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)

Openness
Anyone can participate

Balance
No single interest may dominate

Transparency
Essential information accessible to all

Due Process
Fairness & equity

Consensus
General agreement; not unanimity

Reference Materials

Fitness for intended use
Reference to specified properties
Homogeneity
Stability

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 it competence per a set of requirement (e.g. standard)
ISO Standards Development

ISO and National Mirror Committees: Roles and Responsibilities

Technical Committee: Voting / Strategic Directioning / Policy

Technical Committee (TC)
Players: Countries
US Role: Represent US Position

US Technical Advisory Group
(US TAG)
Players: US Organizations
Role: Represent Org./US Interest

Working Groups (WG)
Players: International Experts
US Role: Represent Expertise in context of US Position

Mirror Working Groups (WG)
Players: US Experts
Role: Represent Expertise

Working Group: Technical Work / Writing / Reviewing

ISO Development stages

PWI  • Preliminary Work Item*
NP   • New Work Item Proposal
WD   • Working Draft*
CD   • Committee Draft*
DIS  • Draft International Standard
FDIS • Final Draft International Standard*
IS   • International Standard

*optional stages

Considerations

What will be covered?
- Material A?
- Material B?
- Material C?
- All of the above?

What problem(s) will this standard address?
- Common understanding?
- Specific protocol?
- Guidance to improve the quality of data?

Who will be affected?
- Researchers?
- Manufacturers?
- Supplier?
- Testing labs?
- Others?

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

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<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Level of requirements</td>
<td>Informative (No requirements: may contain guidance or supplemental information)</td>
<td></td>
<td></td>
<td>Normative (requirements)</td>
</tr>
<tr>
<td>Consensus level required</td>
<td>Technical Committee (simple majority of P members)</td>
<td>Working Group</td>
<td>Technical Committee (2/3 p-member approval)</td>
<td>Technical Committee &amp; &lt; 25% disapproval</td>
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