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A talk by Trevor Thompson

Laboratory Internal Audits

Making them Effective, Happy and Wanted

An informal look at this subject with the aim of enhancing both the value of audits and the perception of the auditees

Laboratory Internal Audits

What is this?

A laboratory's own examination of its compliance with requirements, usually based on a management system and defined procedures, including witnessing of crucial activities being undertaken

How is this done?

By having a programme, determined in advance, of studying both the policies, and the practices of the laboratory by comparison with defined requirements. Needs to ensure follow-up and actions when necessary

Laboratory Internal Audits

Why do it?

For several good reasons!

It gives you confidence in the validity of your work
It convinces bosses and owners
Staff get a good sense of their contribution and involvement
Informed customers would like you to do this, and sometimes ask to see

It is also required by most modern management system standards i.e. ISO 17025

You should spot anything significant before any accreditation body or regulator might see it!

It drives continuous improvement

Laboratory Internal Audits

Getting Started: consider the principles

It is best to consider the three main strands of good laboratory practice and indeed of the requirements of standards like ISO 17025:2017. The terms used in different industries and in different standards differ but the same principles apply as shown on the next slide.
We need to examine:

1. Policy

2. Practice

3. Actual Results

Laboratory Internal Audits

ISO/IEC 17025 requires technical competence and a reliable consistent management system

If these features exist, you may comply…….but who knows?

1. Technical Competence: This involves people, knowledge, equipment, supplies and process. So a lab is capable of : "getting it right" "valid results"

2. Add to this a Management System to ensure impartiality, consistency, reliability: "consistent" "once right……always right" but is it, in practice?

3. Check that it is right in practice: PT, ILCs, blind work, repeat work, etc "Demonstrated Competence" for yourselves and for 17025 compliance.

"The proof of the pudding is in the eating!

1. Policy

What have you said you will do?

Do your policies as described in your management system accurately reflect the requirements for the work?
This involves seeing that if you actually did what you say you will do then it would be valid.

This is the starting point and involves document review against requirements in standards, regulations and customer orders
This may appear a large task initially but things that don't often change tend to need auditing less frequently

The emphasis later would be on seeing that changing requirements are properly accommodated

2. Practice

Are you doing what you say you shall?

Good audit programmes do this well. Traditionally some people tended to limit their activities to the document review covered earlier. That is very bad. There needs to be a programme of going to places and seeing people doing things!

Typically the auditor would quietly read the relevant procedure while watching the staff to see if they are doing the work in accordance with the procedure. Sometimes called "witness testing"

Primarily about testing and calibration practices but actually should cover everyone doing anything that affects compliance like sample preparation, goods handling and contract review.

3. Valid Results

Is the work actually valid?

Quality Control = things you do during the work to maintain the validity. Audited as part of auditing the procedure for the test or calibration

Quality Assurance = things you do in addition and separately from the work to maintain the validity. This would include repeat testing, golden samples etc and the essential external ILC/PT Needs to be audited to ensure it is done and actions taken as necessary

It is a requirement of most modern management system standards that laboratories undertake quality assurance including external measures like InterLaboratory Comparisons (ILC) or Proficiency Testing (PT)

Who can do the Audits?

Basically, anyone competent, but no one may audit their own work

If you wrote a procedure you could not therefore audit if it was correct, but you would be fine to audit other people following it.

Auditors may be junior or senior to the auditee, it does not matter

Auditors must understand what they are seeing sufficiently to establish if a procedure is being followed or that a policy is correct

Colleagues may audit each other but be careful in allocating such audits

Choosing Auditors

Not everyone makes a good auditor!

Some people may have great technical skills but be poor at personal communication

We need:
An understanding of auditing and its purpose
An understanding of that being audited
Good interpersonal skills
- **not scarry, stuffy, snooty, snobby or pompous**
- **Be emphathetic, friendly, encouraging**

Communication ability, up and down the organisation
Empathy with the auditee
Methodical approach following procedures

Training and Approving Auditors

Choose them carefully, per previous slide

Maybe send them on a course

Have them watch some audits happening

Do some under supervision

Be watched doing some audits unaided

Approve them subject to monitoring at intervals

All above to be documented as part of person's training records

Putting a plan together

Audits shall be planned, executed and documented

All of the people doing all of the things in all of the places!
Over a period of time

Small lab: two tests, two people in one place

Easy to plan and easy on resource

Large lab: four sites, 100 tests, 40 people

Difficult and resource heavy but pro rata?

Often a complicated mix of different people in different places with a combination of unique and duplicated facilities etc, same for the people. There would typically be an annual cycle of topics but not all of the people in all of the places seen in one cycle.

The Plan

Policy and Practice as described in Quality Manual can usually be split up into maybe a dozen topics, indexed from the Standard or from your QCM. Some are bigger than others. Using ISO 17025:2017 as an example:

Jan: Cl 4,5,6 Structure, Organisation, Quality Policy
Mar: Cl 6 People, Environment
May Cl 6 Equipment, Traceability
July Cl 7 Processes, Contract Review, Handling, UoM
Sep Cl 7 Reporting, Complaints, NCW
Nov Cl 8 Management System, Records, Risk, Improvement
Dec Cl 8 Audits and Review
PLUS…….

More of the Plan

We also need to see things happening!

Feb: Test1, Person 1, Place 1
Apr: Test 2, Person n, Place n
Etc
Aug: Witness of Contract Reviews, Sample Prep, Reporting (if separate)
Oct: Review of Quality Assurance Measures and resultant action

Make a Audit Programme Chart showing who, what, where and when!

Easy for small labs, complicated for larger ones

We need some further mechanisms……..

A bit more plus keeping records

…….we need some further mechanisms:

A form for recording each audit showing "who, what, where and when" with the findings and any actions agreed, follow up and escalation

Some type of prompt or instructions for the auditor, it may be a brief, an aide memoire, a checklist or very little.

A way of tracking the audits and their completion. This is often done on the audit plan, showing due, done, closed for each audit.

The audit form

Usually, a single form used for all audits but……

Shows
Area Audited
Subject audited
Documents seen
People seen
Equipment used
Standards or Requirements covered
General comments on compliance or otherwise
Specific points raised as findings or recommendations (according to system)
Agreed actions (if appropriate)
Escalation arrangements (if appropriate)
Suggested Followup activity and timeframe

Maybe one form for each audit or maybe one form for each finding!

Instructions for Auditor

This is usually written for each topic or test/calibration

It may be a list of requirements taken from specs, standards or regulations
Or just reference to them

It could be reminders of topics, crucial things, common issues, etc

It could be a checklist for ticking (coverage not content!)

Never use just a tick sheet. There should be details, comments on compliance, degree of it or not, for everything ticked.

It might be an almost blank sheet of paper showing just who, what where a when for an experienced auditor left to freestyle the audit.

You need to ensure you do not see the best person doing the simplest test in the nicest lab room each time! So, some study of past audits is indicated.

Styles of auditing

Horizontal:

A look at a topic across the business, best for policies and management system topics

Vertical:

Following a process on a job from start to finish, good for seeing a job from contract review through to reporting. Some of these vertical audits should always be done

Labs should do a mixture of both styles

Styles of auditor

This is very important and where some labs struggle!

Some people make great technicians but awful auditors

Relax the auditee by chatting about the work generally and acknowledging his/her skills. Auditee may be very junior to you or may be your boss, you have to handle both scenarios well!

“I am here for you to show me that you do it just right”
Not “I am here to find what you do wrong”

“We are both on the same side, I just need to see you in action so that I can say how great your work is.”

If watching a test, do not interfere or attempt alter the outcome, just note it for later discussion

Handling a difficult auditee

"Show me" not "Tell me" because some people just talk compliance and can waste ages talking. You are there to see things happen or to confirm a policy. Ask open questions, but do not allow long meandering replies!

If something can't be seen, just note that for later, don't let auditee go away; he may not come back for hours!

Plan carefully and make productive use of the time; don't choose to watch paint dry!

Be respectful but assertive enough to show that you are running the agenda and coverage

Encourage and be supportive if someone appears nervous, allow short breaks and chat. Remind that you are there to see that they are very good.

Records

These should contain sufficient information to understand the findings and to re-investigate a situation

Basically; who, what, where and when.
Identify people, equipment, documents seen.

Include summary of the general situation plus details for any issues.

Acknowledge good work and co-operations

Include all information needed to further investigate and later cause

If your system requires your recommendation for changes or agreement with auditee then document these clearly.

Agreeing dates for actions is often useful

Afterwards

Auditor gives completed audit form to “Quality Manager” who marks that audit as “done” and sets a date for follow-up if required

Sometimes findings suggest actions for other people who may be unaware of the audit. Quality Manager or Auditor (according to your system) organise this and monitor it.

Audit findings contribute to quality manager’s report to bosses at Management Review

When actions taken and follow-up completed then quality manager marks audit as closed (completed)

In Summary

Plan a comprehensive regime showing who what where and when

Keep records of due, done, closed, distribute and escalate

Choose suitable people to be auditors

Involve everyone and make sure they understand

Document comprehensively and explain well

Enjoy the opportunity to improve in a relatively relaxed and informal way