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

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

Resources from NIST - Special Publications



Published September 28, 2018

Available at standards.gov

Considerat

ABC's of Conformity Assessment

NIST Special Publication 2000-01

Lisa Carnahan Amy Phelps Standards Coordination Office

This publication is available free of charge from: https://doi.org/10.6028/NIST.SP.2000-01

September 2018

SHEWENT OF COMMANDS

U.S. Department of Commerce
Wilhur I. Ross, Jr. Secretary

National Institute of Standards and Technology Walter Copan, NIST Director and Undersecretary of Commerce for Standards and Technology NIST Special Publication 2000-02

Conformity Assessment Considerations for Federal Agencies

Lisa Carnahan Amy Phelps Standards Coordination Office

This publication is available free of charge from: https://doi.org/10.6028/NIST.SP.2000-02

September 2018



U.S. Department of Commerce Wilbur L. Ross, Jr., Secretary

National Institute of Standards and Technology Walter Copan, NIST Director and Under Secretary of Commerce for Standards and Technology

Approaches to Optimize Assessment

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

Dietary Supplements Standardization Coordination Meeting
May 13, 2019

Gordon Gillerman

Standards Coordination Office

National Institute of Standards and Technology