

NIST

Standards Services



Basics of Conformity Assessment

Standards Coordination Office, Standards Services

Quarterly Standards Seminar Series No. 1

March 28, 2012

Today's Discussion

- Terminology
- Types of Conformity Assessment
- How it Works
- Standards and Conformity Assessment in Regulation
- Examples

Conformity Assessment

“demonstration that specified requirements relating to a product, process, system, person, or body are fulfilled”

- *ISO/IEC 17000*



1st Party
2nd Party
3rd Party

The Parties – who done it?

First Party	A seller or manufacturer
Second Party	A purchaser or user
Third Party	An independent entity that has no interest in transactions between the first and second parties
Government	Has a unique role in regulation, but is the second party in procurement application of standards

1st Party

2nd Party

3rd Party

Types of Conformity Assessment

- Supplier's Declaration of Conformity (SDoC)
- Inspection
- Testing
- Certification
- Registration
- Accreditation
- ISO/IEC 17050 parts 1 and 2
- ISO/IEC 17020
- ISO/IEC 17025
- ISO/IEC Guide 65
- ISO/IEC 17021
- ISO/IEC 17011

Supplier's Declaration of Conformity (SDoC)

- 1st Party
- 2nd Party
- 3rd Party

Characteristics

- Used when low product risk
- Penalties for noncompliant products
- Effective recall system

Examples



- ISO/IEC 17050



Inspection

1st Party
2nd Party
3rd Party

Characteristics

- Simple test measurement or examination
- Code compliance

- *ISO/IEC 17020*

Examples





Testing

1st Party

2nd Party

3rd Party

Characteristics

Examples

- Measures Characteristics
- Representative samples are often used
- May be element of SDoC or certification system

- *ISO/IEC 17025*



Certification

1st Party
2nd Party
3rd Party

Characteristics

- Used when moderate – high product risk
- More expensive
- Surveillance

- ISO/IEC GUIDE 65

Examples





1st Party
2nd Party
3rd Party

Management System Registration

Characteristics

Examples

- Process requirements
- Scope matters: can be general or specific

- *ISO/IEC 17021*





Accreditation

- 1st Party
- 2nd Party
- 3rd Party

Characteristics

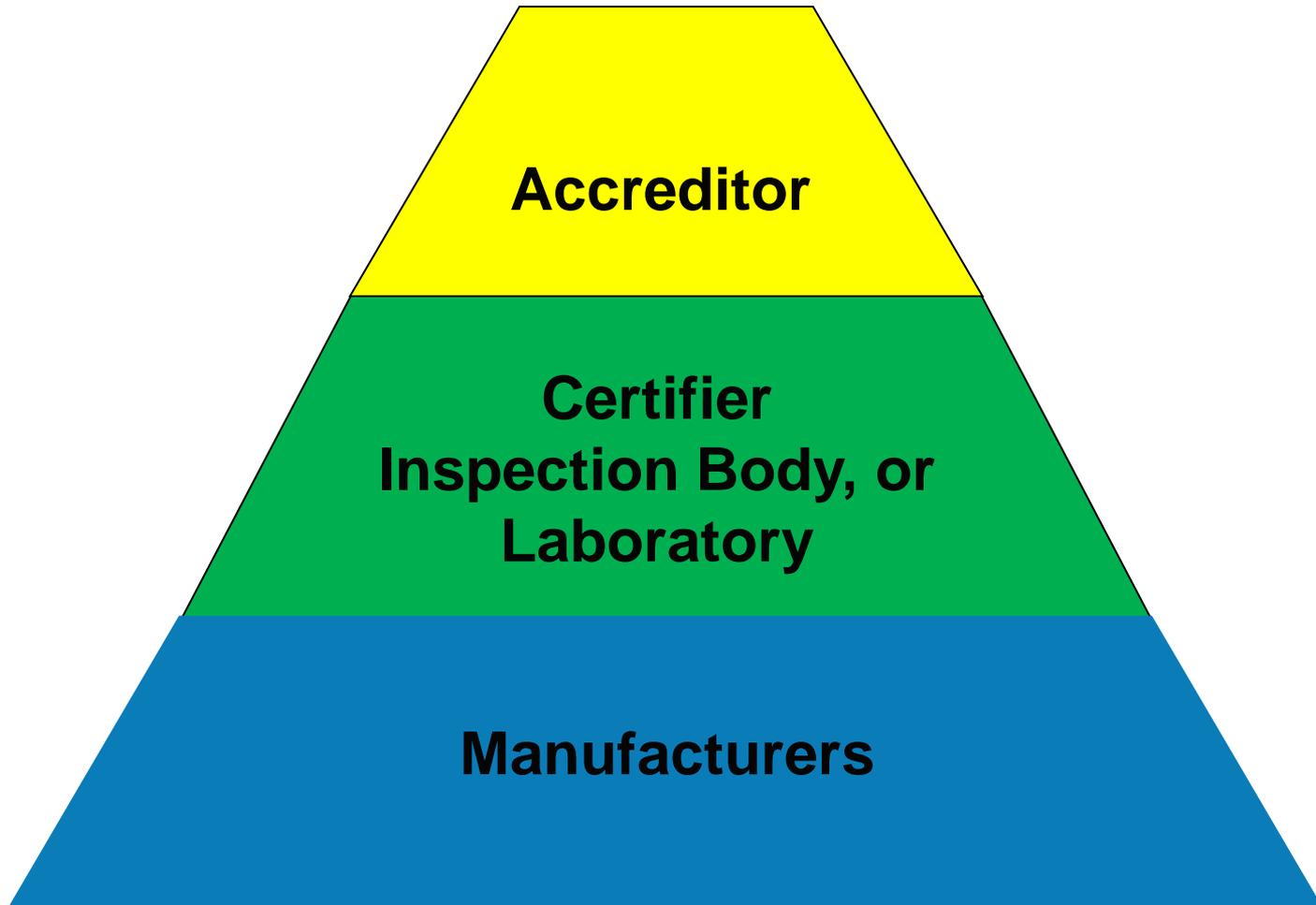
- Formal demonstration of competence to carry out specific tasks
- Provides confidence for purchasers, regulators and consumers

Examples



- ISO/IEC 17011

Who watches the watchers?

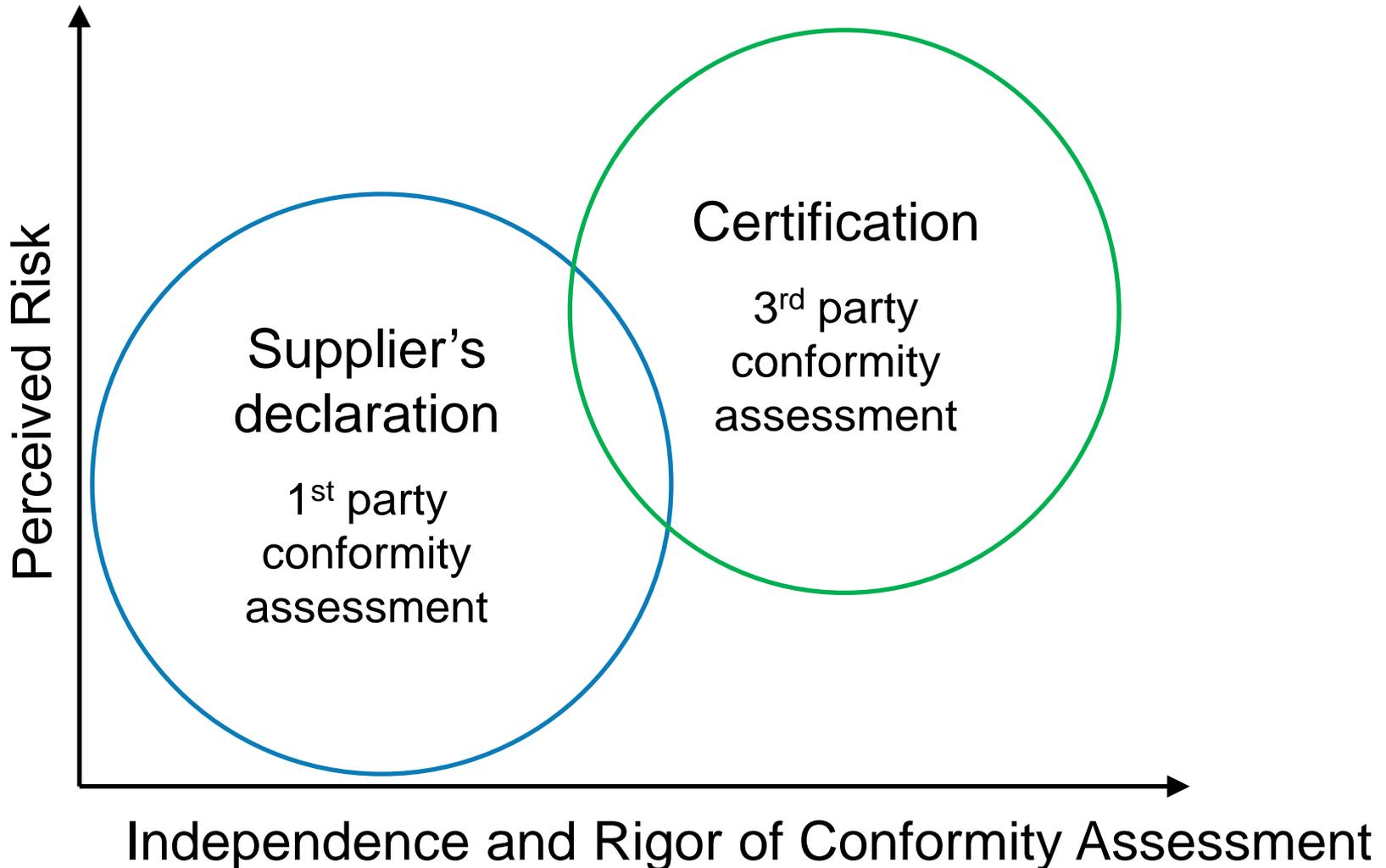




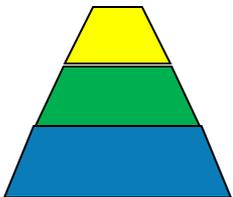
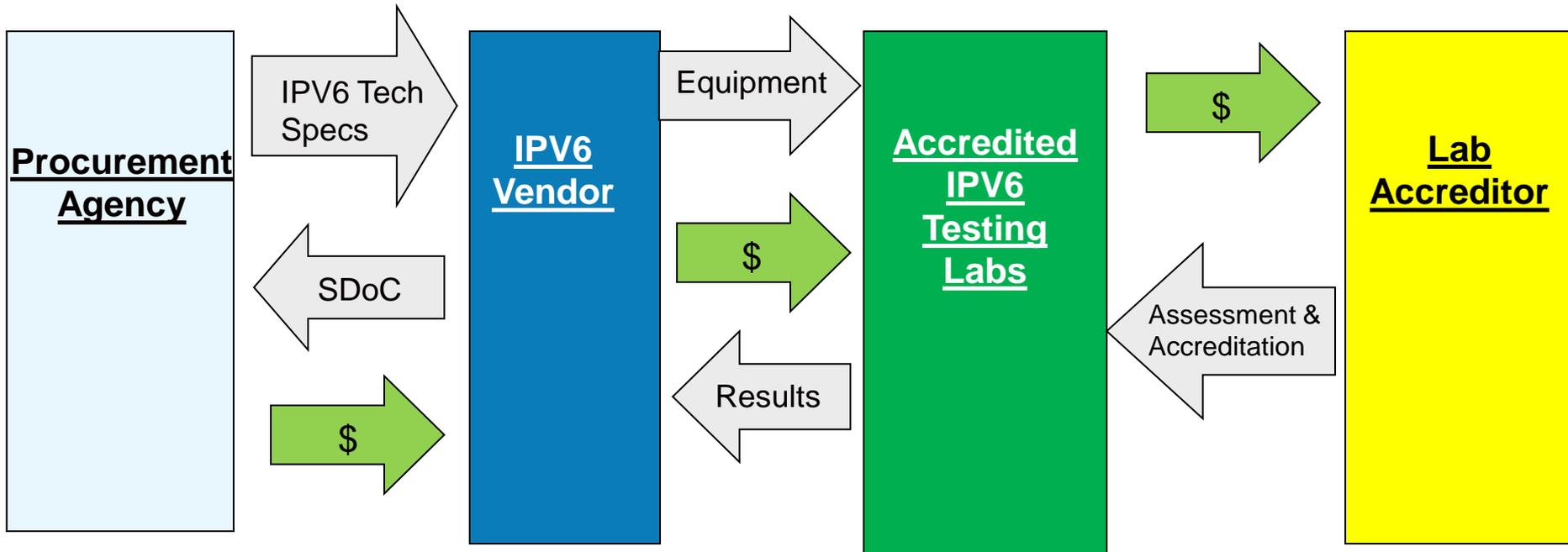
Factors in Conformity Assessment Systems

- 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) & effective recall allow less rigor

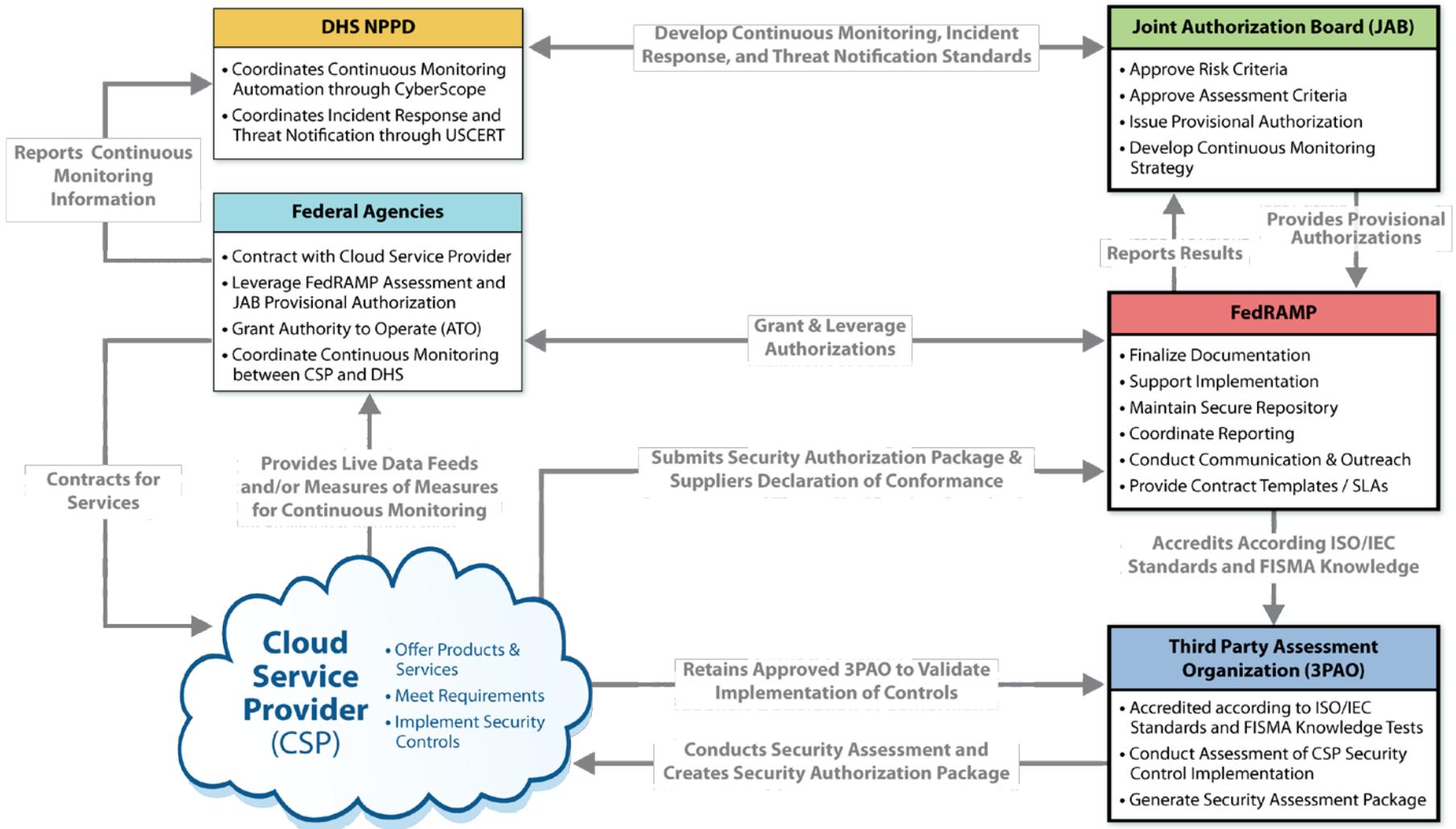
How much confidence is needed?



IPV6 Example of Conformity Assessment System



FedRAMP Stakeholder Roles and Interaction



Review

- Terminology
- Types of conformity assessment
- How it works
- Standards and conformity assessment in regulation
- Examples

Thank You

Basics of Conformity Assessment

Gordon Gillerman

gordon.gillerman@nist.gov

301-975-8406