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3024 – IAS Lead Assessor Course

COURSE HANDBOOK

Based on: ISO/IEC 17025, or ISO/IEC 17020, or ISO/IEC 17065

Rev 3

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1.0 Chapter 1 - Introduction

1.1 Course Development

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1.2 Course Description

This course is aimed at Assessor Candidates who wish to participate in the assessment of competence of applicant and accredited laboratories within the Accreditation Program of an accreditation body recognised by either the International CAB Accreditation Cooperation (ILAC) or the International Accreditation Forum (IAF).

Conformity assessment bodies (CABs = labs, certification bodies, inspection bodies) are increasingly required to be accredited to meet regulator competence requirements. Accreditation bodies that are signatory to ILAC and IAF arrangements provide these services to CABs.

This course will provide information to persons technically competent in a conformity assessment discipline so that they may participate in the overall effort to formally recognize the demonstrated competence of CABs within the context of an internationally-recognized accreditation program.

1.3 Course Learning Objectives

The course will assist participants to:

- **appreciate** the global context of accreditation.
- **determine** the rationale behind CAB accreditation, and
- **determine** how a CAB can structure its quality system to meet organizational goals.
- **identify** appropriate methods for demonstrating continuing competence of personnel.
- **identify** the accommodation and equipment resources required to support the quality system.
- **determine** the most appropriate means for implementing quality control and quality assurance.
- **identify** the requirements of a conformant quality system.
- **understand** the requirements for the conduct of assessments.
- **understand** the requirements for the conduct of assessors.
- **understand** the methods used to document capacity and competence.
- **understand** techniques in identifying non-conformances and opportunities for improvement.
- **manage** opening meetings, closing meetings, and interviews of CAB personnel.
- **document** observations and classify resulting findings.
- **write** assessment reports that are the product of assessments.
- **identify** CAB approaches in recognizing NCs and OFIs.
- **explain** the concepts of corrective and preventive action.
- **identify** the most effective methods for implementing continual improvement.
- **determine** how to close out and follow up findings from all sources.
- **close** out and follow up findings from all sources.

1.4 Completing the Course

The course material is broken down into Chapters. Each Chapter is a method of making use of the tools and techniques provided to participants of this course. Directions are provided to guide you through the reading materials, other reference materials, and work to be completed.

The list of readings for this course includes this **Course Training Binder** and the material contained in the **Assessor Reference Materials**. This course includes several practical exercises and finishes with a formal examination of participant knowledge acquired during the training. See 1.6 below.

1.4.1 All Labs are CABs, but not all CABs are Labs.

A CAB is a Conformity Assessment Body, which conducts testing, calibration, inspection, certification, provision of proficiency testing services, certification, and the production of traceable reference materials. A CAB is more than a CAB and will be referred to that way, in the course material, because the context of the information surrounding that name applies to more than CAB issues, such as general QMS issues that can apply to any CAB.

However, a CAB is a CAB and is named that way, in the course material, because the context of the information surrounding that name specifically applies solely to CAB issues, such as ISO/IEC 17025, which we wrote only for labs.

1.5 Course Content

This course has eight Chapters. They are all focused on the development of specific assessor skill sets.

The syllabus for this course is as follows.

Chapter 1 – Introduction

- Global context of accreditation
- Pre-course Exercise

Chapter 2 – Assessment Basics

- Assessment philosophy and techniques
- Assessor Materials and their Use
- Requirements of Assessors
- Exercise 1 - Using Assessor Tools
- Assessor Behaviours - Good and Bad

Chapter 3 – Assessment Planning

- Planning an Assessment of a lab
- Document Review
- Exercise 2 - Conduct a document review
- Onsite Assessment Activities
- Exercise 3 - Planning an Assessment

Chapter 4 – Meetings and Interviews during an Assessment

- Preparing for Meetings and interviews
- Exercise 4 - Conduct an Opening Meeting
- Exercise 5 - Conduct Interviews of staff

Chapter 5 – Assessment Findings

- Classifying and writing assessment findings
- Exercise 6 – Classify and Write Assessment Findings

Chapter 6 – Assessment Reports

- Assessment report requirements
- Exercise 7 - Write and Deliver the Assessment Report

Chapter 7 – Addressing Assessment Findings

- How labs close out assessment findings.
- Use of RBT and Continual Improvement
- Determining the need for Root Cause
- Finding the Root Cause
- Exercise 8 - Develop Solutions that address the Root Cause

1.6 Course Grading

This course involves the grading of participants based on two measured criteria:

- All participants are required to successfully complete all exercises provided throughout the course. The exercises used emulate real-life situations where an assessor's ability to create solutions and work with others are keys to successful assessments. There is no grading for this effort, only successful completion. If needed, participants may retake these exercises whenever an attempt is not successful.
- All participants are required to achieve a passing grade of 70% on the Final Exam to obtain a Certificate of Successful Completion.
- All participants are eligible to receive a Certificate of Participation.

1.7 Your Personal Course Objectives

Take a few moments to write down your own course objectives. During the in-class and live webinar sessions of this course, your facilitator will document these with all participants at the beginning of the course and refer to them often throughout the course. You will be asked to rate your facilitator's ability to help you attain your personal objectives, using the Facilitator Evaluation form enclosed at the inside back cover of the binder.

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1.7.1 Participation

This course is an intensive endeavour for all participants. Full attendance is expected for a participant to receive a certificate of successful completion. For the self-paced online training version, successful completion of all parts, including reviewing all presentations, is required to take the exam.

1.7.2 Assignments

Homework assignments are part of this course, and participants will be expected to complete their assignments before the next phase of training.

1.8 Pre-Course Exercise – Course Preparation

1.8.1 Learning Objectives

- **read the applicable standard** - ISO/IEC 17025, or ISO/IEC 17020, or ISO/IEC 17065

1.8.2 Pre-Course Exercise Scenario

You are preparing to take a Lead Assessor Course. You must come prepared to this course because the exam is very difficult to pass.

1.8.3 Pre-Course Exercise Objectives

- You are required to read the applicable conformity assessment standard, ISO/IEC 17025, or ISO/IEC 17020, or ISO/IEC 17065.

1.8.4 Pre-Course Exercise Preparation

You are to accomplish the following:

1. You are to respond to the Pre-Course Quiz.

2. You are to participate in marking the Pre-Course Quiz during the first day of training.

1.8.5 Pre-Course Exercise Deliverables

You are to submit your Pre-Course Quiz answers.

1.8.6 Presentation and Group Discussion – 30 minutes

The Pre-Course Quiz will be discussed and scored by the entire group.

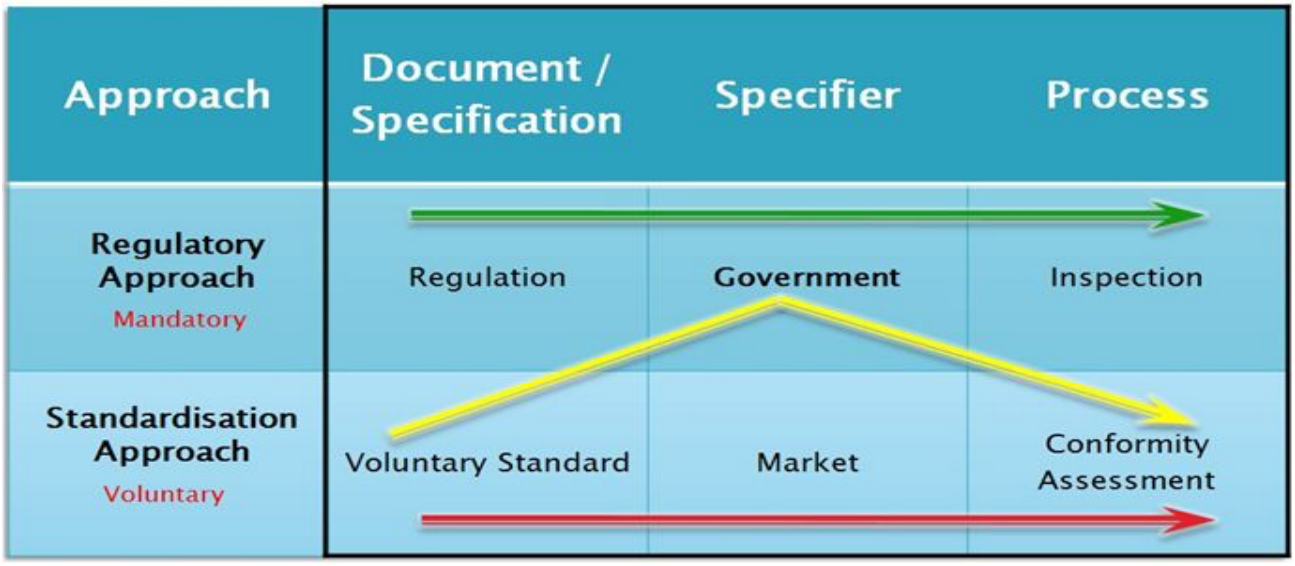
1.9 Global Context of Accreditation

1.9.1 The Structure of Standardization – From Specification to Competence

Within each nation, there are normally two approaches in determining which regulatory and market requirements must be met, and how they shall be met. The first step is the development of the specification. See the chart below. It shows the differences between the two main approaches used by regulators and/or market sector specifiers to execute their primary responsibility, "protecting the health, welfare and safety" of citizens within their jurisdiction.

Internationally, the ISO, the IEC, the ITU and other internationally recognised standards development organisations facilitate the development of consensus-based voluntary conformity assessment standards. Within the USA, organisations such as ANSI, ASTM, IEEE, AWWA, USP, NCSLI, AASHTO, AOAC, ICBO and others also facilitate the development of standards to be applied internationally. Each nation has its own systems and standards development institutions for such work.

The following graphic shows the differences and similarities between standards and regulations



The green line at the top shows how a government develops a regulation, then specifies its use, and finally enforces it through inspection. Examples may include current regulatory inspection programs used by the regulatory agencies and the laws used in the enforcement of criminal laws.

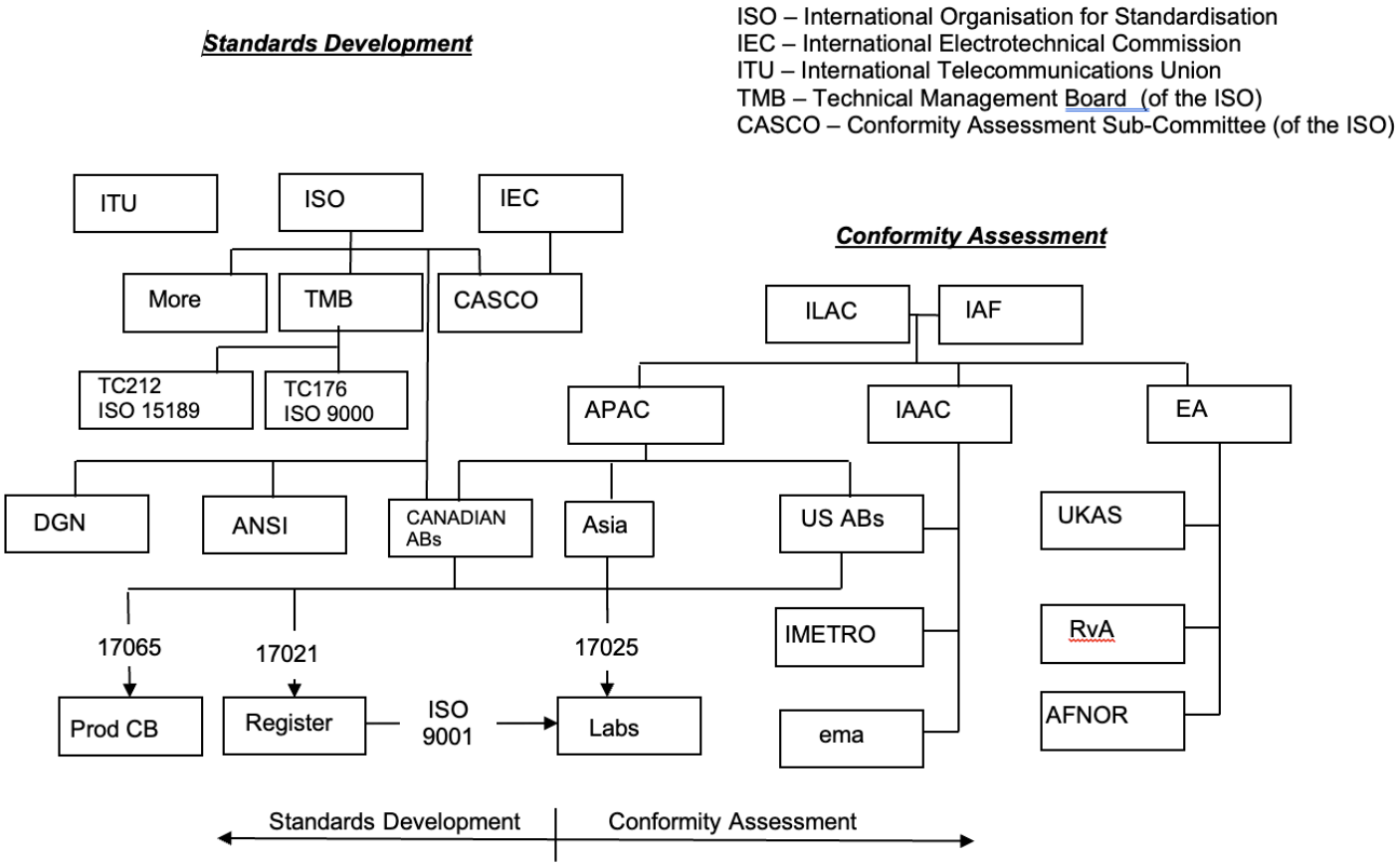
- The red line at the bottom is an example of how ISO 9001 (and ISO/IEC 17025, or ISO/IEC 17020, or ISO/IEC 17065) are normally delivered without any regulator specification – "by the market, from the market, and for the market". These standards were developed from within their own communities. All were developed internationally and included the input of their clients and other stakeholders, including governments. They are delivered using voluntary conformity assessment techniques.

- The solid line (green) in the middle represents how a government can specify a voluntary standard. ISO/IEC 17025, or ISO/IEC 17020, or ISO/IEC 17065 and relevant guidelines are delivered today to CABsd, which, if they wish to do business in some specific fields, must meet regulatory requirements for accreditation. These are now part of regulatory tool kits in the protection of the health, welfare, and safety of citizens of many nations around the world. The most common uses are for environmental testing in support of environmental protection regulations, food testing, and testing in areas where safety is paramount.

The three components (Specification, Specifier, Process) involve:

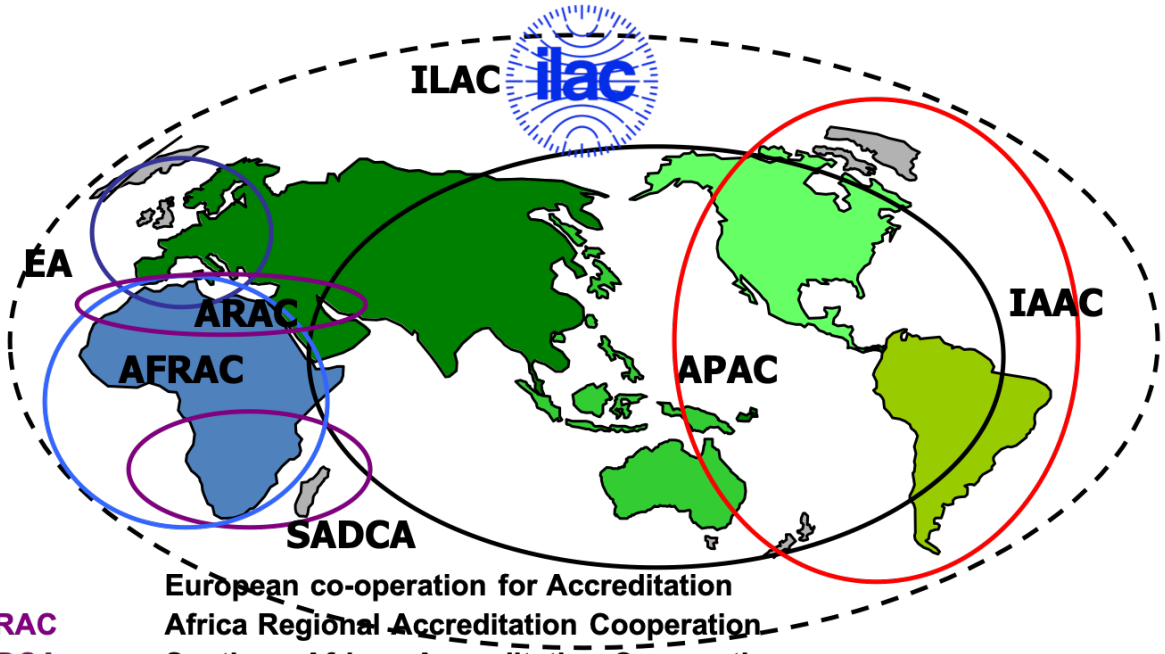
- writing something that can be used to determine acceptable behaviour (standard or regulation),
- specifying the necessity for this behaviour (the market or some legislation), and
- determining how to evaluate performance against the specification (inspection or conformity assessment).

1.9.2 International Structures of Standards Development and Conformity Assessment



1.9.3 Mutual Recognition of Accreditations

This diagram shows the coverage of the mutual recognition arrangements made that allows member bodies to recognise the “equivalence” of each other’s accreditations.



EA	**European co-operation for Accreditation**
AFRAC	**Africa Regional Accreditation Cooperation**
SADCA	**Southern African Accreditation Cooperation**
IAAC	**Inter-American Accreditation Cooperation**
ARAC	**Arab Regional Accreditation Cooperation**
ILAC	**International Laboratory Accreditation Cooperation**
APAC	**Asia Pacific Accreditation Cooperation**

1.9.4 Documents that Accreditation Bodies use to set Requirements

All accreditation bodies will provide specific criteria on certain aspects of demonstrated competence. They will include accreditation policies regarding the following, amongst others:

- Metrological Traceability (ILAC P10 and P14)
- Interpretation of ISO/IEC 17020 (ILAC P15)
- Proficiency Testing and Inter-CAB Comparison (ILAC P9)
- Uncertainty of Measurement
- Method Validation
- Detection Limits and Acceptable range of measurement
- Internal Audit / Management Review
- IAF Mandatory Documents for many issues involving certification
- Use of IT

1.10 Common Management System Concepts

1.10.1 Definitions

ISO 9000 defines "Quality Management System" as:

> "*set of interrelated or interacting elements to establish policy and objectives and to achieve those objectives so as to direct and control an organization with regard to quality."*

The quality system can be the articulation of the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management. While ISO 9000 does not necessarily require documentation for all these things, conformity assessment standards make it clear that a conforming CAB must document everything. It should be noted that the differentiation between a "quality manual" and "complete system documentation" is very, very small. However, the quality system documentation should only be as comprehensive as needed to meet the quality objectives.

1.10.2 Representation of a Basic QMS System

From the definitions given above, it is easy to appreciate that a quality system (or quality management system) is really the *who, what, when, where, and how of supporting the CAB's production of valid results and decisions*.

A documented quality system (quality manual and supporting procedures) can also be described as a *set of rules to live by…and how to live by them*, including the organization, functioning and inter-relation of the resources, and policies and procedures necessary to carry out the quality objectives.

1.10.2.1 What it Might Look Like

This diagram below demonstrates a common approach to the structure of a quality management system. But it is not the only way to do so.

This diagram is only one way of representing a documented and structured quality system. ***Course participants should not consider this representation as the only acceptable one, or even the "best" one***.

Each CAB should develop and implement the system they need, based on their own technical and organisational requirements and SHOULD NOT just consider this diagram as a preferred approach.

1.10.3 Three Approaches to Consider in Documenting a Quality System

There are three main approaches to consider in documenting a Quality System that seeks to be conformant to a conformity assessment standard, in a Quality Manual.

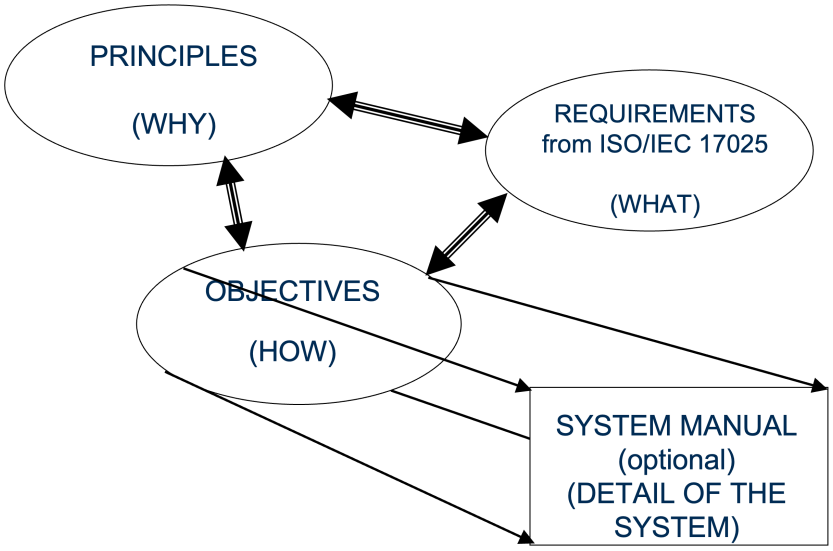
- By Requirement. One approach is to simply state the requirements of the applicable standard and then document how each requirement shall be met within the CAB. This approach has the advantage of making use of the exact wording from the standard to structure the resulting Quality Manual on the skeleton provided by the standard. Its major failing is a Quality Manual that has been built for assessment and assessors, rather than for use within the CAB. It is very **user-unfriendly,** but it is the approach **most used** by developers of management systems.
- By Principle. The second approach is the development of a Quality Manual based on the principles behind the standard – either the ones behind 17025, or the ones contained in Annex A to 17065 that apply to all

other CABs. This approach has the advantage of not getting bogged down in the detail during the development of the Quality Manual. Its major disadvantage is that some stated requirements may be missing from the resulting Quality Manual because it may not be obvious that the missing requirement belongs within one or more of the principles. There are no recorded cases of this approach ever being used – with good reason. It is not appropriate to base a system on principles, instead of actual organisational needs and the requirements given in the reference standard.

- By Objective. The third approach is one that focuses on the **effort** required by the CAB to meet the stated requirements in the standard. This approach makes use of a strategic planning concept called Key Result Areas (KRAs). The resulting Quality Manual starts with broad objectives, the attainment of which allows the CAB to focus its efforts on implementing acceptable solutions. The one disadvantage to this approach is that some care must be exercised to ensure that **ALL** requirements are covered by the stated objectives. However, it is the approach that provides the greatest benefit to the CAB and its people.

The best way to understand these three approaches is to appreciate that they are simply different ways of viewing the requirements given in the standard. They are neither mutually exclusive, nor does one naturally fall from another. The requirements remain unchanged, but they can be thought of as either the result of the "principles" or the force behind the "objectives."

The association (linking) of the three concepts can be pictured as follows:



1.10.3.1 Making use of the Objectives

Each Section of a CAB Quality Manual can deal with one specific Quality Objective. A Quality Objective can be given at the beginning of each Section of the Quality Manual. The remainder of each Section would then deal with the policies, procedures, resources, organization, and overall effort needed to accomplish that stated objective. This approach focuses the CAB effort on the individual and collective work required to accomplish each objective.

1.10.4 Organization, Management, and Management System

This introductory set of requirements in the applicable conformity assessment standards deal with the structure and organization of the CAB. Requirements in Clause 5 include:

- Legal identification of the CAB and its organization.
- Stipulation to meet regulatory requirements
- The necessity to IDENTIFY and DOCUMENT potential conflicts of interest and how to deal with these

Additional documentation requirements include policies and/or procedures to address Impartiality and Confidentiality.

Finally, clause 8 deals primarily with the documented Quality System and its associated quality system documentation (Quality Manual). Initially it requires the CAB to establish an overall quality policy.

1.10.5 Documentation and Document Control

ISO 9001:2015 requires an organization to produce documentation in only six places. Conformity assessment standards require ALL CAB policies and procedures to be documented.

The requirements for document control are contained in a document control clause. The overriding aim for document control is to ensure:

> *All persons who need to use a document in the conduct of their work have access to it and only the most appropriate version of it is available.*

1.10.6 Development, Approval, and Issue of Documentation

Policy and procedure documentation that is developed to meet the aim stated above is best produced when the process used in its development is understood by all staff. It is best conducted by those persons whose responsibilities are aligned with policies and procedures that are the subject of the documentation.

The following are the normal steps that will produce quality system documentation with the least amount of difficulty:

- Identify the people most responsible for the policy or procedure that is the subject of the document.
- List the requirements of the policy or procedure such as its objective or the objective of any higher-level policies or procedures.
- List any factors that may affect the policy or procedure such as scope and related considerations (who, what, where, how, when)
- List the contributors to the policy or procedure (Resources = People, Environment, QC, Procedures)
- Organise these four sets of thoughts into an approach to meet the stated objective. This can be the first draft of the desired policy or procedure.
- Circulate this section to all the people responsible for any of the activities given within the document. Seek their consensus. Have them add up the resources required to meet the stated objective (including time).
- Resolve conflicts and produce a second draft.
- Circulate the second draft and develop more consensus.
- Develop the final draft from the consensus established.
- List the documentation requirements of the policy or procedure
- Formalise and document (records) the approval, issue and distribution of the documented policy or procedure.

The simple aim behind the approval process described above is to ensure that the resulting document (policy or procedure) is approved by the appropriate level of authority within the CAB – and that this same level of authority will continue to exercise responsibility for it by having participated in the decision to develop and issue it.

1.10.7 Maintenance and Modification of Management System Documents

Whether the document produced is a quality manual, a high level policy, a procedure applicable over the whole organization or a detailed technical procedure focused on a specified narrowly-defined process, it must be distributed to all persons who need access to it for their work. Such distribution can include paper copies or electronic formats, provided that "*only the most appropriate version of it is available."*

Normally, the organization records the location and version of each copy. This can be done using a Master List which can record the location and version of all documents that are part of the CAB quality system, **including external documents that are referenced anywhere in the CAB quality system.** This Master List can be paper or electronic in nature – such as the simple list of documents in an appropriate folder on a commonly accessible network drive.

Amendments to documents can be simplified, compared to the formal approval and issue procedure described above, but the results must carry the same level of approval authority and support attached to the original.

Handwritten amendments are also permitted, so long as ALL copies of the amended document are also amended, pending formal modification of a revised version. If this is not possible, then only formal amendments should be allowed, and handwritten amendments should not be authorised.

When all the elements of Section 4.5 here are in place in a CAB, it is possible to identify the location and version of all issued documents, conduct amendments, ensure version control, and facilitate appropriate amendments.

1.10.8 Withdrawal and Archiving of Documentation

The easiest way to consider the processes needed to withdraw a document from service is to consider that it is being amended or modified such that it shall no longer be used. Records such as the Master List are modified to indicate that change, just as if it were being amended or updated.

Document and record retention, once a document has been withdrawn, depends on whichever specification is the longest. This may come from a regulatory authority, the Province/State of the CAB, the Federal Government, or any other specifier, such as a professional association. Whichever is the longest is the one that should be used by the CAB.

1.10.9 Records, Record Keeping, and Control of Records

Conformity assessment standards require a CAB to record the results of ALL CAB activities related to the conduct of their work. The overriding aims for the generation and control of records are to:

> *Produce and control appropriate evidence of the conformant implementation of requirements. In other words, "records" allow laboratories to demonstrate that "documents" have been followed. and*
>
> *"to facilitate, if possible, identification of factors affecting the measurement result and its associated measurement uncertainty and enable the repetition of the CAB activity under conditions as close as possible to the origin."*

1.10.9.1 Generation and Retention of Records

Once a record is generated, it is normally controlled the same way as a document, in that it must be stored to protect it from deterioration, unauthorised viewing, and unauthorised amendment.

Records are best produced when the processes used in their development are understood by staff conducting their generation and normally the result of specific recording procedures. These may include specific formats, into which data can be placed to become records. The original controlled formats are part of documents, and only become records when the observed data is inserted into each format.

Records are best generated by those persons whose responsibilities are aligned with the documented procedures containing the controlled recording format.

The simple aim behind the generation process described above is to ensure that the resulting record is generated by the appropriate level of authority within the CAB – and that this same level of authority can exercise responsibility for the generated record.

1.10.9.2 Maintenance of Records

Once generated, and the information has been manipulated and used in the production of reports, records are normally stored for future reference. Such storage can include paper copies or electronic formats.

Amendments to records must identify the person (with the authority to make the change) and allow the CAB to track the original observation through the change and when such change occurred. Handwritten amendments are also permitted, with the same provisos.

1.10.9.3 Archiving of Records

Unlike documents, records are not "withdrawn" from service. Records are normally archived when the CAB no longer needs immediate access. When their information is no longer required, they can be destroyed.

The timelines for archiving and destruction should follow the same criteria as for Document Control (8.3). The CAB should use whichever is the longest specifications that apply from regulatory authorities, Provincial or State regulations, Federal regulations, or any other specifier, such as a professional association.

1.10.10 IT used to Support CAB Operations

Many CABs make use of electronic systems (computers and software - information technologies-IT) that:

- Support the operation of equipments used in conformity assessment operations.
- Support the collection, manipulation, and reduction of data.
- Support the storage, retrieval, amendment, archiving and transmission of data, documents, and records.
- Support the development of quality system documents and records.

1.10.10.1 General Guidelines

General guidance on acceptable and appropriate methods for making use of IT in support of testing are the most common ones intended from the standard:

- Ensure the continuing validation of software used in measurement equipment.
- Ensure the continuing integrity of electronic data, documents, and records.
- Ensure the continuing confidentiality of electronic information.
- Ensure adequate control and tracking for the amendment of electronic documents, data, and records.
- Ensure the continuing retrieval of electronic data, documents, and records.

The following are the areas that would normally be addressed by electronic system policies and procedures in use at accredited laboratories:

- Integrity and control of electronic data
- Validation of information technology solutions, including software and applications
- Confidentiality/security of information – access control
- Retrieval of electronic data, documents, and records
- Maintenance of electronic systems in all forms to support CAB operations.

1.10.10.2 Validation of IT Systems

The validation of computer-based applications is the result of measures taken to validate the ability of the applications to perform as specified. Specifications can vary from simple word-processing applications to complex algorithms in dedicated measurement applications, such as Coordinate Measuring Machines (CMM). Some conformity assessment standards indicate that validation of commercial off-the-shelf software does not apply to computing applications that are used to collect, manipulate, or reduce data.

CABs should develop and implement procedures to formally document the validation of computer systems (software and applications) in support of CAB operations. Such validation should be commensurate with each type of computer-based solution used in the CAB and its intended purpose and scope.

- See paper by Gregory D. Gogates, A2LA Assessor, member EA ad-hoc group on the use of computers, "Software Validation in Accredited Laboratories," 27 Sep 2001

- Determine the level of validation required for the electronic system (hardware, firmware, or software, or parts of all of them) from its classification as Commercial, Commercial-user-modified, or User-developed.
- Document the validation process used. See Figure 3 of "Software Validation in Accredited Laboratories."
- Monitor the continuing validation of the electronic system throughout its life cycle in the CAB. See Figure 1 of "Software Validation in Accredited Laboratories."

1.10.10.3 Integrity and Control of Data, Documents and Records

The integrity and control of electronic data, documents and records may depend on the measures taken for their protection from inadvertent or unauthorized amendment and of their direct correlation to original data, documents, records, and observations.

Accredited CABs should develop and implement procedures to prevent the inadvertent and/or unauthorized amendment of computer software, electronic records, documents, and data. The procedures should stipulate the steps to be taken to formally amend computer software, electronic data, documents, and records.

- Controlled access to software, electronic records, documents, and data.
- Create multiple roles that read-only or read-write.
- Specify the persons who are normally granted access.
- Use of user ID and/or passwords
- Use of read-only storage media
- Clear and simple procedures to modify software, documents, records, and data that provide the tracking information for amendments, which normally includes the identity of person amending, date and time of amendment, identity of person approving amendment (if applicable), date and time of approval include the reason(s) for change.
- Backups of current versions, to allow restoration to current condition, if current storage media discontinues normal retrieval access.
- Consider migration of data to new media types during the record retention period.

1.10.10.4 Confidentiality/Security of Information – Access Control

The security of software and electronic information, regardless of its configuration as data, records, or documents, is the result of measures taken to protect it from unauthorized access, viewing and dissemination.

Accredited CABs should develop and implement procedures to provide adequate protection for software, electronic records, documents, and data to prevent access and viewing by unauthorized persons. Such protection should be commensurate with each type of record, document or observation/data point collected, stored, or maintained by the CAB.

- Controlled access to software, electronic records, documents, and data.
- Specify the persons who are normally granted access.
- Use of passwords or "digital signatures."
- Tracking of access to software, electronic records, documents, and data
- Use of increased levels of security, such as Public Key Infrastructure (PKI), or other types of encryptions, in the transmission and receipt of electronic records, documents and data.
- Use of "firewalls" to control external access
- Assurance that electronic signatures are permanently linked to specific instances of data.

1.10.10.5 Retrieval of Electronic Data, Documents and Records

The retrieval of electronic data, records, or documents is a continuing measure of its availability, both during and after its use within the CAB.

Accredited CABs should develop and implement procedures to provide adequate facility for the continuing retrieval of electronic records, documents, and data to permit access and reference to such records, documents, and procedures for as long as the CAB may require such access and reference.

- Off-site storage
- Use of formats that are likely to be used in the future such as Adobe Acrobat (*.pdf) format or XML format or ASCII format.

- Use of media that are likely to be used in the future such as CD-ROM
- Ensure migration of data when it needs to be transferred to new media.
- Use of an appropriate method of indexing archived data to facilitate ease of retrieval

1.10.10.6 Maintenance of Electronic Systems (Computers/Software)

The maintenance of electronic systems (software and applications) in a CAB is a measure of the ability of the CAB to monitor the performance of all the components of the electronic system and effect preventive and corrective actions on their use.

Accredited CABs should develop and implement procedures to affect the maintenance of electronic systems (software and applications), which may include software, firmware and/or hardware, to prevent non-conforming operation of the electronic system. See paper by Gregory D. Gogates, A2LA Assessor, member EA ad-hoc group on the use of computers, "*Software Validation in Accredited Laboratories,"* 27 Sep 2001

- Operation by trained and qualified personnel
- Preventive maintenance schedules for hardware.
- Document the validation process used. See Figure 3 of "Software Validation in Accredited Laboratories."
- Monitor the continuing validation of the electronic system throughout its life cycle in the CAB. See Figure 1 of "Software Validation in Accredited Laboratories."
- Inclusion of electronic systems within CAB calibration program, as required.
- Identification of triggers to re-validate that define when re-validation needs to occur and the level of detail required.

1.11 Measuring and Monitoring a 17025 Management System

1.11.1 The Need for Measurement

When an organization wishes to see how well an instrument is performing, it is submitted for calibration. Its ability to measure is compared to another instrument of known measurement uncertainty (performance). This comparison is called calibration.

The same approach applies to a CAB quality system. To determine if the quality system is performing as required, it must be measured. This measurement is generally in the form of an internal audit.

Normally, internal audits have two specific goals.

- The first is to measure the effectiveness of the system to determine if it conforms to requirements and adequately supports the ability of the CAB to produce technically valid results.
- The second aim of an internal audit is to determine if the system allows people to identify PNCs and OFIs.

An internal audit is the best tool an organization can use to determine how well the quality system is functioning, but it is only one of the inputs placed before top management in monitoring how well it supports the operations of the organization.

Conformity assessment standards normally separate these measurement and monitoring functions into two clauses, *Internal Audits* and *Management Review*. Note that an internal audit and an external assessment have very different aims.

- An external assessment is to determine the competence of the organization to produce technically valid results and concentrates on the requirements of the standard.
- An internal audit concentrates on the requirements articulated in the organization's own quality system.

1.11.2 International Requirements

In North America and throughout the Pacific Rim nations, assessment of CABs is restricted by the distances involved. The assessment cycle of accreditation bodies in these areas is two years. In Europe, it is generally one year.

However, current versions of conformity assessment standards have verying requirements for the frequency of either the internal audit or the management review activities. CABs that select a one-year frequency do not

need to demonstrate more evidence of risk analysis associated with their frequency. Those that select another frequency may wish to consider gathering and maintaining evidence of the appropriate analysis of risk to CAB operations associated with such a decision.

1.11.3 Internal Audit

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 the objective aspect of "meeting requirement" or "not meeting requirement." 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 valuable information to correct or improve processes. It allows top management to do their job.

Top management:

- Are the owners of this process,
- Sell the requirement for internal audits to the staff,
- Approve the internal audit program and plan,
- Facilitate implementation of the requirement (remove obstacles for its accomplishment),
- Provide the 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.

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

In good organizations, 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 / OFI challenges are encountered.
- Implement corrective action solutions when approved.
- Maintain the quality system as specified.
- Actively seek out OFIs.
- 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 laboratories:

- 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. Recognize 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 NCs. 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

1.11.4 Management Review

One role of top management is to carry out regular systematic evaluations of the suitability, adequacy, effectiveness, and efficiency of the quality management system with respect to the quality policy and quality objectives. This review can include consideration of the need to adapt the quality policy and objectives in response to changing needs and expectations of interested parties.

The review includes determination of the need for actions. Amongst other sources of information, audit reports are used for review of the quality management system.

This activity demonstrates and documents top management commitment to monitoring the quality system and its implementation.

Management review can also introduce any necessary changes or improvements, such as:

- organizational changes,
- hiring additional staff,
- providing specialised training,
- modifying the services offered,
- purchasing additional equipment, and
- modifying existing policies and procedures.

Each conformity assessment standard has a list of agenda items required for management review. This list comes from two sub-clauses in ISO/IEC 17025:

*"**8.9.3** The inputs to management review shall be recorded and shall include information related to the following:*

a) changes in internal and external issues that are relevant to the CAB;
b) fulfilment of objectives.
c) suitability of policies and procedures.
d) status of actions from previous management reviews.
e) outcome of recent internal audits.
f) corrective actions.
g) assessments by external bodies.
h) changes in the volume and type of the work or in the range of CAB activities.
i) customer and personnel feedback.
j) complaints.
k) effectiveness of any implemented improvements.
l) adequacy of resources.
m) results of risk identification.
n) outcomes of the assurance of the validity of results; and
o) other relevant factors, such as monitoring activities and training.

***8.9.3** The outputs from the management review shall record all decisions and actions related to at least:*

a) the effectiveness of the management system and its processes.
b) improvement of the CAB activities related to the fulfilment of the requirements of this document.
c) provision of required resources.
d) any need for change."

Management review normally considers the types of information provided by:

- Managerial reports
- Quality system audits
- Performance audits (such as proficiency testing or inter-aboratory comparison results)

- Client feedback
- Internal quality control measures and trends
- Eternal assessments by regulators or accreditation bodies
- Trends in NCs, PNCs and complaints.

1.11.5 Follow up and Review of Findings

Quality system measurement and monitoring exercises such as internal audit and management review will produce findings requiring action on the part of all CAB staff. These findings will most likely be NCs, PNCs, or OFIs. (See Chapter 7 – Addressing Assessment Findings)

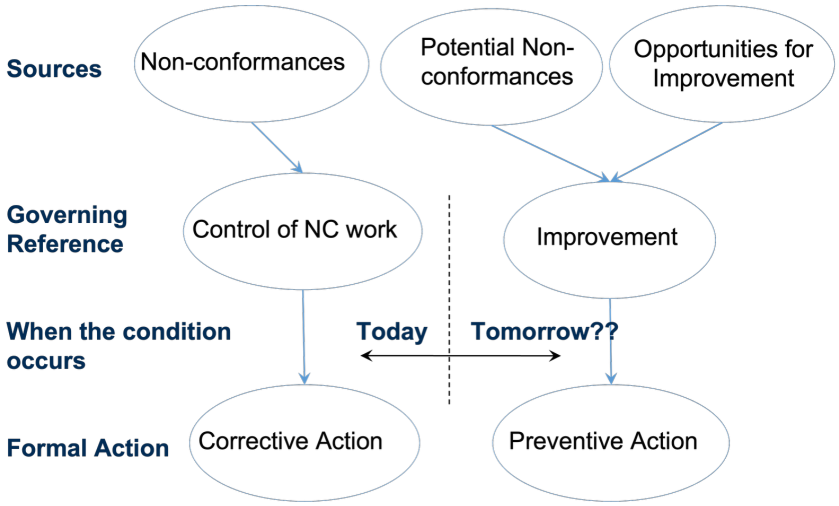
Once raised and recorded within the CAB's continual improvement program, they become corrective and preventive actions the same as for those raised from other quality system identification mechanisms. Within the continual improvement program of the CAB, as with other corrective and preventive actions,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

Follow up activities for both corrective- and preventive-actions allow a CAB to determine that the implemented action did what was required.

Management review findings can sometimes be treated separately, depending on the top management perception of the type of findings raised during management review. If treated separately, they must still be tracked, closed out and followed up for effectiveness within the management review processes, if not the overall continual improvement program.

1.12 Implementing Risk Based Thinking and Continual Improvement

1.12.1 Holistic RBT and Continual Improvement System



1.12.2 Formal Action (when required)

- Root cause analysis
- Possible range of solutions
- Selection of one solution
- Implementation of the selected solution
- Documenting the implementation
- Monitoring the solution for effectiveness

1.12.3 Step 1 – Remediate the Condition

Clean up the mess, stop the condition from continuing, put the band-aid on the cut. These are all remediation steps for non-conforming conditions that have already occurred. This is known as **Correction**

Preventing the potential non-conformance from becoming a non-conformance (this time) is known as **Prevention.**

Document the action taken.

1.12.4 Step 2 – Is Corrective- or Preventive-Action always Necessary?

Whenever non-conformances, potential non-conformances or opportunities for improvement are identified, the CAB may normally address them in one of two ways. Remember that the current version of 17025 allows for Risk Based Thinking to cater to both the bad things (non-conformances and potential non-conformances) and good things (opportunities for improvement).

- Correct/prevent the problem (or exploit an improvement) by implementing a solution and documenting both the problem and the solution. This is known as correction / prevention or improvement (all of which are only remediation) and should not be confused with corrective- / preventive-action or exploitation.
- Complete full corrective- or preventive-action, commencing with root cause analysis as described below.

The decision to select either approach should normally be done by asking three questions and determining, from the answers, which is the most appropriate approach – simple remediation or full-fledged corrective- or preventive-action.

The three questions are:

Question 1: Does this condition create unacceptable risk to the organization or its people or visitors, or might it provide significant benefit? This has traditionally been derived by estimating the impact associated with the non-conforming condition (or potential opportunity for improvement), whether it has already occurred or may occur as for a potential non-conformance and multiplying that number by its probability of occurrence. In Quality and HSE disciplines, IMPACT always governs over PROBABILITY.

RISK = IMPACT of NON-CONFORMANCE X PROBABILITY

Question 2: Does this condition adversely affect our demonstrated competence, such as producing and delivering an invalid result, or potentially doing so? Or might it significantly enhance our demonstrated competence?

Question 3: Does full corrective- / preventive-action or full exploitation cost less to implement than simple (and repeated) remediation?

If any of these questions result in a "Yes," full corrective- / preventive-action or exploitation is needed, starting with an analysis for root cause. If ALL these questions result in a "No," root cause analysis is NOT needed, and simple remediation (even if repeated) is acceptable.

1.12.4.1 Next steps if the Formal Process is not required

If full corrective- or preventive-action is not required (from the results of the three questions above), simple remediation (as described in 4.8.3 above) followed by documenting the condition is sufficient.

1.12.4.2 If Formal Action is Required

Once it has been decided that a root cause is required to allow the CAB to undertake corrective- or preventive-action, that happens next.

1.12.5 The Goals of Corrective- and Preventive-Actions

For corrective actions, the desired result is the elimination of any recurrence of a previously identified non-conforming condition. For preventive actions, the desired result is the prevention of the first-ever occurrence of a condition deemed to be non-conforming. For exploitation, the desired result is to determine why this improvement has not been implemented before now?

1.12.6 Implementing Corrective and Preventive Actions

Conformity assessment standards are focused on a CAB's ability to produce valid results and decisions. Non-conformities 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-fulfilment of specified requirements, then it becomes much easier to determine the best course of action in their treatment.

If we understand that opportunities for improvement are only identification of a condition that MAY enhance CAB capacity or competence, then it becomes easier to determine how to exploit it to the benefit of the CAB and its people and positively affect other parts of the system.

These are the six steps that formally respond to any one of the conditions noted above:

Step 1. Root cause analysis
Step 2. Determine a range of potential solutions
Step 3. Select one
Step 4. Implement the selected solution
Step 5. Document the implementation
Step 6. Monitor the implemented solution for effectiveness

1.12.7 Step 3 – Root Cause Analysis (RCA)

1.12.7.1 Getting Started.

At the beginning of the process, it is easy to get stumped by not being able to determine the Direct Cause. Take a mental picture of the incident or condition, as it would look at the time it takes place. Can you see it in your mental picture?

You are looking at the Direct Cause. For example, if a person slips on some water on the floor and the incident is an injury. Your mental picture of the incident in progress has the puddle of water on the floor and you are looking at the direct cause – water on the floor.

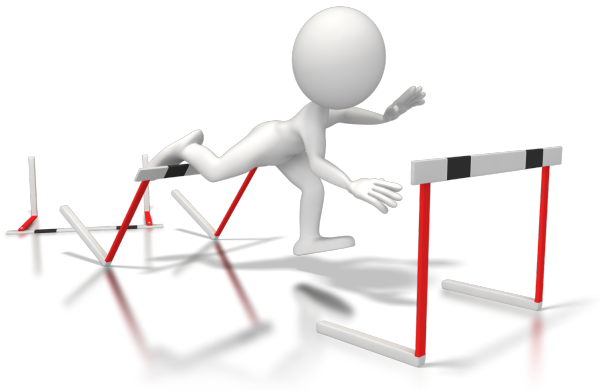
Contributing causes that go back in time from when the water appeared will take you to the Root Cause.

1.12.7.2 The Chain of Causes leads us to the Root Cause

There are three types of causes to be examined in this process. They are:

1.12.7.2.1 A Direct Cause is the Picture you Took of the Non-Conformance

This is either the actual condition (or incident) itself or the last thing that occurred prior to the condition (or incident). For example, if a organisation issues an incorrect result, the last activity that occurred prior to this obvious deviation was putting an envelope in the mail or pressing the "Return" key on a keyboard to transmit the results to a client. Those would be identified as direct causes.



The condition pictured here can be said to be non-conforming. There is no way that the runner desires to fall during this race.

When pictured in our mind, the runner caught their foot on one of the steeples. That is the **direct cause,** and you can see it happening right before your eyes at the same time as you witness the non-conformance.

1.12.7.2.2 Contributing Causes are the path to the Root Cause

These are the causes identified by asking the question "Why did this happen?" They will draw the investigator back from the Direct Cause to the first one in the chain of causes that is still within the scope of the organisation – the Root Cause. It is very common to have more than one Contributing Cause.

Here is an example (but the Root Cause determined is not so good)

Why was I late for work this morning?

DIRECT CAUSE	Why didn't I get to work on time?	Why?
CONTRIBUTING CAUSE:	Car wouldn't start	Why?
CONTRIBUTING CAUSE:	Battery was dead.	Why?
CONTRIBUTING CAUSE:	Dome light stayed on all night.	Why?
ROOT CAUSE:	Kids played in car, left door ajar.	

Blaming our kids for our lack of supervision of their activities (check the garage and note if the car doors are open when we call the kids in for bed) is NOT really a good idea.

1.12.7.2.3 Contributing Causes are the path to the Root Cause

After you have identified the Direct Cause, ask three or four more "Why's" back along the chain of events and get to the condition or circumstance whose resolution will permanently resolve the problem (and is still within your scope of responsibility). **Find the hole in your System and fill it.**

> **NOTE: *Any cause identified as outside the scope of responsibility of the organisation cannot be addressed and should never be used as a root cause. Blaming the delivery of an invalid result on the political party that has most seats in a government will not allow the CAB staff to undertake any corrective- or preventive-action. The only root causes that can be addressed are those inside our organization.***

Use the indicators from the ISO/IEC 17025 Principle of "Capacity" to help. This first principle behind ISO/IEC 17025 is the concept that a organisation has the resources (*people with the required skills and knowledge, the environment with the required facilities and equipment, the quality control, and the procedures*) in order to undertake the work and produce competent results. Root causes within CAB operations means that one of these components has a hole in it.

1.12.7.2.4 Write it Down!!!!!

Whatever the outcome of the Root Cause Analysis that occurs, the work is not finished until we have documented all the components of the effort. This is needed to allow us to review it if the offending condition recurs.

These results of the analysis form part of the overall Corrective- or Preventive-Action.

1.12.7.3 A Root Cause is Recognition that Something is Missing

1.12.7.3.1 Use a Comprehensive Approach to Finding the Hole in the System.

Whenever a condition is discovered during an audit, an assessment, a QC failure, the issuance of an invalid result, a complaint or an appeal that has been validated, management review, or the simple recognition of something out of place at the CAB, the cause will **ALWAYS** be a hole in our system. Always. That hole exists in one of the following areas that affect our organization:

- 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.

Sometimes an organization can have all of these things in place and still have difficulties. The most common cause 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.

In any organization, 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.

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 **17025 Principle of Capacity – which is also the method used by the DNV approach referred to in 1.12.7.3.3 below.**

> This first principle behind ISO/IEC 17025 is the concept that a organisation has the resources (*people with the required skills and knowledge, the environment with the required facilities and equipment, the quality control, and the procedures*) in order to undertake the work and produce competent results.

This is the most basic list, therefore, of system components that need to be in place for the organization to do its work. The most likely root causes are that one of them is missing. At the point of discovery of an undesirable condition, whether it has already occurred, the best approach is to recognize that the undesirable condition exists only because something is "missing" from this basic list:

People:

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

The Environment:

- *with the required facilities, and*
- *with the required equipment,*

The Quality Control/Quality Assurance, and

The Procedures

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

This list provides us with several "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.

Sometimes an organization can have all of these things in place and still have difficulties and the most common cause for this condition is the organization culture that emanates from its leadership. Organizational culture and leadership are, therefore, the final category for root cause considerations.

There is a catch to citing this category of Organizational Culture, 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.

1.12.7.3.2 Blame is a Waste of Time.

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. To permanently eliminate the adverse condition – its root cause must be identified and then addressed/eliminated. In the case of an exploitation, we are trying to determine what prevented us from recognising this opportunity for improvement before now.

Organizations often treat non-conformances as "errors" when they are only indications that the quality (or health and safety) 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.

We tend to blame others when something goes wrong for two very good reasons:

- The problem needs to be "fixed," and
- We are not able to do the "fixing" (workload or other reason)

However, blame hides the real root cause and prevents others from actively participating in a search for the root cause and an appropriate solution.

1.12.7.3.3 These types of Root Causes are used in Other Systems.

The Systematic Cause Analysis Technique (SCAT) developed by Det Norske Veritas (DNV) uses an identical approach for the investigation of the root causes of accidents. This comprehensive approach can be reviewed at

https://www.dnv.com/oilgas/international-sustainability-rating-system-isrs/systematic-cause-analysis-techniques-scat.html.

1.12.7.4 Root Causes Based on Personnel Factors

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

Physical capacity

- 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

Intellectual capacity (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)

1.12.7.5 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

1.12.7.6 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

1.12.7.7 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

1.12.7.8 Root Causes based on Organizational Culture

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 comprehensive, they do not cover all possible root causes. This list of missing pieces describes the holes in a quality system which 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 just indications that the quality system is not sufficiently supporting the work of the people within the system.

1.13 Step 4 – Addressing Individual Findings

1.13.1 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.

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. They do not consider how people, other than us, work within the quality system and if they cannot support people in their implementation 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 endure. This approach involves the development of consensus within the group expected to implement 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 endure and 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.
3 Obtain consensus for this solution/
4 Implement the solution agreed by all.

1.14 Step 5 – Documenting (Recording) the Effort

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

Accepting this, the records created for one, can use the same format as the other. The sample provided in this chapter 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.

1.15 Step 6 – Monitoring, Follow up and Timelines

Some conformity assessment standards require the monitoring of corrective actions to ensure that, at some later date, the CAB can determine that a particular corrective action has eliminated a root cause. Such requirements include the possibility of requires additional audits whenever 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 shown below.

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.

1.15.1 Sample RBT/Continual Improvement Form with Sample Finding

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

1.15.1.1 Raising the Finding

This example is directly from an Assessment Report showing only the finding itself, as raised by the assessment team. Other than numbering the finding, citing the reference (requirement), only Block 1 has been completed. This ends the work of the assessment team for this finding.

Incident and Deviation Report

Date: 16 Feb 2013
Serial #: 12
Number of pages attached: 0

Note: Only one incident or deviation per report.

Source: ☐ Internal Audit → ☒ 3rd Party Assessment ☐ Regular Work → ☐ Others

Deviation → ☒ Potential Deviation → ☐ Opportunity for Improvement → ☐

(Select one ref only) → ☐ QMS: ☒ External: 17025, cl 7.2.1.5

1. Description of the incident or deviation

The laboratory did not verify the performance of its concrete method (LAB 006), contrary to 17025, clause 7.2.1.5

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

1.15.1.2 Steps 1 and 2 – Remediation, Assignment of Responsibilities, and Simple RBT

This next step involves the implementation of a correction (remedial action) by the CAB staff. The person doing this has been assigned this task by the Quality Manager of the lab.

The person assigned to remediate the condition writes their action in Block 2, as directed by the Quality Manager. The assigned person then undertakes RBT in the form of a risk analysis in Block 3 to determine the impact of the condition with respect to the work of the lab, its people and the maintenance of its accreditation.

Incident and Deviation Report

Date: 16 Feb 2013
Serial #: 12
Number of pages attached: 0

Note: Only one incident or deviation per report.

Source: ☐ Internal Audit → ☒ 3rd Party Assessment ☐ Regular Work → ☐ Others

Deviation → ☒ Potential Deviation → ☐ Opportunity for Improvement → ☐

(Select one ref only) → ☐ QMS: ☒ External: 17025, cl 7.2.1.5

1. Description of the incident or deviation

The laboratory did not verify the performance of its concrete method (LAB 006), contrary to 17025, clause 7.2.1.5

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

Verification of test method LAB 006 was conducted, and the method was deemed fit for purpose. Verification records are on the method file.

QM review (initials): IM QM | Investigation assigned to: AD Labs | Date: 20 Feb 2013

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

	Yes	No
Is there an unacceptable risk to the lab?	☒	☐
Is the integrity or credibility of work adversely affected?	☒	☐
Is it easier to effect permanent resolution than many little remediations?	☐	☒

If all answers are "No" then only remediation is required.

4. Proposed Solution (and Investigation of Root Cause if required) → Date Due: 16 Mar 13

1.15.1.3 Steps 3, and 4 – RCA (if required) and Corrective/Preventive Action

In this next step, Block 4 now contains the root causes of the condition and the proposed corrective action that addresses the root cause.

At this point, Block 5 is now also completed with agreement of the responsible persons in the CAB as regards the implementation of the corrective action.

Incident and Deviation Report

Date: 16 Feb 2013
Serial #: 12
Number of pages attached: 0

Note: Only one incident or deviation per report.

Source: ☐ Internal Audit → ☒ 3rd Party Assessment ☐ Regular Work → ☐ Others

Deviation ☒ → Potential Deviation ☐ → Opportunity for Improvement ☐

(Select one ref only) → ☐ QMS: | ☒ External: 17025, cl 7.2.1.5

1. Description of the incident or deviation

The laboratory did not verify the performance of its concrete method (LAB 006), contrary to 17025, clause 7.2.1.5

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

Verification of test method LAB 006 was conducted, and the method was deemed fit for purpose. Verification records are on the method file.

QM review (initials): IM QM | Investigation assigned to: AD Labs | Date: 20 Feb 2013

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

	Yes	No
Is there an unacceptable risk to the lab?	☒	☐
Is the integrity or credibility of work adversely affected?	☒	☐
Is it easier to effect permanent resolution than many little remediations?	☐	☒

If all answers are "No" then only remediation is required.

4. Proposed Solution (and Investigation of Root Cause if required) → Date Due: 16 Mar 13

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

The technician did not understand that method verification was needed and thought that simply following the published ASTM procedure was sufficient.

Proposed solution: → Corrective Action ☒ → ~~Preventive Action~~ ☐ → ~~Remediation Only~~ ☐

All technicians are now aware of the requirements for both method validation and method verification contained in 17025. Training records have been updated and all technicians have demonstrated the ability to conduct method verification of published methods.

Investigator's Signature and Date: IM AD Labs, 17 Mar 2013

5. Confirmation of Solution Implementation

Condition resolved (root cause eliminated/opportunity exploited) → ☒ Date implemented: 17 Mar 2013

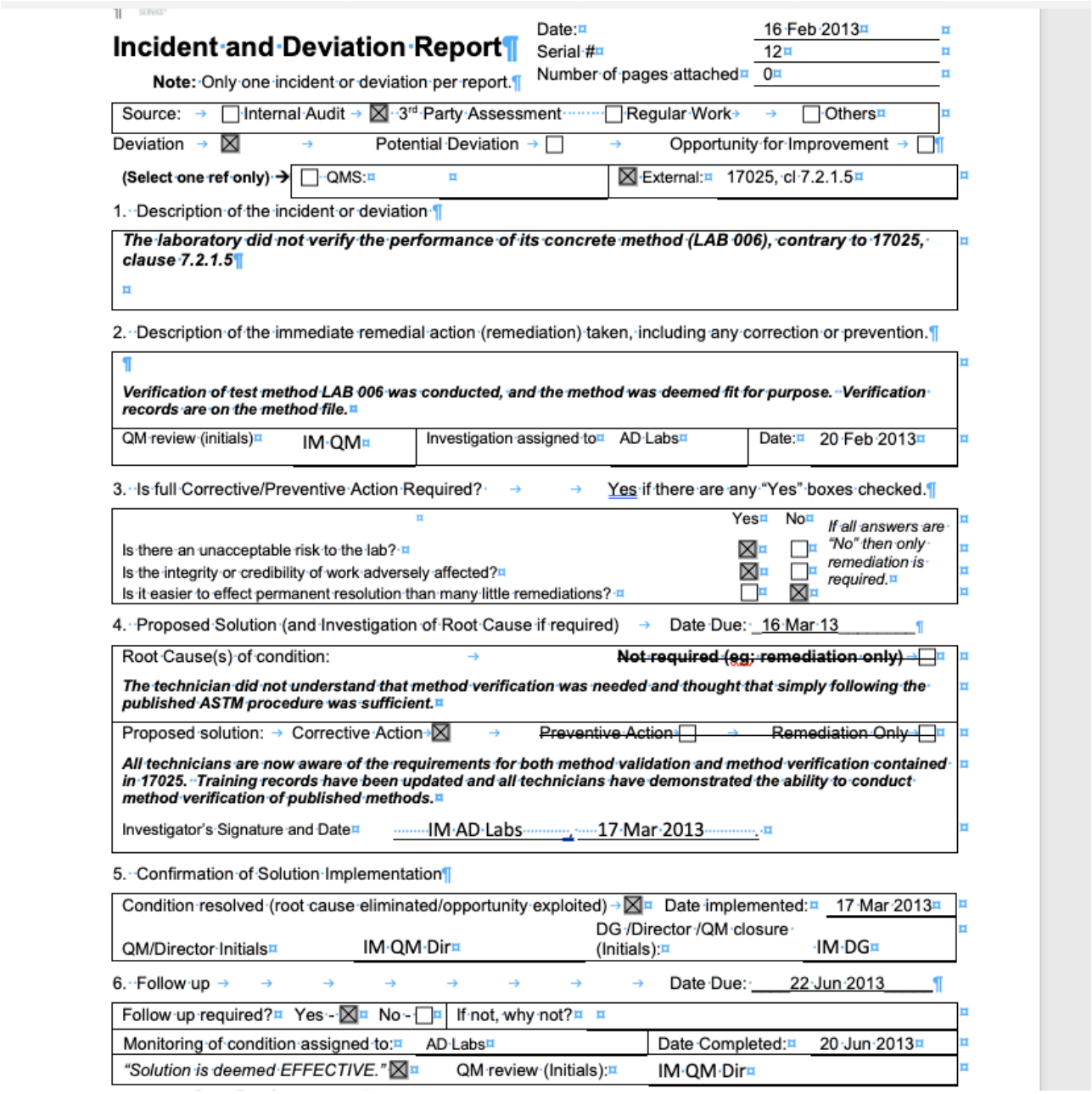
QM/Director Initials: IM QM Dir | DG /Director /QM closure (Initials): IM DG

6. Follow up → → → → → → → Date Due:

1.15.1.4 Step 6 – Follow up for Effectiveness

This sample now has the final block, Block 6, completed. This would normally take place at 90 to 180 days past the implementation of the Corrective Action.

This work is done by the person who developed the root cause and the corrective action. The effort consists solely of looking in the non-conformance tracking logs to see if the condition has arisen again in the interim. If it has not, the solution is deemed EFFECTIVE, and the Quality Manager can now close the finding within the lab.



Incident and Deviation Report

Date: 16 Feb 2013
Serial #: 12
Number of pages attached: 0

Note: Only one incident or deviation per report.

Source: → ☐ Internal Audit → ☒ 3rd Party Assessment ☐ Regular Work → ☐ Others

Deviation → ☒ → Potential Deviation → ☐ → Opportunity for Improvement → ☐

(Select one ref only) → ☐ QMS: | ☒ External: 17025, cl 7.2.1.5

1. Description of the incident or deviation

The laboratory did not verify the performance of its concrete method (LAB 006), contrary to 17025, clause 7.2.1.5

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

Verification of test method LAB 006 was conducted, and the method was deemed fit for purpose. Verification records are on the method file.

QM review (initials): IM QM | Investigation assigned to: AD Labs | Date: 20 Feb 2013

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

	Yes	No	
Is there an unacceptable risk to the lab?	☒	☐	*If all answers are "No" then only remediation is required.*
Is the integrity or credibility of work adversely affected?	☒	☐	
Is it easier to effect permanent resolution than many little remediations?	☐	☒	

4. Proposed Solution (and Investigation of Root Cause if required) → Date Due: 16 Mar 13

Root Cause(s) of condition: → ~~Not required (eg; remediation only)~~ → ☐

The technician did not understand that method verification was needed and thought that simply following the published ASTM procedure was sufficient.

Proposed solution: → Corrective Action ☒ → ~~Preventive Action~~ ☐ → ~~Remediation Only~~ ☐

All technicians are now aware of the requirements for both method validation and method verification contained in 17025. Training records have been updated and all technicians have demonstrated the ability to conduct method verification of published methods.

Investigator's Signature and Date: IM AD Labs 17 Mar 2013

5. Confirmation of Solution Implementation

Condition resolved (root cause eliminated/opportunity exploited) → ☒ Date implemented: 17 Mar 2013

QM/Director Initials: IM QM Dir | DG /Director /QM closure (Initials): IM DG

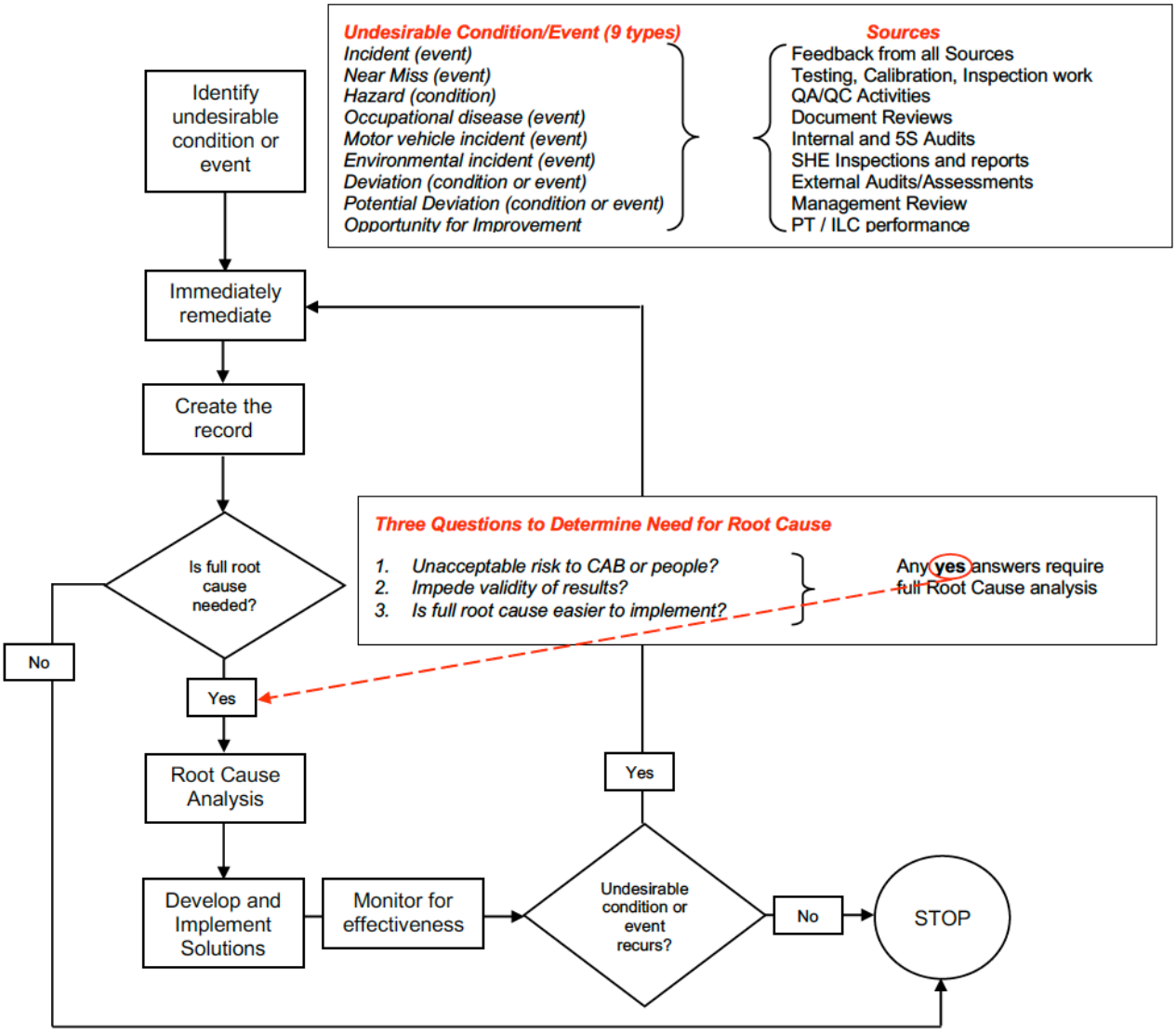
6. Follow up → → → → → → → → Date Due: 22 Jun 2013

Follow up required? Yes - ☒ No - ☐ | If not, why not?

Monitoring of condition assigned to: AD Labs | Date Completed: 20 Jun 2013

"Solution is deemed EFFECTIVE." ☒ | QM review (Initials): IM QM Dir

1.16 Implementing RBT and Continual Improvement



2.0 Chapter 2 – Assessment Basics

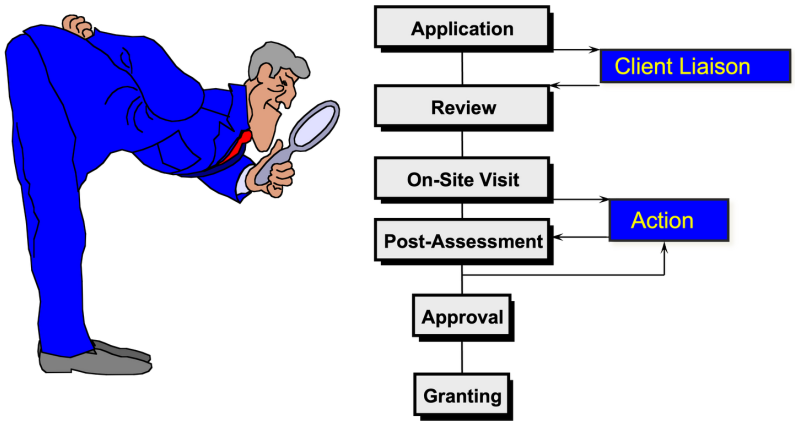
2.1 Learning Objectives

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

- **understand** the requirements for the conduct of assessments,
- **understand** the requirements for the assessors conduct and behaviours

2.2 Assessment (part of Accreditation) Overview

This graphic provides a high-level overview of Accreditation Processes.



2.3 Assessment Philosophy

2.3.1 Definition of an Assessment

The best assessments are described as:

> "***An objective comparison of actual conditions to stated requirements in order to facilitate and document the CAB's demonstration of conformance to requirements"***

Assessors, to succeed in gathering enough information to document the CAB's competence, must treat all those assessed with the **utmost respect**. People working within the CAB are already afraid of assessors because they know that assessors are required to render judgment on the competence of the CAB and those assessed as part of the assessment. Such is the power given to an assessor.

Assessors are cautioned to remember that with such power comes great responsibility. Frightening the CAB staff will impede the gathering of information needed to document competence.

To clarify the best practices in assessment interaction, given in ISO 19011:2018, assessors are to note that a true assessment is just "***a technical discussion between technically competent peers about a list of things to do."***

The assessor's primary duty in the conduct of an assessment is to **protect the integrity of the accreditation program**. Without such integrity, the program is not worth anything.

2.3.2 Overall Assessor Conduct

ISO 19011:2018 – *Guidelines for auditing management systems,* serves as the international guidance document for all types of auditors. Accreditation bodies also use it for guidance on the conduct of assessors.

The knowledge and skills required of assessors (auditors) is contained in ISO 19011. These include:

- Audit/assessment 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 (assessors), from the same document, are:

- Ethical,
- Open minded,
- Diplomatic,
- Observant,
- Perceptive,
- Versatile,
- Tenacious,
- Decisive,
- Self-reliant.
- Act with fortitude,
- Open to improvement,
- Culturally sensitive, and
- Collaborative

"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 reach a decision, albeit considered, than about making it quickly.

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

The primary responsibility of all assessors is to safeguard the integrity and credibility of the Accreditation Program. Any activity, circumstance, or incident, which detracts from either of these two aspects of the program, will reduce the confidence that stakeholders, laboratories, and regulators have in the program.

2.4 Who works for Whom during an Assessment

Reporting relationships within the context of an assessment should not be different than for any other aspect of an organisation's operations. While onsite, assessors represent, and their primary function is to protect the integrity and credibility of the Accreditation Program. But it is important to appreciate that other lines of responsibility are temporarily established for the conduct of an assessment.

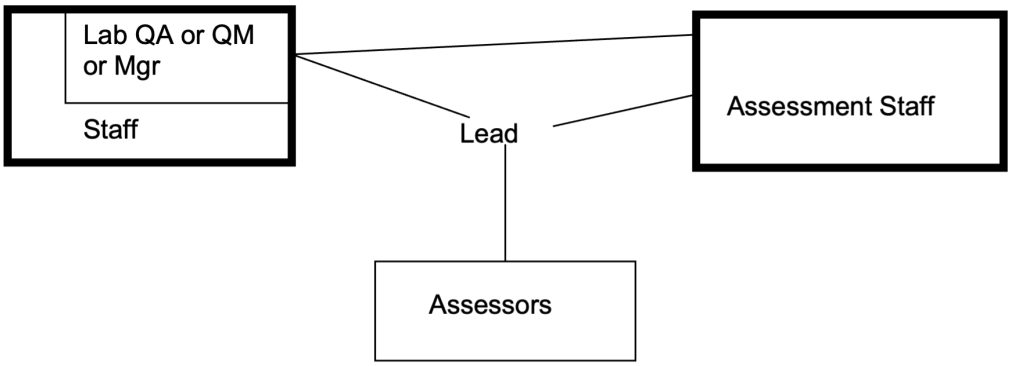
The CAB is the client for an assessment. The CAB is also the auditee (assessee). The assessment team represents the auditing authority, which is ABC. If the assessment team consists of more than one person, then the lead assessor is the primary onsite representative of ABC.

The senior CAB representatives also have direct access to ABC staff and there may be occasion for discussion between them on issues that cannot be addressed by the assessment team or their lead assessor. All assessors, normally through the lead assessor, also have continuous direct access to ABC staff during the conduct of their assessment duties.

The auditors on an assessment team are responsible to the lead assessor and the CAB staff has their own supervisor as well – the senior auditee. This provides clear lines of communication and responsibilities in the event of disagreements between any assessors and CAB staff undergoing assessment. The solutions to issues rest between the lead assessor and the senior auditee. If they cannot solve them, then ABC staff may have to be approached.

The person who carries the whole weight of responsibility with regard to the conduct of a successful assessment – is the assessor. In the case of a multi-person team, it is the lead assessor. With this responsibility comes a leadership task that is not always easy to fulfil.

This diagram shows the relationships between all parties participating in the assessment. Note how the lead assessor responds to the needs of the AB, the CAB (quality manager / CAB manger) being assessed, and the members of the audit team.



The best lead assessors embody the following characteristics:

- They know that they work for everyone else – the AB, the lab, the CAB staff, and the members of the assessment team.
- They know that there is no glory in their work, so they seek none.
- They know that there is lots of blame for things that go wrong – and they will have to accept all of it and share none of it with their team members.
- They know that success depends on removing impediments that prevent their team members from accomplishing their work and that the team succeeds only when the team members succeed.
- They know that failure is only theirs to bear.
- They believe strongly in this approach and in the responsibilities they have been given.

In other words, if this set of circumstances does not make an assessor positively joyful, THEY SHOULD NOT SEEK TO BECOME A LEAD ASSESSOR. They should step aside and let someone else take up those responsibilities.

2.5 Gathering Evidence during an Assessment

Since an assessment is relatively objective, assessors are required to gather evidence to support the demonstrated competence of the CAB and any conditions which may not conform to requirements.

There are three types of objective evidence that can be gathered during an assessment:

- **Reading (document review).** This is done prior to the assessment visit during the document review of CAB policies and procedures. Document review also includes review of records obtained during the onsite assessment.
- **Watching (observation).** This is normally only done during the onsite visit, where a process is examined, and evidence is obtained by noting the execution of the process.
- **Listening (interview).** This is normally done only during the onsite visit and evidence is obtained from the description of processes provided during interviews with CAB staff.

2.6 Assessment Techniques and Behaviours – (Some Good, Some Bad)

2.6.1 Assessors cannot Express their own Opinions.

There should be no opinions involved in an assessment. The task of an assessor is to gather the evidence in support of a determination of competence, or failing to gather sufficient evidence, the lack thereof.

- Assessors do not have opinions. **Opinions have no value in an assessment.**

- If an assessor pushes their opinion on the lab, they may be invited to leave the lab. Any time someone says: "…In my lab…." they are expressing an opinion.
- An assessment should not be subjective or about anyone's opinion.

2.6.2 Assessors must be Prepared.

Once onsite, it is too late to be opening documents and commencing a review of CAB policies and procedures. Preparation MUST be completed before this point. See 6.2.3 *Pre-Assessment Activities, including Document Review* below. Note that most checklists should contain space for notes to be made during a document review, as a separate activity from the onsite observations. See *AF04 – Assessment Checklist for 17025* and *AF07 – Test and Measurement Checklist*.

2.6.3 Assessors must Avoid Surprises

No member of the CAB staff should experience any surprises during the preparation, conduct, or follow up of any assessment activity. Surprises cause concern to those being assessed and they may react badly to being surprised. It does not matter if it is a new requirement imposed on all concerned or a finding that was not discussed prior to the preparation of the assessment report. Surprises are not a good thing.

To prevent them, assessors are reminded that ***every step in the assessment process should be confirmation of agreements made to that point***. Following this approach always makes the assessment process more enjoyable and rewarding for all involved.

2.6.4 Assessors can never Tell the CAB what to do (Consulting)

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

- The quality system belongs to the CAB being assessed, not the assessors. Telling the CAB what to do impinges on their ownership. Assessors are observers and reporters, not owners of their processes.
- The solutions implemented by those assessed must meet their own needs, not the needs of the assessor(s).
- If the assessor(s) is/are well received by CAB staff, they may be repeatedly requested to offer advice on how to overcome challenges within their quality system. **General discussion is both acceptable and encouraged in these circumstances. That is part of the value added of an assessment. The provision of specific solutions is not acceptable.**
- If assessors do have some help to extend and this happens very often, it must include several (not less than three) possible options – with consideration on how **ANY OF THESE OPTIONS** may be used to meet the requirement. It must also be emphasized that the solution selected is entirely the decision of the CAB – and not the assessor.
- Findings of assessments shall never include solutions. Findings are only an articulation of current conditions and, from the evidence available, a determination of the level of conformance demonstrated by these conditions as measured against specified requirements.

2.7 Assessor Materials and their Use – Assessor Tool Kit

The following typical assessment documents are contained in the **Assessor Tool Kit**. Please take a few moments and review them.

2.7.1 Accreditation Criteria (Including the Generic sample AB requirements listed)

ISO/IEC 17025 General Requirements for the competence of testing and calibration laboratories (standard)
AB01 Terms and Conditions for Accreditation
AB02 PT Policy as per ILAC P9
AB03 Traceability Policy
AB04 Code of Ethics

AB05 Confidentiality and Impartiality
AB07 ABC Disputes and Appeals

2.7.2 Assessment Procedures

AS01 Assessment Preparation Procedure
AS02 Assessment Procedure

2.7.3 Assessment Forms

Prior to an Assessment Activity
AF01 Assessment Schedule
AF02 Requested scope of Testing
AF03 Requested scope of Calibrations

During the Onsite Assessment Activity
AF04 Assessment Checklist for 17025
AF05 Assessment Report Form
AF06 Attendance list
AF07 Test and Measurement Checklist
AF08 Assessment Finding Form
AF09 Assessor Monitoring Form

2.8 Exercise 1 – Using the Assessor Tool Kit

2.8.1 Learning Objectives

- **identify** the assessment processes covered by the **Assessor Tool Kit**
- **identify** the forms and procedures contained in the **Assessor Tool Kit**
- **use** the tools provided by the Assessor Tool Kit

2.8.2 Exercise Scenario

You are part of the assessment team that has been assigned to conduct the re-assessment of MOTIVA Laboratories Inc. using the recently updated **Assessor Tool Kit** and you to familiarize yourself with its contents.

2.8.3 Exercise Objectives

You are to create a list that differentiates the documents within the **Assessor Tool Kit** that are based on the standard (ISO/IEC 17025) as opposed to those that are based on an ILAC Policy.

2.8.4 Exercise Preparation

Review all documents, contained in the **Assessor Tool Kit,** and document the following information for each entry:

- Objective of the document as described within the document.
- Is the document based on the requirements in ISO/IEC 17025 or an ILAC Policy

2.8.5 Exercise Deliverables

You are to be prepared to discuss this list.

2.8.6 Presentation and Group Discussion

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

3.0 Chapter 3 – Planning and Conduct of Assessments

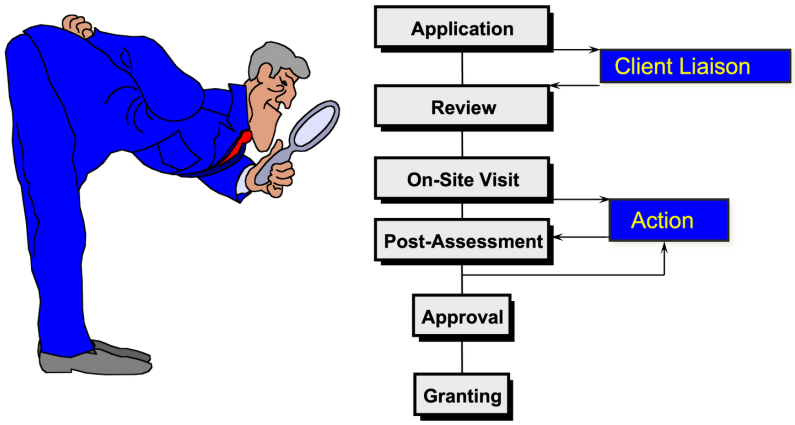
3.1 Learning Objectives

- **understand** the requirements for the conduct of assessments
- **understand** the methods used to document capacity and competence
- **understand** techniques in identifying non-conformances and opportunities for improvement

3.2 Assessment Planning

3.2.1 Overview of Accreditation Processes

Accreditation processes fall into the following activities:



3.2.1 Overview of Assessment Processes

Assessment processes fall into the following activities:

1. Review of Assessment Package from AB
2. Activities prior to the Onsite visit
3. Opening meeting
4. Tour of facilities
5. Assessment of specific tests
6. Interview with staff
7. Recording findings
8. Writing the report
9. Closing meeting

The **Assessor Tool Kit** documentation is provided to all assessors. These materials are used as the means of dividing up the activities involved in the assessment and contain several forms, reference materials, and accreditation requirements documents.

3.2.2 Selection of the Assessment Team.

The most important activity undertaken by the accreditation body, in preparation for the assessment of an applicant lab, is the Selection of the assessment team members. The following are the most important steps to follow in selecting potential assessors, in order:

1. Only assessors with the competencies to match the scope are considered and the whole scope is covered.
2. No conflict of interest exists with any assessor being considered.
3. The number of tests/calibrations on the scope determines how many assessors are needed.
4. The Lead Assessor is selected and assigned.
5. Distance of travel for the assessors.

3.2.3 Receipt of Assessment Packages.

Each individual assessment activity begins with the distribution of the assessment packages and the examination of this assessment package by the assessor(s). See the sample assessment package contained in the Sample Assessment Package provided separately.

3.2.3.1 Contents of the Assessment Package

Assessment packages contain information relevant to the identification of the CAB to be assessed, its desired scope of accreditation, and the identification of the team to conduct the assessment activity.

The documents are as follows (where applicable). The documents submitted by the CAB are normally submitted electronically only. The AB may gather all this documentation together and send to the assessors, or they may provide only those portions of the assessment package noted as provided by them, and ask the assessors to contact the CAB to acquire those parts that come from the lab.

1. *Assessment Report* (AF05) of the previous assessment (if applicable and provided by the AB)
2. Record on lab's Participation in PT (as appropriate and provided by the lab)
3. Requested Scope of Accreditation (AF02 for Testing and AF03 for Calibration and provided by the AB)
4. CAB Quality Documentation (provided by the lab)
5. CAB Quality Procedures (provided by the lab)
6. CAB Technical and Test/Calibration Procedures (provided by the lab)

3.3 Activities prior to the Onsite Visit, including Document Review

3.3.1 Prior to Onsite Assessment Activities – Document Review

Assessment activities are divided between those that occur offsite (first) and those that occur onsite (second). The offsite activities are primarily restricted to preparatory work and aimed at reducing the workload onsite to something that is manageable by mere mortals (assessors). This preparatory offsite work is normally called document review. It includes:

- Conduct a thorough **Document Review** of all CAB policy and procedure documents to determine CAB conformance to 17025, and accreditation body (ILAC) requirements and to develop their understanding of the processes that exist in the lab, and
- Review the forms and documents they will need for each assessment activity.

DOCUMENT REVIEW IS THE MOST IMPORTANT ASSESSOR ACTIVITY PRIOR TO AN ASSESSMENT.

Document review also serves the purpose of not wasting the CAB staff time by having all participants reviewing assessment documents together. CAB staff is already very familiar with their own processes, but the assessors are not. It is the assessor who needs to become familiar with these documents and doing so prior to the assessment provides a better understanding of CAB processes and saves onsite time.

All document reviews are normally completed before any onsite assessment activities. The onsite activities will include examination of issues discovered during the assessor document review.

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

- Determine the **level of conformance** of the CAB policy and procedure documents prior to the actual onsite visit,
- Gain familiarity with the **documents that govern** the CAB processes, and
- Understand the **processes** used by the lab.

3.3.2 Prior to Onsite Assessment Activities – Overview of Checklists

When ready to conduct the assessment, the assessor needs to establish their lines of inquiry, investigation, and examination. Simply taking a copy of a procedure through an organisation and asking questions “off the cuff” is not best practice. It does not make best use of time. It does not make the line of inquiry clear to those being assessed and it does not promote a systematic approach to assessing. Prior to the assessment, all

assessors should have prepared appropriate checklists to guide their search for objective evidence of conformance.

There are two main objectives in using checklists:

- They document the minimum line of inquiry required to establish conformance (or not) of a process, and
- They create a clear and visible line of inquiry for both the assessor and the CAB staff.

While provides all checklists to be used during assessments, there may be an occasion when the assessor needs to create one specific to a process not covered elsewhere. In these circumstances, checklists should be created using open-ended questions that allow CAB staff to describe how the process meets requirements. The following are the types of considerations that an assessor should use to develop the questions that will eventually make up the checklist:

- Does the process conform to requirements?
- Is it well implemented?
- Is it effective?
- Does it allow for improvement?
- How is it measured?
- How does it affect the ability of the CAB to produce technically valid results?

3.3.3 Prior to Onsite Assessment Activities – Checklists during Document Review

Checklists for use during the document review are provided in Tabs 4 and 5 of the **Assessor Tool Kit**. These include:

- ISO/IEC 17025-*General Requirements for the competence of testing and calibration laboratories*
- AF07 *Test and Measurement Checklist* (4 copies)

Most of these checklists make provision for assessor comments resulting from a document review.

At the end of the document review process, the assessor has a much better understanding of the quality system and technical aspects to be assessed. The outputs of the document review process, regardless of which checklist approach is used, is a set of questions (checklist) to pose during the actual onsite visit.

These questions (checklist) will allow the assessor to concentrate on those onsite issues which are not clear, and whose answers will complete the picture regarding the level of conformance and implementation of the quality system, as well as any issues affecting the competence of the lab.

3.3.4 Prior to Onsite Assessment Activities – Obtaining Agreement

To ensure a smooth and uneventful assessment, assessors are reminded that every step in the assessment process should be confirmation of agreements made to that point. Following this approach always makes the assessment process more enjoyable and rewarding for all involved.

It is important for the assessment team to obtain agreement from the CAB regarding assessment timings, scope, logistics, and related activities.

3.3.5 Start the Onsite Visit by Reaching Agreement with the lab.

The final step in preparing for the assessment is to establish agreement on the resources that will be required to support it. The CAB normally provides these but establishing agreement on their provision is the responsibility of the assessor/lead assessor.

3.3.6 What to do when an NC, PNC or OFI is observed.

Observations used to gather evidence of conformance and competence of the CAB starts with the document review. It does not matter when an observation that may, or may not, lead to a finding is discovered. It may be during the document review, the opening meeting, the tour of the lab, the assessment of a technical process, an interview, or the assessment of a QMS process. Assessors should follow the following steps from the moment of discovery:

- Record the name of the process being reviewed, observed, or assessed.
- Record the condition within that process that is being observed?
- Record the requirement document that governs the process being observed. 17025? ILAC/AB policy? CAB procedure?
- Record the evidence that indicates the observation may, or may not, be following the requirement?
- Speak to the CAB person present and ask them to help you understand the observation.

3.4 Exercise 2 – Conducting a Document Review

3.4.1 Learning Objectives

- **use** the assessment processes covered by the **Assessor Tool Kit**
- **use** the forms and procedures contained in the **Assessor Tool Kit**
- **use** the tools provided by the **Assessor Tool Kit**

3.4.2 Exercise Scenario

Your group is the re-assessment team that has been assigned to conduct the re-assessment of MOTIVA Laboratories Inc. You have been sent the Sample Assessment Package review prior to the actual re-assessment.

3.4.3 Exercise Objectives

You are to conduct document reviews for the MOTIVA Laboratories Inc quality system documentation attached to the Sample Assessment Package.

3.4.4 Exercise Preparation – homework assignment

You are to conduct an individual document review of the following documents. The documents are to be reviewed using the associated checklists:

- MOTIVA Quality Manual and one MOTIVA Quality System Procedure using AF04-*ISO/IEC 17025 Assessment Checklist*), and
- One MOTIVA Test Procedure using AF07-*Test and Measurement Checklist*

3.4.5 Exercise Deliverables

You are to be prepared to answer specific questions (self-paced online course) or discuss your document review with the facilitator (acting as the MOTIVA Laboratories Inc Quality Manager).

3.4.6 Presentation and Group Discussion – 10 minutes per person

Each participant is to present completed checklists to the facilitator and the other groups. Once all presentations are complete, the class will discuss the issues arising, and the salient points to retain.

3.5 Onsite Assessment Activities

3.5.1 Onsite Assessment Activities - Opening Meeting

The Lead Assessor chairs this meeting. The agenda for this meeting is contained in AS02-*Assessment Procedure* in the **Assessor Tool Kit**.

The on-site assessment commences with an opening meeting involving the top management of the CAB to:

- confirm the objectives of the assessment and the scope of testing and calibration activities to be covered.
- confirm the assessment plan, including witnessing of testing and calibration,
- make arrangement for reporting the outcomes of the assessment in the form of both the individual findings and summary report.

The Opening Meeting Agenda is normally as follows:

Review the opening meeting agenda contained in AS02-Assessment Procedure of the **Assessor Tool Kit**. It contains the following information:

- Introductions and thanks
- Assessment scope and objectives
    - Agreement on scope and objectives. Emphasize “facilitating their demonstration of conformance.”
    - Scope and objectives understood by CAB and CAB staff
    - Reiterate the “official” links between CAB staff and assessors
- Assessment plan
    - Agreement on the planned approach (Site Visit Agenda)
    - Respond to necessary adjustments to this plan
    - Confirm arrangements for logistics and resources
    - Confirm arrangements and timings for subsequent meetings (Interview with key CAB staff, etc)
    - Follow up on findings raised in any previous assessment
    - Confirm arrangements for the end of the assessment
- Assessment methods and procedures
    - Clearly explain investigation activities
    - Be open about the process and emphasize its transparency
    - Confirm the definitions of assessment findings
- Confidentiality
    - Confirm assessment team’s responsibilities
    - Confirm AB’s responsibilities
- Respond to questions
    - Be prepared to handle questions from CAB staff – focus on the benefits of the approach and the transparency of the activities.
- Depart for the tour of the facility.

3.5.2 Onsite Assessment Activities - Tour of Facilities

This is an opportunity for the assessor to view the CAB environment and experience how the CAB is laid out, where people work, where equipment is located, and how samples flow through the CAB from reception to disposal. This is an important activity and must not be overlooked. It normally occurs immediately after the Opening Meeting and before the assessment of any activities.

3.5.3 Onsite Assessment Activities - Assessment of Specific Tests

At this point in the assessment, the activities involved in helping the CAB demonstrate their competence to an assessor are fully underway. See AF02 for Testing and AF03 for Calibration scopes of accreditation and note the types of checklists used in the assessment of CAB methods and procedures.

The assessment of specific tests and calibrations is done using *AF07 Test and Measurement Checklist*. This checklist contains all the questions that an assessor may wish to ask during the witnessing of specific tests and calibrations.

AF04 Assessment Checklist for 17025 should be used for questions and the recording of observations that are not part of the witnessing of a specific test or calibration.

3.5.4 Onsite Assessment Activities - Interviews with Staff

This assessment process concentrates on the assessment of the CAB staff and the evidence that supports a conclusion of their competence. Assessors attempt to determine, from a discussion with staff and the

examination of specific personnel records and whether they can effectively manage the quality system and produce technically valid results. See *AS02-Assessment Procedure* in the **Assessor Tool Kit**.

This activity will be covered in Chapter 7 **Meetings and Interviews** below. Assessors should always refer to their checklists for their inquiries into CAB activities. See *AF04* and *AF07* within the **Assessor Tool Kit**. Use the checklist to guide the discussion and then use it to record responses and observations. Some interview observations may become actual findings.

3.5.5 Onsite Assessment Activities - Recording Observations

All observations made during an assessment must be recorded. Assessors should use the checklists provided by the accreditation body. See *AF04* and *AF07* within the **Assessor Tool Kit**. Some of these observations may become actual findings.

3.5.6 Onsite Assessment Activities - Writing Findings

Whenever an observation rises to the level of becoming a finding, the assessor must be fully aware of the requirements to correctly write one. See Section 8.4 – Writing Findings below.

3.5.7 Onsite Assessment Activities - Writing the Report

The format for the report is contained in AF05-*Assessment Report*. The writing of Findings and completion of the assessment report is discussed in Chapters 8 and 9 of this Course Handbook.

3.5.8 Onsite Assessment Activities - Closing Meeting

All on-site assessment activities end with a closing meeting. This meeting is much like the opening meeting, and the lead assessor chairs it. The agenda for this meeting is contained in AS02-*Assessment Procedure* in the **Assessor Tool Kit**. The Lead Assessor chairs this meeting.

The closing meeting involves top management of the CAB to enable the lead assessor to present them with a summary of the results of the assessment, and to inform them of the team conclusions and any action that may be required as a condition of accreditation or continuation of accreditation.

The team should make clear that the object of the assessment has been to seek as much evidence of conformance of CAB operations so that the AB can accredit them based on such evidence. Where findings have been noted, the object is to provide the CAB with all the appropriate information to allow them to address the underlying conditions and meet accreditation criteria, not to make extra work. If the finding forms and the summary report are properly completed during the assessment, there should be no need for any further report on the proceedings for presentation at the closing meeting.

The Closing Meeting Agenda is normally as follows:

- Introductions and thanks
- Assessment scope and objectives
    - Reiterate scope and objectives (facilitation of conformance)
- Assessment methods and procedures
    - Reiterate investigation methods
- Confidentiality
    - Confirm assessment team's responsibilities – leave all documents with auditee
    - Confirm responsibilities
- Present the Assessment Report
    - Present the findings, if any, that have been raised and ensure that they are fully understood by the CAB staff and note a disclaimer that there might be unrecorded findings in areas that were not discovered during this assessment.
    - Explain the significance of categories of findings

- Present the requirements for CAB response
- Confirm the desired scope of accreditation.

- Respond to questions
    - Be prepared to handle questions from the lab. Focus on the benefits of their continued demonstration of competence.
    - Advise the CAB on the methods to dispute any findings contained in the report, or appeal any accreditation decisions made by ABC, by referring to AB07 *ABC Disputes and Appeals* procedure.

3.6 Post Assessment Activities

Once all on-site activities are complete, assessors are expected to deliver the report and carry out the few remaining activities described in AS02-*Assessment Procedure* in the **Assessor Tool Kit**.

The following are the most common Post Assessment activities to be carried out by an assessor:

- Submit the assessment report to the AB as well as any appropriate supporting records/checklists
- Submit travel claims and supporting records
- Review responses from the lab
- Respond to queries from AB
- Discuss appropriateness of responses with team and AB staff or help determine such appropriateness.

3.7 Exercise 3 – Planning an Assessment

3.7.1 Learning Objectives

- **use** the assessment processes covered by AS02-*Assessment Procedure* in the **Assessor Tool Kit**
- **use** the forms and procedures contained in the **Assessor Tool Kit**

3.7.2 Exercise Scenario

You are part of the assessment team that has been assigned to conduct the **re-assessment** of MOTIVA Laboratories Inc. ABC staff have recently sent you the Sample Assessment Package provided separately. This sample contains some associated procedures, the most recent assessment report, and the requested scope of accreditation for this re-assessment.

3.7.3 Exercise Objectives

Develop a schedule for the re-assessment of MOTIVA Laboratories Inc using AF01-*Assessment Schedule* of the **Assessor Tool Kit**.

3.7.4 Exercise Preparation – 60 minutes

You are to accomplish the following:

1. You are to create a re-assessment schedule using the forms contained in AF01-*Assessment Schedule* of the **Assessor Tool Kit**.
2. You are to reach agreement on a schedule for the re-assessment of MOTIVA Laboratories Inc., to meet the following requirements:
    - Plan for the assessment of all the tests listed in the re-assessment package
    - Create the entire schedule using AF01-*Assessment Schedule* of the **Assessor Tool Kit**.
3. Obtain agreement from the lab, on the approach to be used.

3.7.5 Exercise Deliverables

You are to be prepared to discuss your schedule and obtain agreement from the CAB on the approach to be used during the re-assessment.

3.7.6 Presentation and Group Discussion – 15 minutes per group

You are to present a completed re-assessment schedule using AF01-*Assessment Schedule* of the **Assessor Tool Kit**. Obtain agreement from the CAB on the approach to be used.

4.0 Chapter 4 – Meetings and Interviews

4.1 Learning Objectives

The course will assist you to:

- **understand** the methods used to document capacity and competence
- **understand** techniques in identifying non-conformances and opportunities for improvement
- **manage** opening meetings, closing meetings, and interviews of CAB personnel

4.2 Preparation and Agreement

From Chapters 3 and 6, agreements on assessment and logistic specifics should be reached prior to the actual assessment. We also learned that each step in the assessment cycle is also confirmation of agreements made to that point.

This is no different for the opening meeting.

4.3 Opening Meeting Agenda

Review the opening meeting agenda contained in AS02-Assessment Procedure of the **Assessor Tool Kit**. It contains the following information:

- Introductions and thanks
- Assessment scope and objectives
    - Agreement on scope and objectives. Emphasize “facilitating their demonstration of conformance.”
    - Scope and objectives understood by CAB and CAB staff
    - Reiterate the “official” links between CAB staff and assessors
- Assessment plan
    - Agreement on the planned approach (Site Visit Agenda)
    - Respond to necessary adjustments to this plan
    - Confirm arrangements for logistics and resources
    - Confirm arrangements and timings for subsequent meetings (Interview with key CAB staff, etc)
    - Follow up on findings raised in any previous assessment
    - Confirm arrangements for the end of the assessment
- Assessment methods and procedures
    - Clearly explain investigation activities
    - Be open about the process and emphasize its transparency
    - Confirm the definitions of assessment findings
- Confidentiality
    - Confirm assessment team’s responsibilities
    - Confirm AB’s responsibilities
- Respond to questions
    - Be prepared to handle questions from CAB staff – focus on the benefits of the approach and the transparency of the activities.
- Depart for the tour of the facility.

4.4 Assessor Approaches

Openness and transparency are important for the success of every meeting during an assessment. The assessors can be seen as “police” and every effort should be made to overcome this impediment to a

successful assessment. The responsibility for the success of the opening meeting rests with the lead assessor alone. This is the same as for the remainder of the assessment.

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

- The level of conformance of the quality system,
- The demonstrated competence of the lab.

Assessment Secret

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

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

4.5 Responsibilities for Conduct and Communication

The success of the entire assessment rests with the assessor. 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 assessor is the one doing all the work, and theirs is the responsibility for the resulting report.

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

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

- the opening meeting,
- interviews of CAB staff,
- wash up meetings, and
- the closing meeting.

4.5.1 Communication Styles

Typically, assessors tend to either want to:

- "get to the point" in discussions or
- "get a feeling for the circumstance."

These are very different communication styles. They each have their advantages. In an assessment, where those being assessed are already frightened of the assessor, 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 do this process…" questions indicate an open mind that is interested in what CAB staff has to say.

4.5.2 Conducting Interviews

Besides the closing meeting, interviews can be the most stressful part of an assessment, for both the assessor and CAB personnel. It is important that, like other events in the assessment, 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. In most instances, this is the reference test method. In others, it is ISO/IEC 17025, or the lab's own QMS documents, or another requirements document.

4.5.1.1 Objective of Interviews (Why we interview)

The aim of any interview is to acquire an understanding of how CAB staff perceive and execute their processes. Assessors are trying to understand how the CAB staff perceives requirements. Simply judging a CAB approach to be conformant or not is not helpful to them or to the AB if they do not understand the same way as others might. Without common language, the finding is just one more thing being forced on them.

It is also important to acquire such an understanding so that a complete and honest determination can be made regarding the conformance of the process to requirements. CAB staff may also be able to provide good and valid reasons why a process is being conducted differently than how the assessor may perceive the requirement.

4.5.1.2 Selecting Records during Interviews

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.

4.5.1.3 Responding to Conflict and Challenges during the Interview

An assessment can be a stressful activity for all concerned. Many assessors and CAB staff do not have a great deal of comfort within themselves in this type of circumstance. The responsibility for the conduct of the interview, as in all things associated with an assessment lies solely with the assessor.

Assessors should take steps to reduce the potential for stress throughout the process. As already discussed, much of the effort comes in the form of the assessors' personal conduct.

In the event, however, that challenges arise from CAB staff that may impede the conduct of the assessment, the responsibility for the solution rests with the assessor, or if the assessor is part of a team, the lead assessor.

If the assessor is alone for the visit, they should approach the quality manager or CAB manager to resolve the issue as a first step. If this will not resolve the issue, and the successful completion of the assessment is at risk, the decision on how to resolve the issue – remove the challenge or amend the assessment plan – can be discussed with assessment staff.

In the case of an assessment team, the lead assessor should normally exercise the first attempt at a solution. This is part of the primary function of the lead assessor – overcome obstacles so that the team can do their work.

The solution normally lies between the lead assessor and the quality manager or CAB manager. Other CAB staff may not be able 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 an interview, the best course of action to take involves the following:

- assessors remain neutral or withdraw from the area of conflict,
- inform the lead assessor,
- inform the quality manager or CAB manager,
- if the problem persists, pause the assessment until the conflict is resolved.
- if resolution is not possible, contact the AB.

4.6 Recording Assessment Observations

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

4.6.1 During the Document Review (System Audit)

During the document review, an assessor may make observations on the level of conformance of the documents against requirements. These observations are normally written in the space provided on the checklist forms and they form part of the discussion during the onsite assessment. See the AF04 and AF07 forms in the **Assessor Tool Kit**.

If they are retained until the assessment, they may be raised as issues, and allow evidence to be gathered to either confirm or deny the validity of the observation.

4.6.2 During the Onsite Assessment

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

4.6.3 "Selling" the Observation to the Interviewee

For the purposes of this Chapter, let us assume that an observation may lead to a finding that will appear in the final assessment report.

Whenever a process or some circumstance leads the assessor to believe a non-conformance may exist, their main aim is to "sell" the idea that the condition observed may not meet requirements – and a finding may have to be written.

The evidence should be clear, and the circumstance should be obvious that it does not conform to the stated requirements. The differences between the two should be objective and obvious. When presented to CAB staff, 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 CAB staff may have no choice but to ask you to document the observation as a potential finding. Do so. You have their concurrence.

4.7 Washup Meetings

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

This keeps them apprised of the progress of the assessment 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 the assessment evidence has been gathered and is under review for the final report.

4.8 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 assessment activity between the assessor(s) and the lab. For reasons like the ones that drive an opening meeting, it has a similar agenda. See AS02-Assessment Procedure of the **Assessor Tool Kit**.

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

4.8.1 Closing Meeting Agenda

- Introductions and thanks
- Assessment scope and objectives
    - Reiterate scope and objectives (facilitation of conformance)

- Assessment methods and procedures
    - Reiterate investigation methods
- Confidentiality
    - Confirm assessment team's responsibilities – leave all documents with auditee
    - Confirm responsibilities
- Present the Assessment Report
    - Present the findings, if any, that have been raised and ensure that they are fully understood by the CAB staff and note a disclaimer that there might be unrecorded findings in areas that were not discovered during this assessment.
    - Explain the significance of categories of findings
    - Present the requirements for CAB response
    - Confirm the desired scope of accreditation.
- Respond to questions
    - Be prepared to handle questions from the lab. Focus on the benefits of their continued demonstration of competence.
    - Advise the CAB on the methods to dispute any findings contained in the report, or appeal any accreditation decisions made by ABC, by referring to AB07 *ABC Disputes and Appeals* procedure.
- Close the Meeting

4.8.2 Team Debriefing

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

It is also a good time for the team leader to exercise their responsibilities regarding formal recognition of the contributions of individual team members the overall success of the assessment.

4.9 Exercise 4 – Conducting an Opening Meeting

4.9.1 Learning Objectives

- **use** the assessment processes covered by the **Assessor Tool Kit**
- **use** the forms and procedures contained in the **Assessor Tool Kit**

4.9.2 Exercise Scenario

You are part of the re-assessment team that has been assigned to conduct the re-assessment of MOTIVA Laboratories Inc. ABC staff has recently sent you the Sample Assessment Package provided separately. You are now working the night before the re-assessment begins and you are preparing for the opening meeting to be held the next morning at the lab.

4.9.3 Exercise Objectives

Conduct an opening meeting at the lab.

4.9.4 Exercise Preparation – 60 minutes

You are to accomplish the following:

1. Use the assessment schedule created during Exercise 3, (*AF01-Assessment Schedule* of the **Assessor Tool Kit**).
2. Conduct an opening meeting at MOTIVA Laboratories Inc, to start the assessment process and deliver the AF01-Assessment Schedule of the Assessor Tool Kit to meet the following requirements:

- Use the Agenda shown in either the Course Handbook or the AS01 of the Assessor Tool Kit
- Cover at least three methods shown in the desired scope of accreditation
- use all the forms normally associated with an opening meeting, including *AF08-Attendance List*.

3. During the presentation, obtain agreement from the CAB on the approach to be used.

4.9.5 Exercise Deliverables

You are to deliver the opening meeting and the AF01-Assessment Schedule of the **Assessor Tool Kit** and obtain agreement from the CAB on the approach to be used.

4.9.6 Presentation and Group Discussion – 15 minutes per group

Each group is to present a completed schedule to the facilitator. Other groups may represent other members of the CAB staff. Obtain agreement from the facilitator, representing the CAB, on the approach to be used. Once all presentations are complete, the class will discuss the issues arising, and the salient points to retain.

4.10 Exercise 5 – Conducting Interviews

4.10.1 Learning Objectives

- **use** the assessment processes covered by the **Assessor Tool Kit**
- **use** the forms and procedures contained in the **Assessor Tool Kit**

4.10.2 Exercise Scenario

You are part of the re-assessment team that has been assigned to conduct the re-assessment of MOTIVA Laboratories Inc. Staff has recently sent you the re-assessment package associated with this re-assessment. See the Sample Assessment Package provided separately. You are part of a team that has been herded into the conference room of the CAB to conduct the interview of key staff, in this case, the quality manager. You are to interview the quality manager.

4.10.3 Exercise Objectives

Conduct an interview of key staff.

4.10.4 Exercise Preparation – 60 minutes

You are to accomplish the following:

1. Refresh your document review of CAB quality system processes to prepare for the interview of key staff.
2. Prepare two checklist questions for your interview so that the CAB staff can demonstrate the conformance of their processes to you.
3. Pose at least one question to the CAB staff to document the conformance (or non-conformance) of their processes.

    - Ask two questions. If a non-conformance is raised during the first question, there will be no need to ask the second question.
    - If a non-conforming condition is discovered, obtain the agreement of the interviewee that that the observed condition does not (or may not in the future) conform to requirements or that the CAB could exploit an opportunity for improvement and demonstrate greater efficiency or effectiveness.

4.10.5 Exercise Deliverables

Your group is to be prepared to interview key staff, based on a thorough document review of CAB procedures.

4.10.6 Presentation and Group Discussion – 15 minutes per group

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

5.0 Chapter 5 – Assessment Findings

5.1 Learning Objectives

The course will assist you to:

- **understand** the methods used to document capacity and competence
- **understand** techniques in identifying non-conformances and opportunities for improvement

5.2 Recording Assessment Observations

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

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

5.2.1 During the Document Review (System Audit)

During the document review, an assessor may make observations on the level of conformance of the documents against requirements. These observations are normally written in the space provided on the checklist forms and they form part of the discussion during the onsite assessment.

If they are retained until the assessment, they may be raised as issues, and allow evidence to be gathered to either confirm or deny the validity of the observation.

5.2.2 During the Onsite Assessment

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

5.3 Composition of Assessment Findings

Within the Annex of AS02-Assessment Procedure of the **Assessor Tool Kit**, assessors can acquire a summary related to the classification of findings. Appreciating that findings are really the clean, clear, and objective comparison of observed circumstance to stated requirement. Where they are the same, OK. Where they are different, findings that identify non-conforming conditions must be written.

A finding consists of all three of the following parts:

- A statement of the requirement,
- A statement of the condition, and
- Identification of the evidence that links one to the other.

5.3.1 Requirements

Requirements that specify conditions at the CAB come from four sources.

- ISO/IEC 17025 (or other applicable standard or test method)
- Requirements documents, such as Traceability or Uncertainty policies
- Regulations and laws that govern the operations of the CAB or the jurisdiction within which it operates
- The lab's own quality system

Any condition that is identifiably different than any specification contained in any of these requirements is a non-conforming condition.

5.3.2 Observed Condition

The conditions observed by assessors during an assessment are those that deal with the conduct of tests and calibrations, the implementation of supporting CAB procedures and quality system work, and any other circumstance that bears upon the production of results listed in the scope of accreditation.

5.3.3 The Evidence that links the Condition to the Requirement

No finding can exist without evidence of the conformance (or lack thereof) pertaining to any condition when compared to a requirement. No evidence; no finding. Simple as that. Evidence comes in three forms: document review, interview, and observation.

Since an assessment is relatively objective, assessors can easily gather evidence to support the demonstrated competence of the CAB and any conditions that may or may not conform to requirements.

There are three types of objective evidence that can be gathered during an assessment:

- **Reading (document review).** This is done prior to the assessment visit during the document review of CAB policies and procedures. Document review also includes review of records obtained during the onsite assessment.
- **Watching (observation).** This is normally only done during the onsite visit, where a process is examined, and evidence is obtained by noting the execution of the process.
- **Listening (interview).** This is normally done only during the onsite visit and evidence is obtained from the description of processes provided during interviews with CAB staff.

5.4 Writing Assessment Findings

An assessment Report documents findings in the manner shown on the *AF08-Assessment Finding Forms* in the **Assessor Tool Kit**. These include:

- All observed conditions which do not conform to requirements, and
- Areas where the CAB excels.

5.4.1 Classification of Assessment Findings

All observations made during an assessment must be recorded. Some of these may become actual findings.

The following is a summary related to the classification of findings drawn from many accreditation bodies. This list is generic, and many accreditation bodies will have different classification systems.

The Assessment Report documents:

- All Findings from the assessment activity, and
- Areas where the CAB excels.

Once an observation becomes a finding, it falls into one of four categories:

Non-Conformance. A non-conformance against the requirements of the standard (ISO/IEC 17025), against the CAB's own procedures, or is a condition that adversely affects the validity of the test result. A response on action taken and supporting evidence of this action is required within the specified time frame (30 days for accredited labs, and somewhat longer for applicants).

Examples include:

- Failure to follow specified test methods or other supporting work instructions.
- Test methods not validated or verified or inappropriate supporting work instructions.
- Faulty equipment.
- Non-conformances relating to test organisms, materials, supplies, etc. (includes availability, functioning, labelling and storage).
- Failure to meet traceability requirements
- Failure in recordkeeping relating to measurement (i.e., absence of records for CAB reagents, or measurements of time, length, volume, temperature, or mass).

- Failure in recordkeeping relating to sample reception, test data including identified non-conformances, equipment maintenance, test sample maintenance.
- Failure to properly identify or store samples.
- Failure in documenting test reports (e.g., absent, or nonconforming data not flagged, inappropriate use of digits or inappropriate reporting of low-level data).
- Absence of internal audit and Proficiency Testing or InterCAB Comparison records.
- Absence of quality policy and supporting objectives.
- Absence of policies and procedures for: staff training, procurement of goods and services including sub-contracting, method validation, document control, review and audit, internal quality control, sample management, data management including recordkeeping, test report authorization, workload management, confidentiality, and complaints.
- Absence of organization chart and Job Descriptions of all key staff.

Potential Non-Conformance: A condition that may result (in the future) in a non-conformance against the requirements of the standard (ISO/IEC 17025) or the CAB's own procedures but has not yet occurred. A potential non-conformance should be considered to exist if the condition may result in a Non-Conformance in the future. A response on action taken and supporting evidence of this action is required within the specified time frame (30 days for accredited CABs, and somewhat longer for applicants).

Examples include:

- Potential failure to follow specified test methods or other supporting work instructions.
- Test methods potentially not validated or verified or potentially inappropriate supporting work instructions.
- Equipment that is potentially faulty.
- Potential non-conformances relating to test organisms, materials, supplies, etc. (includes availability, functioning, labelling and storage).
- Potential failure to meet traceability requirements.
- Potential failure in recordkeeping relating to measurement (i.e., absence of records for CAB reagents, or measurements of time, length, volume, temperature, or mass).
- Potential failure in recordkeeping relating to sample reception, test data including identified non-conformances, equipment maintenance, test sample maintenance.
- Potential failure to properly identify or store samples.
- Potential failure in documenting test reports (e.g., absent, or nonconforming data not flagged, inappropriate use of digits or inappropriate reporting of low-level data).
- Potential absence of internal audit and Proficiency Testing or InterCAB Comparison records.
- Potential absence of quality policy and supporting objectives.
- Potential absence of policies and procedures for: staff training, procurement of goods and services including sub-contracting, method validation, document control, review and audit, internal quality control, sample management, data management including recordkeeping, test report authorization, workload management, confidentiality, and complaints.
- Potential absence of organization chart and Job Descriptions of all key staff.

Opportunity for Improvement: A condition that may allow the CAB to better meet the requirements of the standard or other specification, or more easily or efficiently enhance processes within the lab. Opportunities for improvement are to be used judiciously and not to force an opinion onto the CAB staff.

Examples include:

- Opportunity to enhance ease of implementation of specified test methods or other supporting work instructions.
- Opportunity to enhance ease of implementation of test methods or their validation or verification or supporting work instructions.
- Opportunity to enhance ease of use of equipment.
- Opportunity to make enhanced use of test organisms, materials, supplies, etc. (includes availability, functioning, labelling and storage).

- Opportunity to enhance ease of implementing traceability requirements.
- Opportunity to enhance ease of recordkeeping relating to measurement (i.e., records for CAB reagents, or measurements of time, length, volume, temperature, or mass).
- Opportunity to enhance ease of recordkeeping relating to sample reception, test data including identified conditions, equipment maintenance, test sample maintenance.
- Opportunity to enhance ease of properly identifying or storing samples.
- Opportunity to enhance ease of documenting test reports (e.g., overcoming absent data, or flagging nonconforming data, appropriate use of digits or appropriate reporting of low-level data).
- Opportunity to enhance internal audit and Proficiency Testing or InterCAB Comparison records.
- Opportunity to enhance quality policy and supporting objectives.
- Opportunity to enhance policies and procedures for: staff training, procurement of goods and services including sub-contracting, method validation, document control, review and audit, internal quality control, sample management, data management including recordkeeping, test report authorization, workload management, confidentiality, and complaints.
- Opportunity to enhance organization chart and Job Descriptions of all key staff.

5.4.2 Other Comments that may be contained in the Report

Critical Non-conformances: If any non-conformances seriously call accredited and reported test results into question, assessors must document the nonconformity, grade it as Critical Non-Conformance, and immediately notify the AB in writing. Include all relevant information, and if possible, copies of the objective evidence. Critical Non-Conformances are those conditions that can bring the accreditation program into disrepute and must be highlighted to both the CAB and the AB quickly.

Comments not needing any Action: The assessment team may highlight areas where the CAB excels. Use these comments judiciously, and always discuss with the CAB representative.

5.4.3 Assessment Findings are aimed at Conformance Only (NCs and PNCs Only)

A finding normally aims to have the CAB establish conformance to requirements. Experience has shown that a non-conforming condition related to the operation of a CAB falls into one of three distinct activities, each of which is in response to a specific hole in their management system. The assessment team cannot ask the CAB to do any of this as they are limited to only reporting the hole they encounter, but they should be aware of what the most likely outcomes will be.

5.4.3.1 NC or PNC that the CAB QMS is Missing a Policy or Procedure

The assessment team has observed that a required policy or procedure is missing or lacking sufficient information. The CAB will end up writing a policy to obligate itself to do something called for in a requirements document or write a procedure to document how to do something called for in a requirements document.

5.4.3.2 NC or PNC that the QMS has some Policies or Procedures that lack Sufficiency.

The assessment team has observed that a required policy or procedure is present, but may not be sufficient, or adequate or appropriate to meet the requirement. The CAB will end up modifying the CAB policy to obligate itself to do something called for in a requirements document or modify a procedure to document how to do something called for in a requirements document.

5.4.3.3 NC or PNC that the CAB lacks evidence of Implementation of a Policy or Procedure

The assessment team has observed that a required policy or procedure is present, and it is sufficient, adequate, and appropriate to meet the requirement, but the CAB may not be following it. The CAB will end up recording evidence that the CAB policy to obligate itself to do something called for in a requirements document or record evidence that a procedure to document how to do something called for in a requirements document is being implemented and followed.

5.4.4 NC and PNC Findings are normally cited against ISO/IEC 17025

Most findings on an assessment report are cited against ISO/IEC 17025.

The following examples illustrate this for ease of citation:

- Any finding that notes a regulatory requirement not being met by the lab. The assessor may cite the finding against, for example, clause 5.4 which is the global requirement for laboratories to follow the law.
- Any finding where a method is not being followed, the citation is normally against clause 7.2 – *Selection, Verification and Validation of Methods*.
- Any finding where a CAB procedure is not being followed, clause 5.3 – *Document Control* may be cited, or another more appropriate clause in 17025 that deals with the specific impact of lack of implementation. For example, a procedure not being followed may be the subject of something specific such as internal audits (5.8), or method validation (7.2), or obtaining agreement on a Decision Rule (7.1.3).

Most accreditation bodies also want their assessors to cite findings against their own (AB) policies, or ILAC requirements, or even the lab's own QMS. **In essence, if a requirement exists in any of these documents, and it is not being followed, such a circumstance must be the subject of a finding.**

5.4.5 Assessment Findings relate to Only the Desired Scope of Accreditation

ISO/IEC 17011 is the standard that describes the methods to be used by accreditation bodies that accredit, amongst other things, laboratories. This standard applies to assessments and accreditation for "a defined scope of accreditation." All issues which neither impact the scope of accreditation, nor are part of it, are outside the things for which an assessor can write a finding.

If a condition does not affect the desired scope of accreditation, does not affect the ability of the CAB to produce technically valid results, is not part of its own management system, and is not a regulatory or accreditation requirement, IT CANNOT BE THE SUBJECT OF AN ASSESSMENT FINDING and the ASSESSOR SHOULD NEITHER REPORT ON IT, NOR COMMENT ON IT. When in doubt, call the accreditation body assessment staff.

5.4.5. Writing Assessment Findings

It is now possible to write the findings that are based on the observations acquired during the document review and the onsite assessment.

This applies to both quality system assessment activities and technical assessment activities.

In accordance with the requirements contained in the AB's own assessment procedure, AS02-Assessment Procedure, the assessors now prepare the report by adding information specific to an item from AF04-*Assessment Checklist for 17025* or AF07-*Test and Measurement Checklist*.

5.5 Exercise 6 – Classifying and Writing Findings

5.5.1 Learning Objectives

- **use** the assessment processes covered by the **Assessor Tool Kit**
- **use** the forms and procedures contained in the **Assessor Tool Kit**
- **use** the tools provided by the **Assessor Tool Kit**

5.5.2 Exercise Scenarios

Write **one finding** from the Assessment of MOTIVA CAB using the information from one of the following Scenarios.

5.5.2.1 Scenario 1

The CAB does not record any Analytical QC failures which are rerun prior to determination of an NC, and not recorded in the CAB non-conformance tracking log contrary to ISO/IEC 17025, clause 8.7.1

5.5.2.2 Scenario 2

The CAB cannot provide evidence of legally enforceable agreements with any of its personnel to support demonstration of conformance to ISO/IEC 17025, clauses 4.2.1 and 4.2.3.

5.5.2.3 Scenario 3

The CAB does not maintain records of the qualification of a “sister” CAB within the same corporate entity for the provision of results used in CAB reports to Clients 123 and 456 although these tests appear on both lab’s scopes of accreditation, contrary to ISO/IEC 17025, clause 6.6.2.

5.5.2.4 Scenario 4

The CAB does not control handwritten amendments on issued documents, specifically Procedure 003 and 006 which each have conflicting handwritten amendments, contrary to ISO/IEC 17025, clause 8.3.1.

5.5.2.5 Scenario 5

The CAB procedure for its use of Decision Rules does not require obtaining agreement with the customer on the Decision Rule used by the CAB for concrete testing, contrary to ISO/IEC 17025, clause 7.1.3.

5.5.3 Exercise Objectives

Classify the finding that applies to the records you have been provided.

5.5.4 Exercise Preparation – 60 minutes

You are to write one finding using AF07- Assessment Finding Form from the Assessor Tool Kit.

5.5.5 Exercise Deliverables

You are to deliver your finding based on your study of the assigned observations provided in the Sample Scenarios above. If you are working in a group, you are to deliver all of your individual findings based on your study of the assigned observations provided in the Sample Scenarios above.

5.5.6 Wrap up Group Discussion – 90 minutes

During the discussion that follows, the most appropriate articulation of findings from all Sample Scenarios will be shared.

6.0 Chapter 6 – Assessment Reports

6.1 Learning Objectives

The course will assist you to:

- **manage** opening meetings, closing meetings, and interviews of CAB personnel
- **write** accreditation assessment reports

6.2 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 assessment activity between the assessor(s) and the lab. For reasons like the ones that drive an opening meeting, it has a similar agenda. See AS02-Assessment Procedure of the **Assessor Tool Kit**.

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

6.2.1 Deliver one Copy of the Report During the Closing Meeting

Present the Assessment Report

- Present the findings, if any, that have been raised and ensure that they are fully understood by the CAB staff. Note a disclaimer that there might be unrecorded findings in areas that were not discovered during this assessment.
- Explain the significance of categories of findings.
- Present the requirements for CAB responses to findings.
- Confirm the desired scope of accreditation.
- Advise the CAB on the methods to dispute any findings contained in the report, or appeal any accreditation decisions made by the Accreditation Body, by referring to their disputes and appeals policy (AB07 ABC Disputes and Appeals).

Ensure one copy of the report remains with the CAB and one copy is forwarded to ABC Accreditation Body.

6.3 Assessment Report Formats

Review the sample CAB Assessment Package provided separately and used in previous Exercises of this course. All assessment reports eventually assume the form shown in the Corrective Action Summary at the end of the Proposed Scope of Testing. This format is presented in that exercise to show the previous report of a CAB prior to an upcoming assessment.

Note the elements of the report and compare them to format of F04-*ISO/IEC 17025 Assessment Checklist*. Compare both of those documents to the format of the AF05-*Assessment Report* shown in the **Assessor Tool Kit**. The common elements of all findings forms are as follows:

Findings Form. Using the supplied sample format, this is always on the top right-hand corner of the *AF08-Assessment Finding Form a*ttached to the assessment report.

1. The **Reference** that the finding is drawn from in ISO/IEC 17025 or the lab's own QMS requirements.
2. The **type** (or **classification**) of finding. This is where the finding is listed as being a Non-Conformance, Potential Non-Conformance, or Opportunity for Improvement.
3. The **Description** of the actual condition that was observed and the evidence that demonstrates how the condition relates to the **Reference**. Essentially this is the **Finding,** and it is a combined statement of requirement, condition, and the evidence that links the two.

6.4 Assessment Report Preparation

6.4.1 Completing the Assessment Report:

The Assessment Report is completed using AF05-*Assessment Report Form* contained in the **Assessor Tool Kit** described in Chapter 5 above.

6.4.2 AB Requirements for Responses to Findings

All Non-Conformances and Potential Non-Conformances would normally be addressed within the following timeframes, because ILAC, IAAC, and APAC all wish ABs to not accredit current labs that have findings outstanding beyond this time. For new, not-yet-accredited labs, there is more leeway.

- New (applicant) Laboratories – 90 days.
- Accredited Laboratories – 30 days.

Laboratories have the right to dispute findings. Refer to AB07 *ABC Disputes and Appeals* procedure of the **Assessor Tool Kit**.

Appropriate evidence of implementation (e.g., updated documentation, samples of records, purchase orders, photographs, etc.) must be provided to accreditation body with any submitted responses to findings. Major Non-Conformances may be subject to on-site verification by the AB. Confirmation of corrective action for all written findings is reviewed at the subsequent regularly scheduled re-assessment and does not normally require a supplementary visit prior to that re-assessment.

If a Non-Conformance is deemed serious and calls the accreditation into question, ABC may require a response sooner than 30 days, or recommend suspension.

6.5 Exercise 7 – Writing and Delivering an Assessment Report (AF06)

6.5.1 Learning Objectives

- **use** the assessment processes covered by the **Assessor Tool Kit**
- **use** the forms and procedures contained in the **Assessor Tool Kit**
- **use** the tools provided by the **Assessor Tool Kit**
- **write** accreditation assessment report
- **manage** opening meetings, closing meetings, and interviews of CAB personnel

6.5.2 Exercise Scenario

You are part of the re-assessment team that has completed the re-assessment of MOTIVA Laboratories Inc. Your team was sent the Sample Assessment Package provided separately. Your team has assessed the CAB and have written findings from the observed conditions determined from previous exercises. You are now required to write a complete report using AF05-*Assessment Report Form.*

You must use the findings created in Exercise 6 as well as the desired scope of accreditation shown in the Sample Assessment Package.

6.5.3 Exercise Objectives

Prepare and deliver a re-assessment report to present to the CAB during a closing meeting.

6.5.4 Exercise Preparation – 90 minutes

You are to accomplish the following:

1. Deliver a re-assessment report during a closing meeting to the CAB manager and staff.
    - Use the AF05-*Assessment Report Form* to prepare the report.
    - Ensure that each finding contains all three required components within the text of the finding. See Section 8.3 – **Composition of Findings***,* above.

6.5.5 Exercise Deliverables

Your group is to be prepared to deliver a complete closing meeting.

6.5.6 Wrap up Group Discussion – 30 minutes

Each group is to deliver their report, including their findings from the study of the document set contained in Tab 5. During the discussion that follows, all findings will be examined for completeness and inclusion of all three required components.

6.6 Presentation and Group Discussion – As long as needed.

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

7.0 Chapter 7 – Addressing Assessment Findings

7.1 Learning Objectives

The course will assist you to:

- **determine** how to close out and follow up assessment findings.

7.2 Follow up and Review of Findings (See Chapter 4)

Assessments findings require action on the part of CAB staff. These findings will be non-conformances, potential non-conformances, or opportunities for improvement. Assessment reports can result in all of these.

Once raised and recorded within a CAB's continual improvement program, they become corrective and preventive actions the same as for those raised from other quality system identification mechanisms. See **Chapter 4** above. Within the continual improvement program of the lab, as with other corrective and preventive actions, the implementation of these actions must be followed up some time after close out, to determine if they have achieved the desired results.

7.2.1 The Simplest Approach in any CAB.

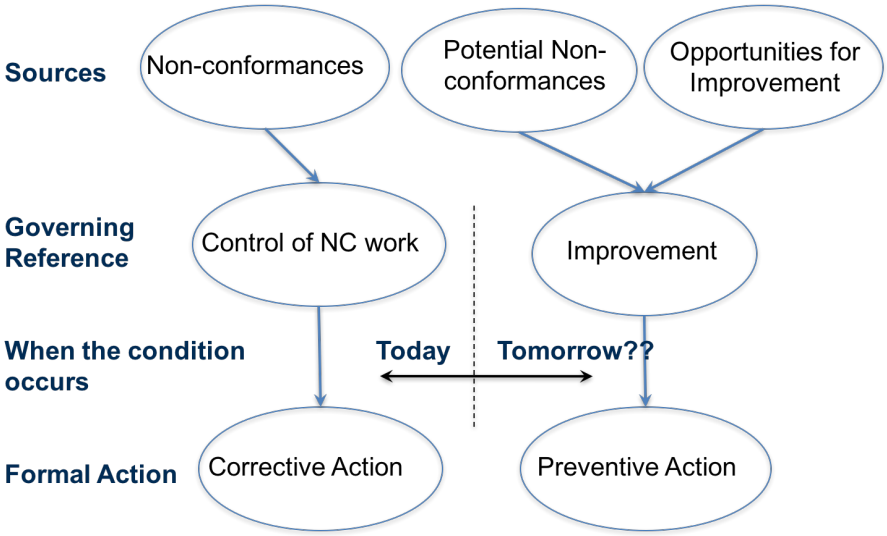
Most CASCO standards now contain seven (7) clauses that facilitate our ability to find these "NCs." They are (in 17025):

8.6 – Improvement (including Feedback)
7.9 – Complaints
7.7 – Quality Assurance / Quality Control
8.5 – Actions to address risk and opportunities
8.7 – Corrective Action
8.8 – Internal Audits
8.9 – Management Review

All of these clauses provide some direction on the search for NCs. Because these standards are not perfect documents, they neglect to specify that these same clauses can also be used to search for "PNCs" as well. In fact, some dedicate an entire clause on what to do when a non-conformance is discovered (identified). Some have only recently included wording on what to do when a "PNC" is discovered.

The types of clauses cited above are the best sources of procedures against which non-conforming and PNC (OFIs) can be identified and raised.

CAB policies and procedures written against these clauses provide the best means of identifying circumstances that should be considered under continual improvement.



- Root cause analysis
- Possible range of solutions
- Selection of one solution
- Implementation of the selected solution
- Documenting the implementation
- Monitoring the solution for effectiveness

The unique clauses are those dealing with feedback and service to the customer, because they may require the CAB to undertake work to determine whether a situation is conforming or not, before any identification is made. In other words, an investigation into the validity of feedback is necessary in order to determine whether a circumstance is non-conforming (or potentially non-conforming).

7.2.2 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 2026**
Finding # **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 2026*

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 2026
Supervisor/Manager Initials _____ QM closure (Initials) _____

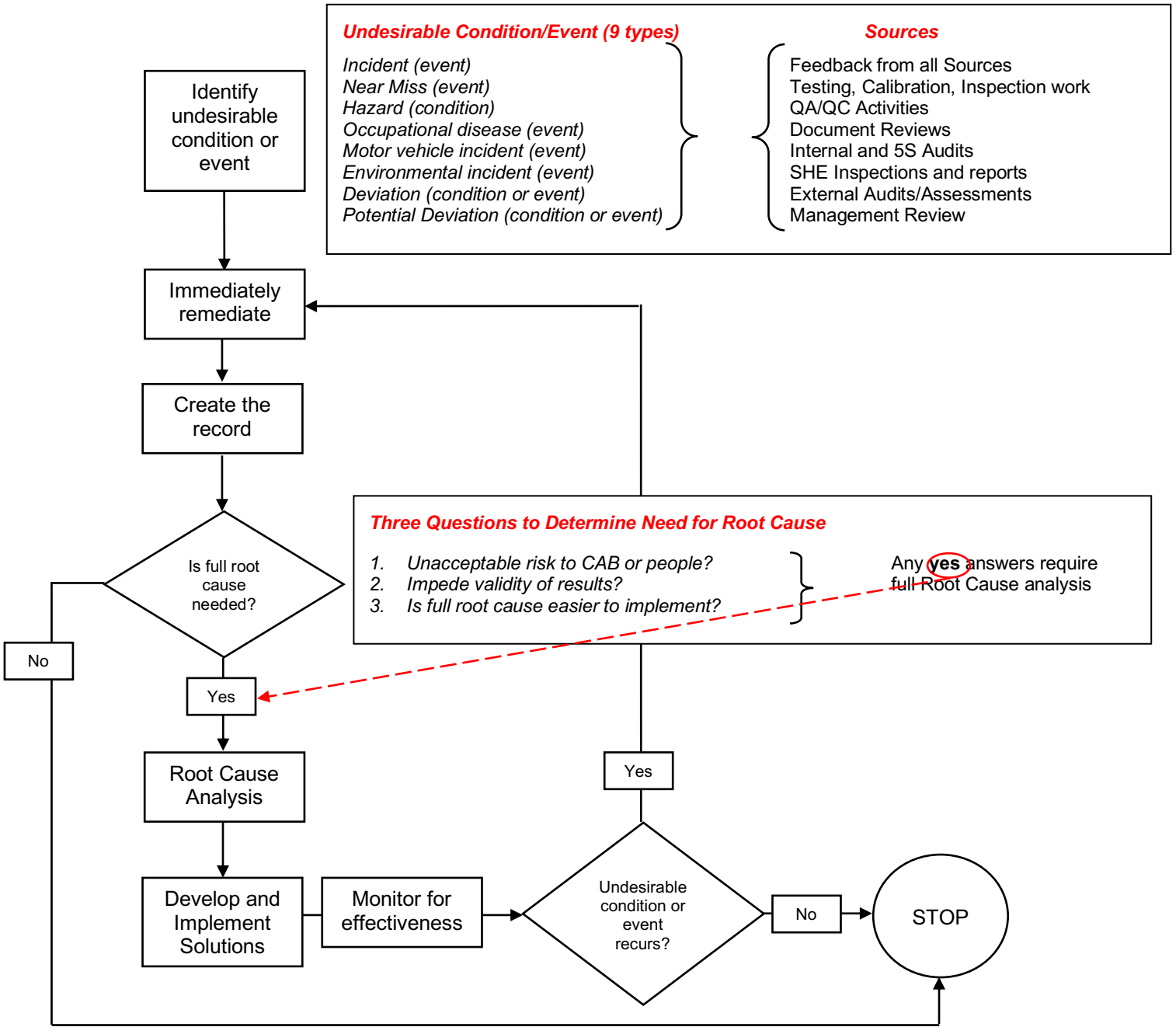
6. **Follow up** Date Due: 16 October 2026

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

7.2.3 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.

7.2.4 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.

7.2.5 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 8.5 and 8.6,
- ISO 15189, clauses 8.5 and 8.6,
- ISO/IEC 17043, clauses 8.5 and 8.6
- ISO 17034, clauses 8.8 and 8.10,
- 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, 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 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 diagram in Section 7.2.2 above. 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

7.3 Addressing Individual Findings

7.3.1 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.

7.3.2 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 7.2 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 Quality Assurance and Quality System), 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.

7.3.3 Root Causes based on Personnel Factors

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

Physical capacity

- 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

Intellectual capacity (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 – Second most Common Root Cause

- 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 – Most Common Root Cause

- 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)

7.3.4 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

7.3.5 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

7.3.6 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

7.3.7 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. These root causes are the most difficult and least accepted root causes in any organization. They are nearly IMPOSSIBLE to defend. **USE WITH CAUTION.**

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.**

7.3.8 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 Section 7.2, 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.

Organizations 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.

7.3.9 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.

7.4 Monitoring, Follow up and Timelines

Clause 8.7 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. This clause 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 Incident and Deviation Report shown above.

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.

7.5 Exercise 8 – Solutions that address the Root Cause

7.5.1 Learning Objectives

- **understand** techniques in identifying non-conformances and opportunities for improvement.
- **close** out and follow up findings from all sources.

7.5.2 Exercise Scenarios

You work in a CAB that was recently re-assessed by the AB. They left five findings at the lab. You have been gathered by the Managing Director to address these findings so that an appropriate response can be forwarded to AB staff.

Use any two of the five following sample findings to document how you would address them.

7.5.2.1 Scenario 1

The CAB does not record an NC when encountering Analytical QC failures which are then rerun and found OK, contrary to ISO/IEC 17025, clause 8.7.1.

7.5.2.2 Scenario 2

The CAB cannot provide evidence of legally enforceable agreements with any of its personnel to support demonstration of conformance to ISO/IEC 17025, clauses 4.2.1 and 4.2.3.

7.5.2.3 Scenario 3

The CAB does not maintain records of the qualification of a "sister" CAB within the same corporate entity although the sister lab's results are included in their own CAB reports to Clients 123 and 456, contrary to ISO/IEC 17025, clause 6.6.2. These tests appear on both lab's scopes of accreditation,

7.5.2.4 Scenario 4

The CAB does not control handwritten amendments on issued policies and procedures, specifically Procedure 003 and 006, which have conflicting handwritten amendments, contrary to ISO/IEC 17025, clause 8.3.1.

7.5.2.5 Scenario 5

The CAB procedure for its Decision Rules does not require obtaining agreement with the customer on the Decision Rule used by the CAB for concrete testing according to ASTM C39, contrary to ISO/IEC 17025, clause 7.1.3.

7.5.3 Exercise Objectives

Complete the documentation and address findings from the recent assessment using *AF08 Assessment Finding Form* for each finding.

7.5.4 Exercise Preparation and Group Discussion – 60 minutes

You are to use an *AF08-Assessment Finding Form* for each of the two of the sample findings and complete Blocks 1 through 4 and Block 6 for each one:

- Write the Sample Finding (exactly as written above) into Block 1
- Write a remedial action to simply correct this problem in Block 2
- Determine the need for corrective or preventive action from the three questions in Block 3
- Determine root causes (where corrective or preventive action is deemed required) in Block 4
- Propose acceptable solutions (where corrective or preventive action is deemed required) in Block 4
- Propose requirements for any follow up (where corrective or preventive action is deemed required) in Block 6

7.5.5 Exercise Deliverables

You are to deliver two completed *AF08-Assessment Finding Forms*.

7.5.6 Wrap up Group Discussion

Group discussion will take place following the development of solutions.

8.0 Chapter 8 – Final Course Exam

8.1 Demonstration Objective

Demonstrate understanding of the knowledge and skills acquired during the Lead Assessor Course.

8.2 Exam Scenario

You have completed 36 hours of a Lead Assessor Course. You are now required to document (record) your understanding of the knowledge acquired during the course.

8.3 Exam Objectives

Complete the final exam.

8.4 Exam Time – 120 minutes

You are to accomplish the following:

1. Place all your materials around your exam space.
2. At the appointed time, open your exam and write your name and the course details on the front page of the exam.
3. Complete the remainder of the exam within the 120 minutes remaining, discussing your options with your colleagues

8.5 Exam Deliverables

You are to submit your completed exam 120 minutes after the appointed start time.

8.6 Wrap up Group Discussion

Group discussion will take place after the exam has been submitted and will be marked in class by all participants.

8.7 Course Wrap up.

Participants are to review course objectives and provide feedback on how to improve course design, delivery, and course materials.