

Standards Basics

What are standards?

Common and repeated use of rules, conditions, guidelines or characteristics for products or related processes and production methods

Documentary standards:

- Performance characteristics
- Testing methodology
- Manufacturing practices
- Management systems
- Conformity assessment

Reference Materials (reference standard)

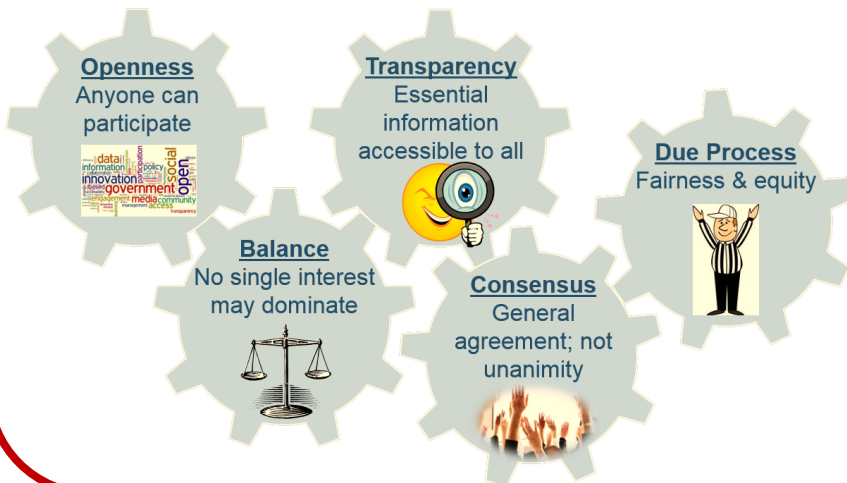
- Physical artifacts

Why Standards?

- Facilitate commerce and trade
- Protect public health, safety, and the environment
- Promote technology innovation and commercialization
 - ❖ Improved operations, procedures, processes, products, systems, & training
 - ❖ Equivalent results
 - ❖ Harmonization

Standards Development Principles

Documentary Standards (Voluntary Consensus)



Reference Materials

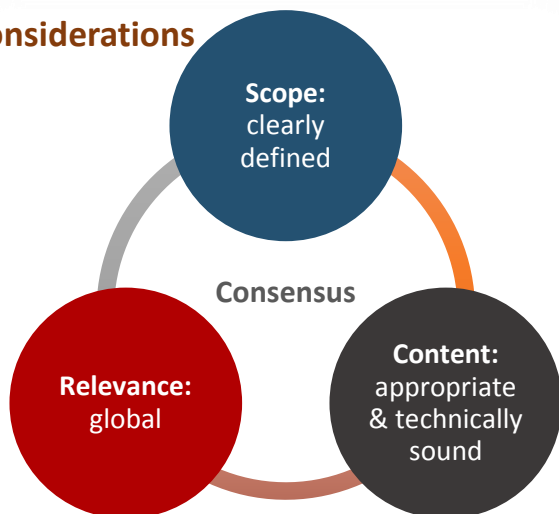
Fitness for intended use

Reference to specified properties

Homogeneity

Stability

Considerations



How might standards be used?

- Followed to accelerate new technology / product development
- Referenced in regulatory submission
- In conformity assessment: demonstration that specified requirements (e.g. as defined by a standard) are fulfilled
- In accreditation: third party attestation that an entity has formally demonstrated its competence per a set of requirements (e.g. standard)

ISO Standards Development

ISO and National Mirror Committees: Roles and Responsibilities

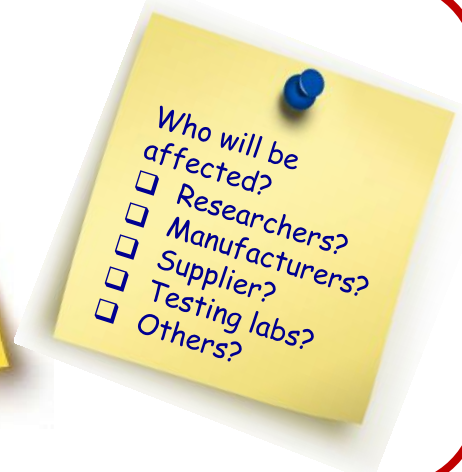
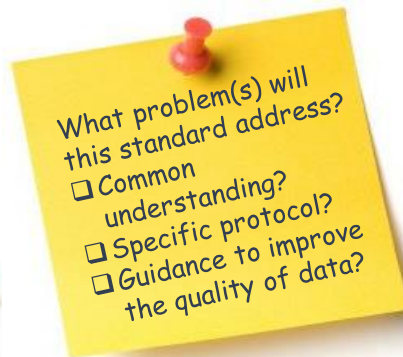


ISO Development stages



*optional stages

Considerations



Effective Standards Writing

- **Clear, consistent, plain language**
- **"Shall"** indicates a normative requirement
- **"Should"** indicates a recommendation
- **"May"** indicates a permission
- **"Can"** indicates a possibility or a capability

ISO Deliverables

	Technical Report (TR)	Publicly Available Specification (PAS)	Technical Specification (TS)	International Standard (IS)
Level of requirements	Informative (No requirements: may contain guidance or supplemental information)	Normative (requirements)		
Consensus level required	Technical Committee (simple majority of P members)	Working Group	Technical Committee (2/3 p-member approval)	Technical Committee & < 25% disapproval