

National Committee on Vital and Health Statistics Subcommittee on Standards Listening Session

Healthcare Standards Development/Adoption/Implementation
August 25, 2021

Conformity Assessment Fundamentals
and ANAB's Role

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ANSI National Accreditation Board



Basic Terminology

standard: □.

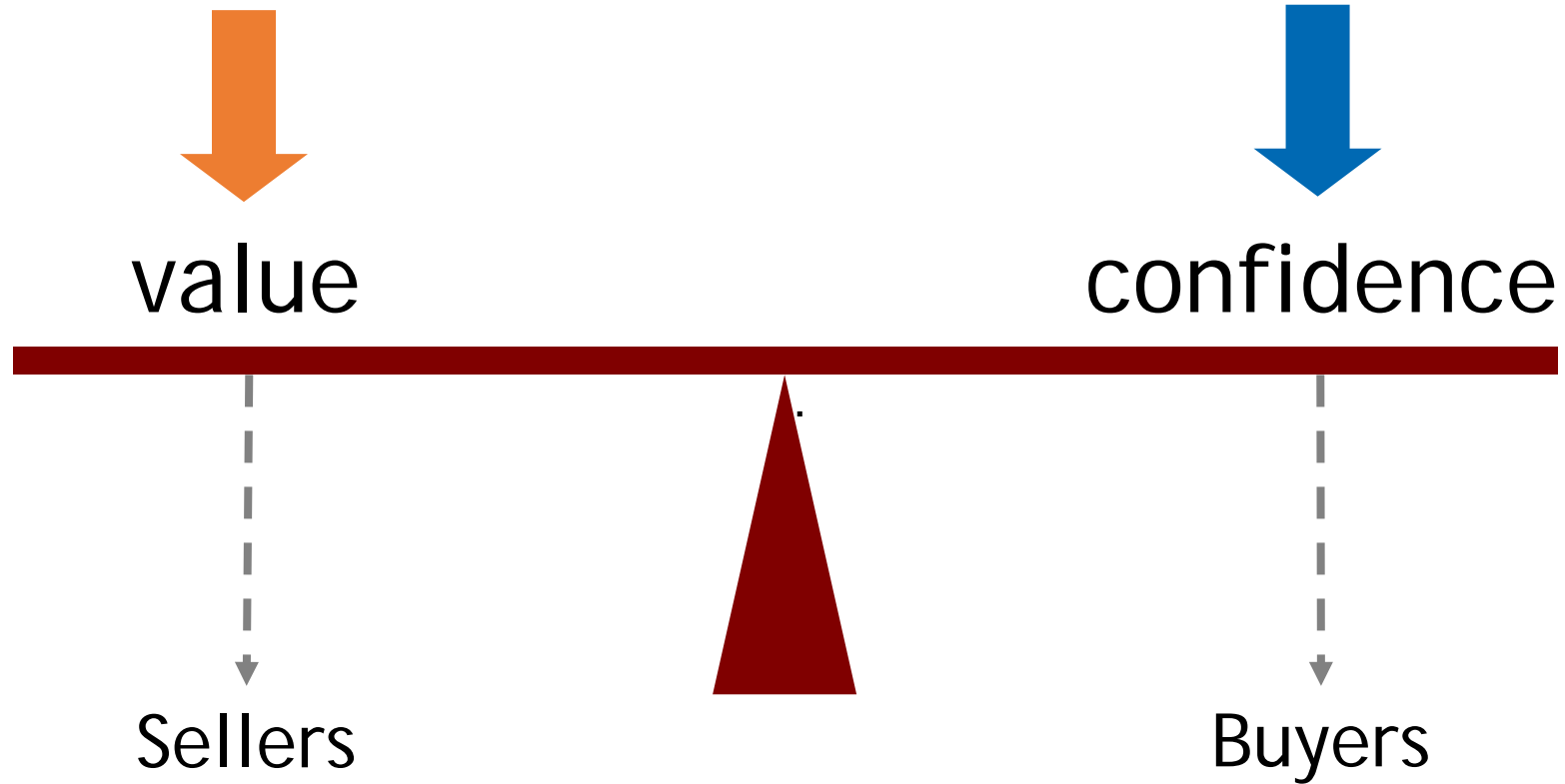
document...that provides...characteristics

conformity assessment:

demonstration that...requirements...are fulfilled



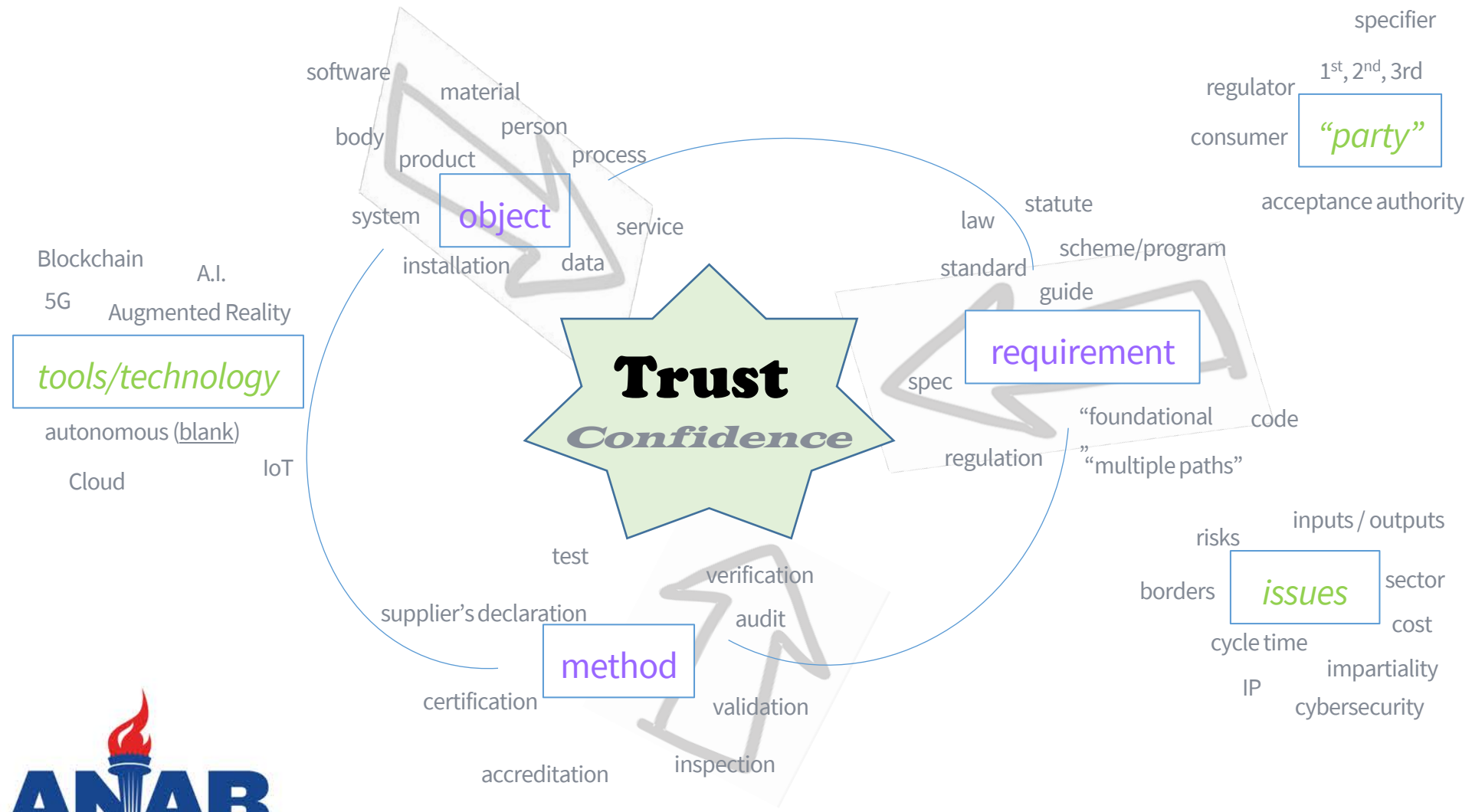
The Conformity Assessment Balance



...other stakeholders...

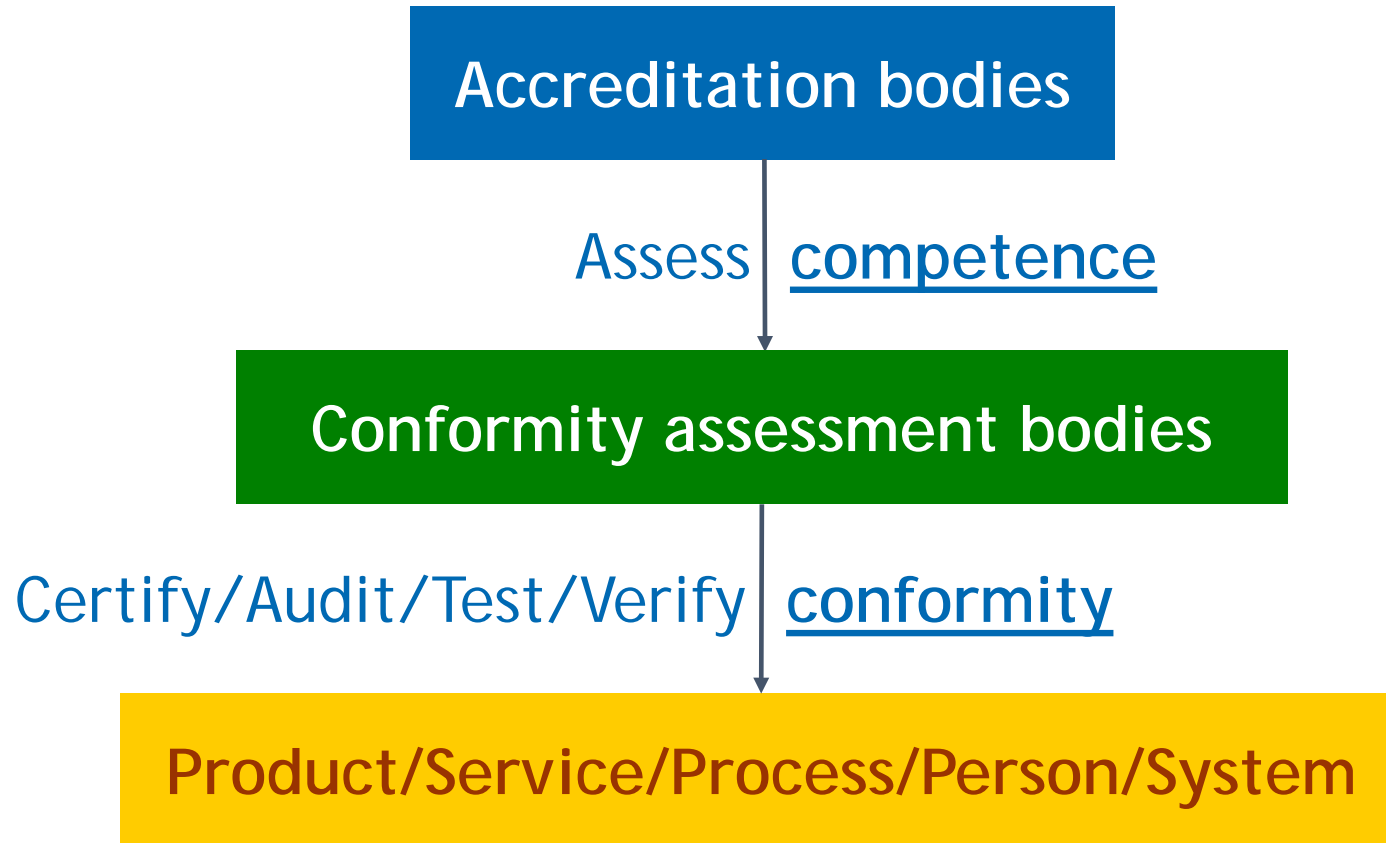


Framework for Conformity Assessment



Accredited 3rd-Party Hierarchy

(ISO/IEC 17011 standard for accreditation bodies)



ISO/CASCO “toolbox”

specific standards/guides for each conformity assessment activity

Testing

Inspection

Certification

Management system
Personnel
Product

Accreditation

Mutual recognition &
Peer assessment

Supplier's declaration
of conformity

decision to use which conformity assessment method depends on:

- *customer's requirements*
- *risk associated with product/service*
- *regulatory requirements*



**Conformity Assessment Programs
(ISO 17011)**

	client	standard
	Product Certification Body	ISO/IEC 17065
	Personnel Certification Body	ISO/IEC 17024
	Certificate Issuer	ANSI-ASTM E2659
	GHG Validation/Verification Body	ISO/IEC 14065
	Management Systems Certification Body	ISO/IEC 17021
	Laboratory	ISO/IEC 17025
	Inspection Body	ISO/IEC 17020
	Proficiency Test Provider	ISO/IEC 17043
	Reference Material Producer	ISO Guide 34
	Medical Lab	ISO 15189



Multilateral Recognitions are Important



