

Quality Assurance Auditors & Industry Conference  
February 2023 | New Orleans, LA.



# Effective Corrective Action Evaluation

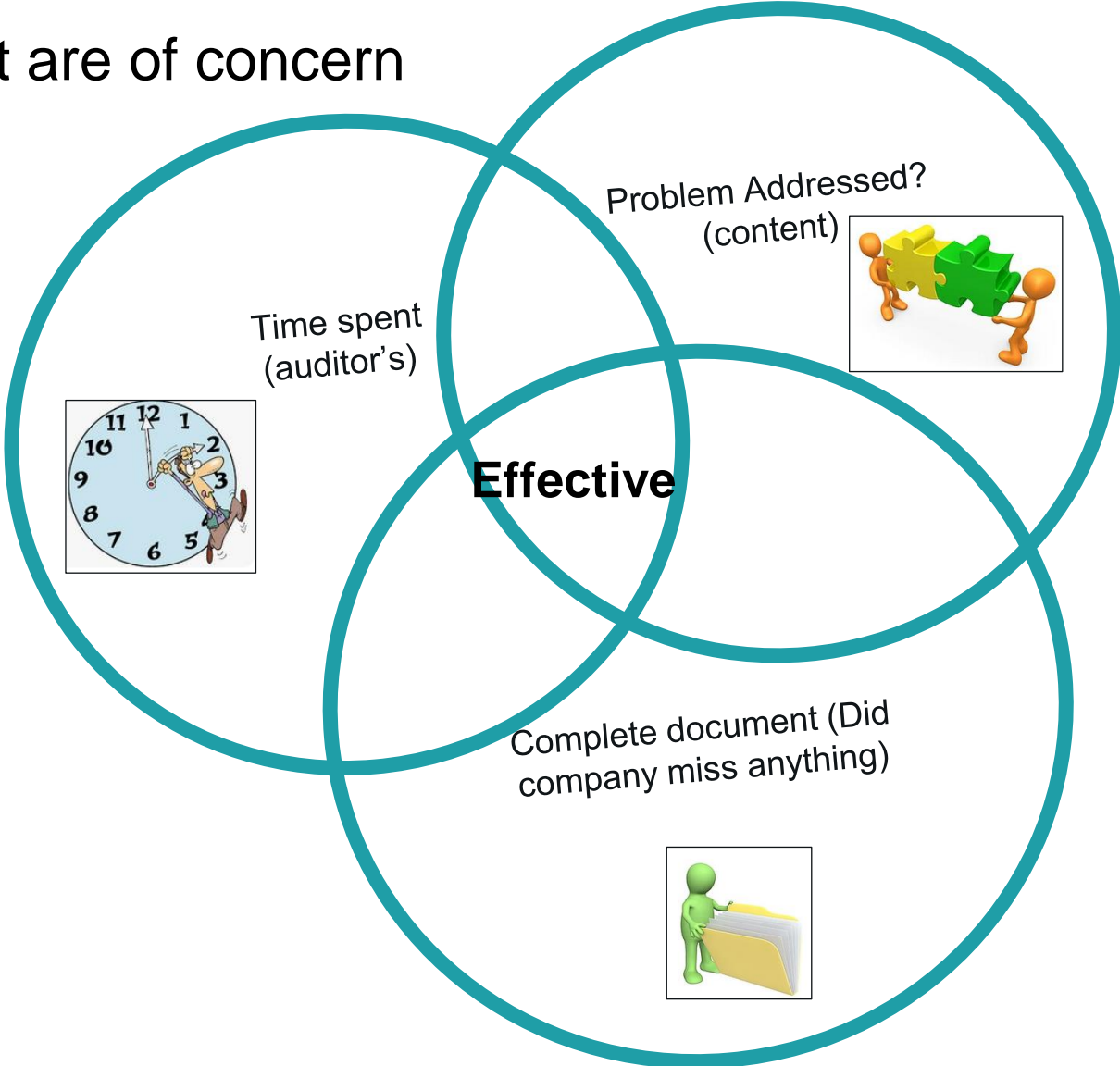
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# Different areas that are of concern



REPORTE DE HALLAZGOS (Continuación)

Número de hallazgo de auditoría: No. QA-13-ABDC--CT-0 Fecha de auditoría: Fecha de apertura

Acción correctiva:

Acción requerida (5 Paso RCCA)	Descripción de las acciones adoptadas – Incluir evidencia objetiva	Fecha de finalización
1) Identificar el problema: ¿Cuál es la no-conformidad? Indique claramente el hallazgo.		
2) Contener el problema (contención): Definir claramente las medidas inmediatas tomadas para evitar que el problema continúe?		
3) Análisis de causa raíz (RCA): Defina claramente la(s) causa(s) raíz que causaron el hallazgo (vease: párrafo 3.1). Use una herramienta RCA apropiada para determinar la Causa Raíz como ejemplos: 5-porqué, Diagrama de Causa y Efecto, Gráfica de Pareto, Herramientas de resolución de problemas Six Sigma.		
<ul style="list-style-type: none"> <li>Identificar la herramienta RCA utilizada:</li> </ul>		
4) Acción correctiva: Defina claramente quién, qué y cuándo se tomarán las medidas correctivas que eliminarán la(s) causa(s) raíz.		
5) Seguimiento: Defina claramente los planes de seguimiento que garantizarán que las acciones correctivas fueron eficaces para eliminar los riesgos futuros.		

2) Containment – Stop (When)

3.1) How

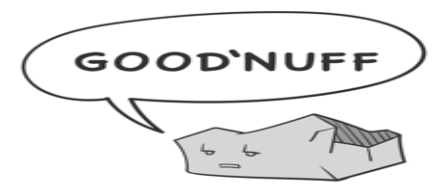
5) Follow-up (Implementation)

1) Acquire information for the finding (What)

3) Root Cause (Why)

4) Corrective (New) Action – Nonconformance mitigated (What, when ,Where ,Who)

Maintained



Fecha en la que completó el seguimiento: Seleccione Fecha

Firma: Seleccione Fecha Firma Seleccione Fecha  
Enviado por: Aprobado por la Administración Nombre de la administración

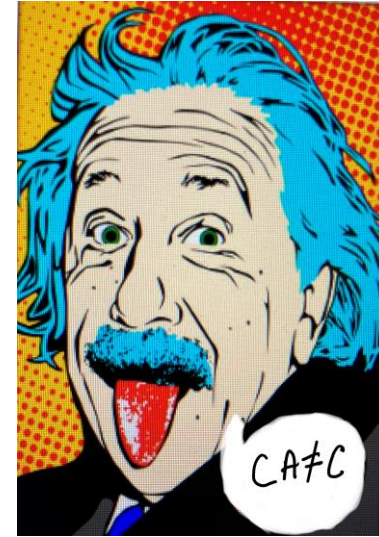
Evaluación de la acción correctiva propuesta  
Respuesta aceptable Sí  No  Firma: Seleccione Fecha  
Auditor Líder:

Verificación del cierre de las medidas correctivas  
Verificación aceptable Sí  No  Firma: Seleccione Fecha  
Si no, ingrese el nuevo AAFR # Auditor Líder: Conducir Nombre del Auditor

## CONTAINMENT

Actions necessary to prevent unintended spread of a nonconformance

- Work not started
- In-process
- Outbound
- Shipped Product/Service



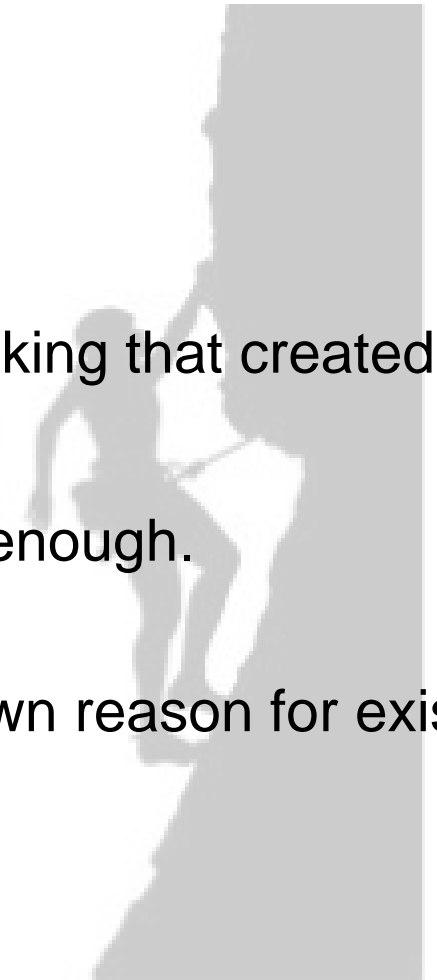
## Quotes by Albert Einstein

Significant problems we face cannot be solved by the same level of thinking that created them.

If you can't explain it simply, you don't understand it well enough.

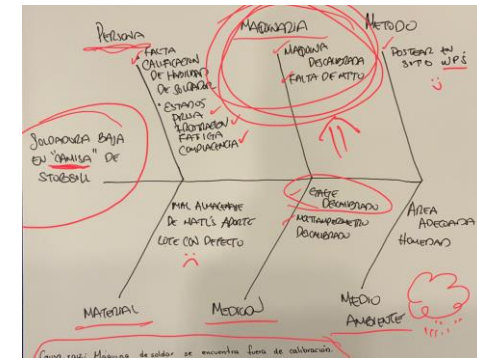
The important thing is not to stop questioning. Curiosity has its own reason for existing.

Withing every difficulty lies opportunity



## ROOT CAUSE

“The most basic cause (or causes) that can reasonably be identified that management has control to fix and, when fixed, will prevent (or significantly reduce the likelihood of) the problem’s recurrence.”



## CORRECTIVE ACTION PLANNING AND IMPLEMENTATION

This stage identifies and implements actions to prevent the reoccurrence of the defect or nonconformance. Retrain or reinstruct the craftsman is not corrective action.

- Have balanced (technical, economical, timely, and mistake proof) corrective actions been identified and rank ordered?
- Have the “pro and cons” of the corrective actions been identified?
- Has the best-balanced corrective action been selected?
- Have actions, milestones, target dates and resources been properly identified and allocated?
- Has Sales and/or Customer Support been informed of the corrective action?
- Has information for future problem prevention been conveyed to the appropriate personnel and/or departments?
- Has a process or system change, if necessary, been identified and defined?
- Has verification of corrective actions been planned?
- Other items for consideration in the corrective action planning and implementation stage include:
  - Is the action directed toward a specific root cause?
  - Is the action directed toward the elimination of the root cause?
  - What process will be changed?
  - What specific nonconformance will be eliminated?
  - Have the criteria for solution - been defined?
  - Who will specify the change?
  - When will the change be implemented?
  - How will the change be documented?
  - Who must be informed and concur with the change?



Corrective Action:  
Action Taken to eliminate the causes of non-conformities  
or other undesirable situation, so as to prevent recurrence.



The process of reacting to an existing non-conformity and eliminating the cause. Simply put, Corrective action is based on a nonconformance event that has happened in the past.



# What is a good corrective action?



	Description of Action(s) Taken – Include Objective Evidence
Identify the Problem:	Jim's fix-it <b>did not do the Internal Audit</b> within the specified time limit.
Contain the Problem (Containment)	<b>Send a reminder</b> to start the internal audit in August via outlook calendar reminders to all managers.
Root Cause Analysis	Root cause was management <b>failed to complete</b> the inspection in September 2021.
Corrective Action:	Management has put into Action a <b>yearly occurring reminder</b> to do the audit starting in August to meet the September requirement.

	Description of Action(s) Taken – Include Objective Evidence
<b>Identify the Problem:</b>	Records were incomplete or incorrect. <ol style="list-style-type: none"><li>1. Checklist for Rail ITPs were <b>missing information</b> or had the header information filled out in the wrong place.</li><li>2. Records were not signed.</li></ol>
<b>Contain the Problem (Containment):</b>	Reviewed this finding at all shops and with personnel that specifically <b>review completed documents</b> . Correction of filed documents is NOT required.
<b>Root Cause Analysis (RCA):</b>	Operators were <b>not confident</b> of which areas of each form were theirs to complete. This was especially common when multiple personnel were involved due to group work centers or shift changes.
<b>Corrective Action:</b>	<b>Training of reviewers and supervisors</b> on the procedures for Final Inspection Records in order to recognize that errors in documentation must be corrected prior to acceptance.

# What is a good corrective action?

	Description of Action(s) Taken – Include Objective Evidence
<b>Identify the Problem:</b>	<p>Contrary to the above requirement, during the audit 4 different gages had issues with the sticker or other calibration record issue. 1-8987-5-C2 inner gib gage sticker read due 7/5/23 however, calibration record said it is due 1/5/23. EC-1090-66 pedestal lug gage was found on the shop floor and found that it was out of calibration however, it was not removed from service or tagged. SW-12 was found to be in calibration however, the stopwatch <b>did not have a sticker or a calibration card</b>. 106-C5 height gage sticker read it was due 12/28/21 however, calibration record had it due 12/3/22 therefore, <b>the sticker is incorrect</b>.</p>
<b>Root Cause Analysis (RCA):</b>	<p>During the investigation, two root causes were determined. The first cause was human error. It was determined that in three of the gage issues, the calibration tech did not remove a sticker or a gage in the instance of a status change with a gage or location change. The second root cause was a method error. The QA department never used a sticker for a gage kept in the calibration lab and relied on GAGE-pack for the calibration date. This meant that the calibration date could not be easily always known.</p>
<b>Corrective Action:</b>	<p>A new location was created for all gages in the calibration lab. Using a location card instead of stickers will eliminate stickers with wrong information as it will be dictated by GAGE-pack. This will also show all calibration dates of all gages in the calibration lab. A new document, Form 8.1 Gage Change Log, was created to document all location or status changes for gages. This document will have two people initial that gages are removed or added to a location. This will also control gages being moved from locations that dictate the need of a sticker or calibration card.</p>



	Description of Action(s) Taken – Include Objective Evidence
<b>Identify the Problem:</b>	Contrary to the above requirement, during the audit it was found that Craig’s Railcar Service has implemented some new statistical methods however; they <b>do not have a procedure</b> addressing what they are capturing.
<b>Root Cause Analysis (RCA):</b>	We do not have a procedure addressing what we are capturing in terms of Process Capabilities / Statistical Methods. We needed to define the Process Capabilities / Statistical Methods that effected Craig’s Railcar Service. We had to use the out of the box thinking styles to look at what statistics were important to us, and define the tools and resources that we would need to make this a successful launch. We knew we immediately needed to create the procedure that would control how we evaluated this element, and the requirements that it produces. We came to the conclusion that both our findings were actually tied into each other. When we didn’t provide all the objective evidence on the Internal Audit, it would allow for a requirement to not be met.
<b>Corrective Action:</b>	Craig’s Railcar Service Quality Assurance Personal created a procedure and standard for Process Capabilities/Statistical Methods. We created a new controlled form to obtain the statistics (ABC-123) that we find most to affect our company. We have also involved the CAR-LOG to help capture some of the other important statistics, as noted in our procedure.



## Follow-up

Follow-up measures are the measurements of process or product to determine effectiveness of corrective actions implemented to mitigate nonconformance's or unintended results.



Who  
What  
Where  
When  
How long



# ACRONIM *(Spanglish)*

*Definition of the problem:*

**A** – **Acquire** information for the finding

*Containment:*

**C** – **Containment** of the Problem/

*Root Cause*

**R** – **Root Cause** analysis –

**O** – **Officially** communicate

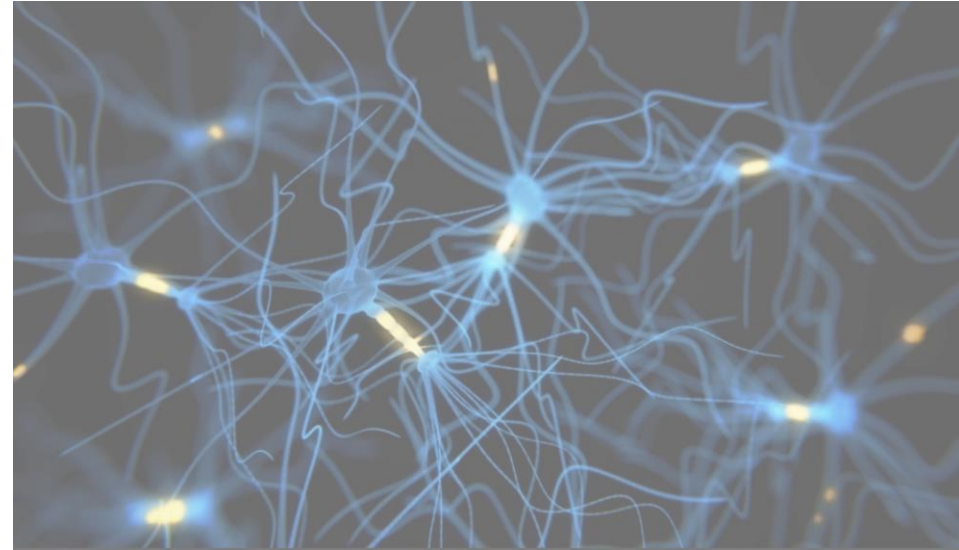
*Corrective Action Planning and Implementation:*

**N** – **New Rule, New Plan** –

**I** – **Implementation** of new program/procedure/test stems

*Follow up:*

**M** – **Maintained** the process





# Thank You

# Be Safe !

