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

A2LA

June 13, 2018

A Better World Through Accreditation

Speaker Introduction

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High Level Changes

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

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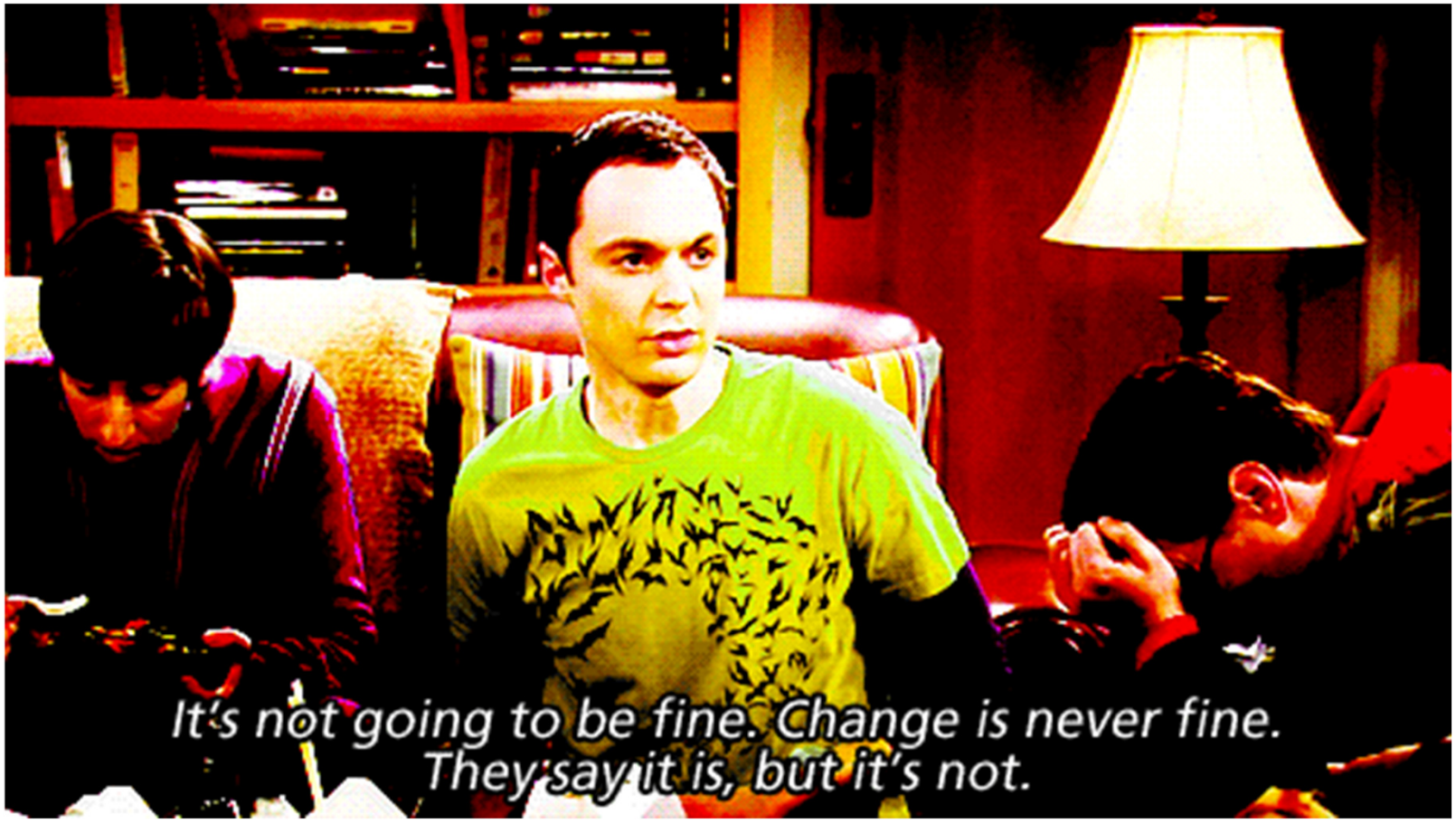
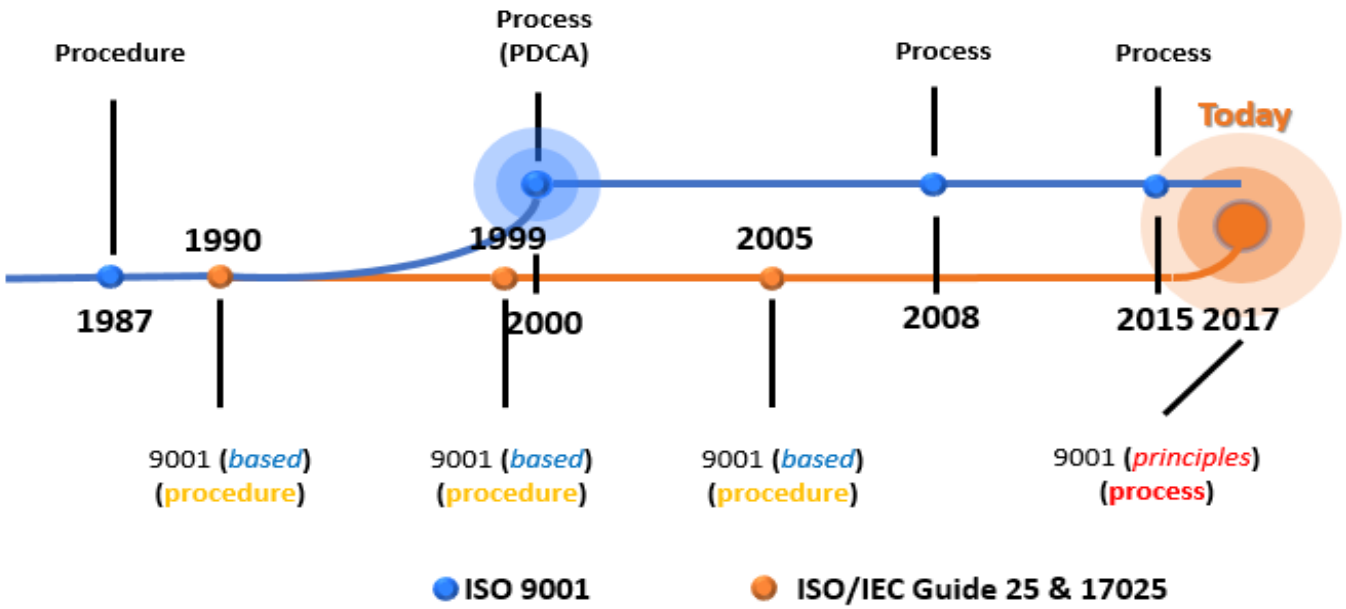
High Level Changes (cont)

- 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



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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

Working Group Thoughts on Document/Procedural Requirements

- 34+ Different References to "Procedure" in 2005
- How many actually affected technical work?
- Could some be trimmed out?
- Are these requirements value added to the output of the laboratory?

2017 – Procedures / Documents

- Range of Lab Activities (5.3)
- *Organizational Structure (5.5)*
- Personnel Competence Management (6.2.5)
- *Lab Environmental 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)***

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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)*

Changes to the 2005 Document / Procedural Requirements

~~Confidentiality / Impartiality~~	~~Record Control~~	Intermediate Checks
Org Structure	Internal Audit	~~Correction Factors~~
~~Central Quality Manual~~	~~Management Review~~	~~Reference Standard Use & Cal~~
~~Quality Policy Statement~~	ID and Provide Training	Sampling
Supporting Procedures	~~Job Descriptions~~	~~Recording Sampling Data~~
~~Document Control~~	Lab Enviro Conditions	Handling Customer Items
Contract Review	Test / Cal Methods	Customer Item ID System
Purchase & Receiving	~~Method Validation~~	~~Special Storage of Customer Item~~
Complaint Handling	~~Estimation of MU~~	QC Checks
Non-Conforming Work	~~Software & Data Protection~~	Limits for QC Checks
~~Corrective Action~~	Calibration Program	
~~Preventive Action~~	Use of Lab Items	

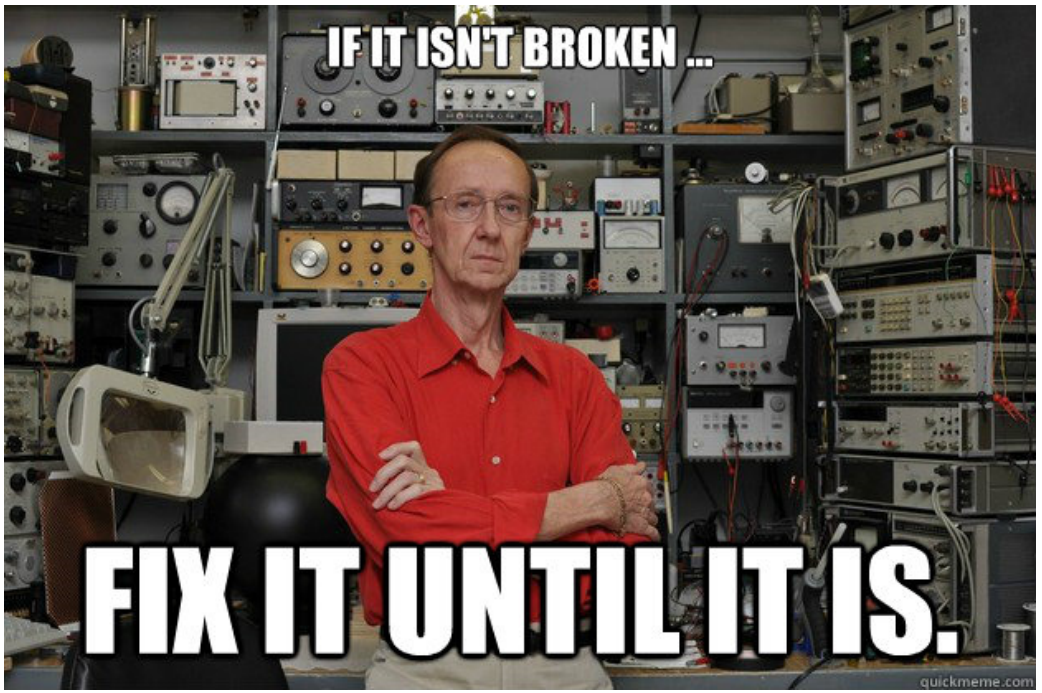
Do The Labs Need to Change?

- "New" things that need to be added to existing practices:
  - Competence instead of Qualification and Monitoring (6.2)
  - Requirements for and Monitoring of Service Providers (6.6)
  - More Robust Complaint Process (7.9)
  - Risk Identification and Handling (4.1, 8.5, and 8.9)
  - Confidentiality Requirements more detailed (4.2)
  - Document "Range of Lab Activities" (5.3)
  - Handling Decision Rules / Statement of Conformity (7.1 and 7.8.6)
  - Records for Verifying Performance of New Methods (7.2)
  - Functionality of LIM Systems (7.11)

The Changes in Summary

- While the requirements for some documents were removed the purpose having those documents remain in the standard
- Just because the standard removed some document requirements doesn't mean laboratories will scrap their old procedures
- Remember....

If it Ain't Broke, Don't Fix It!!!



A Bit More Info on the "New Stuff"

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
- Focus on the managers who are “in the trenches” and know the day to day business
- Empower your staff

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!
- ILAC P09 was incorporated as requirement for ALL labs under 17025, not just those in the ILAC accreditation world
- ILAC P09 (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 – What does the "Option" Really Mean?
- Policies and Objectives to address Competence, Impartiality and Consistent Operation

Risks and Opportunities

- The standard is clear this is an improvement process, NOT an encouragement to race to the bottom
- It 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?

The Path Forward

- All ILAC MRA signatories (A2LA included) must have labs accredited to the new standard no later than November 30, 2020
- September 30, 2018 is the cutoff for when labs have a choice as to which version of the standard for which they wish to be assessed
- If a lab is not accredited to the new version by November 30, 2020 they will not have a valid accreditation

Recognition of 2017

- ISO and ILAC issued a communique in November 2017 stating:
  - "During this transition period, it is important to note that both ISO/IEC 17025:2005 and ISO/IEC 17025:2017 are equally valid and applicable"
  - "Formal accreditation to either standard granted by an accreditation body that is a signatory to the ILAC Arrangement should be recognised by the market place"
  - "…it is strongly recommended that specifiers equally recognise both versions until after the 3-year transition period has closed"

Recognition of 2017

- Government organizations are in the process of reviewing and updating regulations to accept the 2017 version.
- The FCC Office of Engineering and Technology Laboratory Division has issued a memo dated March 2, 2018 accepting 2017 as equivalent to 2005
- A2LA expects that other bodies will follow the FCC's approach to adopting 2017 as equivalent

In Closing…

- There are changes to the standard but it isn't as drastic as it might appear
- The focus on technical competency has increased
- ISO and ILAC have determined that the 2017 is equivalent to 2005 and during the transition period they will be equally recognized

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