

NIST

Standards Coordination Office



Introduction to Conformity Assessment

September 17, 2015

Objectives

You will be able to:

- Identify a variety of types of conformity assessment
- Describe the relationship among parties involved in a conformity assessment system

Conformity Assessment

“demonstration that specified requirements relating to a product, process, system, person, or body are fulfilled” [*ISO/IEC 17000*]

Verification

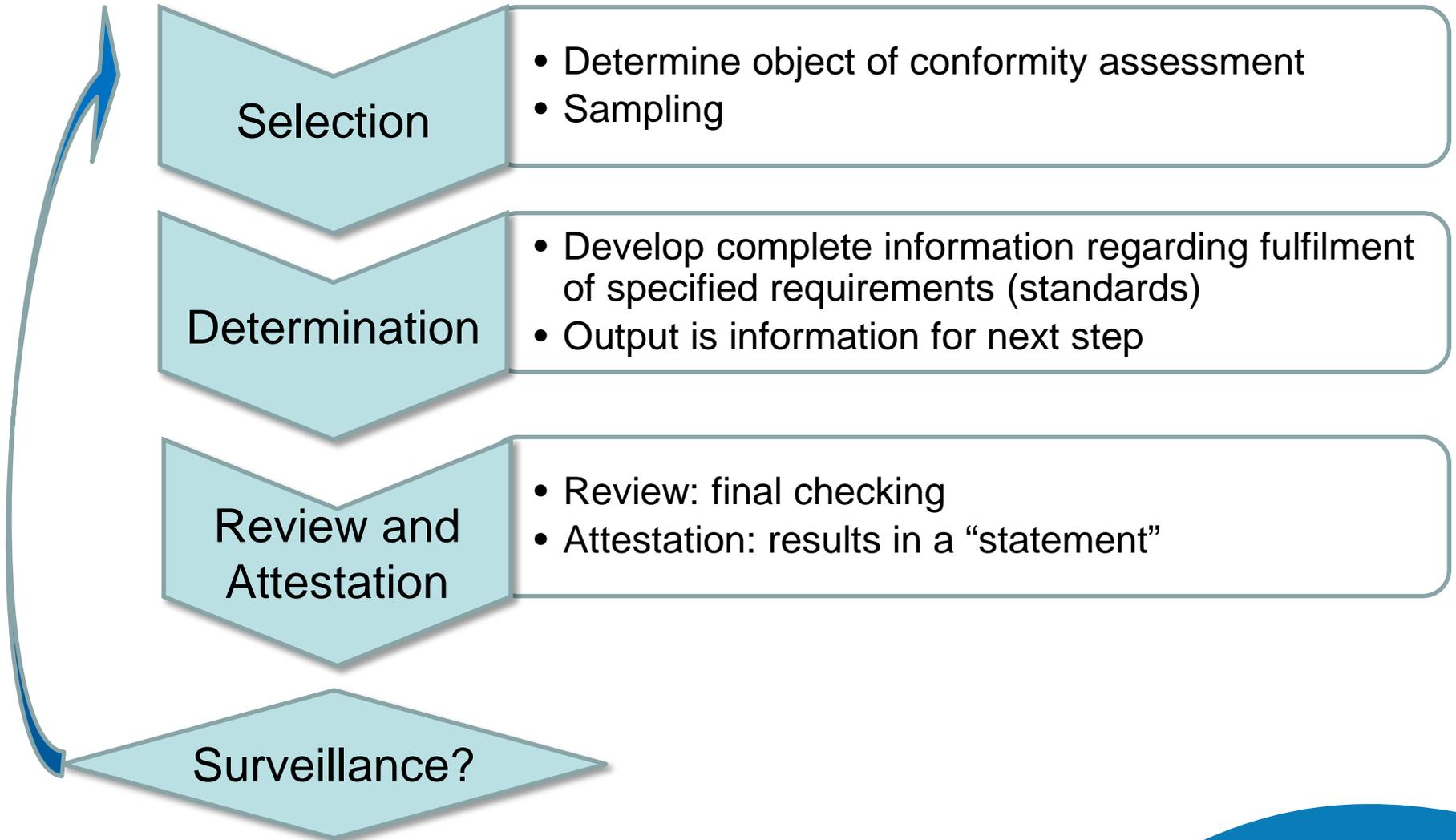
“provision of objective evidence that a given item fulfills specified requirements” [*JCGM 200:2012*]

Calibration

“operation that, under specified conditions, in a first step, establishes a relation between the **quantity values** with **measurement uncertainties** provided by **measurement standards** and corresponding **indications** with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a **measurement result** from an indication” [*JCGM 200:2012*]



Functional approach to conformity assessment



1st Party
2nd Party
3rd Party

The Parties – Who does what?

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
- NIST has activities that fall into all three categories

Types of Conformity Assessment

- Supplier's Declaration of Conformity (SDoC)
- Inspection
- Testing [Calibration]
- 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) - ISO/IEC 17050

1st Party

2nd Party

3rd Party

Characteristics

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

Examples



Inspection

- ISO/IEC 17020

1st Party

2nd Party

3rd Party

Characteristics

- Examination and determination of conformity
- May involve professional judgment if requirements are general
- Code compliance

Examples



Testing - ISO/IEC 17025

1st Party

2nd Party

3rd Party

Characteristics

- Characteristics are measured
- Representative samples are often used
- May be used in a SDoC or certification system

Examples



Certification - ISO/IEC 17065

1st Party
2nd Party
3rd Party

Characteristics

- moderate – high product risk
- Generally, more expensive
- Includes surveillance

Examples



Management System Registration

- ISO/IEC 17021

1st Party

2nd Party

3rd Party

Characteristics

- Process-based requirements
- Determination based on audit
- Scopes can be general or specific

Examples



1st Party

2nd Party

3rd Party

Accreditation - ISO/IEC 17011

Characteristics

- Formal demonstration of competence to carry out specific conformity assessment tasks
 - ✓ Testing
 - ✓ Certification
 - ✓ Inspection
- Added confidence for purchasers, regulators, and consumers

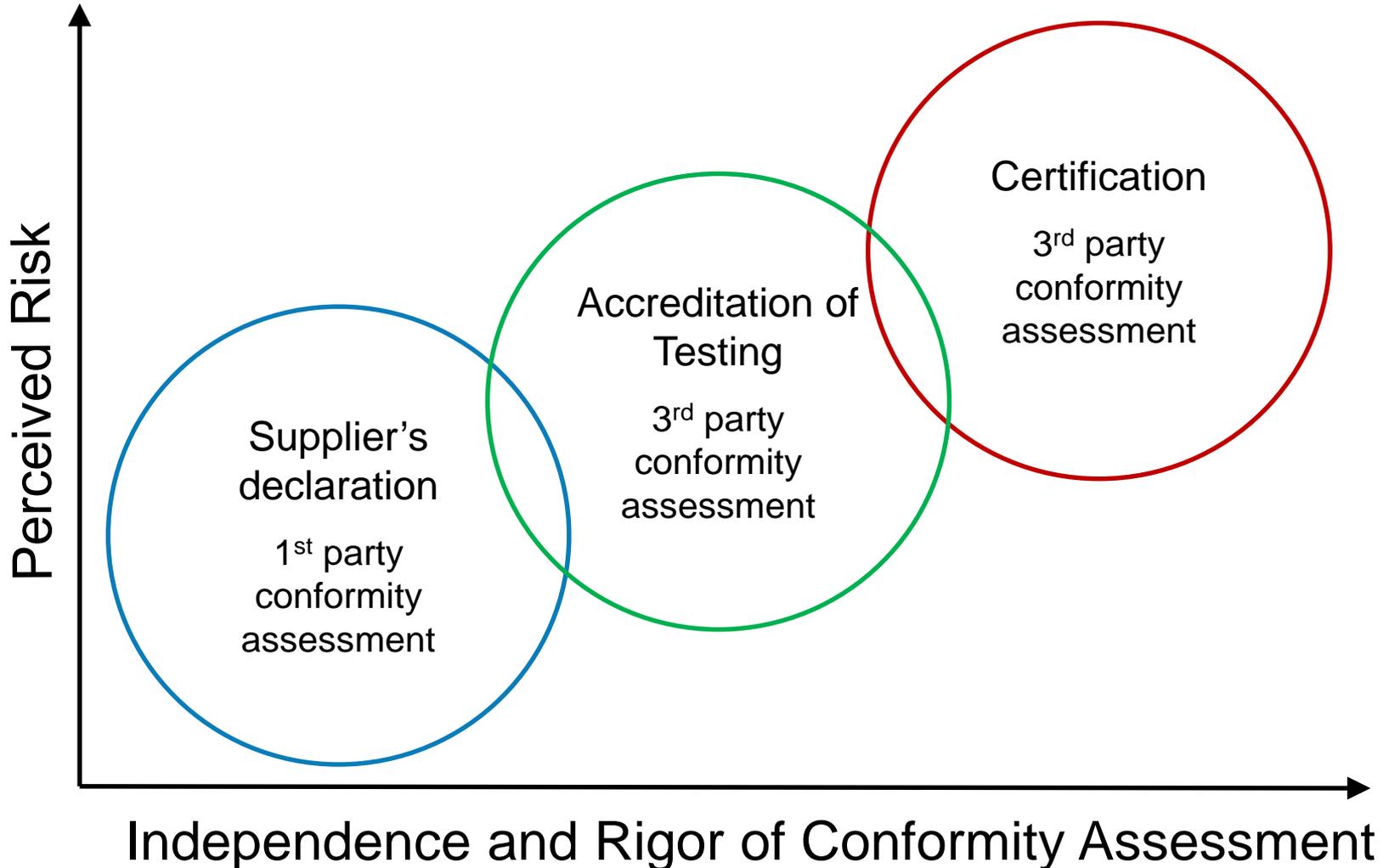
Examples



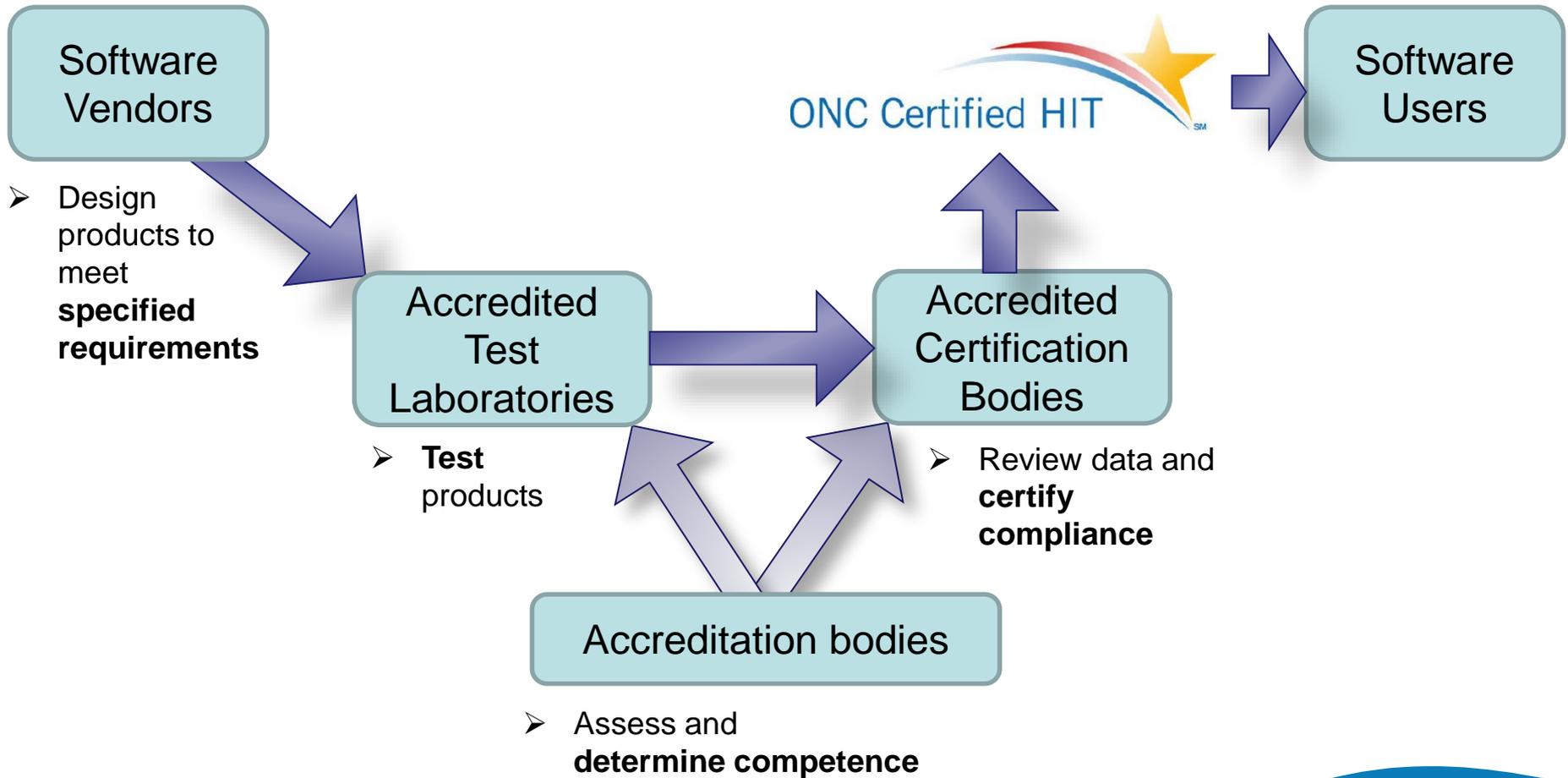
Factors in Conformity Assessment Systems

- Rigor of the system design should be proportional to the risks associated with non-compliance
 - Over-design costs too much
 - Under-design gives too little confidence
- Marketplace consequences (penalties) & effective recall allow less rigor
- One size does not fit all...

How much confidence is needed?



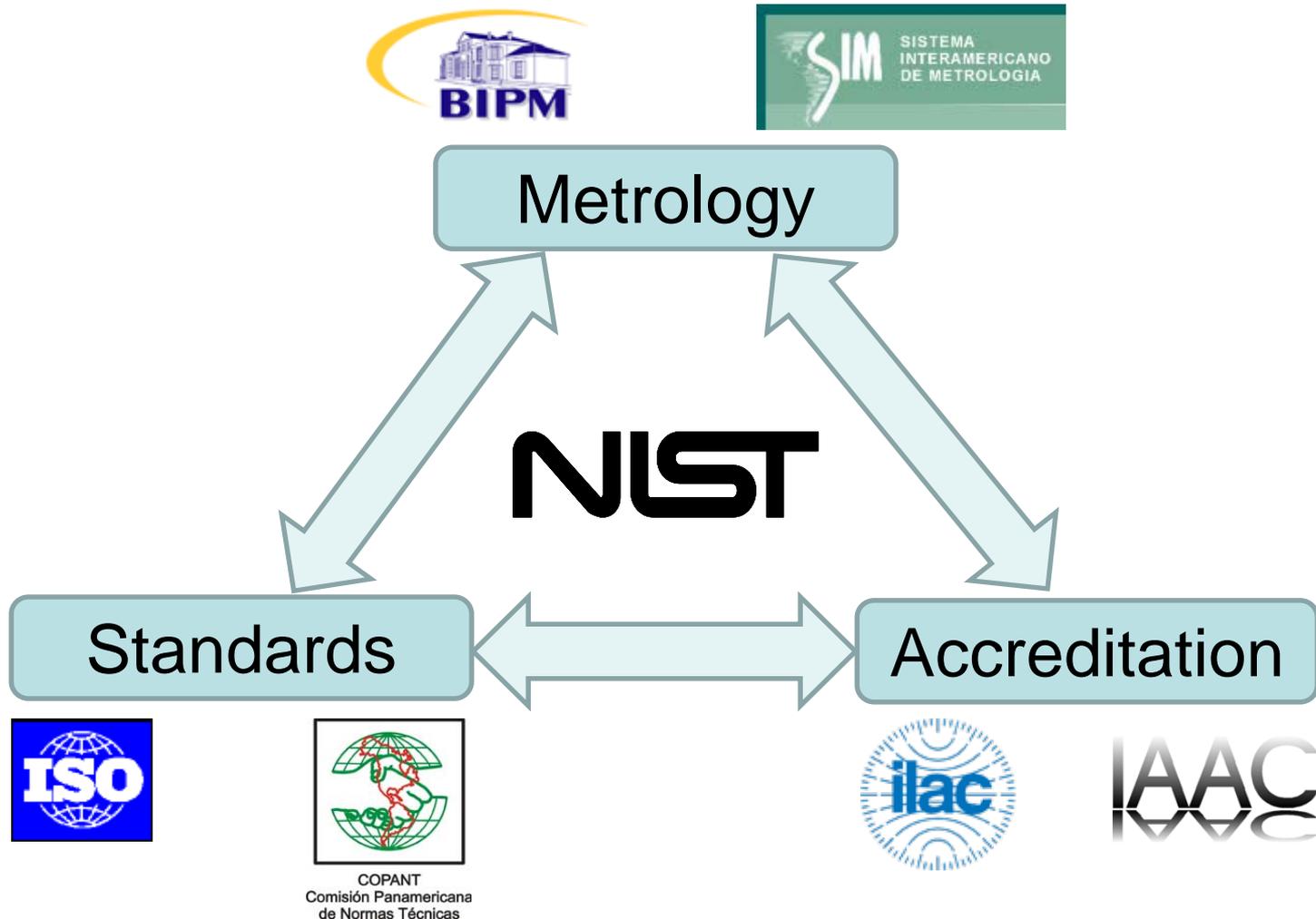
Government Regulator:
Office of the National Coordinator for Health Information Technology



Parting thoughts...

- Various types of conformity assessment used to meet particular needs
- The parties involved in conformity assessment depends on the activities needed, related risks, and level or rigor required
- Measurements and standards are integral to conformity assessment decisions

International Quality Infrastructure





Questions?

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