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International Accreditation Service

COURSE HANDBOOK

For All Technical Conformity Assessment Bodies – CABs

(Labs, IBs, CBs, PTPs, RMPs)

IAS Training: Training that Reaches People

Rev 5

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Introduction

Course Description

This course is for the staff of accredited technical conformity assessment bodies (CAB). Technical CABs include:

- Testing and calibration CABs accredited to ISO/IEC 17025
- Inspection bodies accredited to ISO/IEC 17020
- Product certification bodies accredited to ISO/IEC 17065
- Proficiency testing providers accredited to ISO/IEC 17043
- Reference material producers accredited to ISO Guide 34
- Medical/clinical CABs accredited to ISO 15189

The processes contained in this course also apply to Management system registrars accredited to ISO/IEC 17021, but they include consideration of technical aspects of CAB operations not normally part of a registrar's scope of practice.

Normally, the CAB staff most interested in the conduct of internal audits are:

- Those employed in a quality position, or
- Those who wish to participate in the internal audit processes of their CAB.

CABs are accredited in order to meet regulator and client competence requirements. Internal audits provide CAB staff with the very best information on the state of the quality management system (QMS) that is supposed to support them in their work and facilitate the production of technically valid results.

This course will provide information to CAB staff seeking to participate in the internal audit process – so that they may be able to identify those conditions that either impede the competent work of the CABs or provide unacceptable risk to the business.

Course Learning Objectives

The course will assist you to:

- **understand** the basics of a continual improvement process;
- **understand** the internal audit cycle;
- **understand** the responsibilities for the preparation, planning, conduct and close out of internal audits;
- **conduct an** opening meeting;
- **conduct** interviews of auditees;
- **record** observations and audit evidence;
- **document** audit findings;
- **prepare** an audit report, and
- **conduct** a closing meeting.

Completing the Course

The course material is broken down into 4 chapters. Within each chapter, specific objectives are listed as well as instructions on how to complete each chapter. Directions are provided to guide you through the readings, other reference materials, and work to be completed.

Course Content

The syllabus for this course is as follows.

Chapter 1 – The internal audit process
- QMS support to CAB operations
- Continual improvement within CABs
- Internal audit processes
- Internal auditor behaviours

Chapter 2 – Planning internal audits
- Internal audit planning
- Audit planning exercise

Chapter 3 – Meetings and interviews
- Document review
- Meetings
- Auditor behaviours
- Recording observations

Chapter 4 – Writing findings
- Components of a finding
- Audit report content and structure
- Presenting audit reports

Chapter 5 – Closing out findings
- Who does it
- Determining the need for Root Cause Analysis
- Implementing the Solution
- Follow up for Effectiveness

Course Grading

Participants are graded on their participation during the exercises and a quiz at the end of the day. 70% is required in order to pass this course.

All participants are eligible to receive a Certificate of Participation. Participants who wish to receive a Certificate of Successful Completion must do two things:

- Participate in the discussions in class, and
- Pass the quiz at the end of the course.

Chapter 1 – QMS and Internal Audit Process

1.1 Learning Objectives

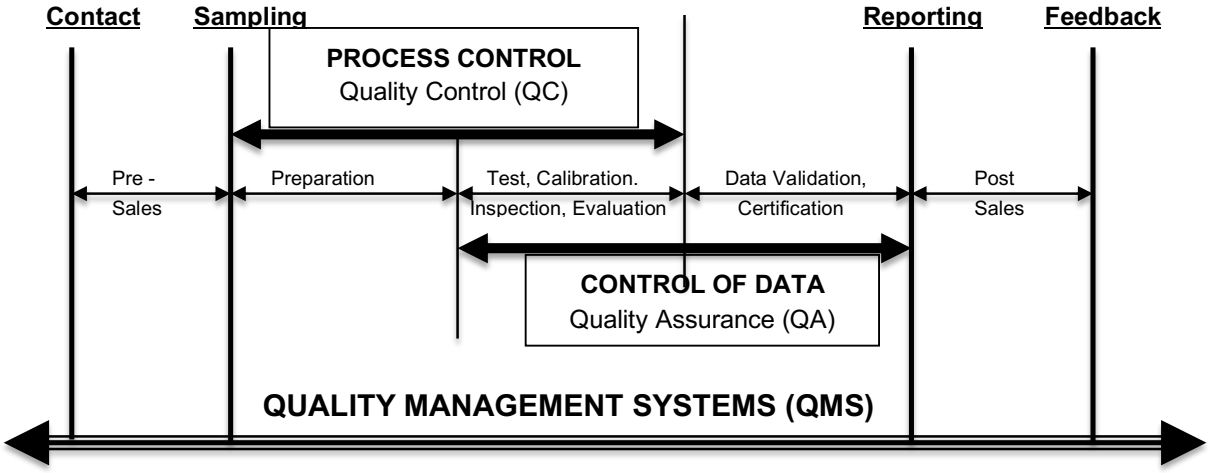
Upon completion of this chapter, you should be able to:

- **appreciate** how QMS is meant to assist the CAB in its operations;
- **understand** the basics of a continual improvement process, and
- **understand** why internal audits are important to the CAB.

1.2 QMS and the Operations of a Technical CAB

1.2.1 The Integration of Business Functions

This diagram shows where QMS provides support to the overall CAB business.



Includes all functions that influence the validity of technical results

- All business operations functions
- All management and administrative functions
- All finance functions
- All HR functions
- All purchasing and contract review functions
- All marketing and communications functions
- All maintenance functions

1.2.2 CAB Continual Improvement Processes

The most basic of the technical CAB standards is ISO/IEC 17025 and it is based on 8 principles, four of which are technical. Considering perfection in a testing CAB was to be described, and this perfection was based on the principles behind ISO/IEC 17025:2005, the description would probably look like this:

"We produce consistent results, day after day, within the 95% confidence region at the specified uncertainties."

Drawing by Iutta Waloschek.
From the website of the University of St. Andrews, Scotland.

http://www-gap.dcs.st-nd.ac.uk/~history/PictDisplay/Einstein.html

The authors of ISO/IEC 17025 envisioned labs to be able to **consistently produce results at specified uncertainties, within the 95% confidence region, day after day after day after boring day.** In the world of laboratories, boring stability means **TRUST**. This can be considered the state of *perfection* for a testing lab – or the **goal of a continual improvement program**.

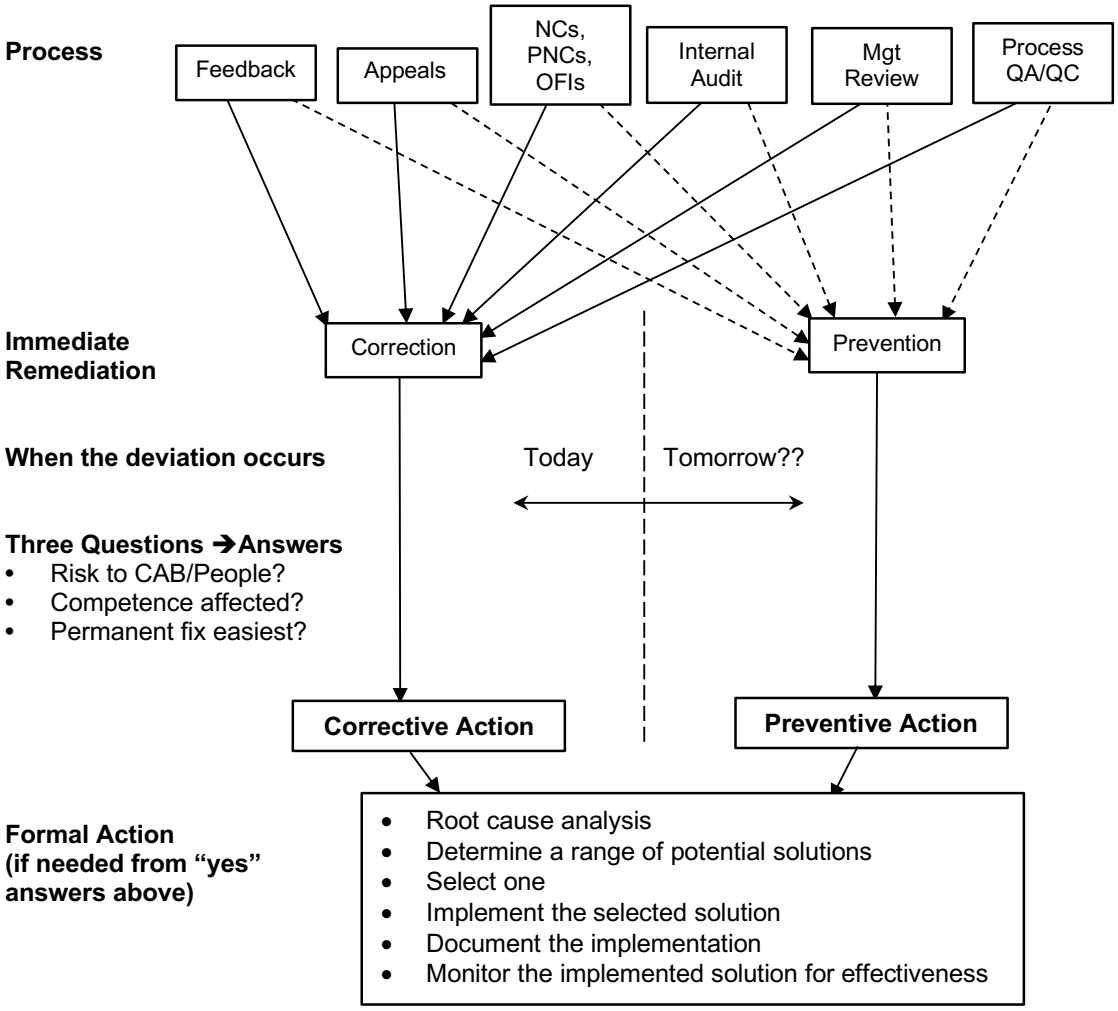
For inspection bodies and product certification bodies, and to a great extent, management system registrars, there are even more stringent requirements to establish this level of trust in their ability to deliver competent inspections regarding conformance and certifications of the conformance and safety of products sold in our markets. It involves their focus on maintaining integrity through impartiality and openness.

Aside from these, the thing that most commonly interferes with any technical CABs ability to attain this state of perfection is change: change in personnel, change in structure, change in equipment, change in procedure, change in environment etc. The thing that best supports attaining such a state of perfection is **stability**.

No one can prevent change. However, our management systems (health, safety, environmental and quality) can help us manage it. It provides a systematic method of identifying and addressing those things that would bring about some change and eventually impede the consistent production of valid results. In a good business unit, continual improvement is mostly about the management of change.

The consistency facilitated by a CAB's QMS also promotes safe working conditions. The single greatest safety enhancement an organisation can implement is to provide a stable, supportive environment to its own people and allow them to identify and address the undesirable conditions that are impediments to safety and to quality.

1.2.2.1 From Identification to Action



1.2.2.2 How Does Internal Audit Help The CAB?

Undesirable conditions (deviations, non conformances, accidents, hazards) will recur unless the reason they occurred in the first place is eliminated – permanently. The reason, or cause, of the occurrence is called a "root cause" and the elimination of the root cause is required to prevent recurrence. Internal audits are traditionally the single most comprehensive source of identifying deviations and other undesirable or potentially undesirable conditions.

Internal audits allow a CAB to identify just which things need to be addressed so that the undesirable condition is prevented from either happening the first time, or recurring after it first occurred. Consequently, any corrective- or preventive-action taken to address undesirable conditions can only occur after the original deviating condition has been identified.

Internal audits allow CAB management and staff to determine if the Management system is implemented, effective and allows for improvement. In other words:

> *Does the Management system adequately support the CAB's ability to produce technically valid results/inspections/certifications, and does it allow for continual improvement (read: identify potential deviations)?*

1.3 Standard audit requirements

- 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.

1.4 Involvement of CAB Staff in the Internal Audit Process

The audit processes described above are quite informative for a professional in the field of auditing or assessing, but they are not very useful for a staff that is expert in other things. So making it simple for others will motivate their participation in a process that works best when more people are doing the auditing.

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
- Observation
- Interview

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.

Top management:

- Are the owners of this process,
- Sell the requirement to the staff,
- Approve the internal audit program and plan,
- Facilitate implementation of the requirement (remove obstacles for its accomplishment),
- Provide Quality Manager with sufficient levels of responsibility to develop and, upon approval, implement the plan,
- Approve solutions resulting from the process, and
- Monitor the continuing effectiveness of the process.

An organisation that seeks to have detailed knowledge about how well it is doing its own business is headed in the right direction. Such an organisation is well led and not afraid to ask itself the hard questions.

In good organisations, the normal role of staff in internal audits is:

- Participate in the process, including the planning stages.
- Promote its benefits (if understood).
- Propose solutions when non-conformance / opportunity for improvement challenges are encountered.
- Implement corrective action solutions when approved.
- Maintain the quality system as specified.
- Actively seek out opportunities for improvement.
- Make use of the benefits of the process.

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

1.5 Overview of the Onsite Audit Process

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:

1. The management system is implemented,
2. The management system is effective, and
3. The management system allows for continual improvement.

This is done by gathering objective evidence and using this evidence to compare the actual conditions in the CAB with the requirements and stipulations given in the CAB management system documentation.

Management system documents (our own policies and procedures) are the references we use to measure the conformance of the current set of conditions.

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.

Objective evidence comes in three forms and this evidence supports the view that a condition does, or does not, conform to the stated requirement (from our own documents or an external requirement):

- Reading (document review),
- Listening (interview), and
- Watching (observation)

1.6 Process and Procedural Audits

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

- Process based auditing, and
- Checklist based auditing.

Process based audits focus on the outcome of the process and checklist based procedure audits focus on the level of conformance. CABs mostly use procedure audits because they can use the accreditation body checklist and there is less need to conduct audit planning.

Each has their advantages. Process based auditing allows for a fresh and open approach to the processes being audited and closely follows the actual processes used in the CAB. Procedures used to describe these processes can be modified to reflect practice and are not necessarily the reference documents which forms the basis of the audit. Much discussion is needed in order for the auditor to understand all the nuances of each process.

Procedure audits conducted on the basis of checklists rely heavily on written procedures for document review and for reference to conformance. In essence, if something is not being done according to the written procedure, it does not conform. This can be a more straightforward and simpler method of conducting an internal audit.

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.

1.7 Different types of “audits” within a CAB QMS

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.

The CAB audits of technical processes can be included in this type of audit activity but it is restricted to simple determination of whether CAB technical procedures and test methods are conducted as specified in SOPs, Methods and Work Instructions.

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.

1.8 The conduct of Internal Auditors

Take this simple test.

- Consider a tall gruff, obnoxious, loud and physically aggressive person entering your office and berating you.
- Now consider a short, demure, quiet person using a very small voice to tell you that they are there to audit you.

Which one of these two persons frightens you more? The answer is almost always "the auditor."

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.

1.8.1 CAB Internal Auditor Skills and Personal Attributes

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.

The personal attributes of auditors, from the same document, are:

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

"Personal attributes" are not the same as "skills" and "knowledge." They can be considered as characteristics. They describe the person. Skills and knowledge are about what the person does.

Note that "tenacious" and "decisive" can often be misinterpreted to mean the same thing as "stubborn" and "quick to react." In the best sense of the term, tenaciousness implies a desire to attain the mutually agreed objective, overcoming challenges to do so. Decisiveness is more about the ability to make a decision, albeit considered, than about making it quickly.

For the remainder of this course, the importance of auditor conduct will be repeatedly emphasised. It is the **single most important factor** determining the success of an internal audit.

1.8.2 CAB Internal Auditor Appointments

CAB internal auditor personnel are appointed by local top management, based on the recommendation of the local QMS representative. Such appointments are recorded in the employee's personnel files

1.9 Auditor Involvement in Resolving Findings

The prime function of an internal auditor is to provide information. That information is a structured report on the performance of a management system and its components when compared to a set of specifications, most commonly the management system requirements stated in CAB policies and procedures.

Such information is objective and related solely to the current state of the management system. Changes to the management system are the responsibility of its owners – local top management. Auditors do not normally participate in the changes to systems resulting from internal audits.

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).
- 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.**

Chapter 2 – Planning Internal Audits

2.1 Learning Objectives

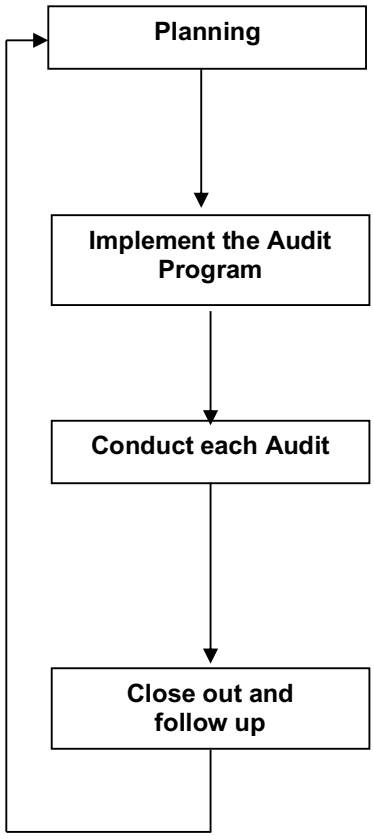
Upon completion of this chapter, you should be able to:

- **understand** the internal audit cycle;
- **understand** the responsibilities for the preparation, planning, conduct and close out of internal audits;
- **understand** the planning processes for internal audits, and
- **practice** the planning and preparation of a mock internal audit

2.2 The Internal Audit Cycle.

The internal audit cycle is a series of recurring activities that can allow a business unit to implement effective audit processes. For most CABs this cycle can be represented in the diagram below.

The cyclical nature of this process also allows the business unit to implement changes based on past performance. In other words, the effectiveness of this process can be measured with all the others.



- Based on the needs of the management system, previous audits, frequency, scope, resources, etc.
- Established by the General Manager and the QMS team
- Agreed by all participants, auditees, auditors

- Plan for each individual audit occurrence
- Allocate resources and establish timings, scope, objectives for each audit
- Each individual audit agreed by all participants, auditees, and auditors.

- Document review (System Audit), checklists prepared, timings for each audit activity established beforehand and agreed
- Onsite Audit (Conformance Audit)
- Opening meeting (if needed)
- Areas audited as agreed
- Findings agreed and written
- Report presented during closing meeting

- Auditee action – corrective/preventive action
- Formal close out of findings
- Follow-up as required, including any further audits

2.3 Ensuring the System is Ready

A business unit management system must also meet some internal requirements in order to be considered "auditable." It must be:

- Documented,
- Structured, and
- Implemented,

Documented – The CAB Management system normally consists of the following types of documents:

- Policy document
- Process documents
- SOPs / Instructions

} These are created within the CAB

- Specifications
- Standards
- Codes of Practice
- Regulations

} These are created externally (eg 17025, 17020, 17065).

- Records — Not really a document

Structured – CAB documents are created and maintained under CAB document control procedures and published for general use within the CAB. Document control procedures have one overall goal: to ensure that the most appropriate version of a needed document is available to everyone who needs it. Very simple. Only the correct version is available and everyone who needs it can access it.

The same procedure includes the requirements for Control of Records for a similar objective. Records are created and maintained to provide sufficient information for the traceability for all business activities, and to document the exercise of responsibility for all involved in these processes.

Retention periods of archived documents (see how they have become records?) and other records are normally dependent on the needs of CAB clients, regulatory agencies, or professional practice. Note that accreditation bodies are normally looking to see records not older than the date of the last assessment visit. Many regulatory bodies require retention beyond this period, including revenue agencies.

Implemented – The implementation of the management system is demonstrated by the existence of its records. Records are proof that the system is being used.

2.3.1 Planning Internal Audits

An internal audit can be considered one of the key processes in an organisation that has a conformant management system. It can be as important as the budgeting, marketing or other global processes. Like these other processes, internal audits are planned by the people in the organisation with the responsibility to oversee them. It the case of the internal audit program, the QMS team is normally responsible for this activity.

These planning stages for the internal audit cycle will normally result in formal approval of the internal audit program by top management. It must be preceded by agreement of all persons involved in the process.

> **Internal Audit Secret #3**
>
> People do not like surprises in auditing.
>
> In order to obtain and retain support for the process throughout the organisation, it is important to appreciate that surprises in audits are a bad thing. Prevent them.
>
> Get agreement at every stage. In fact, each step in the audit cycle, audit program and each audit, should be confirmation of agreements made to that point of the process.

The resulting internal audit program is approved by the appropriate member of the CAB management team and this approval includes:

- Direction to the organisation to implement (support) an internal audit program,
- The allocation of resources to implement a successful internal audit program,
- Scope and objectives of specific internal audit activities, and
- Timelines to be met for the overall activity.

This is an example of a simple internal audit program

Audit Area / Period	**Q1–2010**	**Q2–2010**	**Q3–2010**	**Q4-2010**
Admin		Sally	George	
Engines	Karen			
Polymers				Bruce
Sample Reception / dispatch			Jill	

2.3.2 Relationships

From the definitions given in the previous lesson, the responsibilities for the planning, oversight, conduct and follow up of internal audits can be perceived. These apply to the three different types of audits: first party, second party and third party.

Internal audits are an instance of CAB auditing itself and are first party audits. Second party audits are audits conducted by a client in support of a contractual agreement that may exist between CAB and them. They are the ones paying the money so they seek to audit us. Third party audits are those purely for the purpose of demonstrating conformance to a requirement and the CAB pays the auditing organisation for the work. There is no other relationship between the two.

If an *audit client* is the organization or person requesting an audit, then the audit client for an internal audit is top management. Note that audit client for a second party audit is an CAB client/customer and the audit client for a third party audit is CAB.

The *auditees* for an internal audit are those CABs and business units that are being audited. Note that the CAB is the auditee for a second party audit and the audit client for a third party audit is CAB, also the subject of the audit.

The local CAB QMS representative is normally responsible for the planning and conduct of an internal audit. This person also represents top management during this activity and can be perceived to be working at their direction.

It is important that the local CAB QMS representative obtain agreement from all auditees and auditors throughout the organisation before the program is presented to top management for approval.

2.3.3 Implementing the Internal Audit Program

Once the internal audit program has been agreed by all participants and approved by top management, the QMS team can normally proceed to negotiating agreements for each individual audit.

Dates, times, participants, scopes, objectives, resources and even locations should be agreed well in advance for each individual audit event. The sample program shown above does not contain sufficient detail to conduct any one audit or audit event.

Some of the items and issues for which agreement is required can only be handled between the auditee and the audit client – in other words, between the senior auditee representative and the QMS representative. This may include considerations such as:

- Scope and objectives of the audit,
- Number of auditors, and
- Onsite duration.

Other considerations, such as resource requirements, can be agreed in discussion between the auditee representative and the auditor, lead auditor.

Each audit or audit event should be developed using an audit plan, which contains much of the detail of the agreements made to this point. A sample plan is shown here.

AUDIT PLAN		
Area: *Sample reception and preparation CAB*		Date: *24 June 2010*
Audit Scope: *Sample reception and preparation CAB*		Audit Objectives: *Regularly scheduled review of processes*
Time	**Lead: John**	**Member: Bruce**
08:00	*Opening Meeting – Orientation within facility*	
09:00	*Training and qualification processes*	*Traceability and calibration*
10:00		
11:00	*Orders and contracts*	*Qualification of suppliers*
12:00	*- Lunch -*	*- Lunch -*
13:00	*Orders and contracts (cont'd)*	*Qualification of suppliers (cont'd)*
14:00	*Team meeting and prepare report*	
15:00	*- Closing meeting -*	
16:00		
17:00		
Resources Required		*Safety goggles for the calibration site.*
Form No: *XYZ - 123*		Page *1* of *1*

Note that this plan does not indicate who will participate as auditees.

2.4 Presenting the Plan during Opening Meetings

The audit plan is normally the used to guide discussion of planned audit activities during an opening meeting. More course material on Opening meetings is presented in Chapter 3.

The agenda of the Opening meetings it presented below to facilitate participant work in Exercise 1.

- Introductions and thanks
- Audit scope and objectives
    - Agreement on scope and objectives – emphasise “facilitation of conformance”
    - Scope and objectives understood by auditees
    - Reiterate the “official” links between the auditees and auditors
- Audit plan
    - Agreement on the planned approach
    - Respond to necessary adjustments to the plan
    - Confirm arrangements for logistics and resources
    - Confirm arrangements and timings for subsequent meetings
    - Confirm arrangements for the end of the audit
- Audit methods and procedures
    - Clearly explain investigation activities
    - Be open about the process and emphasise its transparency
- Confidentiality
    - Confirm audit team’s responsibilities
    - Confirm auditing authority’s responsibilities
- Respond to questions
    - Be prepared to handle questions from the auditees – focus on the benefits of the approach and the transparency of the activities.
- Depart for the tour of the facility.

2.5 Exercise No. 1 – Planning the Audit for a CAB

Learning Objectives:

- **understand** the planning processes for internal audits,
- **understand** the responsibilities for the preparation, planning, and conduct of internal audits, and
- **practice** preparing audit plans.

Exercise Objectives:

Your group consists of the designated team leader for the audit of one of the sections or processes within MOTIVA CAB. Your QMS representative has just asked your group to conduct this regularly scheduled audit of processes. You will be asked to audit one of:

- SP001 – Continual Improvement procedure (Ref = QM, Audit Doc = SP001)
- SP002 – Feedback procedure (Ref = QM, Audit Doc = SP002)
- SP003 – Internal Audit and Management Review procedure (Ref = QM, Audit Doc = SP003)
- SP004 – Document control and control of records procedure (Ref = QM, Audit Doc = SP004)
- SP006 – Job Hazard Assessment procedure (Ref = QM, Audit Doc = SP006)

Exercise Preparation – 60 minutes

Your group is an audit team and it is to accomplish the following:

1. The team to conduct a document review of the relevant SP.
2. The team leader is to reach agreement with the auditee on the following:

    - Scope and objectives
    - Audit resources
    - Dates and timings, and
    - Participation

3. The team leader is to complete sufficient Audit Plan Forms on the following pages to involve all team members in the audit such that one person from the team is auditing each of the following aspects of your selected procedure:

    - Training and qualification processes of personnel involved in the procedure
    - Processed for document control and control of records used and created by the procedure
    - Processes for continual improvement of the procedure
    - Processes for documenting and responding to feedback as regards the procedure
    - Processes for the assessment of job hazards associated with the procedure.

4. Each team member is to prepare two open-ended questions that will allow him or her to conduct the minimum line of inquiry to establish conformance of the process they are to audit within the audit team's selected procedure. The questions are to be related to the following processes.

    - Training and qualification processes of personnel involved in the procedure
    - Processed for document control and control of records used and created by the procedure
    - Processes for continual improvement of the procedure
    - Processes for documenting and responding to feedback as regards the procedure
    - Processes for the assessment of job hazards associated with the procedure.

Exercise Deliverables – 10 minutes per group

You are to present an Audit Plan using forms provided. Account for all team members on the Audit Plan Forms submitted

Presentation and Group Discussion – 30 minutes

Each group is to present their plan to the local QMS representative (your facilitator). Once all presentations are complete, the class will discuss the issues arising, and the salient points to retain.

AUDIT PLAN		
Area:		Date:
Audit Scope:		Audit Objectives:
Time	**Lead: _____**	**Member 1: _____**
08:00		
09:00		
10:00		
11:00		
12:00		
13:00		
14:00		
15:00		
16:00		
17:00		
Resources Required		
Form No: _____		Page _____ of _____

AUDIT PLAN		
Area:		Date:
Audit Scope:		Audit Objectives:
Time	**Member 2: _____**	**Member 3: _____**
08:00		
09:00		
10:00		
11:00		
12:00		
13:00		
14:00		
15:00		
16:00		
17:00		
Resources Required		
Form No: _____		Page _____ of _____

Chapter 3 – Conducting an Internal Audit

3.1 Learning Objectives

Upon completion of this chapter, you should be able to:

- **understand** the requirements behind the conduct of audit meetings and interviews;
- **conduct** interviews of auditees, and
- **record** observations and audit evidence;

3.2 Document Review

Actual audit activities are divided between those that occur on site and those that occur off site. The off site activities are primarily restricted to preparatory work and aimed at reducing the workload onsite to something that is manageable by mere mortals (auditors). This preparatory offsite work is normally called document review.

It also serves the purpose of not wasting the auditee's time by having all participants reviewing audit documents together. Normally, the auditee is already very familiar with them. It is the auditor who needs to become familiar with these documents and doing so prior to the audit provides a better preparation and saves onsite time.

Document review is also called a system audit and it is primarily aimed at allowing the auditor to:

- Determine the level of conformance of the auditee documents prior to the actual onsite visit,
- Gain familiarity with the documents that govern the auditees processes, and
- Understand the processes actually used by the auditees.

3.3 Opening Meetings

Opening meetings to commence an audit are not always the norm within CABs. This course includes the possibility that a formal opening meeting is required. So long as the information exchanged at the beginning of the audit activity covers the requirements ISO 19011, the need for an opening meeting is by agreement between the auditors and the auditees.

- Introductions and thanks

- Audit scope and objectives
    - Agreement on scope and objectives – emphasise "facilitation of conformance"
    - Scope and objectives understood by auditees
    - Reiterate the "official" links between the auditees and auditors

- Audit plan

    - Agreement on the planned approach
    - Respond to necessary adjustments to the plan
    - Confirm arrangements for logistics and resources
    - Confirm arrangements and timings for subsequent meetings
    - Confirm arrangements for the end of the audit

- Audit methods and procedures
    - Clearly explain investigation activities
    - Be open about the process and emphasise its transparency
- Confidentiality
    - Confirm audit team's responsibilities
    - Confirm auditing authority's responsibilities
- Respond to questions
    - Be prepared to handle questions from the auditees – focus on the benefits of the approach and the transparency of the activities.
- Depart for the tour of the facility.

3.4 Auditor Approaches

Openness and transparency are important for the success of this meeting. The responsibility for the success of the opening meeting rests with the lead auditor alone. This is the same as for the remainder of the audit.

Not portraying oneself as a know-it-all will go a long way to allowing the audit team to gather the information required to determine:

- The level of implementation of the quality system,
- The level of effectiveness of the quality system, and
- The capacity of the system to effect continual improvement.

Internal Audit Secret #4

Open every meeting with "Thank you for agreeing to……"

This includes the opening meeting, the intermediate wash-up meetings and the closing meeting.

3.5 Responsibilities for Conduct and Communication

The success of the entire audit rests with the auditor. To go with this accountability is the authority to conduct meetings, ask questions, observe processes, exercise judgments, raise issues, investigate and write findings. In other words, the auditor is the one doing all the work, and theirs is the responsibility for the final result.

To emphasise, the opening meetings are chaired by the auditor, or for an audit team, the lead auditor. They control the flow of the discussion so it is very important that the conduct of the auditors are such as to engender trust and openness.

This goes for all instances of communication during the audit. There are four formal occasions and a number of informal ones. The formal ones include:

- the opening meeting,

- interviews of auditees,
- wash up meetings, and
- the closing meeting.

We have already examined the opening meeting and the closing meeting will be covered in Lesson 4.

3.5.1 Communication Styles

Typically, people tend to either want to "get to the point" in discussions or to "get a feeling for the circumstance." These are very different communication styles. They each have their advantages. In an internal audit, where auditees are already frightened of the auditor, the softer approach is the one that is preferred.

Direct questions and crossed arms indicate a closed mind and a hunter. Standing at ease with an open posture asking "how do you…" questions indicate an open mind that is interested in what the auditee has to say.

3.5.2 Conducting Interviews

Besides the closing meeting, interviews can be the most stressful part of an audit. It is important that, like other events in the audit, the interview can be considered confirmation of agreements made to date. What agreements? Well, the agreement that the requirements given in the reference documents are the measure against which conformance is determined.

The aim of any interview is to acquire an understanding of the auditees processes. It is important to acquire such an understanding so that a complete and honest determination can be made regarding the conformance of the process to requirements.

There are two effective techniques:

- discuss the process and pick up records along the way, or
- ask for some records which help document how the process works – then discuss as you examine records.

If there are few process records, the first approach works best. If there are many records and the process is complex, the second approach works best.

3.5.3 Responding to Conflict and Challenges

An audit can be a stressful activity for all concerned and many auditors and auditees do not have a great deal of comfort within themselves in this type of circumstance. This should be understood by the auditors and steps taken to reduce the potential for stress throughout the process. As already discussed, much of the effort comes in the form of the auditors' personal conduct.

In the event, however, that any challenges arise that may potentially impede the team in the conduct of their audit, the responsibility for the solution rests with the auditor, or if the auditor is part of a team, the lead auditor. Resolution of a potential conflict may involve the following:

- Approaching the most senior of the auditee staff to resolve the issue is the usual first step. If this will not resolve the issue, and the successful completion of the audit is at risk, the decision on how to resolve the issue – remove the challenge or amend the audit plan, is then passed up to the quality manager or quality coordinator.

- In the case of an audit team, the first attempt at a solution should normally be exercised by the lead auditor. This is part of the primary function of the lead auditor – overcome obstacles so that the team can do their work.

- The chain of responsibility for this work is between the lead auditor (or the auditor if working alone) and the senior auditee. Other auditees may not be in a position to address the issue and the decisions on how to proceed must be decided by the same persons who made the original agreements.

If conflict arises during the course of the audit, the best course of action to take involves the following:

- auditors remain neutral or withdraw from the area of conflict,
- inform the lead auditor,
- inform the senior auditee,
- if the problem persists, inform the quality manager/coordinator,
- if resolution is not possible, pause the audit until the conflict is removed.

3.6 Recording Audit Observations

Audits require auditors to make many notations. All circumstances of note should be recorded, as these may eventually become part of the audit report. This includes the good and the bad. Both may appear on an audit report and audit findings require evidence.

Observations may include times, processes, locations, equipment, records, and procedures. All of these can be cited as evidence of a finding.

3.6.1 During the Document Review (System Audit)

During the document review, an auditor may make observations on the level of conformance of the documents against requirements. These observations may either form part of an initial report regarding conformance of the documents, or they may be saved until the conformance audit is conducted.

If they are retained until the conformance audit, they may be raised as issues, if evidence gathered confirms the observation. Conversely, they may be disposed of, if evidence indicates that observed practice does conform.

3.6.2 During the Onsite Audit (Conformance Audit)

During the interview process, or at any time during the audit, when an observation seems to indicate a non conforming activity or circumstance, the auditee present should be made aware of this possibility. It is not important to declare a non conformance, but it is important that the reasons behind the possibility of one are made known. This prevents surprises in the closing meeting.

In fact, whenever a process or some circumstance leads the auditor to believe a non conformance exists, their main aim is to “sell” the idea that the condition observed may not meet requirements – and a finding may have to be written.

Evidence should be clear. Requirements should be clear. The differences between the two should be clear. When presented to the auditee, it can be almost a question: “We have found this. What would you like me to do?”

Any hint at not reporting it is patently unethical and the auditee may have no choice but to ask you to document the observation as a potential finding. Do so. You have the concurrence of the auditee.

3.7 Wash up Meetings

At the end of every day of a multi-day audit, except the last day when the closing meeting takes place, it is a good idea to hold wash up meetings and brief the quality staff and management on the observations made during the day.

This keeps them apprised of the progress of the audit and allows them to prepare for these observations as findings during the closing meeting and in the report. Only observations are discussed at this point. No decisions on findings are necessary until all of the audit evidence has been gathered and is under review for the final report.

3.8 Exercise No. 2 – Gathering Objective Evidence, Interviews

Learning Objectives:

- practice conducting interviews,
- practice recording observations and audit evidence, and
- practice raising observations with auditees.

Exercise Objectives:

Your group consists of the designated team leader for the audit of one of the sections or processes within MOTIVA CAB. Following on from Exercise Number 1, you are now fully engaged in the internal audit. It is now time to interview one of the key staff members for the section/process being audited. Each team member will now interview this lucky auditee.

Exercise Preparation – 10 minutes

Your group is to accomplish the following:

- You are to allocate two questions to each team member from your previously developed checklist.
- During the course of the interview, one of you will speak to the auditee and the other will record the answers.

Exercise Deliverables – 10 minutes per group

Each group is to conduct an interview of the auditee (your facilitator) to record relevant information from the interview, including any records provided to support auditee statements. Each team member will ask at least one question.

If a deviation, a potential deviation, or an opportunity for improvement is raised, the team member conducting the interview is to ensure that the auditee is aware of the issue, and its potential for appearance in the report.

Presentation and Group Discussion – 30 minutes

Once all interviews are complete, the class will discuss the issues arising, and the salient points to retain.

Chapter 4 – Writing Findings

4.1 Learning Objectives

Upon completion of this chapter, you should be able to:

- **document** audit findings;
- **understand** the required content and structure of an internal audit report;
- **prepare** an audit report, and
- **conduct** a closing meeting.

4.2 Audit Findings

4.2.1 Each Finding has Three Components

Since audits are the very objective comparison of conditions and circumstances against requirements, the result of the comparison should also be objective. Such are good audit findings.

Findings are, by definition, the result of this comparison supported by audit evidence. In other words, an audit finding must contain **ALL** of the following:

- A statement of the condition observed,
- A statement of the requirement, and
- A reference to the evidence that supports the comparison of these two.

No finding can be made without evidence. Without evidence, it is just an opinion.

4.2.2 Types of Evidence

Audit evidence comes in one of three distinct forms:

- Review of reference documents and audit documents and records,
- Interview of auditees, and
- Observation of processes.

4.2.3 How much Evidence?

When gathering records to demonstrate that a process conforms to requirements, it is good practice to randomly select records in the following manner:

- Some recent ones,
- Some not-so-recent ones, and
- Some from shortly after the last audit.

In gathering evidence, the auditor is attempting to obtain a sense of the overall conformance of the process to requirements. If one or two records indicate a problem, then more should be acquired to confirm the level of conformance (or non-conformance) of the process.

Auditors should also be mindful that the selection of records is a sampling process and will not produce absolute certainty of conformance.

As well, observation of processes can provide a good overview of the level of conformance of the process and records can be used to back up the sense of conformance developed during observation.

4.3 Internal Audit Report

The audit report is the responsibility of the audit team leader, or if working alone, the auditor. This responsibility draws from the responsibility for the success of the audit and for its conduct. They are one and the same.

Only the auditor (or audit team leader) is required to sign the report.

The auditees are not required to sign the report, but it is a good idea to do this as it demonstrates commitment on the part of the auditees, to undertake the corrective and preventive action necessitated by the issues raised in the report.

If the audit is conducted by a team of auditors, it must be clear that only the team leader is responsible for the content of the report. In other words, the final decision on any part of the content resides solely with the lead auditor. If the team leader understands their responsibilities to the team, they will seek consensus on the content – but the responsibility lies with them.

4.3.1 Internal Audit Report Content

There are only two primary requirements for the contents of an audit report:

- The report represents a factual description of the audit activities that led to the production of the report.

  All of the detail regarding the areas audited, the evidence gathered and examined, the scope and objectives of the audit and the principal participants must be part of the report. It must also contain the information that supports the audit findings, conclusions and recommendations.

- The report contains a fair and accurate presentation of the current state of the quality system that was audited.

  The report answers clearly indicates the demonstrated level of conformance of the quality system, or part thereof, that was audited.

4.3.2 Internal Audit Report Structure

The following pages contain the principal elements of an audit report:

- Audit Report Cover Page

  The cover page contains all of the information required to detail the audit direction and involvement. It also allows the record to trace the actual dates of the activity and to record which documents were used as reference for the audit and the status of the documents that were part of the audit.

  The cover page also contains the signatures of the audit team, although only the Lead Auditor is actually required to sign the report, in accordance with international best practice given in ISO 19011.

  The names of the principal auditee participants are also listed on the cover page. Note that a separate “attendance” sheet is often used to record the names of attendees for opening and closing meetings.

  It is good practice, as shown in the example, to indicate that the audit may not have caught everything in its sampling of records and processes. It is also good practice to reinforce the requirement for confidentiality.

While this example shows a signature of the senior auditee at the bottom of the page to signify their agreement with its contents, this is not a requirement of an audit report. But it is good practice.

- Audit Report Summary

  The summary page contains the final recommendations and conclusions resulting from the audit activity.

  The comments box contains the overall sense of conformance of the audited system that was gained by the auditor(s). It is based on the findings contained in the report and provides a picture of the system as seen through the eyes of the auditor(s).

  The conclusions are the formal summary of the findings contained in the report. They are the formal determination of the demonstrated level of conformance of the system, based on the evidence contained within the set of findings.

  The recommendations are the set of suggestions provided by the auditor(s) regarding the work to close out the findings within the audit and regarding the frequency and scope of future audits so as to monitor the continued conformance and improvement of the activities that were the subject of this report. The proposed dates of future audits is noted.

- Audit Activity Summary

  The activity summary page notes all of the activities that formed part of the audit. This page is one of the reasons why auditors need to keep good notes.

  Each audit activity should refer to the document or process that governs the activity to be audited. Evidence of conformance should be noted. Findings resulting from the examination of each aspect is also noted on this page, in sequence.

- MOTIVA CAB Incident and Deviation Report.

  There are many formats that can be used to document individual internal audit findings. They must all have the following content:

  - A statement of the condition observed,
  - A statement of the requirement, and
  - A reference to the evidence that supports the comparison of these two.

  Some formats allow for the finding to start other continual improvement activities that may documented / recorded on the same form. This may include the investigation of a root cause (where applicable), the recording of the corrective or preventive action taken and the follow-up activity undertaken.

AUDIT REPORT COVER PAGE	Audit Report No. *2009 - 003*
Area: *Photo Voltaic Testing Lab*	Date: *23 March 2009*
Audit Scope: *Document control and sample reception processes*	Audit Objectives: *Regularly scheduled internal audit*
Reference Document Status: Quality Manual Rev, 1.4, 21 Jan 2008 Procedures Manual, Rev 1.7, 30 June 2009	
Documents that form part of the Audit, including revision and status: *Photo Voltaic Laboratory Work Instructions, Rev 1.3, 17 Dec 2005*	
Audit Team: *The contents of this report are confidential to MOTIVA CAB.* *The findings contained within this report are the result of limited sampling and therefore it cannot be assumed that others do not exist.* *I. M. Good, L/A* I.M. Good *Out O. Luck* O.U. Luck	Area Representatives: John H Boss Melanie Analyst George K Technician Sandy Helper Samantha Safety
The signature below of the area's representatives indicates their agreement and understanding of the findings identified that are the subject of this report. Signed John H Boss	
Form No: _____	Page *1* of *6*

AUDIT REPORT SUMMARY	**Audit Report No.** *2009 - 003*
Comments or concerns of the Auditors: *The audit team is concerned about an apparent lack of documentation for some peripheral processes that are not deemed important enough to document. These procedures may have an impact on the validity of test results.*	
Conclusions and Follow-up Action: *The CAB quality system is considered effective and well implemented. It supports the identification and treatment of incidents and deviations within a well established continual improvement program*	
Recommendations: *It is recommended that the non-conformances and opportunities for improvement raised during this audit be addressed by the lab within the timeframe specified in SP001 – Continual Improvement.* *It is recommended that this lab maintain its current internal audit cycle and should be audited six months from the date of this report.*	
Date of Next Planned Audit: *23 September 2009*	
Form No: _____	Page 2 of 6

AUDIT ACTIVITY SUMMARY	Audit Report No. *2009 - 003*	
Reference:	**Activities / Areas / Evidence**	**Findings**
Quality Manual	*Reviewed QA/QC policies*	
Procedures Manual	*Reviewed supporting procedures from SP__*	
Work Instruction 12	*Order # A2209, 2310, Enquiry No. A64.1*	***1***
Work Instruction 12	*Reviewed Job Nos. 11123, 16123*	
Work Instruction 3	*Reviewed records, G. Wagner, J. Jones, B. Cook*	
Work Instruction 3	*Reviewed Projects QPL, Sando, DIA*	***2***
Work Instruction 5	*Calibration certificates 1275, 1323, and 270*	
Work Instruction 9	*Reports 223, 410, ASL (1.6.04)*	***3***
Work Instruction 6	*Reviewed J/B# 11123, 14123, 9993*	
Work Instruction 10	*Reviewed Pipettes Nos. 8123, 28113, 1113*	
Comments:		
Form No: _____	Page 3 of 6	

Incident and Deviation Report

Date: 27 March 2011
Serial # # 1
Number of pages attached

Note: Only one incident or deviation per report.

Deviation ■ Potential Deviation ☐ Opportunity for Improvement ☐

(Select one ref only) → ■ MOTIVA QMS: Work Instruction 12 ☐ External:

1. Description of the incident or deviation (Include immediate action taken if incident)

Order #'s A2209, 2310, and Enquiry No. A64.1 did not have sample reception clerk signature in accordance with Work Instruction 12.

2. Description of the immediate remedial action (remediation) taken, including any correction or prevention

QM review (initials)	Investigation assigned to	Date:

3. Is full Corrective/Preventive Action Required? **Yes,** if there are any "Yes" boxes checked.

	Yes	No	
Is there an unacceptable risk to MOTIVA CAB?	☐	☐	*If all answers are "No" then only remediation is required.*
Is the technical validity of MOTIVA CAB results affected?	☐	☐	
Is it easier to effect permanent resolution than many little remediations?	☐	☐	

4. Proposed Solution (and Investigation of Root Cause if required) Date Due:

Root Cause(s) of condition: **Not required (eg: remediation only)** ☐

Proposed solution: Corrective Action ☐ Preventive Action ☐ Remediation Only ☐

Investigator's Signature and Date _____, _____

5. Confirmation of Solution Implementation

Condition resolved (root cause eliminated/opportunity exploited) ☐ Date implemented
Supervisor/Manager Initials QMS closure (Initials)

6. Follow up Date Due:

Follow up required? Yes - ☐ No - ☐	If not, why not?	
Monitoring of condition assigned to:	Date Completed	
"Solution is deemed EFFECTIVE." ☐	QMS review (Initials)	

Incident and Deviation Report

Date: 27 March 2011
Serial # # 2
Number of pages attached

Note: Only one incident or deviation per report.

Deviation ■ Potential Deviation ☐ Opportunity for Improvement ☐

(Select one ref only) → ■ MOTIVA QMS: Work Instruction 3 ☐ External:

1. Description of the incident or deviation (Include immediate action taken if incident)

No formal review of PV lab capacity prior to acceptance of samples for projects QPL, Sando, and DIA contrary to Work Instruction 3

2. Description of the immediate remedial action (remediation) taken, including any correction or prevention

QM review (initials)	Investigation assigned to	Date:

3. Is full Corrective/Preventive Action Required? **Yes,** if there are any "Yes" boxes checked.

	Yes	No	
Is there an unacceptable risk to MOTIVA CAB?	☐	☐	*If all answers are "No" then only remediation is required.*
Is the technical validity of MOTIVA CAB results affected?	☐	☐	
Is it easier to effect permanent resolution than many little remediations?	☐	☐	

4. Proposed Solution (and Investigation of Root Cause if required) Date Due:

Root Cause(s) of condition: **Not required (eg: remediation only)** ☐

Proposed solution: Corrective Action ☐ Preventive Action ☐ Remediation Only ☐

Investigator's Signature and Date _____, _____

5. Confirmation of Solution Implementation

Condition resolved (root cause eliminated/opportunity exploited) ☐ Date implemented

Supervisor/Manager Initials QMS closure (Initials)

6. Follow up Date Due:

Follow up required? Yes - ☐ No - ☐	If not, why not?	
Monitoring of condition assigned to:	Date Completed	
"Solution is deemed EFFECTIVE." ☐	QMS review (Initials)	

Incident and Deviation Report

Date: 27 March 2011
Serial # # 3
Number of pages attached

Note: Only one incident or deviation per report.

Deviation ☐ Potential Deviation ☐ Opportunity for Improvement ■

(Select one ref only) → ■ MOTIVA QMS: Work Instruction 9 ☐ External:

1. Description of the incident or deviation (Include immediate action taken if incident)

Work Instruction 9 calls for verification of all consumables, including non-critical ones. This may be more stringent than is required by the MOTIVA Purchasing Policy.

2. Description of the immediate remedial action (remediation) taken, including any correction or prevention

QM review (initials)	Investigation assigned to	Date:

3. Is full Corrective/Preventive Action Required? **Yes,** if there are any "Yes" boxes checked.

	Yes	No	
Is there an unacceptable risk to MOTIVA CAB?	☐	☐	*If all answers are "No" then only remediation is required.*
Is the technical validity of MOTIVA CAB results affected?	☐	☐	
Is it easier to effect permanent resolution than many little remediations?	☐	☐	

4. Proposed Solution (and Investigation of Root Cause if required) Date Due:

Root Cause(s) of condition: **Not required (eg: remediation only)** ☐

Proposed solution: Corrective Action ☐ Preventive Action ☐ Remediation Only ☐

Investigator's Signature and Date _____, _____

5. Confirmation of Solution Implementation

Condition resolved (root cause eliminated/opportunity exploited) ☐ Date implemented
Supervisor/Manager Initials QMS closure (Initials)

6. Follow up Date Due:

Follow up required? Yes - ☐ No - ☐	If not, why not?	
Monitoring of condition assigned to:	Date Completed	
"Solution is deemed EFFECTIVE." ☐	QMS review (Initials)	

4.4 The Closing Meeting

The closing meeting, not surprisingly, is another step of confirmation of agreements made to that point. It is also the final formal meeting of the audit activity between the auditor(s) and the auditees. For reasons similar to the ones that drive an opening meeting, it has a similar agenda.

The major difference however, is that the honeymoon is over. Bad news is about to be delivered and the auditor(s) is/are now required to deliver it. Of all the types of meetings surrounding the audit – this one can be the most stressful. It can also be the most rewarding.

4.4.1 Closing Meeting Agenda

Note how close the following agenda corresponds to the agenda presented in Section 3.3 of this course.

- Introductions and thanks
- Audit scope and objectives (Audit Report Cover Page)

  Reiterate scope and objectives (facilitation of conformance)
- Audit methods and procedures

  Reiterate investigation methods
- Confidentiality (Audit Report Cover Page)

  Confirm audit team's responsibilities – leave all documents with auditee
  Confirm auditing authority's responsibilities
- Present the Audit Report (Audit Report Summary)

  Present the areas examined (Audit Activity Summary)
  Present the Findings (Incident and Deviation Reports)
  Present the Comments (Audit Report Summary)
  Present the Conclusions (Audit Report Summary)
- Respond to questions

  Be prepared to handle questions from the auditees – focus on the benefits of the findings presented and the new opportunities available to the auditees to undertake continual improvement.
- Discuss Recommendations and Follow Up (Audit Report Summary)

  Present the Recommendations (Audit Report Summary)
- Obtain Signatures (Audit Report Cover Page)

  Ensure one copy remains with the auditee and one copy is forwarded to the QMS representative.

4.5 Team Debriefing

Following the closing meeting, it is good practice for an audit team to gather and discuss the overall success of the audit endeavour. This is the time when opportunities for improvement of the audit process can be identified and forwarded to the QMS representative.

It is also a good time for the team leader to exercise their responsibilities with regard to recognizing the contributions of individual team members.

4.6 Exercise No. 3 – AUDIT REPORTS

Learning Objectives:

- **practice** writing findings,
- **practice** preparing an internal audit report, and
- **practice** delivering an internal audit report to auditees.

Exercise Objectives:

Your group consists of the designated team leader for the audit of one of the sections or processes within MOTIVA CAB. Following on from Exercises Numbers 1 and 2, you are now prepared to write your audit report based on the observations you recorded during your interviews. Your team will now prepare the internal audit report and deliver it to the auditees, whose supervisor is played by the facilitator. Use the attached IDR forms to present your findings.

Exercise Preparation – 60 minutes

Your group is to accomplish the following:

- You are to write three non-conformances and one opportunity for improvement resulting from your interviews in Exercise Number 2.
- You are to complete the audit report for this internal audit activity.
- You are to use the attached forms provided to you for this purpose.

Your group is to prepare itself to present these findings using the Closing Meeting Agenda given in 4.4.1 above.

Exercise Deliverables (Closing Meeting) – 15 minutes per group

Each group is to conduct the closing meeting and present their audit report with all findings to the other groups (representing the auditees) and your facilitator (representing the auditee manager). All relevant aspects of the audit report are to be presented.

Presentation and Group Discussion – 30 minutes

Once all presentations are complete, the class will discuss the issues arising, and the salient points to retain.

Date: _____
Serial # _____
Number of pages attached _____

Incident and Deviation Report

Note: Only one incident or deviation per report.

Deviation ☐ Potential Deviation ☐ Opportunity for Improvement ☐

(Select one ref only) → ☐ MOTIVA QMS: _____ ☐ External: _____

1. Description of the incident or deviation

2. Description of the immediate remedial action (remediation) taken, including any correction or prevention

QM review (initials) _____	Investigation assigned to _____	Date: _____

3. Is full Corrective/Preventive Action Required? **Yes,** if there are any "Yes" boxes checked.

	Yes	No	
Is there an unacceptable risk to MOTIVA CAB?	☐	☐	*If all answers are "No" then only remediation is required.*
Is the technical validity of MOTIVA CAB results affected?	☐	☐	
Is it easier to effect permanent resolution than many little remediations?	☐	☐	

4. Proposed Solution (and Investigation of Root Cause if required) Date Due: _____

Root Cause(s) of condition: **Not required (eg: remediation only)** ☐
Proposed solution: Corrective Action ☐ Preventive Action ☐ Remediation Only ☐
Investigator's Signature and Date _____, _____

5. Confirmation of Solution Implementation

Condition resolved (root cause eliminated/opportunity exploited) ☐	Date implemented _____
Supervisor/Manager Initials _____	QM closure (Initials) _____

6. Follow up Date Due: _____

Follow up required? Yes - ☐ No - ☐	If not, why not?
Monitoring of condition assigned to: _____	Date Completed
"Solution is deemed EFFECTIVE." ☐	QM review (Initials) _____

Date: _____
Serial # _____
Number of pages attached _____

Incident and Deviation Report

Note: Only one incident or deviation per report.

Deviation ☐ Potential Deviation ☐ Opportunity for Improvement ☐

(Select one ref only) → ☐ MOTIVA QMS: _____ ☐ External: _____

1. Description of the incident or deviation

2. Description of the immediate remedial action (remediation) taken, including any correction or prevention

QM review (initials) _____	Investigation assigned to _____	Date: _____

3. Is full Corrective/Preventive Action Required? **Yes**, if there are any "Yes" boxes checked.

	Yes	No	
Is there an unacceptable risk to MOTIVA CAB?	☐	☐	*If all answers are "No" then only remediation is required.*
Is the technical validity of MOTIVA CAB results affected?	☐	☐	
Is it easier to effect permanent resolution than many little remediations?	☐	☐	

4. Proposed Solution (and Investigation of Root Cause if required) Date Due: _____

Root Cause(s) of condition: **Not required (eg: remediation only)** ☐
Proposed solution: Corrective Action ☐ Preventive Action ☐ Remediation Only ☐
Investigator's Signature and Date _____, _____

5. Confirmation of Solution Implementation

Condition resolved (root cause eliminated/opportunity exploited) ☐	Date implemented _____
Supervisor/Manager Initials _____	QM closure (Initials) _____

6. Follow up Date Due: _____

Follow up required? Yes - ☐ No - ☐	If not, why not?
Monitoring of condition assigned to: _____	Date Completed
"Solution is deemed EFFECTIVE." ☐	QM review (Initials) _____

Date: _____
Serial # _____
Number of pages attached _____

Incident and Deviation Report

Note: Only one incident or deviation per report.

Deviation ☐ Potential Deviation ☐ Opportunity for Improvement ☐

(Select one ref only) → ☐ MOTIVA QMS: _____ ☐ External: _____

1. Description of the incident or deviation

2. Description of the immediate remedial action (remediation) taken, including any correction or prevention

QM review (initials) _____	Investigation assigned to _____	Date: _____

3. Is full Corrective/Preventive Action Required? **Yes**, if there are any "Yes" boxes checked.

	Yes	No	
Is there an unacceptable risk to MOTIVA CAB?	☐	☐	*If all answers are "No" then only remediation is required.*
Is the technical validity of MOTIVA CAB results affected?	☐	☐	
Is it easier to effect permanent resolution than many little remediations?	☐	☐	

4. Proposed Solution (and Investigation of Root Cause if required) Date Due: _____

Root Cause(s) of condition: **Not required (eg: remediation only)** ☐
Proposed solution: Corrective Action ☐ Preventive Action ☐ Remediation Only ☐
Investigator's Signature and Date _____, _____

5. Confirmation of Solution Implementation

Condition resolved (root cause eliminated/opportunity exploited) ☐	Date implemented _____
Supervisor/Manager Initials _____	QM closure (Initials) _____

6. Follow up Date Due: _____

Follow up required? Yes - ☐ No - ☐	If not, why not?
Monitoring of condition assigned to: _____	Date Completed
"Solution is deemed EFFECTIVE." ☐	QM review (Initials) _____

Chapter 5 – Addressing and Closing Out Findings

5.1 Learning Objectives

Upon completion of this chapter, you should be able to:

- **understand** the requirements for implementing corrective and preventive action;
- **identify** the types of root causes of non-conformances and potential non-conformances;
- **document** corrective and preventive actions, and
- **understand** how to close out and follow up findings from all sources.

5.2 Follow up and Review of Findings

Quality system measurement and monitoring exercises such as internal audit and management review produce findings requiring action on the part of CAB staff. These findings will most likely be either non-conformances, potential non-conformances or opportunities for improvement.

Once raised and recorded within the CAB's continual improvement program, they become corrective and preventive actions the same as for those raised from other quality system identification mechanisms. Within the continual improvement program of the CAB, as with other corrective and preventive actions, the implementation of these actions should be followed up after close out, to determine if they have achieved the desired results.

5.2.1 Sample Format

A sample format of a corrective action, recorded from the internal audit process described in Chapter 4, is shown on the next page. Note that the root cause, corrective action and follow up boxes have been completed for this example.

Date: **16 March 2012**
Serial # **27**
Number of pages attached N/A

Incident and Deviation Report

Note: Only one incident or deviation per report.

Deviation **X** Potential Deviation ☐ Opportunity for Improvement ☐

(Select one ref only) → **X** MOTIVA QMS: *Procedure 9* ☐ External:

1. **Description of the incident or deviation**

No examination of received materials was conducted contrary to Procedure 9.

2. **Description of the immediate remedial action** (remediation) taken, including any correction or prevention

Sign posted in Shipping/Receiving to ensure that all received materials are inspected on receipt.

QM review (initials)	Investigation assigned to	Date:

3. **Is full Corrective/Preventive Action Required?** **Yes**, if there are any "Yes" boxes checked.

	Yes	No	
Is there an unacceptable risk to MOTIVA CAB?	X	☐	*If all answers are "No" then only remediation is required.*
Is the technical validity of MOTIVA CAB results affected?	☐	X	
Is it easier to effect permanent resolution than many little remediations?	X	☐	

4. **Proposed Solution** (and Investigation of Root Cause if required) Date Due: *17 April 2012*

Root Cause(s) of condition: **Not required (eg: remediation only)** ☐
Shipping/receiving staff did not appreciate need to inspect all materials on receipt.

Proposed solution: Corrective Action **X** Preventive Action ☐ Remediation Only ☐
All shipping staff trained on necessity and consequences of receiving inspections. All personnel reminded of receiving inspection procedure.

Investigator's Signature and Date _____, _____

5. **Confirmation of Solution Implementation**

Condition resolved (root cause eliminated/opportunity exploited) **X** Date implemented 13 Apr 2012
Supervisor/Manager Initials QM closure (Initials)

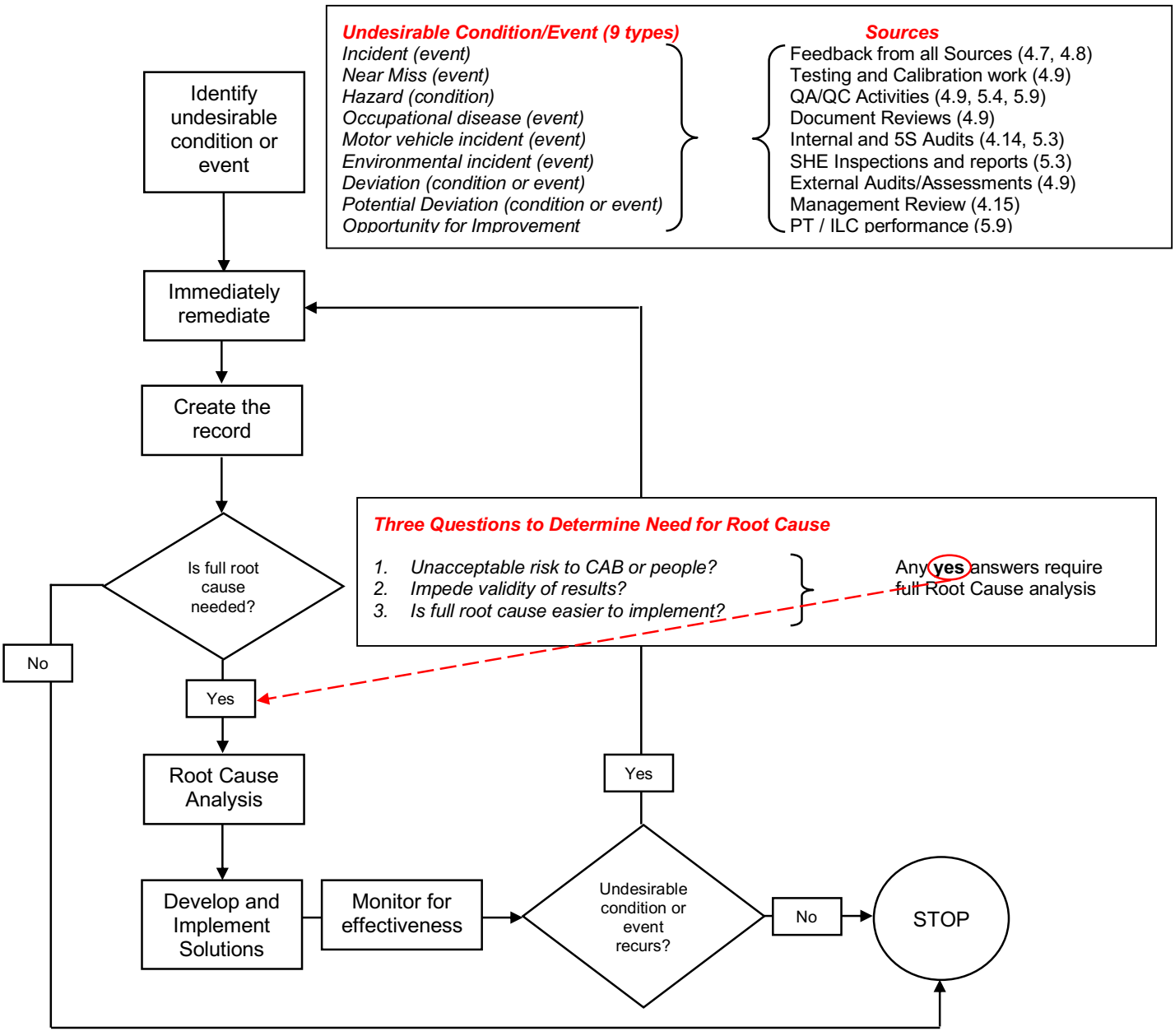
6. **Follow up** Date Due: 16 October 2012

Follow up required? Yes - **X** No - ☐	If not, why not?
Monitoring of condition assigned to:	Date Completed
"Solution is deemed EFFECTIVE." ☐ QM review (Initials)	

5.2.2 Steps to address identified deviating conditions.

Whenever non-conformances, potential non conformances or opportunities for improvement are identified, the CAB may normally address them by either immediate remediation only or by determining the need for full root cause leading to full corrective- or preventive-action.

This chart shows the most common steps taken to go through the process of addressing the identified impediments to producing technically valid results.



Note that the three questions are:

- Does this condition adversely affect my demonstrated competence, such as producing and delivering an invalid result, or potentially doing so?

- Does this condition create unacceptable risk to the organization? This can be most simply derived by determining the impact associated with the non-conforming condition, whether it has already occurred or may occur (potential non-conformance) and multiplying that number by its probability of occurrence.

RISK = IMPACT OF CONDITION X PROBABILITY

- Does full corrective- or preventive-action take less effort and cost to implement than simple (and repeated) correction/prevention?

If any of these questions result in a "Yes", **full corrective- or preventive-action is needed**, starting with an analysis for root cause. If ALL of these questions result in a "No", **no root cause analysis is needed** and simple correction / prevention (even if repeated) is acceptable.

5.2.3 The Goals of Corrective and Preventive Actions

The goals of both corrective- and preventive-actions are to prevent something. For preventive actions, the desired result is the prevention of the first-ever occurrence of a condition deemed to be non-conforming. For corrective actions, the desired result is the prevention of any recurrence of a previously-identified non-conforming condition. Both of these activities are an attempt to eliminate the source (root cause) of the problem.

5.2.4 Corrective and Preventive Action

All technical CAB standards are focused on a CAB's ability to produce valid results (or valid inspections or certifications), and non-conformities within the CAB can be thought of as those circumstances that prevent this. Corrective and Preventive action, therefore, can be thought of as those activities which mitigate the adverse effects of non-conformities – today and tomorrow.

If we understand that potential non-conformances are only the identification of a POTENTIAL or POSSIBLE non-fulfillment of specified requirements, then it becomes much easier to determine the best course of action in their treatment.

The wording in technical CAB standards, as regards corrective and preventive action are getting better with each new edition of these standards. This list below is given in order of the standard moving from the approach used in 17025 to the other CASCO standards:

- ISO/IEC 17025, clauses 4.10 and 4.12,
- ISO 15189, clauses 4.10 and 4.11,
- ISO/IEC 17043, clauses 5.11 and 5.12
- ISO Guide 34, clauses 4.9 and 4.10,
- ISO/IEC 17020, clauses 8.7 and 8.8,
- ISO/IEC 17065, clauses 8.7 and 8.8

The most appropriate version of these concepts used to be contained in ISO 9001:2005 (clauses 8.5.2 and 8.5.3).

> ***8.5.2 Corrective action***
>
> *The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered. A documented procedure shall be established to define requirements for:*
>
> *a) reviewing nonconformities (including customer complaints),*
> *b) determining the causes of nonconformities,*
> *c) evaluating the need for action to ensure that nonconformities do not recur,*
> *d) determining and implementing action needed,*
> *e) records of the results of action taken (see 4.2.4), and*
> *f) reviewing corrective action taken.*
>
> ***8.5.3 Preventive action***
>
> *The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems. A documented procedure shall be established to define requirements for:*
>
> *a) determining potential nonconformities and their causes,*
> *b) evaluating the need for action to prevent occurrence of nonconformities,*
> *c) determining and implementing action needed,*
> *d) records of results of action taken (see 4.2.4), and*
> *e) reviewing preventive action taken.*

Note how the steps in these clauses compare to the six bulleted steps shown at the bottom of the "**Identification to Action**" diagram in Chapter 1 (Section 1.2.2). Note also how these standards are moving to accept that the process for both Corrective- and Preventive-Actions follow the same six steps.

- Root cause analysis
- Determine a range of potential solutions
- Select one
- Implement the selected solution
- Document the implementation
- Monitor the implemented solution for effectiveness

5.3 Addressing Individual Findings

5.3.1 Recognition that something is Missing

The first step in the conduct of either preventive or corrective action is an analysis of the root cause. Root causes are the reason that a non-conformance or potential non-conformance came to exist in the first place. In order to permanently eliminate the adverse condition – its root cause must be identified and then addressed/eliminated.

Organizations often treat non-conformances as "errors" when they are only indications that the quality system is not adequately supporting the work of the people within the system. It is the quality system that needs to be corrected, in most instances – not people.

5.3.2 Looking for the Missing Piece in the Principles of the Standard

At the point of discovery of a non-conformance, or a potential non-conformance, the best approach to take is to recognize that the root of the non-conforming condition is that something is "missing" from the basic list drawn from the set of components needed to operate a conformant CAB. The processes shown in the diagram in Section 1.2 above are backed, in most cases by principles behind each of the technical CAB standards. For ISO/IEC 17065, they are contained in Annex A to that document. For ISO/IEC 17025, they are included in the training materials for this course.

Using the 17025 set of principles, the **Principle of Capacity** provides the elements that must exist for a laboratory to produce technically valid results. They are (from the principle)**:**

People:
- *With the required skills, and*
- *With the required knowledge,*

The Environment:
- *With the required facilities, and*
- *With the required equipment,*

The Quality Control, and

The Procedures

in order to undertake the work and produce technically valid results.

This list provides us with a number of "categories" of root cause and we can select the most appropriate of these as our first approximation of the actual root cause. They are:

- Personnel Factors dealing with the demonstrated skills and knowledge of the persons involved.
- Environmental Factors dealing with the physical plant, facilities, and equipment.
- Quality Factors including quality control and quality assurance, and
- Procedural Factors including the basis and validity for the work being executed.

For the technical CAB standards that rely heavily on demonstrating impartiality, that component must also be present.

5.3.3 Root Causes based on Personnel Factors

The following list groups those root causes falling under the category of personnel factors.

<u>Physical capacity</u>

- Inappropriate height, weight, size, strength, dexterity, reach, aural and visual acuity, etc.
- Restricted range of physical motion
- Restricted physical endurance
- Physiological sensitivities to conditions or substances or breathing or other impairment
- Restricted use of physical senses

<u>Intellectual capacity</u> (Most of these can only be determined by a doctor)

- Fears and phobias
- Emotional instability
- Inability to comprehend and collate

- Inability to exercise judgment
- Lack of situational awareness
- Lack of aptitude
- Memory failure
- Psychological medical disorder or condition

Physical or physiological stress

- Injury or illness
- Fatigue (workload or reduced physical capacity)
- Fatigue (lack of rest)
- Fatigue (sensory overload such as noise)
- Exposure to hazards
- Medication
- Working in confined spaces

Emotional or psychological stress (Most of these can only be determined by a doctor)

- Emotional overload
- Fatigue (workload or speed of work)
- Extreme judgment/decision demands
- Routine, monotony, uneventful demand for vigilance
- Extreme concentration/perception demands
- “Meaningless” or “degrading” activities
- Confusing direction and demands
- Conflicting direction/demands
- Pre-occupation with personal problems
- Frustration
- Psychological medical disorder or condition
- Inappropriate effort to gain attention

Individual skill

- Lack of formal training (initial and follow-up)
- Lack of experience
- Infrequent opportunity to exercise skill
- Lack of coaching
- Lack of review of performance

Individual knowledge

- Lack of formal training (initial and follow-up)
- Lack of experience
- Misunderstood direction
- Lack of situational awareness

Care and attention

- Unintentional improper conduct
- Intentional improper conduct (refusal to exercise care and attention)

5.3.4 Root Causes based on Environmental Factors

The following list groups those root causes falling under the category of environmental factors.

Physical plant and facilities

- Space not correctly sized / oriented for the work
- Lack of physical or other security
- Facility materials / construction / finishes not appropriate to tasks
- Incompatible uses within facility
- Lack of availability of facility
- Lack of appropriate access to facility

Environment

- Inappropriate environment for tasks
- Inadequate control of environmental conditions

Tools and equipment

- Inappropriate tools for tasks
- Inadequate control of tools
- Inadequate use of tools
- Inadequate conditioning / preparation of tools

Materials and supplies

- Inappropriate for tasks
- Inadequate controls
- Inappropriate uses
- Inadequate conditioning/inspection/verification

Plant, facility, tool and equipment maintenance

- Insufficient rigor in maintenance
- Inappropriate types of maintenance
- Inadequate control of maintenance activities
- Inadequate inspection or monitoring

Physical wear and tear on plant, facilities, tools and equipment

- Inadequate planning of use
- Inappropriate use (overloading/overuse/excessive/wrong task)
- Inadequate inspection or monitoring
- Use by untrained / unqualified personnel

5.3.5 Root Causes based on Quality Factors

The following list groups those root causes falling under the category of quality factors.

Quality control

- Insufficient controls

- Insufficient monitoring of controls
- Inappropriate use of information acquired from controls

Quality assurance

- Insufficient quality assurance
- Insufficient monitoring of quality assurance results
- Inappropriate use of information acquired from quality assurance

Quality system

- Inadequate quality planning
- Inadequate monitoring and review of quality system
- Inappropriate use of information acquired from monitoring quality system
- Inadequate implementation of continual improvement
- Insufficient monitoring for effective implementation of system

5.3.6 Root Causes based on Procedural Factors

The following list groups those root causes falling under the category of procedural factors.

Use of standard procedures

- Reference to inappropriate/expired standards
- Insufficient reference to appropriate standards
- Inadequate development of appropriate specifications

Development of specifications and procedures

- Inappropriate specifications included in procedures
- Insufficient use of appropriate specifications in procedures.
- Inappropriate processes to develop procedures
- Inappropriate orientation of procedures
- Insufficient consensus on content

Implementation of procedures

- Insufficient training / communication upon implementation
- Insufficient monitoring for effective implementation

Selection of vendors, personnel, supplies

- Lack of appropriate review of specifications
- Lack of application of appropriate specifications
- Lack of review of acquired supplies
- Lack of review of vendor, personnel performance

5.3.7 Root Causes based on Organizational Culture - Sometimes the issue is Leadership

The following list groups those root causes falling under the category of organizational and leadership factors.

Leadership

- Confusing direction and demands
- Conflicting direction/demands
- Lack of coaching
- Acceptance of (or reward for) non-conforming performance
- Lack of recognition for conforming performance
- Tolerating inappropriate peer pressure
- Inappropriate incentives
- Unintentional improper conduct that is condoned
- Intentional improper conduct that is condoned
- Inappropriate delegation (accountability without authority etc)

Communications

- Lack of review of performance
- Inadequate performance feedback
- Inappropriate treatment of disputes/complaints from all parties (external / internal)
- Inappropriate treatment of feedback from all parties

Motivation

- Reward for non-conforming performance
- Lack of recognition (reward) for conforming performance
- Inappropriate incentives, peer pressure, save time/money/effort, gain attention, etc
- Excessive frustration or aggressiveness

While the lists above are fairly comprehensive, they do not by any means cover all possible root causes. This list of missing pieces describes the holes in a quality system whose absence is a cause of non-conforming conditions. The most common missing pieces have to do with procedures, quality controls, and leadership. Organizations often treat non-conformances as “errors” when they are really just indications that the quality system is not sufficiently supporting the work of the people within the system.

The most common causes for this condition is its leadership and the organization culture that emanates from the leadership. Organizational culture and leadership are, therefore, the final category for root cause considerations.

There is a catch to this final category, however. If the root cause of a non-conformance can be traced back to something missing in either the culture or leadership of the organization, it may be very difficult to have this root cause accepted.

5.3.8 Solutions that fit

Once the actual root cause of the non-conforming condition has been determined, the work in developing solutions (corrective / preventive actions) must focus on eliminating the root cause.

Corrective action is aimed at preventing recurrence of an identified non-conformance. Preventive action is aimed at preventing the first-time occurrence of a potential non-conformance.

Examining the approach described in Lesson 1 (Section 1.4.5), the determination of root cause is most appropriately followed by the identification of a set or spectrum of solutions – any of which will address the root cause. This choice of potential solutions is impersonal and may be developed independent of others.

The actual selection of the corrective / preventive action solution, however, is entirely dependent on others and their input. Solutions implemented in isolation do not last. People who work in isolation to develop and

implement solutions are not considering how others work within the quality system. The solutions developed will not support the work of those people who actually implement the affected portion of the quality system. The same, or similar, non-conformances may occur again.

The most appropriate approach for the selection of the corrective / preventive action addresses the actual root cause and will endure. This approach involves the development of consensus within the group expected to implement the selected corrective / preventive action. Consensus makes the solution stronger and allows others to identify problems and take preventive action as similar conditions are encountered following implementation. These types of solutions actually prevent recurrence of non-conformances.

Organisations attempting to develop systematic approaches in this area should consider the following steps:

1 Develop a set of potential solutions, all of which address the identified root cause,

2 Determine the solution that best meets the needs of those affect by the root cause condition and those that will be required to implement it. Develop consensus.

3 Select the solution agreed by all.

5.3.9 Documenting the Effort

A comprehensive quality system can work best when the CAB treats non-conformances and potential non-conformances in a congruent fashion, understanding that these two conditions are the same – except for the time of their occurrence.

Accepting this, the records created for one, can also use the same format as the other. The sample provided in this lesson can be used for any non-conformance leading to corrective action, any potential non-conformance leading to preventive action and any opportunity for improvement leading to preventive action.

5.4 Monitoring, Follow up and Timelines

Clause 4.11.4 of ISO/IEC 17025 requires the monitoring of corrective actions to ensure that, at some later date, the CAB is able to determine that a particular corrective action has eliminated a root cause. Clause 4.11.5 then requires additional audits whenever a non-conformance casts doubt on the CAB's conformance to requirements. Follow up activities allow a CAB to determine that the implemented action did what was required.

These monitoring and follow-up activities are required to complete the corrective action and preventive action processes. Best practice in continual improvement for corrective and preventive action therefore includes a mechanism for tracking monitoring and follow-up. See the last box on the sample ICAR.

Monitoring and follow up is aimed at a formal consideration of the effectiveness of implemented corrective and preventive actions. The simplest method of doing this is to set a date, at some time in the future, to examine the condition to see if the corrective action has effectively eliminated the underlying root cause.

This method provides semi-automatic triggers to bring the issue forward at some time in the future – and can be well supported by database applications.

5.5 Exercise No. 4 – ADDRESSING THE FINDINGS

Learning Objectives:

- practice examination of findings to determine the need for root cause,
- practice determining root causes, and

- practice determining solutions (corrective and preventive actions).

Exercise Objectives:

Your group consists of the designated team from the sections within MOTIVA CAB that has just undergone an internal audit. Following on from Exercises Numbers 1, 2 and 3, you are now prepared to address the findings from the report. Your team will now examine the findings and conduct the analysis in order to determine any remediation, and the need for corrective or preventive action. As well, any solutions implemented are to be recorded. Use the attached format.

Exercise Preparation – 60 minutes

Your group is to accomplish the following using the attached forms provided to you for this purpose:

- You are to write the remediation for one or two of the findings raised during Exercise Number 3.
- You are to determine any remediation.
- You are to determine the need for implementing full corrective or preventive action.
- If full corrective or preventive action is needed, you are to determine the root cause.
- You are to determine an appropriate solution (corrective or preventive) action to address the identified root cause.

Exercise Deliverables – 15 minutes per group

Each group is to present their solutions to the other groups (representing the other auditees) and your facilitator (representing the quality manager). All relevant aspects of the solution are to be presented.

Presentation and Group Discussion – 30 minutes

Once all presentations are complete, the class will discuss the issues arising, and the salient points to retain.

Date: _____
Serial # _____
Number of pages attached _____

Incident and Deviation Report

Note: Only one incident or deviation per report.

Deviation ☐ Potential Deviation ☐ Opportunity for Improvement ☐

(Select one ref only) → ☐ MOTIVA QMS: _____ ☐ External: _____

1. Description of the incident or deviation

2. Description of the immediate remedial action (remediation) taken, including any correction or prevention

QM review (initials) _____	Investigation assigned to _____	Date: _____

3. Is full Corrective/Preventive Action Required? **Yes**, if there are any "Yes" boxes checked.

	Yes	No	
Is there an unacceptable risk to MOTIVA CAB?	☐	☐	*If all answers are "No" then only remediation is required.*
Is the technical validity of MOTIVA CAB results affected?	☐	☐	
Is it easier to effect permanent resolution than many little remediations?	☐	☐	

4. Proposed Solution (and Investigation of Root Cause if required) Date Due: _____

Root Cause(s) of condition: **Not required (eg: remediation only)** ☐
Proposed solution: Corrective Action ☐ Preventive Action ☐ Remediation Only ☐
Investigator's Signature and Date _____, _____

5. Confirmation of Solution Implementation

Condition resolved (root cause eliminated/opportunity exploited) ☐	Date implemented _____
Supervisor/Manager Initials _____	QM closure (Initials) _____

6. Follow up Date Due: _____

Follow up required? Yes - ☐ No - ☐	If not, why not?
Monitoring of condition assigned to: _____	Date Completed
"Solution is deemed EFFECTIVE." ☐	QM review (Initials) _____

Date: _____
Serial # _____
Number of pages attached _____

Incident and Deviation Report

Note: Only one incident or deviation per report.

Deviation ☐ Potential Deviation ☐ Opportunity for Improvement ☐

(Select one ref only) → ☐ MOTIVA QMS: _____ ☐ External: _____

1. Description of the incident or deviation

2. Description of the immediate remedial action (remediation) taken, including any correction or prevention

QM review (initials) _____	Investigation assigned to _____	Date: _____

3. Is full Corrective/Preventive Action Required? **Yes**, if there are any "Yes" boxes checked.

	Yes	No	
Is there an unacceptable risk to MOTIVA CAB?	☐	☐	*If all answers are "No" then only remediation is required.*
Is the technical validity of MOTIVA CAB results affected?	☐	☐	
Is it easier to effect permanent resolution than many little remediations?	☐	☐	

4. Proposed Solution (and Investigation of Root Cause if required) Date Due: _____

Root Cause(s) of condition: **Not required (eg: remediation only)** ☐
Proposed solution: Corrective Action ☐ Preventive Action ☐ Remediation Only ☐
Investigator's Signature and Date _____, _____

5. Confirmation of Solution Implementation

Condition resolved (root cause eliminated/opportunity exploited) ☐	Date implemented _____
Supervisor/Manager Initials _____	QM closure (Initials) _____

6. Follow up Date Due: _____

Follow up required? Yes - ☐ No - ☐	If not, why not?
Monitoring of condition assigned to: _____	Date Completed
"Solution is deemed EFFECTIVE." ☐ QM review (Initials) _____	