

# Standards and Global Market Success

- Understand all the characteristics and attributes of the products/services that are subject to regulatory and/or market requirements – may vary by country/market/customer
- Harmonized standards are generally ideal
- Avoid mutually exclusive technical requirements
- Anticipate conformity assessment procedures
- Design product and processes with regulatory and market requirements as inputs

# Factors in Designing Conformity Assessment Systems

- Risks associated with non-compliance should be proportional to the rigor of the system design
  - Over-design costs too much
  - Under-design gives too little confidence
- Marketplace consequences (penalties) and effective recall can allow for less rigor in conformity assessment
- One size does not fit all...

# Common Approach - Standards for Conformity Assessment

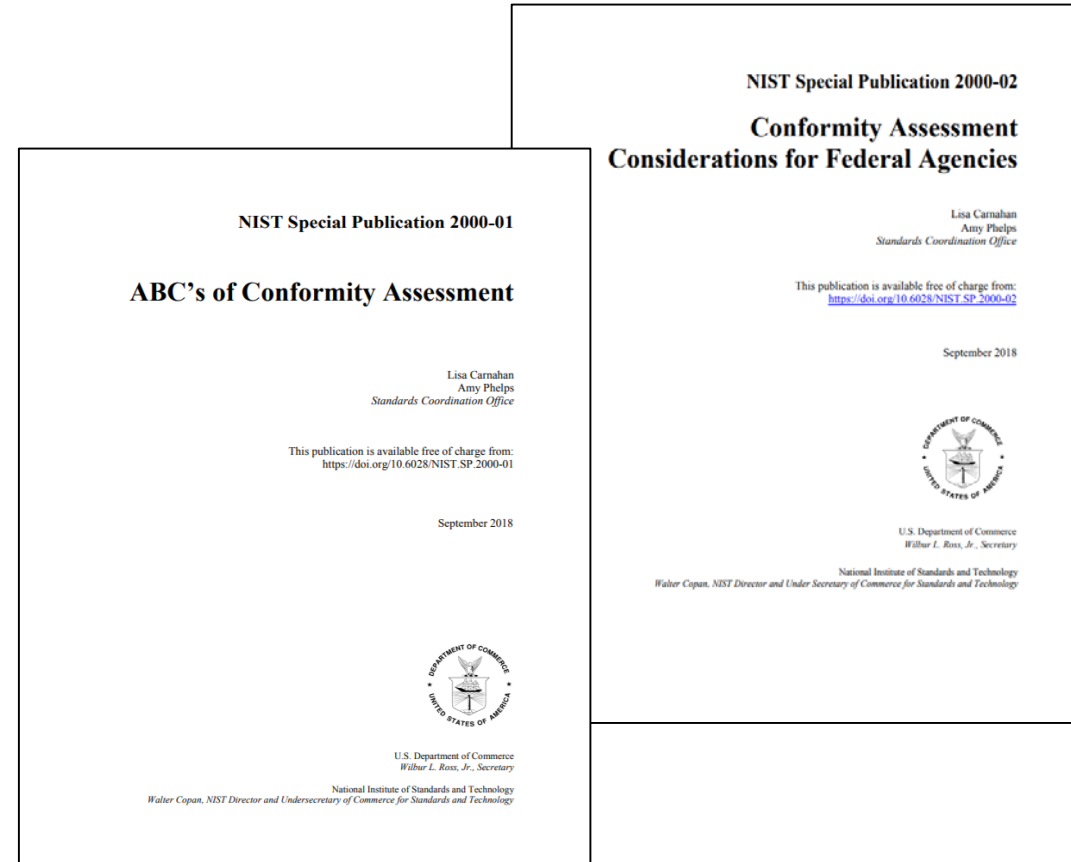
Type	Parties			Standard(s)
	1 <sup>st</sup>	2 <sup>nd</sup>	3 <sup>rd</sup>	
Testing	✓	✓	✓	ISO/IEC 17025
Inspection	✓	✓	✓	ISO/IEC 17020
Supplier's Declaration of Conformity (SDoC)	✓			ISO/IEC 17050 Parts 1 and 2
Certification				
Products, processes, services			✓	ISO/IEC 17065
Management systems			✓	ISO/IEC 17021
Persons			✓	ISO/IEC 17024
Accreditation			✓	ISO/IEC 17011

# Resources from NIST - Special Publications



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Available at [standards.gov](https://standards.gov)



# Approaches to Optimize Assessment

Resources and Results: What Works and What are the Issues?

Dietary Supplements Standardization Coordination Meeting

May 13, 2019

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National Institute of Standards and Technology