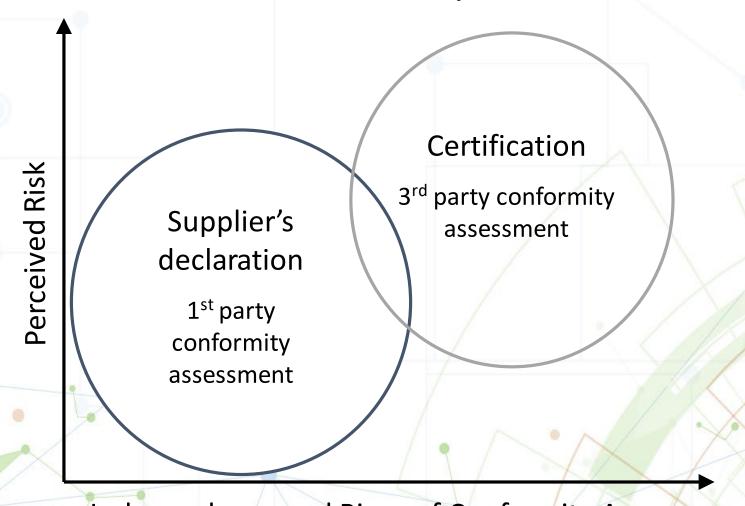


Risk and Conformity Assessment



Independence and Rigor of Conformity Assessment

Demonstration of Conformity

Testing makes use of a Test Method

https://www.healthit.gov/policy-researchers-implementers/testing-and-test-methods - Certification Program Test Method

- Inspection makes use of professional judgement and sometimes testing
- Can be performed by the manufacturer, the purchaser, or a 3rd party.

Demonstration of conformity results in a Test Report or

Inspection Report



Source: cityinspections of tware.com



Source: FlickrStar5112

000		TEST R	EPORT		
SGS					
			Received Dat	e : D	ec. 4, 2003
			Report Numb	er : P	X/2003/C00350
			Report Date	: D	ec.30, 2003
			The number of	of Page :	1 OF 1
Following Test Sample i					
Product Name	: Air-Zone Oa	one Air Purifier			
Product Description	;				
Style / Item No	; XT-6000				
Manufacturer/Vendor	: Air-Zone In	U.S.A.			
Object	: Effect amount of fungi by using Air-Zone Ozone Air Purifier(XT-6000) in a 1 m closed space.				
Method	closed space dishs in dif	. Sampling ind	iameter) including fr ividually for bacteria before using XT-6	incubation fro	m the treated pe
Result :					
Test Items	Unit	Sampling timings before/after using XT-6000			
	OIIII	Before	After 30 minutes	After 1 hour	After 2 hours
Amount of bacteria	CFII/64cm ²	7.7×10 ⁷	< 5	< 5	<5

Outcomes, What is Success?

- Demonstrate Conformity so We Can Understand our Risks
- Minimize impact to products, markets and innovation
- Allow for the potential for other types of assessment within risk tolerance
- Minimize assessment, maximize test
- Work together for effective and efficient development, deployment and use