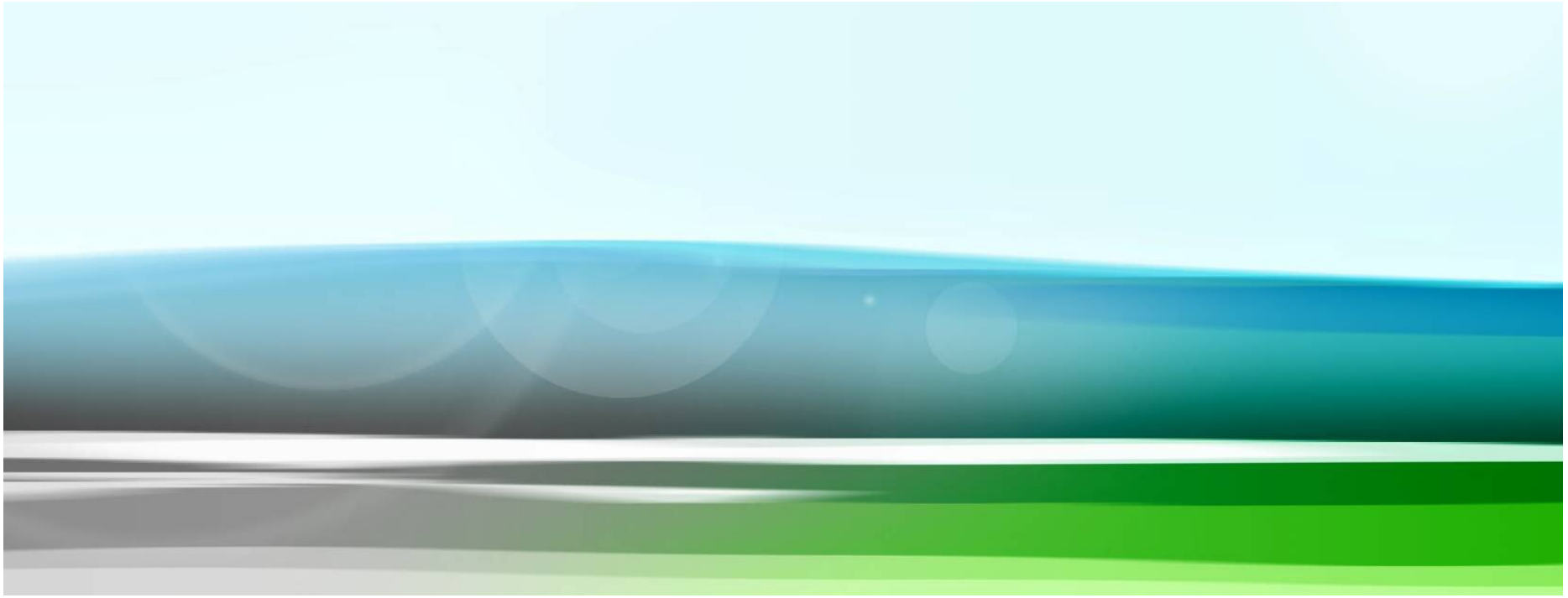


Effective Root Cause Analysis
For Corrective and Preventive Action

Manuel Marco

ASQ - March 9th, 2011

MANAGING RISK DNV

Understanding Key Principles

- Requirement – need or expectation that is stated, generally implied, or obligatory

  "*Generally implied" means that it is custom or common practice for the organization, its customers, and other interested parties that the need or expectation under consideration is implied.*

Understanding Key Principles

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

Understanding Key Principles

- Preventive action – action taken to eliminate the causes of a potential nonconformity or other undesirable potential situation

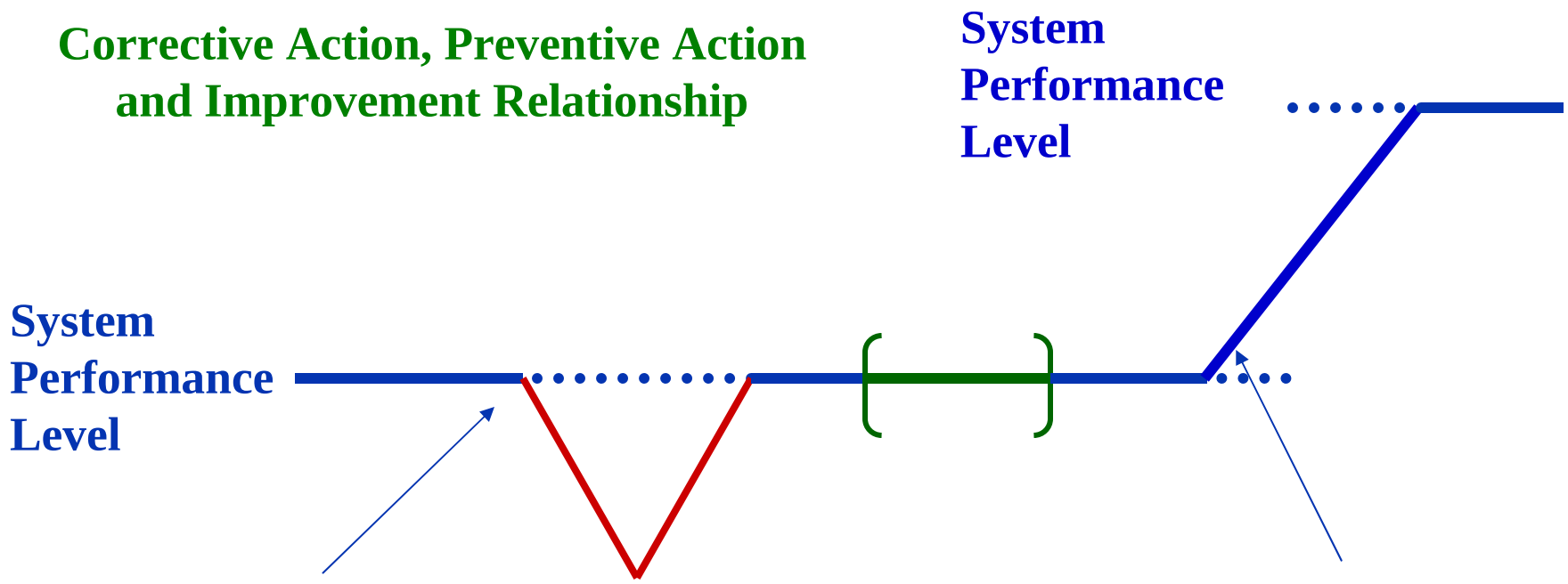
Before it happens - 'Proactive' approach

- Corrective action – action taken to eliminate the causes of a detected nonconformity or other undesirable situation

After it happens - 'Reactive' approach

Understanding Key Principles

Corrective Action, Preventive Action and Improvement Relationship



Problem

Causes system to drop below performance level

Corrective Action

Brings system back to identified performance level

Preventive Action

Prevents system from dropping below performance level

Improvement

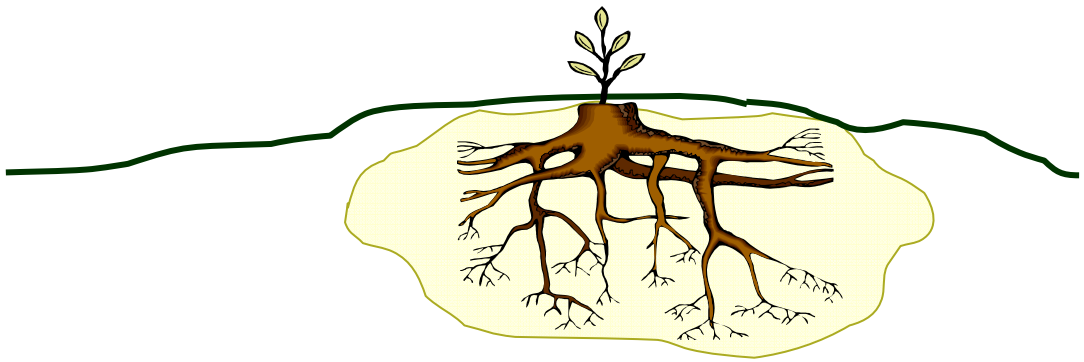
Moves system to higher level of performance, e.g., more effective, more efficient, etc.

Understanding Key Principles

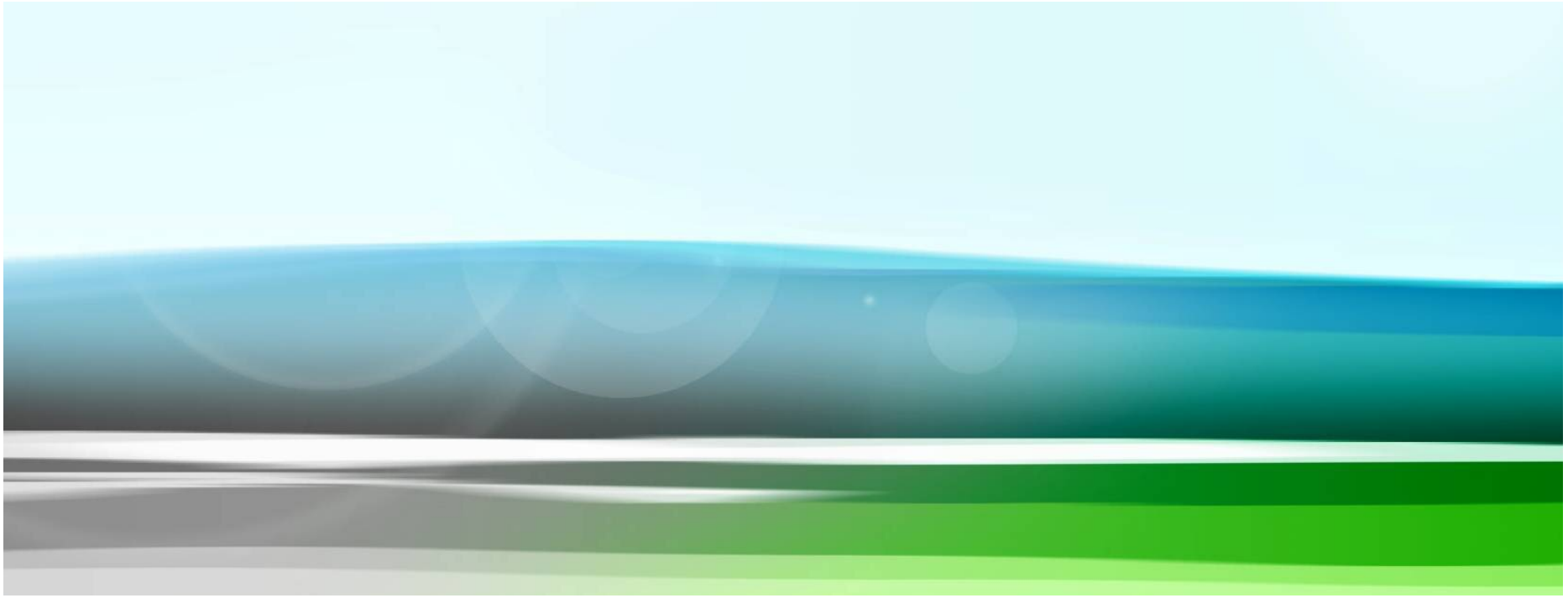
- Correction – Action to eliminate a detected nonconformity
  - ✓ Rework – action on a nonconforming product to make it conform to requirements
  - ✓ Repair – action on a nonconforming product to make it acceptable for intended use
  - ✓ Regrade – alteration of the grade of a nonconforming product in order to make it conform to requirements differing from the initial ones

Understanding Key Principles

- Immediate causes – the circumstances leading directly to mistakes or errors that in turn lead to nonconformities.
- Basic causes (root causes) – the causes that, if corrected, would prevent recurrence of this and similar occurrences.



The real problems behind the symptoms; the reason(s) why substandard behavior or conditions occur.



Drivers for Corrective and Preventive Action

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Drivers for Corrective/Preventive Action

- ISO 9001:2008 lists several clauses that provide a strong emphasis on effective corrective and preventive action and improvement.

Drivers for Corrective/Preventive Action

Common categories for analysis:

- Nonconformity frequency and severity rates by organization and process
- Nonconformity trends by causal factor
- Nonconformities by experience level of people involved
- Nonconformities by day or time into work shifts
- Nonconformities by project, product, or service line
- Nonconformity trends by categories of inadequacies in processes, programs, standards, and conformance with standards

(Note: these are all lagging indicators!)

Drivers for Corrective/Preventive Action

"The organization should ***incorporate root cause analysis, as appropriate, into the corrective action process.*** Root cause analysis results should be verified by testing prior to defining and initiating corrective action."

*ISO 9004:2000, 8.5.2**

Root- causes is referenced in ISO 9004:2009 in 5.3.2 and 8.3.3

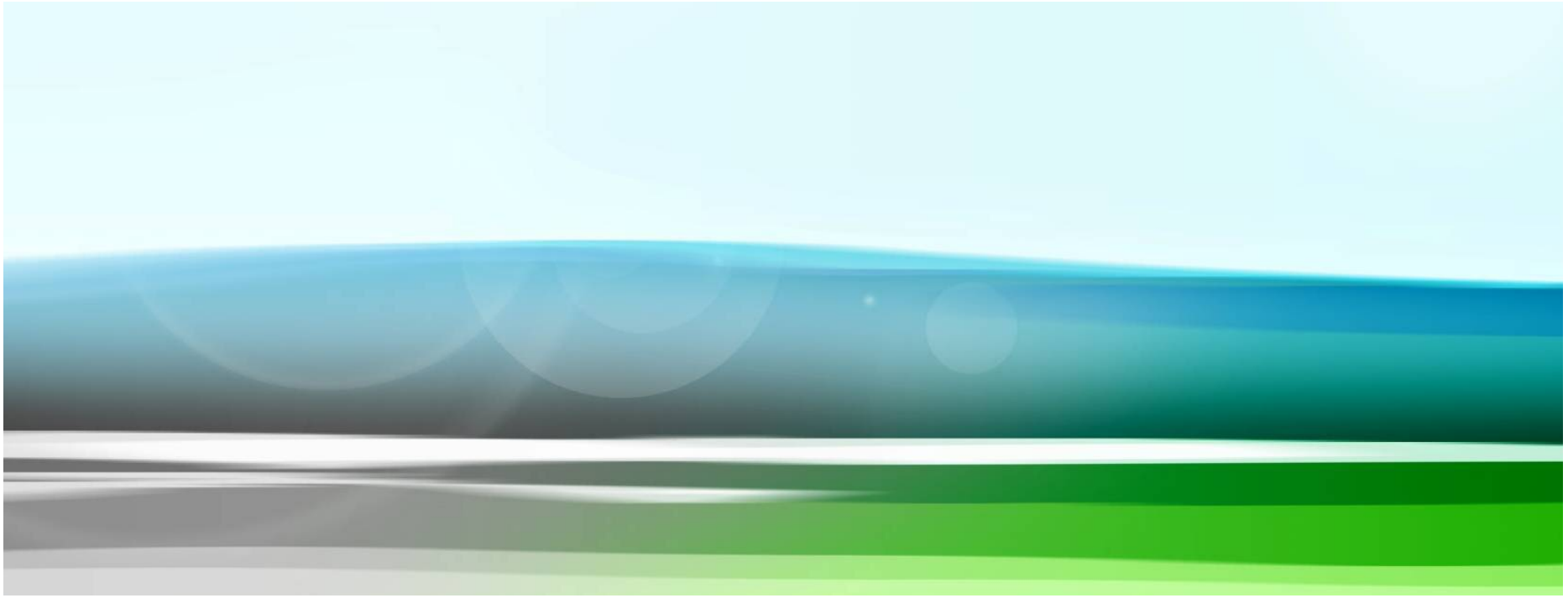
Notes:

- *ISO 9004:2009 - Managing for the sustained success of an organization -- A quality management approach*
- *ISO 9004:2009 provides guidance to organizations to support the achievement of sustained success by a quality management approach. It is applicable to any organization, regardless of size, type and activity.*
- *ISO 9004:2009 is not intended for certification, regulatory or contractual use.*

Drivers for Corrective/Preventive Action

Others:

- Customer feedback/complaints
- Trends in product
- Trends in process performance
- Supplier performance
- Competition
- Statutory/regulatory requirements
- Risk, consequence, and potential impact



Systematic root cause analysis

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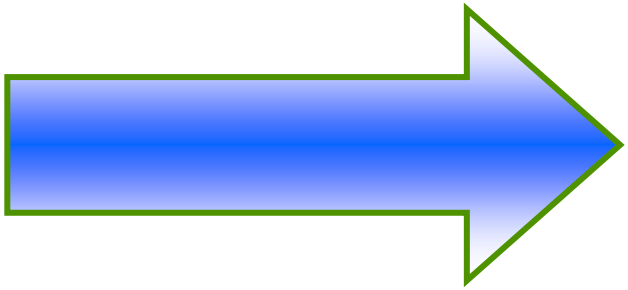
Cause Analysis

Some organizations' root cause investigation and corrective action process look like this:



Pin-Point Investigation (PPI)

Guaranteed to give you a root cause for any problem!

Instructions:

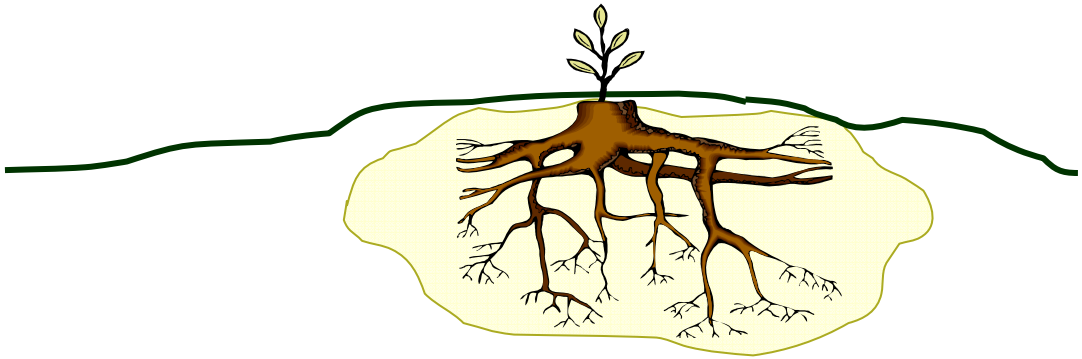
Step 1 – Stand anywhere you want.
(User friendly!)

Step 2 – Close your eyes then toss!
(Objectivity!)

Step 3 - There ya' go!
(Results oriented!)

Cause Analysis

Corrective and preventive actions can only be effective
if the root cause analysis has been effective!



Cause Analysis

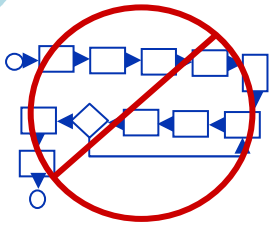
Reasons for inadequate root cause analysis:

- Lack of know how

- Failure to do a thorough investigation

- Failure to take enough time

- Failure to use a systematic approach



- Lack of or forgetting previous training

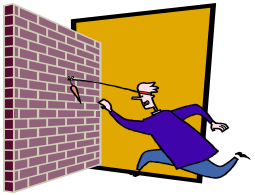
Cause Analysis

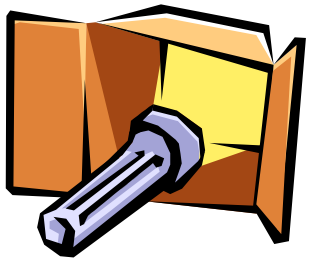
Reasons for inadequate root cause analysis:

- Improper motivation

- Lack of method for checking results
- Identifying only obvious (symptomatic) causes

- Many causes easy to overlook
- Some causes difficult to identify





- Causes selected haphazardly

Cause Analysis – Systematic Approach

- Root cause investigation should be a structured approach designed to provide reliable results that can be acted upon.
- The selection and proper use of problem solving models and analysis tools give greater probability and confidence that true root causes will be identified for proper action.

Cause Analysis

The result of a nonconformity or problem is a loss of quality. The most obvious losses are loss of product (service), loss of profit, loss of time, loss of reputation, loss of customers and loss of future business opportunities.

Cause Analysis - Example

It was discovered during testing of a completed tool that they were leaking due to incorrect assembly. Each assembler in the Assembly Department is assembling a complete tool and then sending them to the test department. The assembly requires the assembler to follow the service manual for the particular tool. Each assembler is relying on his own copy of the service manual to perform the work. When asked to see the service manuals in various locations, it was observed that the manuals had different issuance dates.

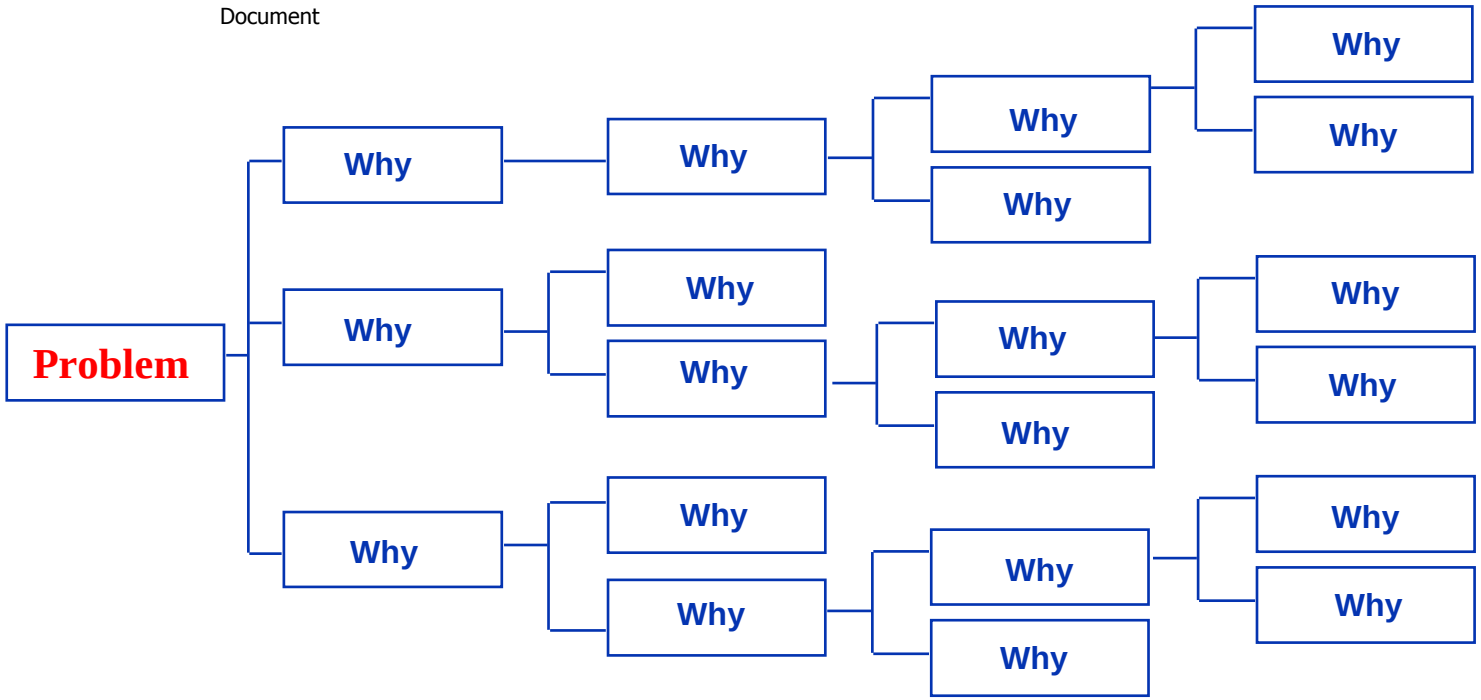
Loss of Quality? **Undesired Event?** **Immediate Cause?** **Root Cause?**

Cause Analysis – Key Methods and Tools

Why-Why Analysis

Asking “Why?” at least five times while seeking the root cause.

Adobe Acrobat Document



Immediate Cause

Immediate cause is the most apparent cause of the nonconformance.

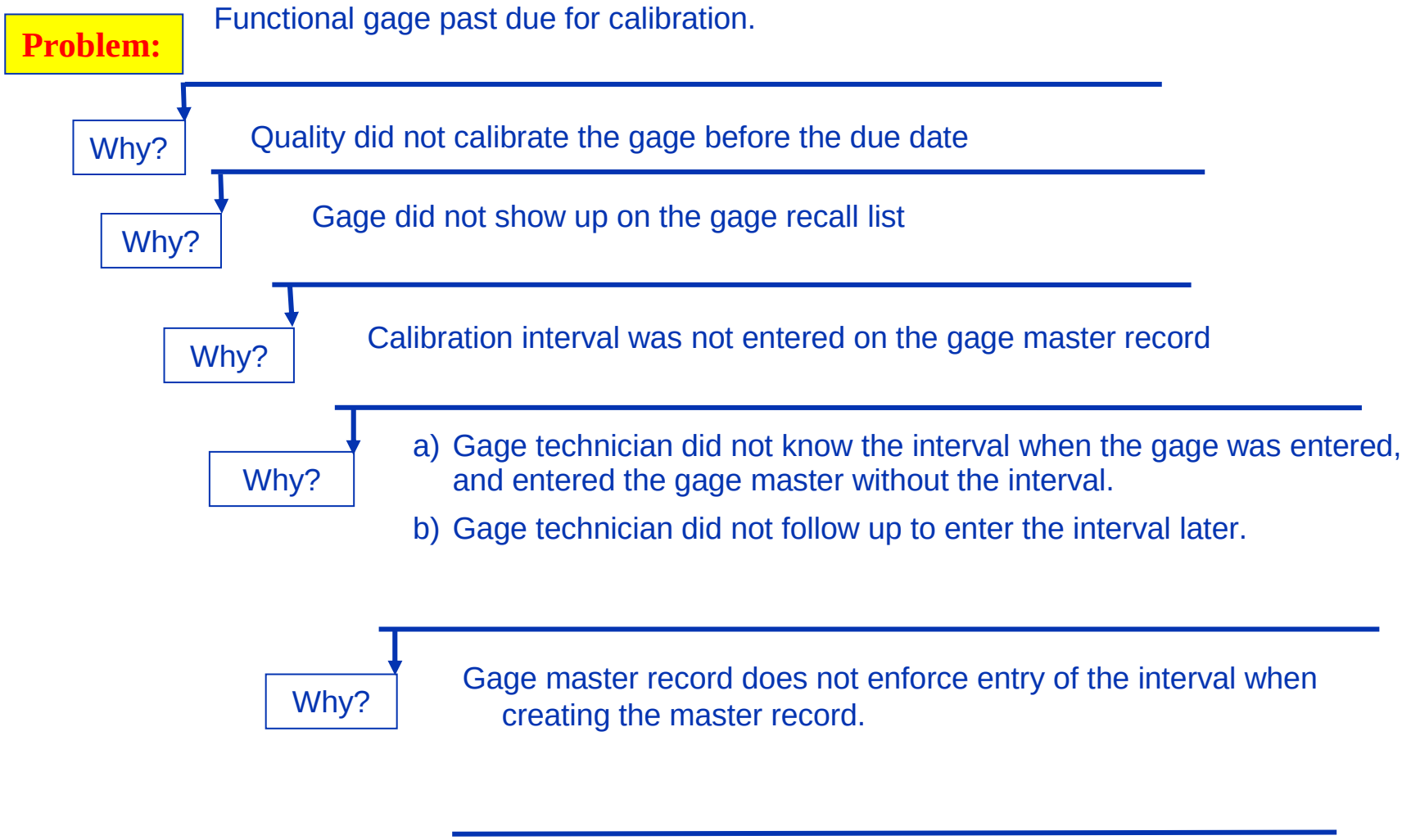
Typical immediate causes:

- Operator error
- Failure to follow procedures
- Work instruction was not updated
- Inspection was not recorded by the operator
- Gage was not turned in for calibration
- Operator not trained
- Inadvertent omission

Immediate Cause Example - Calibration past due

- Nonconformity: Functional gage past due for calibration.
- Proximate Cause: Quality did not calibrate the gage before the due date.
- Corrective Action: Calibrate the functional gage.

Cause Analysis – Example calibration past due

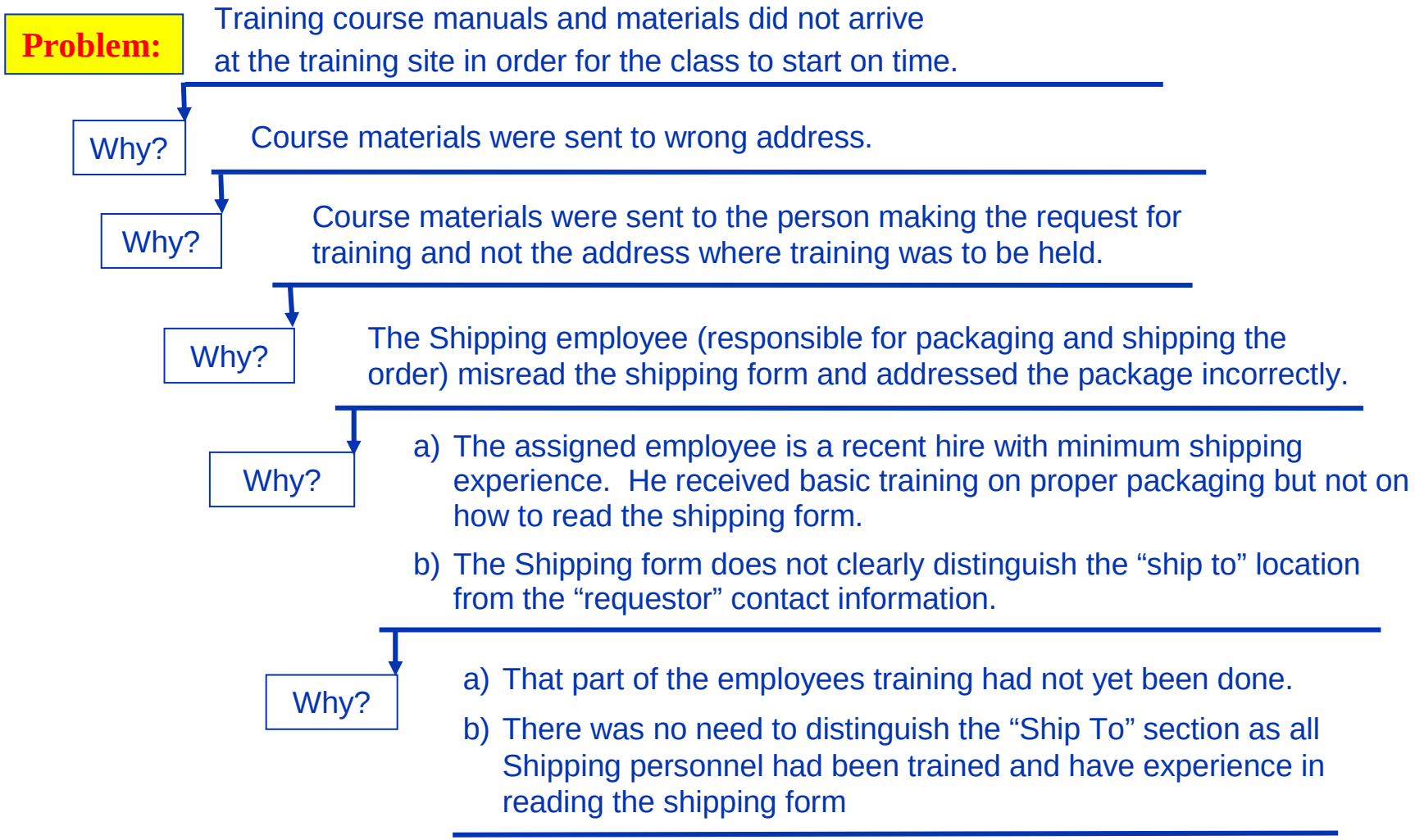


Cause Analysis – Example calibration past due

- Immediate Containment Action:
  1. Calibrate the functional gage.
  2. Review the gage master file for other gages that do not have a calibration interval defined, record the interval, calibrate as needed.

- Permanent Corrective Action:
  1. Revise the gage calibration software to enforce entry of the calibration interval before any new or revised master record is accepted.
  2. Add an exception report to the monthly recall list to show any active gages in the system with no interval.

Cause Analysis – Training materials didn't arrive



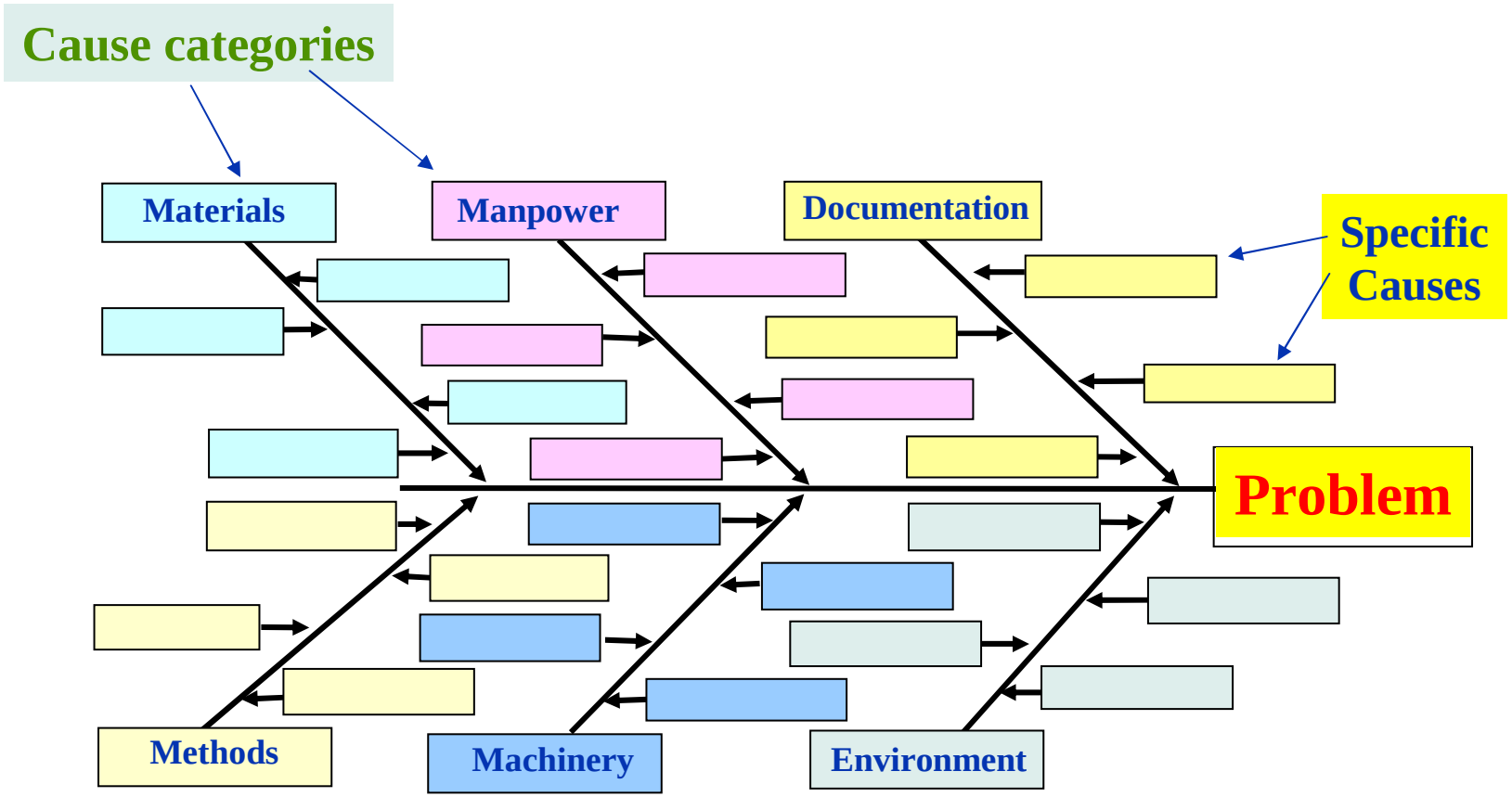
Cause Analysis – Training materials didn't arrive

- Immediate Containment Action:
  1. Locate course materials and arrange "hot shot" delivery to course location.
  2. Check all orders in work to ensure "Ship To" addresses are correct prior to shipment.

- Permanent Corrective Action:
  1. Revise the Shipping form to clearly distinguish the "Ship To" portion of the form. Make this section of the form more prominent by bolding this portion of the form.
  2. Train all personnel to ensure they can distinguish the "Ship To" address from the "requestor" contact information.
  3. Ensure all new employees receive all necessary training before assigning them total responsibility for packaging, labeling and shipping the product. Supervisors will monitor shipments for proper addresses when work is assigned to newly trained employees.

Cause Analysis – Key Methods and Tools

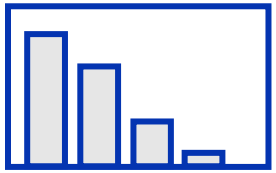
Fishbone Diagram



Cause Analysis – Key Methods and Tools

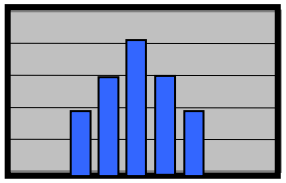
Other methods and tools:

- Pareto diagrams



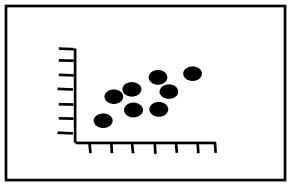
- Brainstorming

- Histogram



- Check sheets

- Scatter diagram



Cause Analysis – Key Methods and Tools

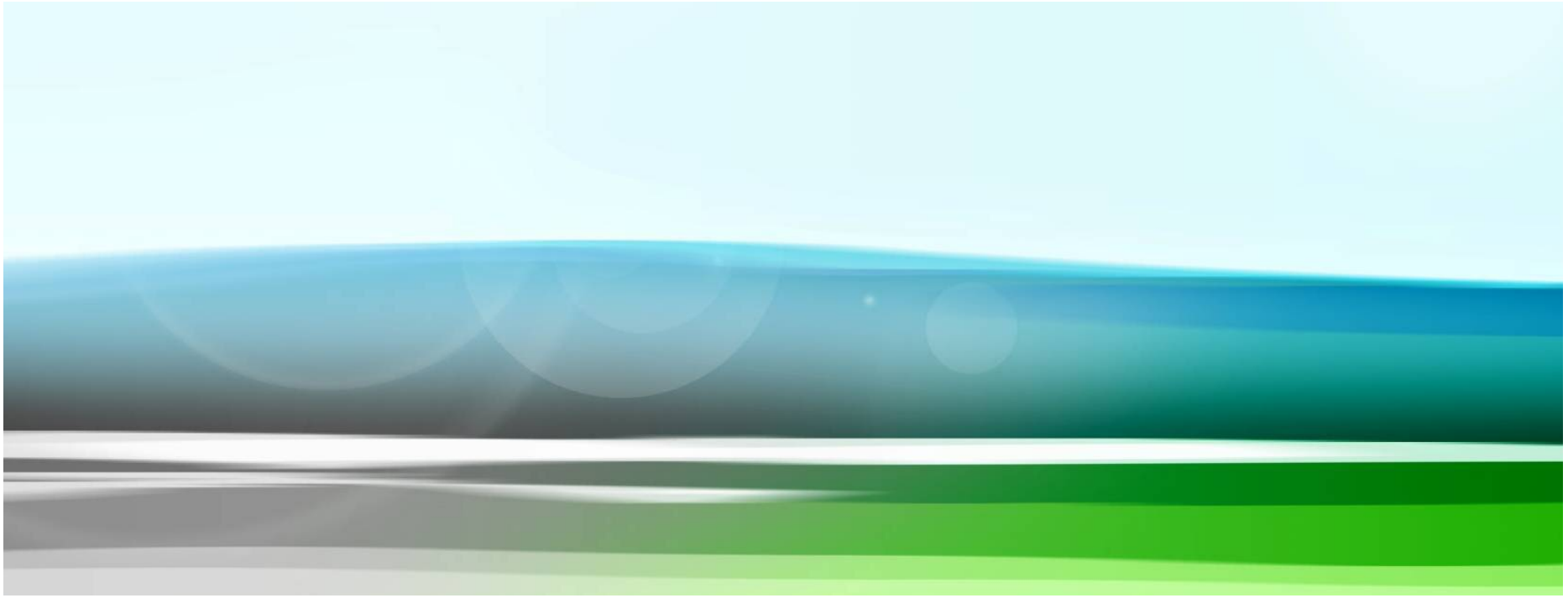
And even other methods and tools:

- Events and Casual Factors Charting
- Change Analysis
- Barrier Analysis
- Fault Tree Analysis
- Design FMEA and Process FMEA (Failure Mode and Effects Analysis)
- Reality Charting
- Storytelling
- For a comparison of RCA Tools and Methods
  http://kscsma.ksc.nasa.gov/Reliability/Documents/Gano's%20comparison%20the%20Root%20Cause%20Analysis%20Methods.pdf

Corrective and Preventive Action

Factors affecting successful Corrective and Preventive Action:

- Documented procedures
- Defined responsibilities and authorities
- Data collection and analysis methods
- Screening of actual and potential problems (assessment of risk/impact)
- Internal communication (timely)



Implementing successful corrective and preventive action

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Corrective and Preventive Action

"Intellectuals solve problems,

geniuses prevent them."

- Albert Einstein

Corrective and Preventive Action

Factors affecting successful Corrective and Preventive Action (Continued):

- Definition of time frames
- Accountability for status reporting
- Periodic reviews of incomplete actions
- Adequate cross-function coordination
- Planning and allocation of resources
- Proper selection and use of tools (training)

Management Commitment!

Corrective and Preventive Action

Corrective actions shall be appropriate to the effects of the nonconformities encountered. (ISO 9001:2008, 8.5.2)

Preventive actions shall be appropriate to the effects of the potential problems. (ISO 9001:2008, 8.5.3)

Guide to Corrective Action Decisions

1. Probability that a nonconformity will occur or recur:
A — High B — Moderate C — Low

2. Potential consequence severity if a nonconformity occurs or recurs:
A — Major B — Serious C — Minor

3. Degree of Control (Probability that the action will correct the problem):
A — Substantial (67 - 100%) B — Moderate (34 - 66%) C — Low (0 - 33%)

4. Cost of recommended control:
A — High B — Medium C — Low

5. What are the alternatives?

6. Justification: Why the control(s) suggested?

Corrective and Preventive Action

Corrective Action Plan:

- Who is to do it?
- What is to be done?
- How often is it to be done?
- What are the requirements?
- What measuring and monitoring will be undertaken?
- Where is it to be done?
- When is it to be done?
- What records are kept?
- What reviews are performed?

Thanks

Thank you for your participation.

Manuel Marco

Phone: (562) 453-4621

Office: (562) 426-0500

Email: manuel.marco@dnv.com

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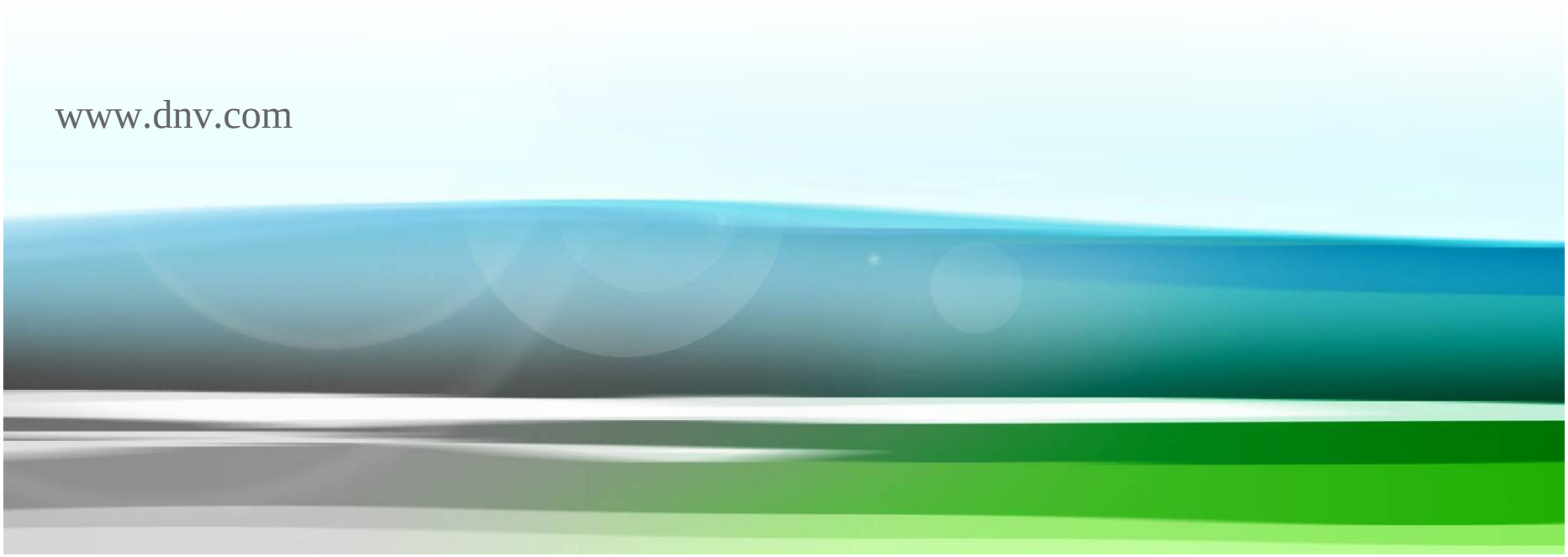

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