INTERNATIONAL ACCREDITATION SERVICE®

IAS Lead Assessor Course
Chapter 6 – Addressing Assessment Findings

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Course Outline

1. Introduction
2. Accreditation and Assessment Basics
3. Planning and Conduct of Assessments
4. Meetings and Interviews
5. Writing Assessment Findings
6. Writing Assessment Reports
7. **Addressing and Closing out Findings**
8. Final Exam

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Addressing and Closing out Findings

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. Within the continual improvement program of the CAB, 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.

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Determining the need for Root Cause Analysis

Determine if root cause analysis is required. Ask the "Three Questions."

If the results do not require root cause analysis, stop and submit the record created in the Identify and Remediate steps.

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Is RCA Necessary? - Questions

Three Questions:	Answers:
1. Does this condition (or might it) present unacceptable risk to organisation (or its people or visitors) or provide significant benefit? (Risk/Benefit = IMPACT X Probability of occurrence)	Yes/No?
2. Has this condition (or might it) prevent the organisation from producing technically valid results or making technically valid decisions or significantly enhance its ability to produce technically valid decision?	Yes/No?
3. Is permanent prevention easier than repeated remediation?	Yes/No?

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Is RCA Necessary? - Answers

Results of the Three Questions:

1. If ALL answers are “no,” then root cause is not required and only remediation (correction or prevention) is needed. Submit the record created in the Identify and Remediate steps. Your job is done!!
2. ANY “yes” answers means a full root cause analysis is REQUIRED. Continue the record created in the Identify and Remediate steps.

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Root Causes Processes

1. Where root causes live
2. Start with the identified condition
3. Doing the root cause analysis
   - Determine the Direct Cause.
   - Determine the Root Cause.
   - Document the results

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Look for the Root Cause from the First Principle in ISO/IEC 17025

Capacity ***(This is where they live)***

Concept that a laboratory 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 technically valid results.

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Identify

Identify the problem from Injury, Hazardous Condition/Near Miss, Environmental Incident, Motor Vehicle Accident, or from Deviation (or Potential Deviation) that adversely affects technical validity of CAB results.

Create a record and write it down!!!!

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Identify – 1 (HSE - OSHA)

1. **Injury** (to a person): any event in which a person has suffered pain or distress AND where a minimum of first aid treatment is required (including eye wash). Injury types include Lost Time Injury, Medical Aid Injury, Modified Work Injury, and First Aid Injury. Each type calls for a different level of medical treatment and produces different work-related results for the injured person. Very minor incidents such as paper cuts and stubbed toes need not be recorded unless associated with a Hazardous Condition (below). First Aid Injuries do not result in lost time.
2. **Near Miss**: an event in which a person would have suffered pain or distress AND where a minimum of first aid treatment would have been required (including eye wash).
3. **Hazardous Condition**: condition that could potentially cause injury to persons or damage to property. Oil leaking from machines, obstructed walkways, dangerous conditions, and unguarded machinery are examples of hazardous conditions.
4. **Occupational Disease**: a disease or illness which has occurred as a result of working conditions. This includes: allergic reactions, dermatitis, infections, cancer, hand / arm vibration syndrome etc.

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Identify – 1 (HSE - OSHA)

1. **Environmental Incident**: release of hazardous materials. Examples are emissions into the atmosphere, waterways, drains or soil. This includes the release of toxic smoke or gas, liquid chemicals, radioactive materials, contaminate water, biohazards, or oil.
2. **Motor Vehicle Incident**: a company vehicle is involved in an accident resulting in damage to the vehicle or injury to the occupants. This includes all other motors vehicles being driven by an company driver of a company car or van while traveling to and from work.

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Identify – 2 (Quality)

Deviation: a perceived or actual departure from policies, procedures or processes in our management system or technical operations, or from a requirement from an external specification such as a standard that has already occurred. Note: This term encompasses all concepts previously referred to as a “non-conformance” or “anomaly.” It includes the concepts behind other, more specific terms, such as “finding,” or “issue,” or “condition.”

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Identify – 2 (Quality)

Potential Deviation: a potential departure from policies, procedures or processes in our management system or technical operations, or from a requirement from an external specification such as a standard. Note: This term encompasses all concepts previously referred to as a "potential non-conformance" or "potential anomaly." It includes the concepts behind other, more specific terms that deal with future events, such as "finding," or "issue," or "condition."

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Identify – 2 (Quality)

Opportunity for Improvement:
A potential improvement in some aspect of CAB operations in terms of a savings in time or effort, a reduction in complexity, an enhancement to health and safety, an expansion of scope, or other measurable advantage to the business itself or the people working in the CAB.

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Root Cause Process

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Root Cause Process

1. Direct Cause. Ask the first “Why” and identify the Direct Cause.
2. Root Cause. Ask three or four more “Why’s” back along the chain of events and get to a condition or circumstance whose resolution that will permanently resolve the problem (and is still within your scope of responsibility). Find the hole in the System and fill it.
3. Document the results of the analysis as part of the overall Corrective or Preventive Action.

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Identify the Direct Cause

1. Direct Cause. Ask the first “Why” and identify the Direct Cause.

   OR

2. Visualise it: Take a mental picture of the actual occurrence (incident, deviation, etc.). You are looking at the Direct Cause in that picture.

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Example 1

Why was I late for work this morning?

PROBLEM: Why didn't I get to work on time? DIRECT CAUSE

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.

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Example 2

Received ticket for safety violation.

→ Car exhaust too loud.

→ Muffler knocked loose from tail pipe.

→ Daughter hit pothole.

→ Potholes in road.

→ Winters damaged roads.

→ Govt won't approve extra money for better roads.

→ Govt doesn't have extra money.

→ Govt spent money on welfare and legal issues.

→ Too many lawyers in politics.

- **Solution?** Drive car in Sweden where there are fewer lawyers. (??)

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The Chain of Causes

1. Direct Cause: The cause that directly resulted in an event. (The first cause in the chain.)
   - *This is the answer to your first question (your problem statement).*
2. Contributing Cause: A cause that contributed to an event but, by itself, might not have caused the event (the causes before the direct cause) or are back in the chain of events between the Direct Cause and the Root Cause.
   - *For a very simple problem there may not be any contributing causes.*
3. Root Cause: The fundamental reason for an event, which if corrected, would prevent recurrence or first-time occurrence. (The first cause in the chain).
   - *Root Causes that are outside the ability of an organization to address it are not useful for anything. Stick to the ones we can actually fix.*

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Root Causes Processes

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Identify the missing pieces

- Knowledge/skill of the people involved
- Environment surrounding the work:
  - Physical
  - Physiological
  - Equipment
- Quality control / assurance of the work
- Suitability of the procedures involved

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Root Cause Listing

Possible root causes include the following categories.

- Personnel Factors
- Environmental Factors
- Quality Factors
- Procedural Factors
- Organisational Factors

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Personnel Factors

- Physical capacity
- Intellectual capacity
- Physical or physiological stress
- Emotional or psychological stress
- Individual skill
- Individual knowledge
- Care and attention.

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Environmental Factors

- Physical plant and facilities
- Environmental conditions
- Tools and equipment
- Materials and supplies
- Maintenance
- Wear and tear

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Quality Factors

- Quality control
- Quality assurance
- Quality system

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Procedural Factors

- Standard procedures
- Specifications
- Implementation
- Selection of support

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Organisational Factors

- Leadership
- Communications
- Motivation

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Exercise 8 – Solutions from RCA/RBT

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

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Exercise 8 – Solutions from RCA/RBT

- You will use two of the five of the findings shown in Section 10.3.2 of the Handbook.
- For each finding complete one of the sample Incident and Deviation Reports and follow the steps given in Section 4.11 of the Handbook.

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Exercise 8 – RCA and Solutions

You are to determine the following:

- Whether corrective or preventive action is required
- The root causes whenever corrective or preventive action is required
- Acceptable solutions where corrective or preventive action is required
- Requirements for any follow up where corrective or preventive action is required

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