Cultivate Trust

Manage Risk
How do we get from requirements to having confidence?
Risk and Conformity Assessment

Perceived Risk

Supplier’s declaration
1st party conformity assessment

Independence and Rigor of Conformity Assessment

Certification
3rd party 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: cityinspectionsoftware.com

Source: FlickrStar5112
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