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Preventive Action, Correction, and Corrective Action: From Requirements to Effective Processes

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Introduction

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- Dan O'Leary
  - Dan has more than 30 years experience in quality, operations, and program management in regulated industries including aviation, defense, medical devices, and clinical labs. He has a Masters Degree in Mathematics; is an ASQ certified Biomedical Auditor, Quality Engineer, Reliability Engineer, and Six Sigma Black Belt; and is certified by APICS in Resource Management.
- Ombu Enterprises, LLC
  - Ombu works with small manufacturing companies, offering training and execution in Operational Excellence. Focusing on the analytic skills and systems approach of operations management, Ombu helps companies achieve efficient, effective process and regulatory compliance.

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Outline

Our Perspective

The Topics We Will Cover

The Problem

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- The contrast of technical terms can confuse:
  - Preventive Action ⇔ Corrective Action
  - Correction ⇔ Corrective Action
  - Repair ⇔ Rework
  - Nonconformity ⇔ Defect
- The technical dictionary is essential
  - ISO 9000:2005 contains the dictionary, but not many people look at it
- The FDA, with QSR, didn't define many of these terms, and seems to confuse some of them.

The Problem (cont.)

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Fred: We just had a rejected lot of the new model of framitz. We will fix them, so they will be OK to ship, but I'd like to prevent this problem from happening again.

Jane: Thanks for letting me know. Don't forget to document your work in the CAPA process.

Question: When we "fix the framitz", what technical term applies?
Question: When Fred "prevents the problem from happening again" is he taking Corrective Action or Preventive Action?

Our Approach

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- We will look at the formal definitions
  - Introduce the concept diagrams from ISO 9000:2005
- Use examples to help clarify the differences
- Use our knowledge to extract the process from the requirements
- Build and measure our process

Outline

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- We look at three standards . . .
  - ISO 9001:2008
  - ISO 13485:2003
  - QSR (21 CFR Part 820)
- and bring forward the associated definitions
  - ISO 9000:2005
  - QSR (21 CFR Part 820)
- We analyze the requirements
- We define and characterize metrics
- We design and implement processes

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ISO 9000:2005

Definitions

Concept Diagrams

Definitions

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- ISO 9000:2005 groups concepts
  - They are not listed alphabetically as in a standard dictionary
  - The groupings use concept diagrams
- The definitions capture the essential characteristics of the concept
- In theory, if a term is substituted by its definition, the text will not change meaning

Concept Diagram for Conformity (3.6)

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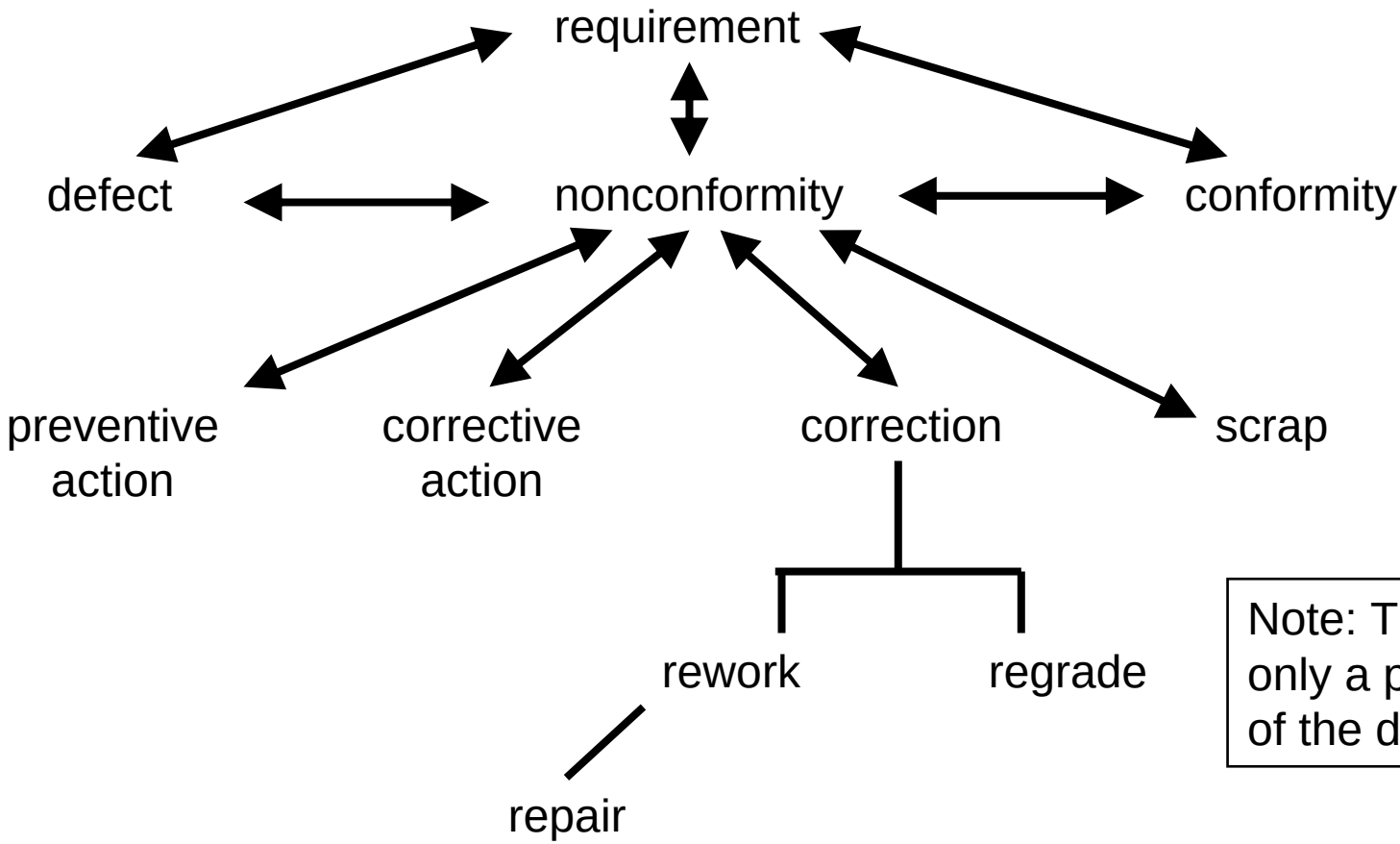

Note: This is only a portion of the diagram.

Symbols on the concept diagram

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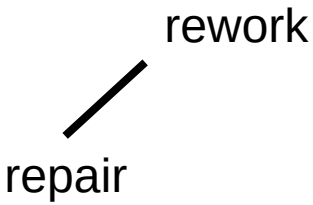
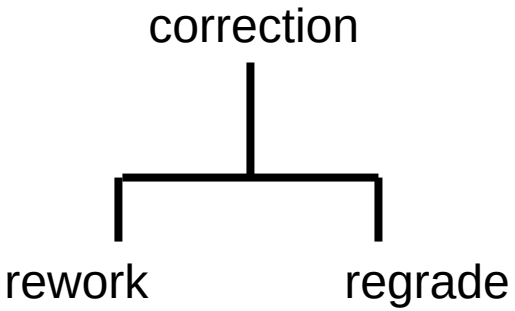
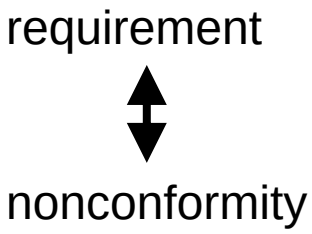


Generic Relation: The subordinate inherits all the characteristics of the concept above. The definition contains distinguishing characteristics.



Partitive Relation: The subordinates are the constituent parts of the concept above.



Associative Relation: Identifies a relationship between concepts that are not subordinate.

Definitions

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nonconformity

defect

Nonconformity – non-fulfillment of a requirement

Defect – non-fulfillment of a requirement related to an intended or specified use

Discussion & Examples

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nonconformity

defect

Discussion

Legal connotations, especially in product liability, suggest we should avoid the word “defect”. The standard raises the issue in Note 1.

We should change the Six Sigma term “DPMO” to NPMO.

Example

I buy a blender so I can make frozen daiquiris (intended use). As I unpack it, I notice a run in the painted base near the power cord. This is a nonconformity (requirement for paint system), but not a defect. I can still use the blender to make my daiquiris.

Definitions

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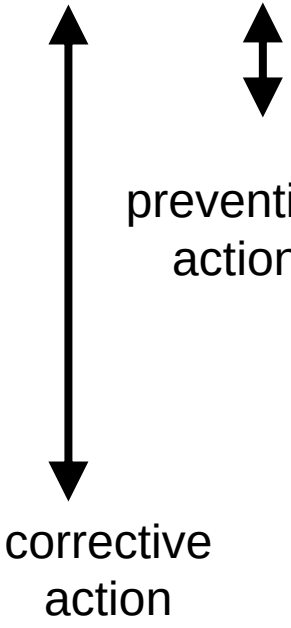

Nonconformity – non-fulfillment of a requirement

Preventive action – action to eliminate the cause of a **potential** nonconformity or other undesirable potential situation

Corrective action – action to eliminate the cause of a **detected** nonconformity or other undesirable situation

Discussion & Examples

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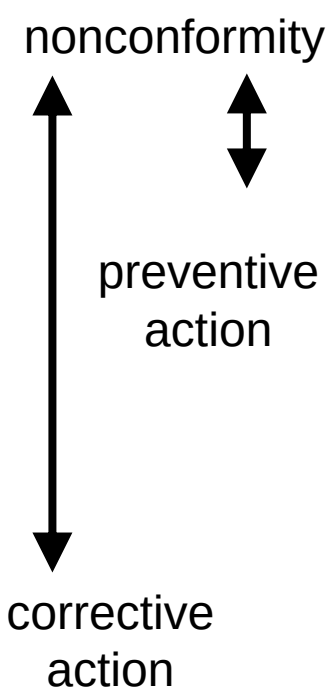

Discussion

- Corrective action happens *after* the nonconformity already occurred.
- Preventive action happens *before* the nonconformity can occur.
- Corrective action stops the nonconformity from happening again.
- Preventive action keeps the nonconformity from ever happening.

Examples

→ **Preventive Action:** My company has never had an OSHA reportable eye injury, but we require everybody in the machining area to wear safety glasses with side shields.

→ **Preventive Action:** My company makes electronic equipment and enjoys a robust ESD program.

The Language Trap

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The language trap confounds colloquial terms with technical terms. Consider the following conversation between two Quality Engineers.

John: Our in-line process check revealed a problem on widget machine #2. We will need to rework the completed batch.

Mary: I'll look for the root cause; I'd like to understand it so we can prevent this problem from happening again!

As Mary works on her assignment to prevent the problem from happening again, is she performing Preventive Action or Corrective Action?

Corrective Action: She is working on a **detected** nonconformity.

Definitions

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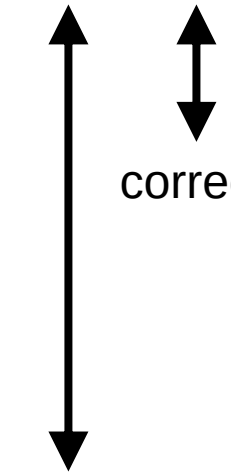

Nonconformity – non-fulfillment of a requirement

Correction – action to eliminate a detected nonconformity

Corrective action – action to eliminate the cause of a detected nonconformity or other undesirable situation

Discussions & Examples

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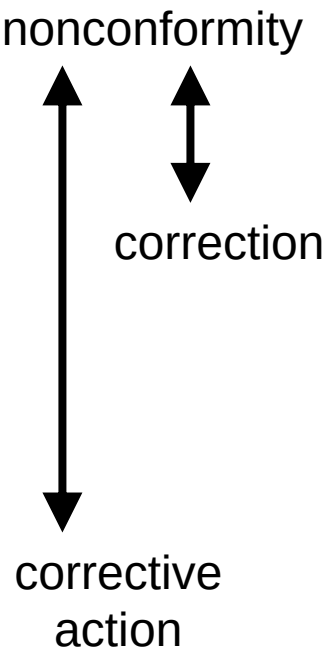

Discussion

- Correction applies when we have a nonconformity and we eliminate it
- Corrective action stops the nonconformity from happening again

Example

- We restructured the production line, following lean principles, to put a small drill press in the flow. The operator drills six holes in a cover, but sometimes misses a hole; the line uses pass-back. We add an output check to the process step.
- The pass-back is *correction* to fix the nonconformity (requirement is six holes).
- The output check is *corrective action* to ensure the nonconformity doesn't recur.

Definitions

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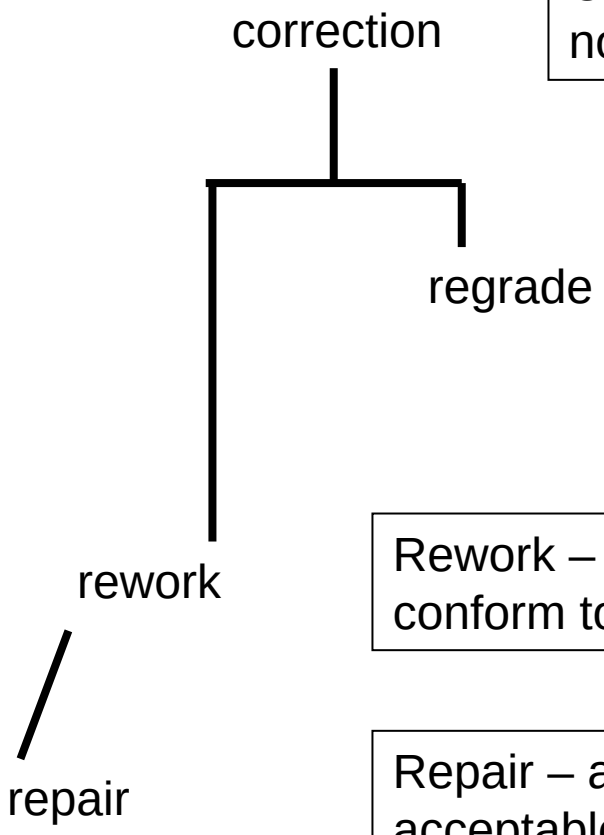

Correction – action to eliminate a detected nonconformity

Regrade – alteration of the grade of a nonconforming product in order to make it conform to requirements differing from the initial ones

Rework – action on a nonconforming product to make it conform to the requirements

Repair – action on a nonconforming product to make it acceptable for the intended use

Discussions & Examples

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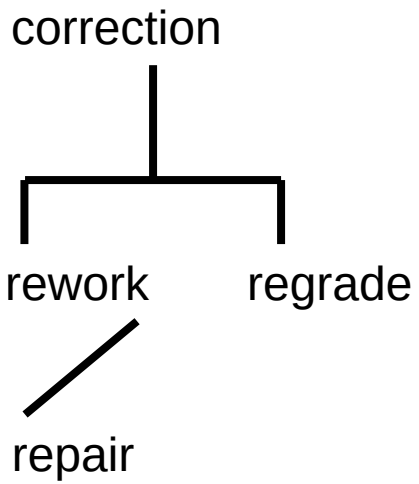

Discussion

Regrade classifies a part to a new set of specifications
Rework achieves conformance with the specification
Repair achieves fitness for use, but not conformance with the specification

Example

When the flow line passes-back the cover to add the missing hole, it is *rework*.

Example

In the flow line the fixture slipped, so I have six holes, but one is in the wrong place. If I add a seventh hole, so the cover is fit for use, this is *repair*.

Example

When shoes were hand sewn, a missed stitch allowed the pair to be regraded as a second, and sold at a lower price.

Correction ◁▷ Corrective Action

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- Correction
  - Implies a nonconformity has occurred, *i.e.,* some requirement isn't fulfilled
  - Correction eliminates the detected nonconformity in one of three ways
    - Rework makes it conform to the initial specification
    - Regrade makes it conform to an alternate specification
    - Repair makes it fit for use
- Corrective Action
  - Implies a nonconformity has occurred, *i.e.,* some requirement isn't fulfilled
  - Corrective action eliminates the cause of the detected nonconformity

Corrective Action ◁▷ Preventive Action

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- Corrective Action
  - Implies a nonconformity **has** occurred, *i.e.,* some requirement isn't fulfilled
  - Corrective action eliminates the cause of the **detected** nonconformity
- Preventive Action
  - Implies a nonconformity **could** occur, *i.e.,* some requirement may not be fulfilled
  - Preventive action eliminates the cause of the **potential** nonconformity

An Example

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Traffic Control

Jane's car was hit by another car at an intersection. The investigation revealed the other driver couldn't see the STOP sign because it was obscured by the leafy branches of a tree.

Requirement: All traffic control signs should be clearly visible
Detected nonconformity: The STOP sign was obscured by a tree branch
Correction: Trim the tree branches that obscure the sign
Corrective Action: Initiate a maintenance program to check all traffic control signs in the city and clean obstructions to visibility

Discussion

Notice the structure here:
The requirement and the detected nonconformity are in the same terms.
The correction eliminates the nonconformity
The corrective action eliminates the cause of the detected nonconformity

Another Example

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Theft Prevention

Another manufacturer in my industrial park had a break in, and the thieves stole some computers, monitors, *etc*. It hasn't happened at my plant. The loss control agent from my insurance carrier helps me improve the external lighting and the alarm system.

Requirement: The building is secure against undetected unauthorized entry
Potential nonconformity: Thieves gain undetected access to the building
Correction: N/A, the nonconformity hasn't happened
Preventive Action: Improve the external lighting and the alarm system

Discussion

Notice the structure here:
The requirement and the potential nonconformity are in the same terms.
There is no correction, because there is no nonconformity
The preventive action eliminates the cause of the potential nonconformity

Laying out the language

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C: Eliminate a detected nonconformity

CA: Eliminate the cause of a detected nonconformity

PA: Eliminate the cause of a potential nonconformity

A Summary Diagram

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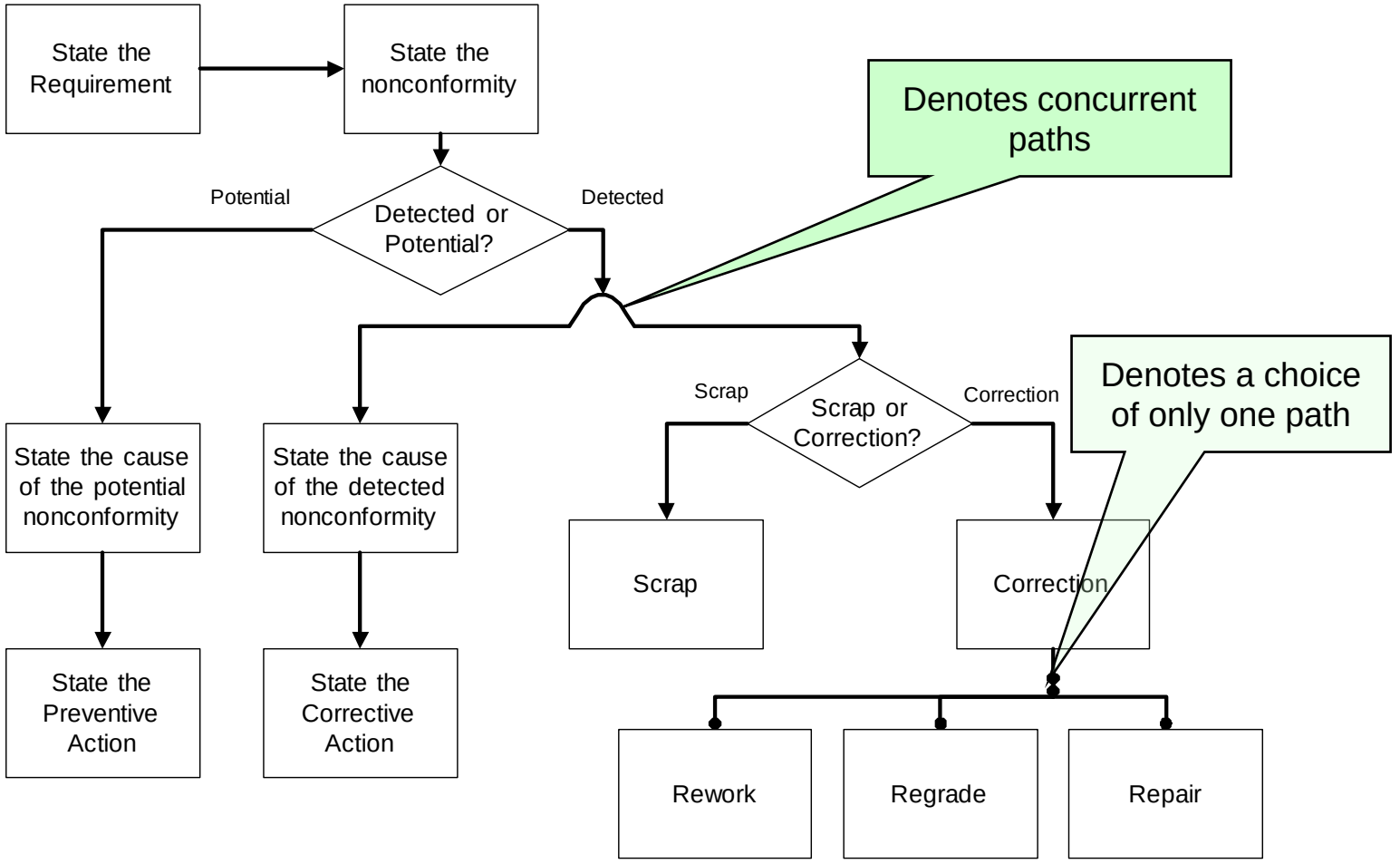

Which terms are defined?

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- We looked at definitions and examples of terms
- It is instructive to see where the terms are defined.
- We compare the list for ISO 9000 and 820.3

Term	ISO 9000	820.3
Conformity	3.6.1	Not defined
Correction	3.6.6	Not defined
Corrective action	3.6.5	Not defined
Defect	3.6.3	Not defined
Grade	3.1.3	Not defined
Nonconformity	3.6.2	3(q)
Preventive action	3.6.4	Not defined
Regrade	3.6.8	Not defined
Repair	3.6.9	Not defined
Requirement	3.1.2	Not defined
Rework	3.6.7	3(x)
Scrap	3.6.10	Not defined

The definitions compared

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We have looked at 12 technical terms, but the QSR only defines 2 of them. The material below is a comparison of the ISO and QSR definitions.

Nonconformity

ISO: non-fulfillment of a requirement

QSR: Nonconformity means the non-fulfillment of a specified requirement

Rework

ISO: action on a nonconforming product to make it conform to the requirements

QSR: Rework means action taken on a nonconforming product so that it will fulfill the specified DMR requirements before it is released for distribution.

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Characterizing a Process

Define

Measure

Set Targets

Defining a Process

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- ISO 9000:2005 says that a process is a “set of interrelated or interacting activities which transforms inputs into outputs”
- What we expect to find
  - A process owner
  - Defined process inputs
  - Defined process steps
  - Defined process outputs
  - Key process indicators
  - Identified process customer

A SIPOC Diagram is a useful tool

A SIPOC Diagram

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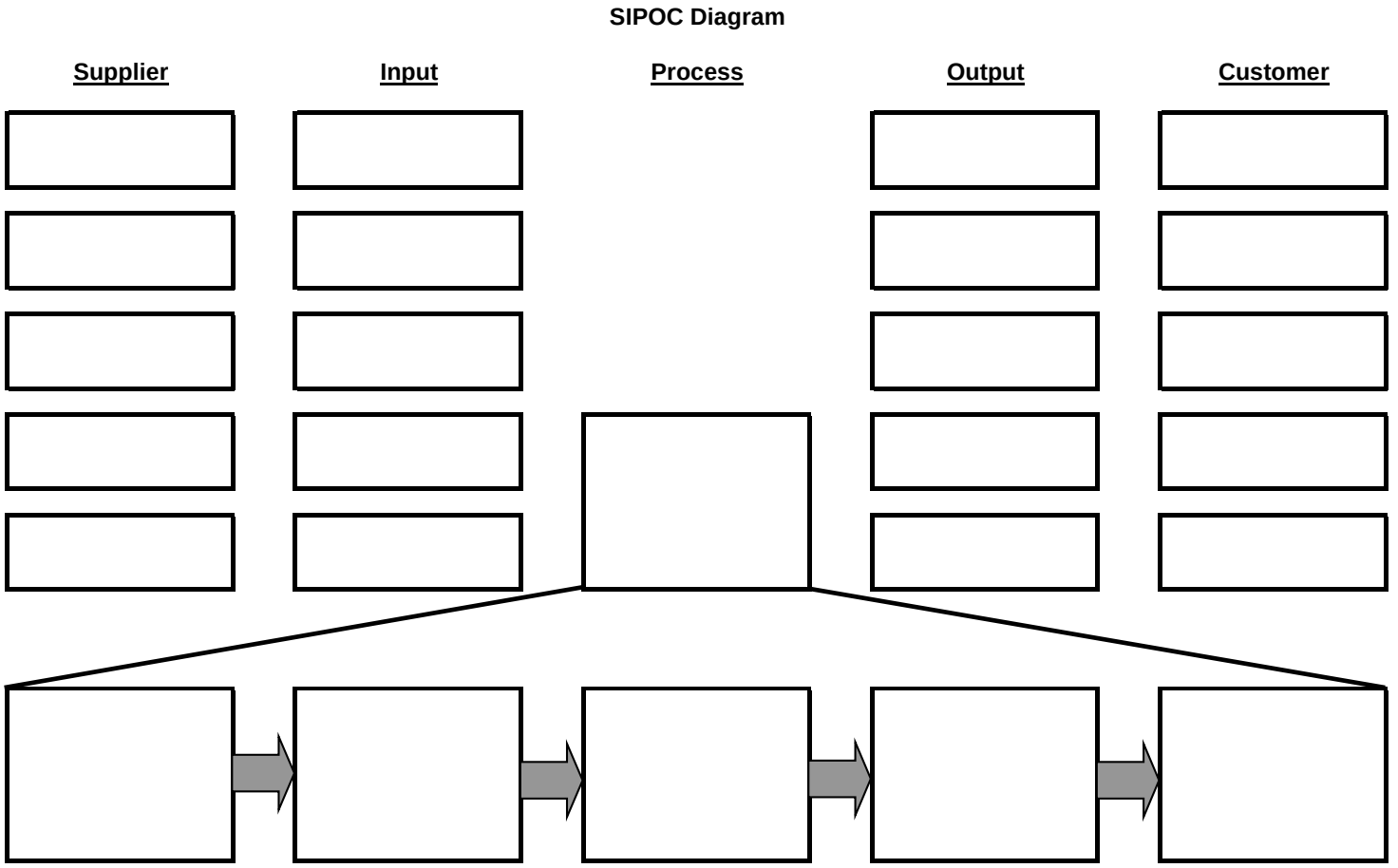

Key Process Indicators

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- Measurements help us understand and improve processes.
- We define some Key Process Indicators (KPIs) based on three types of measurements
  - Effectiveness measurements tell how well the process satisfies customer requirements
  - Efficiency measurements tell how well the process utilizes resources
  - Cycle time measurements tell how quickly the process converts inputs to outputs

A Purchasing Process Example

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- Effectiveness
  - # of PO lines rejected ÷ # of PO lines received
  - # of PO lines received late ÷ # of PO lines received
- Efficiency
  - # of PO lines received ÷ Total labor hours expended (purchasing, receiving, inspection, stockroom, *etc*.)
- Cycle time
  - Days from MRP generated demand signal to lot availability in inventory

Logan International Data Set

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- The FAA tracks scheduled airline on time arrival and makes the data available on their web site
- We can use the data for an effectiveness measure.
- Late arrivals at Logan for 2008 is

  # late operations ÷ # operations

  = 31418 ÷ 117944 or 266381 ppm (26.6%)

Logan International Late Arrival Pareto

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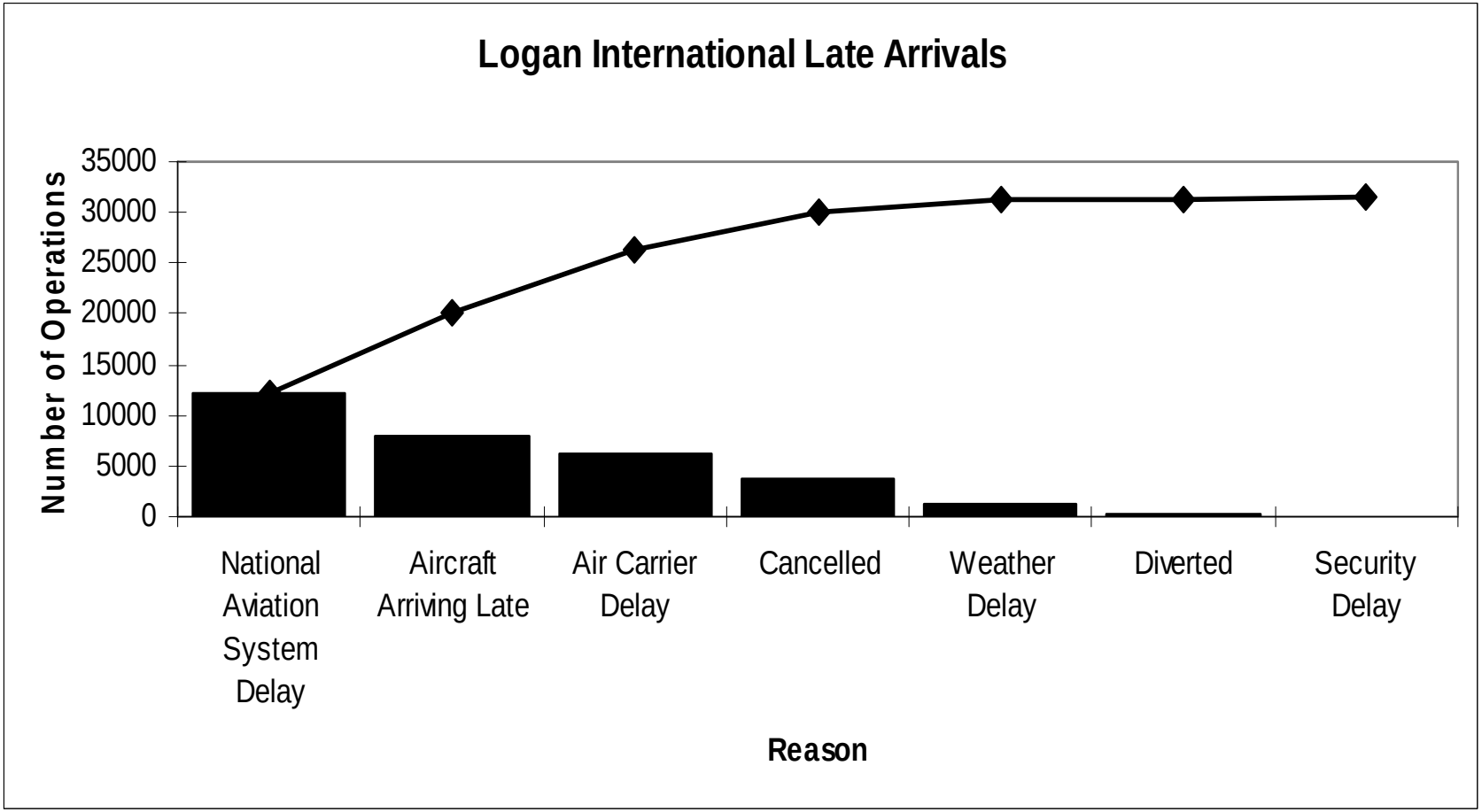

Approaches for Target Setting

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- Set the target based on historical data
  - Maintain or improve current results
  - Assumes the current results satisfy customer requirements
- Set the target based on customer (or market) requirements
  - Learn the customer needs and set the target
  - Your process historical results may not align

Setting the improvement rate

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- Improve by a fixed amount each year, say 20%
  - For example, 2007 year end was 100,000 ppm
  - 2008 target is 0.8 × 100,000 ppm = 80,000
  - 2009 target is 0.8 × 80,000 ppm = 64,000
  - 2010 target is 0.8 × 64,000 ppm = 51,200
  - 2011 target is 0.8 × 51,200 ppm = 40,960

An Example of a Process Effectiveness

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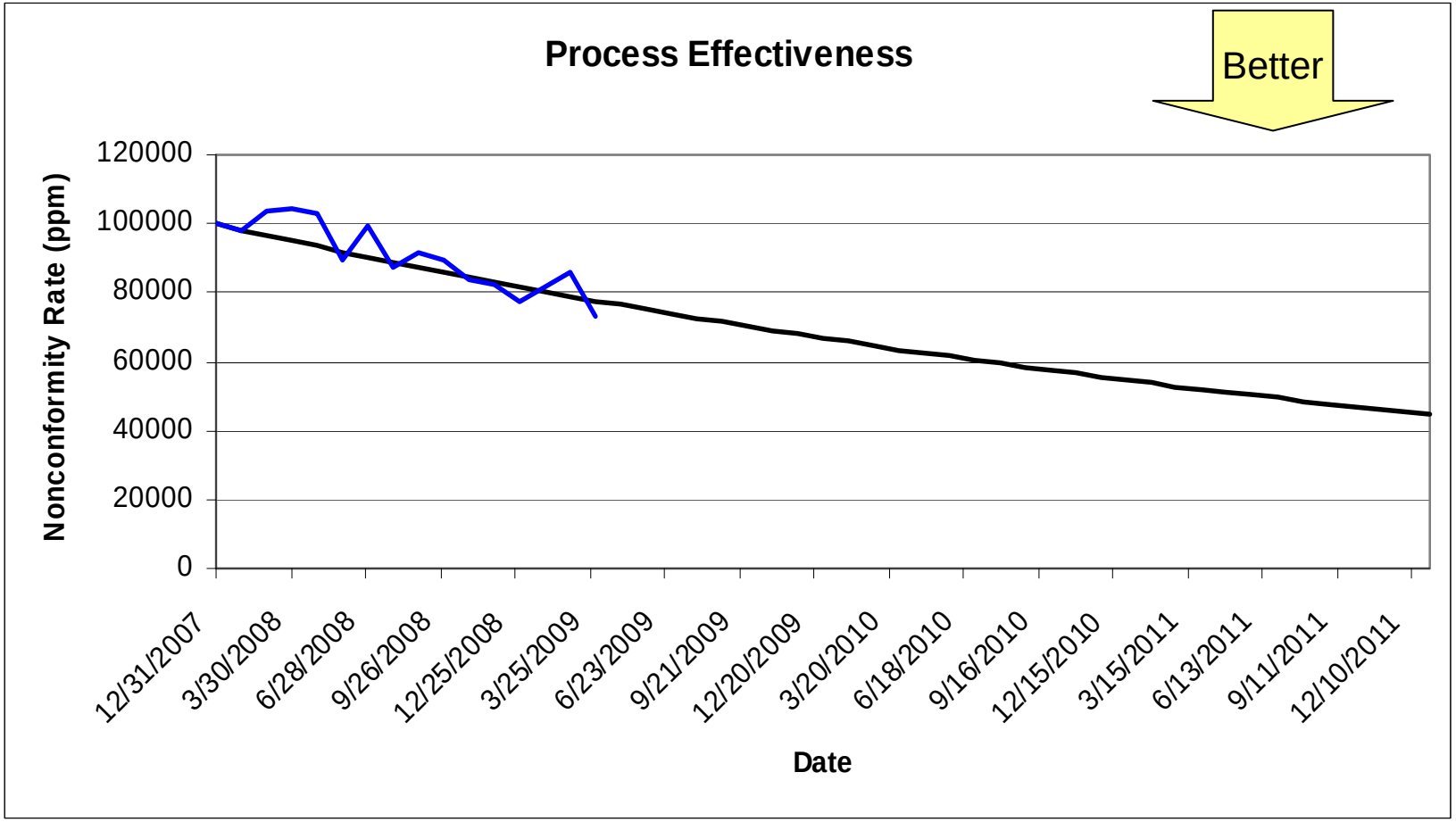

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Where the CAPA Process Fits

Understanding the Requirements

ISO 9001: 2008 QMS

Totality of FDA Requirements

QMS Process Relationship Examples

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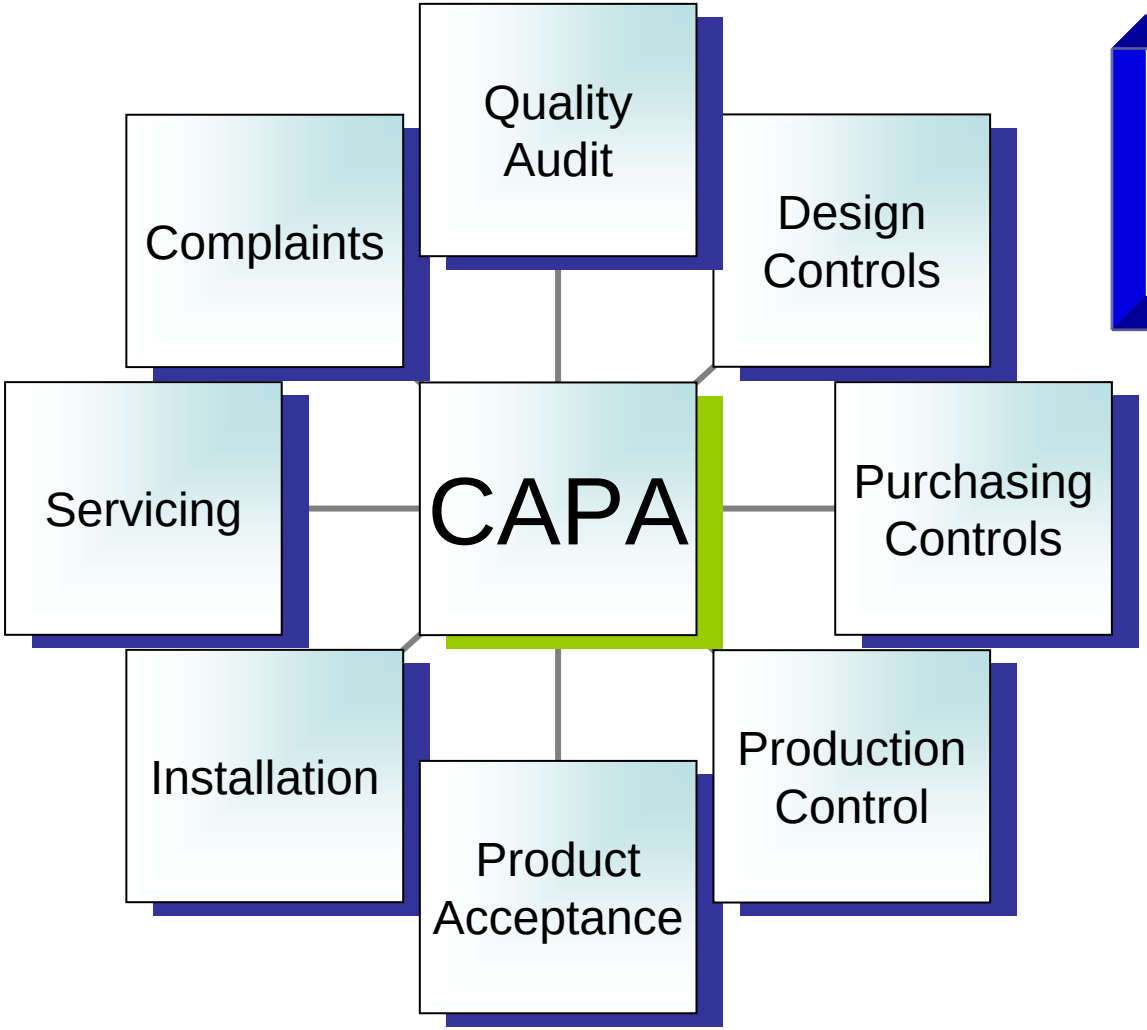

If a process has requirements, there is opportunity for nonconformity!

FDA Specific Activities Related to CAPA

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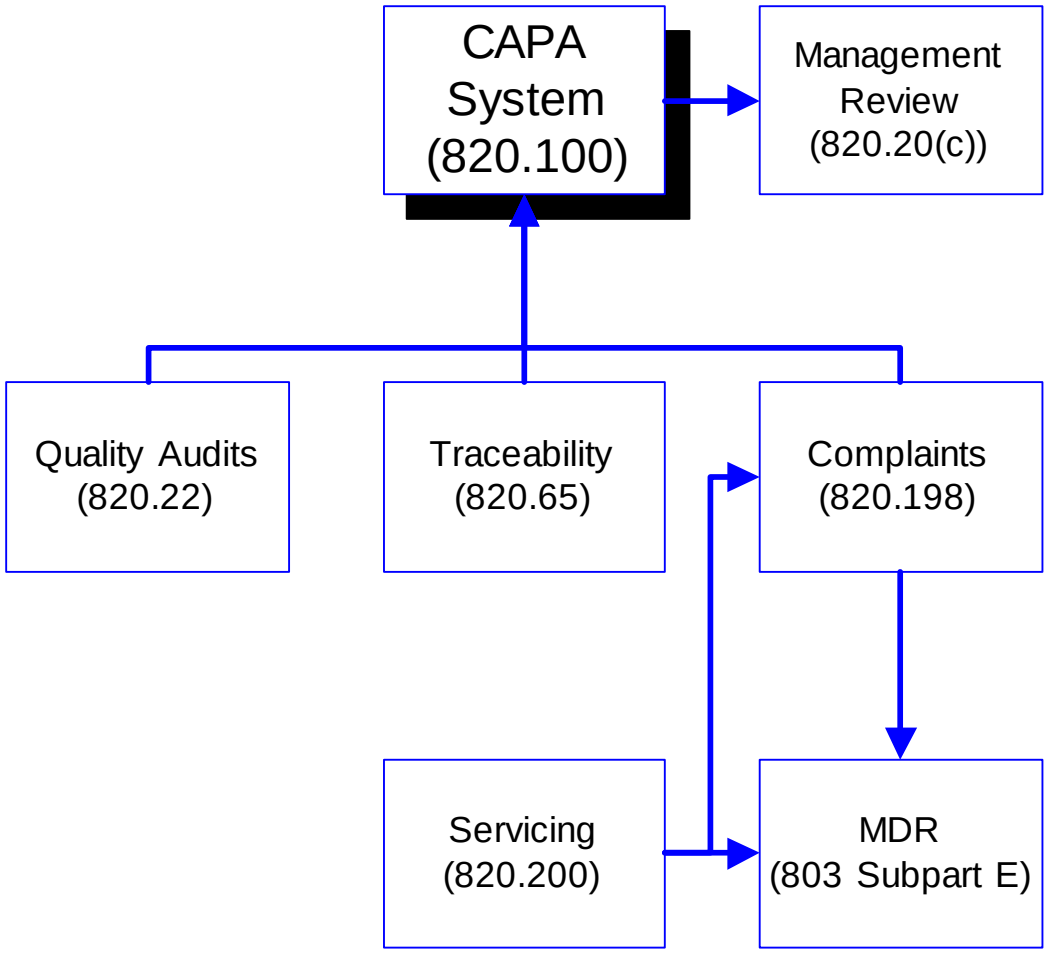

We look at some specific requirements from the FDA regulations.
Don't forget there is more to the FDA than just QSR.

Some Process Elements for CAPA

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	Preventive Action	Corrective Action
Input	Potential Nonconformity	Detected Nonconformity
Outputs	Changes Implemented Information Disseminated	Changes Implemented Information Disseminated
Customers	Process Owner Senior Management	Process Owner Senior Management

CAPA Process Elements

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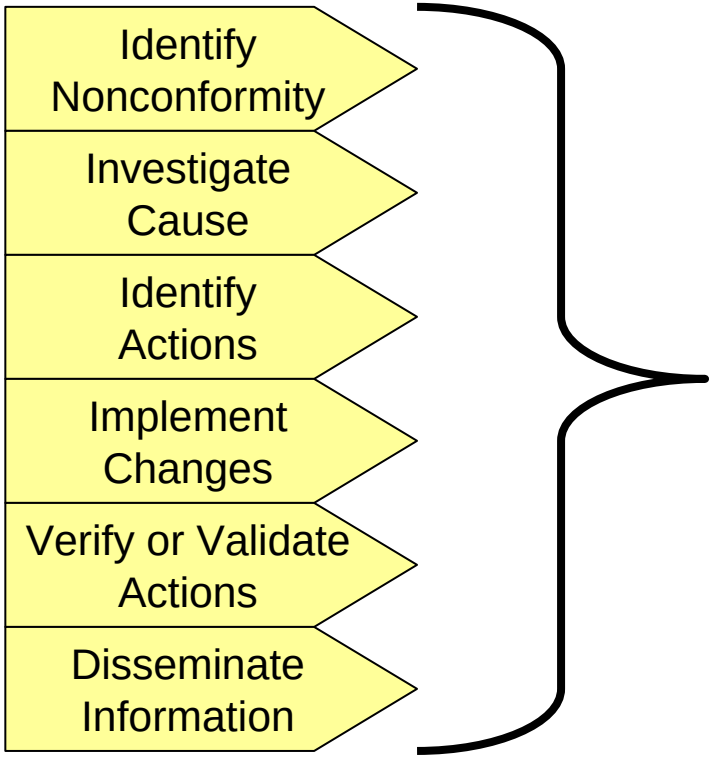

The basic elements of the QSR CAPA system

The CAPA system also requires documentation of all activities and their results

CAPA Process Analysis

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Identify Nonconformity

Requirement 820.100(a)(1)

[Procedures establish requirements for] analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify *existing* and *potential* causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems

Discussion

- Review the processes, especially those listed, to identify existing (detected) or potential nonconformities.
- Use “appropriate statistical methodology”. This can be more than just tend analysis.
- The Logan International data set demonstrates Pareto Analysis as a first step to preventive action.

CAPA Process Analysis

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Investigate Cause

Requirement 820.100(a)(2)
[Procedures establish requirements for] investigating the cause of nonconformities relating to product, processes, and the quality system

Discussion
- Investigation is a skill
- Assign the process owner as the [lead] investigator. This is the person with the most knowledge of the process.

Identify Actions

Requirement 820.100(a)(3)
[Procedures establish requirements for] identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems

Discussion
- The phrase “correct and prevent recurrence” includes both corrective and preventive action.
- It is one of places where the FDA language creates confusion

CAPA Process Analysis

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Implement Changes

Requirement 820.100(a)(5)

[Procedures establish requirements for] implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems

Discussion

- The FDA doesn't always require documented instructions or SOPs, but, if you have them, you must record CAPA initiated changes.

Verify or Validate Actions

Requirement 820.100(a)(4)

[Procedures establish requirements for] verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device

Discussion

- This effectiveness verification or validation will be one of the recommended CAPA process effectiveness metrics.

CAPA Process Analysis

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Disseminate Information

Requirement 820.100(a)(6)

[Procedures establish requirements for] ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems

Discussion

- Unlike ISO 9001, QSR requires that you inform people responsible for quality of the product or process.
- Recall that 820.25(b)(1) requires, “As part of their training, personnel shall be made aware of device defects which may occur from the improper performance of their specific jobs.”
- The CAPA system asks that you maintain and update this information.

Building the Process

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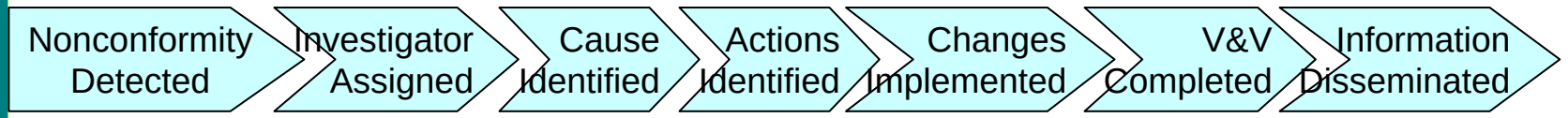
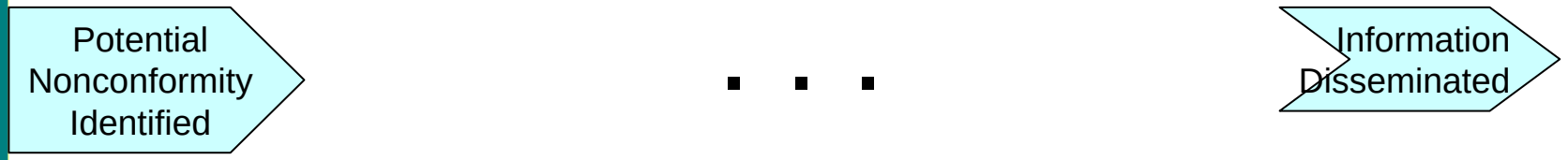
Corrective Action Steps



Preventive Action Steps



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Metrics Related to CAPA

Effectiveness

Cycle Time

Effectiveness Metric for CAPA

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- We base our CAPA effectiveness metric on a requirement.
  - Establish procedures for verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device
- We need to show that each CAPA satisfies two criteria
  - Effective
  - No adverse impact on the finished device

The CAPA is Effective

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- Does the CAPA prevent the occurrence or recurrence of the nonconformity?
- Attribute data with two possible outcomes:
  - Either YES of NO
- Plot the initial verification/validation finding as a graph

CAPA Impact on the Finished Device

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- Does the CAPA have an adverse impact on the finished device?
- Attribute data with three possible outcomes:
  - NO meaning no adverse impact
  - YES meaning the CAPA does have an adverse impact
  - N/A meaning the CAPA does not involve a finished device
- Plot the results as a graph, without the N/A values.

An Example of an Effectiveness Line Graph

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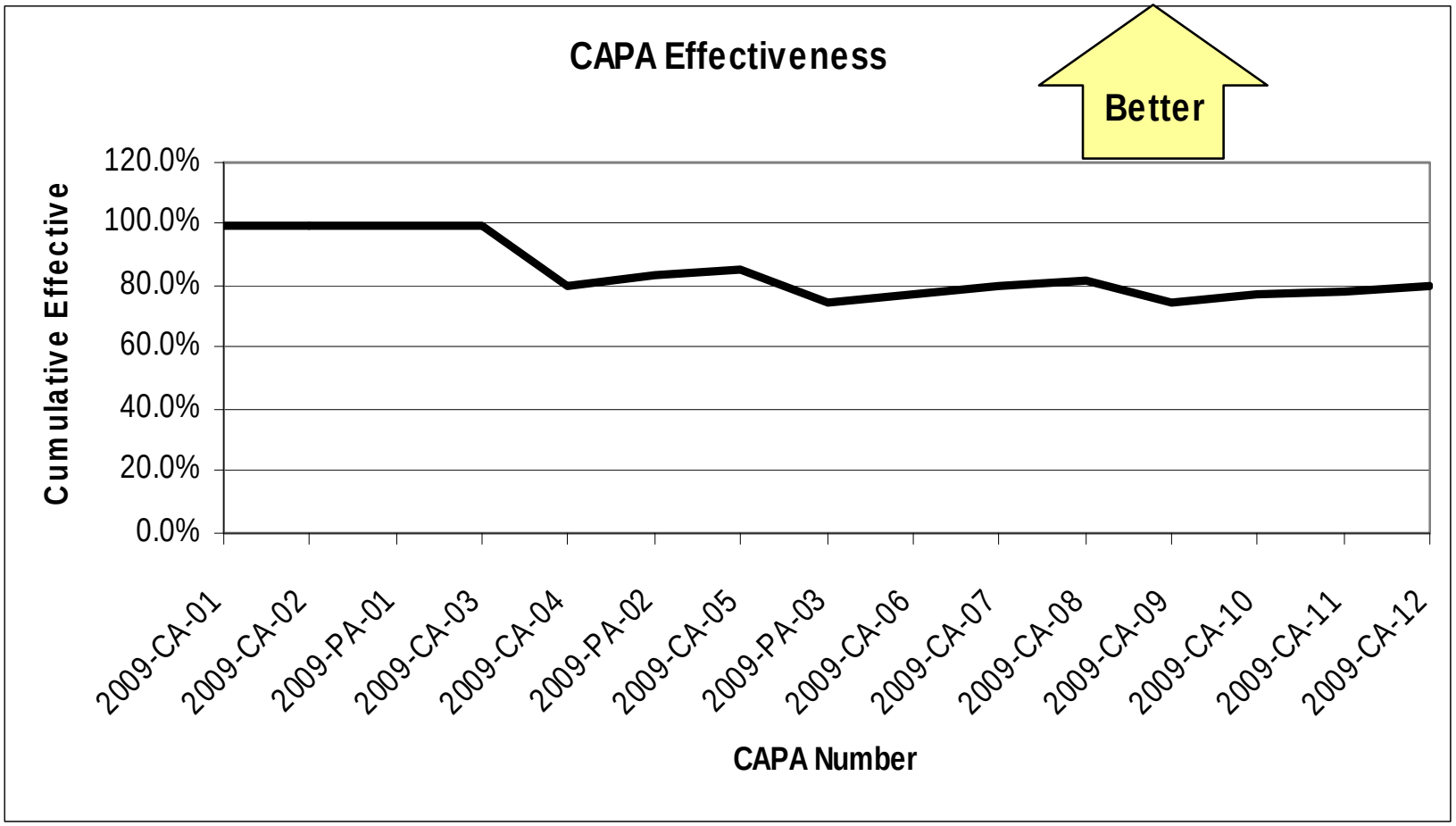

The Process Impact

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- If each CAPA is effective, it will improve the process rolled-through yield.
- Consider a process with five measurement points and 1st yield of 90% at each.

  $90\% \times 90\% \times 90\% \times 90\% \times 90\% = 59\%$
- Each effective CAPA will improve the yield at one point.

Simulation of the Impact of Effective CAPAs on Process Rolled Through Yield

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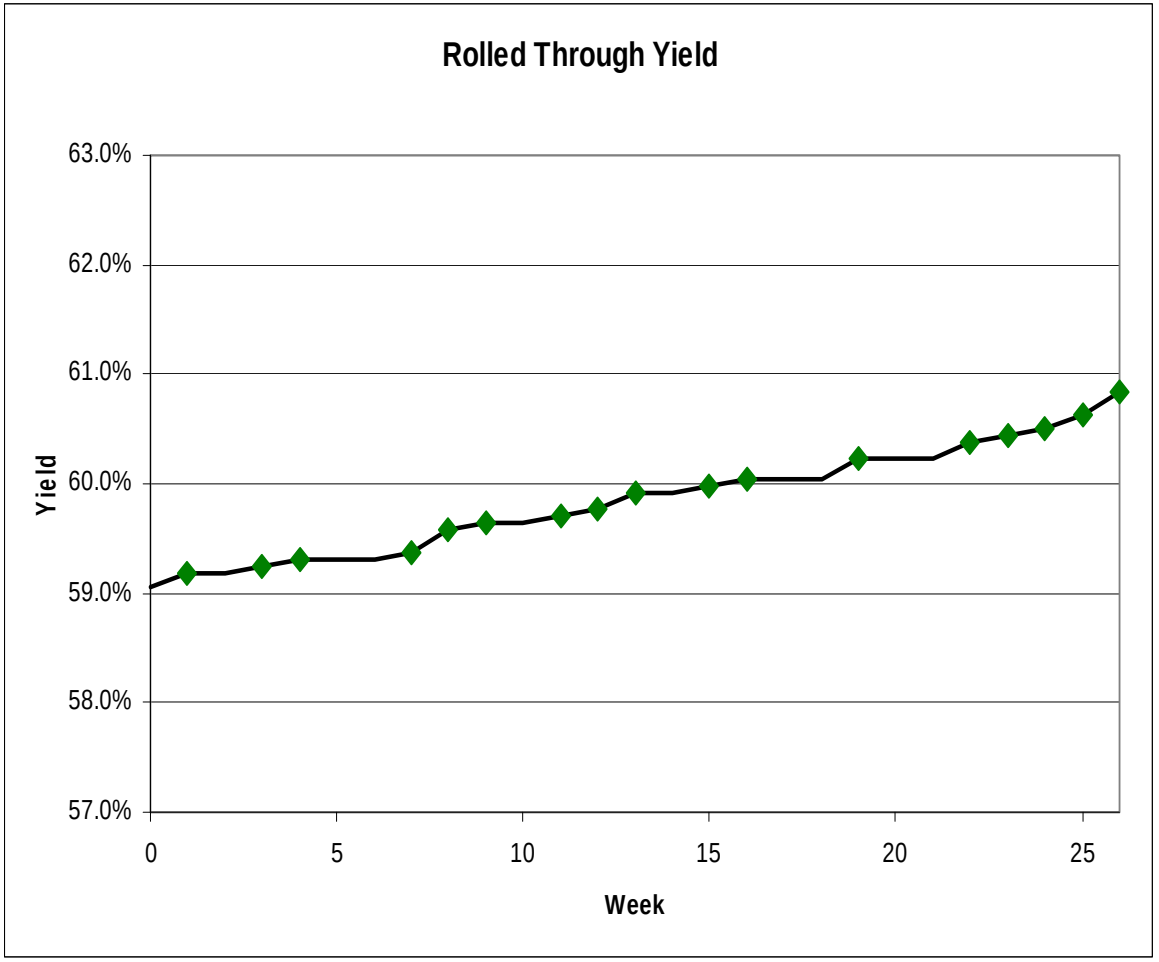
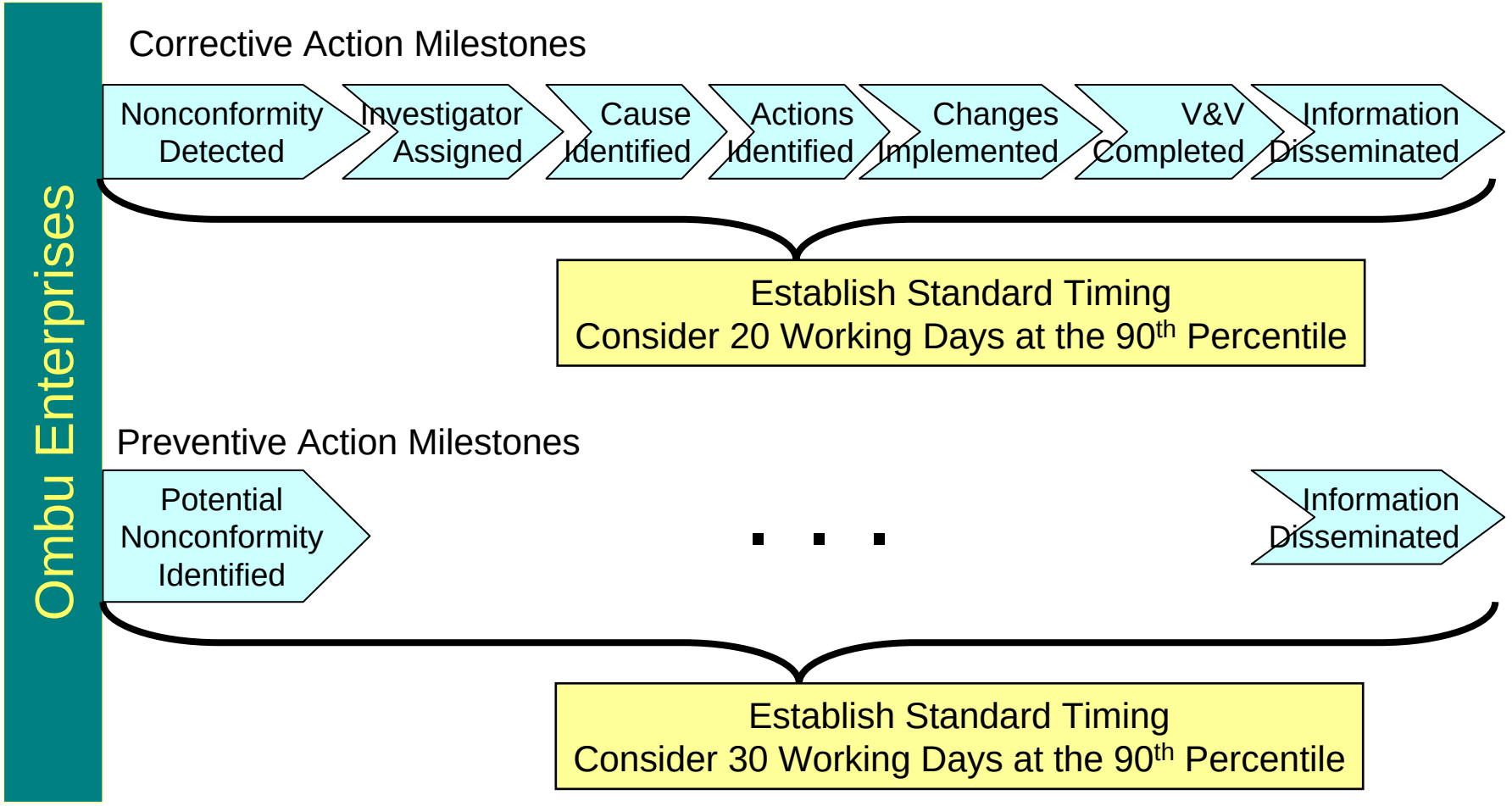


- We simulate a process with five points that check conformity.
- We start with first pass yield of 90% at each point; rolled through yield is 59%.
- We simulate CAPA implementations with an impact of 0.0%, 0.1%, 0.2%, or 0.3%.
- Effective CAPA implementations are sustained in the process.

Consider Standard Timing for Milestones



Closure Time Distribution

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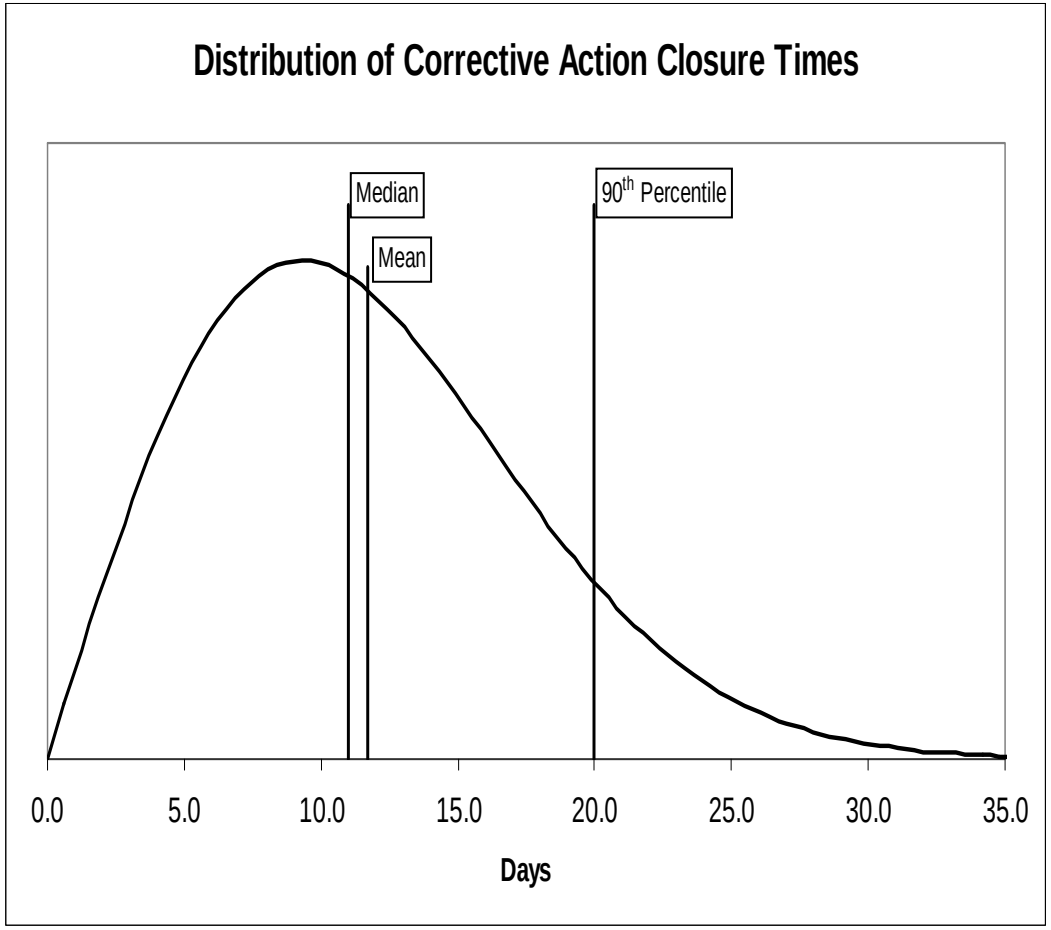

- Measurements of cycle time have an underlying statistical distribution that you should consider.
- Typical distributions are asymmetrical, with a tail to the right.
- Set your target at the 90th percentile, to capture nearly all the results.

Use Box Plots to track weekly results

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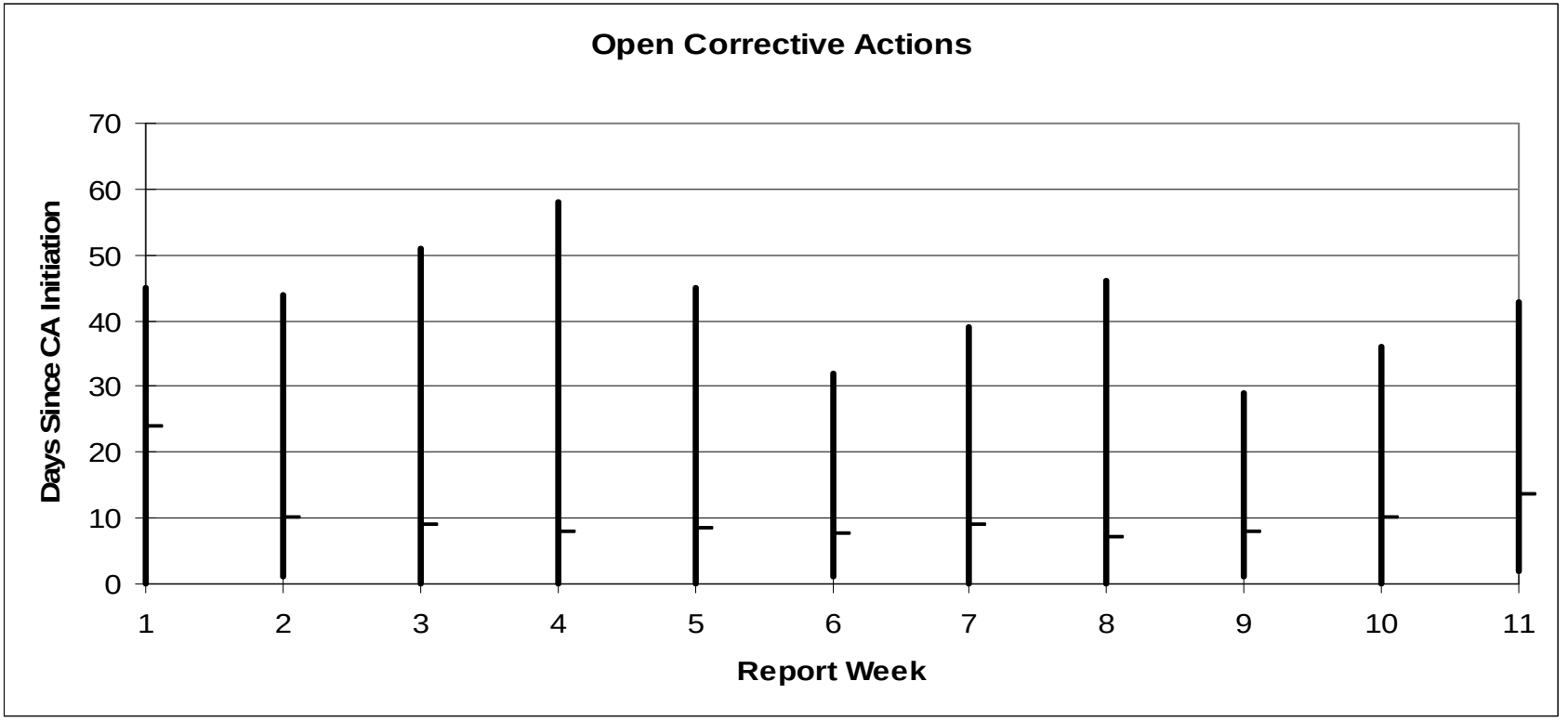
- Excel has a high-low-close graph that we use instead of the traditional box plot.



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Conclusion & Summary

Conclusion #1

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- CAPA systems seem confusing because we use colloquial language in place of technical terms
  - QSR only defines 2 of the 12 terms we looked at, but uses nearly all of them.
  - The CAPA section of QSR appears to lapse into unclear language in places.

Conclusion #2

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- CAPA is a process like any other process and has
  - A process owner
  - Defined process inputs
  - Defined process steps
  - Defined process outputs
  - Key process indicators
  - Identified process customer

Conclusion #3

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- CAPA has process metrics like any other process
  - Effectiveness
  - Efficiency
  - Cycle Time

Conclusion #4

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- CAPA is unlike other processes in a significant way
  - The output of the CAPA process is an improvement of another process
  - An effective CAPA process will drive improvement in the effectiveness metric of all processes in the QMS!