Changes to ISO/IEC 17025:2017
A High-Level Overview

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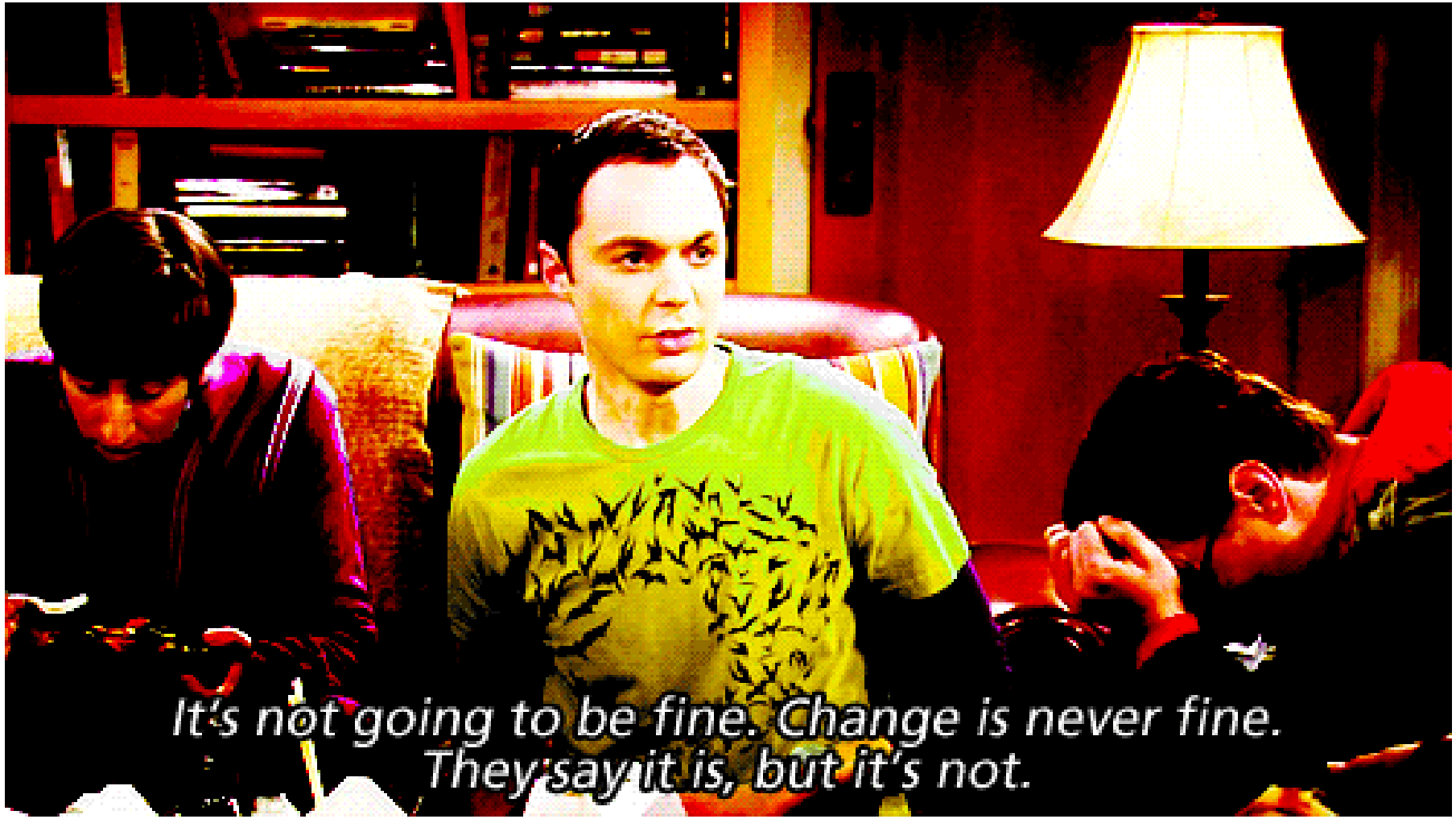
Why We're Here

High Level Changes

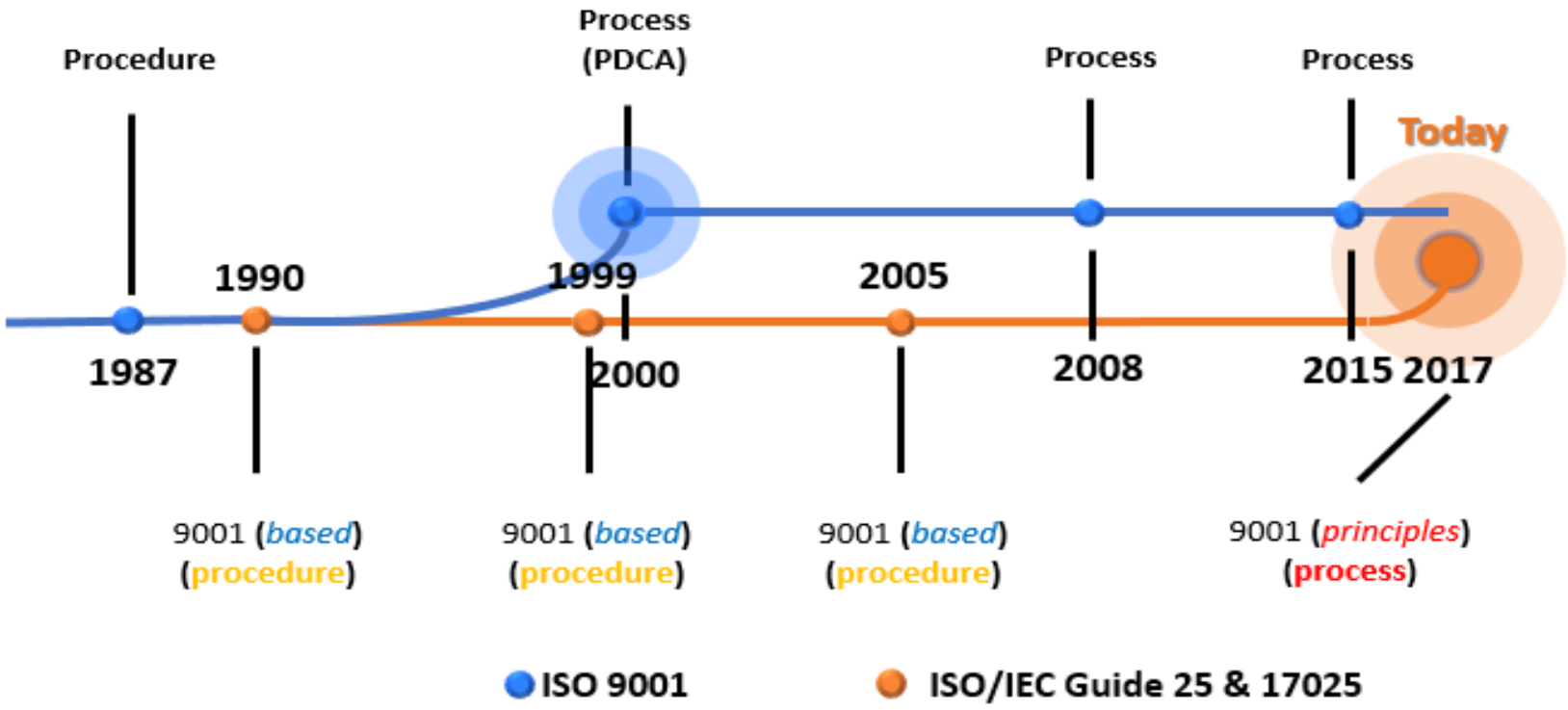
- Structure (8 sections instead of 5)
- Fewer Administrative Procedures
- Stronger Competence Requirements
- Laboratory Management
- Decision Rules for Statement of Conformity

High Level Changes (cont)

- Lab Risks and Opportunities
- Stronger PT Requirements*
- Impartiality Management
- Stronger Complaint Handling


It's not going to be fine. Change is never fine.
They say it is, but it's not.

ISO 9001 and ISO/IEC 17025



New Structure

- ISO/CASCO - Responsible for Writing Standards – Mandatory Language

- 8 sections for almost all ISO standards (2005 had 5):
  - Scope / Normative Documents / Definitions
  - Impartiality / Confidentiality
  - Org Structure
  - People / Tools (“resources”)
  - Technical Activities
  - Management System

2005 – Procedures / Documents

- Confidentiality / Impartiality (4.1.5)
- Org Structure (4.1.4 & 4.1.5.e / f)
- Central Quality Manual (4.2.2)
- Quality Policy Statement (4.2.2)
- Supporting Procedures (4.2.5 & more)
- Doc Control / ML (4.3)
- Contract Review (4.4.1)
- Purchase & Receiving (4.6.1)
- Complaint Handling (4.8)
- Non-Conforming Work (4.9.1)
- Corrective Action (4.11.1)
- Preventive Action (4.12.2)

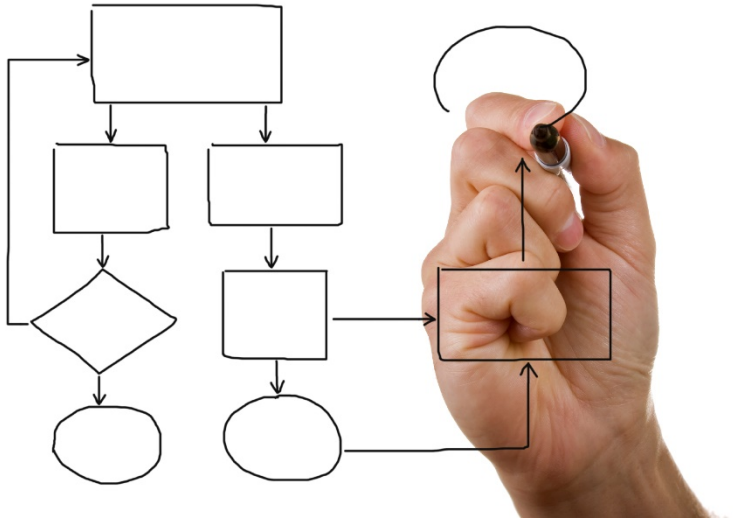
2005 – Procedures / Documents

- Record Control (4.13.1.1)
- Internal Audit (4.14.1)
- Management Review (4.15.1)
- ID and Provide Training (5.2.2)
- Job Description (5.2.4)
- Lab Enviro Conditions (5.3.1)

- Test / Cal Methods (5.4.1)
- Method Validation (5.4.5.2)
- Estimation of MU (5.4.6)
- Software & Data Protection (5.4.7)
- Calibration Program (5.5.2)
- Use of Lab Items (5.5.6)

2005 – Procedures / Documents

- Intermediate Checks (5.5.10)
- Correction Factors (5.5.11)
- Reference Standard Use & Cal (5.6.3)
- Sampling (5.7.1)
- Recording Sampling Data (5.7.3)
- Handling Customer Items (5.8.1)
- Customer Item ID System (5.8.2)
- Special Storage of Customer Item (5.8.4)
- QC Checks (5.9.1)
- Limits for QC Checks (5.9.2)



Working Group Thoughts

- 34+ Different References to “Procedure” in 2005
- How many actually affected technical work?
- Could some be trimmed out?
- Can the labs get back to their customers and their business?

2017 – Procedures / Documents

- Range of Lab Activities (5.3)
- ***Org Structure (5.5)***
- Personnel Competence Management (6.2.5)
- ***Lab Enviro Conditions (6.3.2)***
- ***Use of Lab Items (6.4.3)***
- ***Calibration Program (6.4.7)***
- ***Intermediate Checks (6.4.10)***

2017 – Procedures / Documents

- Service Provider & Subcontractor Use (6.6.2)
- ***Contract Review (7.1.1)***
- Decision Rules (7.1.3)
- ***Test / Cal Methods (7.2.1.1)***
- ***Method Validation (7.2.2.4)***
- ***Sampling (7.3.1)***
- ***Handling of Customer Items (7.4.1)***

2017 – Procedures / Documents

- ***Customer Item ID System (7.4.2)***
- ***QC Checks (7.7.1)***
- ***Limits for QC Checks (7.7.3)***
- Complaint Handling (7.9.1)
- ***Non-Conforming Work (7.10.1)***
- ***Internal Audit Program (8.8.2)***
- ***Management Review Schedule (8.9.1)***

~~Confidentiality / Impartiality~~

Org Structure

~~Central Quality Manual~~

~~Quality Policy Statement~~

Supporting Procedures

~~Document Control~~

Contract Review

Purchase & Receiving

Complaint Handling

Non-Conforming Work

~~Corrective Action~~

~~Preventive Action~~

~~Record Control~~

Internal Audit

~~Management Review~~

ID and Provide Training

~~Job Descriptions~~

Lab Enviro Conditions

Test / Cal Methods

~~Method Validation~~

~~Estimation of MU~~

~~Software & Data Protection~~

Calibration Program

Use of Lab Items

Intermediate Checks

~~Correction Factors~~

~~Reference Standard Use & Cal~~

Sampling

~~Recording Sampling Data~~

Handling Customer Items

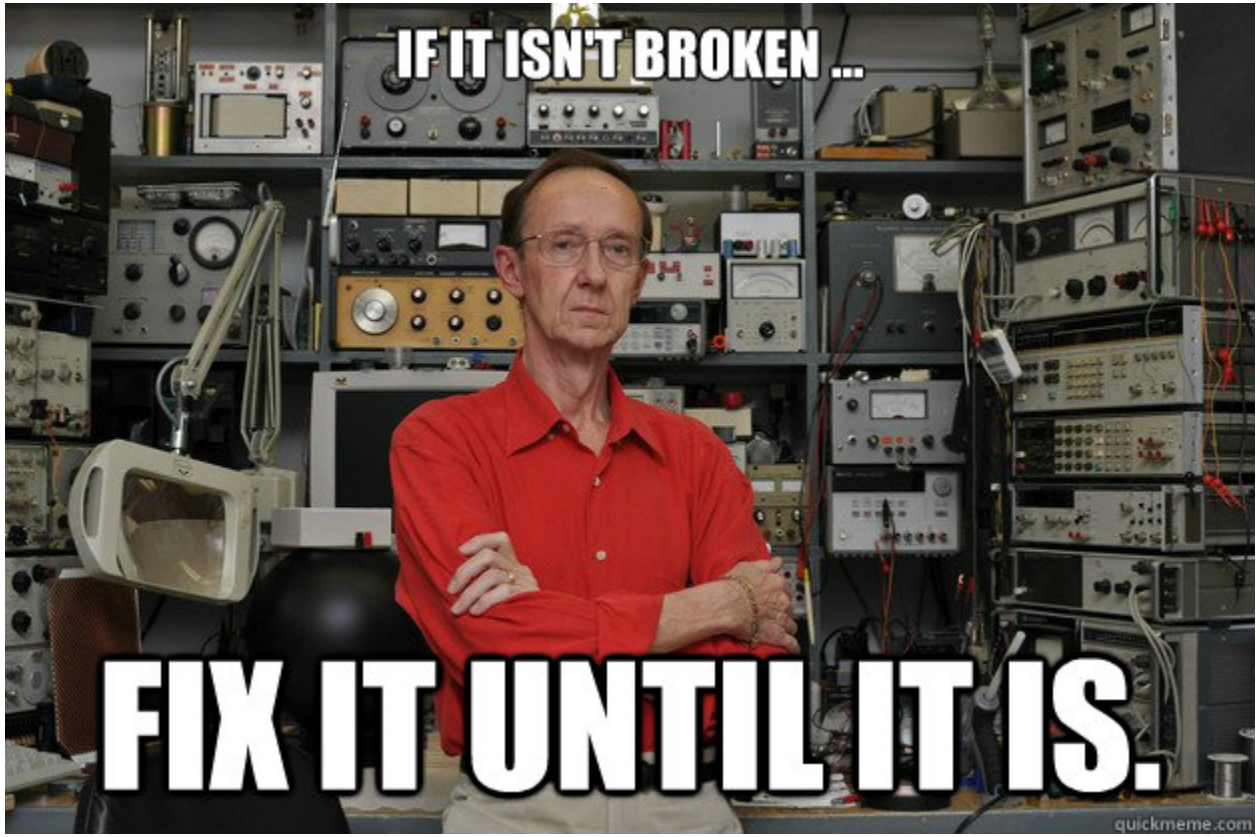
Customer Item ID System

~~Special Storage of Customer Item~~

QC Checks

Limits for QC Checks

Do The Labs Need to Change?



New Definitions

- Impartiality
- Interlab Comparison/Intralab Comparison
- Proficiency Testing
- Laboratory
- Decision Rule
- Verification
- Validation

Impartiality

- Presence of Objectivity / Lack of Bias / Lack of Unfair Treatment
- Focus is on the data your labs produce
- 95% of new requirements should already be addressed from 2005 requirements
- A few new actions (ongoing monitoring/mitigation of risks, and records)

Laboratory Management

- No more reference to “Top Management” or special titles
  - *(Please don’t fire your quality managers, you still need them!)*
- Focus on the managers who are “in the trenches” and know the day to day business
- Empower your staff

Personnel Competence

- Competence = Knowledge + Demonstrated Skill
- Lab Defines Competence Requirements
- Include Training, Supervision, & Repeated Monitoring of Competence
  (*ongoing ability to demonstrate a method*)
- More Than Just Job Descriptions

Personnel Competence

- Competence for each function influencing results (examples):

- Review of Contracts
- Sampling
- Method Performance
- Uncertainty Calculation
- Purchasing / Receiving
- Reporting Results
- Management / Supervision

External Competence

- Subcontractors & Service Providers now “External Resources”
- Procedure Required to Address:
  - Define requirements for products / services
  - Define criteria for provider of products / services
  - Ensure products / services comply with 17025
  - Taking actions to resolve problems with external providers

Decision Rules

- Accredited Calibration Labs are familiar with these
- How do you address this scenario?
  - Customer needs an in- or out-of-tolerance result with their data
  - Your lab is required to calculate its measurement uncertainty for the work
  - No instruction provided on how to apply uncertainty to data to tell in or out of spec
- Requirement to get agreement from customer during contract review, keep records, and include the rule in the final report / certificate

Proficiency Testing

- Accredited labs – Nothing Changes For You!
- ILAC P9 was incorporated as requirement for ALL labs under 17025, not just those in the ILAC accreditation world
- ILAC P9 (and A2LA PT Policy) still exist and still have a few extra requirements, such as timelines on corrective action submission to A2LA

Resolving Complaints

- Required in 2005
- More robust requirements in 2017
- Serves to instill customer confidence in laboratory's process
- More communication requirements for better openness

Management System

- Option A/Option B
- Policies and Objectives to address Competence, Impartiality and Consistent Operation

Management System

- Shall control documents and records
  - No required procedures but shown through objective evidence
- Same requirements for documents-approval, periodic review, changes identified, available at points of use, uniquely identified, obsolete documents not used
- Same requirements for records-identify, store, protect, back-up, archive, retrieve, retain and dispose of

Risks and Opportunities

- NOT an encouragement to race to the bottom
- IS an encouragement to be more aware when making business decisions, taking advantage of opportunities to grow / become better
- Does the risk lead to better competence, impartiality, or consistency?
- Is the lab willing to mitigate residual negative effects?

Corrective Action

- React to the problem
- Act to eliminate the cause
- Review effectiveness

- The term “root cause” has been removed

Internal Audits/Management Review

- Required at planned intervals
- Cover 17025, management system and laboratory activities
- Records required

- New inputs to Management Review

Questions?

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