Training is Not Enough
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The NLA T&M 2018
“Training” in 2005

• In the 2005 version, it was required that the laboratory ensured staff were competent and that when in training they were supervised, etc.,

• The laboratory must have goals with respect to education and training of staff and to ensure the effectiveness of training – and then to authorise specific people to undertake specific tasks.
These clauses do not have a different meaning to the 2005 version. However, they are worded more clearly and emphasise competence.

The organisation performing tests must do so competently – they have to know what they are doing.
6.2.5 The laboratory shall have procedure(s) and retain records for:

a) determining the **competence** requirements;

b) selection of personnel;

c) **training** of personnel;

d) supervision of personnel;

e) authorization of personnel;

f) monitoring competence of personnel.

Competence and training are separate items.
The naughty incubator

- 37 °C incubator
- Monitoring records consistently showed the incubator was running at 37.0 °C
- The actual temperature on the day of assessment was 41.5 °C
When asked, the staff said:

• “oh yes, that incubator plays up all the time."

• ?
  – “ how do you manage that? There are no records of the temperatures being off..... ”

• “I open the door and let it settle down before I take the readings.”
The staff monitoring the incubator did not act “competently”.

But:
• Was the incubator function and purpose explained?
• Was the purpose of monitoring the incubator explained?
• Who was checking this lady was doing the right thing?
• Who followed up on the fact they seldom got high counts of bacteria?
• To this staff, the point of the exercise was to record that the incubator was 37.0 degrees.
  – *She had clearly been trained to read the thermometer.*

• For her: The reason the incubator existed and was being monitored was all about having perfect records and not about the purpose of the test.
This occurred pre-2017

- In terms of the 2005 version of 17025, this event still caused a non-compliance to be raised
  - Training misdirected
  - Inadequate supervision and monitoring
  - Procedure either not clear or not well targeted

- The 2017 version requires the competence requirements for each function to be documented and monitored
• Was the lady recording the incubator temperature competent to do that?
• Possibly.
• Was she competent to make decisions and act on the out-of-spec incubator temperature?

• No. ➔ ....... Maybe?
  – We don’t know what occurred. We can make assumptions about her knowledge, but what if she was told to do this? What if the instruction came from her boss?
• The procedure may have lacked an instruction to report out-of-spec readings
• The management may not have been inclined to act on out-of-spec equipment
• The culture of the organisation may have been to see equipment malfunctions in a bad light
• Whatever...... it was not about getting the test right, only about the records.
The new edition focuses on “getting the test results right” – which means satisfying the necessary aspects of the test, leading to reporting a correct test result.

(Not just documentation)

This means someone that is competent needs to be at the helm and to be driving “competent acts” all the way down the line.
One “trivial” finding

- Resulted in a lot of doubts.

- This activity did not occur in isolation. The lab had several staff. The likelihood that one person never takes a day off and always reads the thermometer is slim.

- Other staff knew about this and condoned the behaviour, (or at least did not caution against “bad practices”).
Individual staff?
• Staff training
• Staff supervision

Incubator reliability?
• Didn’t meet the specification?
• Equipment control and calibration?

Procedures?
• Are they adequate?
• Do they meet their purpose?

Supervisor competence?
• What other decisions has this supervisor made?
• Do their decisions impact anything else?
Test verification and validation?
- (There were few positive results)
- Were control records really correct?

Other lab records?
- Are these realistic? Correct? Truthful? Relevant?
- Trending?, other equipment?

Effect of incubator on the test results?
- Incorrect results
- Re-calls and re-issue of test reports

Relevance of Management?
- Information provided for management review
- Consequences of providing dubious information
Who needs to be competent?

• Not one person!
  – The laboratory needs to be competent as a whole.

• “Competence begets confidence”

• Training is only one part of attaining competence.
What are the features of competence?
- Appropriate for the task
- How the test fits in with the whole system
- The requirements for obtaining correct results
- To know when something goes wrong