Key Steps to Address Assessment Findings

- What are the specific details – what did NATA see? Insist on getting this info & go and look for yourself.
- Which requirements does NATA reference? Look them up and compare to the assessment finding.
- What is the intention of the clause? What problem is it trying to prevent?
- What is the current risk associated with the process? Consider the impact on test results.
- Is there any evidence of problems with this process?

- Record the results of your investigation and keep it for reference.

And now to some examples...

No specifics

Competence assessment records were not available for review for all personnel.

What

Does this mean that there weren't competency records for ANY personnel? Do we have to send them all in again? Or were just particular ones missing? Without any specifics, it's difficult to know how to respond.

In this case, the lab manager interpreted it as none of the records supplied to demonstrate competency were adequate and started a major revamp of the competency assessment system.

We advised them to ask the lead auditor for specific examples and follow up from there.

Why

The Lead auditor was probably rushed and forgot to give specific examples.

Action

Ask for specific examples & address those.

> *Never try to address an assessment finding without getting the specifics of what the assessment team saw.*

Confusing Assessment Finding

Documents must be periodically reviewed to ensure they remain fit for purpose. The following issues were noted and must be addressed:

- Quality Manual references an incomplete list of accredited tests.
- Quality Manual Section 3 states that equipment records are kept for the working life plus 3 years, however, Section 8 states that these records are kept for the working life plus 4 years.

What

On reading the first sentence, it seemed like they were saying that all or most of our documents had not been reviewed at all, had not been reviewed periodically, or were not fit for purpose. Or possibly all three. We started to feel very annoyed.

Then we moved on to the second sentence, realising that the first was a quote directly from the standard (ISO 15189). So we could ignore that and move on to the specifics.

Why

This is a common structure for NATA assessment findings, though not all lead auditors use it. Restating the words from the standard can make it very clear where the problem is, but it can also lead you to think that the problem is more widespread than it really is.

Action

The lead auditor listed the specific issues, (which were valid) so we fixed those, then had a quick look to see if the problem was more widespread.

> *Ignore the generic wording from the standard and jump straight to the specifics. After you've verified that they are valid, address them and send your response.*

Creeping Criteria

Whiteout must not be used in controlled documents. The methods in the Serum Rhubarb section contain multiple examples of its use.

What

The dreaded whiteout! We checked the clause referenced and found that the clause was about test records.

The *real* problem was that there were changes to the methods & no way to tell who authorised the changes. But NATA didn't quite nail that.

Why

It was just a mistake. The lead auditor was quite new and knew there was some kind of problem with whiteout. When the technical assessor mentioned the changes in the methods (which she was not used to seeing), she linked the two.

Our investigation did find out why there was a whiteout in the methods (more than you would expect) and we made some changes to our document control procedures.

Action

We explained to NATA that the clause they quoted wasn't relevant to methods, and no action was required. There was no need to tell NATA about what we did to fix the real problem.

Always check the clause from the standard. Work out for yourself what is wrong and fix that.

A Transplanted Requirement

Each line in the training records must be individually dated and initialled. (I.e. you can't draw a bracket around a group of training topics and mark them with one date and initials.)

What

Well who says you can't? All of those topics were covered on the same day. We checked the requirements quoted – nothing there.

What problem is this suggestion addressing?

Why

We think that the lead auditor had been at another lab where everyone agreed this was a requirement, and the lab wanted it that way. How your training records look will depend very much on how you do your training and how often you update the records.

Action

We explained that this was not a requirement for training records and that the training had all occurred at one time.

*When a finding doesn't make sense, check back through the standard/s first. Then consider whether their suggestion would reduce risk in the process **and** be efficient.*

Unrealistic expectations

The lab has held two meetings in the past 7 months, about 4 months apart. (Listed as a C & no indication of what was wrong with that.)

What

At first the lab was going to reply that they would hold a meeting every month. This seemed to be what NATA wanted. Then we investigated:

- The referenced requirements talk about communication rather than meetings.
- It's a small lab with 4 staff members who all work the day shift and see and speak to each other 5 days a week.
- We discussed what communication needs the lab has other than what they normally cover in staff meetings and how these can be recorded.

Why

We think the assessment team was so used to seeing records of meetings held on a strict schedule, that they thought it was actually a requirement. It's a necessity in a large lab, but not a requirement from the standard.

Action

They decided to put up a notice for any document updates, which could then be discussed in the staff meetings when they occurred. We explained this to NATA , who accepted the response.

Just because everybody else does it doesn't mean that you have to! Resist the push to adopt management practices more suited to completely different types of labs.

The never-ending story

Condition: "Staff member Orange at lab G conducted testing to method One; however, records to indicate whether the staff member had been assessed for competence or authorised to conduct the testing were not available."

What

The training records were there, but the new lab manager had been unable to find them on the day. They sent in the training records for the whole lab (as an extract from the database, the easiest way to do it), including those for staff member Orange.

Lead Auditor's response: Thank you but there do not appear to be records to show that staff member Brown or Green have been approved to do test methods Two, Four or Seven.

Our investigation showed all of these training records were in order according to the duties those staff were required to fulfill.

Why

This is a mystery. Perhaps this lead auditor had too much time on their hands or wanted to make sure they really nailed this lab. They started trawling through the records that we sent and decided to continue the assessment.

Action

Response to NATA: We have supplied the training records requested and are unsure why you are asking for other training records that were available at the assessment.

> *The assessment is over when the assessment team leaves – they can't keep asking you to send more records and then pick them over to find more issues.*

Over-reach

The laboratory must document a procedure for addressing risks and opportunities.

What & Why

We checked the clauses quoted. There's no requirement for a procedure. You have to do it, not write about how you do it.

We confirmed that the lab had addressed risks and opportunities in management review, quality improvements and change management.

Action

We replied to NATA, explaining how we incorporate risk-based thinking into our processes and mentioning that it's not necessary to write a procedure for it.

With the updates to ISO 17025 and ISO 15189 in recent years, you no longer have to write procedures for everything. If you have a system and it is working, that is the evidence that you meet the requirements.

Another Confusing Assessment Finding

Evidence of verification that equipment conforms with specified requirements must be retained. There was no evidence to indicate that (one specific piece of equipment) meets the specified requirements.

What

The lab manager was distracted by the first paragraph and started reviewing and trying to improve how they stored this information. An old hand recognises the first paragraph for what it is: simply a restatement of the clause from ISO 17025 6.4.13 b).

The only thing that needs attention is the records for that one piece of equipment.

Why

This is a format for writing findings that some lead auditors adopt.

Action

Skip to the second line to find out what they actually discovered during the assessment.

Once you have sorted out the issue in the second line (the specific), you may go back and review how that error occurred in the first place and that may warrant a closer review of the system for collecting and storing calibration records.

> *Ignore the generic wording from the standard and jump straight to the specifics. After you've verified that they are valid, address them and send your response.*

Book a call with Cathy to find out how we can help.