ISO 17025 - Auditing Experience

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ISO 17025 - Auditing Experience

Experience as Technical Expert, supporting Lead Assessor

- LA– section 4 – Management Requirements
- TE – section 5 – Technical Requirements

- Lessons – weaknesses and strengths
- Some questions for you!

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CALIBRATION - a set of operations that establish the relationship between values of quantities indicated by a measuring system and the corresponding values realized by the standard.

TEST - technical operation that consists of the determination of one or more characteristics of a given product, process or service according to a specified procedure.

Q. Which is relevant?

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The Quality Manual should not just repeat the standard.

Standard:

“5.4.7.1 Calculations and data transfers shall be subject to appropriate checks in a systematic manner.”

QM:

“5.4.7.1 Calculations and data transfers are subject to appropriate checks in a systematic manner.”

Q. What would be better here?

4.2 Management System

4.2.2 . . . The quality policy statement shall be issued under the authority of top management . . .

Q. Who are "top management"?

A. Those who have the authority to grant you all the resources you need.

Culture

4.1 (Organization) and 4.2 (Management System)

If followed, these lead to a good quality culture.

Auditors can often tell, by talking to staff, what their attitude to quality is.

But an audit is about getting evidence.

4.4 Review of Requests, Tenders and Contracts

4.4.1 Review of Requests

Have you the capability?

-technical

-capacity

Difference between dealing with a small request and a large one.

4.5 Subcontracting

Does your IMS subcontract any part of its service?

What happens if your IMS has a problem? Would you turn to another IMS for help?

4.8 to 4.12 – Problems and How They Are Fixed

A good QMS:

- identifies non-conformances
- corrects them quickly
- identifies root cause
- identifies preventive measures
- follows up, to make sure they are effective

4.10 – continual improvement

4.9 Nonconformances

(“Nonconforming work”)

Q. Do we need to record every problem?

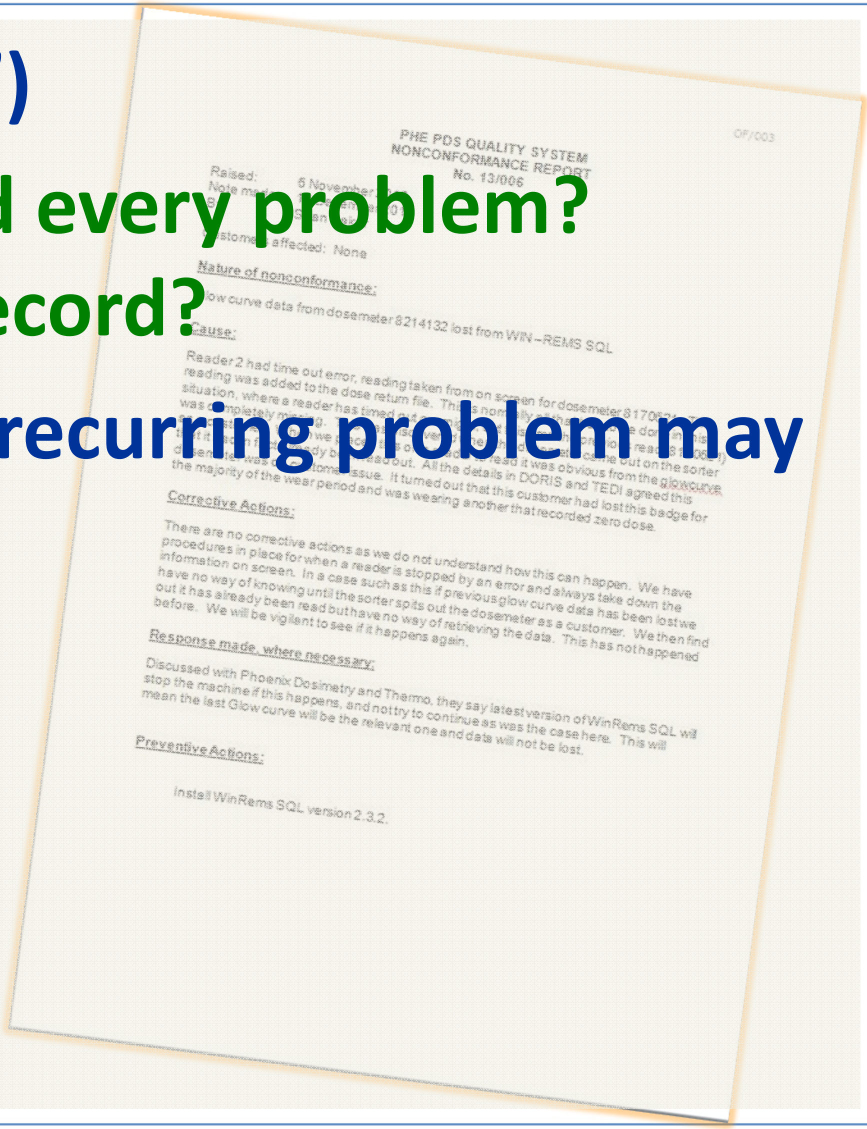
When should we NOT record?

Remember: a small but recurring problem may lead to a bigger one.

REPORT

- Details
- Cause ➔ ROOT Cause
- Corrective actions
- Preventive actions

- Also: follow-up



OF/003

PHE PDS QUALITY SYSTEM
NONCONFORMANCE REPORT
No. 13/006

Raised: 6 November

Customers affected: None

Nature of nonconformance:

Glow curve data from dosemeter 8214132 lost from WIN–REMS SQL

Cause:

Reader 2 had time out error, reading taken from on screen for dosemeter 8170 reading was added to the dose return file. ... situation, where a reader has timed out ... was completely missing. ... read out. All the details in DORIS and TEDI agreed this ... issue. It turned out that this customer had lost this badge for the majority of the wear period and was wearing another that recorded zero dose.

Corrective Actions:

There are no corrective actions as we do not understand how this can happen. We have procedures in place for when a reader is stopped by an error and always take down the information on screen. In a case such as this if previous glow curve data has been lost we have no way of knowing until the sorter spits out the dosemeter as a customer. We then find out it has already been read but have no way of retrieving the data. This has not happened before. We will be vigilant to see if it happens again.

Response made, where necessary:

Discussed with Phoenix Dosimetry and Thermo, they say latest version of WinRems SQL will stop the machine if this happens, and not try to continue as was the case here. This will mean the last Glow curve will be the relevant one and data will not be lost.

Preventive Actions:

Install WinRems SQL version 2.3.2.

4.15 Management Review

Typically has fixed agenda

Be careful to take a view over the whole system

Performance indicators?

Main question: is the Quality System working?

Avoid too much focus on details

5.2 Personnel

5.2.2 Education & Training

Remember to evaluate the effectiveness of training:

- **did the trainee learn enough?**
- **would you use the same trainers again?**

5.2.4 Job Descriptions

If these are used for your institute's own purposes, do they still state the person's Quality System responsibilities?

5.4 Test Methods and Method Validation

5.4.5 Method Validation

Q. How can an IMS tell that a method is valid?
("Relevant to the customer's needs")

- **Usually, customer does not specify their needs**
- **Meets published standard, e.g. IEC 62387-1**
  - hence: type testing
- **Meets any other requirements (customer, national etc.)**

5.4 Test Methods and Method Validation

5.4.7 Documented and Validated Software

- Care needed with in-house systems – may not be documented sufficiently.
- If contracted out, make sure contractor has coding and documents in a usable state.

Q. How is software validated?

- thorough test programme
- outputs (compare with independent sources)

5.5 Equipment

Q. Why are logs and maintenance records useful?

- confidence in equipment
- trends visible - diagnosis
- anticipate problems
- information on efficiency – hence costs
- maximises reliability

5.6 Traceability

UNBROKEN chain from national/ international standards

Q. In an IMS, what are the “reference standards” and “intermediate checks”?

A. (i) TLD: Calibration dosemeters; QC dosemeters

(ii) Film: Batch calibration films; Set-up films for densitometer

(See also 5.9.)

5.8 Handling

Q. IMS had defined storage conditions for dosemeters (cool, dry, away from sources of radiation). Was this enough?

A. No. They needed to demonstrate that the storage conditions were suitable (no effect on dosemeters), by:

- **carrying out and recording their own validation, or**
- **referring to manufacturer data.**

. . . and keeping evidence available.

5.9 Assuring the Quality of Test Results

5.9.1 The laboratory shall have quality control procedures for monitoring the validity of tests . . . undertaken. The resulting data shall be recorded in such a way that trends are detectable . . .

This monitoring . . . may include, but not be limited to, the following:

a) regular use of certified reference materials and/or internal quality control using secondary reference materials;

b) participation in interlaboratory comparison or proficiency-testing programmes;

c) replicate tests or calibrations using the same or different methods;

d) retesting or recalibration of retained items;

e) correlation of results for different characteristics of an item.

5.9.2 Quality control data shall be analysed and, where they are found to be outside pre-defined criteria, planned action shall be taken to correct the problem and to prevent incorrect results from being reported.

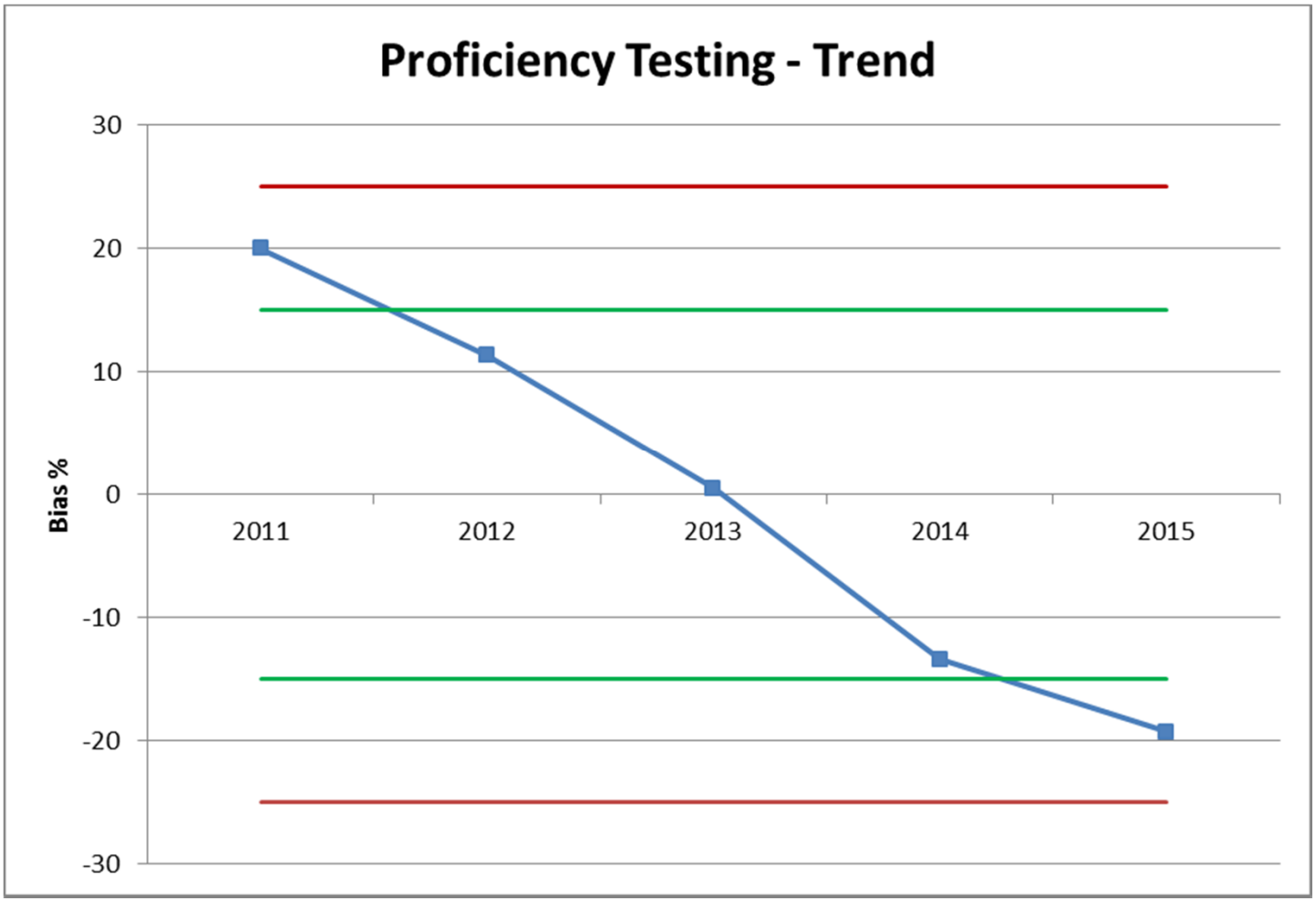
5.9 Assuring the Quality of Test Results

- Laboratory had records of results in local intercomparisons (ICs) for last 5 years.
- Each IC result had been analysed and a report produced by the Quality Manager.
- Report commented on whether result was Good (within ±15%) , Acceptable (within ±25%) or Requiring Action.

Q. What else should they have done?

Year	Judgement
2011	Acceptable
2012	Good
2013	Good
2014	Good
2015	Acceptable

5.9 Assuring the Quality of Test Results



What will happen in 2016?

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Summary

- not everything is straightforward
- some parts of ISO 17025 are more challenging than others
- read the standard properly
- think it through carefully
- you need evidence!

Any questions?