

Course Outline – Chapter 5

IAS

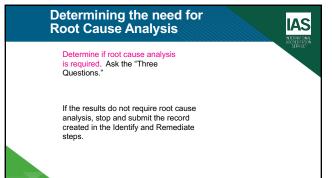
- 1. QMS and the need for internal audits
- 2. Planning internal audits
- 3. Meetings and interviews
- 4. Writing findings
- 5. Closing out findings

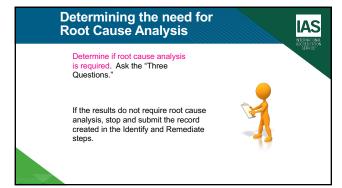
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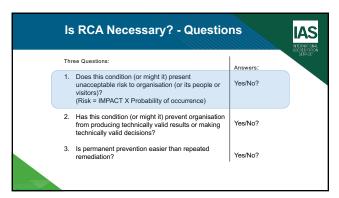
Addressing Departures

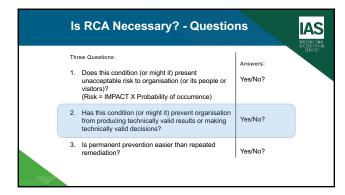


Examine the flowchart on page 42 of the Course Handbook. This is the absolute simplest method of addressing all findings, regardless of their source.









Three Questions:

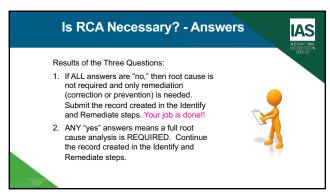
1. Does this condition (or might it) present unacceptable risk to organisation (or its people or visitors)?
(Risk = IMPACT X Probability of occurrence)

2. Has this condition (or might it) prevent organisation from producing technically valid results or making technically valid decisions?

3. Is permanent prevention easier than repeated remediation?

Yes/No?

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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)

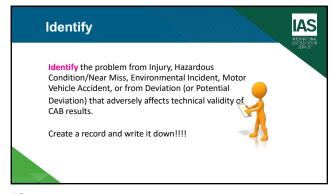
Concept that a laboratory has the resources (PEOPLE with the required skills and knowledge, the ENVIRONMENT with the required facilities and equipment, the QUALITY CONTROL, and the PROCEDURES) in order to undertake the work and produce technically valid results.

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Root Causes Processes



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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 could be the time. 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)



- 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. Motor Vehicle includent 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.

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 "nonconformance" 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.