Standards and Conformity Assessment

Key Concepts
U.S. Standards & 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
- Standards users drive standardization activities

United States
*Bottom Up*
U.S. Standards & 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
National Conformity Assessment Principles (NCAP)

- Articulates principles for conformity assessment activities in the U.S.
  - Guidance document to be considered along with the U.S. Standards Strategy
  - Improves the ability of the marketplace to understand and have confidence in conformity assessment processes
Key Terms *(per the NCAP)*

- **Conformity Assessment**
  Demonstration that specified requirements relating to a product, process, system person or body are fulfilled.

- **Accreditation**
  Third party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks. (These tasks include sampling and testing, inspection, certification and registration.)

- **Certification**
  Third party attestation related to products, processes, or persons that conveys assurance that specified requirements have been demonstrated.
Conformity Assessment and Risk

Perceived Risk

Independence and Rigor of Conformity Assessment

Supplier’s Declaration

1st party conformity assessment

Certification

3rd party conformity assessment
The Conformity Assessment Balance

value for suppliers

confidence for acceptance interests
Confidence/Regulation Spectrum

unregulated → complete trust

100% inspection → very regulated

paperclip → produce

produce → pharmaceuticals
Accredited 3\textsuperscript{rd}-Party Hierarchy

(ISO/IEC 17011 standard for accreditation bodies)
International Recognition Bodies

IAF
INTERNATIONAL ACCREDITATION FORUM

ILAC
INTERNATIONAL LABORATORY ACCREDITATION COOPERATION

PAC
PACIFIC ACCREDITATION COOPERATION

APLAC
ASIA-PACIFIC LABORATORY ACCREDITATION COOPERATION

IAAC
INTERAMERICAN ACCREDITATION COOPERATION

EA
EUROPEAN ACCREDITATION COOPERATION