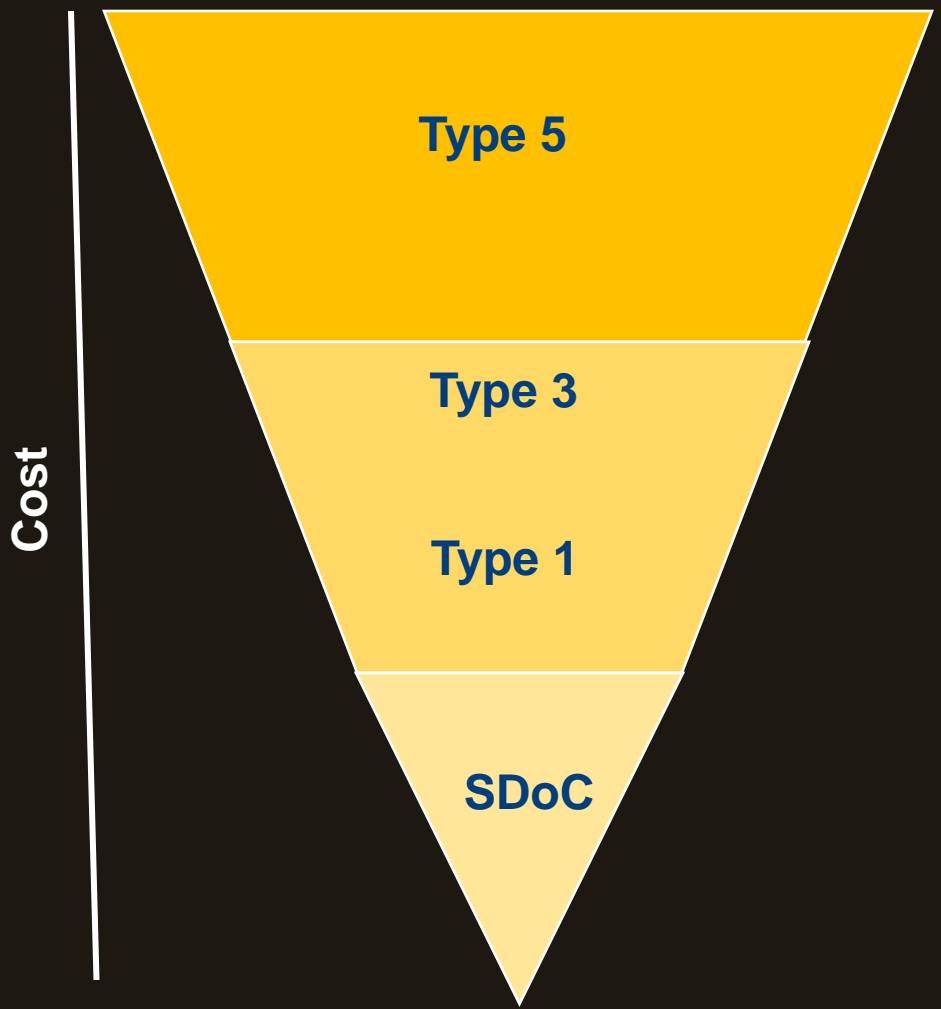
Formally known as risk transfer:

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:

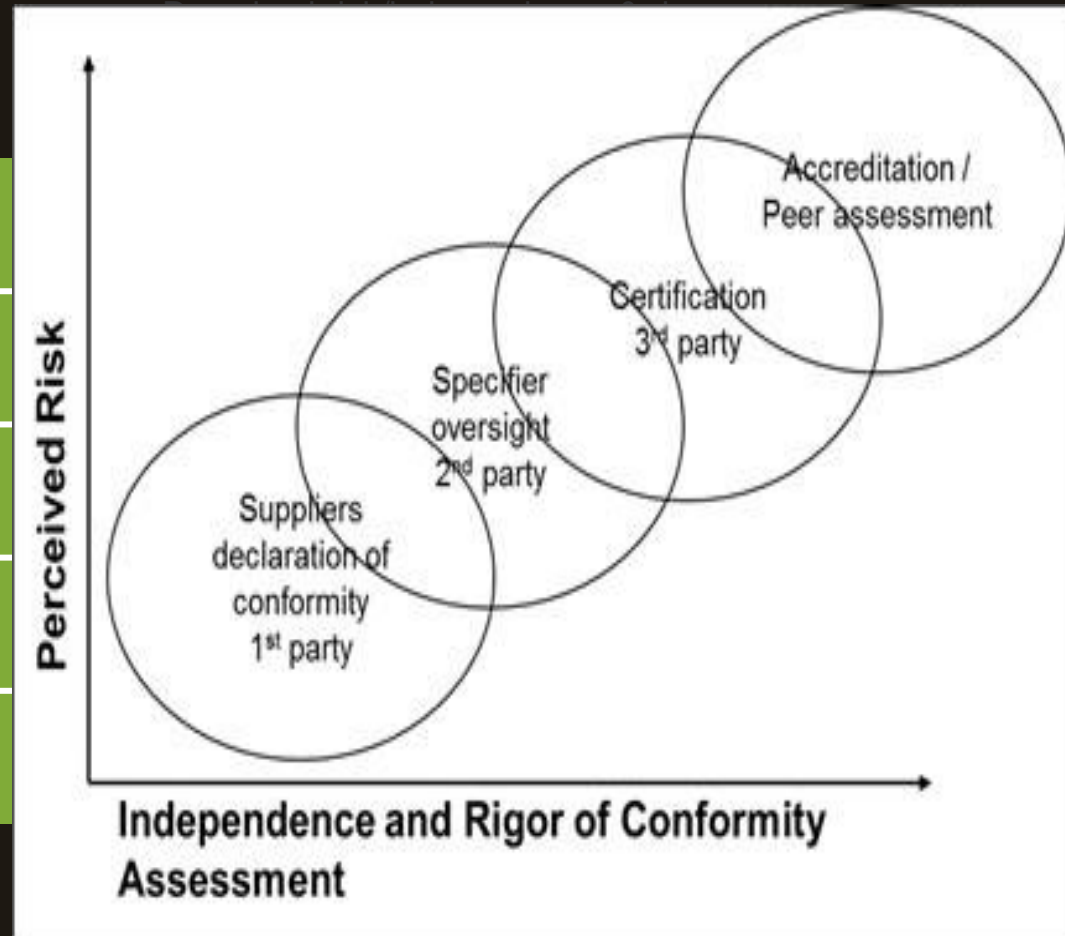
SDoC versus 3rd Party

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?)

Pre - Market

At Border

Post Market

SAMPLE INSPECTION / TESTING

PVOC (Pre Shipment Verification of
Conformity)



**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

