

**DOES YOUR LAB FACE  
THESE 5  
ISO/IEC 17025  
CHALLENGES?**



## **Even the best labs can find themselves floundering a bit when external audit or assessment time rolls around.**

As consultants and mentors, we've visited a LOT of client's labs over the years. And although each lab faces different challenges, we've found that there are a few issues that regularly crop up that can lead to some anxiety during audits or assessments.

If you have an audit or assessment coming up, here are our top five ISO/IEC 17025 issues you may want to investigate before the team arrives:

### **Issue 1: Management reviews**

We've written previously about management reviews so it's worth revisiting this article to be sure you're covering everything you need to.

While section 8.9 covers management reviews in general, clause 8.9.2 contains a list of information. It's this list of 15 items that you must cover as part of the management review.

The items in clause 8.9.3 are not additional items you need to cover; they are about the output and content of your records of the management review process.

### **Issue 2: Internal auditing**

Your internal audit program should confirm that your lab is compliant to ISO/IEC 17025, your management system, and your lab's activities.

This clause allows the lab to decide on the frequency and depth of the audits, depending on the lab's needs and risks associated with the various lab processes.

However, you must keep records of your internal audit plan and outcomes. If you can't stick to the plan, think about changing it and recording these changes.

The assessment team will want to see your internal audit schedule, as well as your records of completed internal audits, so be sure to have this available for them.

Of course, labs should not be doing internal audits just because the Standard and NATA says so. Read our article about how you can take your audits from mediocre to meaningful to see some ideas of how to zhooosh up your internal audits.

### **Issue 3: Personnel**

This is guaranteed to come up during an assessment. And while we're sure all your staff are competent and know exactly what they're doing, NATA won't take your word for it!

Clause 6.2.5 of ISO/IEC 17025 covers personnel procedures and records. Your lab must have these to demonstrate a broad range of HR processes, including the competence, training, and monitoring of your staff.

There are also specific topics that must be addressed (either in one procedure or individual procedures). All these must be adhered to for all relevant personnel and the lab must have records of implementing and following these procedures.

You'll also need to document staff competencies and have supporting records (6.2.2). These competency requirements need to include training, education, and experience for the various positions within the lab.

### **Issue 4: Ensuring the validity of results**

This section of the ISO/IEC 17025 Standard specifies that your lab must have a procedure for monitoring the validity of its results. It also includes the required elements of the monitoring activities.

Your lab must collect and analyse data from its monitoring activities and use these to evaluate (and potentially improve) its activities.

You should also be monitoring your lab's performance by comparing results with other labs (interlab comparisons or proficiency testing). If this option isn't available, you'll need to explain why.

You'll also need to demonstrate what you've done to mitigate the risks of not carrying this out.

## Issue 5: Technical records

This is a big one. The clause is all about the 'paperwork' traceability of your results. Your activities must have records that are detailed enough to replicate the exact process that produced them. Who did what, when and how?

This means that you will need to consistently record all relevant factors relating to your testing. Plus, you'll need to retain all the original records and any amendments.

## Do any of these ISO/IEC 17025 issues sound familiar?

If not, congratulations! Your next assessment should be a breeze!

However, if you are facing problems with implementing any ISO/IEC 17025 clauses in your lab, we have some training that will help.

**Our training is different.** Naturally we examine the clauses of the Standard and discuss their application in your lab.

But we also understand that often the reason you want to attend training is because of a specific issue.

Perhaps there's a clause you don't understand or have difficulty implementing.

Or perhaps you thought you had it covered but at the last assessment, the lab was given a nonconformance. So, we ask you to think about which clauses you need more information about; which ones you'd like to discuss with someone outside your facility and get insights into its implementation.

Then we'll ask you to send us those clauses and any specific questions before the course starts so we can drill down into those a bit more during the training.

So you'll get exactly what you need to go back to lab and implement it right away.

Sounds perfect, right? If you have a few people you'd like trained, call us and we can run an inhouse session for you.

But perhaps you have an issue that doesn't need a full day of training to address. That's when our mentoring service can help.

To take advantage of these options, you can call Maree (0411 540 709), Diane (0402 012 781) or you can email us [info@masmanagementsystems.com.au](mailto:info@masmanagementsystems.com.au) to set up a confidential discussion.

You can also head to our website and check out the range of services we offer.

***Remember, you don't have to do this alone!***