



NQA WEBINAR DEMYSTIFYING CORRECTIVE ACTION & ROOT CAUSE ANALYSIS

20th February 2025



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DEMYSTIFYING CORRECTIVE ACTION & ROOT CAUSE ANALYSIS

Aim:

- To pass on some knowledge relating to root cause analysis & corrective action.
 - To give some information on common tools for root cause analysis & problem solving.
 - To give some information about the disciplines for completing root cause analysis & corrective actions.
 - To raise awareness regarding some common issues people experience during these processes.
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Introductions:

My name is Martin Little & I'm NQA's field operations manager for our southern region.

I've worked for NQA for nearly 10 years.

I've been a lead auditor for nearly 20 years.

I've worked in & audited for various industries for 30 years.

I'm a lead auditor for:

- ISO9001
- ISO14001
- ISO45001
- IATF16949





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What is Corrective Action?

An action that eliminates the cause of a nonconformity and prevents it from happening again.

What is a Non-Conformance?

When a requirement is not fulfilled.

What is Root Cause Analysis?

A systematic process used to identify the underlying reasons for problems or issues, allowing for more effective and long-term solutions rather than just addressing symptoms.

Sources of Non-Conformance:

- Customer complaints for non-conforming products or services.
 - Suppliers or sub-contractors providing non-conforming products or services.
 - Routine inspections identifying non-conformance.
 - Internal audit.
 - Customer audit.
 - External audit (3rd party audit or regulatory body audit).
 - Reports from other people, such as members of the public.
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Potential Effects of Non-Conformance:

- Risks to health & safety.
 - Risks to the environment.
 - Breaches of legal requirements.
 - Customer dissatisfaction.
 - Products failing or having limited use.
 - An insufficient or incomplete service being provided.
 - Loss of business.
 - Financial penalties & additional costs.
 - Legal proceedings.
 - Damage to reputation.
 - Loss of certification.
 - Deterioration of morale.
 - Resource consumption.
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ISO Standard Requirements:

Most ISO standards include a clause for Non-Conformity & Corrective Action.

Typically, this is clause 10.2 of the standard, but not always (ISO27001 = Clause 10.1).

This clause places the following requirements onto an organisation:

- To react to the nonconformance & to act as applicable to control & correct it.
- To deal with the consequences of the nonconformance.
- To assess the need for corrective actions to prevent the nonconformance from recurring or occurring elsewhere.
- To review the nonconformance & to determine what caused the nonconformance.
- To see if this nonconformance could occur elsewhere?
- To take the actions needed to address the nonconformance & to review the effectiveness of these actions.
- To make changes to management systems as needed.
- To document the nonconformance & the corrective actions taken in response, along with outcome of these actions.



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The Nonconformance & Corrective Action clause of the ISO standards is typically followed by the clause for Continual Improvement.

Whenever there is nonconformance there is always an opportunity for improvement as well.

These improvements, beyond addressing the nonconformance & preventing it from recurring, or occurring elsewhere, are opportunities to improve still further & to enhance products, services & processes to greater heights of performance & to further minimise or eliminate associated risks.

Plan, Do, Check, Act Cycle (PDCA):

Within the PDCA cycle the Nonconformance & Corrective Action requirements firmly sit within the 'Act' part of the cycle.

Continual Improvement also sits within the 'Act' part of the cycle.

Remember – The more thorough & comprehensive you 'Plan' the better things should work when you 'Do'. Then when you 'Check' you should realise how effective your planning was. Then with the data you have you can 'Act' to address nonconformance & to improve before going around the cycle again.

ISO45001 – Incident Investigation:

Clause 10.2 of the ISO45001 standard requires us to review incidents in the same manner as nonconformities.

What is an Incident?

An incident is an occurrence that could or does cause injury or ill health.

So, from a health & safety standpoint the standard requires us to see the potential for an incident to cause harm & to address it with the same rigour as if it had caused harm.

ISO45001 also has requirements for us to participate with workers & other interested parties when we investigate the incident's root cause(s) & to identify suitable corrective actions.

To review existing risk assessments as needed.

To apply the Hierarchy of Controls when taking corrective actions.

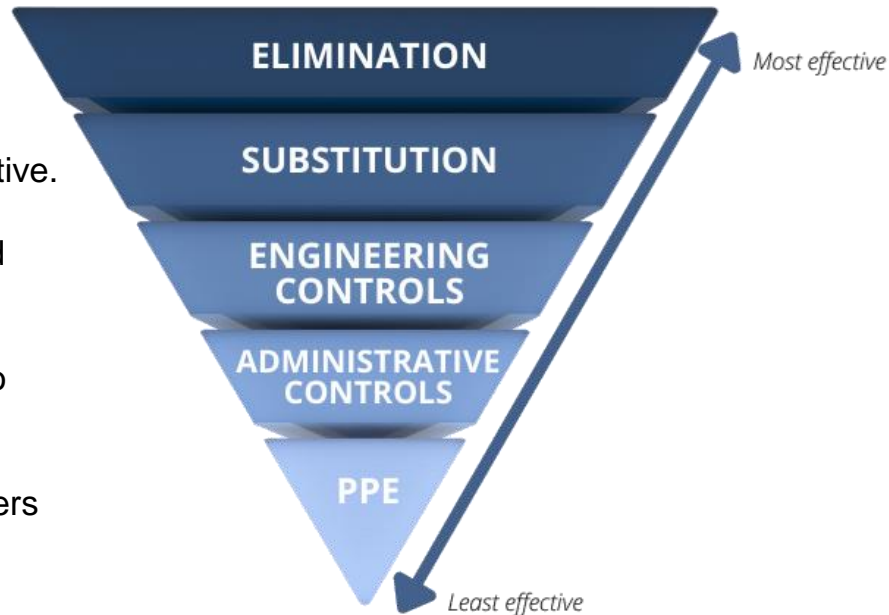
To communicate actions taken to workers & interested parties. So, everyone is aware of actions taken & new or changed working practices.

Hierarchy of Controls:

The five levels of the hierarchy of controls.

- **Elimination:** Remove the hazard from the workplace.
- **Substitution:** Replace the hazard with a safer alternative.
- **Engineering controls:** Isolate people from the hazard using physical devices or processes.
- **Administrative controls:** Change how people work to reduce exposure to hazards.
- **Personal protective equipment (PPE):** Protect workers from residual hazards.

THE HIERARCHY OF CONTROLS





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How to Address Nonconformities:

Nonconformities can come in all shapes & sizes. You should choose the right tools to address each nonconformance appropriately.

Don't mandate the use of certain tools for every nonconformance as these tools maybe inappropriate. It's best to have a few options available to you. We'll review some of these tools in a moment.

Each nonconformance should be managed via the following steps:

1. Identify the nonconformance & assigned responsibility for addressing it. This could be an individual or a team effort. The right people need to be involved to ensure the nonconformance is fully addressed.
2. Clearly define the nonconformance. Ensure all facts are captured.
3. Identify & deploy suitable containment actions.
4. Use the right tools to fully identify true root cause(s) of the nonconformance.
5. Identify permanent corrective actions that will address all true root cause(s) to prevent the nonconformance from recurring or occurring elsewhere.
6. Implement your corrective actions & verify their effectiveness.
7. Take preventive actions as necessary. Ensure corrective actions are applied to all similar products, services & processes. This should prevent this issue from occurring elsewhere & help drive continual improvement.
8. Document the above. Communicate the corrective actions to all applicable interested parties. Formally close out the nonconformance. Review as part of Management Review.

What is the Difference Between Correction & Corrective Action:

Every nonconformance will have symptoms. These are the things that are directly affected by the nonconformance:

Examples:

- Nonconforming products are quarantined & reworked to specification. Damaged tooling is corrected.
- The oil spillage is contained, cleaned up & the waste generated is correctly disposed of. All other barrels of oil are moved to a bunded area.
- The person that fell into the trench was given first aid & taken to hospital. The trench was cordoned off to stop anyone else from falling in.

These are all Corrections. They address the immediate effects of the nonconformance only. They correct what is wrong & helps prevent the nonconformance from recurring in the short term.

None of these actions address the true root cause(s) that led to these nonconformities occurring.

Corrective Actions address the root cause(s) that allowed the nonconformance to occur. These are permanent actions & will require changes within your processes & management system if you have one.

Before Corrective Actions can be identified the true root cause(s) must be defined.
Only when true root cause(s) are defined can suitable Corrective Actions be identified!

Root Cause Analysis must be appropriate for the nonconformance being investigated.

If the nonconformance is limited in scope & risk then a brief root cause analysis could be completed.

Example:

- Incorrect part number given on a delivery note. **Root cause** = Manually generated delivery note & the person entered the wrong part number. Data entry error.

Such a nonconformance doesn't require a team of people using complicated, time consuming, root cause analysis tools to find out what happened.

Your corrective action maybe to introduce a scanning system to enter the part numbers & data to the delivery note. Or, the delivery notes could receive a second check for accuracy before being issued.



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More complicated nonconformities will require a more detailed root cause analysis.

A team of appropriate, competent, people should be involved in this exercise.

Appropriate people could include – **Always remember to allow everyone to contribute to the process.**

- The person(s) affected by the nonconformance, e.g. the person producing the parts or providing the service.
- Quality, health & safety, environmental personnel, as needed.
- Process owners.
- Area supervisors.
- Support personnel, e.g. HR, Maintenance, Logistics, etc.
- Union representatives.
- Management.

The reason for assembling such a team is to ensure that all the necessary knowledge & experience is involved in the process of identifying true root cause(s).

Some non-conformities may have multiple root causes. All root causes must be identified for corrective actions to be effective & prevent recurrence/occurrence.

Never assume you know the root cause of a non-conformance. Take the time to analyse & review the facts before identifying permanent corrective actions!



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Corrective Action & Root Cause Analysis Tools:

There are many effective tools you can use to help with your corrective actions & root cause analysis. Here is a review of some of these tools.

PDCA (Plan, Do, Check, Act):

This is a good tool for simple non-conformities. The PDCA cycle can be combined with other tools as needed, e.g. 5 Whys, etc.

Plan:

- Define the problem & collect data/evidence.
- Identify root cause(s) using appropriate tools, e.g. Brainstorming, 5 Whys, etc.
- Identify corrections & corrective actions to contain the nonconformance & address the root cause(s).
Assign responsibilities for these actions.

Do:

- Implement the corrections & the corrective actions.
 - Verify the effectiveness of these actions.
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Check:

- Collect data/evidence to verify that all actions are effective.
- Internal audits can be used to verify effectiveness of actions.

Act:

- Standardise all corrective actions taken.
- Update documentation.
- Providing training & communication to interested parties as applicable.
- Apply actions to similar products, services, processes as applicable.

If actions prove ineffective then return to the 'Plan' stage & begin the cycle again.

PDCA Example:

Nonconformance = Quotations not provided to clients within 48 working hours.

Plan 5 quotations were not provided to 5 different clients, with 48 working hours, by salesperson A. Quotation Log reviewed. Detailing enquiries coming in & dates of quotations being supplied. Root Cause Analysis = Brainstorming.

Root Causes

- Salesperson A is absent from work due to illness.
- Suitable resource not provided to process salesperson A's enquiries during their absence.
- This action is not captured within the Sales Process Flow.
- Responsibility for taking this action has not been clearly communicated.
- Risks associated with the Sales Process were not fully effective.

Do Resource allocated to process the 5 overdue enquiries & update the Quotation Log. Sales Manager to communicate with the clients affected & ensure the quotations are provided. Update the Sale Process Flow. Assign responsibility for providing suitable resource when a team member is absent for any reason. Update the Process Mapping process to ensure all associated risks are captured.



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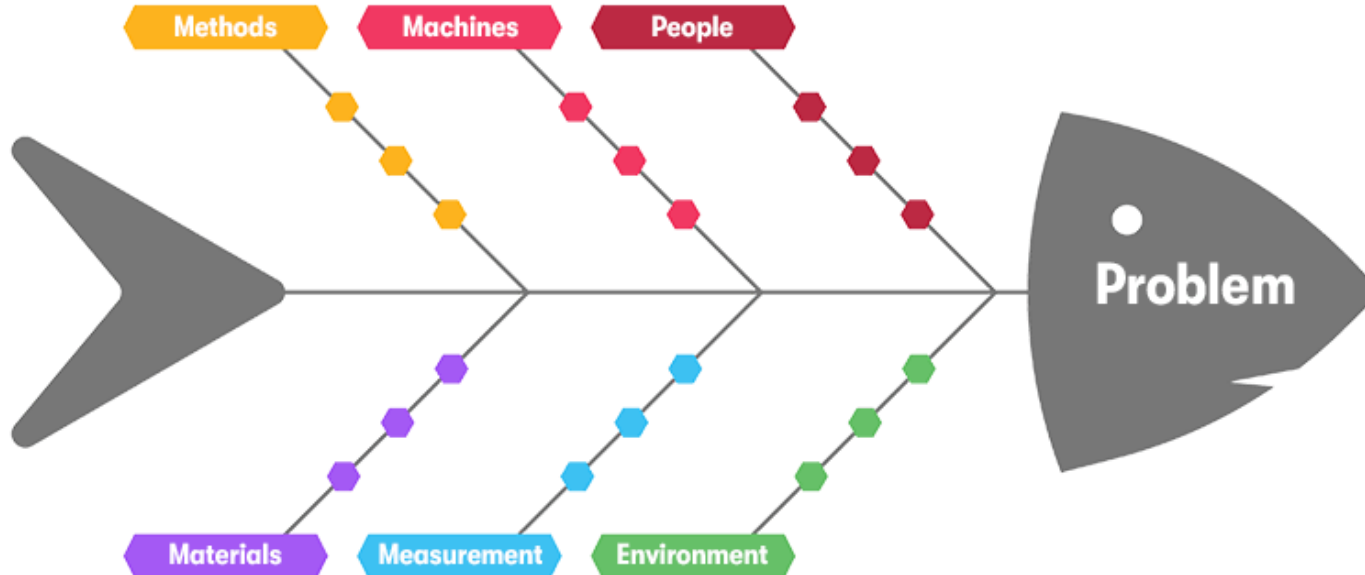
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- Check** Complete an internal audit of the Sales Process one month after the deployment of the revised process.
Increase the risk of the Sales Process. Increase frequency from annual to 6 monthly for 1 year.
Management Team to monitor Sales KPI for responding to enquiries within 48 working hours monthly.
- Act** Update the Sales Process Flow.
Update the Process Mapping Process Flow.
Communicate updated processes to all interested parties & provide training.
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Fishbone Diagrams 'Ishikawa' or Cause & Effect:

This is visual tool for root cause analysis. The tool resembles the skeleton of a fish with the problem being analysed as the head & various areas of potential root causes protruding from the backbone of the skeleton like ribs.





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Within the 'Head' of the fish the problem-solving team must clearly define the problem, e.g. whilst working at height via a ladder Operator A dropped a hammer, which struck the Injured Party on the head.

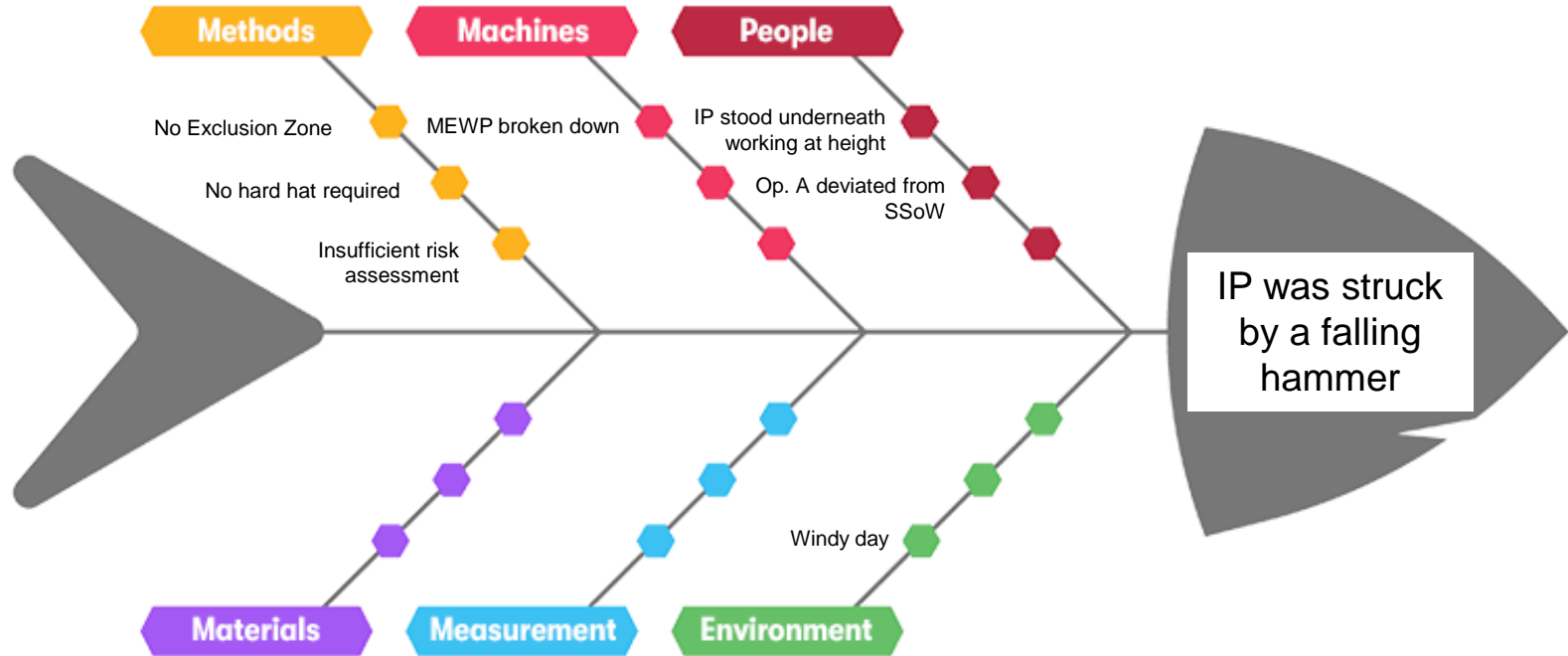
The problem-solving team can then work together to identify all the potential causes for the problem. The various categories, e.g. People, Machine, Method, etc. will help guide the team to think of potential causes in these areas.

These could include the following as examples:

- Method – No exclusion zone established underneath the person working at height.
- Method – No requirement for personnel on the ground to wear a hard hat.
- Method – The risk assessment for this task did not consider items falling from height.
- People – The Injured Party had not been trained to not stand/work underneath someone working at height.
- People – Operator A deviated from the safe system of work & used a ladder instead of a MEWP for this task.
- Machine – The MEWP had broken down & was unavailable because routine maintenance had not been completed.
- Environment – The wind caused the ladder to move & Operator A dropped the hammer whilst holding onto the ladder.

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The completed Fishbone diagram may look like this.



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Each of the potential root causes can be captured in the diagram. They can then be investigated & either proven to be valid or rejected.

Those that are proven to be valid can then be addressed via effective, systemic, corrective actions.

Examples:

- Risk Assessment reviewed & updated for working at height. Consideration for tools falling from height to be included. Controls = Exclusion Zone of 2 meters for all such jobs. Hard Hats are mandatory PPE for all staff present. Review of weather conditions before starting work. Postpone job if weather is not suitable, e.g. windy.
- Update the Safe System of Work to include the above.
- Communicate & train out the Risk Assessment & Safe System of Work to all applicable staff.
- Counselling for Operator A & the Injured Party for this incident & the above actions.
- Site Safety Visits increased for Operator A & the Injured Party for 6 months.
- Site Safety Visits increased for all such working at height jobs for 6 months.
- MEWP repairs completed & routine maintenance updates provided to the Maintenance Manager each month.
- Working at Height Permit to Work not issued unless MEWP is available, staff competence is verified & weather is suitable.

5 Why's:

This Root Cause Analysis tool is often combined with the Fishbone diagram to help drill down into the proven root causes identified.

The process involves the problem-solving team asking 'Why' as many times necessary to drill down to the true root cause of the problem. This means that true root cause is found rather than just the symptoms of the problem being addressed.

The process is called 5 Why's but it is important to ask Why as many times as needed to find the true root cause. It is very important to keep going until this is achieved. If not the systemic corrective actions identified may not address the root cause & the problem could recur.

Here are some examples based on the problem we've just seen.



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Why was the Injured Party stood underneath the person working at height?

They were holding the ladder for Operator A.

Why was the Injured Party holding the ladder for Operator A?

To prevent the ladder from moving & Operator A falling.

Why would the ladder have moved?

It was a windy day & the wind was blowing the ladder.

Why was the work being performed on a windy day?

Because the weather conditions hadn't been taken into consideration before starting work.

Why had the weather conditions not been taken into consideration?

Because the risk assessment performed for the task didn't consider weather conditions.

Why didn't the risk assessment consider weather conditions?

Because the risk assessment was insufficient because it hadn't been completed by a competent person.

Why wasn't the risk assessment completed by a competent person?

Because sufficient risk assessment training wasn't provided.

Systemic Corrective Action:

- Mandatory risk assessment training for all staff that work at height.
- Annual refresher training for these staff.
- Six monthly site safety visits to review competence & review of the competence process.



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This 5 Why could also have followed a different path.

Why was the Injured Party stood underneath the person working at height?

They were holding the ladder for Operator A.

Why was Operator A using a ladder for this job?

Because the MEWP was unavailable.

Why was the MEWP unavailable?

Because it had broken down.

Why had the MEWP broken down?

Because routine maintenance had not been completed.

Why had routine maintenance not been completed?

Because the maintenance engineer that organised the maintenance has left the business.

Why was the responsibility for organising MEWP maintenance not reallocated?

The maintenance manager has not yet hired a new maintenance engineer & in the meantime the responsibility had not been reallocated.

Why was the responsibility not temporarily reallocated?

Ineffective management of change.

In this instance corrective actions would focus on the Change Management process & the reallocation of roles & responsibilities. Once this process has been improved Internal Audits could be used to verify its effectiveness.

There are several other, less well known, root cause analysis, or failure analysis tools that can also be used.

Here are a few examples:

Pareto Analysis:

Pareto analysis is often called the 80/20 rule.

Basically, it means that typically 80% of the problem is caused by 20% of the contributing factors.

By identifying these 'vital few' contributing factors you can focus your efforts & resource on addressing them, which will give the greatest gains in the shortest time possible.

If you focused on all the contributing factors at the same time then you may use your resources on addressing contributing factors that aren't responsible for the majority of the problem.

So, Pareto Analysis can aid in efficient problem solving.

Here is how Pareto Analysis works.

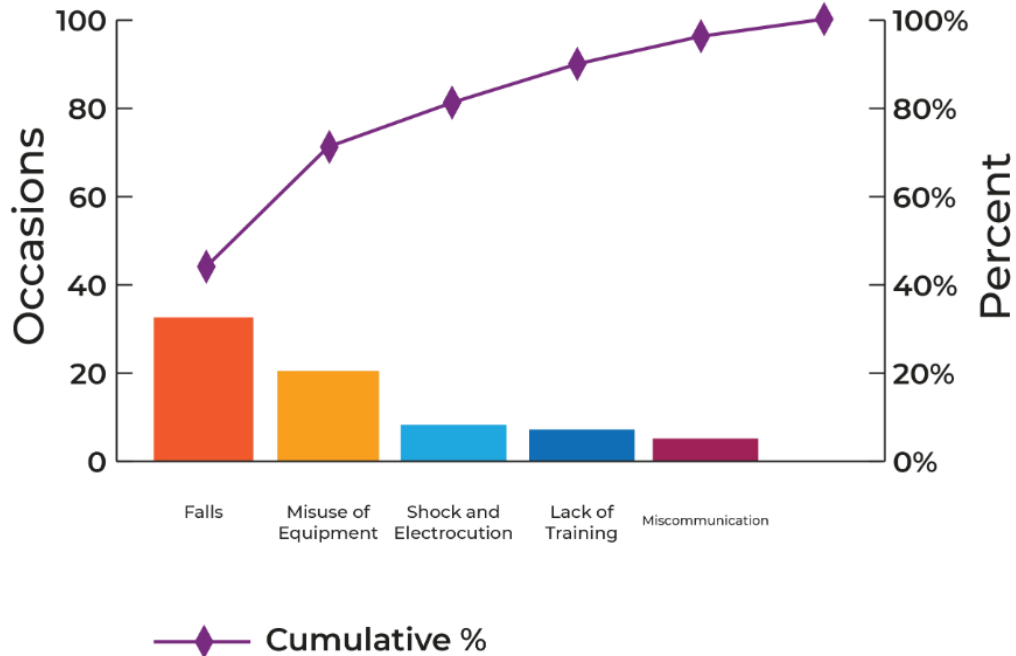
How to Perform Pareto Analysis:

- 1. Define the Problem:** Clearly state the problem or issue you want to address.
- 2. Gather Data:** Collect data related to the problem, identifying the different causes and their frequencies or impacts.
- 3. Categorize Causes:** Group the causes into categories or types.
- 4. Rank Causes:** Rank the causes by frequency or impact, from most to least significant.
- 5. Create a Pareto Chart:** Plot the causes on the x-axis and their frequencies or impacts on the y-axis.
- 6. Analyse the Chart:** Identify the "vital few" causes that contribute to the majority of the problem.
- 7. Prioritize Solutions:** Focus on addressing the most significant causes to achieve the greatest impact.

Here is a completed Pareto Analysis for the problem of injuries on a construction site.

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Cause of Injuries On Site



From this data we can see that the primary causes of injury are Falls & the Misuse of Equipment.

By focusing our efforts in these areas we could effectively reduce injuries by nearly 60%.

We could then complete additional Pareto Analysis in these areas to gain more detailed information. Such as:

- Where & when are the falls occurring?
- Which equipment is being misused the most?

With this information we can again focus our efforts in the areas that will have the greatest benefit to our organisations.

Proactive Failure Analysis (Risk Assessment):

Rather than waiting for a problem to occur it is possible to predict problems in advance & take proactive, preventive measures, to stop the problem occurring.

The most common example of this is a Risk Assessment. Typically used for Health & Safety reasons but can be used in any circumstance.

The 5 steps of generic risk assessment are:

- Identify the hazard or problem.
- Define who could be harmed, or the effects of the problem, & how?
- Evaluate the risk & identify appropriate controls.
- Document your findings & implement your controls.
- Review your assessment & improve where needed.

Here is an example.



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Risk Assessment Example:

Hazard identification = Working at height.

Who could be harmed? = The person working at height, or people below the person working at height.

Risk 1 = Falls from height resulting in injury or death.

Risk 2 = Items falling from height resulting in injury or death.

Controls:

- Permit to work for working at height.
- MEWP to be used for all working at height + suitable fall arrest equipment.
- IPAF training for MEWP operators.
- Tools to be secured in toolbox & materials/parts held securely within the MEWP.
- Prepare assemblies or sub-assemblies are ground level to minimise assembly time at height.
- Exclusion zone of 2 meters whilst working at height.
- Trained, competent personnel only to be used for working at height.
- Mandatory PPE = Hard Hats, Safety Boots, Gloves, Glasses.

By completing this risk assessment in advance & training it out we could avoid an incident from occurring.

Fault Tree Analysis (FTA) & Failure Mode & Effects Analysis (FMEA):

These tools are quite complicated & typically require formal training & experience to utilise them properly & effectively. Both tools can be used to analyse potential system failures & to assess what controls can be put in place to eliminate or mitigate these failures before they occur.

Fault Tree Analysis (FTA):

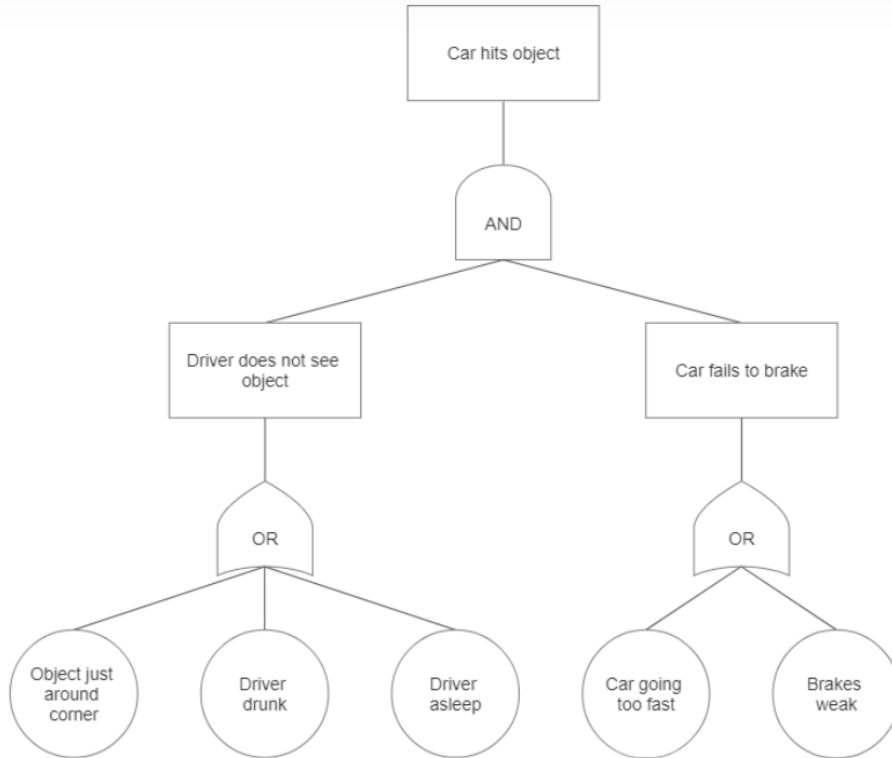
FTA helps determine the root causes of failures and identify potential vulnerabilities in a system, aiding in risk assessment and reliability analysis.

It's a top-down approach, meaning it starts with the undesired event (e.g. a system shutdown or a component failure) and works backward to find the underlying causes.

It uses a visual representation, the fault tree diagram, to illustrate the relationships between events and their causes.

The diagram uses logic gates (AND, OR) to combine events and determine how they contribute to the top event.

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This FTA could then be progressed further to gain a greater understanding of why the event happened.

- Why was the driver drunk?
- Why was the driver asleep?
- Why was the driver going too fast?
- Why were the brakes weak?

The deeper we go the more information we'll gain & the stronger our actions will become to prevent the event from recurring or occurring.

Failure Mode & Effects Analysis (FMEA):

An FMEA is an automotive risk analysis tool. It's typically used to analyse potential failure modes in the design of a product (DFMEA) or the process that produces the product (PFMEA).

The FMEA considers a feature of the product or a process step.

It then considers the requirement that must be met, e.g. the corrosion resistance of the product, or the correct positioning of a QR code.

The FMEA then considers the potential failure modes relating to this requirement, e.g. the product corrodes too easily, or the QR code isn't legible or isn't in the correct position.

The FMEA then considers the effects of these failure modes should they occur, e.g. the product corrodes & a wheel falls off. Potentially a fatal incident. The QR code can't be read & product can't be identified. Not too serious.

We then score the failure mode for Severity (What happens if it occurs?), Occurrence (Likelihood of it happening) & Detection (If it happens likelihood of it being detected?).

Scores are typically out of 10 per category. We then multiply these scores together to get a Risk Priority Number (RPN).

The bigger the number the bigger the risk. Now we know where to act.

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Example of a Process Failure Mode & Effects Analysis (PFMEA):

| Process Step / Requirements | Potential Failure Mode | Potential Effect(s) of Failure | Severity Class | Potential Cause(s) / Mechanism(s) of Failure | Occurrence | Current Process Controls Prevention | Current Process Controls Detection | Detection R.P.N. | Recommended Action(s) | Responsibility & Target Completion Date | Action Results | | | | |
|---|---|---|----------------|--|------------|---|--|------------------|--|---|------------------------------------|----------|------------|-----------|--------|
| | | | | | | | | | | | Actions Taken & Completion Date | Severity | Occurrence | Detection | R.P.N. |
| Name, Part Number, or Class Function | Manner in which part could fail: cracked, loosened, deformed, leaking, oxidized, etc. | Consequences on other systems, parts, or people: noise, unstable, inoperative, impaired, etc. | | List every potential cause and/or failure mechanism: incorrect material, improper maintenance, fatigue, wear, etc. | | List prevention activities to assure process adequacy and prevent or reduce occurrence. | List detection activities to assure process adequacy and prevent or reduce occurrence. | | Design actions to reduce severity, occurrence and detection ratings. Severity of 9 or 10 requires special attention. | Name of organization or individual and target completion date | Actions and actual completion date | | | | 0 |

Once this risk analysis has been completed the organisation can decide if the current controls are sufficient?

If they're deemed not to be then improvement actions can be taken to further reduce the RPN.

This should safeguard the organisation from the failure mode occurring & requiring corrective action.

Human Factors:

What are Human Factors? – Human Factors are the underlying causes of human error.

Human Error is often given as a root cause for a non-conformance. Simply stating Human Error means that your root cause analysis has not gone far enough.

We must understand what led to the Human Error. Typical there are 13 recognised Human Factors that contribute to Human Error. These are:

- 1 - Lack of Communication – A lack of necessary information.
 - 2 - Complacency – A lack of focus.
 - 3 - Lack of Knowledge – Lack of training & competence.
 - 4 - Distractions – Something that shifts one's focus from the task at hand.
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- 5 - Lack of Teamwork – Failure to work together to complete a shared goal or task.
 - 6 - Fatigue – Physical or mental exhaustion that affects work performance. Working long hours. Lack of sleep or breaks.
 - 7 - Lack of Resources – Not having sufficient people, equipment, time, etc. to complete a task.
 - 8 - Pressure – Constant pressure to work harder and faster. Unrealistic deadlines.
 - 9 - Lack of Assertiveness – Failure to speak up or document concerns about instructions, orders or the actions of others.
 - 10 - Stress – Stress is the subconscious response to demands on a person. A certain amount of stress is good, but excessive stress can have negative effects.
 - 11 - Lack of Awareness – Failure to recognise a potential problem situation and predict negative results.
 - 12 - Norms – Unwritten rules of behaviour that develop over time; organizational culture.
 - 13 - Attitude – Frequently an underlying cause of human error. A positive or negative attitude will positively or negatively impact work performance.
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Too often human error is diagnosed as lack of knowledge and retraining is the only corrective action.

As this list indicates there are other human factors that will not be improved by training.

Potential corrective actions include redesigning a process and improving the work environment or working conditions.

Whatever human factor is identified an appropriate corrective action needs to be determined to address the human factor or factors identified.

Problem Solving Tools:

Two popular Problem-Solving Tools are 8D (8 Disciplines) & A3.

8 Disciplines:

Benefits = Structured Approach to Problem Solving. Team orientated. Focuses on Root Cause Analysis. Includes preventive measures as well as corrective & helps to drive continual improvement.

D1 Put Together a Suitable Team.

D2 Define the Problem Clearly & Factually.

D3 Implement Containment Measures & Verify Effectiveness.

D4 Identify Root Causes and Chose Systemic Corrective Actions.

D5 Verify the Effectiveness of Corrective Actions.

D6 Fully Implement the Corrective Actions.

D7 Prevent Recurrence by taking Preventive Actions.

D8 Thank the Team & Celebrate your Success.



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Example of 8D:

| Step | | Customer schedule | Organization schedule | Step description | Yes | No | N / A | Quality Manager Signature | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Closing Audit for 8D Report steps | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Report number: | | | | Complaint date | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Client / Location | | | | Responsible: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Part number / Description | | | | Production line: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Problem Description | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Complained part numbers | | | | Accepted: | | YES | NO | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="2">Step</th> <th>Customer schedule</th> <th>Organization schedule</th> <th>Step description</th> <th>Yes</th> <th>No</th> <th>N / A</th> <th>Quality Manager Signature</th> </tr> </thead> <tbody> <tr> <td rowspan="3">1D</td> <td rowspan="3"></td> <td rowspan="3"></td> <td rowspan="3">24 hours</td> <td>Defined interdisciplinary team</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Problem registered</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Sub-supplier (Tier 2) component issue</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td rowspan="3">2D</td> <td rowspan="3"></td> <td rowspan="3"></td> <td rowspan="3">24 hours</td> <td>Problem correctly defined and described</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Other parts / projects suspected?</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Have currently manufactured parts been checked? Are they marked as certified parts?</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td rowspan="3">3D</td> <td rowspan="3"></td> <td rowspan="3"></td> <td rowspan="3">24 hours</td> <td>Interim Containment Actions / repair agreed (optional scenario)</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Interim Containment Actions (ICA) / repair at client location implemented (optional scenario)</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Should parts be held in stock / in transit?</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td rowspan="3">4D</td> <td rowspan="3"></td> <td rowspan="3"></td> <td rowspan="3">7 days</td> <td>Is a replacement part required?</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Initial information sent to the client (on his form or in his system)</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Root Cause Analysis (Ishikawa)</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td rowspan="3">5D</td> <td rowspan="3"></td> <td rowspan="3"></td> <td rowspan="3">7 days</td> <td>Root Cause Analysis (5xWhy)</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Confirmed root cause</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Plan for corrective actions implementation</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td rowspan="3">6D</td> <td rowspan="3"></td> <td rowspan="3"></td> <td rowspan="3">14 days</td> <td>Actions implemented</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Effectiveness of activities confirmed (e.g. by R&R)</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>ICA finished</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td rowspan="2">7D</td> <td rowspan="2"></td> <td rowspan="2"></td> <td rowspan="2">14 days</td> <td>FMEA / Documentation updated</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Preventive actions defined</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td rowspan="2">8D</td> <td rowspan="2"></td> <td rowspan="2"></td> <td rowspan="2">In accordance with the action plan approval by management</td> <td>Long term activities fully implemented</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Final answer accepted by the client</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td colspan="4"></td> <td>Comment:</td> <td colspan="4"></td> </tr> <tr> <td colspan="4"></td> <td>Closing date:</td> <td colspan="4"></td> </tr> </tbody> </table> | | | | | | | | | Step | | Customer schedule | Organization schedule | Step description | Yes | No | N / A | Quality Manager Signature | 1D | | | 24 hours | Defined interdisciplinary team | | | | | Problem registered | | | | | Sub-supplier (Tier 2) component issue | | | | | 2D | | | 24 hours | Problem correctly defined and described | | | | | Other parts / projects suspected? | | | | | Have currently manufactured parts been checked? Are they marked as certified parts? | | | | | 3D | | | 24 hours | Interim Containment Actions / repair agreed (optional scenario) | | | | | Interim Containment Actions (ICA) / repair at client location implemented (optional scenario) | | | | | Should parts be held in stock / in transit? | | | | | 4D | | | 7 days | Is a replacement part required? | | | | | Initial information sent to the client (on his form or in his system) | | | | | Root Cause Analysis (Ishikawa) | | | | | 5D | | | 7 days | Root Cause Analysis (5xWhy) | | | | | Confirmed root cause | | | | | Plan for corrective actions implementation | | | | | 6D | | | 14 days | Actions implemented | | | | | Effectiveness of activities confirmed (e.g. by R&R) | | | | | ICA finished | | | | | 7D | | | 14 days | FMEA / Documentation updated | | | | | Preventive actions defined | | | | | 8D | | | In accordance with the action plan approval by management | Long term activities fully implemented | | | | | Final answer accepted by the client | | | | | | | | | Comment: | | | | | | | | | Closing date: | | | | |
| Step | | Customer schedule | Organization schedule | Step description | Yes | No | N / A | Quality Manager Signature | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1D | | | 24 hours | Defined interdisciplinary team | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | Problem registered | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | Sub-supplier (Tier 2) component issue | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 2D | | | 24 hours | Problem correctly defined and described | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | Other parts / projects suspected? | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | Have currently manufactured parts been checked? Are they marked as certified parts? | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 3D | | | 24 hours | Interim Containment Actions / repair agreed (optional scenario) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | Interim Containment Actions (ICA) / repair at client location implemented (optional scenario) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | Should parts be held in stock / in transit? | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 4D | | | 7 days | Is a replacement part required? | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | Initial information sent to the client (on his form or in his system) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | Root Cause Analysis (Ishikawa) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 5D | | | 7 days | Root Cause Analysis (5xWhy) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | Confirmed root cause | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | Plan for corrective actions implementation | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 6D | | | 14 days | Actions implemented | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | Effectiveness of activities confirmed (e.g. by R&R) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | ICA finished | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 7D | | | 14 days | FMEA / Documentation updated | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | Preventive actions defined | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 8D | | | In accordance with the action plan approval by management | Long term activities fully implemented | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | Final answer accepted by the client | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | Comment: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | Closing date: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <small>* - a minimum of two managers is required to close activities for the 8D audit</small> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |



NEVER STOP IMPROVING

DEMYSTIFYING CORRECTIVE ACTION & ROOT CAUSE ANALYSIS

A3:

Benefits = Improved problem solving within the business via this structure approach. Visual tool that enhances communication. Encourages collaboration & teamwork during problem solving. PDCA approach drives continual improvement. Empowers employees to participate in problem solving activities.

A3 Structure & Steps:

- Problem description. Stating the facts.
- Current state description. Including data, diagrams, images, etc.
- Future state description. The desired outcome or state.
- Root cause analysis.
- Containment measures. What is to be done, by who & by when.
- Permanent corrective actions. Define to address the root cause(s).
- Implementation plan. Who will do what by when.
- Verification of action effectiveness. Prove actions are effective.
- Follow up actions. Apply lessons learnt. Standardise. Document. Communicate.

DEMYSTIFYING CORRECTIVE ACTION & ROOT CAUSE ANALYSIS

Example of A3:

Support Launch Objectives with Accurate, Timely Document Translations

K5
8/8/08
DP
8/7/08

I. Background

Acme plant to double capacity. Much document translation required

- Poor English translations of Japanese documents caused many problems at original plant startup.
- Expansion plans call for aggressive launch timeline and cost reduction.

Document translation problems could impede launch!

II. Current Conditions

Documents by department, Documents by type, Current-state map

Problems:
 Cost = 10% over budget
 Delivery = Over 50% late, long, variable lead times
 Quality = Much rework > 50%, many errors reach customer
 Overall = 😞

Lead time = 8.5 to 6.0 days

III. Goals/Targets

Quality - 0 defects at launch
 - Rework less than 10%

Delivery - 100% on-time
 - Level weekly volume (heijunka)
 - Consistent short lead time with predictable delivery

Cost - 10% decrease — Rework down; overtime down

IV. Analysis

Lost in translation

- A. Large backlog**
 - Random causes
 - No ability to track
 - Unclear expectations
- B. Poor English**
 - Poor document creation skills
 - Many document formats
 - Complex use of technical vocabulary
 - Unclear expectations
 - Written descriptions of complex operations
- C. Poor translators**
 - Poor or wrongly skilled translator
 - No or poor editing
 - Unclear expectations
 - Large batches and uneven and unpredictable workloads

V. Proposed Countermeasures

| Cause | Countermeasure | Description | Benefit | Responsible/support |
|-------|--|--|-----------------------------|--|
| A | Central document-flow tracking process | Overall process ownership established Document flow and timing management - Timing control chart, weekly check - Segmentation by document type | Delivery Quality Cost | Porter - Each department - Vendors |
| B | Standard vocabulary database and templates | Standard terms for processes, equipment tools, work flow across job sites Create standard templates and include photos and videos Gathered from each department, input into database for use by internal document creators and translators | Quality | Administration IT Each department |
| C | Standard vendor three-step process | Step 1 Translation by topic specialist Step 2 Rewrite by native English speaker Step 3 Check by highly skilled bilingual | Quality Delivery | Administration - Each vendor - Procurement |

VI. Plan

| Deliverables | Timeline | Responsible | Support | Review |
|--|--|-----------------------|-----------------|---|
| Overall Launch Timeline | Planning | Administration/Porter | Each department | Plant management Committee Japan HQ |
| Documents creation | Document creation | Administration/Porter | Each department | Administration/Sanderson |
| Document translation management system | Document translation management system | Administration/Porter | Each department | Administration/Sanderson |
| Midproject review | Midproject review | Administration/Porter | Each department | Administration/Sanderson |

VII. Followup

Midterm review
 Prelaunch review

Ensure ongoing collaboration
 Monitor system weekly. All metrics, especially quality and delivery



NEVER STOP IMPROVING

DEMYSTIFYING CORRECTIVE ACTION & ROOT CAUSE ANALYSIS

Further information on everything discussed within this webinar is available online.

Templates for all tools discussed can also be found online.

This webinar is not exhaustive. There are other root cause analysis, corrective action & problem-solving tools & methodologies out there.

I hope this webinar has given you an insight into the disciplines needed to identify true root cause & to implement systemic, effective, corrective actions.

Thank you for your time & attention.

Q&A

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