“Audit 101”

Collaborative Food Safety Forum

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What’s Conformity Assessment?

ISO/IEC 17000:

“demonstration that specified requirements relating to a product, process, system, person or body are fulfilled”

 NOTE…includes activities…such as testing, inspection and certification as well as accreditation of conformity assessment bodies”
ISO* CASCO “Toolbox”

**Vocabulary**
17000, 17027, 17029

**Supplier’s Declaration**
17050 – 1 & 2

**CA & Standards**
17007, Guide 23

**Accreditation & CA Bodies**
17011
17020, 17021-1 thru 9
17024, 17025
17040, 17043, 17065

**CA Code/Principles**
Guide 60, PAS 17001-5

**Product Certification**
17065, 17067, 17026
Guides 28 & 53

**CA Results**
Guide 68, 17022

**Marks**
Guide 27, 17030

*predominantly co-published with IEC*
So...what’s an “Audit”?

**Dictionary** - **Noun**: official examination and verification of accounts and records...report or statement...inspection to evaluate. **Verb**: examine for purposes of verification...to attend

**ISO/IEC 17000:2004** - Systematic, independent, documented process for obtaining records (objective evidence), statements of fact or other relevant information and assessing them (and evaluating it) objectively to determine the extent to which specified requirements (audit criteria) are fulfilled.

**ISO 9000:2015** - ditto (except); plus Notes:

a) **Elements** - conformity determination, object, procedure
b) Can be 1st, 2nd or 3rd Party (internal/external) and **combined** (objects/standards) or **joint** (2 or more auditing organizations)
c) **Independence** can be demonstrated by freedom from responsibility for the activity being audited
The Conformity Assessment Balance

- Value for suppliers
- Confidence for acceptance interests
Why-who-what-when-where-how?  
(...lots of variables)

- Purpose, Risk
- **Object(s)** of Conformity Assessment
- Standards, Policies, Procedures
- Scope (boundaries/locations/activities/processes)
- Team (competencies/independence)
- Extent (date/duration/frequency/samples)

- **Cost!!!**
Who decides (specifies)?

- **Supplier’s Declaration**: 1\(^{st}\) party conformity assessment
- **Supplier Audit**: 2\(^{nd}\) party conformity assessment
- **Certification**: 3\(^{rd}\) party conformity assessment

**Perceived Risk**

**Independence / Rigor**
Accredited 3rd-Party Hierarchy

(ISO/IEC 17011 standard for accreditation bodies)

Accreditation bodies

Assess competence

Conformity assessment bodies

Certify/Audit/Test/Verify conformity

Product/Service/Process/Person/System
Confidence/Regulation Spectrum

unregulated → complete trust

produce → very regulated

paperclip

pharmaceuticals

100% inspection
# ANSI Accreditations

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