

# NIST

Standards Coordination Office



## Basics of Conformity Assessment

June 9, 2014

# 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*

1<sup>st</sup> Party

2<sup>nd</sup> Party

3<sup>rd</sup> 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

1<sup>st</sup> Party

2<sup>nd</sup> Party

3<sup>rd</sup> 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)

1<sup>st</sup> Party

2<sup>nd</sup> Party

3<sup>rd</sup> Party

## Characteristics

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

## Examples



- ISO/IEC 17050

# Inspection

1<sup>st</sup> Party

2<sup>nd</sup> Party

3<sup>rd</sup> Party

## Characteristics

- Simple test measurement or examination
- Code compliance

- *ISO/IEC 17020*

## Examples



# Testing

1<sup>st</sup> Party

2<sup>nd</sup> Party

3<sup>rd</sup> Party

Characteristics

Examples

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

- *ISO/IEC 17025*



# Certification

1<sup>st</sup> Party  
2<sup>nd</sup> Party  
3<sup>rd</sup> Party

## Characteristics

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

- *ISO/IEC 17065*

## Examples



1<sup>st</sup> Party

2<sup>nd</sup> Party

3<sup>rd</sup> Party

# Management System Registration

## Characteristics

## Examples

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

- *ISO/IEC 17021*



# Accreditation

- 1<sup>st</sup> Party
- 2<sup>nd</sup> Party
- 3<sup>rd</sup> Party

## Characteristics

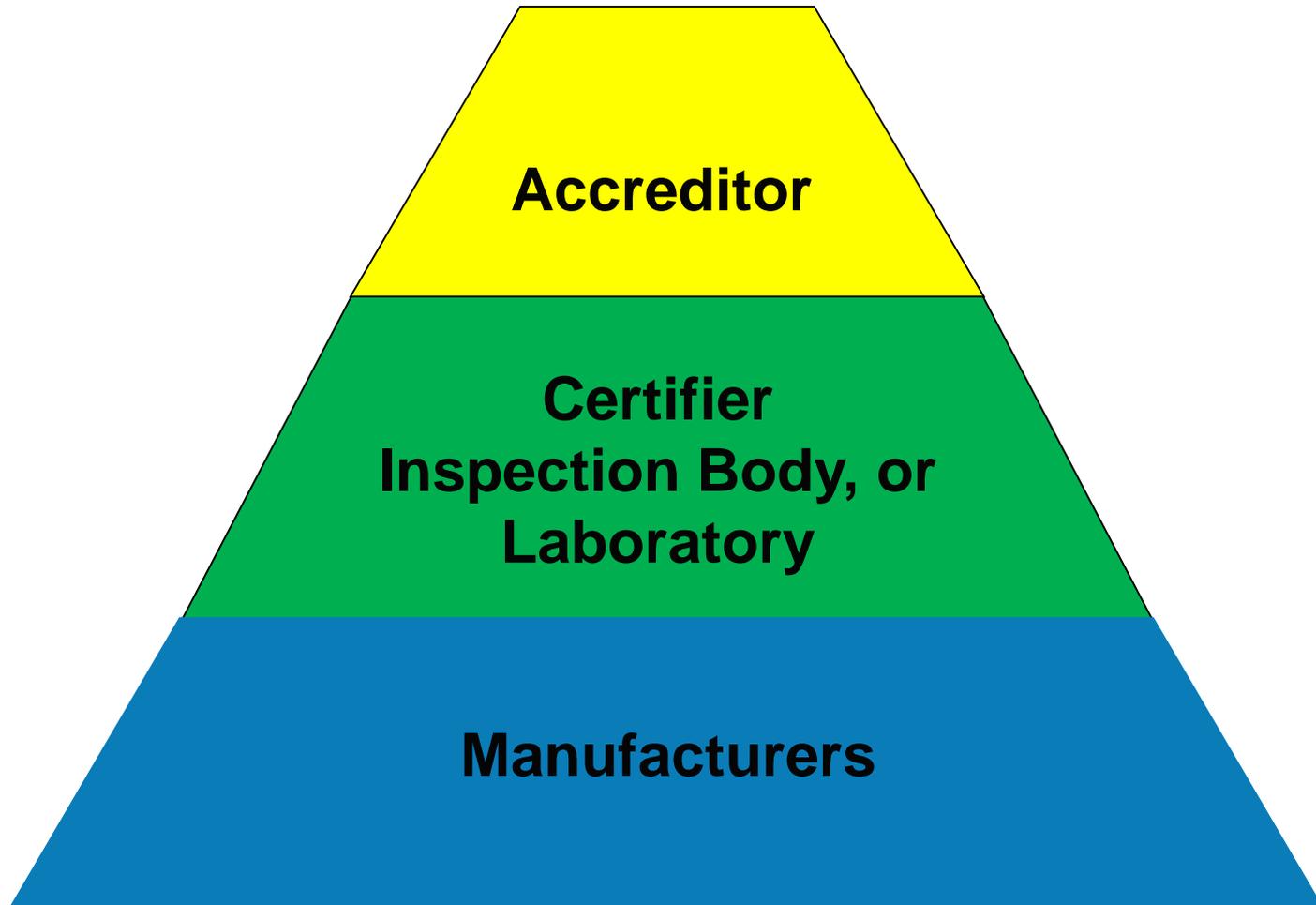
- Formal demonstration of competence to carry out specific tasks
- Provides confidence for purchasers, regulators and consumers

## Examples



- ISO/IEC 17011

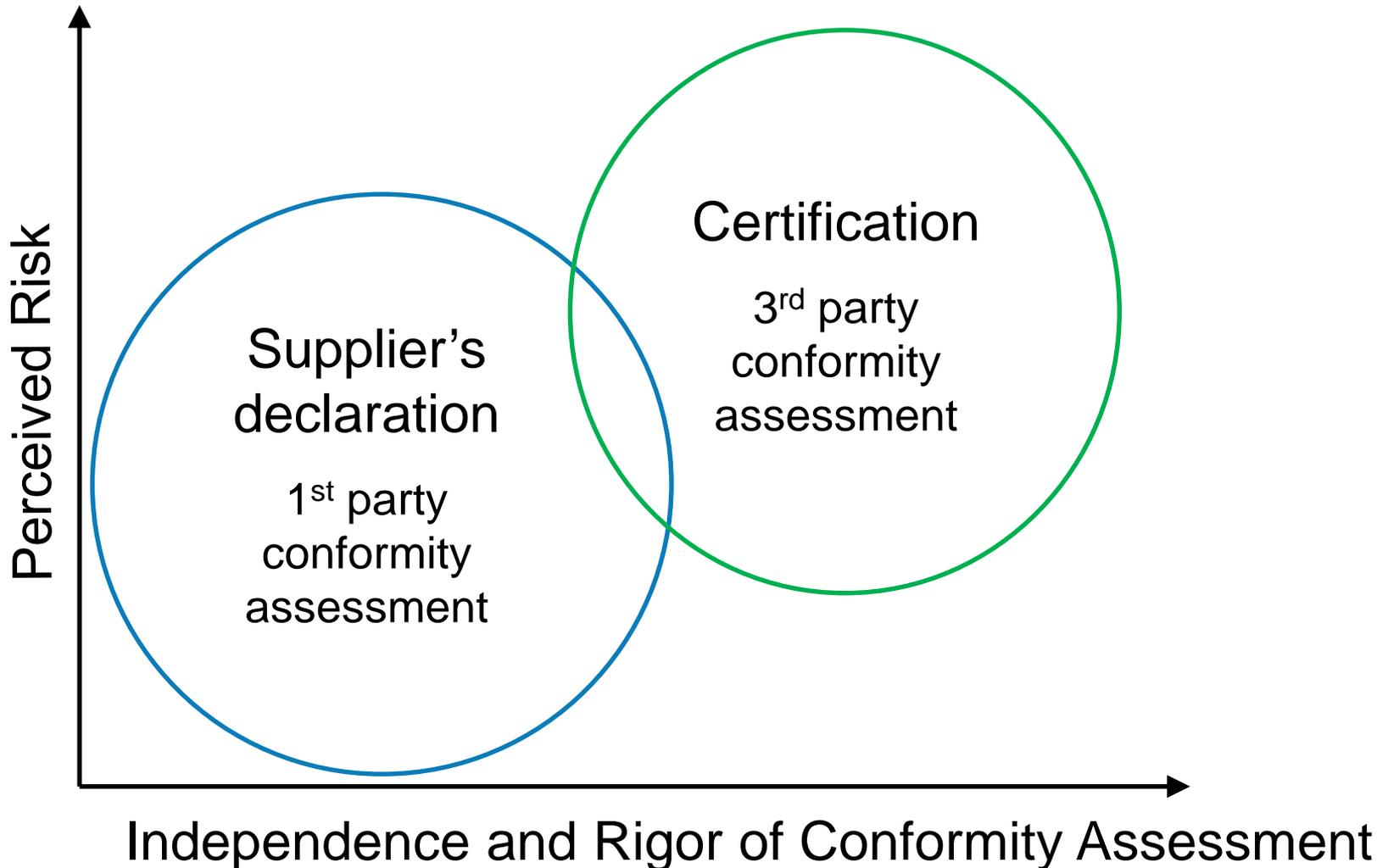
# Who watches the watchers?

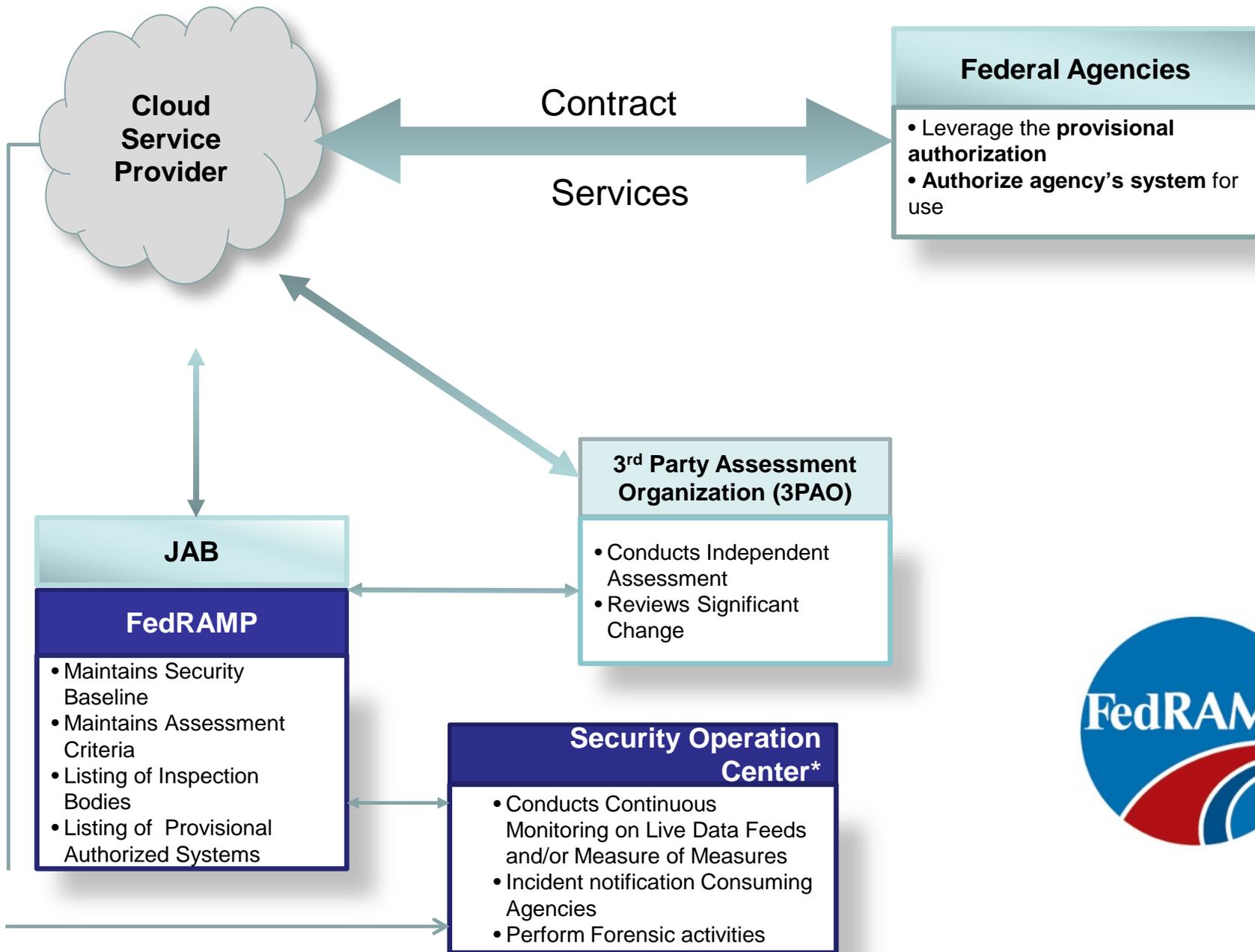


# Factors in Conformity Assessment Systems

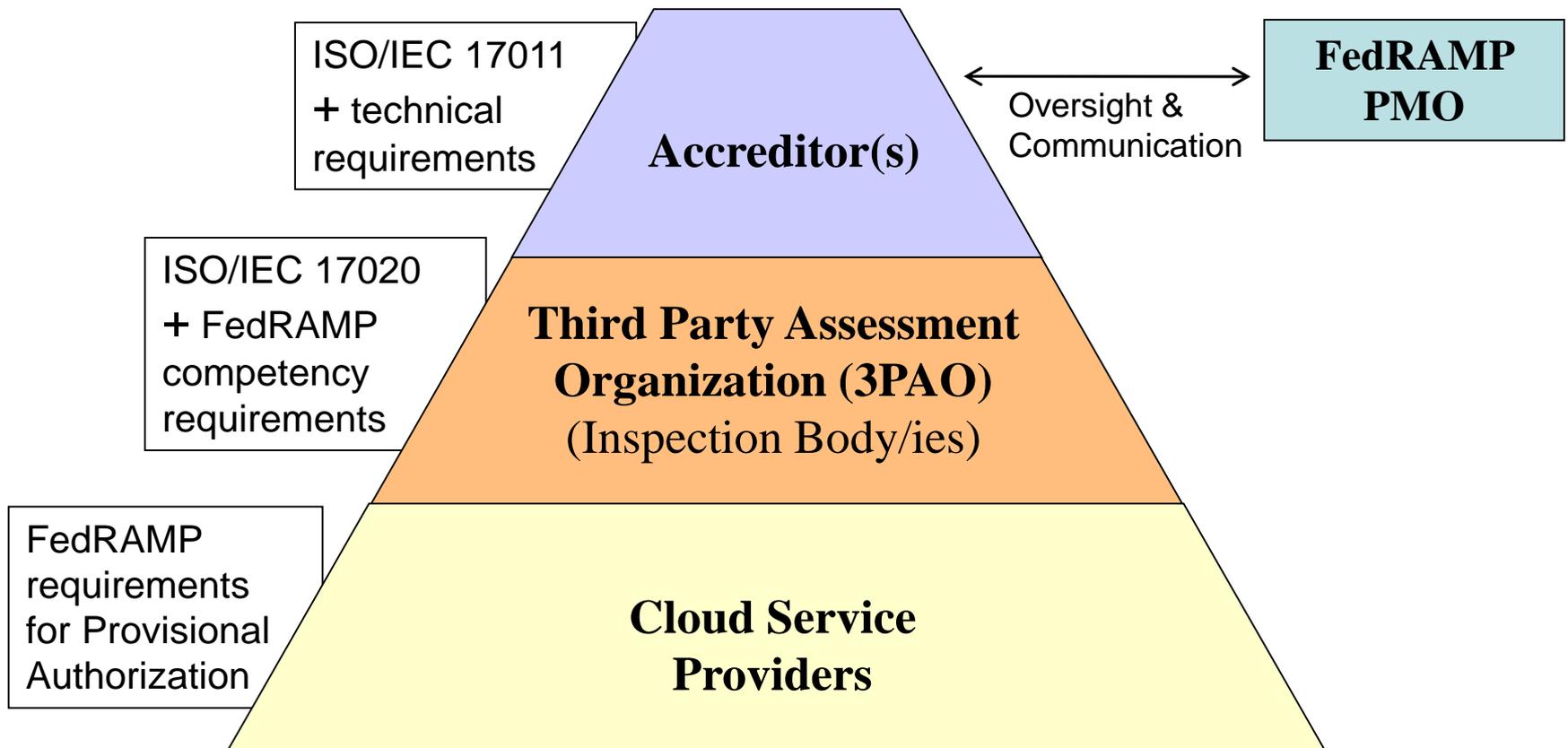
- Risks associated with non-compliance should be proportional to the rigor of the system design
  - ▶ Over-design costs too much
  - ▶ Under-design gives too little confidence
- Marketplace consequences (penalties) & effective recall allow less rigor

# How much confidence is needed?





# FedRAMP 3PAO Hierarchy



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

# Basics of Conformity Assessment

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