



Basics of Conformity Assessment

May 9, 2013

Today's Discussion

- Terminology
- Types of Conformity Assessment
- How it Works
- 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 17065
- ISO/IEC 17021
- ISO/IEC 17011

Supplier's Declaration of Conformity (SDoC)

1st Party

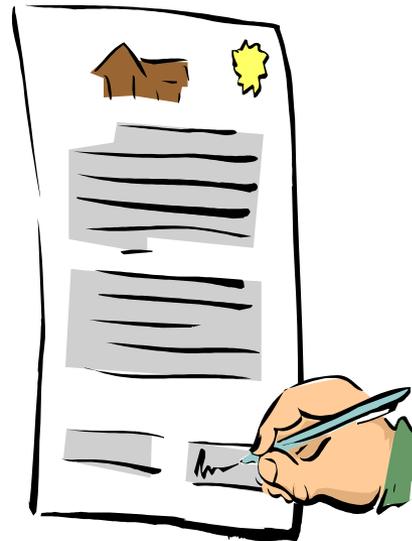
2nd Party

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 17065

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

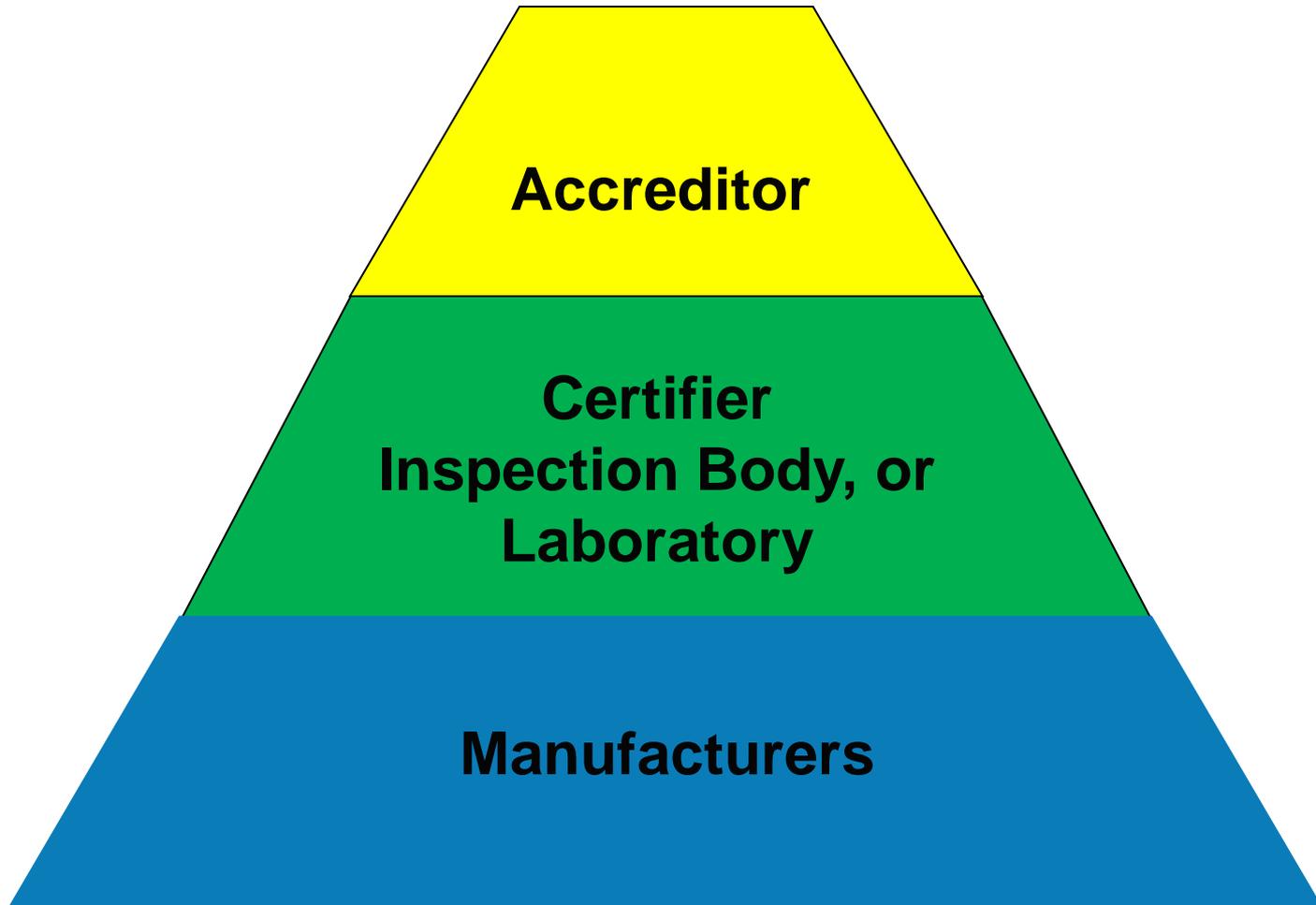
- Formal demonstration of competence to carry out specific tasks
- Provides confidence for purchasers, regulators and consumers

Examples



- *ISO/IEC 17011*

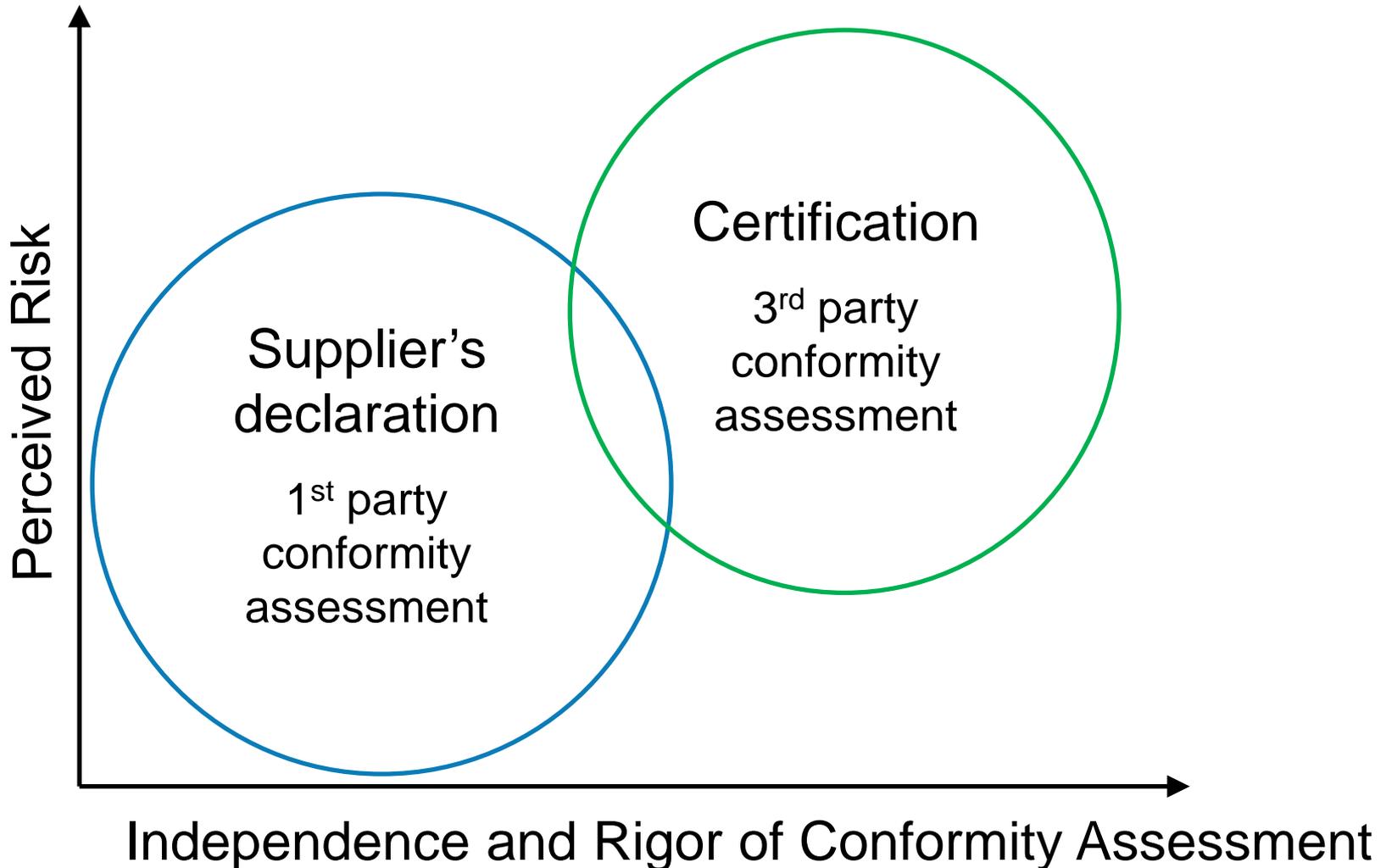
Who watches the watchers?



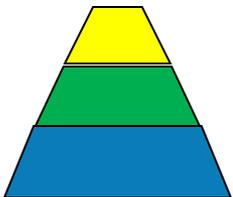
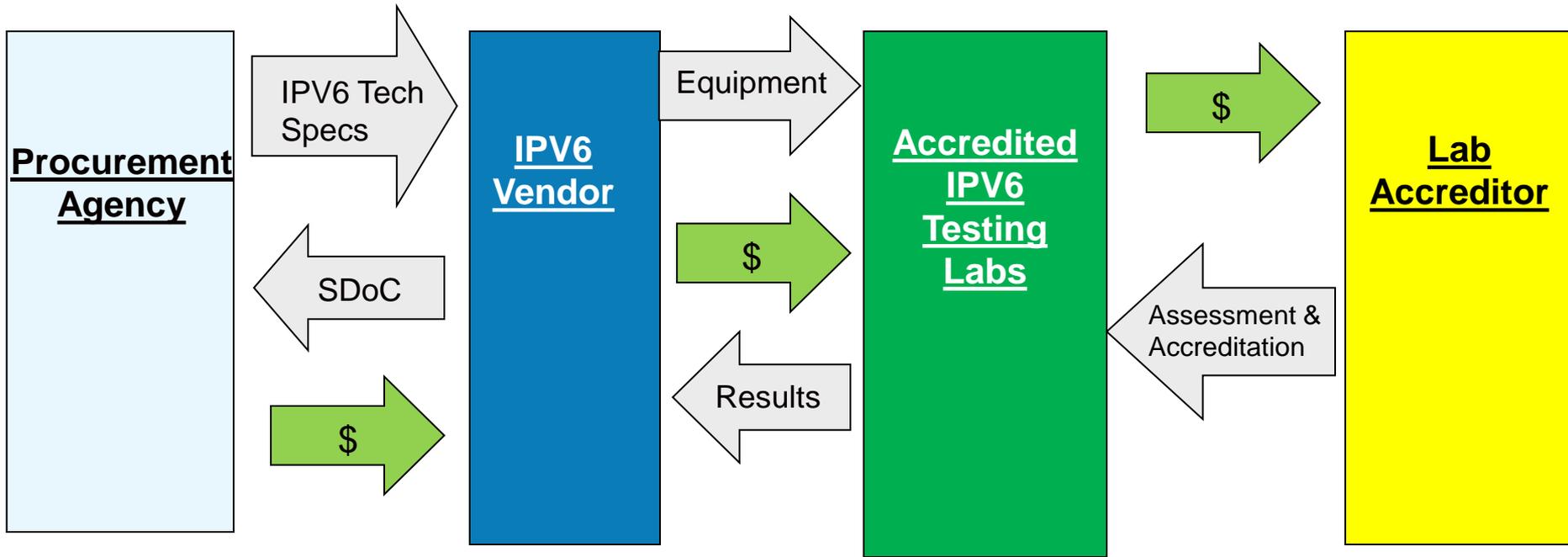
Factors in Conformity Assessment Systems

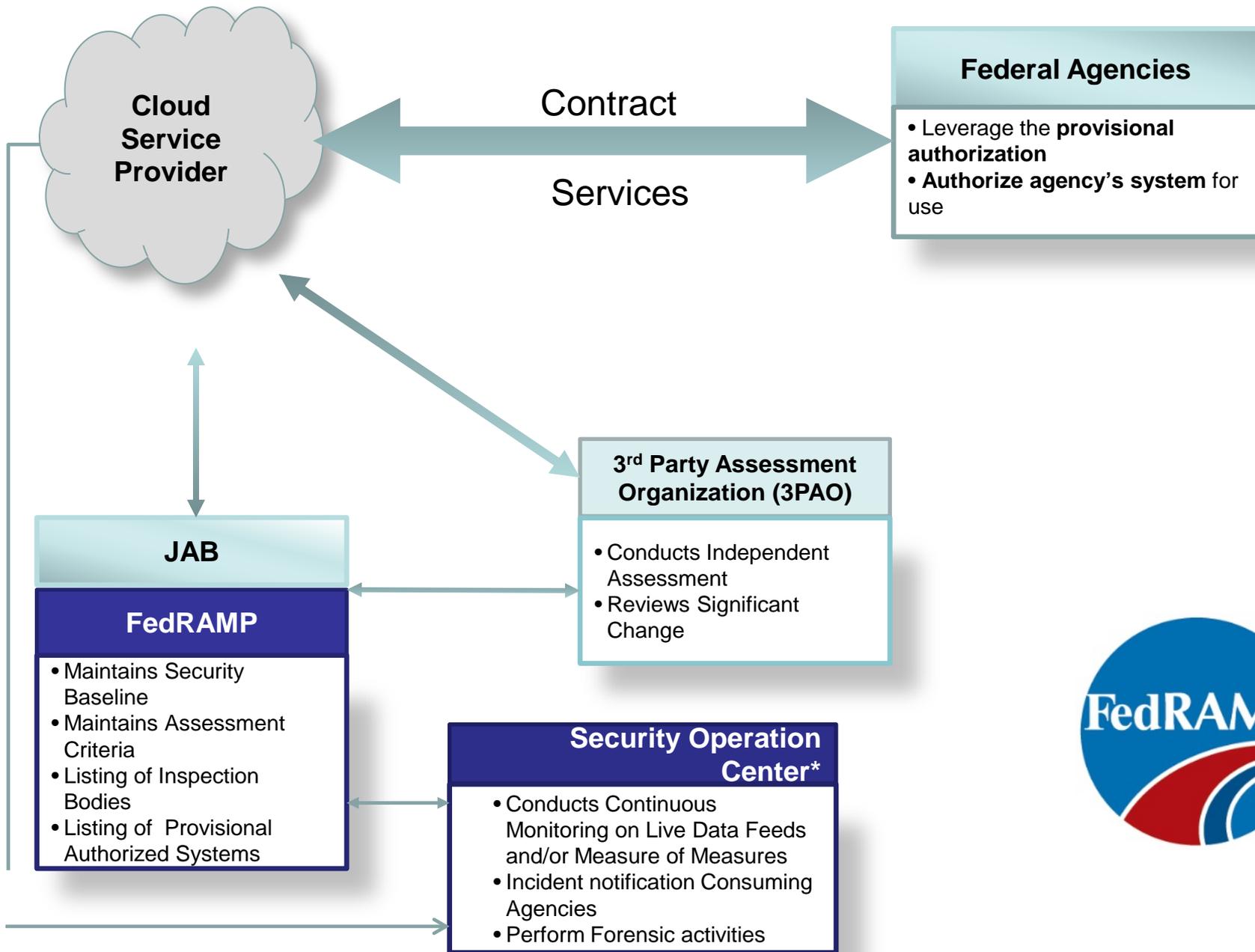
- Risks associated with non-compliance should be proportional to the rigor of the system design
 - ▶ Over-design costs too much
 - ▶ Under-design gives too little confidence
- Marketplace consequences (penalties) & effective recall allow less rigor

How much confidence is needed?

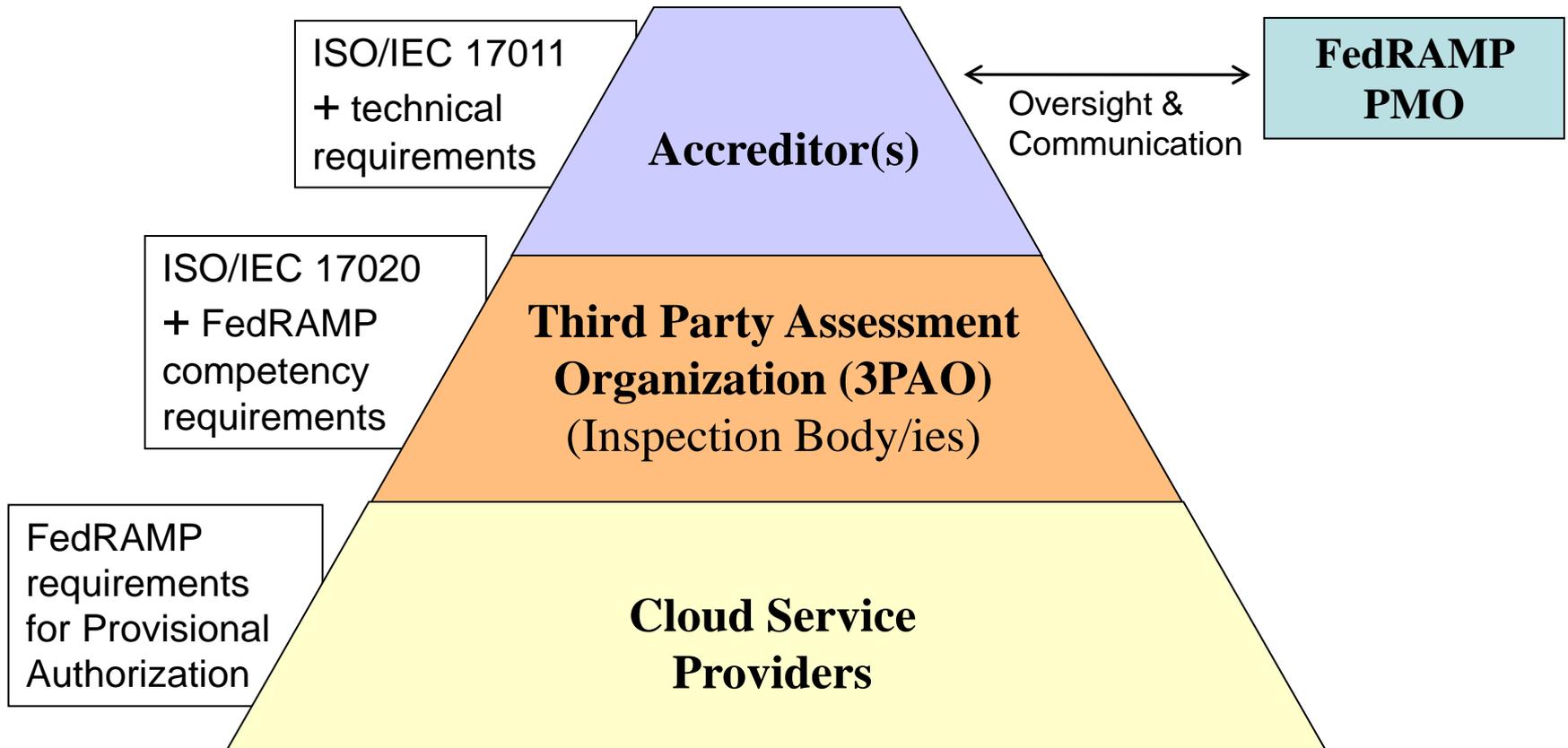


IPV6 Example of Conformity Assessment System





FedRAMP 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

Review

- Terminology
- Types of conformity assessment
- How it works
- Examples

Thank You

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