THE COMPLETE GUIDE TO TRACEABILITY

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Climbing your Traceability

Climbing your Traceability Tree

Most NATA accredited labs will butt up against the requirements for metrological traceability. Those requirements seem to have become more difficult to meet, with even the tiniest and what would seem an insignificant piece of equipment or reference material being the subject of a condition for accreditation.

Many labs have told us of the relentless demands to spend more and more money on expensive calibrations and certified reference materials.

Where are these demands coming from and how can you meet them without breaking the bank? That's what we'll be exploring in this article.

The "why" of metrological traceability requirements

Most labs will understand that there is a need to compare results over time or between different batches or laboratories. To do that, we need to all be going back to the same point to know if we're comparing apples with apples, or apples with oranges.

The only effective way of achieving this is metrological traceability. This concept is like the original blockchain!

Your evidence of metrological traceability provides confidence that you can compare and link your results back to national and international standards.

What is metrological traceability?

Metrological traceability is about measurements and how they compare to other measurements. It helps us to understand what the results we produce mean in a wider context.

In metrology (the science of measurement), traceability is defined internationally as the 'property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty'.

You'll see the same definition in the ILAC Policy on Metrological Traceability of Measurement Results and in NATA's Metrological Traceability Policy document. It's worth reading through NATA's document, particularly if you have an assessment coming up.

Samples and records or paperwork moving through the system also require traceability. However, those are subject to different requirements relating to sample and records traceability.

What does the standard say?

If your lab is accredited to ISO/IEC 17025 or ISO 15189, or looking to become accredited, you'll need to be sure that your measurement system meets the requirements.

In a nutshell, the standard says that:

- If the equipment you're using has a significant effect on your measurements results, it needs to be calibrated.
- You need to have a programme and a procedure in place for equipment calibration.
- If you're a calibration lab, wherever technically possible, you'll need to establish an unbroken calibration chain, linking your measurement standards to a relevant primary standard of the SI unit.

If you're a testing lab, you need to use a calibration service that is competent and capable of demonstrating that traceability. And you'll also need to take a look at the traceability of any reference standards you're using (they come up under the banner of 'equipment').

Perhaps you don't believe that your lab equipment doesn't affect your test. In this case, you need to have objective evidence to support your decision. And yes, an assessor will definitely want to see this!

Where to start with traceability

Think of the exercise as being like climbing a tree. You've got to somehow get to the top.

Climbing a tree may seem like a simple and nostalgic activity, but it comes with its own set of challenges. Climbing your traceability tree is no different.

The first hurdle is finding a suitable tree with sturdy branches and a climbable structure. Assessing the tree's health and ensuring it can bear the weight of a climber is crucial to avoid accidents.

Let's start assessing the health of our traceability tree by thinking about what it is that you're measuring. What are the units of measurement? Are these units of measurement SI units? The SI units provide sturdy branches.

But that doesn't assure us that we have a climbable structure. That is where calibration helps. Often that help comes from outside of our lab.

A Climbable Structure

You have a few options when looking for Metrological Traceability from external services. You can use the services of an NMI, through an ISO/IEC 17025 accredited lab or a certified reference material.

In Australia, the National Measurement Institute has a range of testing and calibration facilities.

For a list of accredited labs, the NATA website has a search function that can be used to find labs in your area.

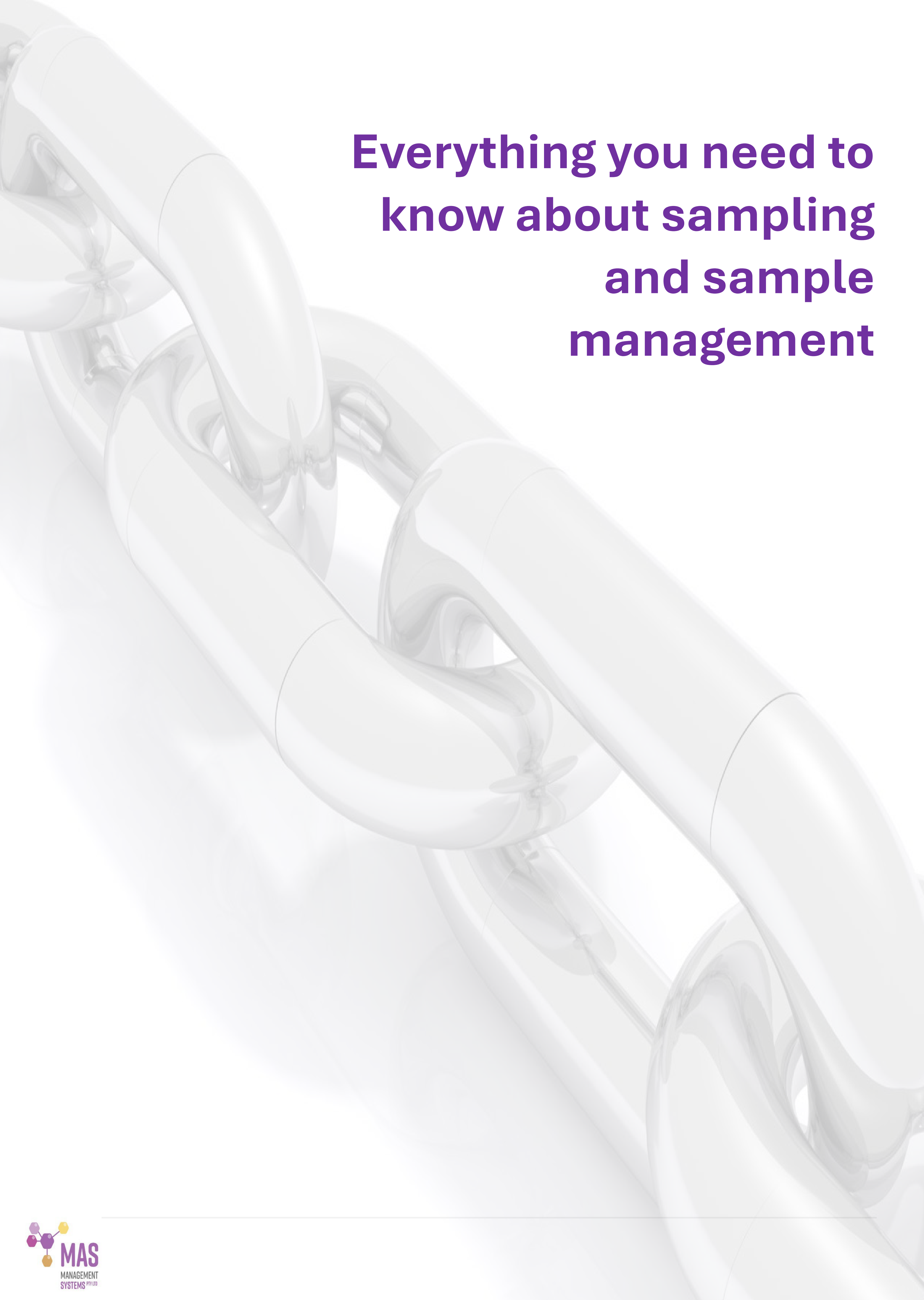
When it comes to certified reference materials, you might need to look a little further afield. The COMAR database and NIST database are two places to search for possible CRMs for your tests. However, many CRMs which are not listed in these databases. Your favourite search engine could lead you to those materials.

What do you do if you can't find a suitable calibration or CRM for your tests? Sometimes the costs of those CRMs are prohibitive and that alone makes them unsuitable.

Well, you could have within your grasp the solution. Anyone who has been through an accreditation assessment can probably relay their own war stories about the thousands of dollars they have had to spend to satisfy the auditor. It need not be that way.

The secret lies in your assessment of the health of the tree and climbing skills.

Everything you need to know about sampling and sample management



The things labs test and calibrate don't magically appear out of nowhere. Somewhere along the line, there is a sample taken.

Many labs aren't in charge of sampling. That's something left to clients, clinical staff and production line staff. Just because it's somebody else's responsibility does not mean laboratories can ignore it.

In fact, even though you answer "Not applicable" in your Assessment Information Document for NATA, the lab is not absolved from answering questions on the topic of sampling.

Let's start with what ISO 17025 has to say.

The ISO 17025 Framework

While it does not provide specific sampling procedures, it does require that laboratories have a documented sampling plan and follow recognised sampling methods appropriate for their specific testing and calibration activities.

SAMPLING PLAN

ISO 17025 requires laboratories to establish a sampling plan that defines how samples will be collected, identified, and handled. The aspect of sample handling often falls within the spectre of labs because samples that have not been handled correctly might mean that they are rejected once they reach the lab. That means, all labs essentially have an active role in sampling even if the actual collection of the sample is not performed by laboratory staff.

The plan should be based on recognized and validated methods. There are often standards covering sampling. A quick check of a standards writing body such Standards Australia or a sector specific association should reveal these types of methods.

Depending on why the testing or calibration is being performed, there could be some merit in confirming with clients what sampling strategy has been used. If the items are from a production process, for instance, what is the statistical basis underpinning the sampling plan?

Sure, you can have that little disclaimer of "The results relate only to the samples tested". But is that really what the people paying for the lab's service are expecting? Be bold and show your clients you care about these kind of things!

SAMPLING PROCEDURES

Laboratories must use appropriate and validated sampling procedures. These procedures should consider factors such as the characteristics of the material being sampled, the purpose of the analysis, and any relevant regulations or standards.

This is where labs can really assist clients, especially those who come to the lab without any significant scientific background. If you're in an environmental testing lab, how many times have you received a water sample in a Coke bottle with instructions to test the water for pesticides from the farmer worried about spray drift into his dam?

REPRESENTATIVE SAMPLES

Sampling is frequently used because gathering data on every member of a target population or every product produced by an organisation is often impossible, impractical, or too expensive. Sampling lets you draw conclusions or make inferences about the population or product lot from which the sample is drawn. But there is an art to ensuring the samples adequately represent the whole population.

Before anything happens to collect the sample, the population itself should be reasonably well defined. What are we trying to measure? It's no good testing an ear swab for microorganisms when the patient is suffering from an infected leg! Nor is it appropriate to calibrate over two points at one end of an item's whole working range if that fails to demonstrate the performance of the equipment.

The samples collected must be representative of the material being tested. This means that the sampling process should minimize bias and ensure that the samples accurately reflect the properties of the larger population from which they are taken.

Many organisations use statistics to sensibly approach the task of sampling. And there will be some variation and uncertainty associated with the act of sampling. We have a course on MU in Sampling that we run periodically. If you'd like to understand more about this topic, drop us a message to join the wait list.

CHAIN OF CUSTODY

Laboratories are required to establish a chain of custody process for samples. It need not be an official chain of custody with tamper-proof seals and signatures at every stage. What this process ensures is that the samples are properly tracked from the time of collection to the time of analysis to maintain their integrity and prevent contamination or tampering.

Once the sample hits the lab, the chain of custody and identification process is more within the control of the lab. Laboratories must establish procedures to ensure that samples are uniquely identified as a component of this chain of custody process.

Each sample should be assigned a unique identifier, and this identifier should be recorded and maintained throughout the entire testing or calibration process.

Typically we give some sort of sample number when there are lots of samples or use a serial number for pieces of equipment. The system for sample identification does not need to be super complex with secret codes using Julian calendar dates. Keep it simple so you can easily find samples and their associated records.

DOCUMENTATION

All sampling and sample management activities must be well-documented. This includes recording details such as the sampling location, date and time of sampling, person responsible for sampling, by whom and when samples were received in the laboratory, and any relevant environmental conditions.

VALIDATION AND VERIFICATION

There’s no getting away from the topic of validation and verification. Any sampling methods used should be validated and verified to ensure their suitability for the specific testing or calibration activities. You can refresh your memory on Validation and Verification with our recent article, **Unveiling the importance of method validation.**

TRAINING

Personnel involved in sampling must be trained and competent in the sampling methods they use. Training records should be maintained. Likewise if there is something difficult with sample management processes in the lab, training will be important.

QUALITY CONTROL

Laboratories must implement quality control measures for sampling, including the use of appropriate equipment, calibration of sampling tools, and the use of suitable containers for sample storage.

QC processes for sample management within the lab should also be established. That could range from double checking sample information against a test request form, through to monitoring temperatures of fridges. The trick is to think about the critical points in the process and put in checks at those points.

STORAGE AND PRESERVATION

Samples should be properly stored and preserved to prevent degradation or contamination until they are analysed. Storage conditions should be in accordance with recognised standards or procedures.

Laboratories must have procedures for proper sample handling to prevent contamination, degradation, or alteration. This includes guidelines for the appropriate storage conditions, container types, and handling protocols specific to the nature of the samples being analysed.

Facilities for sample storage should provide adequate protection against environmental factors that could affect sample integrity, such as temperature, humidity, and security.

While we're on the topic, it's important to think carefully and broadly about the integrity of the sample and preserving that integrity as a whole. This is not just whether the sample has been frozen and in the correct bottle. It might also cover how representative the sub-sample used for testing is of a lake, a production batch, or a person. The considerations about having a representative sample discussed above are just as important at this stage as in the prior stages.

TRANSPORTATION

Procedures for the safe and secure transportation of samples from the sampling site to the laboratory should be established. If you're expecting highway robbers, then extra security might be in order. If not, traditional means of protection should be OK.

SAMPLE RETENTION

Laboratories are required to define and document their policies regarding the retention of samples. This includes determining how long samples will be stored after analysis, as well as procedures for the disposal of samples once retention periods expire.

In determining the sample retention period, think about how long the sample maintains its integrity with respect to the analyses and how long the customer might mandate for sample retention. Often there is a disconnect between these two periods and you should have a discussion with the client if that's the case.

Contingency Plans

Laboratories should have contingency plans in case of sample storage or handling incidents that could compromise sample integrity. These plans should include actions to be taken in case of emergencies, such as equipment failures or power outages. To develop your contingency plan, start by looking at the risks in the sampling and sample management process. **We've written previously on Risk Management** and our tips might help you with this.

That's a lot for a lab to deal with!

The reality is that most laboratories get limited information on samples or items for testing or calibration. We're encouraged to give unique sample numbers but this does not mean lab people should fail to appreciate what a sample represents.

It's all too easy for lab work to be isolated from the outside world. And the pressure of production of numbers makes it more difficult to think beyond the walls of the lab.

Before undertaking the expensive testing or calibration activity your lab has been commissioned to complete, if something doesn't add up between all the things you know the client is trying to achieve and the nature of the sample received, now is the time to speak up! Your client might just have made a mistake and will thank you for catching it.

If you feel a little overwhelmed with how to wrangle samples within your lab, then get in touch. We can cut through the fog to give you clarity to ensure both you and your customers are delighted with the service you deliver to them.

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


ARE YOU DROWNING IN DOCUMENTS?
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Imagine having all the documents you deal with in a week piled on your desk.

If you were to include print outs of your work and personal emails the pile would probably be too high to see over!

Clearly, you're not going to do this (no time, waste of trees) but thinking about that pile will give you some idea of how big a part documents play in our everyday lives.

And if you're in a laboratory, they're even more vital.

Lab documents provide essential guidelines and references for what we do. They allow us to review our activities and train staff.

Even more importantly, they provide proof that our testing and calibrations are accurate and reliable. This information is critical for external accreditation and audit bodies but also for our clients.

Staying on top of it

Since documents do provide those guidelines, they need to be current. Those pieces of information about processes, policies and procedures are like a roadmap for your lab.

To continue the analogy, without clear, concise, and up-to-date instructions you could find your staff heading for an unintended destination.

Lab quality documents can be defined as:

Policies – a statement of overall intent and direction. This is a broad and general direction for the quality system and in essence tells people which way to head.

Processes – these are the steps used to implement the quality policy and achieve quality objectives. They are a set of interrelated or interacting activities that turn lab inputs into outputs. These explain how we get there.

Procedures – the specific, detailed, and step-by-step explanation of carrying out activities. These can be considered an explanation of how to do it.

Records – the pieces of information that prove what you did.

Think of the relationship between these sets of documents as a tree.

The policies are the roots because they form the base for all functions; the processes are the trunk, and the procedures are the branches.

If we follow through with the tree analogy, the fruit could be considered your lab's outputs (records) which are hopefully abundant (although not necessarily tasty…).

What makes a good document?

We’ve all seen instructions or signs that make us scratch our heads and think “What?”

However, in a lab setting, instruction documents must be unambiguous and accurate. They should also be written in a style that considers who will be reading and using them.

A standard outline for documents can be helpful to achieve this.

Current staff will quickly become familiar with the structure and new staff will find documents with the same layout easy to navigate.

Of course, staff should know where to find and access documents, particularly those that relate directly to their role.

Explain their why

It may be tempting for staff to skip over documenting something they think is unnecessary or too time consuming for them to bother. Or perhaps they received a verbal instruction from a colleague, carried out the action but didn’t document it.

That’s why there must be adequate and ongoing training not only on completing relevant documentation but also to explain why. It’s particularly important for staff to have clarity on what place the documents they’re completing have in the system.

Seeing the whole picture should remove the temptation to skip over documenting a piece of work they don’t believe is relevant.

In essence, all systems depend on someone doing a thing. If someone doesn’t do that thing, the system will fail.

Document searching made simple

You could have the best templates and documents in the world but they’re no good to anyone if you can’t find them!

Information is a major product of your lab, so manage it carefully with a good system.

Use a simple, easy to understand naming protocol and be sure staff know and use it. Names should be logical and perhaps include a date in the title.

‘Daveswork’ is unhelpful whereas ‘210202Clientname’ is easily searchable and makes much more sense.

If your lab is accredited or certified by an external body, you can guarantee that an auditor will want to see your documents and records.

Since your documents reflect your lab's organisation and quality management, it's critical they're in good order.

Technical Records

When it comes to traceability of your lab's records, there are some basic principles to remember.

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 and you'll need to retain all the original records and any amendments.

Alterations to records need to show when the alteration was made, who made the alteration, and clearly show what was altered.

Software solutions

Software and digital tools should make finding documents easy. However, any standardised lab approaches to documentation across operations will also streamline the process. Templates will ensure consistency of information and data collection and capture.

There are plenty of vendors that offer document control system software solutions. This could come with its own set of issues including security, access, and compliance. External accreditation bodies would certainly require validation of an electronic system.

For a small lab the cost would probably outweigh the perceived convenience. Larger labs would need to ensure that the navigation and retrieval is both simple and quick. If you decide to go down this path, our recent article will give you some pointers on what to look for.

The final word

While we know that there's plenty to keep you occupied in the lab, working with a clunky, unfriendly documentation system shouldn't be one of them!

We can help you streamline your system and documents to make them user friendly and fit for purpose. And if you need to train your staff in documentation, we can run an inhouse session that can help.

Call Maree (0411 540 709), or you can email us 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!