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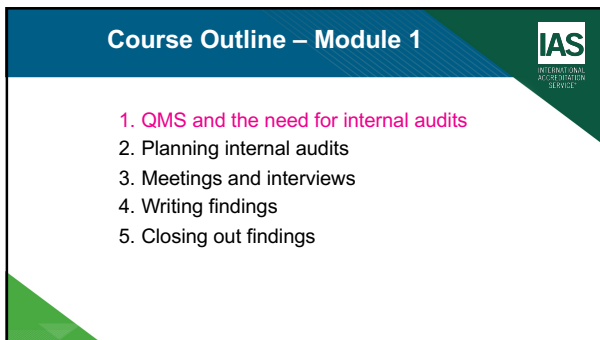
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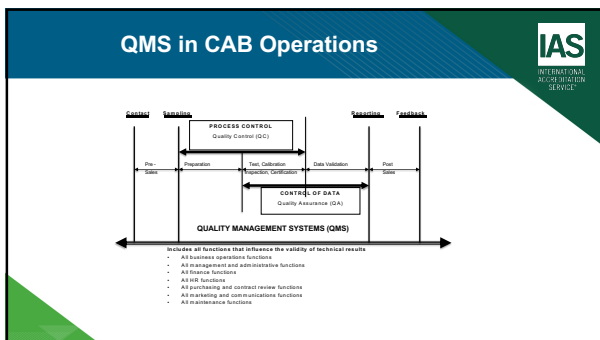
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### Why do Internal Audits?

- Internal audits are the most comprehensive method of determining if the management system is working for us:
  - Is it supporting the work of the people in the CAB?
  - Does it help provide a safe environment?
  - Does it help us produce only technically valid results?
- Internal audits tell us of our management system is:
  - Implemented;
  - Effective, and
  - Allows for continual improvement.



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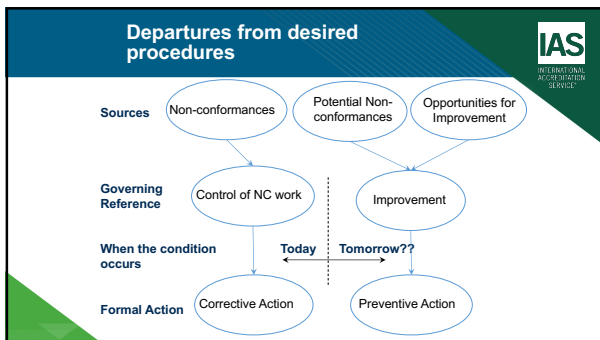
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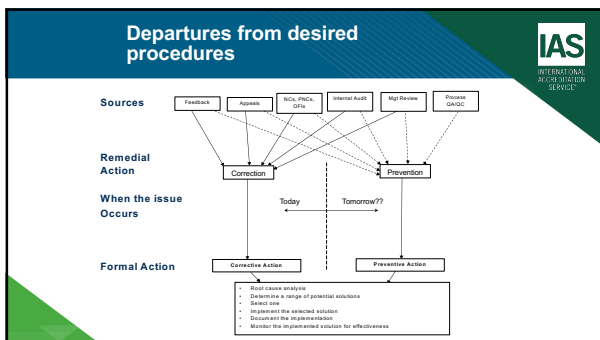
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Continual Improvement Pieces

IAS

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Do we need Corrective- or Preventive-Action?

- Yes, if the risk to the CAB and its people is unacceptable
- Yes, if the deviating condition prevents us from producing technically valid results
- Yes, if permanent resolution is easier than many remediations.

What are the steps to Corrective- or Preventive-Action?

- Root cause analysis
- Determine a range of suitable solutions
- Pick one
- Implement it
- Document it
- Monitor it for effectiveness.

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Standard audit requirements

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- A person cannot audit their own work.
- QMS staff plan and assist in the conduct of internal audits. Top management approves them.
- The auditor's primary function is to identify the condition. Once the condition is identified, it is up to the owners of that part of the Management system to address it. Auditors do not remediate conditions or implement their corrective- or preventive-actions.
- Auditors do not have opinions. Their primary function is the simple, clean, clear, objective comparison of observed condition against a written specification. If no written specification exists, there IS NO FINDING.
- There can be no surprises during an internal audit – every step should be simple confirmation of agreements made to date.

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Standard audit requirements

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In essence, an internal audit, like all types of audits, is a comparison of what is required to what exists. This comparison is based on the gathering of "objective evidence" of current conditions and situations. This objective evidence is gathered by:

- Document review (reading)
- Observation (watching)
- Interview (listening)

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### Standard audit requirements



Contrary to popular belief, there is no "good" or "bad" result from an internal audit. There is only "meeting requirement" or "not meeting requirement." Even "not meeting the requirement" can be considered a "good" result because we now know something we did not know before and can fix it before it becomes a bigger problem.

All results are "good" results, even those that demonstrate the existence of a condition that does not meet the stated requirement. Such a result gives good information to the people that work in the CAB and its top management on where effort may be required to improve the system. It allows top management to do their job.

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### Standard audit requirements



The following are some of the considerations to be examined and addressed when planning and implementing internal audit programs in CABs:

- Auditing is a "formal" process. Take no shortcuts. This ensures that all parties are treated with respect.
- The process selected must be one that can be successfully implemented. Time and resources are key.
- Avoid undue costs. Recognise the real benefits. Promote the positive aspects.
- Avoid the damage (hidden costs) of staff perceiving "failure" because of the audit process. This is a leadership challenge, but it is critical to the success of the program.
- Shorter, and more frequent, audits reinforce the requirement to maintain the quality system and result in fewer non-conformances. Longer and less frequent audits cost less in time and personnel.
- Quality documentation must be in place for an audit to take place. This includes:
  - Quality manual
  - SOPs
  - Test/Calibration Methods
  - Supporting Records

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### Standard audit requirements



In simplest terms, internal audits are systematic examinations of CAB policies, procedures and all related activities to determine whether or not each of the following is true:

- The management system is implemented,
- The management system is effective, and
- The management system allows for continual improvement.

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## Standard audit requirements

**Internal Audit Secret #1**

The measurement (internal audit) is simple comparison of conditions against the reference. This measurement is clean, clear and objective. It must not be subjective.

It is what it is.

It is not about the auditor's personal opinion. It is about the evidence and the comparison.

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## Process vs Procedural audits

There are really only two mechanisms used in internal auditing. They are:

- Process based auditing, and
- Checklist based auditing.

While international practice today is to move towards process based auditing, prescriptive standards like ISO/IEC 17025 are very procedurally oriented. CAB mostly use procedure audits.

Sample checklists for technical CAB internal audits are normally based on an accreditation body checklist for the type of CAB being accredited such as 17025, 17020, or 17065.

**This course teaches process based auditing.**

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## Types of audits

There are two types of "audits" conducted within CAB management systems.

**INTERNAL** audits are aimed at determining whether:

- The management system is implemented,
- The management system is effective, and
- The management system allows for continual improvement.

**TECHNICAL** audits are aimed at documenting the continuing competence of staff in the conduct of specific procedures. This type of audit is essentially a training and qualification process audit. It is not what internal audits are for, but will almost certainly be part of an accreditation body's set of accreditation requirements. Technical audits underpin demonstrations of competence of CAB staff.

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## Auditor Behaviour Counts

**Internal Audit Secret #2**

People are frightened by auditors.

In order to get the best information from the auditees (those persons being audited), auditors **MUST** conduct themselves in the most respectful and polite manner possible.

If not, the auditees will not provide the information required for good internal audit – and the process will not support the management system. It may even fail.



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## ISO 19011 defines auditors

ISO 19011:2002 – *Guidelines for quality and/or environmental management systems auditing*, serves as the international guidance document for all types of auditors and accreditation body assessors.

The knowledge and skills required of auditors listed ISO 19011 include:

- Audit principles, procedures and techniques,
- Management system and reference documents,
- Organizational situations,
- Applicable laws, regulations, and other requirements relevant to the discipline,
- Quality-related methods and techniques, and
- Products, including services, and operation processes.



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## ISO 19011 defines auditors

The personal attributes of auditors from ISO 19011 are:

- Ethical,
- Open minded,
- Diplomatic,
- Observant,
- Perceptive,
- Versatile,
- Tenacious ,
- Decisive, and
- Self-reliant.



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### Auditors Providing Solutions (1)



ISO 19011 makes it very clear that auditing is an activity where any advice to the client is considered consulting and it is unethical. While we all would like to help when we see a situation that might benefit from our experience, we have to be careful of the outcomes that are not obvious to us. Here are a few considerations:

- The management system belongs to the auditees. Telling them what to do actually impinges on their ownership. Auditors are observers, not owners of their processes.
- The solutions implemented by the auditees must meet their own needs, not the needs of the auditor(s).

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### Auditors Providing Solutions (2)



- If auditors do have some help to extend, it must include a number of possible options – with consideration on how they all may be used to meet the requirement and with emphasis that the solution selected is entirely the decision of the auditees.
- Findings of audits do not include solutions. Findings are only articulation of current conditions and, from the evidence available, a determination of the level of conformance demonstrated by these conditions as measured against requirements.
- If the auditor(s) is/are well received by the auditees, they may be repeatedly requested to offer advice on how to overcome challenges within their management system. **General discussion is both acceptable and encouraged in these circumstances. The provision of specific solutions is not acceptable.**

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