

U.S. Approach to Conformity Assessment

**NIST Standards in Trade Conference for the
Association of Southeast Asian Nations**

March 2014

- Terminology
- Types of Conformity Assessment
- How it Works
- Examples
- Facilitating Trade through Conformity Assessment

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 17065
- ISO/IEC 17021
- ISO/IEC 17011

Supplier's Declaration of Conformity (SDoC)

1st Party

Characteristics

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

Examples



- ISO/IEC 17050

Certification

3rd Party

Characteristics

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

- *ISO/IEC GUIDE 65*

Examples



Accreditation

3rd Party

Characteristics

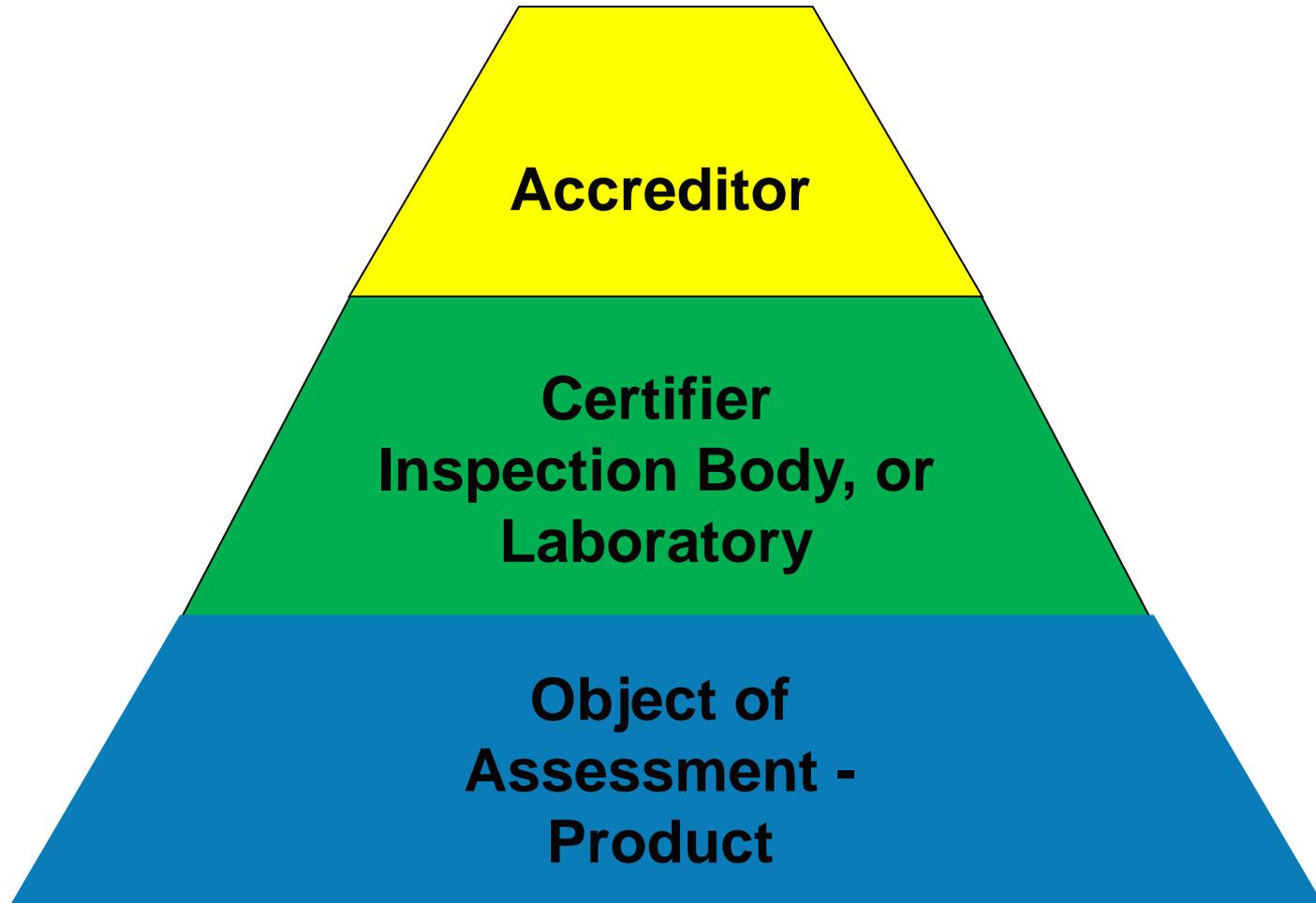
- Formal demonstration of competence to carry out specific tasks
- Provides confidence for purchasers, regulators and consumers

Examples



- ISO/IEC 17011

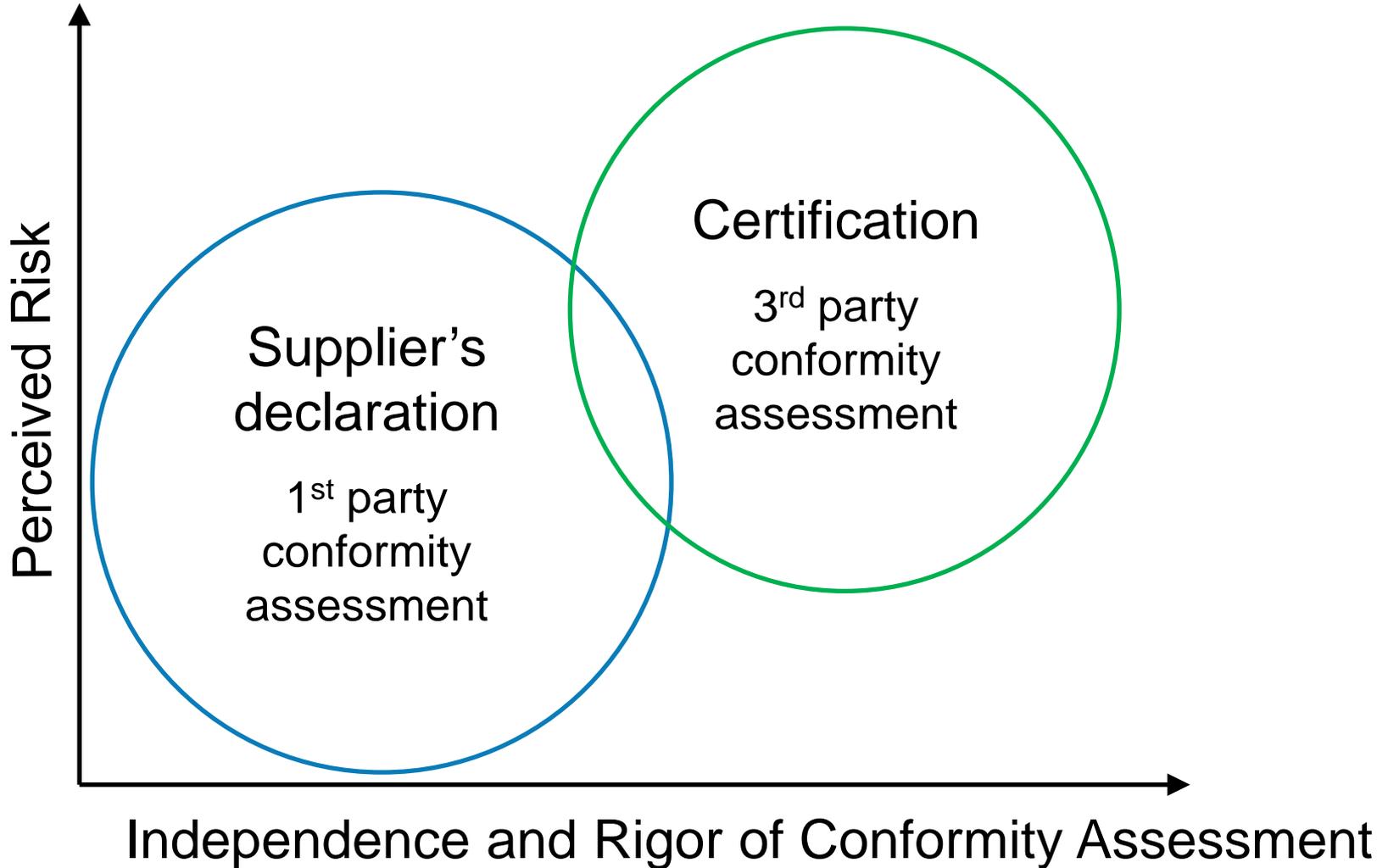
Who watches the watchers?



Factors in Conformity Assessment Systems

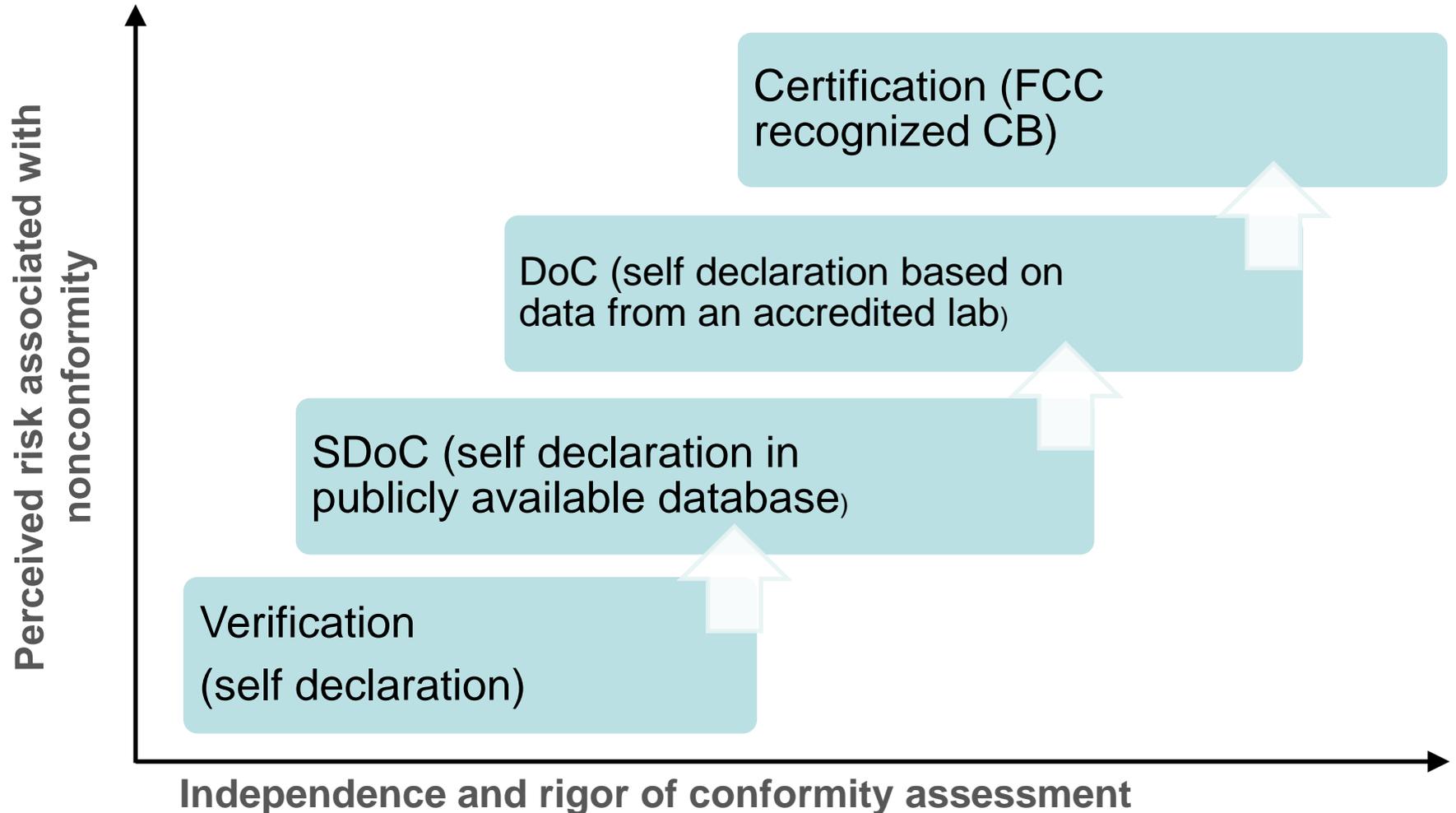
- Risks associated with non-compliance should be proportional to the rigor of the system design
 - ▶ Over-design costs too much
 - ▶ Under-design gives too little confidence
- Marketplace consequences (penalties) & effective recall allow less rigor

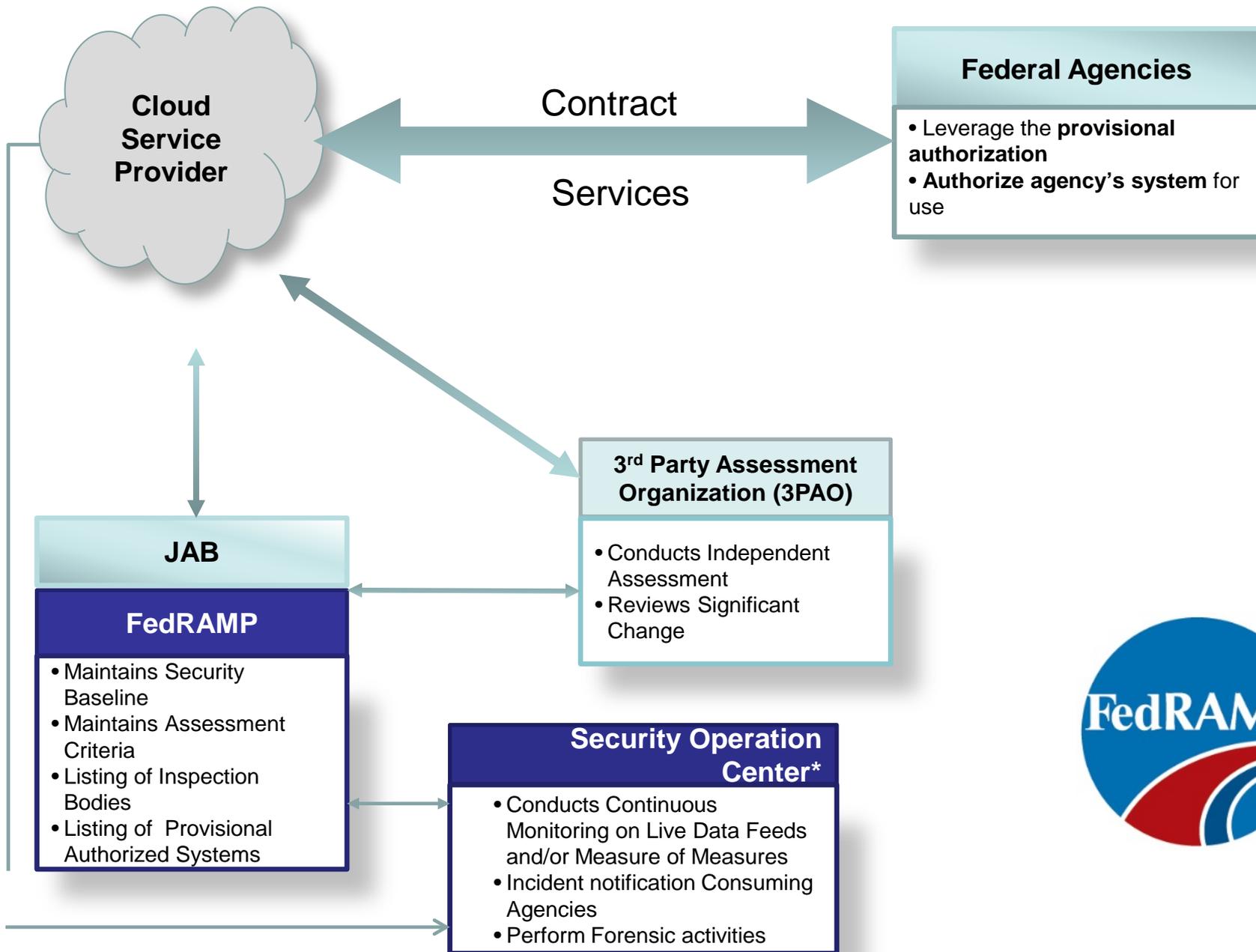
How much confidence is needed?



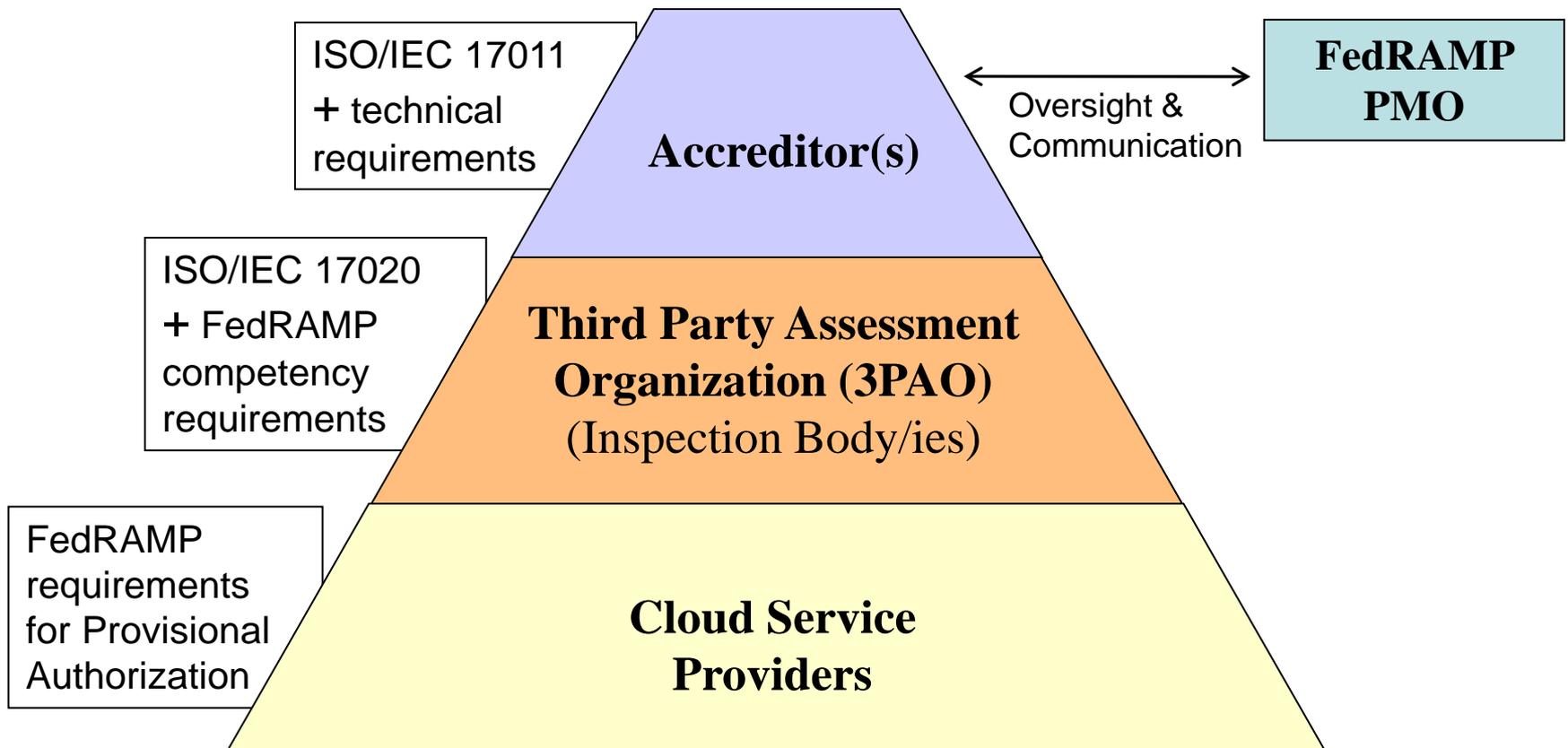
Risk Based Approach to Conformity Assessment

Example: FCC Equipment Authorization Program





FedRAMP 3PAO Heirarchy



ISO/IEC 17011; Conformity assessment -- General requirements for accreditation bodies accrediting conformity assessment bodies
ISO/IEC 17020; General criteria for the operation of various types of bodies performing inspection

Market Access vs. Market Acceptance

Market Access



Product Meets the Legal Requirements

Market Acceptance



Product Meets Non-Regulatory Market Expectations

Mechanisms to Facilitate Trade - Examples

Technical Requirements

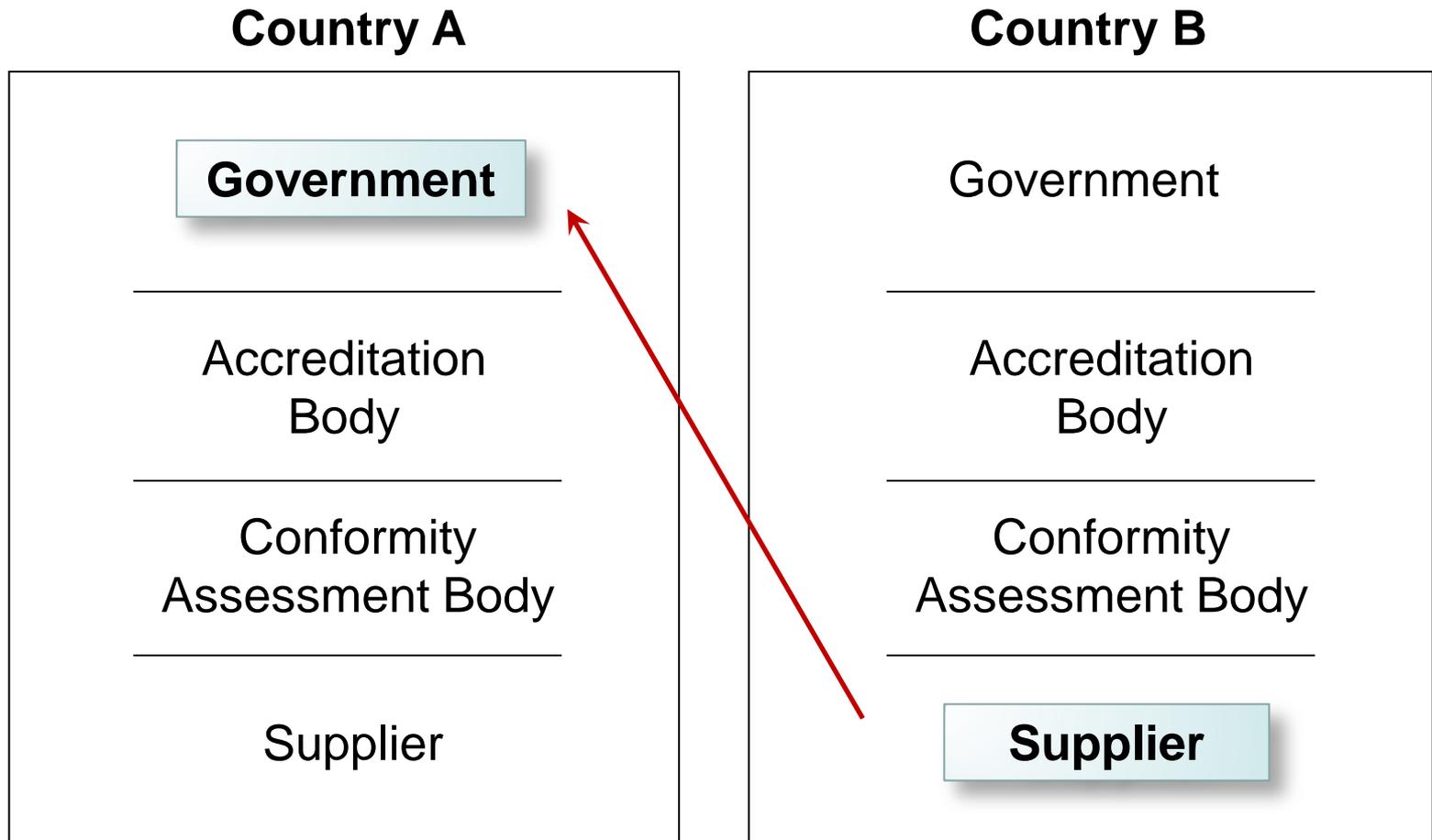
- Harmonization of requirements
- Avoid mutually exclusive requirements

Conformity Assessment

- Supplier's Declaration of Conformity
- Mutual recognition of laboratory accreditation
- National treatment for conformity assessment organizations
- Private sector data exchange agreements among certifiers
- Government-to-Government Mutual Recognition Agreements/Arrangements

Pathways for International Trade

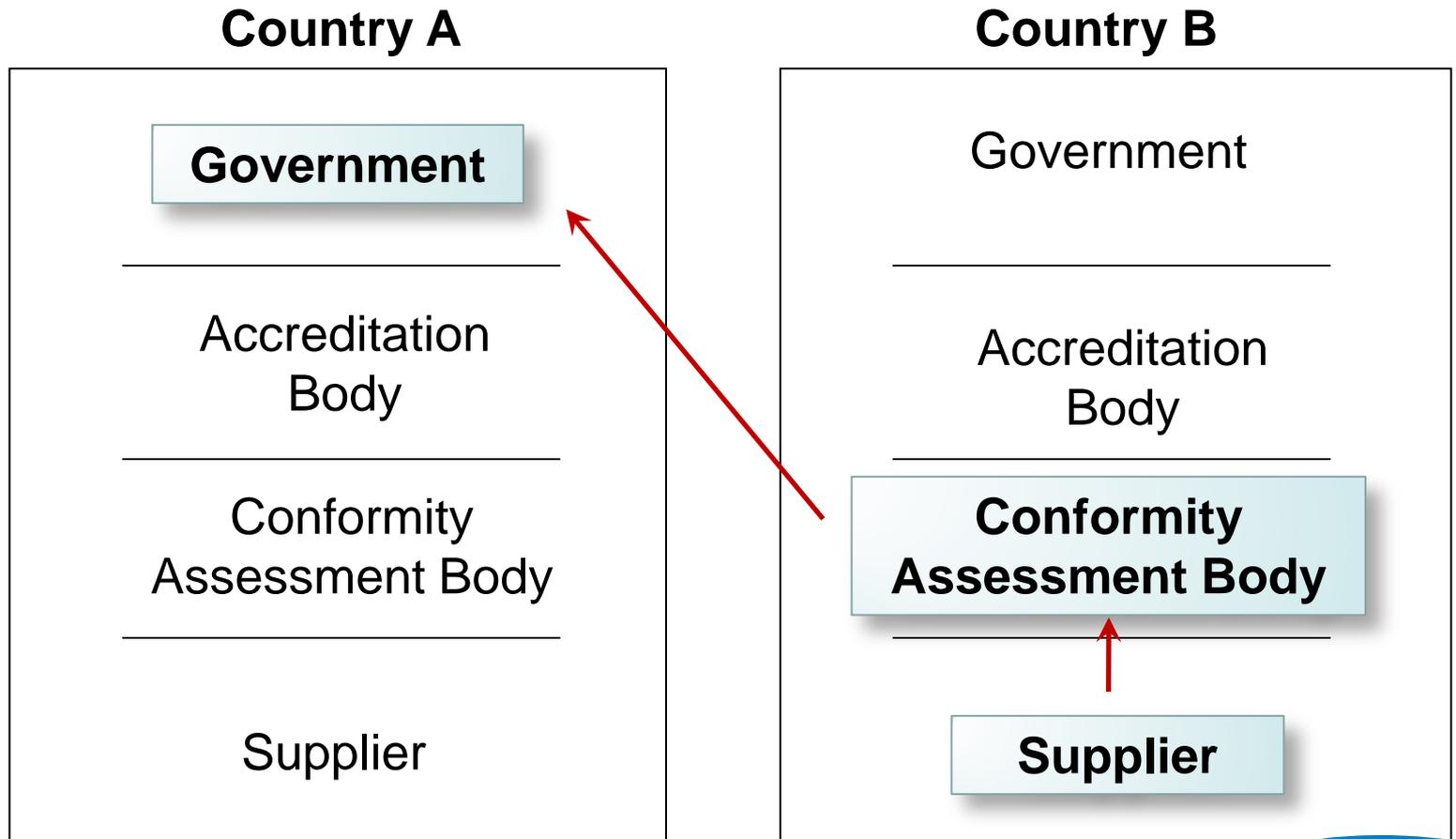
Supplier's Declaration of Conformity



Pathways for International Trade

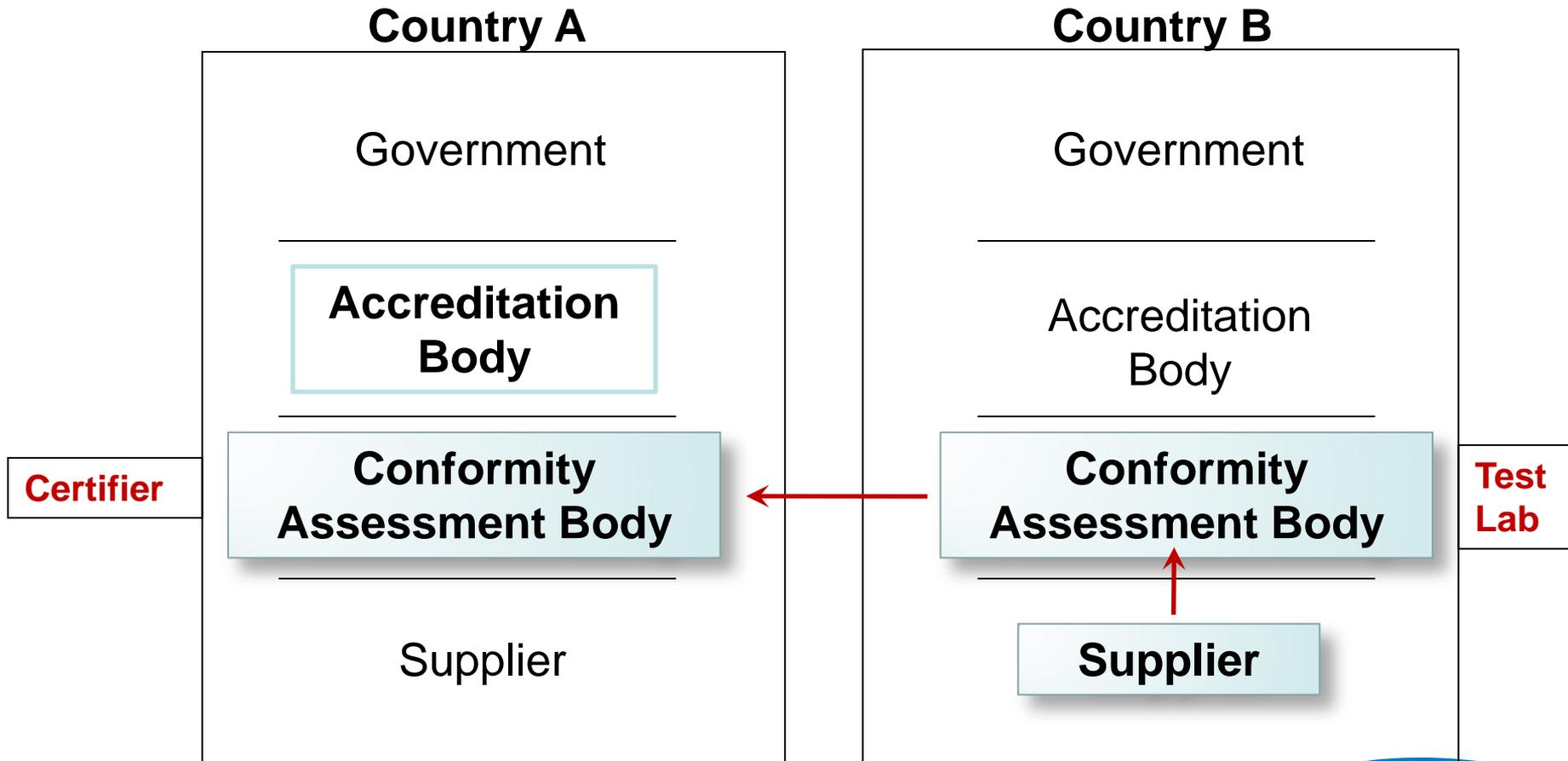
National Treatment

Conformity Assessment



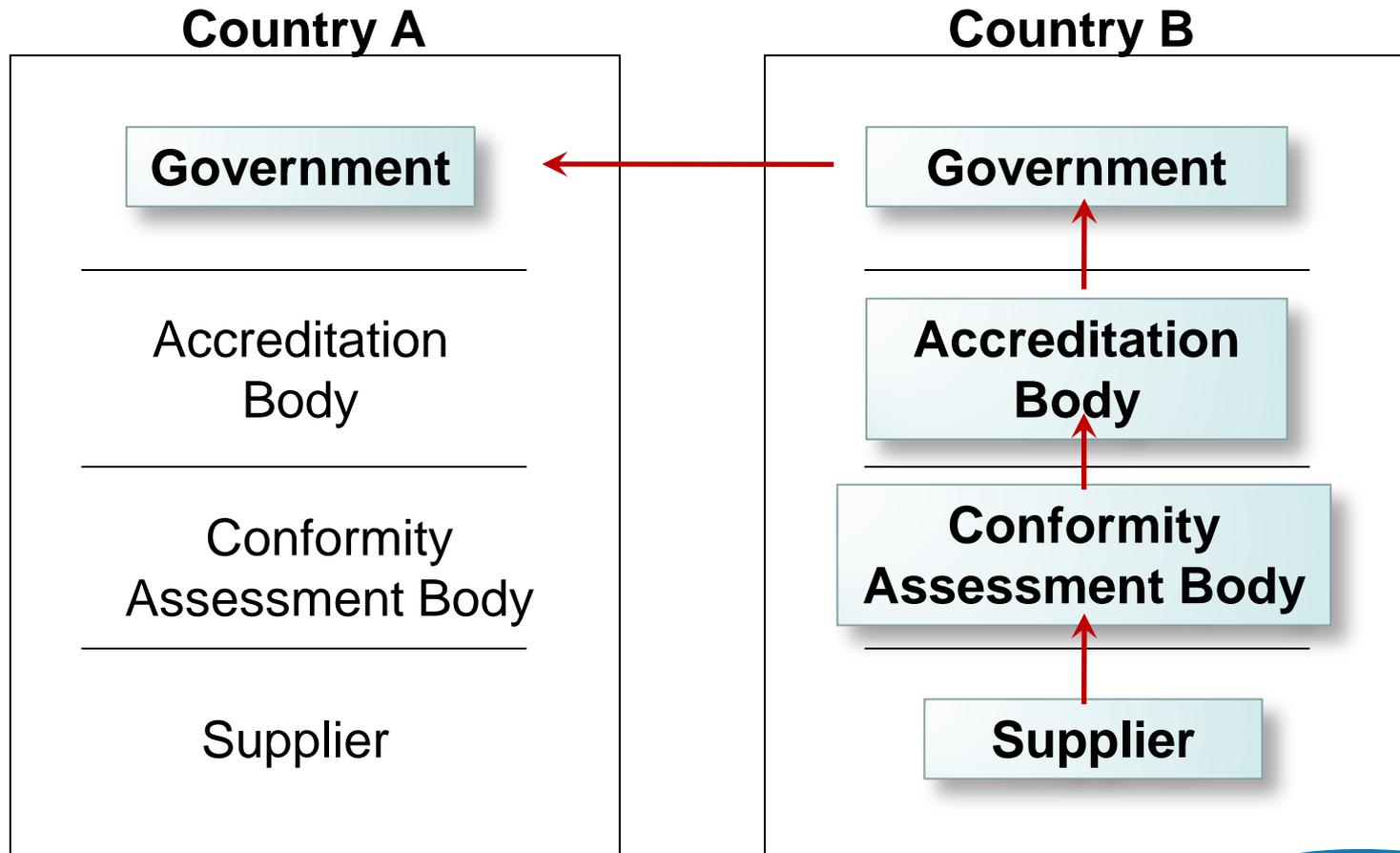
Pathways for International Trade

Data Exchange Agreements



Pathways for International Trade

G2G Mutual Recognition Agreements



Confidence Building

- Acceptance of conformity assessment results is based on confidence in the process.
- Confidence can be developed through various mechanisms
 - Sector-specific information exchanges
 - Witnessing of conformity assessment activities
 - Sector-specific technical training sessions

- Terminology
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- How it works
- Examples
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