ROOT CAUSE ANALYSIS (RCA)

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Objectives

- Develop participants' skills in establishing a comprehensive analysis and formulation of corrective action appropriate to the nature of the nonconformity.
- Learn the tools & techniques in managing Corrective Action Request (CAR).

Notes:

What is a non-conformity?

- Occurrence of a condition that does not conform to the specifications of the prescribed standards.
- Failure or refusal to conform to a prevailing rule or practice

A nonconformity
is defined as a non-fulfillment of a requirement. It is a failure to deliver what is required of you or your activity or process or system.

Nonconformities

- are the unintentional or undesirable outputs.
- demonstrate weakness of the process which resulted to a delay or will not deliver the specified output.

What are the sources of NC

- *Human factors studies showed that an NC mostly caused by human error.*
- *System that was only established because it's only dictated by an auditor/someone:*
  - Failure to determine the criteria for establishing an effective process
- *Machine Methods*
- *Materials*

Operation

8.5 Production and Service Provision
8.5.1 Control of Production and Service Provision (Con't)
Controlled conditions shall include, as applicable:

- the use of **suitable** infrastructure and environment for the operation of processes;
- the appointment of competent persons, including any required qualification;
- the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;
- the implementation of actions to prevent human error;
- the implementation of release, delivery and post-delivery

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- activities.

How do we handle problems
Or nonconformities

Steps in handling non-conformity

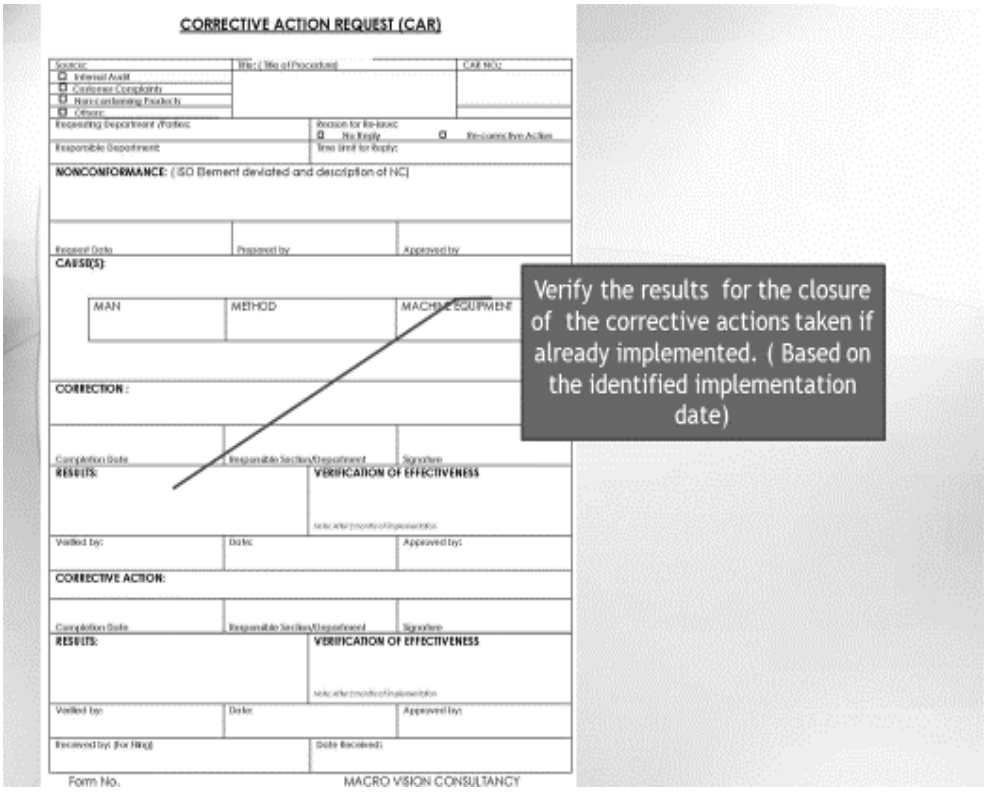
- **Identify > Analyze – Establish action plans**
- **>Verify & Validate then >Implement**

Measure result of actions taken.

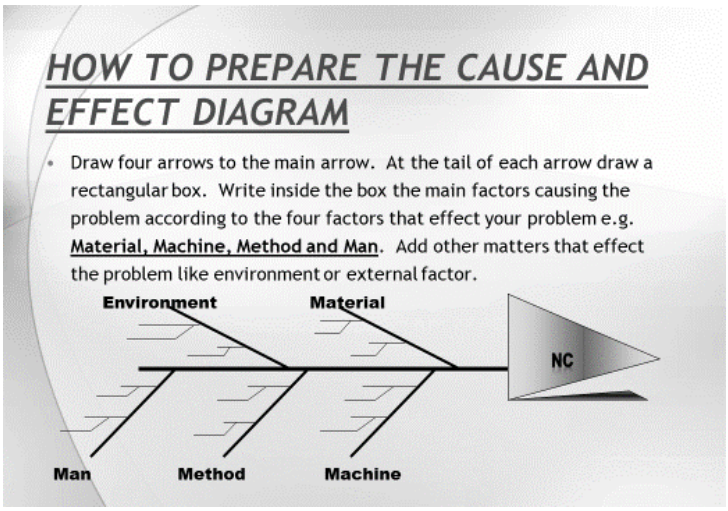
Verify – Validate

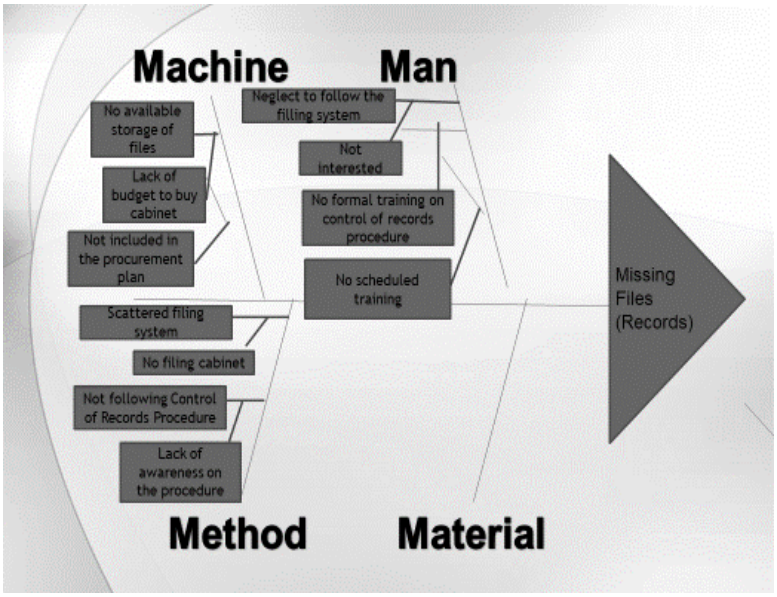
- Verify is a process of confirming if the process had been done.
- Validation is a process of confirming if the process had been done consistently.

- historical data



HOW TO PREPARE THE CAUSE AND EFFECT DIAGRAM





Formulation of correction & corrective action

Determine the correction & Corrective Actions

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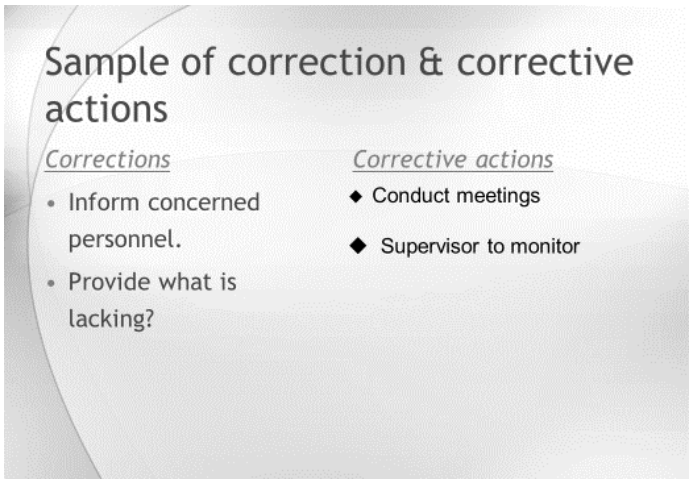
- Determine the corrective action based on the identified "root causes" of the problem/nonconformity.
- Communicate actions to be taken.
- Learn and understand the process of performing internal audit.
- Understand the importance of performing audits.
- Apply the Principles of Auditing
- Be qualified as an Internal Auditor for EMS.

Corrective action

- *Correction* -Immediate action to just stop the problem/nonconformity.
- *Corrective Action*- action that will eliminate the cause/s of the problem/NC to prevent recurrence of the existing problem/nonconformity.



Preventive action now part of the Corrective Action
Action that will eliminate cause/s of a potential problem and prevent occurrence.
Identify associated risk of this action

The Preventive action may now be part of the corrective action.
Sample of corrective Actions

- **Solutions that lead to the revision of action taken**
- **Establishment of new procedure or system**
- **Training related**
- **Review & revise human resource management procedure**

Planning (ISO 9001:2015)
Actions to address Risks and Opportunities
6.1.2 The Organization shall Plan:

a) **Actions to Address these Risks and Opportunities;**
b) **How to:**
    1. **Integrate and implement the actions into the Quality**

Management System Processes;

2. **Evaluate the effectiveness of these actions.**

Actions taken to address risks and opportunities shall be proportionate. to the potential impact on the conformity of products and services.

How Risk based thinking is being applied

1) ***Check process of patrolling/monitoring***
2) ***What to do in case NC will be detected:***
   - check close loop action plan - is there an escalation process
1) ***What are the potential risk associated to the actions.***

ANALYSIS MATRIX

	ROOTCAUSES							
NC	MAN	METHOD	MATERIAL	MACHINE	CORRECTION	CORRECTIVE ACTION	RISK	FINAL CORRECTIVE ACTION
Missing records of purchasing								

Verify the closure of the actions taken

- **Verification of the implementation of the corrective/preventive actions taken**
- **Evidence of implementation should be recorded in the "result" column of the CAR.**
  - **Actual data verified should be recorded.**

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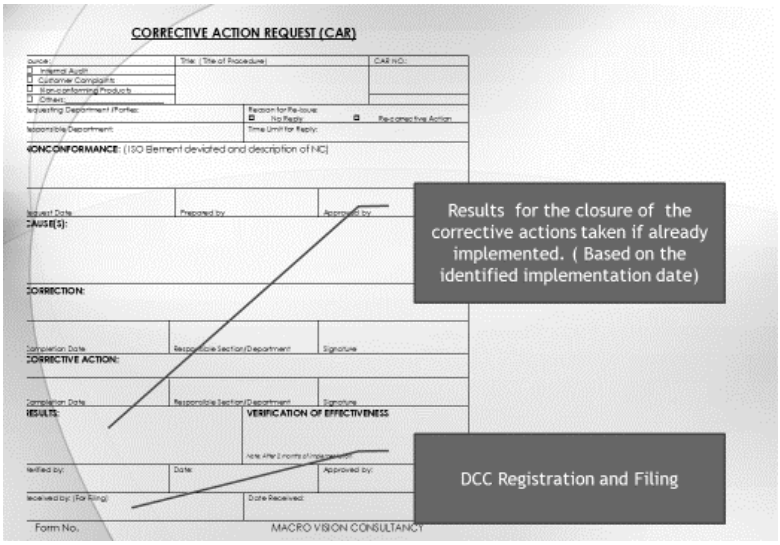

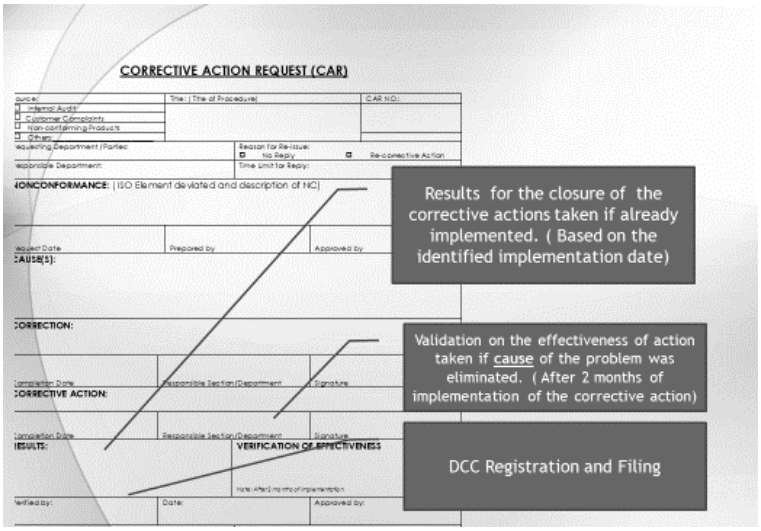

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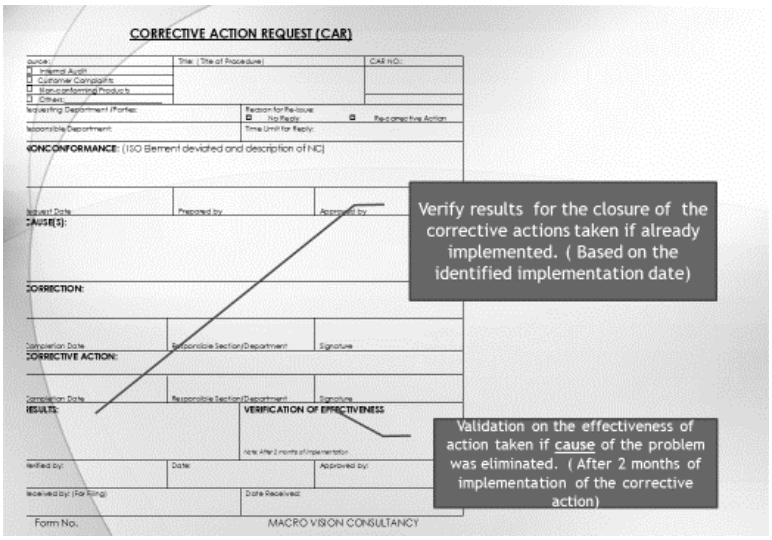
Validation of effectiveness of the actions taken

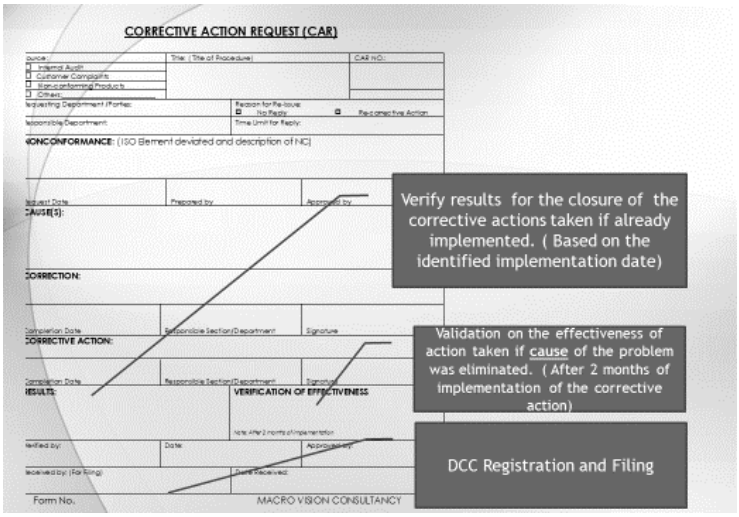


Validate the effectiveness of actions taken (After 2 months of implementation)

- **Determine the effectiveness of actions, the organization needs to check whether the "cause/s" of the problem(NC) were eliminated and prevent recurrence of the existing NC.**
- **A longer period of time may be required to evaluate effectiveness of actions taken.**

Validate the effectiveness of actions taken.

- **Trends of the analysis/data of implementation may be required to further verify the effectiveness of actions taken.**



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Presentation of Non-conformances

Tips in writing nonconformance

1) State the requirement, evidence and nature.

2) It should contain the exact description of the non-conformity.

Example of a Non-conformity Report

10.2 of ISO 9001:2015 require that all documents are approved prior to issuance. However, there are number of Work Instructions posted within the premises of the organization without the signature of the approving authorities.

Case in point: MVC-WI-003, MVC-WI-023 & MVC-WI-025.

Questions?

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