

Self Declaration and Attestation

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Conformity Assessment: Basic Terms and Concepts

Conformity assessment: demonstration that specified requirements are fulfilled

REQUIREMENT

How should it
perform?

DETERMINATION

How do we know
it performs?

ATTESTATION

Who says its
performance
has been
demonstrated?

SURVEILLANCE

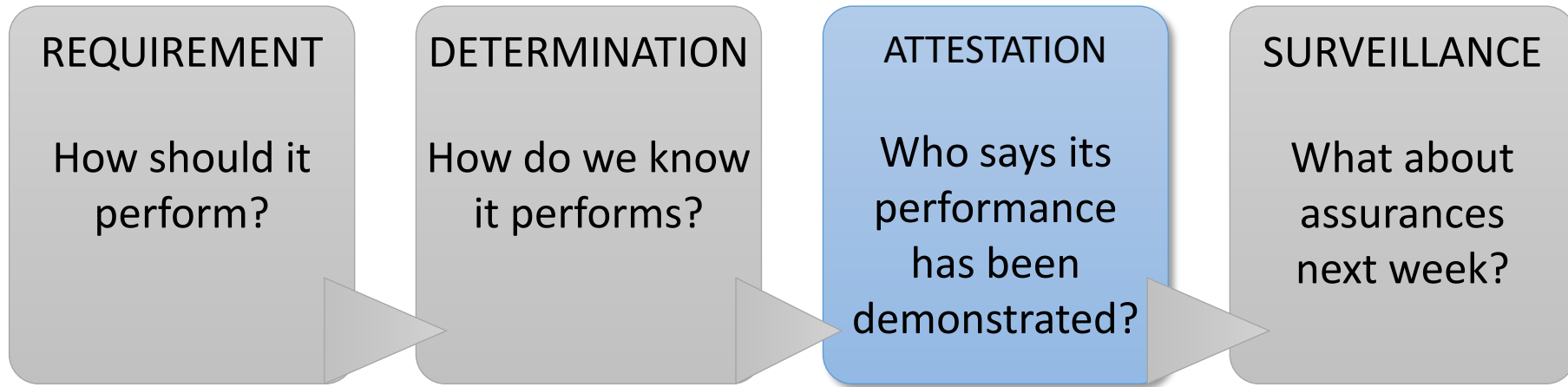
What about
assurances next
week?

Conformity assessment body (CAB): body that performs conformity assessment services

The Parties – Who Does What?

- First Party** Conformity assessment body (CAB) is person or organization that provides the object (seller or manufacturer)
- Second Party** CAB is a purchaser or user
- Third Party** CAB is an independent entity that has no interest in transactions between the first and second parties (...but they do have a financial interest in the conformity assessment)

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

Standards for Conformity Assessment

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

Type	Parties			Standard(s)
	1 st	2 nd	3 rd	
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

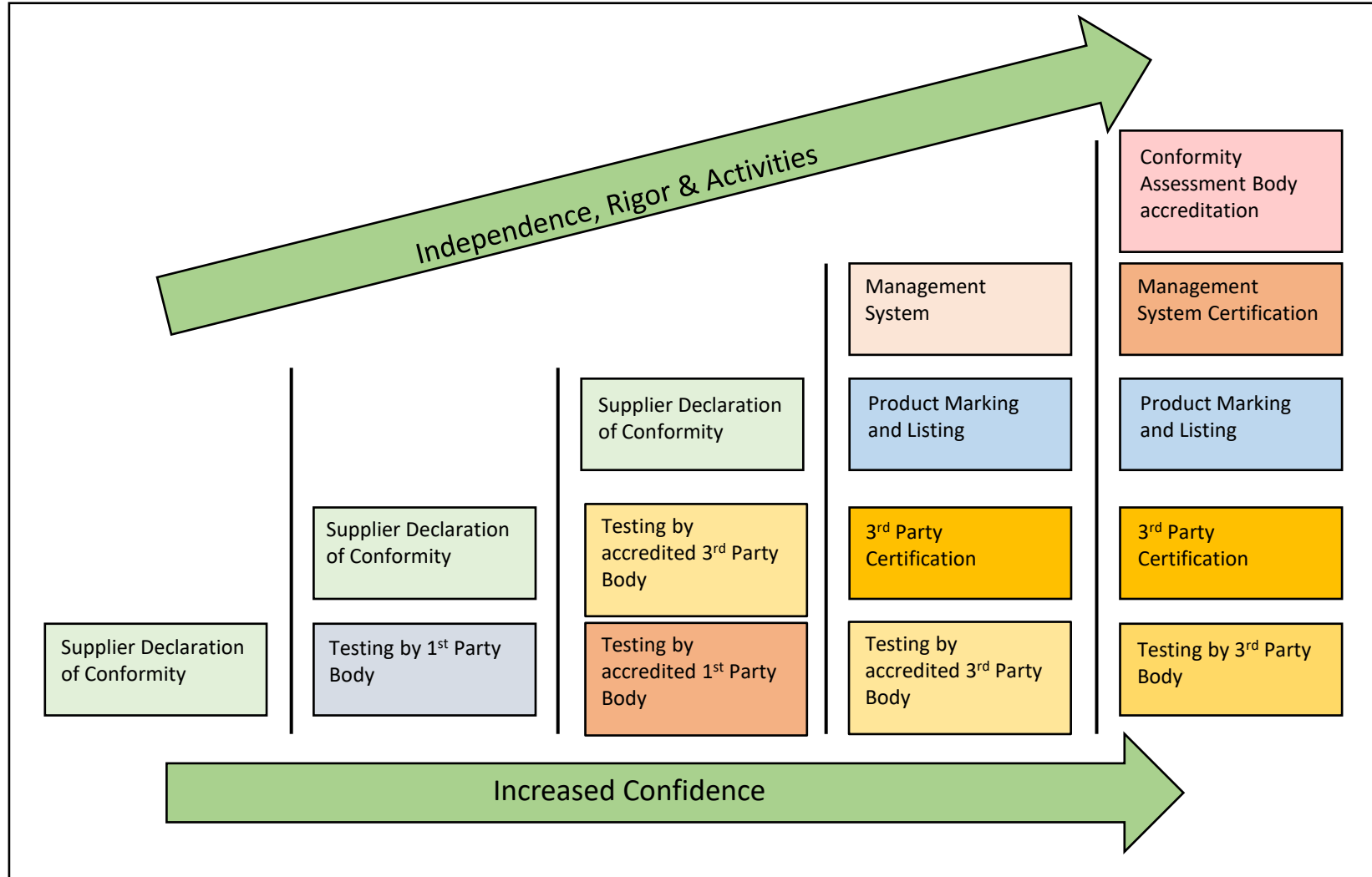
**“CASCO
Toolbox”**



ISO/IEC 17050-1: Conformity assessment— Supplier's declaration of conformity

- Specifies requirements applicable when the individual or organization responsible for fulfilment of specified requirements (supplier) provides a declaration that a product (including service), process, management system, person or body is in conformity with specified requirements.
- Declaration (hardcopy, electronic media, or any other suitable medium):
 - Is uniquely identified
 - Contains sufficient information to enable the recipient of the declaration of conformity to identify the issuer of the declaration, the object of the declaration, the specified requirements with which conformity is declared, and the person signing for and on behalf of the issuer of the declaration of conformity
 - Can make reference to the results of assessments by one or more first, second or third parties
- Issuer require to have procedures to ensure the continued conformity of the object with the stated requirements of the declaration of conformity, and to re-evaluate validity in the event of changes.

Flexibility to Address Confidence



Closing thoughts:

What does a self-attestation really do?

- SDoC is by far the most common conformity assessment practice used for products being placed in the market globally
 - Specified requirements can be in regulation, procurement documents, or voluntary program descriptions
 - Can also be requirements regarding the conformity assessment determinations that support the SDoC and/or the bodies that perform them
- Represents a claim made in the market
 - Attestations made against specific criteria must be supported by appropriate evidence
 - When attestation is publicly available, other interested parties can verify or challenge the attestation

References/Resources

[NIST Special Publication 2000-01, ABC's of Conformity Assessment](#)
(September 2018)

[NIST Special Publication 2000-01, Conformity Assessment
Considerations for Federal Agencies](#) (September 2018)

[ISO's Committee on Conformity Assessment \(CASCO\)](#)