

Conformity Assessment: It is about confidence

ISPAB Meeting
June 24

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Points to remember

1. There is a toolbox of conformity assessment approaches intended to meet a range of needs.
2. Conformity assessment program models vary based on balancing risk and resources.
3. Software and cybersecurity bring challenges to conformity assessment. 

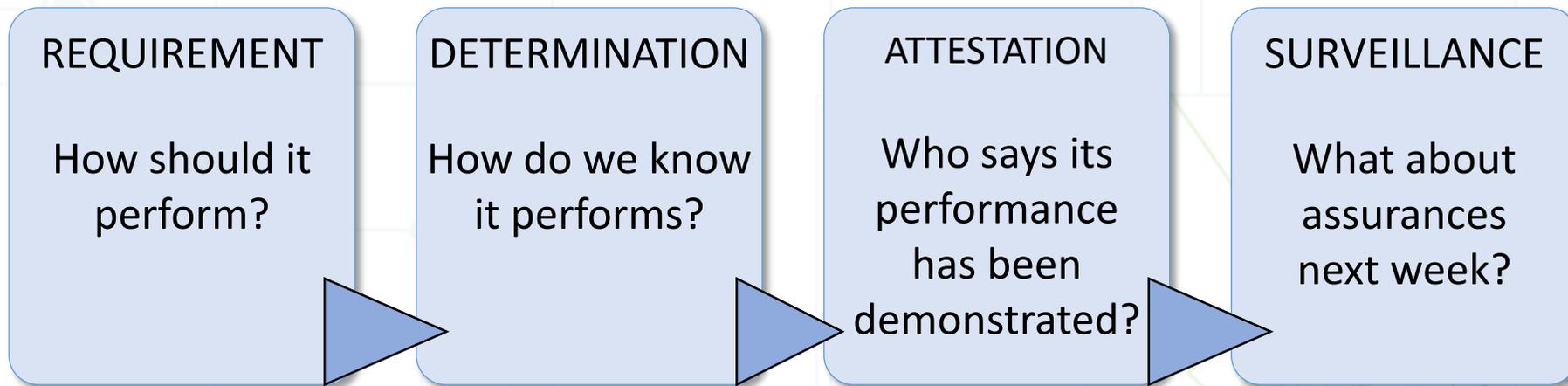
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Conformity Assessment: Basic Terms and Concepts

Conformity assessment is the **demonstration** that specified **requirements** relating to a product, process, system, person or body are **fulfilled**.*



What activities are preformed? Who performs the activities? How robustly?

The Parties – Who Does What?

First Party

Conformity assessment activity performed by the person or organization that provides the product/service/etc. (seller or manufacturer)

Second Party

Conformity assessment activity performed by the purchaser or user

Third Party

Conformity assessment activity performed by an independent entity that has no interest in transactions between the first and second parties

The US Government can be in any of the three and may also have an oversight role.



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REQUIREMENT

How should it perform?



Changing requirements push on process

DETERMINATION

How do we know it performs?

ATTESTATION

Who says its performance has been demonstrated?

SURVEILLANCE

What about assurances next week?

- Defines characteristics of the object of conformity
- Can be expressed in various ways (e.g., standards, regulations, customer requirements...)
- Federal agencies should use voluntary consensus standards



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What about assurances next week?

- **Testing** makes use of a Test Method
- **Inspection** makes use of professional judgement and sometimes testing
- **Audit** document process using records, documents, etc.
- Can be performed by the manufacturer, the purchaser, or a 3rd party.
- Determination of conformity results in a report



Source: cityinspectionsoftware.com



Source: FlickrStar5112



TEST REPORT			
SGS			
Received Date	:	Dec 4, 2009	
Report Number	:	PPX2009C000509	
Report Date	:	Dec 30, 2009	
Number of Pages	:	1 OF 1	
Zone One Air Purifier(XT-6000) in a 1 m ³ including fixed amount of bacteria into a 1m ³ air bacteria incubation from the normal print using XT-6000, after using XT-6000 for 20			
Stages before/after using XT-6000			
Prints	After 1 hour	After 2 hours	
-5	<5	<5	



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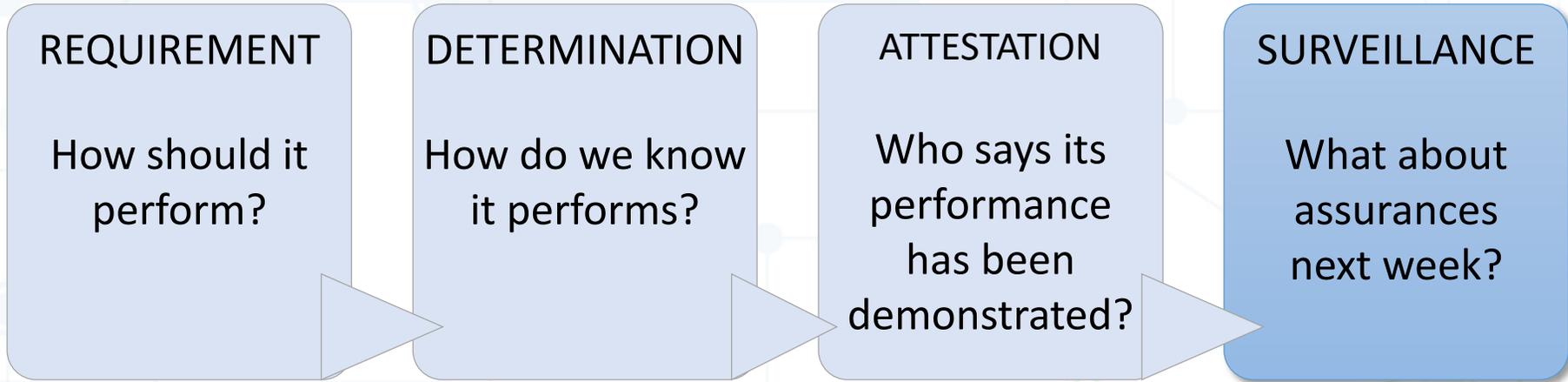
What about assurances next week?

- An **attestation** is a statement made by an organization (generally) that requirements have been fulfilled.
- A manufacturer making an attestation is called a **Suppliers Declaration of Conformity (SDOC)**
- A 3rd-party attestation is called a **Certification**



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Changing environment requires changing requirements

- Conformity decisions are often based on a sample and a point-in-time
- Confidence demands conformity today, tomorrow, next year ...
 - Purchasers & consumers want it
 - Certifiers want to know their attestations are still valid
- **Surveillance** activities help ensure ongoing conformity
 - Pre-market activities (quality checks at manufacturing plants, suppliers, processes, etc.)
 - Post-market activities (sample testing, complaint resolution, etc.)
- IT product market time may be a factor in surveillance activities



Standards for Conformity Assessment

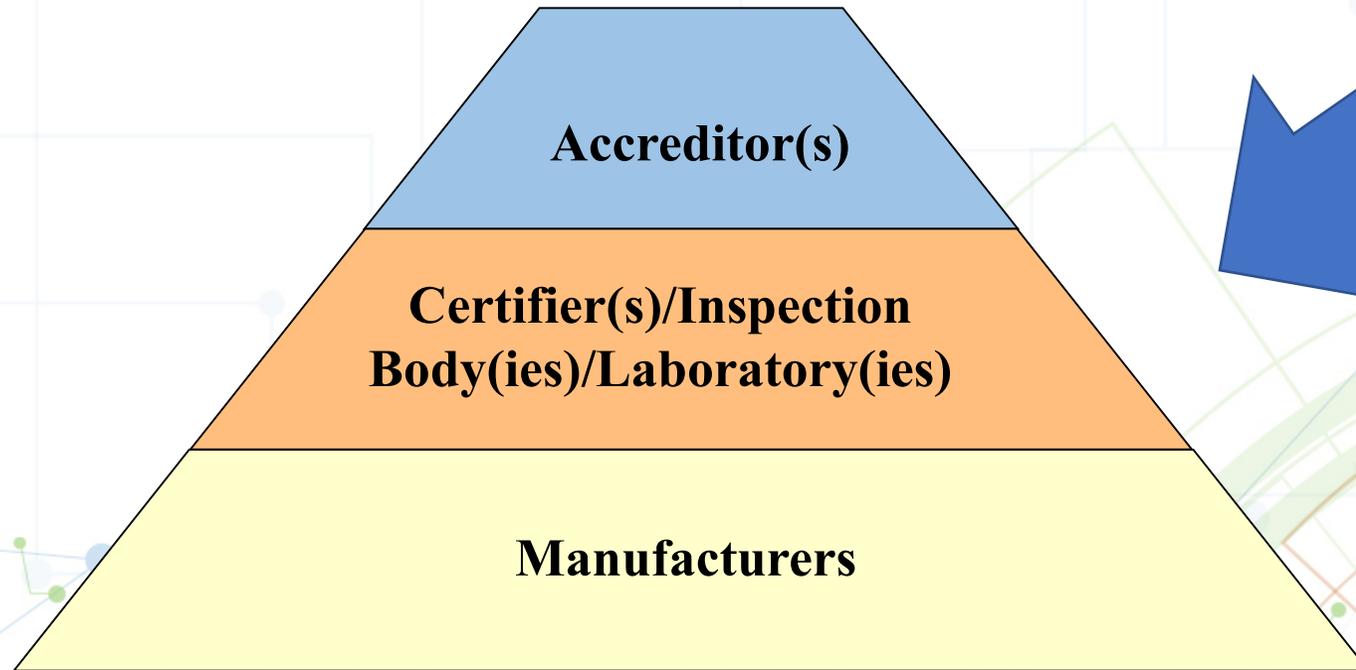
Published by International Organization for Standardization (ISO) Committee on Conformity Assessment (CASCO) in cooperation with the International Electrotechnical Commission (IEC)

CASCO
Toolbox

Type	Parties			Standard(s)
	1 st	2 nd	3 rd	
Testing	✓	✓	✓	ISO/IEC 17025
Inspection	✓	✓	✓	ISO/IEC 17020
Supplier's Declaration of Conformity (SDoC)	✓			ISO/IEC 17050 Parts 1 and 2
Certification				
Products, processes, services			✓	ISO/IEC 17065 [ISO/IEC 17067]
Management systems			✓	ISO/IEC 17021
Persons			✓	ISO/IEC 17024
Accreditation			✓	ISO/IEC 17011

Confidence in testers, inspectors, certifiers, accreditors?

Who Watches the Watchers?



Conformity assessment scheme owner (program owner)



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Factors in building conformity assessment systems

One size does not fit all



Risks associated with non-compliance should be proportional to the rigor of the system design

- Over-design can be costly
- Under-design reduces confidence



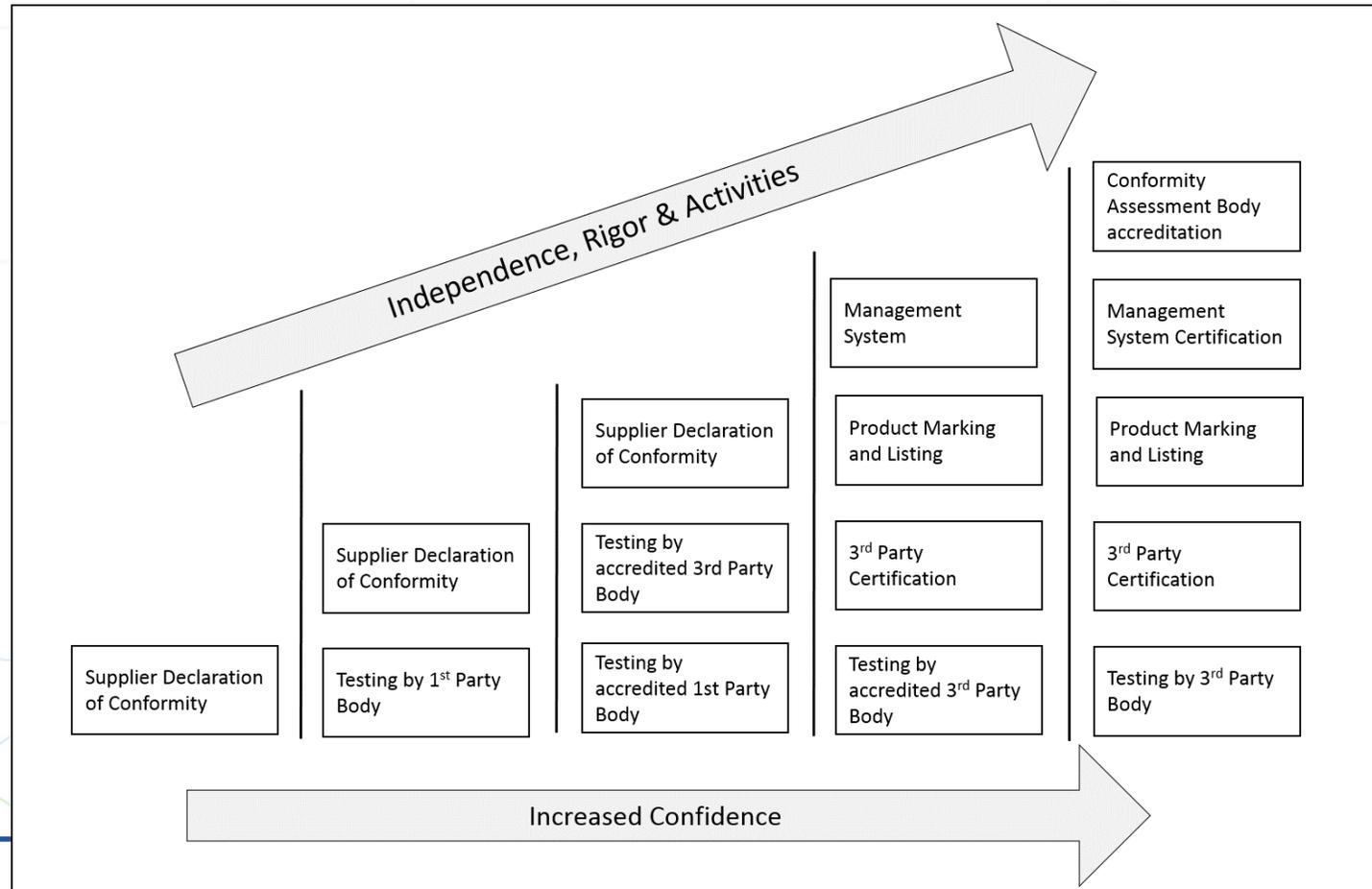
Marketplace consequences, regulatory penalties and effective recall processes can allow less rigor in conformity assessment



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The ABCs of Conformity Assessment, NIST SP 2000-01
Conformity Assessment Considerations for Federal Agencies, NIST SP 2000-02

Flexibility to Address Confidence



(Example models)

Conformity Assessment in the U.S. is unique

- No national level coordinating organization
- Numerous conformity assessment bodies, differing in size and scope
- Sector developed approaches
- Overlap in coverage
- Conformity assessment programs tailored to meet specific private and public sector needs*

RESULTS IN

- **The opportunity for effective conformity assessment programs at the most efficient cost.**

*Authorities and regulators may rely on private-sector conformity assessment to support their missions

NTTAA and OMB A119 require federal agencies to first consider **voluntary consensus standards** and **reduce industry burden** for redundant conformity and compliance mechanisms



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Federal Agency Use of Conformity Assessment

- Legislation & Policy
 - National Technology Transfer & Advancement Act
 - OMB Circular A-119 Revised*
 - WTO Technical Barrier to Trade Agreements (WTO TBT)
 - Legislation focused on topic
- Themes
 - Agencies should first consider using industry standards (conformity assessment standards)
 - Agencies should reduce industry complexity where possible (complexity = time/effort/cost)
 - Consider and leverage private-sector CA programs and other public-sector CA programs

*OMB Circular A-119: Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities – 2016



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Elements of a Conformity Assessment Program

NIST Special Publication 2000-02
**Conformity Assessment
Considerations for Federal Agencies**

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Standards Coordination Office

This publication is available free of charge from:
<https://doi.org/10.6028/NIST.SP.2000-02>

October 2018

Foundational Considerations for Federal Agency Programs

1. Engage Stakeholders
2. Maximize Transparency
3. Leverage Existing Efforts

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Foot Protection in the Workplace

Steel Toe Work Boots and Shoes

DESIGNATION: F2413 - 17 ⓘ

Standard Specification for Performance Requirements for Protective (Safety) Toe Cap Footwear¹

5 | Performance Requirements for Foot Protection

5.1 Impact Resistant Footwear (I):

[Previous](#) [Next](#) | [Top](#) [Bottom](#)

5.1.1 Impact resistant footwear shall also meet the requirements of 5.2 for compression resistant footwear.

5.1.2 Footwear shall be constructed and manufactured so that a protective toe cap is an integral and permanent part of the footwear. This type of footwear is to be worn over the foot only. Overshoes and overboots, including strap on devices with protective toe caps that are meant to be worn over footwear, do not comply with the requirements of this standard. Therefore they can not be marked with ASTM F2413 designation.

5.1.3 The workmanship in the production and assembly of the footwear shall ensure that the footwear provides functionality to the wearer.

5.1.4 Impact 75 shall be determined by evaluating three specimens in accordance with Test Methods F2412. The requirement for impact resistance represents the minimum force required that results in the toe area of the footwear having a minimum interior height clearance of 12.7 mm (0.50 in.) in men's footwear and 11.9 mm (0.468 in.) in women's footwear.

5.1.4.1 Impact resistance of footwear shall be as follows:

(1) Impact 75 product for men's footwear shall demonstrate a minimum interior height clearance of 12.7 mm (0.50 in.) during exposure to impact energy of 101.7 J (75 ft-lbf).

(2) Impact 75 product for women's footwear shall demonstrate a minimum interior height clearance of 11.9 mm (0.468 in.) during exposure to impact energy of 101.7 J (75 ft-lbf).

5.1.4.2 Each protective toe cap shall bear the manufacturer's name or trademark or logo. Cap number or identification, and toe cap size and R (right) or L (left) shall be permanently stamped or marked in a conspicuous location.

5.1.4.3 Any specimen that does not meet the minimum impact performance requirements for Impact 75 constitutes non-compliance for the product category.

[. . .]

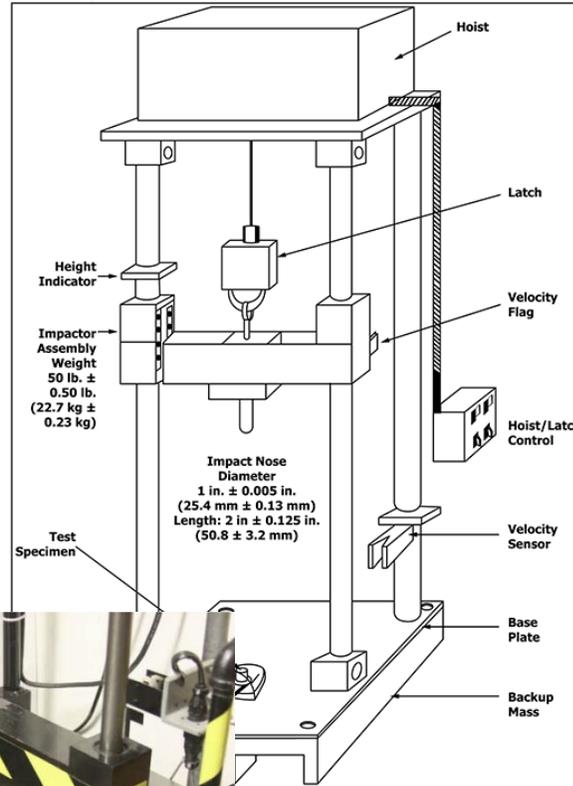


FIG. 6 (a) Metatarsal Impact Testing⁴ (continued)

6.1.4 Line 2 of label shall identify the appropriate gender and the impact and compression rating of the category.

M	I	M I/75/C/75		C	75
Male	Impact Resistant Footwear	75 Impact Rating	Compression Resistant Footwear	Compression Resistant Footwear	75 Compression Rating
F	I	F I/75/C/75		C	75
Female	Impact Resistant Footwear	75 Impact Rating	Compression Resistant Footwear	Compression Resistant Footwear	75 Compression Rating

6.1.5 Lines 3 and 4 have been used to reference additional sections in this standard. Section reference shall be in numerical order.

6.1.5.1 (I)—Identifies protection against impact as discussed in 5.1.

6.1.5.2 (C)—Identifies protection against compression as discussed in 5.2.

6.1.5.3 (M)—Identifies footwear designed to be impact resistant to the top of the foot as discussed in 5.3.

6.1.5.4 (Cd)—Identifies protection against conductive hazards as discussed in 5.4.

6.1.5.5 (EH)—Identifies footwear constructed with and manufactured to have electrical insulation properties; electric.

6.1.5.6 (SD)—Identified discussed in 5.6.

6.1.5.7 (PR)—Identified

6.1.6 Line 4 shall be



DESIGNATION: F2412 - 18 ⓘ

Standard Test Methods for Foot Protection¹

Active Standard ASTM F2412

Points to remember

1. There is a toolbox of conformity assessment approaches intended to meet a range of needs. Many federal programs use these tools and leverage existing programs and activities.
2. Conformity assessment program models vary based on balancing risk and resources. Many federal programs focus on this balance and adjust.
3. Software and cybersecurity bring challenges to conformity assessment. There is no silver bullet. Programs addressing cybersecurity requirements continue to evolve.



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Questions & Discussion

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Visit <https://www.standards.gov> to learn more about conformity assessment and access NIST conformity assessment guidance documents.