 نظام إدارة المختبرات
للعينات و 17025

كفن سميث
This Talk

• Introduction to the standard
• Relevant clauses
• Mapping to LIMS functionality
• Conclusion
ISO 17025 - Background

- Replaces ISO Guide 25 and EN 45001 internationally
  - The above Standards date from 1980’s and early 1990’s and it was recognised that they were outdated
- Much of the ‘thinking’ comes from the ISO 9000 Series of Standards
  - Testing laboratories that comply with this International Standard may therefore also operate in accordance with ISO 9001 or ISO 9002
- Think of ISO17025 as ISO9000 plus the specific requirements of running a good laboratory
Structure of ISO 17025

• Two main sections
  • Section 4 – management requirements
    • Document Control, Supplier management, Review of Requests, Tenders and Contracts, Corrective actions, Records
  • Section 5 – technical requirements
    • Qualification of operators, instruments, methods, Control of data, Reporting
  • Numerous ‘notes’ – pay attention to these!!!

• Comprehensive bibliography of related standards
  • ISO 5725-1 - Accuracy of measurement methods
  • ISO 9000-1 - Quality Management
  • ISO 9000-3 - 9001 for development and supply of software
  • ISO 10012-1 – QA requirements for measuring equipment
  • …
  • Get copies of any relevant ones…
Requirements of ISO 17025

- Requirements which will be most involved with LIMS are in sections:
  - 4.4 Review of requests and contracts
  - 4.6 Purchasing services and supplies
  - 4.8 Complaints
  - 4.9 Control of non-conforming testing
  - 4.10 Corrective action
  - 4.11 Preventive action
  - 4.12 Records
  - 5.2.5 Training and authorization of personnel
  - 5.4.5 Validation of methods
  - 5.5 Equipment
  - 5.9 Assuring the quality of test results
  - 5.10 Reporting results
4.4 Review of Requests and Contracts

- The aim is to ensure mutual understanding, between laboratory and client, at all stages of the work regarding:
  - client requirements
    - Including when results are required!
  - the tests to be performed
  - performance characteristics
- Likely to involve more formalised records of relevant discussions with clients – keep records of these as attachments
  - See also 4.12 - Records
- If properly executed, this section can be of great benefit to labs – clients should have little cause for complaints!
4.4 Agreed Statement of Work to be performed

Standard price lists, discounts, surcharges, turn around times, special sample handling etc are all defined and agreed up front.
4.4 Attachments as evidence of contract review
4.6 Purchasing Services and Supplies

“The laboratory shall use only such services and supplies that are of the quality needed to sustain confidence in the results of tests and/or calibrations”

- Track approved suppliers
  - LIMS stock control for standards, reagents etc…

Keep track of suppliers, their stock and their ratings

Work back from a stock to its suppliers and check their rating
4.6 Purchasing Services and Supplies

- Don’t forget the LIMS and other critical software!
  - ISO 9000-3 (see bibliography)
  - “Think of ISO17025 as ISO9000 plus the specific requirements of running a good laboratory”
  - “ISO 9000-3 is ISO 9000 plus the specific requirements of developing software”
  - If in doubt, be sure to check the software supplier scope statement…!
Scope MUST include Design and Development to be worthwhile
4.8 Complaints

• When something unexpected happens, need to plan and track actions through to closure.
  • LIMS ‘Incident Management’
    • Generated manually or automatically
    • Templates for ‘type of incident’ – defines required actions
    • Each action completed, reviewed and closed
    • Report of all actions to close an incident

• Also used for
  • 4.9 Control of non-conforming testing
  • 4.10 Corrective action (fixing the issue and avoiding recurrence)
4.11 Preventative Action

- **4.11.1 potential sources of non conformances…shall be identified…**

- LIMS SQC/AQC Charts
  - Control charts can identify results that indicate analytical process ‘heading out of control’, even though results today still ‘in spec’
    - AQC Worksheets specifically check the analytical method
      - See 5.4.5 and 5.9

- Also used for
  - 5.4.5 Method Validation
  - 5.9 Assuring the Quality of Test Results
4.12 Records

- Keep general and technical records.
- Prevent unauthorized access
  - Who can do what?
- Audit trails
  - who actually did what and when…(required for patents too)
- LIMS Access controls…
4.12 Records – different types of attachments

• Files
  • Uploaded and stored on the server. Double click downloads to the user PC and displays

• Notes
  • Simple free text fields against any entity

• Links
  • To external files or URLs. Selecting the link opens the file or URL with the default application
4.12 Records – Including attachments in reports

Attachments are available in the Report Designer – and you can add them to your reports.
4.12 Records - Reporting

When you print the report – the attachments are included in your report as images of each available page.

Office Documents, PDF, Images and Text attachments are automatically converted for inclusion.
5.2.5 Training and authorization of personnel

- 5.2.5 *The management shall authorize specific personnel...*
- ‘Operator Approval’ controls access to instruments and methods.

Training records are held against the Operator.

Required Training is held against the Analysis.

In addition can use ‘Attachments’ to store training certificates, or link to external HR system.
5.4.5 Validation of methods

• 5.4.5.1 - Validation is the confirmation by examination and the provision of objective evidence that the particular requirements of a specific intended use are fulfilled.
• The strongest part of the standard - Validation was not mentioned in earlier versions
• Now clear that the primary responsibility to decide on ‘fitness for purpose’ lies with the lab.
5.4.5 Validation of methods

- Process of ‘validation’
  - identify the purpose of the test
  - review method performance data
  - review the data
  - confirm ‘fitness for purpose’

- LIMS AQC Worksheets
  - Initialization checks, Calibration checks, interference checks, matrix spike, matrix spike duplicates, duplicates, controls, surrogates…
  - Can specify ‘patterns’ of standards etc
    - “Run a blank and 5 calibration standards”
    - “Then a check standard after every 10 samples”
    - “Always finish the worksheet with a check standard”

- Also used for
  - 4.11 Preventive action
  - 5.9 Assuring the Quality of Test Results
LIMS AQC Worksheets

Worksheet template contains details of calibration standard patterns etc that need to be run.
5.5 Equipment

- Records shall be maintained of each item of equipment...

Instrument parts can then be associated with their instrument – note they have a status, and may be used by more than one instrument.

In addition can use ‘Attachments’ to store instrument manuals or link to supplier website.
5.5.2 Calibration Program...

Need to specify frequency patterns
5.5.13 Correction Factors…

Fixed Parameters can be associated with an instrument reflecting how it is set up.

Results of Calibration samples (i.e., response factors) also stored here automatically.

Instrument parameters can be used in calculations that make use of this particular instrument.
Equipment Histories

It is important to know what has happened to an instrument over a period of time. Or more importantly - what was the status of the instrument when a reading took place?

Events occur manually or automatically as the instrument and its parts are calibrated and serviced.

This screen is targeted towards incident investigation or compliance audits.
Measurement Traceability

• Instrument, Operator and Date are stored against results
  • Gives the exact instrument configuration and state
  • Shows who was operating the instrument
• Calibration samples linked to instrument
• Tests linked to calibration data via instrument
• Failed instrument QC allows determination of affected tests

This completes the circle – so you can determine which instrument was involved with a reading and what state it was at. Can also prove the operator was trained in it’s use.
5.9 Assuring the Quality of Test Results

- Note that the Standard is not prescriptive – it is the responsibility of labs to plan and review appropriate quality control measures.
- New requirement to ‘record data in such a way that trends are detectable and, where practicable, apply statistical techniques to the reviewing of results’
  - LIMS SQC, AQC Worksheets…(as for 5.4.5)
Benefits of using LIMS to support ISO 17025

Before Implementation

After Implementation

Greatly improved quality and productivity through massive reduction in paper and manual processes
Recommendations

• Take a logical and pragmatic approach – what makes sense for you?
  • It is your lab and hence your quality system
    • Map your requirements on to LIMS functions
• Balance risks and get management and worker buy-in
  • “Present a united front to the auditors” J
• Have evidence of decisions taken regarding 17025 implementation
  • Keep appropriate records…
Thank you

- Questions?
- Kevin.smith@thermofisher.com
- Booth 700