

The Standards Landscape

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U.S. Standardization System



Voluntary,
decentralized,
and market-
driven



Let by private
sector



Public-private
partnership

*Differs from
centralized
standards systems
in other countries*



Reflects U.S.
culture and
public-private
sector
dynamics



Relies on
cooperation,
communication,
and parity
among diverse
stakeholders

Public-Private Sector Responsibilities

PUBLIC SECTOR

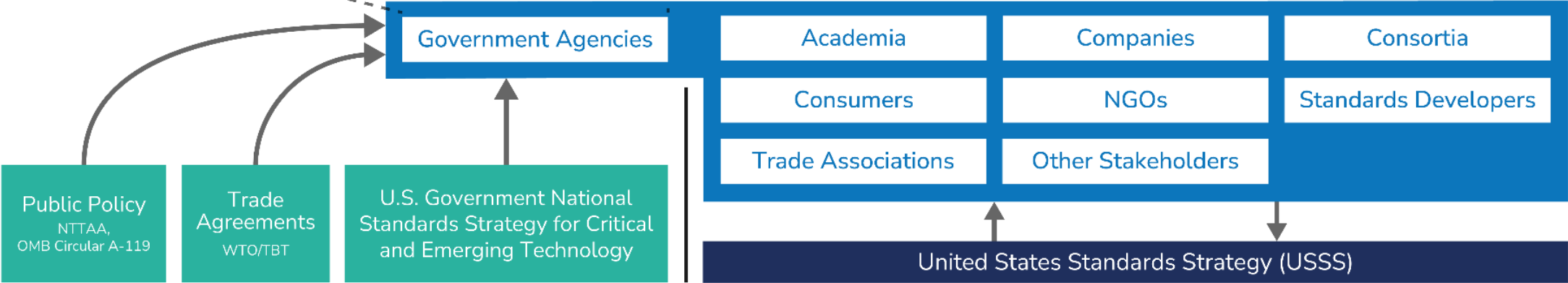
The government participates as a **stakeholder** in the standardization process, but does not mandate or legislate standardization outcomes.



ANSI COORDINATES THE PRIVATE-SECTOR STANDARDIZATION SYSTEM



STANDARDIZATION WORK



Types of Standards | Developer Oriented

- **Company Standard:** Standards developed and controlled by a single company or organization.
- **Government Standard:** Standards developed, adopted, or mandated by government agencies for a government program or regulation
- **Consortium Standard:** Standards developed by a group of organizations that have a shared interest in a technology, market, or issue.
- **Industry Standard:** Standards that become widely accepted and used within a particular sector.
 - Perspectives represented may be limited to the stakeholder type engaged, such as an industry association representing solely manufacturers
- **Voluntary Industry Consensus Standards:** Standards developed through an open, balanced, consensus-based process involving multiple stakeholder groups. Voluntary to use unless referenced by regulation, contract, or policy.

Standards differ in who develops them, the procedures utilized to approve them, and whether their use is voluntary or required.

Diverse Landscape of Standards Organizations

Standards organizations vary widely in how they are structured and operate. They differ on who participates, how decisions are made, and how membership is defined.

Representation	Decision-making	Membership
Individual experts	Consensus or no voting	Open to any individual or organization
Individual organizations	One expert, one vote	Open to any paying member
National bodies or committees	One organization, one vote	Limited to certain classes of members (industry sectors, government)
National governments	Weighted or proportional voting	
	One country, one vote	



Pathways to Globally Relevant Standards

NATIONAL PARTICIPATION

(One country, one vote)



A single organization represents the U.S. and submits comments and votes with input from technical experts...

examples:

ANSI

U.S. federal agencies



...to a non-U.S.-based SDO that adheres to internationally accepted principles for standards development.

examples:

IEC

ISO

DIRECT PARTICIPATION

(One expert, one vote)



A technical expert submits comments and votes directly...



...to a U.S.-based SDO that adheres to internationally accepted principles for standards development.

examples:

ASME

ASTM International

SAE International

CONSORTIA & DE-FACTO PARTICIPATION

(One organization, one vote)



A single organization...



...joins a consortium with others in the same industry to produce their own standards.

examples:

Medbiquitous

OASIS Open

Open Geospatial Consortium

W3C



...creates a widely-used product that becomes a de-facto "standard."

examples:

Android

Windows

Types of Standards | Document Oriented

- **Terminology:** Defines terms and their meanings.
- **Classification:** Provides a system for grouping, labeling, or categorizing items.
- **Guide:** Provides guidance and recommendations but does not establish mandatory requirements. (Recommended Practice / Best Practice)
- **Practice:** Describes a generally accepted procedure or process. (Recommended Practice / Best Practice)
- **Specification:** Defines requirements, features, or characteristics that something must meet.
- **Test Method:** Defines a specific procedure for measuring, evaluating, or verifying performance.
- **Codes:** Establishes requirements intended for adoption or enforcement.
- **Management:** Establish requirements for how an organization or system is managed rather than how a product is designed.
- **Operational:** Define how activities are performed consistently.
- **Frameworks:** Provide structure of what needs to be addressed rather than detailed requirements.

Types of Standards



Technical Standards

Products, systems, interoperability



Test & Measurement Standards

How to evaluate



Management Standards

How organizations are managed



Operational/Process Standards

How work is performed



Terminology & Classification Standards

Common language and categorization

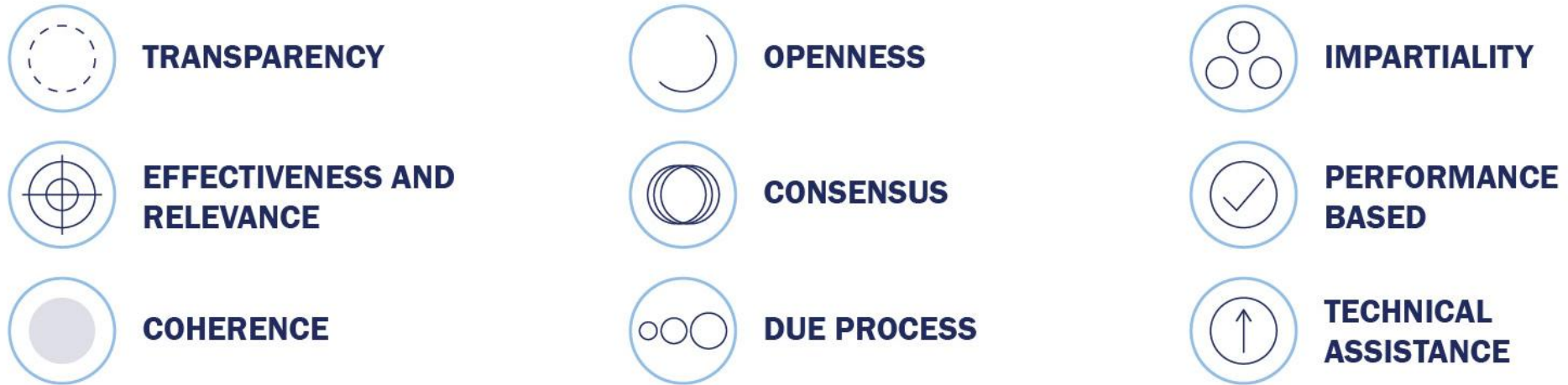


Frameworks & Guidance

Structure, recommendations, best practices

The 12 Principles of Standardization

According to the World Trade Organization (WTO), standards should **meet societal and market needs** and should **not be developed to act as barriers to trade**. The U.S. standards system is based upon the following set of globally accepted principles:



In addition, U.S. interests strongly agree that the standardization process should be:



U.S. Frameworks

1995 National Technology
Transfer and Advancement Act
(NTTAA)

&

1998 OMB Circular A-119

Encourages government
agencies to rely on existing
private-sector standards
whenever possible

&

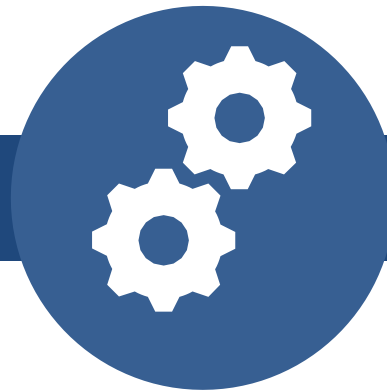
Reinforces these Principles



Openness



Balance



Due Process



Appeals



Consensus

Benefits to Regulatory Bodies

- **Leverage private-sector expertise** by drawing on the knowledge of industry, academia, government, and other stakeholders.
- **Reduce duplication** by using existing standards rather than developing unique government requirements.
- **Promote consistency and interoperability** across products, systems, and markets.
- **Support international trade** through alignment with nationally and internationally recognized standards.
- **Keep regulations current** by allowing technical requirements to evolve through standards updates rather than frequent regulatory revisions.
- **Encourage innovation** by enabling regulators to reference standards while maintaining performance-based regulations.
- **Focus regulations on outcomes rather than methods**, allowing organizations flexibility in how they meet regulatory objectives.

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How Voluntary Standards Become Mandatory



REGULATION OR CODES

Legal requirement

HOW IT BECOMES MANDATORY

- Agency cites a standard in law, regulation, policy, or rule.
- Regulators adopt codes that reference standards.
- Compliance becomes legally required within the defined scope.

EXAMPLES

- Building, electrical & fire safety
- Medical devices
- Aircraft certification



PROCUREMENT

Purchasing condition

HOW IT BECOMES MANDATORY

- Public agencies or large buyers make compliance a purchasing condition.
- Suppliers must comply to compete for the work.

EXAMPLES

- Government IT & cybersecurity
- Transportation & construction
- Defense contracts



CONTRACT

Contractual obligation

HOW IT BECOMES MANDATORY

- Parties name specific standards in their agreement.
- Compliance becomes enforceable under the contract.

EXAMPLES

- Construction & engineering
- Supplier, manufacturing & service contracts



CERTIFICATION & ACCREDITATION

Markings & market access

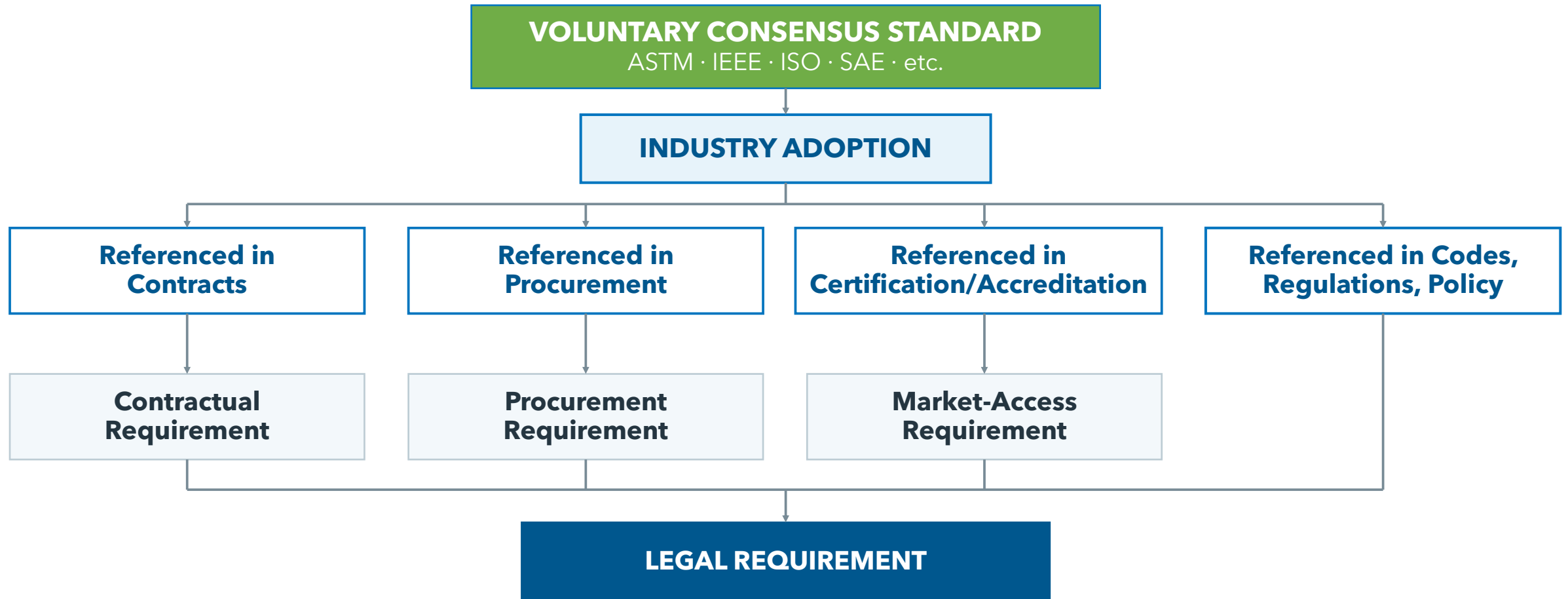
HOW IT BECOMES MANDATORY

- Market access can depend on demonstrating conformity.
- A voluntary standard becomes a practical necessity even without a legal mandate.

EXAMPLES

- Certification & accreditation programs
- Conformity markings
- ENERGY STAR

How Voluntary Standards Become Mandatory



Use of Standards for Compliance

CONFORMITY ASSESSMENT OBJECTIVE

e.g., safety, reliability, security

**Required
Standard**

Only one path

Least flexibility

**Acceptable Means of
Compliance**

Recognized pathway

Flexible compliance

**Alternative Means of
Compliance**

Different pathway

Most flexibility

INCREASING REGULATORY FLEXIBILITY

Standards in Trade

The invisible infrastructure of trade, providing the common technical foundation that enables products and services to move across national and international markets.

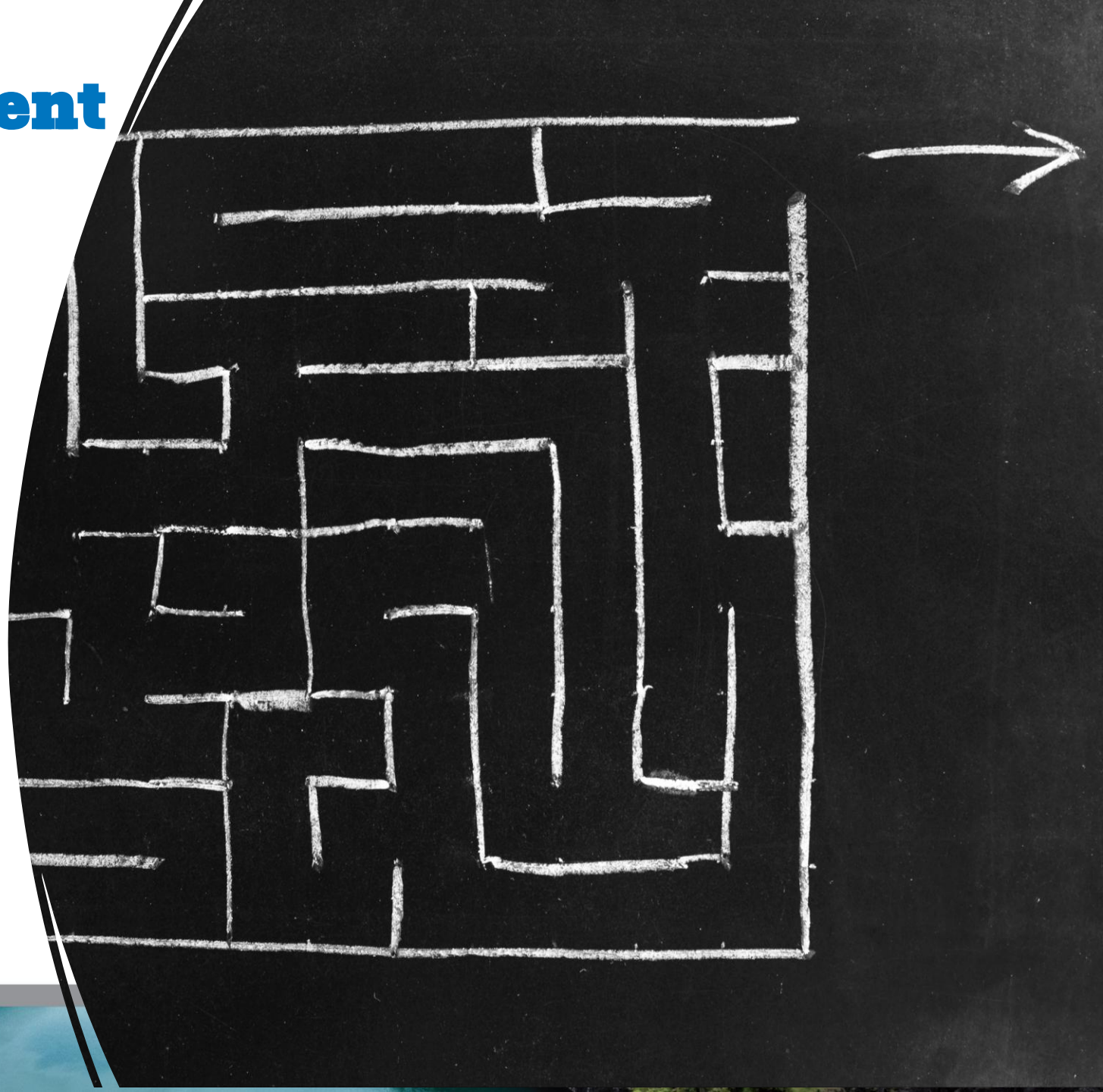


- U.S. Department of Commerce, International Trade Administration (June 2016)

Conformity Assessment

- ✓ Testing
- ✓ Inspection
- ✓ Audit
- ✓ Validation/verification
- ✓ Certification
- ✓ Accreditation

Conformity assessment:
demonstration that specified requirements are fulfilled



Who performs conformity assessment?



First-party conformity assessment activity

performed by the person or organization that provides or that is the object of conformity assessment



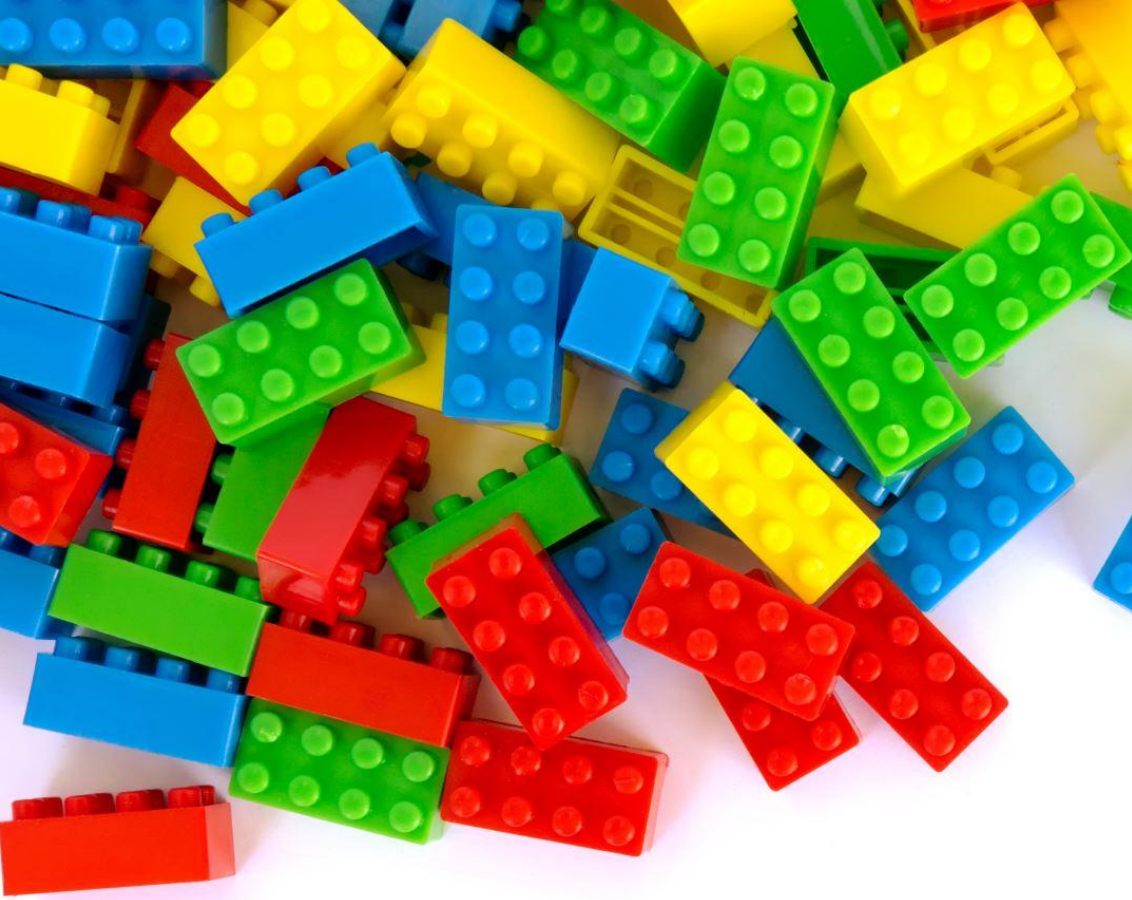
Second-party conformity assessment activity

performed by a person or organization that has a user interest in the object of conformity assessment



Third-party conformity assessment activity

performed by a person or organization that is independent of the provider of the object of conformity assessment and has no user interest in the object



Standards as inputs to conformity assessment

Standards can define:

- Object
 - Methodology
 - Results
-
- Governments, private sector accept/approve standards as acceptable means of demonstrating conformity with stated objectives
 - Conformity assessment process and outcomes provide information for decision makers



Toolbox

Examples of Conformity Assessment Activities	1 st Party	2 nd Party	3 rd Party
Testing ISO/IEC 17025	✓	✓	✓
Inspection ISO/IEC 17020	✓	✓	✓
Validation/Verification ISO/IEC 17029	✓	✓	✓
[Supplier's] Declaration ISO/IEC 17050-1, -2	✓		
Certification			✓
Products/services ISO/IEC 17065			✓
Management system ISO/IEC 17021-1			✓
Persons ISO/IEC 17024			✓

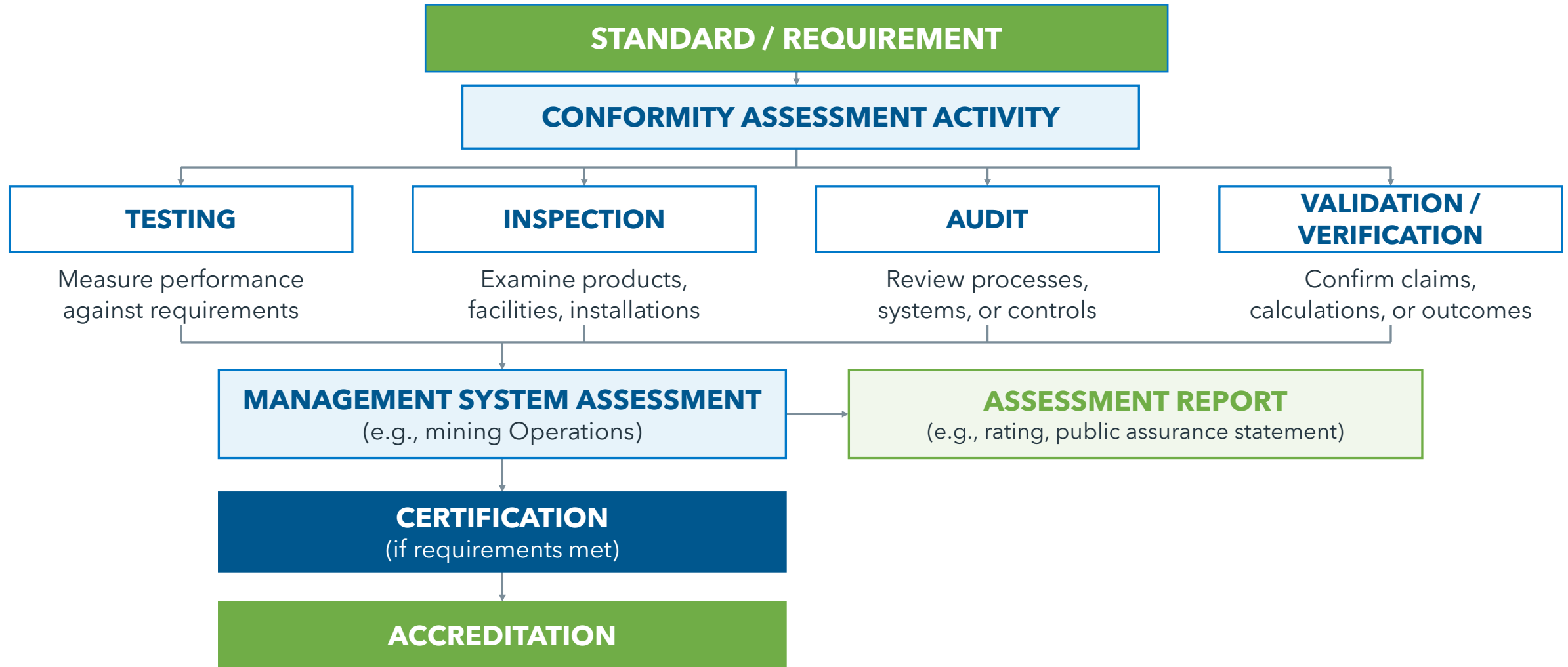
Determination

- Provide information to inform review/decision/attestation
- Single point in time
- 1st, 2nd, or 3rd party

Attestation

- Issue of a statement (based on review and decision) that fulfilment of specified requirements has been demonstrated
- Certification:
 - Only 3rd party
 - Can involve surveillance

Conformity Assessment Matrix



From Mine to Market | Standards and Conformity Assessment



UPSTREAM

Mining & Extraction



PRIMARY STANDARDS TYPES

- Frameworks
- Management Standards
- Operational Standards
- Guides & Practices
- Terminology
- Classification
- Specifications



COMMON CONFORMITY ASSESSMENT ACTIVITIES

- Inspection
- Audit
- Verification / Validation
- Certification
- Accreditation



MIDSTREAM

Processing & Refining



PRIMARY STANDARDS TYPES

- Specifications
- Operational Standards
- Management Standards
- Guides & Practices
- Terminology
- Classification
- Test Methods



COMMON CONFORMITY ASSESSMENT ACTIVITIES

- Testing
- Inspection
- Audit
- Certification
- Accreditation



DOWNSTREAM

Product Manufacturing



PRIMARY STANDARDS TYPES

- Specifications
- Test Methods
- Codes
- Management Standards
- Operational Standards
- Terminology
- Classification



COMMON CONFORMITY ASSESSMENT ACTIVITIES

- Testing
- Inspection
- Certification
- Audit
- Accreditation