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Performing and Recording Effective Internal Audits and Management Reviews

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Disclaimer

This material represents my opinion. It is intended solely as guidance and does not include any mandatory requirements except where such requirements are referenced. This guidance does not establish expectations of being implemented universally, exclusively, in whole, or in part.

Individuals that have questions about the applicability, scope, and use of this guidance may contact me at tfrancis@sawenviro.com.

Agenda

Learn the objectives of internal audits and management reviews and identify the key differences.

Be able to implement internal audit and management review requirements.

Incorporate best practices.

Understand the connection between internal audits, corrective actions, and the quality system.

Learn tools and options for conducting management reviews.

Ensure proper documentation and record keeping.

Internal Audit and Management Review Theory

Internal Audit



Are we *doing* what we say we are doing?

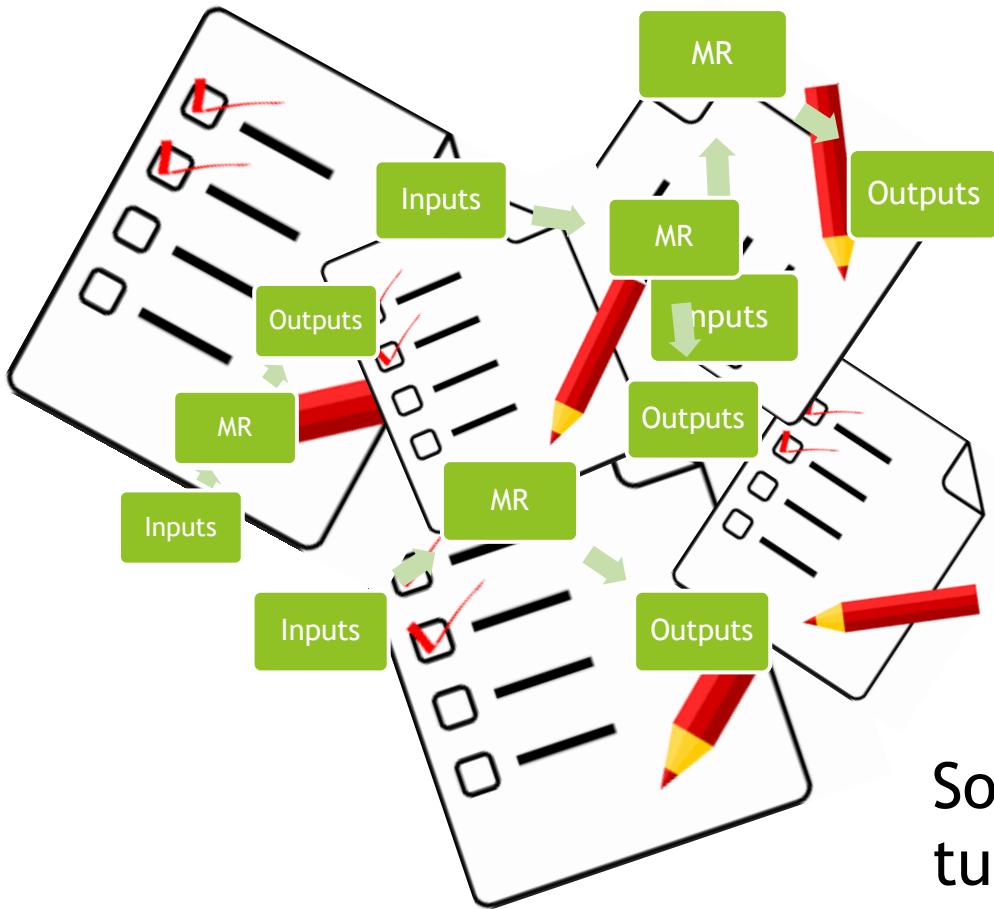
Management Review

Vs.



Should we *change* what we say we are doing?

Internal Audit and Management Review Theory



Labs will often perform both at once.

Sometimes it turns into this.

Requirements of an Internal Audit

From TNI V1M2-4.14.1: The laboratory shall periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the management system and this International Standard.

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Must address both quality system and test methods.

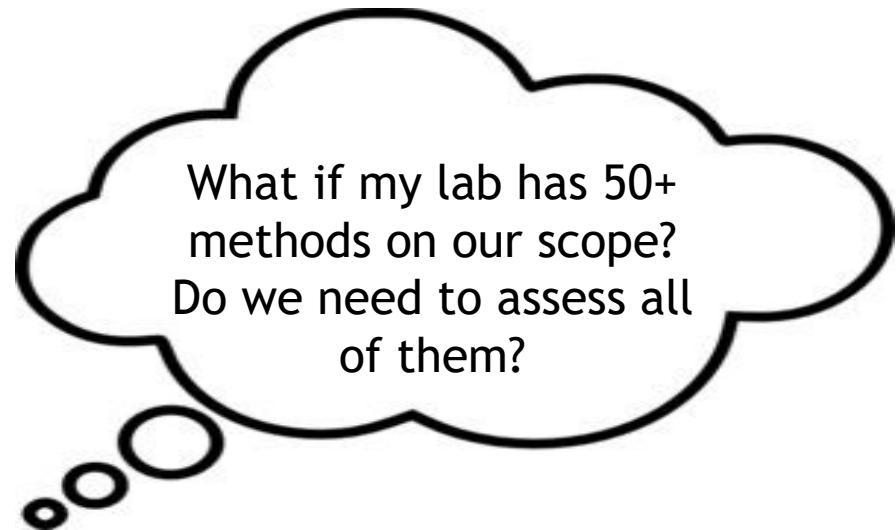
Many labs end up doing one or the other.

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What if my lab has 50+ methods on our scope? Do we need to assess all of them?

Not necessarily. It is expected at least one method of each technology be assessed each year. Best practice is to rotate so all methods are assessed over a reasonable amount of time.

Requirements of an Internal Audit

From TNI V1M2-4.14.1: It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.

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The quality manager is *responsible* for the planning and organizing.

Doesn't mean it is the quality manager's duty to perform.

Wherever resources permit.

Sometimes lab personnel might need to audit their own activities.

What does trained and qualified mean?

IDOC? Technical Manager?

Requirements of an Internal Audit

From TNI V1M2-4.14.2: When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test or calibration results, the laboratory shall take timely corrective action.

Some labs do not complete the process - corrective actions not performed.

“We just fixed it.”
“It was a one-time issue.”
“I wouldn’t call it a finding.”
“I have to fix everything?”

See the section on corrective actions for further direction (V1M2-4.11).

Requirements of an Internal Audit

From TNI V1M2-4.14.3: The area of activity audited, the audit findings and corrective actions that arise from them **shall be recorded.**

If it's not written down.... it might as well not have happened.

Be sure to include in the internal audit records the areas audited.

What parts of the quality system?
Which methods?



Requirements of an Internal Audit

From TNI V1M2-4.14.5.a: The laboratory shall have a policy that specifies the time frame for notifying a client of events that cast doubt on the validity of the results.

Again, the Standard explains what to do, not how to do it.

The lab must specify time frames when audit activities cast doubt on client results.

Most states, including TCEQ, have specific time frames on customer/state notifications (put these in the quality manual or other lab document).

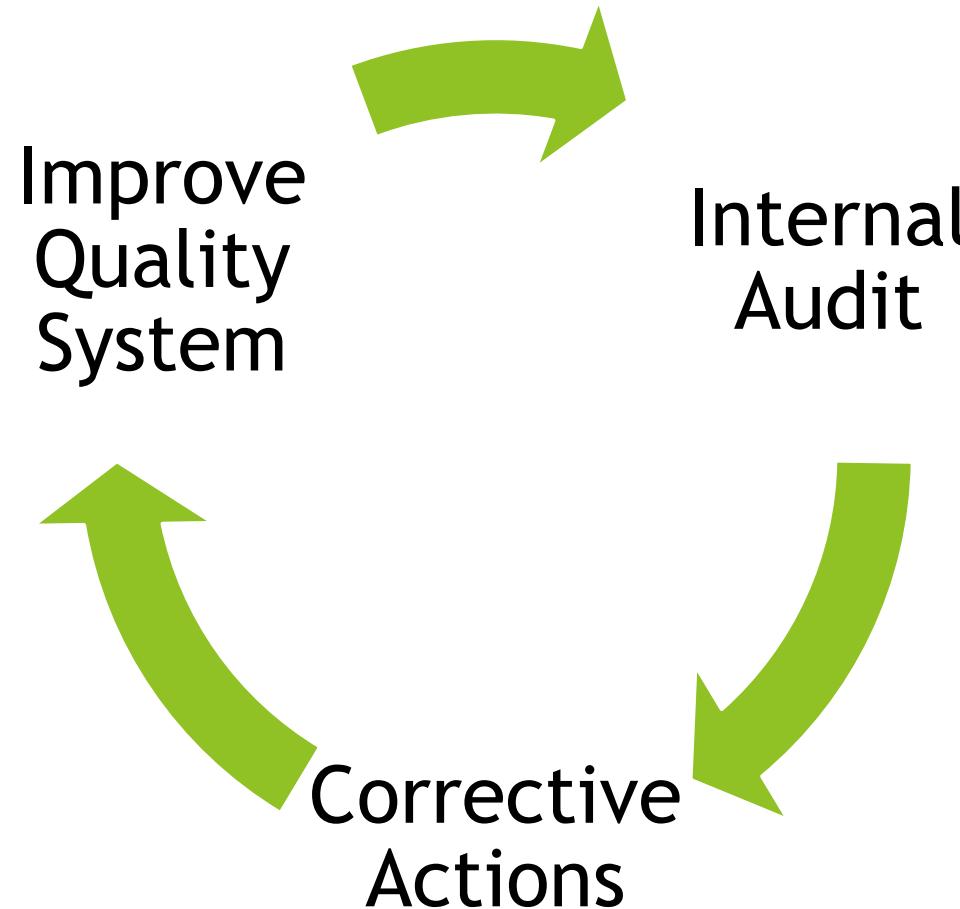
Requirements of an Internal Audit

From TNI V1M2-4.14.5.a: The Internal audit schedule shall be completed annually.

Must be performed annually.

Don't put off recording the results.
Try not to "finish" the internal audit and wait six months to write it up.

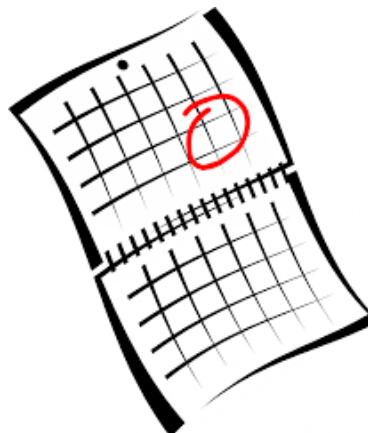
How are internal audits related to improving the quality management system?



Options to Conduct Internal Audits

Timing:

- All at once?
- Similar to an external audit in terms of duration, mechanism.
- Can staff take the necessary time to accommodate?



Options to Conduct Internal Audits

Timing:

- Over the year (monthly or quarterly tasks)?
- Remember, must be predetermined.

| Area | Time frame |
|----------------|--------------------|
| Wet Chemistry | January |
| Metals | February |
| Microbiology | March |
| Organics | June - August |
| Quality System | October - November |

Options to Conduct Internal Audits

Timing:

- Over the year (monthly or quarterly tasks)?
- Remember, must be predetermined.
- Choose based on size of lab, number of methods, and resources.

Options to Conduct Internal Audits

Who is involved?

- Quality manager is responsible, can (and should?) delegate certain duties (*independent and qualified*).
- Swap supervisors of different areas of the lab.
- Swap QA Managers of another laboratory.
- One option is the use of consultants.

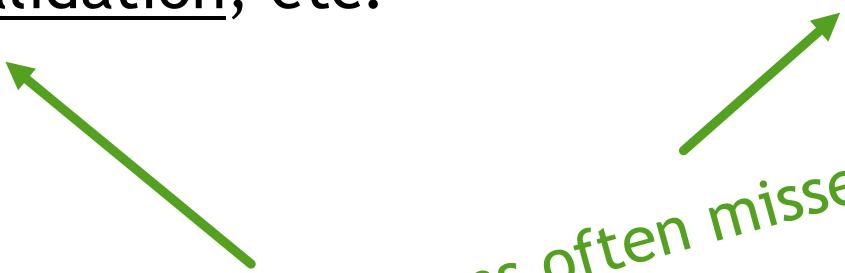
Conducting Internal Audits

- Be realistic and communicate the process with lab management and staff.
- Get in the mindset of information gathering.
- Don't just focus on finding deficiencies (this is a process of continual improvement).
- If audits result in few or no findings, be worried.
 - Was it in-depth enough?
 - Just checking the box?
 - The lab is perfect?

Conducting Internal Audits

- Encompasses ALL aspects of laboratory operations.
 - All quality systems, technical methods, including corrective action effectiveness, sample receipt, purchasing, customer service, PT program, software validation, etc.

These items often missed



Conducting Internal Audits

- If a finding is observed in one area, good chance it exists in other areas.
 - Traceability.
 - Missing aspects in SOPs.
 - Sample preparation steps.
 - Training gaps.
- Use checklists... as a tool.
 - Take time to create your own. Will learn a lot in the process, saves time in the future.
 - Help prevent repeat deficiencies.
 - Balance being detailed oriented and keeping a big picture perspective.

Conducting Internal Audits

Bench audits/interviewing:

- Ask questions, gather information.
- Keep it friendly, not a time for blaming.
- Questions should be open ended - How? What? When?
- Match the interview with records.

Conducting Internal Audits

Follow up activities:

- The audit does not end with the information gathering procedure.
- Need to record results!
- Implement required corrective actions.
 - Use the same corrective action procedures already in place.
 - Monitor for effectiveness.

What are the expected outcomes?

- Internal audits are a snapshot in time.
 - Will not find all nonconformances.
 - Auditing is a sampling event. Follow the information and evidence.
- The goal is not to have zero findings. Internal audits are not a report card on lab activities.

Benefits of Well-Executed Internal Audits

- The lab can find and correct non-conformances and deviations before they become a larger problem.
- Increases the defensibility of data. Our goal as an industry is to produce data of known and documented quality.
- External audits go more smoothly when the lab finds and fixes their own issues.
- A great way to improve systems, practices, and procedure. Can prevent rework (and \$\$).
- Focuses efforts on continuous improvement.

Benefits of Well-Executed Internal Audits

- If the only reason a lab is conducting internal audits is to fulfill accreditation requirements, the lab will waste valuable time, money, and great information to improve the laboratory.
- Internal audits are a great tool to increase productivity, quality, and service to the customer.

Management Review

The backbone of the quality management system.

- Policies and procedures.
- Internal/external audits.
- Corrective actions.
- Continuous improvement.
- Client satisfaction.

Management Review

- Does not have to be complicated and cumbersome.
- Think of it as a strategic planning exercise.
- Must have a procedure and accountability.
- Keep records of management review activities.
- Need an implementation plan.

Management Review

The process:

- 1) Gather information.
- 2) Interact with key personnel (good communication).
- 3) Make an action plan.
- 4) Implement and follow up.

Requirements of Management Review

From TNI V1M2-4.15.1: In accordance with a predetermined schedule and procedure, the laboratory's top management shall periodically conduct a review of the laboratory's management system and testing and/or calibration activities to ensure their continuing suitability and effectiveness

Again, the TNI Standard and TCEQ regulations tell a lab *what* to do, not *how* to do it.

Requirements of Management Review

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Requirements of Management Review

From TNI V1M2-4.15.1:
The management review shall take account of: the suitability of policies and procedures

What does this mean?

Review of documents - quality manual, SOPs, work instructions, etc.

Requirements of Management Review

From TNI V1M2-4.15.1:
The management review shall take account of:
reports from managerial and supervisory personnel

What does this mean?

Receive input from lab management and supervisors.

This is a good time to talk about big picture issues.

Requirements of Management Review

From TNI V1M2-4.15.1:
The management review shall take account of: the outcome of recent internal audits

What does this mean?

This is a good reminder that internal audits and management reviews are two separate functions.

Review findings, corrective actions, effectiveness, etc.

Requirements of Management Review

From TNI V1M2-4.15.1:
The management review shall take account of:
corrective and preventive actions

What does this mean?

Again, big picture perspective.
How many corrective actions?

Are the closed?

Monitored? Effective?

Any trends to worry about?

Requirements of Management Review

From TNI V1M2-4.15.1:
The management review shall take account of:
assessments by external bodies

What does this mean?

Review the process of the lab's recent TCEQ audit.

Review findings, corrective actions, and effectiveness.

Requirements of Management Review

From TNI V1M2-4.15.1:
The management review shall take account of: the results of interlaboratory comparisons or proficiency tests

What does this mean?

Review recent PT studies.

Any not acceptable results?

Trends?

Have additional studies been ordered if applicable?

Should the lab change its PT process?

Requirements of Management Review

From TNI V1M2-4.15.1:
The management review shall take account of:
changes in the volume and type of the work

What does this mean?

Any new contracts?

Need additional staff?

Need to add methods to the laboratory's scope?

Review subcontracting.

Requirements of Management Review

From TNI V1M2-4.15.1:
The management review shall take account of:
customer feedback

What does this mean?

Remember, the lab must seek feedback from its clients. Now is the time to review.

Are there areas needing improvement?

Any business opportunities?

Requirements of Management Review

From TNI V1M2-4.15.1:
The management review shall take account of:
complaints

What does this mean?

Yes, I know, your lab never really receives complaints.

What is a complaint?

Any trends worth looking into?

Any processes needing improvement?

Requirements of Management Review

From TNI V1M2-4.15.1:
The management review shall take account of:
recommendations for improvement

What does this mean?

Brainstorm. What does the lab need to improve?

New or additional equipment?

Analysts often have great ideas - they are where the rubber meets the road and often have ideas to improve operations.

Requirements of Management Review

From TNI V1M2-4.15.1:
The management review shall take account of:
other relevant factors, such as quality control activities, resources, and staff training

What does this mean?

Other items affecting operations and quality.

Any upcoming training that might be of some benefit?

Want to install a new process for data review?

Requirements of Management Review

- From TNI V1M2-4.15.2: Findings from management reviews and the actions that arise from them shall be recorded.
- Must be recorded.
- Many labs do take account of these items through weekly/monthly management meetings; however, records are not kept.
- There are many ways to satisfy this requirement. Could be a sum of all management meetings throughout the year or a one-time meeting with lab management. Either way, keep records.

Requirements of Management Review

Now that the lab has received the inputs, what are the outputs?

What policies, procedures, changes will come as a result of the management review?



Requirements of Management Review

The result should be an analysis of what the lab is doing well and what areas need attention.

Needs to be a formal process, don't just copy and paste from regulations.

Needs to be conducted annually.

- All at once.
- Weekly/monthly/quarterly.

Benefits of Well-Executed Management Reviews

- Lab management will have a clear, broad picture of current laboratory QA/QC operations.
- Trends can be identified to help steer future operations.
- Can help business functions - where are resources best spent?

In Summary

- Internal audits and management reviews (resulting in corrective/preventative actions and future planning) are all part of improving lab operations/quality.
- Do not just do them for compliance purposes.
- Tailor the procedure for *your* lab.
- Be critical and comprehensive.

In Summary

- Whatever you do, do it right.
- Make sure to record all activities.
- Communicate with all involved. Management needs to know but so do analysts.
- Seek feedback about the process, make changes as needed.
- An ounce of prevention is worth a pound of cure.

What Questions Do You Have?

Thank you!

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