ARSO Conference 2016

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

01

CAS – Where is the risk?

01

Here:

Scotland, 1988 Piper Alpha

Loss of life -167

Cost – $ 2 Billion

01

Here:

Australia, Apr 2016.
28 year old woman
from NSW
electrocuted by faulty
USB phone charger.

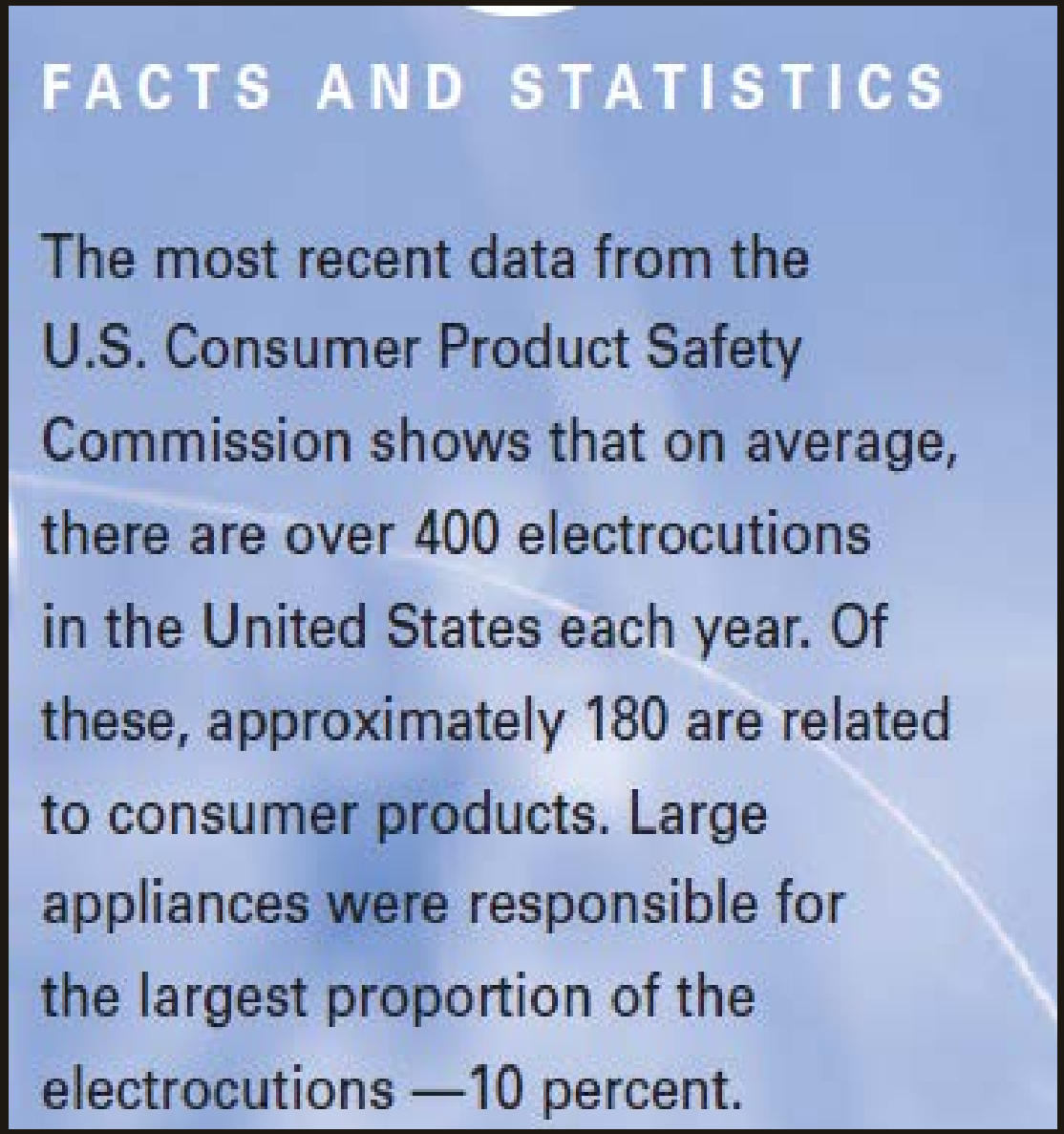
Table 1. Electrocutions Related to Consumer Products and Death Rates Based on U.S. Po

Intertek

01

And here….

2016 - ESFI Extract From Spring Electrical Safety

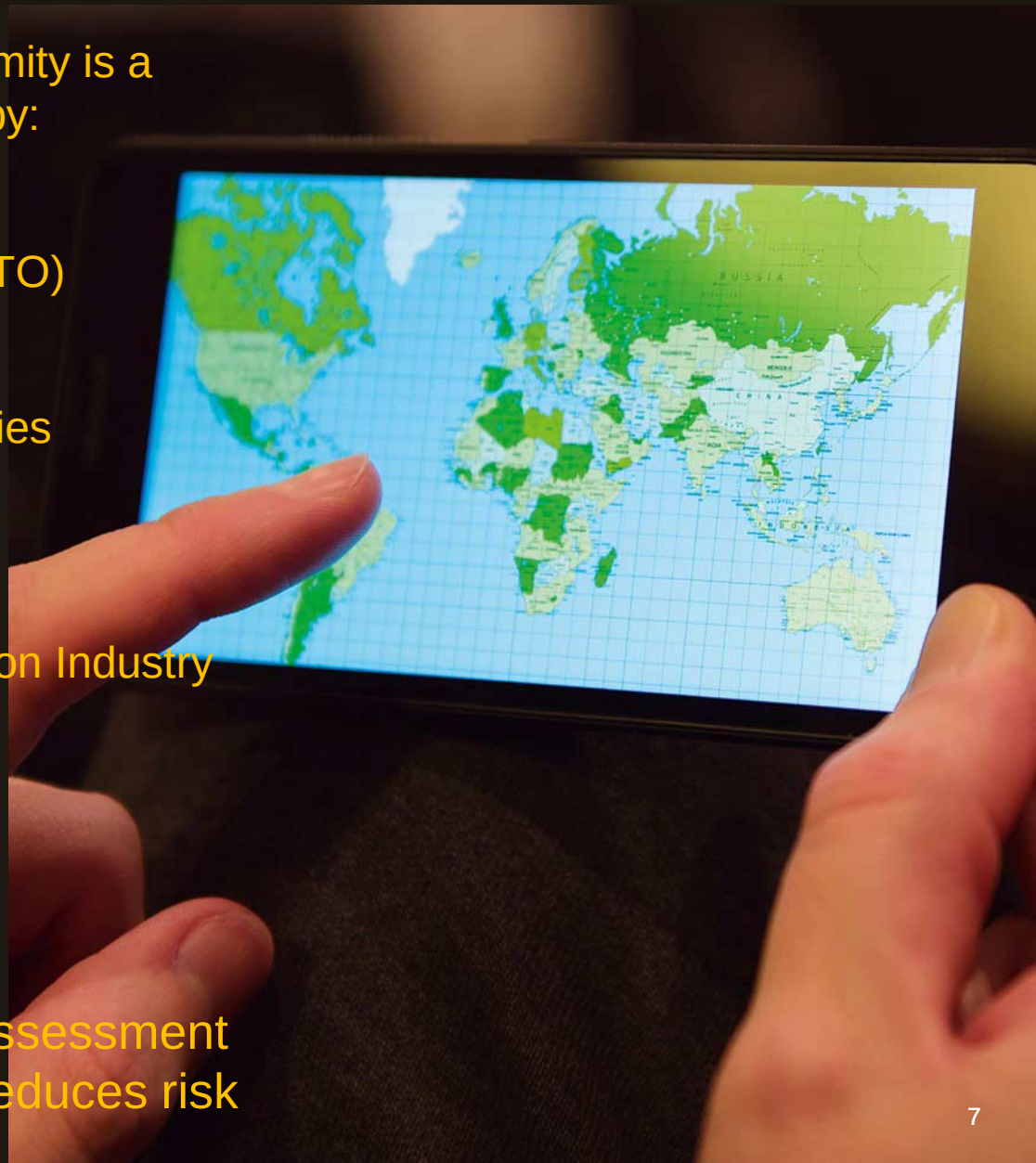


01 Where is the risk? Conformity Assessment Systems (CAS)

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



02

CAS - Factors To be considered

What is a Conformity Assessment System? Ref: ISO / IEC 17000: 2004

01

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

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.

02

03

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.

04

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 Chaim

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

CAS: Factors To Consider:

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

1	Conformity Assessment – By 3 tier mitigation of risk: 1st Party, 2nd Party and 3rd Party, ISO / IEC 17000: 2004 Definitions:
2	First-party conformity assessment activity that is performed by the person or organization that provides the object. (Self Declaration)
3	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)
4	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 authorative body

02: CAS: Factors To Consider

Two trains of thought?

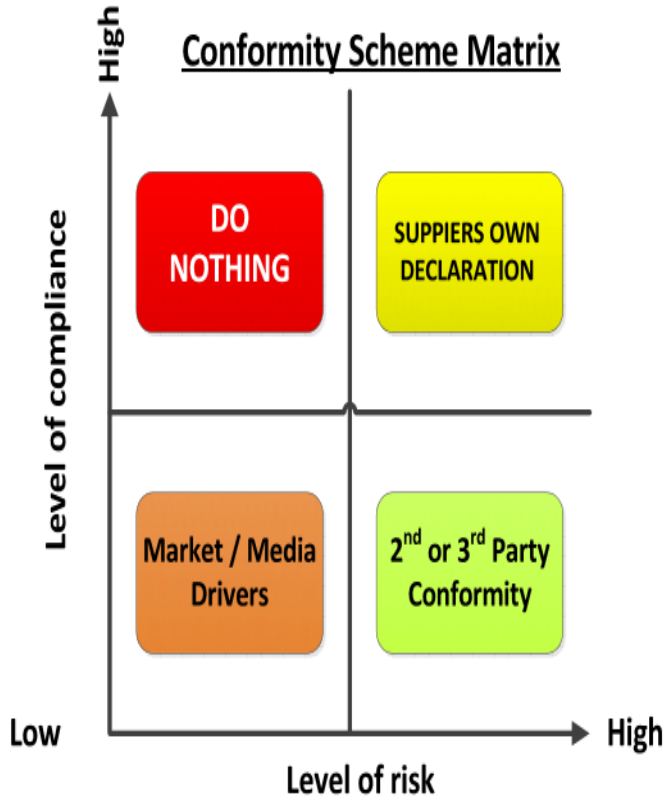
01 Object failure presents low risk - do nothing / 1st party CAS? Perceived high level of compliance?

02 Object failure presents high risk – 2nd / 3rd party CAS to be considered?

03 1st party - conscientious manufacturer/ can result in better conformity than independent third-party assessment?

04 3rd Party considered less frequent with time constraints, thus levels of compliance versus risk questioned?

05 However, 1st party do use 3rd party results / data to verify conformity - CE Marking?



02: CAS: Factors To Consider

But in practice / experience

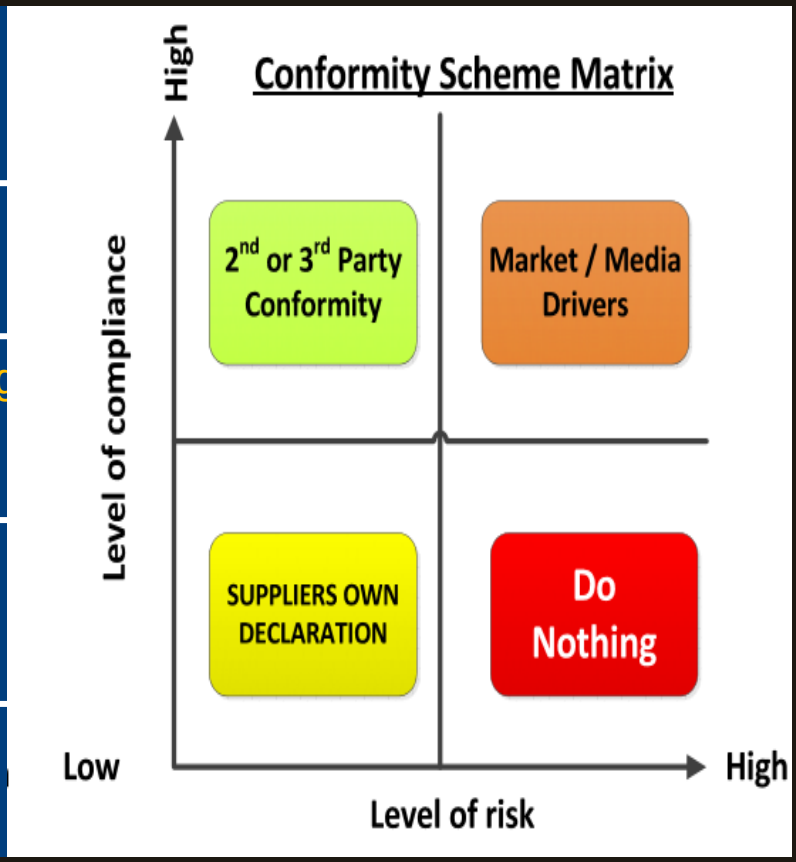
01 3rd Party intervention gives confidence to regulators and market drivers

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

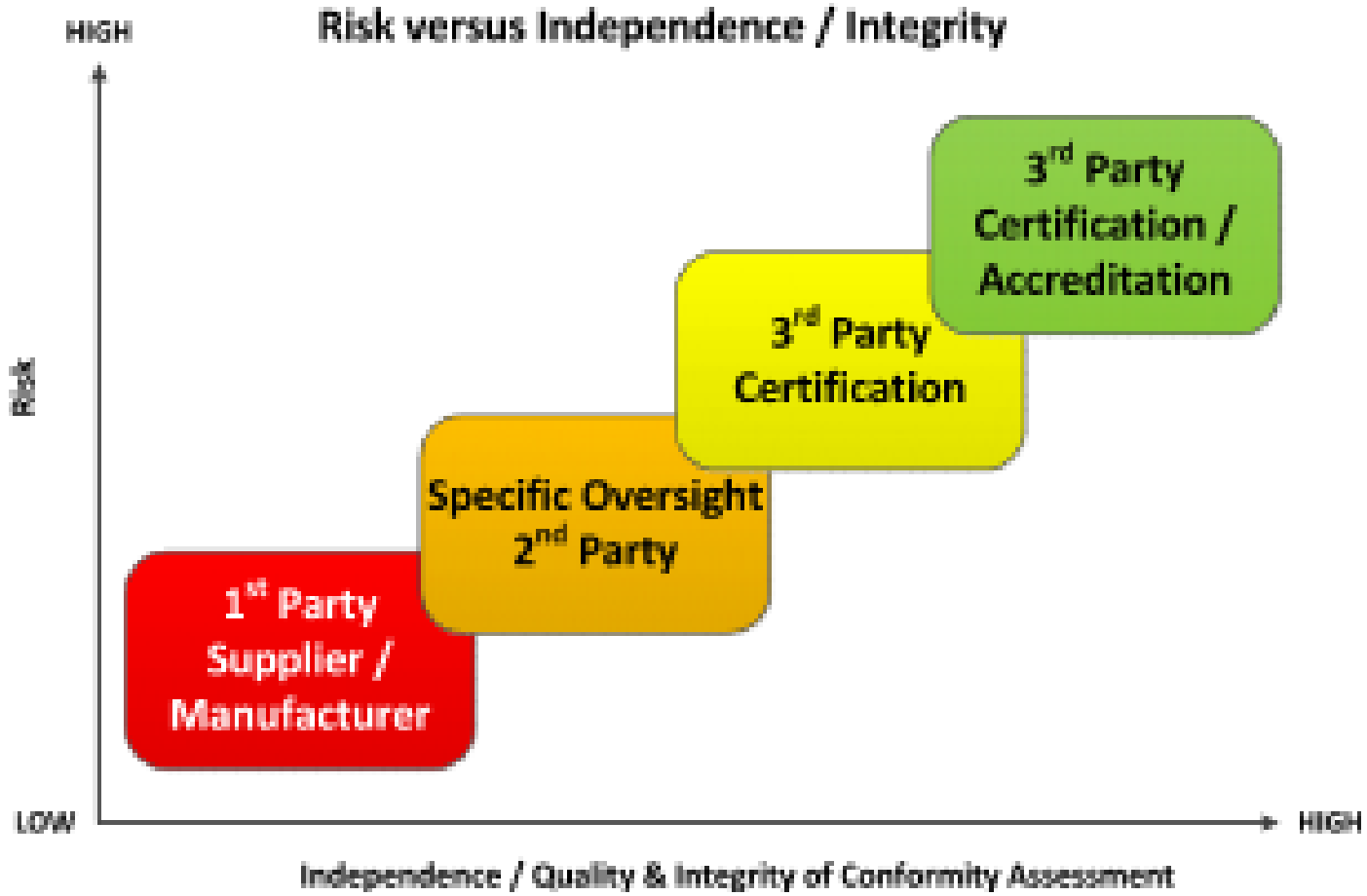
03 Globally market / media drivers are demanding higher integrity and quality lean towards 3rd Party CAS.

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



02: CAS: Factors To Consider



03

Risk Assessment – planning / evaluation

03: CAS: Risk Assessment – planning / evaluation

ISO 31000:2009 - Principles and Guidelines on Implementation
ISO/IEC 31010:2009, Risk Management, Risk Assessment Techniques

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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

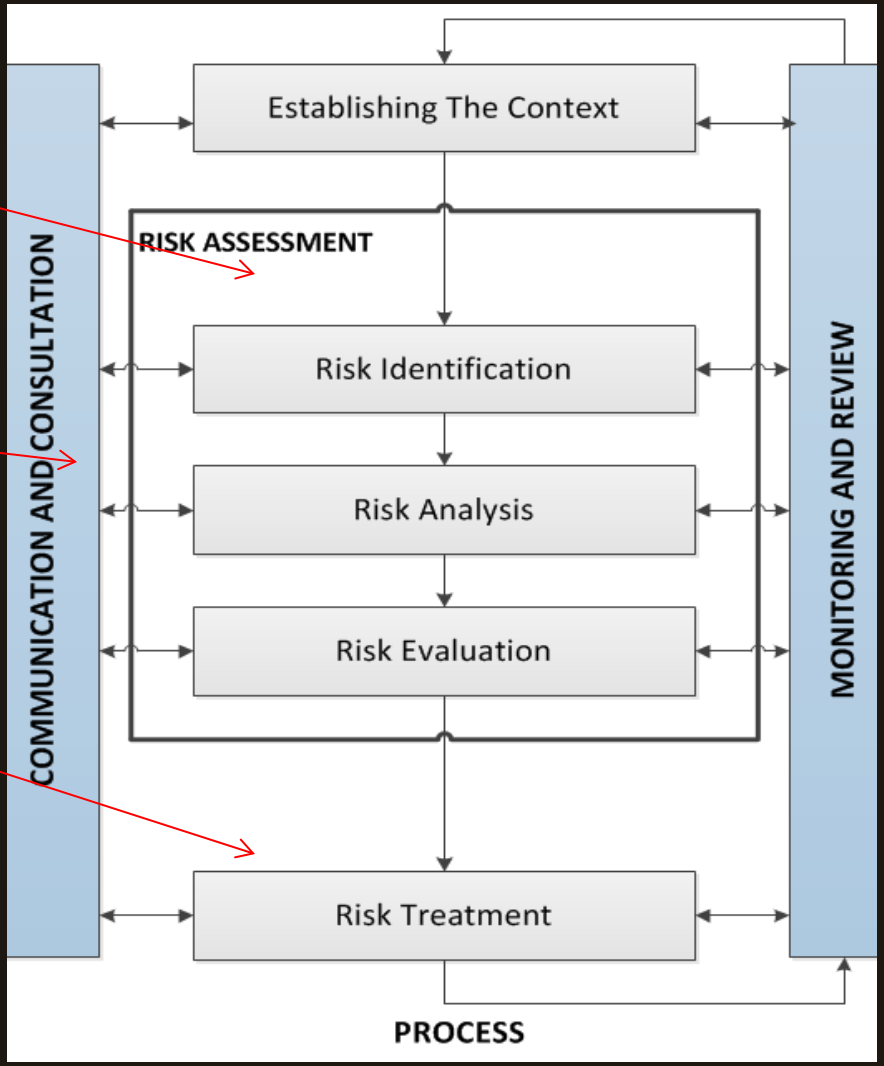
- Mapping out the following:
- The scope of risk management
- The identity and objectives of stakeholders
- The basis upon which risks will be evaluated, any constraints.

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



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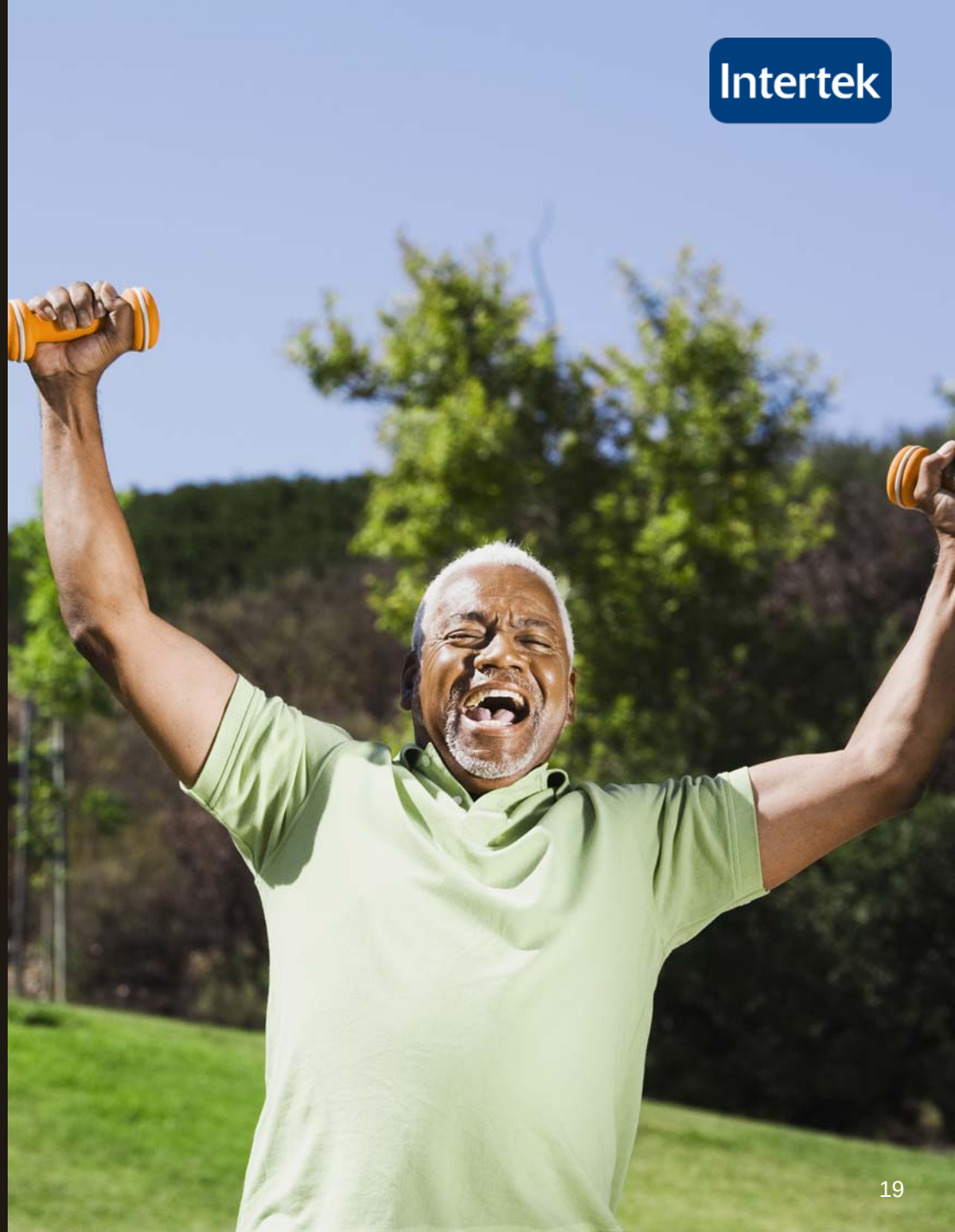
Conformity Assessment - System Design



04. CAS: Conformity Assessment System Design

1	The perceived risks associated with non-conformity The practical means of evaluating the characteristics of interest.
2	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;
3	The effectiveness of penalties for placing non-conforming regulated products in the market; and
4	The effectiveness of systems to recall non-conforming regulated products from the market.

04. CAS: Conformity Assessment System Design

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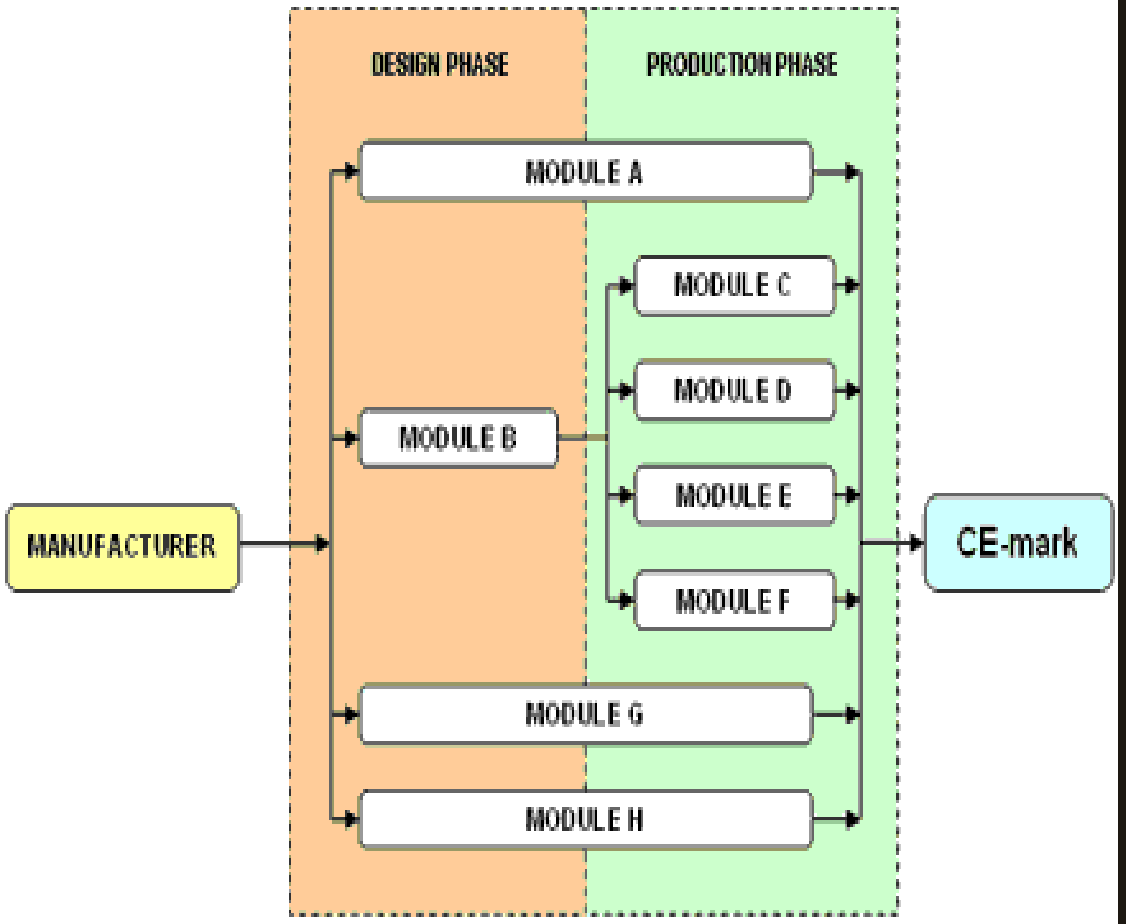
- Meets Market Needs – Manufacturers / Importers / Retailers / Consumers / Regulators
- Regulator Controlled – Deploys Transference of Risk
- Scaled Risk - 1st and 3rd Party Involvement
- Surveillance – Cross Border / Product Recall System
- National Accreditation Bodies / Peer Assessment

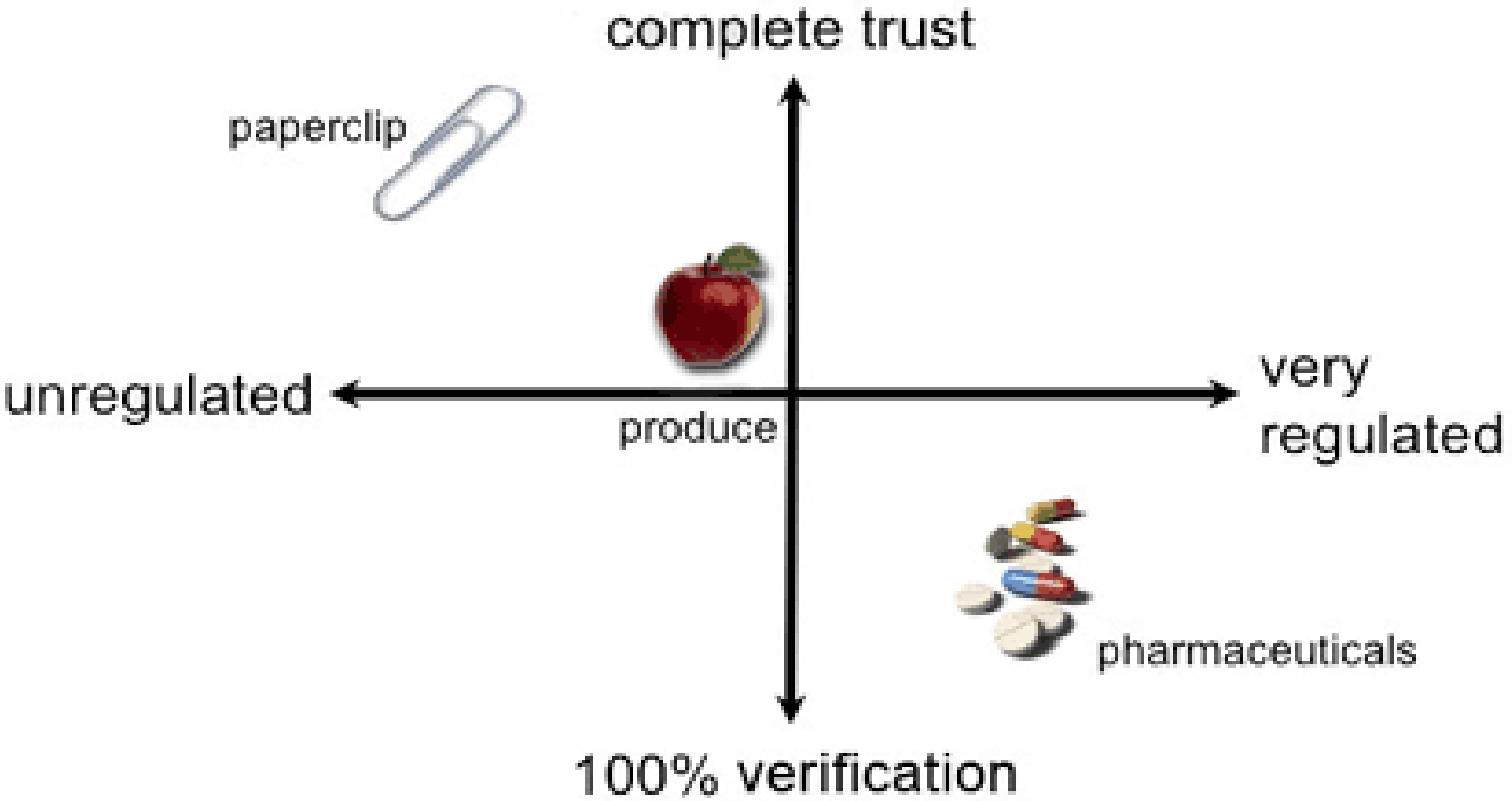


A – Internal control of production	E – Product quality assurance
B – EC type examination	F – Product verification
C – Conformity to type	G – Unit verification
D – Production quality assurance	H – Full quality assurance

05

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
US Regulation evolution:	New regulation – harmonisation of IEC/UL/EN 60079 series standards

…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,

Thank you

Any Questions?