



SMMT A Q M S

Automotive Quality Management
Systems Conference

SMMT Industry Forum

Non Conformance Management

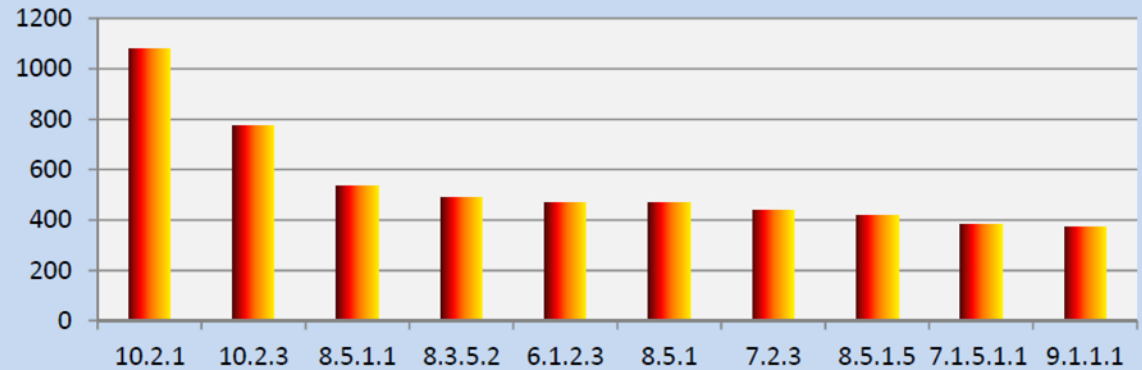
Raising the profile of the
Automotive Quality
Management Profession

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IATF 16949 Major nonconformities – 2018 YTD

IATF Clause	Major NC
10.2.1	1082
10.2.3	773
8.5.1.1	536
8.3.5.2	492
6.1.2.3	471
8.5.1	469
7.2.3	437
8.5.1.5	419
7.1.5.1.1	381
9.1.1.1	374

TOP 10 Major NC

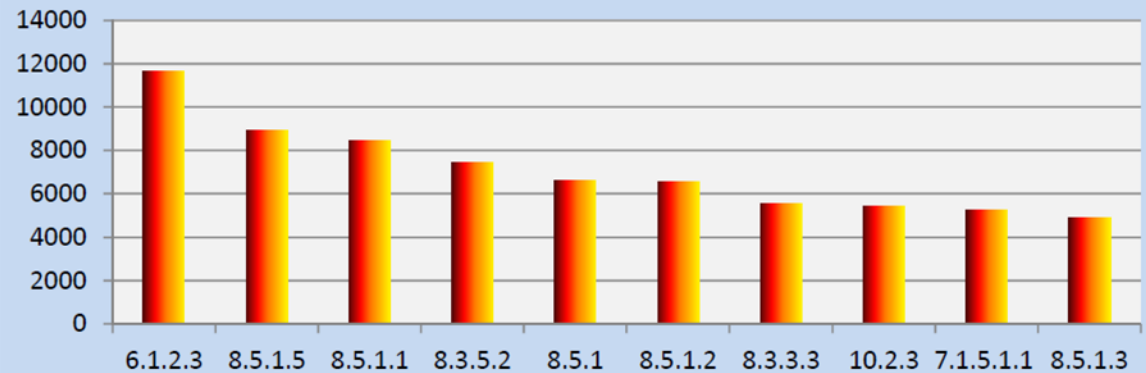


- 10.2.1** (ISO 9001) Nonconformity and corrective action requirements
- 10.2.3** Problem solving process requirements
- 8.5.1.1** Control plan requirements
- 8.3.5.2** Manufacturing design output requirements
- 6.1.2.3** Contingency plan requirements
- 8.5.1** (ISO 9001) Control of production and service provision
- 7.2.3** Internal auditor competence requirements
- 8.5.1.5** Total productive maintenance
- 7.1.5.1.1** Measurement systems analysis requirements
- 9.1.1.1** Monitoring and measurement of manufacturing processes

IATF 16949 Minor nonconformities – 2018 YTD

IATF Clause	Minor NC
6.1.2.3	11641
8.5.1.5	8936
8.5.1.1	8474
8.3.5.2	7470
8.5.1	6595
8.5.1.2	6554
8.3.3.3	5544
10.2.3	5454
7.1.5.1.1	5275
8.5.1.3	4924

TOP 10 Minor NC



- 6.1.2.3** Contingency plan requirements
- 8.5.1.5** Total productive maintenance
- 8.5.1.1** Control plan requirements
- 8.3.5.2** Manufacturing design output requirements
- 8.5.1** (ISO 9001) Control of production and service provision
- 8.3.1.2** Standardised work — operator instructions and visual standards
- 8.3.3.3** Special characteristic requirements
- 10.2.3** Problem solving process requirements
- 7.1.5.1.1** Measurement systems analysis requirements
- 8.5.1.3** Requirements on verification of job set-ups

Nonconformity Management - Major

The certification body shall require the **client** to submit, within a **maximum of twenty (20) calendar days** from the closing meeting of the site audit evidence of the following:

- a) implemented correction,
- b) root cause including methodology used, analysis, and results,

The certification body shall require the **client** to submit within a **maximum of sixty (60) calendar days** from the closing meeting of the site audit, evidence of the following:

- c) implemented systemic corrective actions to eliminate each nonconformity, including consideration of the impact to other similar processes and products,
- d) verification of effectiveness of implemented corrective actions.

28.

Evaluate the client's root cause analysis and systemic corrective actions

Nonconformity Management - Minor

The certification body shall require the **client** to submit the following information to the certification body within a **maximum of sixty (60) calendar days** from the closing meeting of the site audit:

28.
*Evaluate the
client's root
cause analysis
and systemic
corrective
actions*

- a) implemented correction,
- b) root cause including methodology used, analysis, and results,
- c) implemented systemic corrective actions to eliminate each nonconformity, including consideration of the impact to other similar processes and products,
- d) verification of effectiveness of implemented corrective actions.

Nonconformity Management

28.

Evaluate the client's root cause analysis and systemic corrective actions

- The certification body shall review the submitted information and make a decision regarding acceptability within a maximum of ninety (90) calendar days from the closing meeting of the site audit.
- If found acceptable, the nonconformity shall be closed and the certification body shall verify the effective implementation of the identified corrective actions at the next audit , unless a special audit was conducted.

29.

Complete special audit/ follow-up audit (if needed)

Nonconformity Management - Major

28.
*Evaluate the
client's root
cause analysis
and systemic
corrective
actions*

29.
*Complete
special audit/
follow-up audit
(if needed)*

- In cases of **a major** nonconformity the certification body shall conduct an onsite special audit for the verification of the corrective action. The onsite verification shall be considered a special audit and be completed within a maximum of ninety (90) calendar days from the closing meeting of the site audit.
- In cases where the accepted corrective action plan for a major nonconformity is found to be not effectively implemented, **the audit result shall be considered failed, the IATF database shall be updated, and the certificate withdrawn.**
- The certification body shall issue a supplemental report to the client after verification of corrective action is complete, which shall include the verification details of each nonconformity.

Nonconformity Management - Minor

28.

Evaluate the client's root cause analysis and systemic corrective actions

- Onsite verification of the corrective action for a minor nonconformity within a maximum of ninety (90) calendar days from the closing meeting of the site audit is **at the discretion of the certification body based on knowledge and experience.**
- In cases where the accepted corrective action plan for a minor nonconformity is found to be not effectively implemented, **a new major nonconformity shall be issued against the corrective action process and the previous minor nonconformity reissued as a major nonconformity.**
- The certification body shall issue a supplemental report to the client after verification of corrective action is complete, which shall include verification details of each nonconformity.

29.

Complete special audit/ follow-up audit (if needed)

Nonconformity Management

28.

Evaluate the client's root cause analysis and systemic corrective actions

Use of 100% resolved:

In exceptional case(s) where the implementation of corrective actions cannot be completed within a maximum of ninety (90) calendar days from the closing meeting of the site audit, the certification body shall consider the nonconformity open but 100% resolved when the following conditions have been met:

29.

Complete special audit/ follow-up audit (if needed)

- a) containment of the condition to prevent risk to the customer has been taken, including a review of the systemic impact on the client's process,
- b) documented evidence of an acceptable action plan, instructions, and records to demonstrate the elimination of the nonconformity condition, including a review of the systemic impact on the client's process,

Nonconformity Management

28.

Evaluate the client's root cause analysis and systemic corrective actions

29.

Complete special audit/ follow-up audit (if needed)

Use of 100% resolved:

- c) scheduled onsite follow-up audit based on the accepted action plan and prior to the next audit,
 - d) in situations where 100% resolution has been determined, the certification body shall maintain records of the justification.
-
- In cases where the accepted corrective action plan is found to be not effectively implemented, a new major nonconformity shall be issued against the corrective action process (see IATF 16949, section 10.2) and the previous minor nonconformity reissued as a major nonconformity.

Exercise

Evaluation of client corrective action:

- What do the auditors look for?
- What is the criteria for acceptance?
- Prepare to feedback

Acceptance of Corrective Actions

IATF 16949:2016 10.2.3 Problem Solving:

- a) defined approaches for various types and scale of problems (e.g., new product development, current manufacturing issues, field failures, audit findings);
- b) containment, interim actions, and related activities necessary for control of nonconforming outputs (see ISO 9001, Section 8.7);
- c) root cause analysis, methodology used, analysis, and results;
- d) implementation of systemic corrective actions, including consideration of the impact on similar processes and products;
- e) verification of the effectiveness of implemented corrective actions;
- f) reviewing and, where necessary, updating the appropriate documented information (e.g., PFMEA, control plan).

1. The Problem Solving Team

The client shall....

1... **Put together a team** that has the skills needed to solve the problem, and has the time and energy to commit to the problem solving process.

Team approach shall be applied (more than 1 person).

Team should be cross functional.

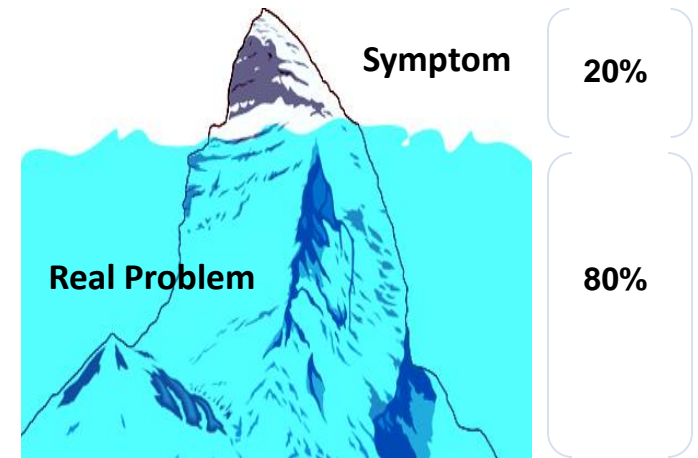
Select 1 person as the “guide” to keep the process on track and meet timing requirements.

Select 1 person for the role of “Fresh Eyes” to review the completed response before it is submitted to the CB office.

2. Problem Investigation

- Why **analyze the situation**?

Because no matter how small the iceberg looks on the surface, 80 percent of the iceberg lies below the water. It's the same with problems.



- Often the nonconformity is a **symptom** of the “real” problem that lies below the surface and needs to be solved.
 - To solve the “real problem” the client needs to **collect data**! Without it, only the symptoms are fixed and it will not stop the real issue from recurring.

2. Problem Statement

To **collect data** about the problem, the problem solving team needs to :

- Ask and document : Who? -- What? -- When? -- Where? -- How many? –
- Ask and document: is problem isolated? -- was this a gradual change? -- an abrupt change? -- or never-been-there performance issue?

Review and document the internal system(s), procedure(s) and form(s) related to the problem and **identify where the breakdown in the process occurred**. Were there any deficiencies in the process or forms that could have contributed to the problem?

Once the extent of the problem is known, record a **short, simple, concise** problem statement.

- Problem statement is generally written as a process or system based issue.
- Problem statement becomes the starting point of the root cause analysis.

**“A problem well defined is
a problem half solved.”**

3. Correction / Containment Action

The Client shall...

1. ... **implement specific and appropriate action(s) to prevent further occurrence of the problem.**
 - The action(s) shall start shortly after the nonconformance is issued or after the problem investigation is complete.
 - The action(s) shall correspond with the magnitude/extent of the problem investigation.
 - There shall be at least one action per piece of objective evidence in the Nonconformity form.
 - The action(s) shall be implemented before the client response is submitted.
 - If the Client determines that correction and/or containment is **not** necessary, an explanation shall be provided.

3. Correction / Containment Action

The Client shall...

2. ... if containment action(s) exist, identify the action(s) and the length of time it is expected to be in place until the permanent corrective actions are implemented.

→ Include the start and end date and who is/was responsible.



3. ... record each action taken in the Correction (Containment).

→ Use past verb tense (e.g. changed or conducted) to show the actions were implemented.

→ Include the date when the action was implemented and who is/was responsible.

→ If actions have not been implemented, use future verb tense (will be changed or will be conducted) and include a target date.

4. Root Cause Analysis

The Client shall...

1.... conduct a root cause analysis that is in line with the problem statement(s).

- Keep the root cause analysis **simple** – recommend using the common 5 WHY approach, but other effective methods are also acceptable.
- Document the steps (e.g. Why? Answer.) until the final root cause(s) is determined. Make sure you have gone “deep enough” with the analysis. Do not stop at the 2nd Why.
- Analysis must focus on...“**what in the system failed such that the problem occurred?**”
- Analysis should consider :
 - Technical** → What problem with the process caused the failure?
 - Detection** → What detection system failed (or should have caught the problem before it escaped)?

4. Root Cause Analysis

Analysed Failure
Modes



Determine Potential
Root Cause(s)



Confirm & Verify
Root Cause(s)

Need to determine 3 types of Root Causes:

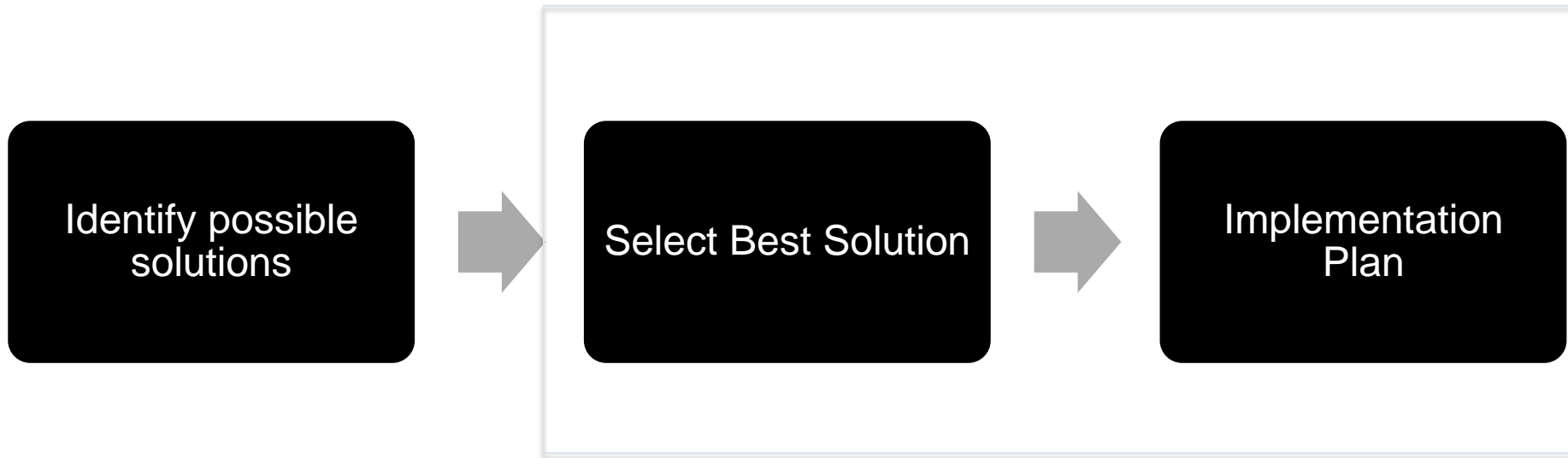
- **Escape:** Why did the concern reach the customer (or next operation)?
- **Occurrence:** Why did the problem occur?
- **Systemic:** Why did the system or planning process fail to detect?

5. Corrective Action

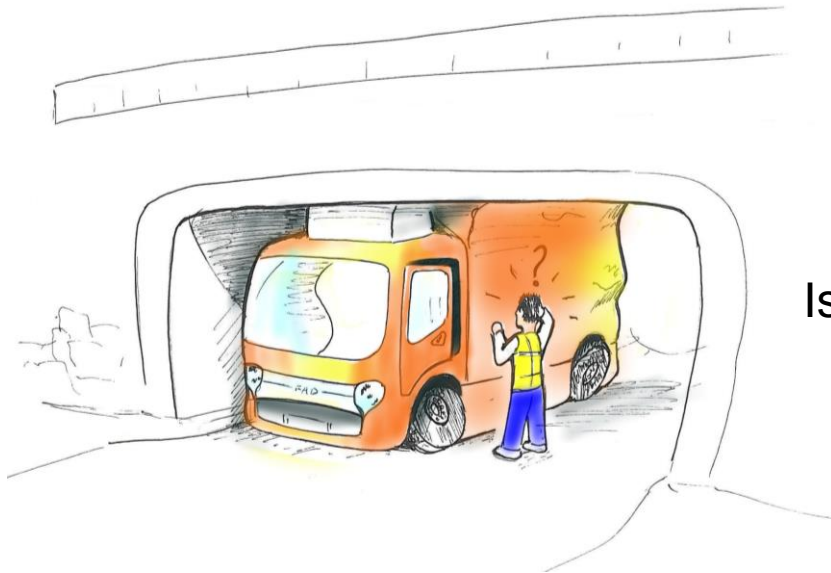
The Client shall...

1.... implement specific and irreversible corrective actions, that

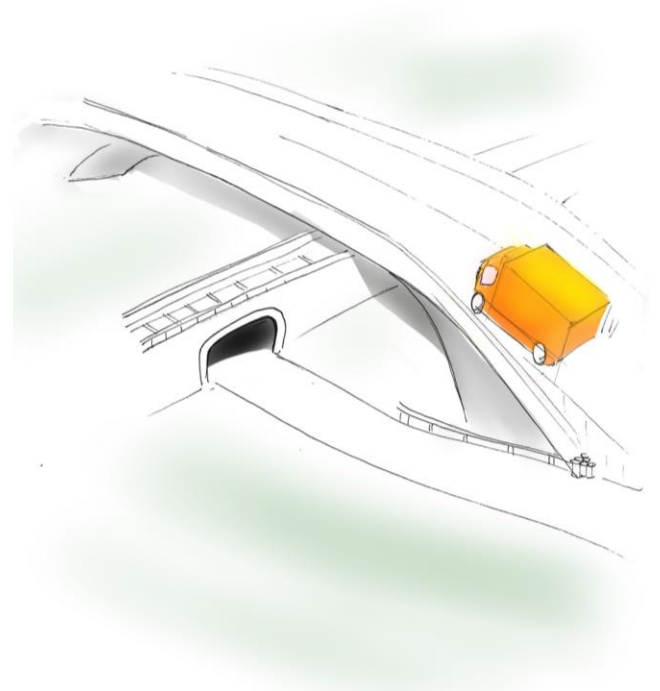
- Eliminate the root cause(s) and prevent recurrence.
- Clearly address the question, “What in the system failed such that the problem occurred?”
- Explain what the organization does and how it is now different.



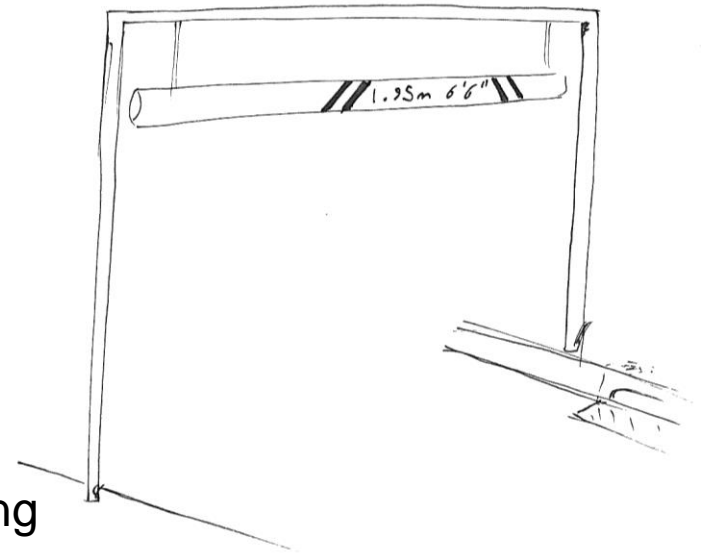
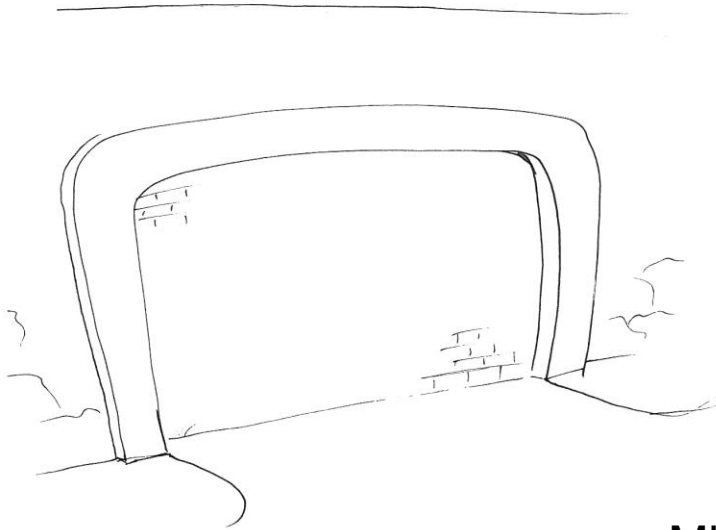
5. Corrective Action



Is this better?

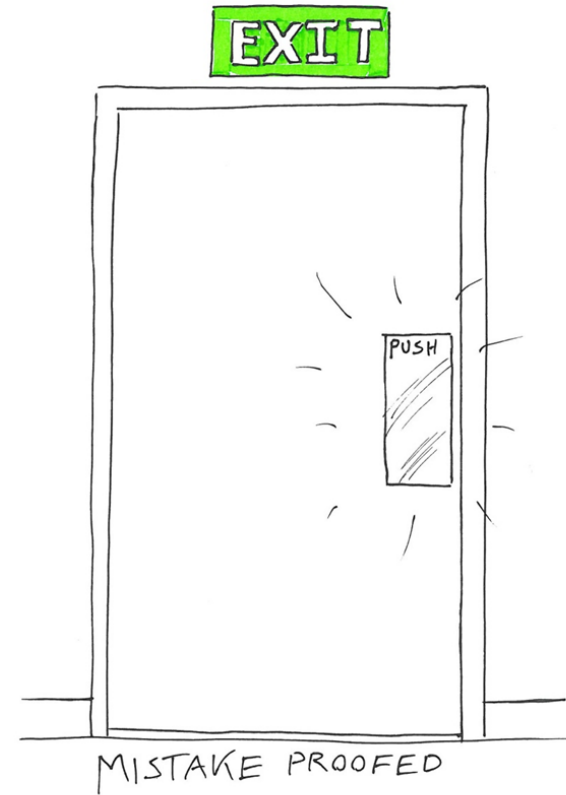
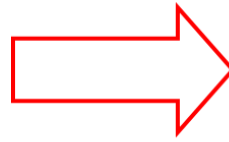
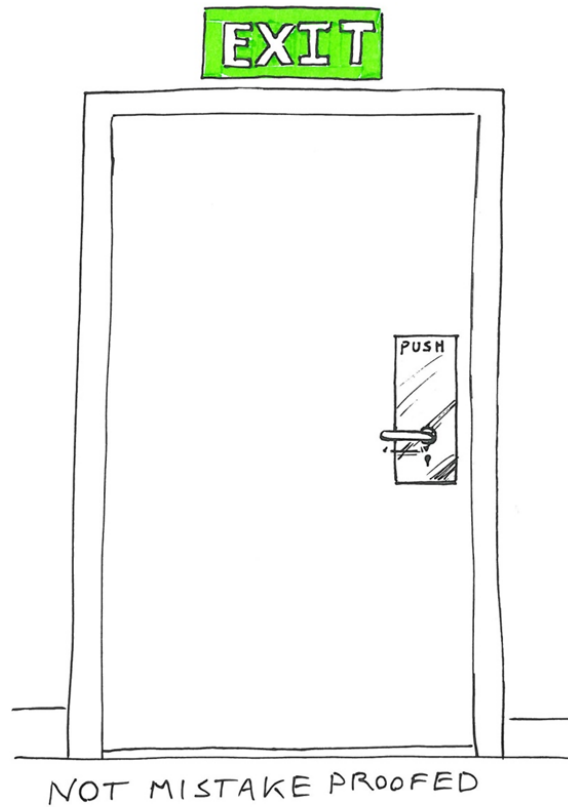


5. Corrective Action



Mistake Proofing

5. Corrective Action



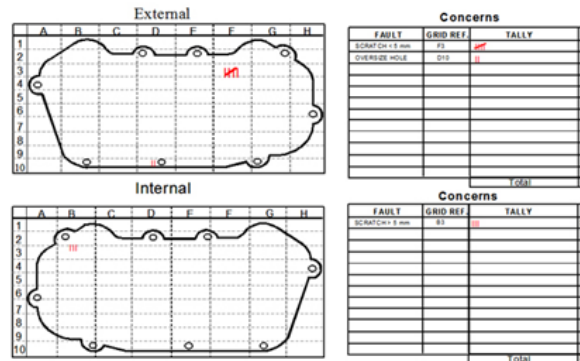
6. Verification Action

The Client...

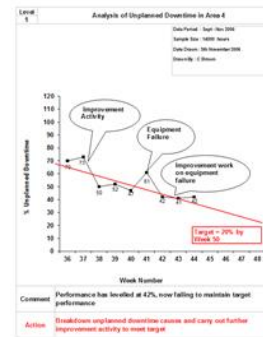
1. ... **plan and implement actions to demonstrate the effectiveness of corrective actions taken.**
2. ... **record the actions in the Verification section.**
 - Include date(s) when the verification was (or will be) completed and who was (or is) responsible.
3. ... **attach evidence if the verification actions have been implemented.**
 - If actions have **not** been implemented, provide a timeframe for when the verification will be performed.

Monitoring & Verifying the corrective actions

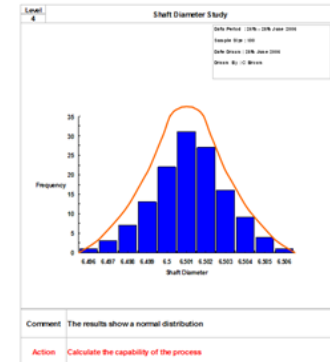
Measles and Tally Charts



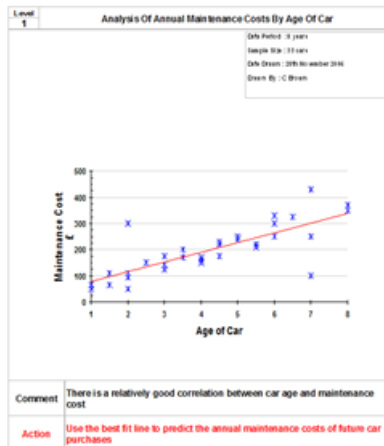
Run Chart Example



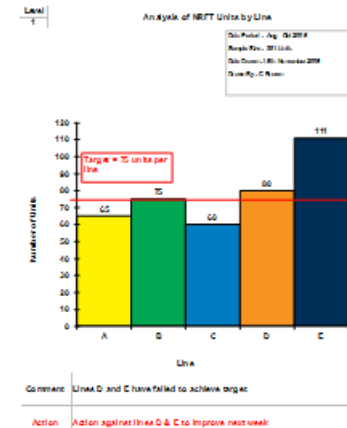
Histogram



Scatter Chart



Bar Chart



7. Prevent Recurrence

The Client shall...

1.**affords the opportunity to preserve and share the knowledge**, preventing problems on similar products, processes, locations or families.
2. Updating documents and procedures / work instructions are expected at this step to improve future use.
3. Review Similar Products and Processes for problem prevention
4. Develop / Update Procedures and Work Instructions for Systems Prevention
5. Capture Standard Work / Practice and reuse
6. Assure FMEA updates have been completed
7. Assure Control Plans have been updated

8. Closure and Team Celebration

Closure and Team Celebration...

Teams require feedback to allow for satisfactory closure. Recognizing both team and individual efforts and allowing the team to see the previous and new state solidifies the value of the process.

Activities include:

- Archive the Documents for future reference.
- Document Lessons Learned on how to make problem solving better.
- Before and After Comparison of issue.
- Celebrate Successful Completion.

Problem solving process



Step 8 – Recognise the team contribution

Step 7 – Preventive actions

Step 6 – Implement & verify actions

Step 5 – Choose permanent corrective actions

Step 4 – Identify & verify root cause(s)

Step 3 – Interim containment actions

Step 2 – Describe the problem

Step 1 – Define the team

8D approach

Questions





@smmtif



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