Overview of the U. S. Standardization System
Key Terms

• **Standards**
  - Market-driven product and service specifications (e.g., technical requirements, management systems, etc.)

• **Regulations**
  - Mandatory technical specifications, which may include particular standards or conformity assessment procedures

• **Conformity Assessment**
  - Processes and systems used to verify the compliance of a product, person, process or system to either a standard or a regulation (e.g., testing, certification)

• **Standardization** (for this presentation)
  - Standards and Conformity Assessment
U.S. Standards and Conformity Assessment System
comparison with many other economies

Many other economies
*Top Down*
Standards bodies drive standardization activities

Approach in many economies

Approach in the United States
*Bottom Up*
Standards users drive standardization activities
U.S. Standards and Conformity Assessment System comparison with many other economies

- Emphasizes private-sector standards solutions

- Relies on private-sector compliance verification for both regulatory and non-regulatory functions

- Provides a strong voice and greater authority to standards users and individual stakeholders
U.S. Standards and Conformity Assessment System
the public-private partnership

• No single government agency has control over standards
  – Each agency determines which standards best meet its needs

• National Technology Transfer and Advancement Act of 1995 (NTTAA) — Public Law 104-113
  – With few exceptions, mandates that all federal agencies use technical standards developed and adopted by voluntary consensus standards bodies, as opposed to using government-unique standards

• Office of Management and Budget (OMB) Circular A-119
  – Establishes policies on federal use and development of voluntary consensus standards and on conformity assessment activities
  – Last revised in 1998, but update expected soon
U.S. Standards and Conformity Assessment System
reliable – flexible – responsive

• Market driven
• Flexible and sector-based
• Industry-led and government-supported

This system is designed to . . .

- Support a broad range of stakeholder engagement
- Address emerging priorities and new technologies
- Allow stakeholders to find the solutions that best fit their respective needs

As defined in the United States Standards Strategy
www.us-standards-strategy.org
## U.S. Standards System
### examples of roles and responsibilities

<table>
<thead>
<tr>
<th>Private Sector</th>
<th>Public Sector</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ANSI</strong></td>
<td><strong>NIST</strong></td>
</tr>
<tr>
<td><strong>Standards Developers</strong></td>
<td><strong>Federal Agencies Other than NIST</strong></td>
</tr>
<tr>
<td>Companies</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td></td>
</tr>
</tbody>
</table>

- Independently run standards development activities
  - ANSI: ✓
  - NIST: 
  - Federal Agencies Other than NIST: 
- Coordinates and monitors USG use of and participation in VCS activities
  - ANSI: ✓
  - NIST: ✓
  - Federal Agencies Other than NIST: 
- Legal metrology and WTO-TBT enquiry point
  - ANSI: ✓
  - NIST: ✓
  - Federal Agencies Other than NIST: 
- Provides technical input for standards development
  - ANSI: ✓
  - NIST: ✓
  - Federal Agencies Other than NIST: ✓
- Participates in U.S. standards policy development
  - ANSI: ✓
  - NIST: ✓
  - Federal Agencies Other than NIST: ✓
# U.S. Standards System

different tools for globally relevant standards

<table>
<thead>
<tr>
<th>Direct Participation</th>
<th>National Participation (one country one vote)</th>
<th>Consortia</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Internationally Accepted</td>
<td>▪ Treaty Organizations</td>
<td>▪ Typically more focused on specific technical need</td>
</tr>
<tr>
<td>▪ Nationally Accepted</td>
<td>▪ Non-Treaty Organizations</td>
<td>▪ Often in IT space</td>
</tr>
</tbody>
</table>

**Examples**

- ASME, other SDOs
- ISO, IEC, ITU, CODEX, etc.
- IGRS, W3C, etc.
U.S. Standards System
guiding principles

• Standards should meet societal and market needs and should not be developed to act as barriers to trade

• The United States endorses the globally accepted standardization principles of the World Trade Organization Technical Barriers to Trade Agreement
  - Transparency
  - Openness
  - Impartiality
  - Effectiveness and relevance
  - Consensus
  - Performance-based
  - Coherence
  - Due process
  - Technical Assistance
  - Flexible
  - Timely
  - Balanced

• Any standard developed by an organization that meets these principles should be able to be referenced in a government regulation
American National Standards (ANS)

- Currently there are approximately 225 ANSI-accredited standards developers, including ASME
  - Not all standards developed by these organizations are submitted for consideration as ANS
  - Standards developers are accredited based on the “ANSI Essential Requirements”
- There are approximately 10,000 American National Standards
- In the United States, regulations can reference ANS, but are not required to do so; any standard developed by an organization meeting the WTO TBT principles can be referenced
Outline

• Standards Development Process – ASME

• Conformity Assessment - A to Z

• Obtaining the Right Product Certification

• Copyright
Volunteers

- Committees are commonly composed of volunteers – Open Meetings and Process
- Volunteers participate “usually” free of charge
- Volunteers or their companies cover their cost of participation – travel, meals, hotels, etc.
- The participating member is the INDIVIDUAL and not the company they work for
- Have a professional and ethical responsibility
- Must meet the requirements set by the committee in order to be accepted
What do Volunteers do?

- Identify Standards issues for discussion
- Work as Project Technical Managers (PTM) and Project Teams to develop Standards proposals
- Vote and provide comments on proposals developed
- Vote and provide comments on proposals developed by other subgroups
Responsibilities of Volunteers

• Contribute to the development of standards proposals
• Contribute technical expertise to discussions and standards proposals
• Participate in working groups, task groups, or international Working Groups (IWG) proceedings by voting and attending meetings
• Do not compromise technical input in favor of personal (employers’) interests
• Comply with ANSI accredited SDO procedures
Participate

Why Participate?

• So that International Standards include/incorporate the needs of Latin America

• To REPRESENT the needs of your industry and country – Nobody knows your needs better than you do

• To PROTECT/DEFEND your countries’ interest

• Participating:
  - In-Person, best and highly recommended
  - On-Line, great option and very economical
  - Specially design programs, i.e. Regulators
COMMITTEES
Committees

• Are Autonomous - independent
• Vary and size and composition – domestic and international participation
• Leadership could affect Effectiveness
• Follow Robert’s Rules - http://www.robertsrules.org/
• Have a communication structure
• Follow a hierarchy
• Organization – chair, vice chair, secretary
Volunteers form the committees with support from ASME staff
Standards Committees and their Subordinate Groups

• Standards Committee:
  - Relevant technical expertise resides here (above the weeds)
  - Responsible for developing consensus on proposed standards actions
  - May delegate certain standards development activities to one or more Subordinate Groups.

• Subordinate Group(s):
  - Develop specific proposals for the committee’s formal consensus consideration (in the weeds)
  - May draw on the expertise of individuals outside of the standards committee.
  - Include Project Teams, Subcommittees, Task Groups, Working Groups and Ad-hoc Groups
Standards Committees and their Subordinate Groups

• International Working Group (IWG)
  – Similar to the working Groups
  – Commonly based in a country
  – Membership is local to the country – Mexico, Brazil, Argentina
  – Facilitates communication
  – Addresses local needs
  – Voting and commenting rights
  – Meetings in native language
  – Reporting required but not face-to-face
  – Committee training must be provided
  – Development curve must be considered
Committee Communication and Reporting Process

Supervisory Board

Standards Committee

Subordinate Group(s)

(Certifies adherence to procedures)

(Consensus vote)

(Proposal Development)
CONSENSUS PROCESS
WHAT DOES "CONSENSUS" MEAN?

• Consensus means
  – Substantial agreement by affected interest categories
  – Consideration of views, attempted resolution is part of the process
  – Unanimity not required

• The Standards Committee is responsible for establishing consensus on proposed standards actions
The Consensus Development Process

Development of standards action

- Initiation
- Project Team
- Review and Comment
- Subcommittee Vote (sub-tier)
- Standards Committee Vote
- Public review
- Supervisory Board approval
- Appeals
- ANSI approval (when desired)
PRINCIPLES OF ASME STANDARDS DEVELOPMENT

• **Balance** is maintained among competing interests

• The process is **transparent** - information on the process and progress is directly available

• **Due process** assures that all views will be considered and that appeals are possible

• Standards development strives for global relevance

• **Responsive** to current technology without invalidating existing products or processes
The Consensus Development Process

Recorded vote (cont’d)

• All standards committee participants have opportunity to vote.

• Voting options are: Approved, Disapproved, Abstain, Not Voting

• Item passes on first consideration vote if no “Disapproved” votes and minimum 2/3 affirmative votes
The Consensus Development Process

Recorded vote (cont’d)

- “Disapproved” votes on first consideration require:
  - An explanation of reason for the disapproval and a recommendation for resolving the disapproval
  - Committee action to attempt to resolve disapprovals

- “Not Voting” - Conflict of interest. Reduces committee membership count

- “Abstain” - Lack of expertise or an insufficient review. Does not reduce committee membership
The Consensus Development Process

Supervisory Board approval

• Conducted after consensus committee approval
• Verifies adherence to policies, procedures and charter
• Conducted by two-week Review or Recorded Vote
The Consensus Development Process

Public review

- **All** proposed standards actions must be announced for public review, normally a 2 month public review takes place (this period may be different in your country)
- Can be conducted concurrently with committee vote (though usually not recommended)
The Consensus Development Process

ANSI approval

- Proposed action submitted to ANSI Board of Standards Review (BSR)
- Information provided includes committee roster and votes
- Technical issues not considered
- Formal/Administrative approval
CONFORMITY ASSESSMENT
Conformity Assessment

• “Any activity concerned with determining directly or indirectly that requirements are fulfilled”

• Conformity Assessment, when properly applied, provides regulators and purchasers of products confidence that the products were manufactured in accordance with the applicable standard, regardless of where in the world they were manufactured.
Conformity Assessment

• Some conformity assessment programs are recognized between various governments through Mutual Recognition Agreements (MRA’s)
• Others are accepted on a contractual basis because of experience and industry recognition, without government-to-government MRA’s
• Others must be registered, approved and ARE required by a local government agency – often Customs
Conformity Assessment

“Any activity concerned with determining directly or indirectly that requirements are fulfilled”

Source: http://celebrating200years.noaa.gov/magazine/tct/01_misaligned.bridge.html
Global Growth
Certified Boiler & Pressure Vessel Manufacturers

Data as of 2014-12-31
What We Want
What We Want to **AVOID**

La Fiscalía mexicana informó que se investigará “hasta las últimas consecuencias” las posibles causas que produjeron la explosión en una planta de Petróleos Mexicanos (Pemex) en Reynosa (noreste del país), donde murieron 26 trabajadores y 46 más resultaron heridos.

**Explosion Mexico**

El 25 de Agosto del 2012, 39 personas han fallecido por la explosión de la refinería de Amuay, estado Falcón, y 82 heridos.

Septiembre 19, 2012 El director general de Pemex, Juan José Suárez Coppel, completa el recorrido para constatar los daños ocurridos por la explosión (Foto: EFE)
Conformity Assessment

- New Products – domestic or export markets
- Existing Products - domestic or export markets
- Do not limit your views of conformity assessment to new products ONLY – think repairs
- Often developed and follow an international standard
- Sometimes linked to Pre-Shipment Inspections
Conformity Assessment

• Benefits
  – High quality CONSISTENT products – again and again
  – Increase exports – open markets worldwide
  – Increase safety – when used instead of poor quality products
  – Inspire confidence – increase customer satisfaction
  – TRACEABILITY

• Third Party Independent Inspections
  – Eliminate conflict of interest
  – Provide assurance
  – Qualified personal
Conformity Assessment

• Applicable to many industries
  – Industrial applications – fabrication processes, material certifications, inspections
  – Energy – wind turbines, solar panels, pressure vessels, boilers
  – Automotive – components, assemblies, testing
  – Medical devices – hip replacements, surgical tools
  – Aerospace – highly regulated, engines, lights, electronics

• THINK schedule maintenance and not REPAIR

• It is a mindset, a cultural shift for some areas and a way of life for others (aerospace)

• When you think of Conformity Assessment think Reliability
Conformity Assessment

- The main bodies of a conformity Assessment program involve

  - Quality Assurance Program
  - Certification
  - Testing
  - Inspection
Guide for Inspections

ASME Section VIII Div. 1 Appendix 10

• 10-1 General
• 10-2 Guide for Quality Control Program
• 10-3 Authority and Responsibilities
• 10-4 Organizational Chart
• 10-5 Drawings, designs, calculations, specifications, control methods
• 10-6 Material control and certifications
• 10-7 Inspection and testing program
• 10-8 Corrective Action Process – material, equipment, or product failures
Guide for Inspections

ASME Section VIII Div. 1 Appendix 10

- 10-9 Welding
- 10-10 Non Destructive Evaluations and Testing
- 10-11 Material Heat Processing
- 10-12 Equipment Calibration
- 10-13 Document Retention – VERY IMPORTANT
- 10-14 Forms Used
- 10-15 Inspection of Pressure Vessels and Components
- 10-16 Inspection of Relief Valves
- 10-17 Certifications
# Compare Certifications

**Certified Welding Inspector (AWS)**

**PART A: FUNDAMENTALS (CWI and CWE)**

<table>
<thead>
<tr>
<th>Subject</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Welding Processes</td>
<td>10%</td>
</tr>
<tr>
<td>Heat Control &amp; Metallurgy (carbon and low-alloy steel)</td>
<td>6%</td>
</tr>
<tr>
<td>Weld Examination</td>
<td>9%</td>
</tr>
<tr>
<td>Welding Performance</td>
<td>9%</td>
</tr>
<tr>
<td>Definitions and Terminology</td>
<td>12%</td>
</tr>
<tr>
<td>Symbols - Welding and NDE</td>
<td>10%</td>
</tr>
<tr>
<td>Test Methods - NDE</td>
<td>8%</td>
</tr>
<tr>
<td>Reports and Records</td>
<td>6%</td>
</tr>
<tr>
<td>Duties and Responsibilities</td>
<td>4%</td>
</tr>
<tr>
<td>Safety</td>
<td>5%</td>
</tr>
<tr>
<td>Destructive Tests</td>
<td>4%</td>
</tr>
<tr>
<td>Cutting</td>
<td>3%</td>
</tr>
<tr>
<td>Brazing</td>
<td>2%</td>
</tr>
<tr>
<td>Soldering</td>
<td>1%</td>
</tr>
</tbody>
</table>

**PART B: PRACTICAL (CWI and CWE)**

<table>
<thead>
<tr>
<th>Subject</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure and Welder Qualifications</td>
<td>30%</td>
</tr>
<tr>
<td>Mechanical Test and Properties</td>
<td>10%</td>
</tr>
<tr>
<td>Welding Inspection and Flaws</td>
<td>36%</td>
</tr>
<tr>
<td>NDE</td>
<td>10%</td>
</tr>
<tr>
<td>Utilization of Specification and Drawings</td>
<td>10%</td>
</tr>
</tbody>
</table>

**PART C: CODE BOOK APPLICATIONS (CWI, CWE and SPIE)**

<table>
<thead>
<tr>
<th>Subject</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Materials and Design</td>
<td>10%</td>
</tr>
<tr>
<td>Fabrication</td>
<td>30%</td>
</tr>
<tr>
<td>Inspection</td>
<td>25%</td>
</tr>
<tr>
<td>Qualification</td>
<td>30%</td>
</tr>
</tbody>
</table>

Qualification Examinations
5.1 Examination Descriptions
5.2.1 General Examination: This written examination consists of a minimum of 50 multiple-choice questions that assess the candidate’s knowledge of the fundamentals, theory and principles of the test method for which certification is sought.

5.2.2 Specific Examinations: These written examinations consist of a minimum of 40 multiple-choice questions that assess the candidate’s knowledge of equipment, operating procedures, and NDT techniques that the individual may encounter during specific assignments in the NDT method(s) in which certification is sought; and covers specifications, codes and acceptance criteria used in the applicable industry sector.

5.2.3 Employers are responsible for administering the visual acuity, practical and any job-specific examinations required by their written practice to complete certification.

Employer Responsibility
9.1 The employer is responsible for performing a Practical examination in accordance with the guidelines of Recommended Practice No. SNT-TC-1A.

9.2 The employer is responsible for the visual acuity and any additional job-specific examinations that may be required by their written practice to complete the certification process.

9.3 The employer, through an NDT Level III or other designated person as denoted in the employer’s written practice, should review the individual’s qualification records for satisfactory completeness in accordance with Recommended Practice No. SNT-TC-1A prior to certifying an individual to perform NDT.

9.4 The employer has the sole responsibility for authorizing qualified employees to perform NDT

Source: https://www.asnt.org/en/MajorSiteSections/Certification/ASNT%20NDT%20Level%20II%20Program.aspx
Product Certification
Product Certification

• Obtaining the right product certification is important
• Do your homework – Trust but Verify

• Following the standard DOES NOT mean MEETING the standard
• Require the appropriate credentials for quotes and prior to contracting
• $$$ matters but it is not the only thing
Conformity Assessment

• It is important to adopt International Conformity Assessment Programs
• Do not reinvent the wheel – the work has been done for you
  – Focus on implementation – to suit your countries needs
  – Think SAFETY – people’s lives
  – Protect your capital investments – plants, buildings, hospitals, etc.
Copyright
Copyright

• We are all in this together – respect and enforce copyright the best you can
• Translating an international standard WITHOUT permission and removing the original author is a violation of copyright
• Ask for permission – many SDO/authors will grant you permission at NO COST
• Consider co-authoring, licensing agreements, royalties – it reduces cost
• Not just Copyright – Logos & trademarks too!
Questions

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