

#### Perspectives on Conformity Assessment

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# Conformity Assessment - Overview (I)

- What: Methods to develop confidence that a product, service or system:
  - Meets specified requirements
  - Demonstrates required characteristics
  - Performs in a specified manner
- How: Assessment rigor/formality can vary:
  - Self-Assertions by Supplier
  - Inspections based on Professional Judgment
  - Testing using Technical Operations, Procedures
  - Certification by Third Parties

# Conformity Assessment - Overview (II)

- Who: Assessment can be performed by:
  - Supplier <u>First-Party</u>
  - Consumer/Purchaser <u>Second-Party</u>
  - Independent Party hired by Supplier or Consumer <u>Third-Party</u>
  - Regulatory Body <u>Third-Party</u>
- When: Assessment timing can be:
  - One Time Prior to Acquisition/Use
  - Periodic Established Interval
  - Ad Hoc As-Needed during Period of Use

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#### Conformity Assessment - Benefits

- Facilitates National and Global Commerce
- Provides Peace of Mind to Consumers
- Promotes Uniformity/Consistency in Marketplace
- Supports Interoperability; Plug-and-Play
- Serves as Market Differentiator for Suppliers
- Promotes Consumer Safety
- Protects broader interests (e.g., Environment)

## Conformity Assessment - Challenges

- Standards/Specifications often not amenable to Conformity Assessment
- Conformity to Requirements may not imply Interoperability
- Transparency and Objectivity of Assessment Methods
- Third-Party Assessor Characteristics:
  - Independence and Impartiality
  - Consistency of Assessment Procedures
  - Strong Configuration Management Practices

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# Conformity Assessment - Trade-Offs

- May stifle Innovation
- May constrain Market Opportunities for Suppliers
- May delay Commerce and Adoption
- Time Consuming and Expensive
- May provide a False Sense of Confidence

### Conformity Assessment Examples (I)

- Personal Identity Verification (PIV) Card Data Model (NIST)
  - Reqts: FIPS 201 Standard and Special Pubs
  - Test Requirements and Test Assertions
  - 800-85B Test Tool (NPIVP)
- PKI-Enabled Products (SAFE Biopharma)
  - Reqts: SAFE PKI Bridge Certificate Policy
  - Vendor Certification Program
  - Test Requirements
  - Test Cases

### Conformity Assessment Examples (II)

- HSPD-12 Products and Services (GSA)
  - Reqts: FIPS 201 Standard and Special Pubs
  - Operate GSA FIPS 201 Evaluation Program
  - Maintain Approved Products List (APL)
  - EP Test & Approval Procedures for 30+ Product Categories
  - EP Technical Test Tools for biometric devices, PKI and smart card products
  - Evaluate 300+ HSPD-12 products and services
  - Qualify 3rd Party Testing Labs

# Conformity Assessment Examples (III)

- Smart Meters (NIST)
  - Reqts: AMI Meter Upgradeability Standard
  - Conformance Test Framework
  - Test Profiles, Derived Test Requirements
  - Test Tools
- Electronic Health Record (EHR) Products (NIST)
  - Reqts: 2014 Edition Release 2 EHR Certification Criteria and Meaningful Use Stage 2
  - Test Procedures and Test Procedure Packets
  - Conformance Tool Documentation

# Conformity Assessment Examples (III)

- Voting Systems (NIST)
  - Reqts: Voluntary Voting Systems Guidelines (VVSG)
  - Stakeholder Consensus Building
  - Test Assertion Framework and Test Assertions
- Cloud Services
  - Reqts: Federal Risk & Authorization Management Program (FedRAMP)
  - Third Party Assessor Organization (3PAO) Assessments
- Identity Service Providers
  - Reqts: GSA ICAM Trust Framework Solutions
  - Kantara Assessments



## Wrap-Up and Contact Information



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