Conformity Assessment

Good Regulatory Practices & Technical Competencies South Africa Health Products Regulatory Authority (SAPHRA) & Regulated Sector

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Learning Objectives

If we are successful, we will be able to:

- Identify different types of conformity assessment activities and associated international standards,
- Leverage risk-based approaches to conformity assessment,
- Explain how technical rigor and independence impact confidence in conformity.

Conformity Assessment: Confidence is the key

The process of conformity assessment **demonstrates whether a product, service, process, claim, system or person meets the relevant requirements**.

- ISO/IEC 17000

OR

”The prove it process”

Conformity Assessment Parties – Who Does What

First Party	Conformity assessment activity performed by the person or organization that provides the product/service/etc. (seller or manufacturer)
Second Party	Conformity assessment activity performed by the purchaser or user
Third Party	Conformity assessment activity performed by an independent entity that has no interest in transactions between the first and second parties

Standards for Conformity Assessment

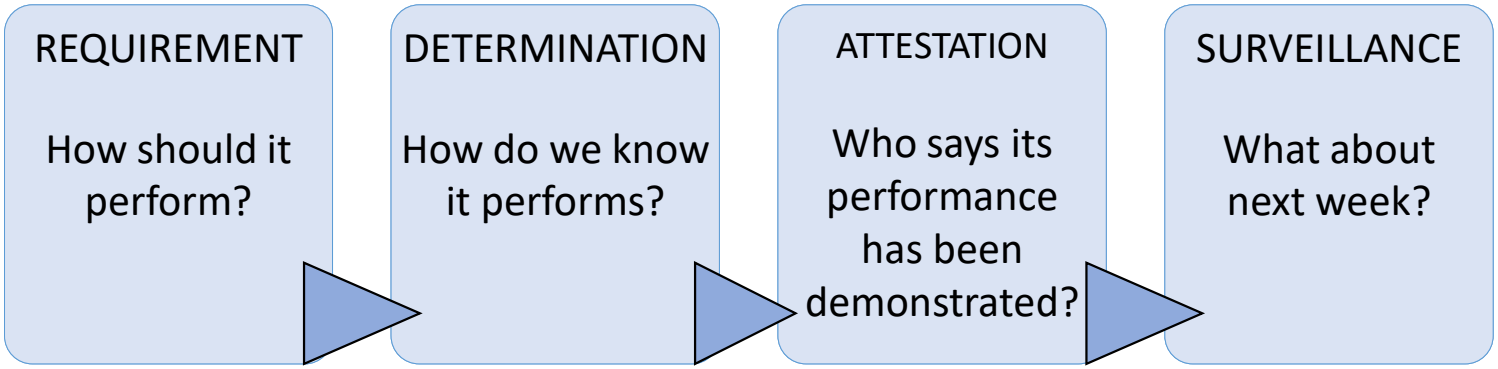
Published by International Organization for Standardization (ISO) Committee on Conformity Assessment (CASCO) in cooperation with the International Electrotechnical Commission (IEC)

CA Standards

Type	Parties			Standard(s)
	1st	2nd	3rd	
Testing	✓	✓	✓	ISO/IEC 17025
Inspection	✓	✓	✓	ISO/IEC 17020
Supplier's Declaration of Conformity (SDoC)	✓			ISO/IEC 17050 Parts 1 and 2
Certification				
Products, processes, services			✓	ISO/IEC 17065 [ISO/IEC 17067]
Management systems			✓	ISO/IEC 17021
Persons			✓	ISO/IEC 17024
Accreditation			✓	ISO/IEC 17011

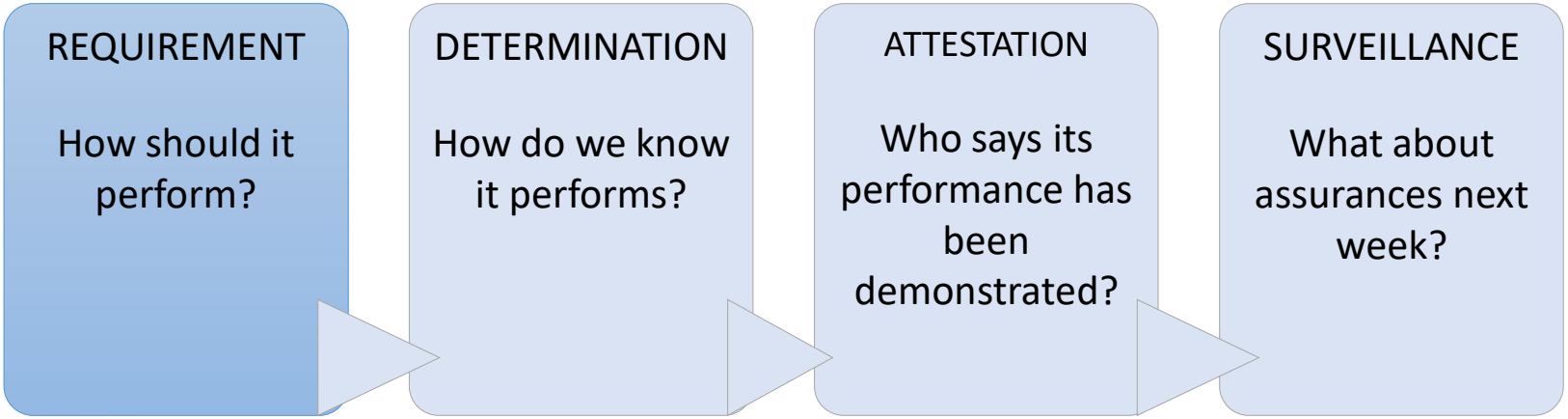
Conformity Assessment: Terms and Concepts

Conceptual View of Conformity Assessment



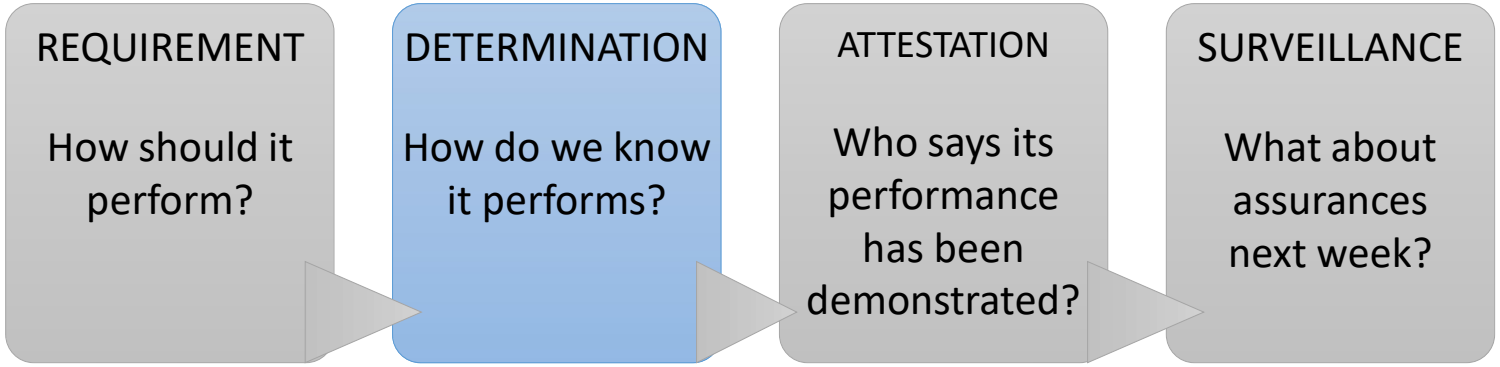
* ISO/IEC 17000 Conformity assessment – Vocabulary and general principles

Requirement



- Defines characteristics of the object of assessment
- Can be expressed in various ways (e.g., standards, regulations, manufacturing specifications, customer requirements…)

Determination



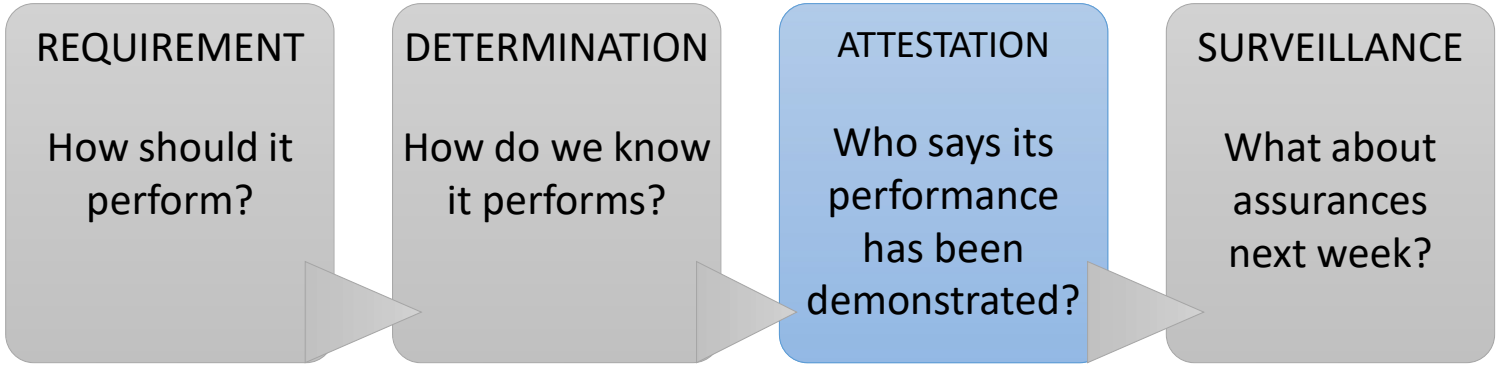
Testing: Determination of one or more characteristics of an object of conformity, according to a procedure

Inspection: Examination of a product design, product, process or installation and determination of its conformity with specific requirements or, on the basis of professional judgement, with general requirements

Audit: Systematic, independent, documented process for obtaining records, statements of fact or other relevant information and assessing them objectively to determine the extent to which requirements are fulfilled

Peer assessment: assessment of a body against specified requirements by representatives of other bodies

Attestation



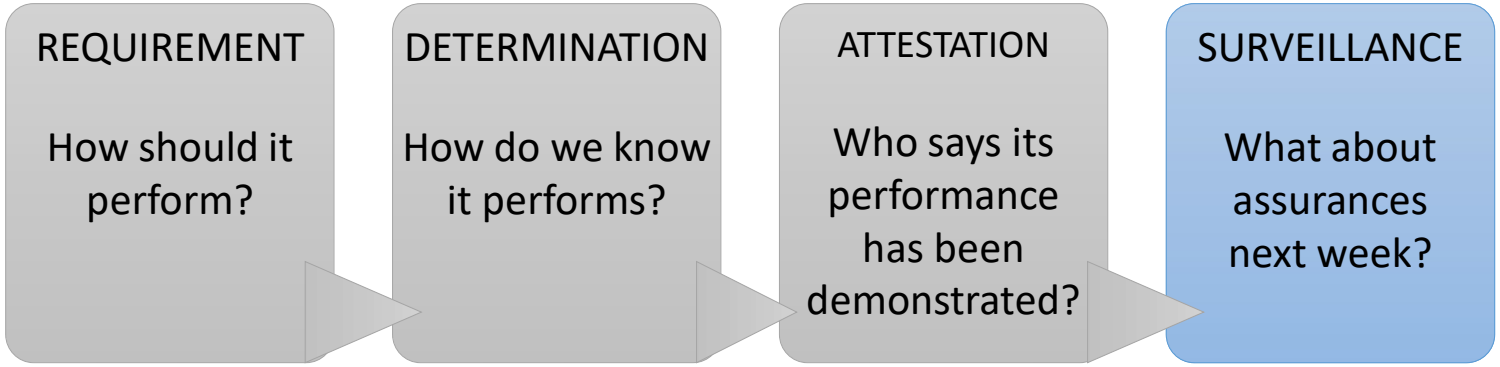
Attestation: Issue of a statement that fulfilment of specified requirements has been demonstrated

By **First Party:** → **Supplier's Declaration of Conformity (SDoC)**

→ **Certification**

By **Third Party:** → **Accreditation**

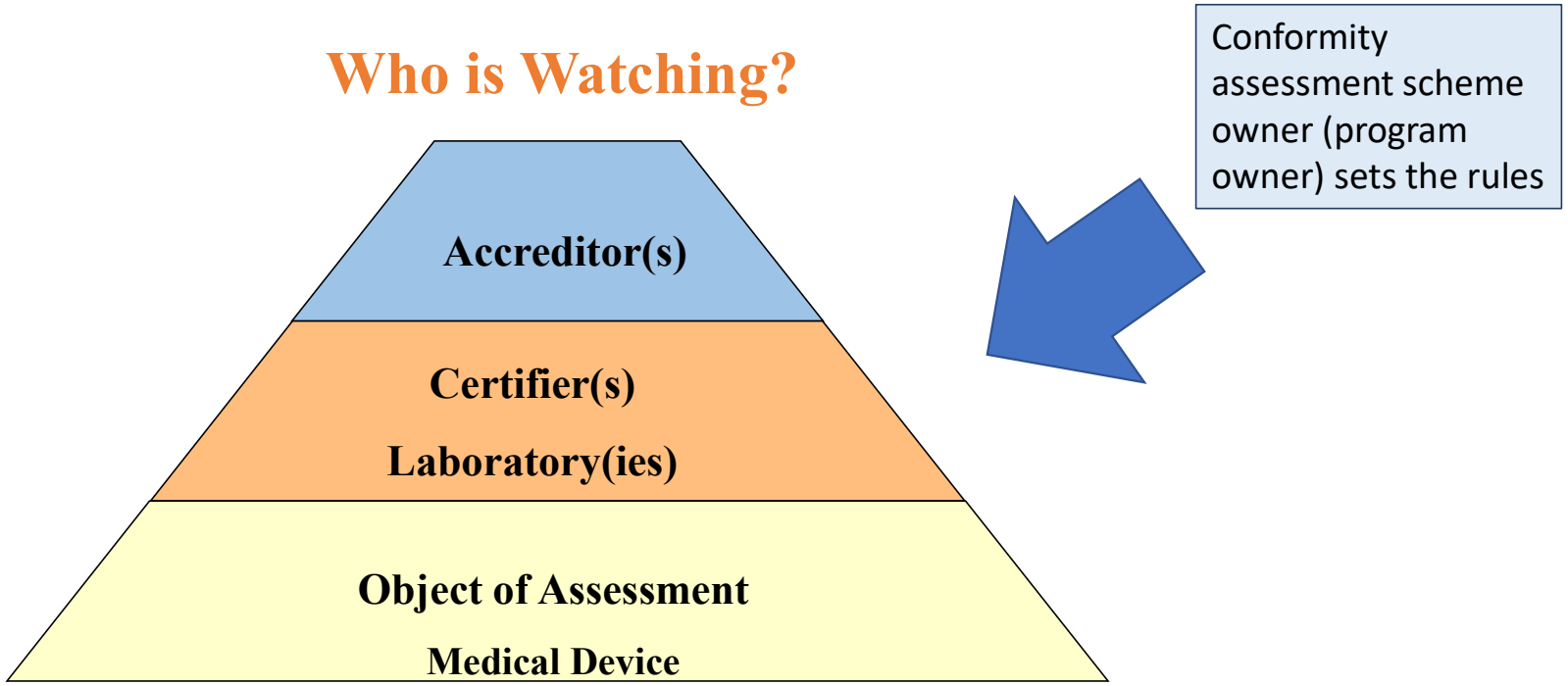
Surveillance



Surveillance: Systematic iteration of conformity assessment activities as a basis for maintaining the validity of the statement of conformity (attestation)

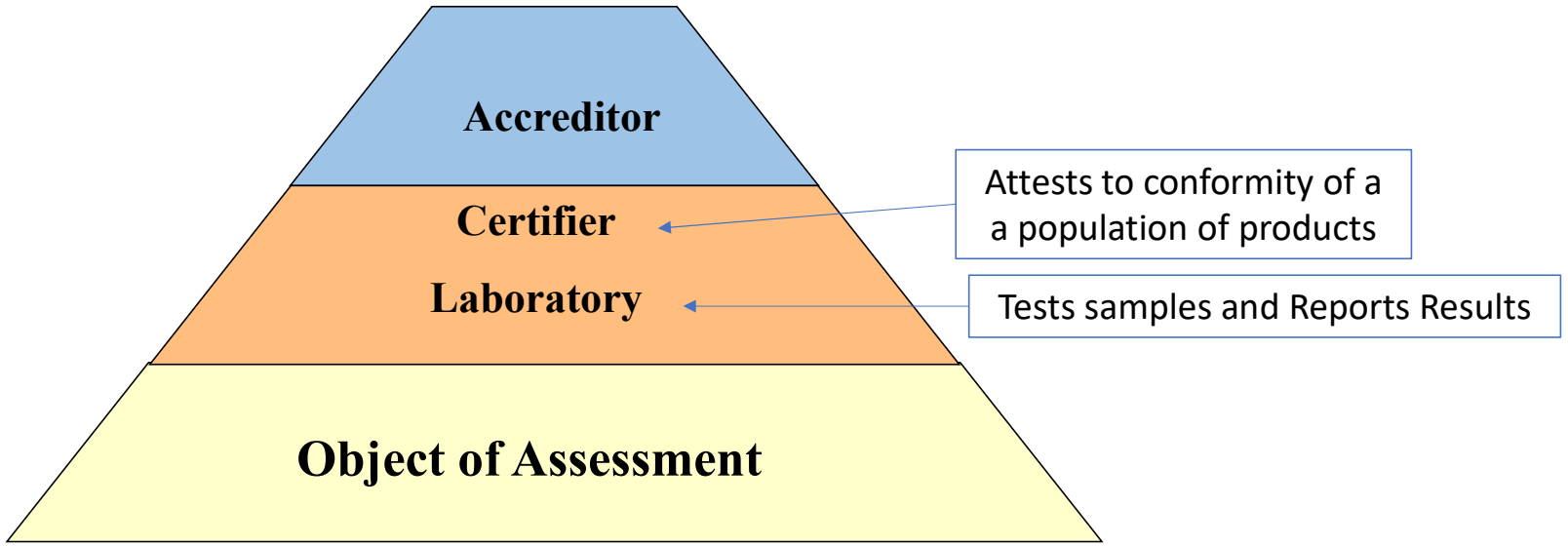
- Conformity decisions are often based on a sample and a point-in-time
- Confidence for: a whole population of products - systems today, tomorrow, next year
  - Purchasers. consumers and regulators want it
  - Certifiers want to know their attestations are still valid
- Can be pre- or post-market

Scheme Owner



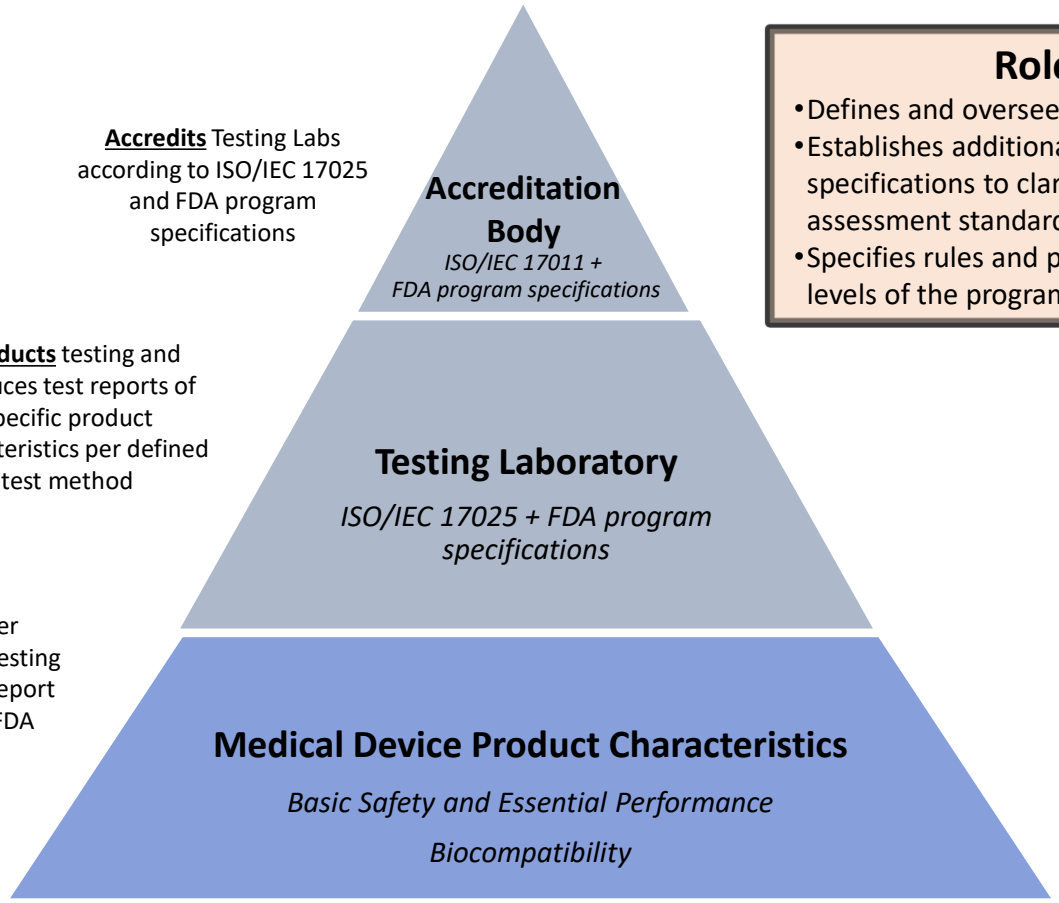
Who Is Watching?

Generally for Products



Example:
FDA Accreditation Scheme for Conformity Assessment (ASCA)

FDA ASCA Program Goal: improve efficiency of premarket review by building confidence in test results from ASCA-accredited test labs



Role of FDA

- Defines and oversees program
- Establishes additional specific program specifications to clarify ISO/IEC conformity assessment standards
- Specifies rules and procedures for approval at all levels of the program

Factors in building conformity assessment systems

One size does not fit all

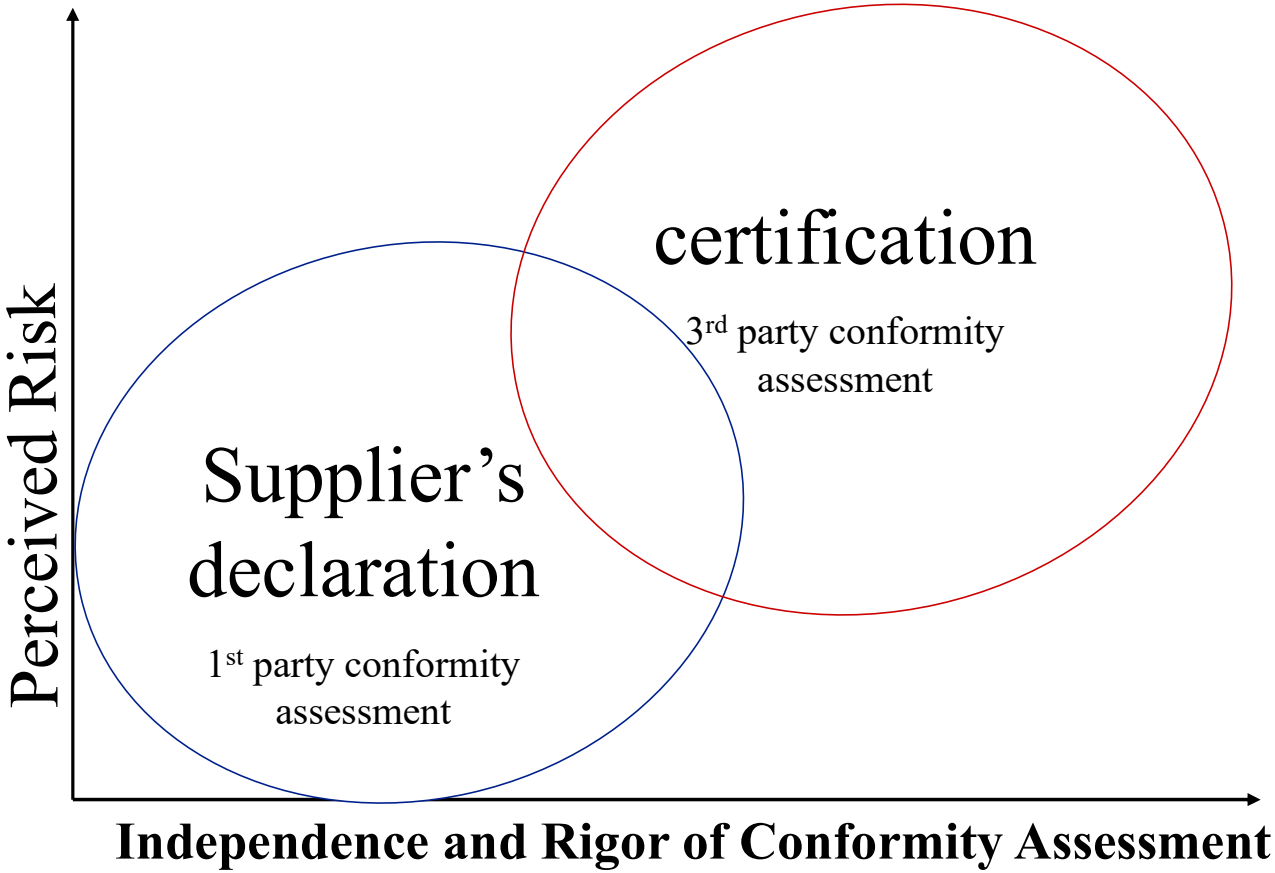
Risks associated with non-compliance should be proportional to the rigor of the system design

- Over-design can be costly
- Under-design reduces confidence

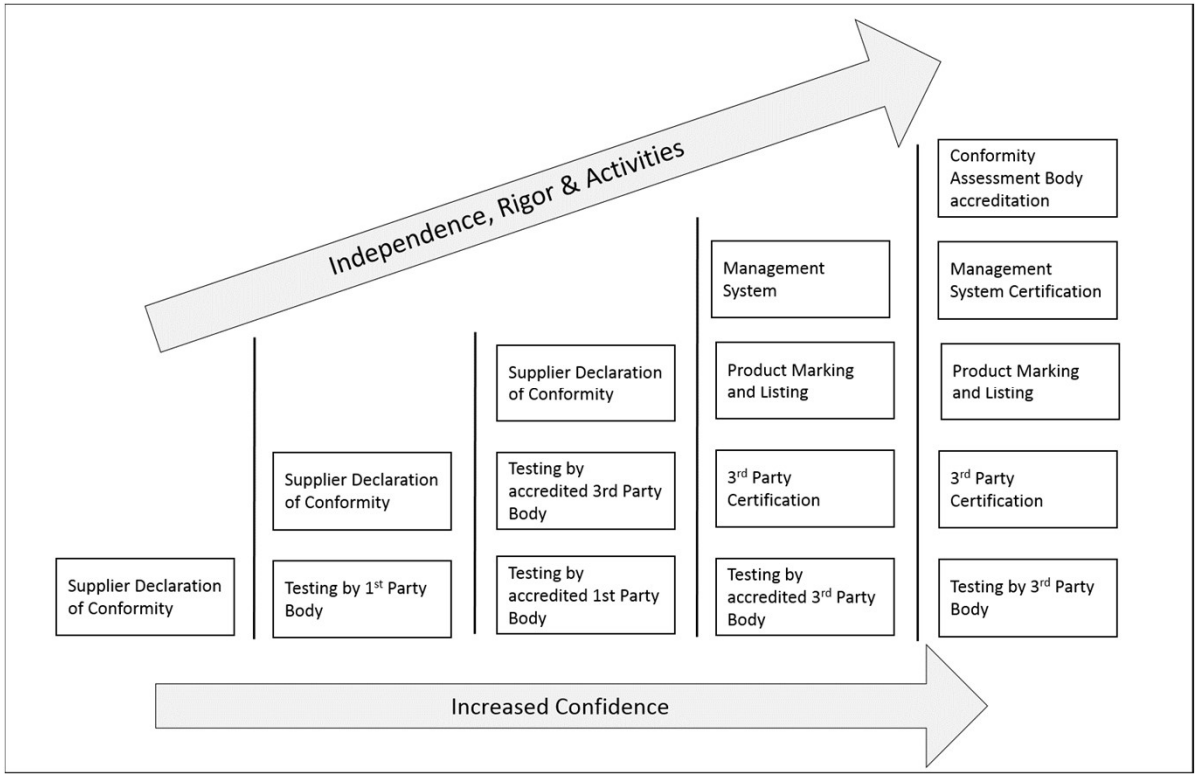
Marketplace consequences, regulatory penalties and effective recall processes can allow less rigor in conformity assessment

The ABCs of Conformity Assessment, NIST SP 2000-01
Conformity Assessment Considerations for Federal Agencies, NIST SP 2000-02

Risk and Conformity Assessment
confidence is the key



Flexibility to Address Confidence



(Example models)

Federal Agency Use of Conformity Assessment

- **Legislation & Policy**
  - National Technology Transfer & Advancement Act
  - OMB Circular A-119 Revised*
  - WTO Technical Barrier to Trade Agreements (WTO TBT)
  - Legislation focused on topic

- **Themes**
  - Agencies should first consider using industry standards (conformity assessment standards)
  - Agencies should reduce industry complexity where possible (complexity = time/effort/cost)
  - Consider and leverage private-sector CA programs and other public-sector CA programs

*OMB Circular A-119: Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities – 2016

Conformity Assessment Resources

NIST Conformity Assessment Special Publications

- **NIST SP 2000-01: ABCs of Conformity Assessment (2018)**
- **NIST SP 2000-02: Conformity Assessment Considerations for Federal Agencies (2018)**

Conclusion

Learning Objectives – Reviewed:

- ✓ Identify different types of conformity assessment activities,
- ✓ Leverage risk-based approaches to conformity assessment,
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