ACTIVITY 1.3 TRAINING SESSION FOLLOWING THE FINDINGS FROM PREVIOUS ACTIVITIES:

NON CONFORMITIES & CORRECTIVE ACTIONS

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FINDING:

an assessment result formalized by ACCREDIA and graded as a Nonconformity (NC), Concern (Cn) or Comment (Cm).

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NONCONFORMITY (NC)

Non-fulfilment of a requirement.
This finding indicates the presence of a failure or deviation which:

a) jeopardizes the reliability of the operations of the Laboratory and/or,

b) affects the capacity of the quality management system (QMS) to retain the established quality level of conformity assessments or indicates a failure in the functioning of the QMS and/or,

c) threatens the credibility of the accreditation process or the integrity/honesty of ACCREDIA, and/or,

d) reveals a failure to respect the applicable mandatory requirements of the scope of accreditation;

e) derives from the persistent failure to resolve a Concern previously raised against a CAB.

A NC may lead to the imposition of sanctions.

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CONCERN

A finding caused by the **incomplete fulfillment** of a requirement (of a standard or a regulation of accreditation) with **no direct negative effect** on the quality of performances and results of a CAB.

For ACCREDIA a concern requires the opening of a treatment or corrective action within the specified timeframe and verified during the next two audit. **An unclosed concern at the next two audit is reclassified as a NC.**

If necessary, evidence of closure of the corrective action is evaluated by ACCREDIA by documental review, before the next surveillance visit.

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COMMENT

A finding raised by ACCREDIA against a Laboratory when the situation is **not an objective failure to meet a requirement**, but its **aim is to prevent** such a situation from occurring and/or to give indications for an improvement in the documents and/or operative modalities of the CAB.

The comments shall be analyzed by the Lab. It can be managed by opening a preventive action (PA) or improvement action. If the Lab does not accept them it shall record its reasons for doing so.

The treatment of comments and/or the decision not to accept them will be evaluated during the next on-site assessment.

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Accredia assessors are required to present and discuss the findings with the laboratory as soon as they are highlighted.

It is recommended not to leave surprises at the final meeting, on the contrary to arrive at the final meeting with the findings already understood and agreed with the laboratory.

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PRESENTATION OF THE FINDINGS

At the **closing meeting of the on-site assessment**, the assessment team:

- presents the findings, showing the contents and motivations to obtaine the understanding and agreement of the Lab;

- gathers the reserves of the Lab (alternatively the Lab may also express its reserves by means of the module DT-Mod-007, within **3 working days**);

- asks the Lab to sign in acceptance the report containing the findings and the summary assessment report (this report is also signed by the members of the assessment team, each for the finding on which is competent);

- gives to the Lab a copy of the report, specifying that ACCREDIA has the right to confirm or not to confirm the contents.

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REQUEST FOR, AND EVALUATION OF, CORRECTIVE ACTIONS (CAs)

Following the on-site assessment the ACCREDIA technical officer, after reviewing the findings of the assessors **to confirm** or **to modify** and/or **re-classify** them, sends the definitive version of the findings to the Lab, along with the request for CAs.

The Lab shall:

- **identify causes** of the NCs and Concerns ;

- identify and **implement** the CAs for the **removal of the causes**;

- analyze the comments.

- communicate the action plan for the closure of the NCs and concerns, specifying the timeframe involved (not exceeding the maximum deadline of 3 months fixed by ACCREDIA).

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REQUEST FOR, AND EVALUATION OF, CORRECTIVE ACTIONS (CAs)

All NCs and Concerns raised by ACCREDIA require treatment and CAs by the CAB on a case by case basis and **approved by ACCREDIA**.

The Technical Officer, in collaboration with the assessors after receiving:

- **the action plan,** reviews the CAs and, if the results of the review are not positive due to an analysis of the causes and/or CAs inadequate, the Lab is required for a new proposal (plan).

- **the evidences**, reviews the CAs and, if the results of the review are not positive due to unsuitably implemented CAs, the Lab is required for a new proposal (evidence).

The verification of the implementation of CAs may require an extra on-site visit.

Corrective actions

Analysis of the causes

According to the requirements of the standard, the Lab shall:

- distinguish if the cause of the problem is technical or managerial;
- go back to the roots of the problem (root cause);
- then appoint the more appropriate persons to implement the necessary corrective actions.

Selection and implementation of corrective actions

To avoid repetition of the same or very similar NCs, each corrective action shall correspond to the revision of at least one prescription (of the manual and/or the procedures).

Monitoring of the corrective actions

The Lab shall distinguish among an audit of the implementation of the CAs and an audit of the effectiveness of the CAs.

ACCREDIA-DT MOD.006 notice of the findings and request for corrective action (1/3)

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Rilievo individuato da ACCREDIA DT e richiesta di trattamento:

Dipartimento Laboratori di taratura		Laboratorio/Centro	XXXXXXX	N°	LAT XX
		Valutazione su campo del	24 settembre 2015		
Identificazione: Mod-006 Revisione 11					

Descrizione del rilievo Classificazione: ¨ NC ☒ OSS ☐

1 alla prescrizione della Norma ISO 17025 § 5.6.1 ,del MQ- § - , della procedura - § -

(a cura Ispettore):

Il laboratorio non ha previsto la taratura della sonda di umidità ambientale, considerato l'ampio intervallo di valori accettato (da 70% a 20%). Essendo l'umidità una grandezza di influenza per le misure di taratura, una taratura dell'igrometro è comunque richiesta con periodicità ed incertezza adeguati all'uso.

Firma Ispettore: M.Toni Firma per Lab/Centro: R.Rossi Riserve: SI ☐ NO ☒

2 Rilievo n: 1

☒ ACCREDIA approva il rilievo riscontrato, oppure:

☐ ACCREDIA varia il rilievo con la seguente formulazione: Classificazione: NC ☐ OSS ☐

(a cura Funzionario Tecnico):

Firma Funzionario Tecnico: Prot. N: DT2015MT005 del 29 settembre 2015

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ACCREDIA-DT MOD.006 notice of the findings and request for corrective action (2/3)

Trattamento pianificato dal Laboratorio/Centro (a cura Lab/Centro)						
3	**Causa del rilievo riscontrato**:					
	Considerato l'ampio intervallo di valori accettato per l'umidità ambientale il laboratorio non aveva ritenuto opportuno pianificare la taratura del sensore. In nessuna occasione i valori rilevati dal sensore sono stati al di fuori di tale intervallo.					
4	**Correzione proposta:**					
	Verificare se ci sono casi in cui la differenza tra i valori di umidità misurati e i limiti è inferiore al 10%. In questi casi correggere il valore di incertezza stimato applicando una componente di incertezza aggiuntiva.					
5	**Azione correttiva proposta:**				Documenti da aggiornare:	
	Taratura della sonda di umidità con periodicità biennale. La taratura sarà effettuata da Centro LAT in concomitanza con le sonde di temperatura e pressione, poichè la centralina termometrica è unica per le tre sonde. Si pianifica la taratura della centralina per marzo 2016 e l'emissione del relativo ordine di tartura entro la data di chiusura dell'azione correttiva.				DOC.03.05 "Strumentazione, attrezzature e campioni del Centro" DOC.03.04 "Lista di taratura e conferma metrologica" - Istituzione scheda apparecchiatura	
	Funzione incaricata	**Resp. Centro**	**Incaricato**	**R.Rossi**	**Chiusura entro il**	**28 dicembre 2015**
6	**Evidenze da fornire ad Accredia entro la data di chiusura:**					
	DOC.03.05 in rev. 9 - DOC.03.04 in rev. 13 - Ordine emesso per la taratura - Scheda apparecchiatura					
					Prot. N: DT2015MT006	del 19 ottobre 2015
7	Firma Lab/Centro:	R. Rossi	Firma Ispettore:	MP Toni	Firma Funz. Tecnico:	MP Toni
	Data:		Data: 19 ottobre 2015		Data: 19 ottobre 2015	

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ACCREDIA-DT MOD.006 notice of the findings and request for corrective action (3/3)

Valutazioni previste da ACCREDIA (a cura Funzionario Tecnico/Ispettor incaricato Valutazione su campo)							
8	su evidenze fornite	☐	prossima valutazione su campo	☐	valutazione su campo straordinaria	☐	
	altro : ☐						
9	Valutazione attuazione:						
	Firma FT/ISP:			Data:			
10	Valutazione efficacia:				Chiusura efficace: SI ☐ NO ☐		
	Firma FT/ISP:			Data:			

What is a Root Cause Analysis (RCA)

- A system of problem solving methods aimed at identifying the root causes of problems or incidents.
- Predicated on the belief that problems are best solved by attempting to correct or eliminate root causes, as opposed to merely addressing the immediately obvious symptoms.
- By directing corrective measures at root causes, it is hoped that the likelihood of problem recurrence will be minimized.

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Where is this Required?

- **ISO/IEC 17025:2005 Section 4.11**
  - 4.11.1 The laboratory shall establish a policy and procedure for implementing corrective action.
  - 4.11.2 The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.

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Start with a New Mindset

- People are generally not the ultimate causes of problems.
- People implement processes.
- Most people don't come to work each day planning to sabotage their own work.
- Don't want to waste all your energy fighting the surface issues.
- Passive voice is preferred to avoid casting blame.
  - Bob didn't complete form A21 correctly.
  - Form A21 lacked necessary review and approval.

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Identify the Types of Causes

Cause (Causal Factor): Event or condition that results in an effect. Anything that shapes or influences the outcome.

Proximate Cause: The event(s) that occurred, including any condition(s) that existed immediately before, which directly resulted in its occurrence and, if eliminated or modified, would have prevented the undesired outcome. Also known as the direct cause(s). Can be both equipment and human based.

Root Cause: One of multiple factors (events, conditions or organizational) that contributed to or created the proximate cause and subsequent undesired outcome and, if eliminated, or modified would have prevented the undesired outcome. Typically multiple root causes contribute to an undesired outcome.

Example: the failure of the air conditioning can be a proximate cause (direct) of an observed effect, but the lack of maintenance can be the cause (indirect). The root cause analysis could allow to identify other weaknesses : bad or missing maintenance plan or insufficient budget allocation or inadequate purchasing service or non-compliance with deadlines or …..

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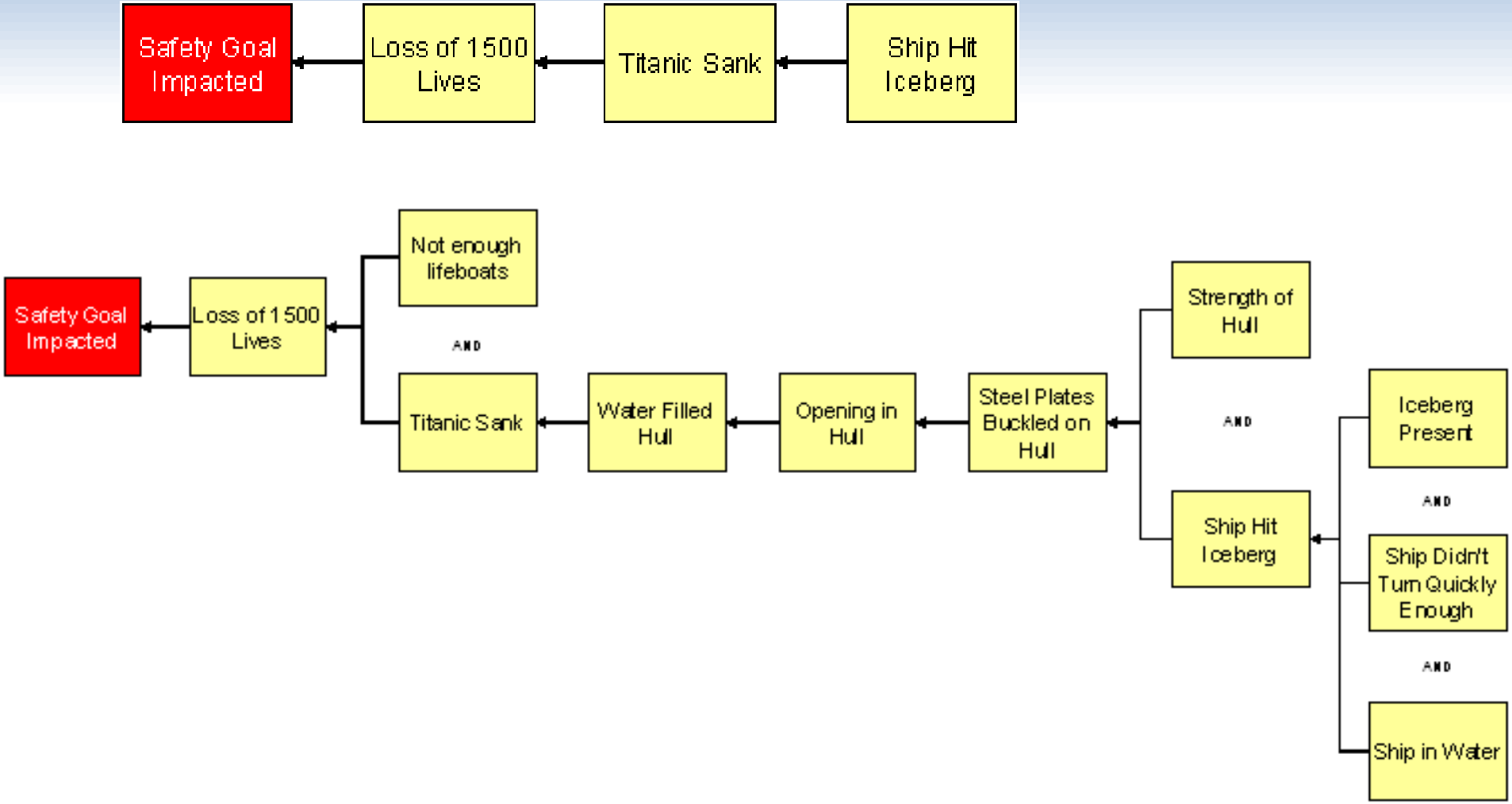

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The root cause of a problem is not the initial reaction or response.

Initial response is usually the *symptom*, not the root cause of the problem.

For example, normal responses are:

- **Equipment Failure** or
- **Human Error**.

But most times root cause turns out to be much more:

- **Process or program failure**
- **System or organization failure**
- **Poorly written work instructions**
- **Lack of training**

Focus is on systems and processes

Focus is not on individuals

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Five Whys for Root Cause Analysis

- **Why?** Cause 1 (proximate)
- **Why?** Cause 2
- **Why?** Cause 3
- **Why?** Cause 4
- **Why?** Cause 5

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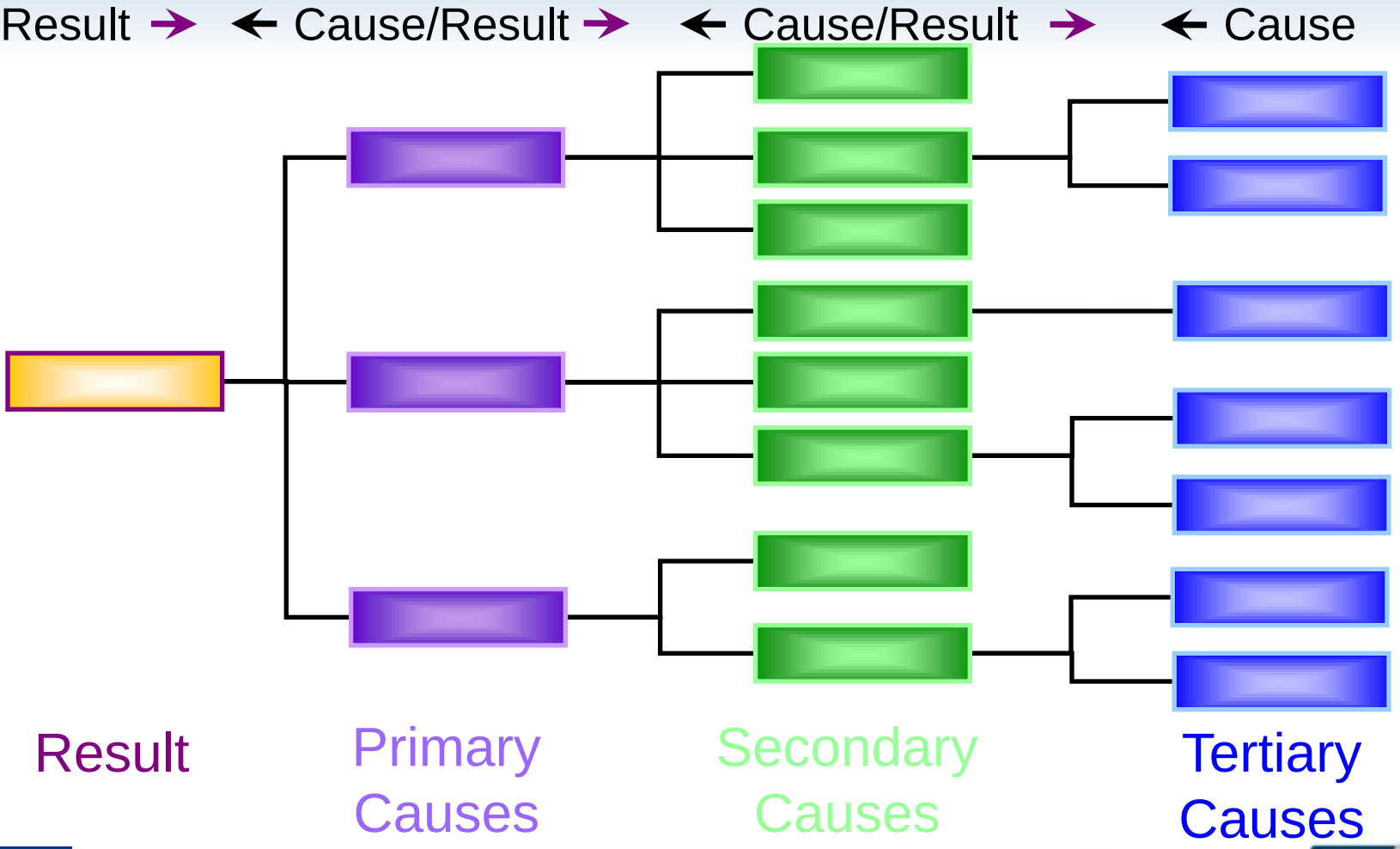
Tree Diagram



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General Process for Performing a RCA

1. Define the problem.
2. Gather data/evidence.
3. Ask why and identify the true root cause associated with the defined problem.
4. Identify corrective action(s) that will prevent recurrence of the problem.
5. Implement the corrective action(s).
6. Observe the corrective actions to ensure effectiveness.
7. If necessary, reexamine the RCA.

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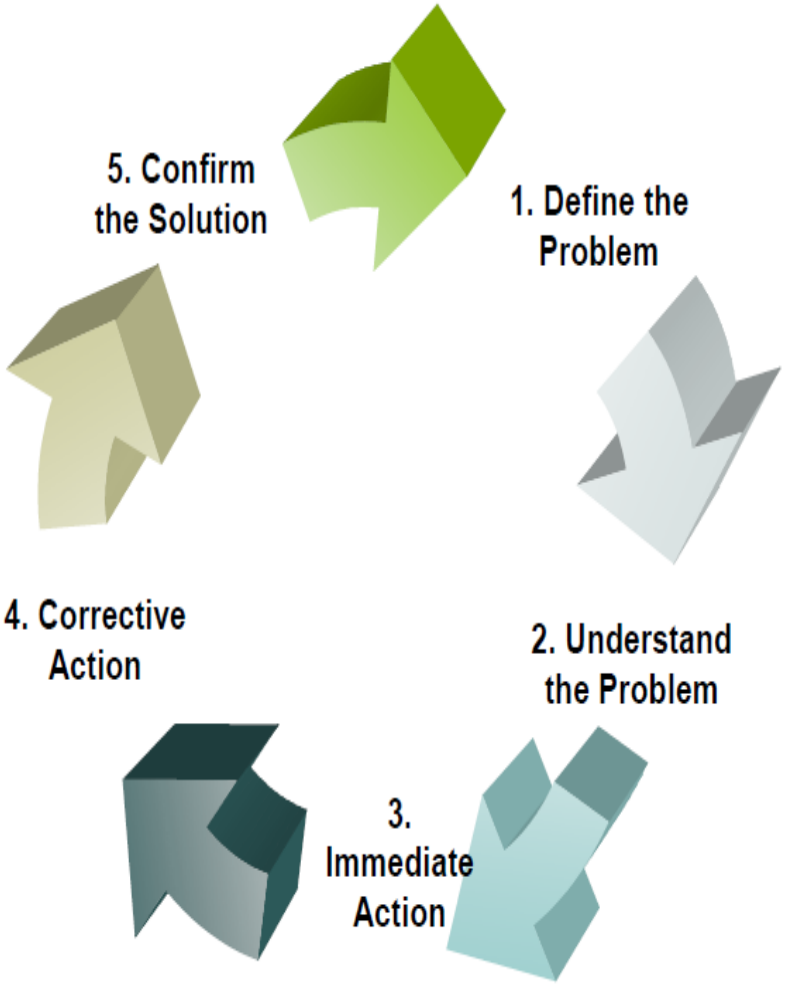
I. **Define the Problem**: Try and use **SMART** principles, i.e. **S**pecific; **M**easurable, **A**ctions oriented; **R**ealistic; **T**ime constrained. Unless the problem is defined accurately, the RCA whole process maybe prone to failure. This phase will usually also define how the RCA will be run as a Project.

II. **Understand the Problem**: Check the information, obtaining real data regarding the problem, gaining a clear understanding of the issues. This is when the various tools and techniques, such as Cause and Effect, brainstorming, etc, can be used.

III. **Immediate Action**: Implement temporary counter-measures at the place of the problem. 'The further away from the problem source the solution is determined, the less likely that the solution will be effective'.

IV. **Corrective Action**: Determine and prioritise the most probable underlying causes of the problem, as the temporary counter-measure may not resolve the root cause. Taking corrective actions to at least mitigate or preferably eliminate the causes.

V. **Confirm the Solution**:. After the measures have been determined and implemented the success of the adopted approach needs to be established. Having confirmed the success of the suggested solution then rules or control methods need to be established that will avoid the problem ever happening again. . **This is probably the most important phase in the RCA, but the one most often missed**.



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To follow examples of findings in calibration scheme and their treatment

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