PROBLEM STATEMENT

(The 1st Step in Taking Corrective Action)

March 12, 2014

Princeton Section ASQ

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Correction vs Corrective Action

- Problem statement is:
- Not always needed for a *CORRECTION*
- A must for a *CORRECTIVE ACTION*

(Need to understand the difference)

- Problem solving is the most important part of management.
- The formation of the problem statement is the essential part in problem solving.
- We often seek to find solutions before understanding what the problem is.

- A problem statement is a clear, concise description of the issue that is to be addressed by solving team.

- Used to focus the team at the beginning, keep the them on track, and used to validate the solution solved the problem.

- Is a declarative statement – not a question

- Problem statement communicates to others – especially higher-up management
- Too often we think “they know” when “they don’t” (big mistake here)
- Especially needed in large organizations

Problem Statement?

- “Too many leakers, more than usual.”

“Too many leakers, more than usual.”

- Manufacturing is experiencing more leakers than usual. After bottle cap placement rejects due to cap leakers have increased 28%. This is causing late delivery of product and 20% increase in manufacturing costs.

“Too many leakers, more than usual.”

- Manufacturing is experiencing more leakers than usual. After bottle cap placement only on liquid fill Line 3 for Product Alfa rejects due to cap leakers have increased 28% since Jan 8, 2014. This is causing late delivery of product and a 20% increase in manufacturing costs.

Problem Statement?

- “**Customers are complaining that the safety holder is failing to lock in place.”

- **Because this was a safety product complaint top management was immediately involved – RED ALERT

"Customers are complaining that the safety holder fail to lock in place."

- One safety holder failed to lock in place only at one hospital in Paris, France. The other ten hospitals in the Paris network re-told the same failure to the sales representative who in turn forwarded ten complaints to the DCU.

- (No RED ALERT)

Basic Structure

5 W's

- Who?
- What?
- Where?
- When?
- Why?

NOTE: Oder or sequence not important

Basic Structure

Who?	• Who does the issue affect?
What?	• What is the issue? What is the opportunity? • What are the boundaries of the issue? • What is the impact of the issue • What will happen when it is fixed? • What are the consequences of inaction?
Where?	• Where is the issue occurring?
When?	• When does the issue occur? • When does it need to be fixed?
Why?	• Why is it important to fix?

Who?

- Who does the issue affect?
  - Specific location
  - Group
  - Organization
  - Customers
  - etc.

What?

- What is the issue? What is the opportunity?
- What are the boundaries of the issue?
- What is the impact of the issue?
- What will happen when it is fixed?
- What are the consequences of inaction?

When?

- When does the issue occur?
- When does it need to be fixed?

Where?

- Where is the issue occurring?

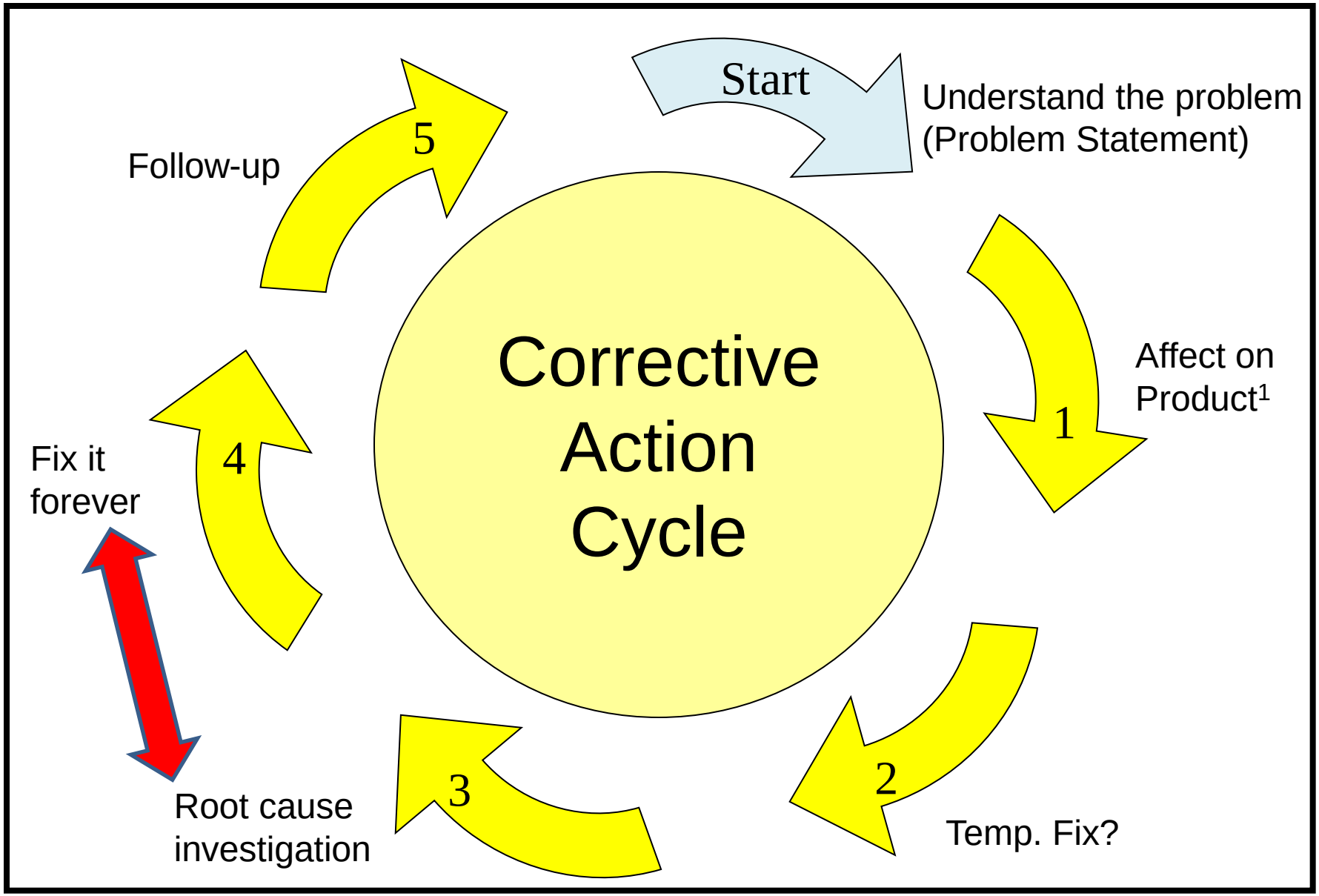
  (Only in certain locations, processes, products, etc.)

Why?

- Why is it important to fix?
  - Impact it has on the business and customer
  - Impact it has on all stakeholders – employees, suppliers, customers, shareholders, etc.

Need Problem Statement for:

- CORRECTIVE ACTIONS:
  - CAPA's
  - Customer Complaints
  - Audit Nonconformances
  - Etc.
- The "D" in DMAIC for 6-Sigma Projects


Start
Understand the problem
(Problem Statement)
1
Affect on
Product1
2
Temp. Fix?
3
Root cause
investigation
4
Fix it
forever
5
Follow-up
Corrective
Action
Cycle

Corrective Action Cycle

Start with *Problem Statement*

1. Affect on product
2. Temporary fix
3. Root cause investigation
4. Fix if forever – ***fix the Root Cause***!
5. Follow-up – Did we really fix it?

Revisit the Problem Statement

PROBLEM STATEMENT ?

- QAD (order management system) allows to create shop orders for product codes that have a Quality “hold” and are not allowed to be manufactured. W21716 (GF9123097) was created in QAD and shipped to sterilization. As a containment action for a design related non conformance, code W21716 was to be maintained on hold until final disposition is defined as part of a CAPA project. NC INT-NC057482-09.

Interpretation of the problem statement

- The *control of nonconforming product* is inadequate in that QAD (the order management system) does not recognize product that is under QA Hold. This allows a shop order to be created using product that is under hold in the Pilgrim system. The current practice relies on people's memory which can result in nonconforming product being mistakenly released for distribution and then later recalled.

PROBLEM STATEMENT ?

- When an ECO is created in Agile system to perform some Engineering change there is no specific process to define the appropriate approvers to involve all affected areas in each facility. We are depending to the internal communication on the facility in order to synchronize the implementation change.

Interpretation Problem Statement

- The *change control process* is ineffective when the change affects multiple plants. When an ECO is created in Aglie the necessary approvers of the change at each affected facility is not prescribed. The current process relies on people at each facility to communicate with each other. This could result in a facility unaware of the change and not prepared to implement it.

PROBLEM STATEMENT ???

DFMEA storage, retrieval, and change process:

- For all company facilities, DFMEA's are not archived in a common location. This makes it difficult for Design Engineers as well as production facility personnel to retrieve the document of interest or to even know if it exists. Without this source of product knowledge, risks may not be properly addressed in the production inspection and testing activities potentially passing on risks to the end user and patient.
- To compound the issue, the DFMEA change process is a laborious long process. The potential impact could be failure to initiate timely redesigns or slow additions of new tests and inspections that could catch and prevent the release of unsafe product.
- A common, user friendly retrieval system would allow R&D and manufacturing facility engineers to obtain documents quickly saving much time and would help identify any gaps in the risk assessment document archives.
- Integrating a more efficient change process with this common archive system would expedite the documenting of new or elevated risk and in turn accelerate the implementation of new checks and tests at the manufacturing facility for minimizing end user and patient risk. A comprehensive plan with implementation by the end of year would be realistic. Inaction will continue to put us at risk from newly discovered issues.

Interpretation of the problem #1

- The *document control* of Design Failure Mode Effect Analysis (DFMEA) is not is not well established and maintained throughout the corporation. This makes it difficult to retrieve a DFMEA of interest or even know if one exists. This puts an unnecessary risk in that the DFMEA may not be correctly translated into acceptance activities during production. This could result in inspections and tests not being done resulting in customer dissatisfaction.

Interpretation of the problem #2

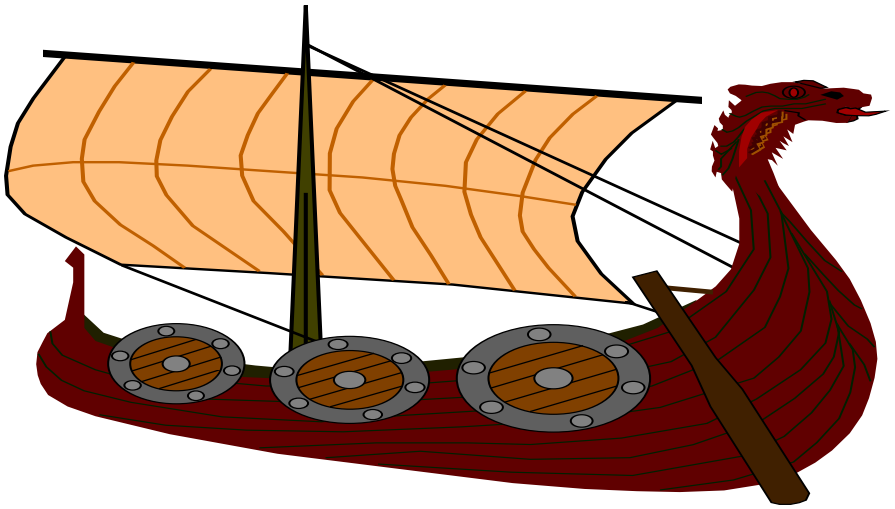
- The existing *change control process* for Design Failure Mode Effect Analysis (DFMEA) is not is not well established and maintained throughout the corporation to timely allow for making and implementing changes in production. This impacts the timely initiation of design changes and the associated inspection and tests related to the change.

Problem Statement?

- Low Sense of Urgency by Corporate Functions (SA/RD/Regulatory) when it comes to sustaining engineering and CIPs projects at plant level.

KEEP FOCUSED ON ORIGNAL PROBLEM

- The Problem Statement sets the course.
- NO problem “creep” that’s not defined in the original problem statement.



Summary:

- Title – Give the statement a title
- Statement – follow with the problem statement.

Summary:

- Title: Excessive Leakage on Line 3
- Statement: Manufacturing is experiencing more leakers than usual. After bottle cap placement on liquid fill Line 3 for product Alfa rejects due to cap leakers have increased 28% since Jan 8, 2014. This is causing late delivery of product and a 20% increase in manufacturing costs.

Summary:

5 W's

- Who?
- What?
- Where?
- When?
- Why?

NOTE: Oder or sequence not important

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