1

Course Outline

- Introduction – Welcome and objectives
- Chapter 1 – Background and principles
- Chapter 2 – Basic technical requirements
- Chapter 3 – Technical measurement requirements

- -

- Chapter 4 – Management system requirements
- Chapter 5 – Continual improvement requirements
- Chapter 6 – Monitoring and measuring the quality system

2

Outline of Continual Improvement

Requirements

- Overview of Basic Concepts
- Purpose of Continual Improvement
- From Feedback (Clauses 7.9 and 8.6)
- Non-conformance and Opportunity for Improvement (Clauses 8.5 and 8.6)
- Corrective and Preventive Action (Clauses 8.6 and 8.7)
- Internal Audit and Management Review

How to Implement the Requirements

- Implementing a Continual Improvement Program

3

Definitions

Non-conformance = Non fulfilment of specification:

- Failure of resources to meet either performance requirements or other specified requirements
- Failure of organisation to comply with documented policies and procedures or work instructions
- Failure of test data

5

Definitions

Potential Non-conformance = Potential Non fulfilment of specification:

- Possible failure of resources to meet either performance requirements or other specified requirements
- Possible failure of organisation to comply with documented policies and procedures or work instructions
- Possible failure of test data

6

Definitions

Opportunity for Improvement = Potential to be better or enhance…:

- Possible betterment of processes and other issues to enhance performance
- Possible betterment of organisation to comply with documented policies and procedures or work instructions
- Possible enhancement of test data

7

Continual Improvement

These seven clauses in 17025 provide some direction on the search for non-conformities, potential non-conformities and opportunities for improvement.

8.6 – Improvement (including Feedback)
7.9 – Complaints
7.7 – Quality Assurance / Quality Control
8.5/8.6 – Actions to address risk and opportunities
8.7 – Corrective Action
8.8 – Internal Audits
8.9 – Management Review

8

Purpose of Continual Improvement

"To produce consistent results, day after day, within the 95% confidence region at the specified uncertainties."

Drawing by Iutta Waloschek.
From the website of the University of St. Andrews, Scotland.
http://www-gap.dcs.st-and.ac.uk/~history/PictDisplay/Einstein.html

NOTE: ISO/IEC 17025 is silent on the issue of risks to the health and safety of the people who work in the lab or visit it.

9

Managing Change – Mitigating Risk

Consistency means stability. Change prevents stability.

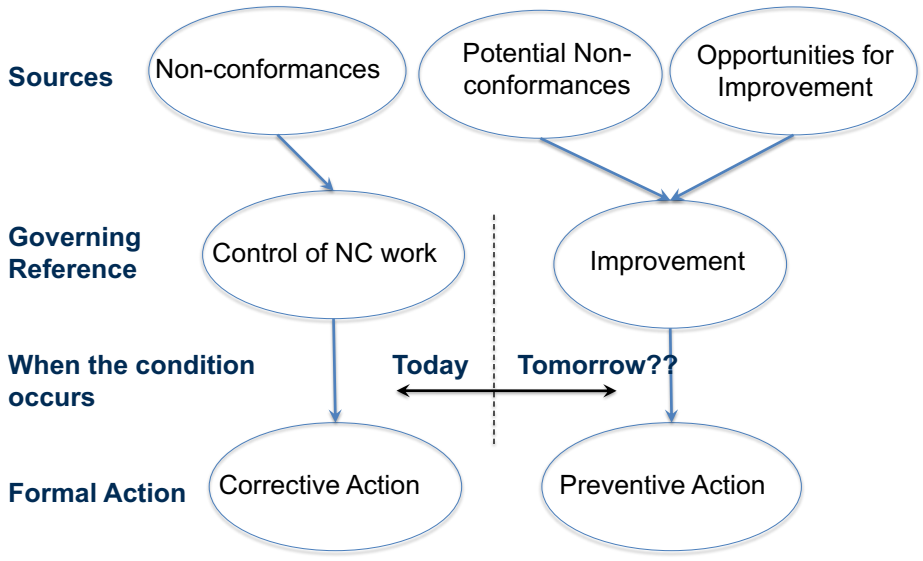
ISO/IEC 17025 provides a systematic method of identifying and addressing those changes and risks that may impede the consistent production of valid results.

17025 also provides some ideas on how to identify opportunities and exploit them to the benefit of the laboratory's operation.

In a good laboratory, continual improvement is mostly about the management of change and the mitigation of risk.

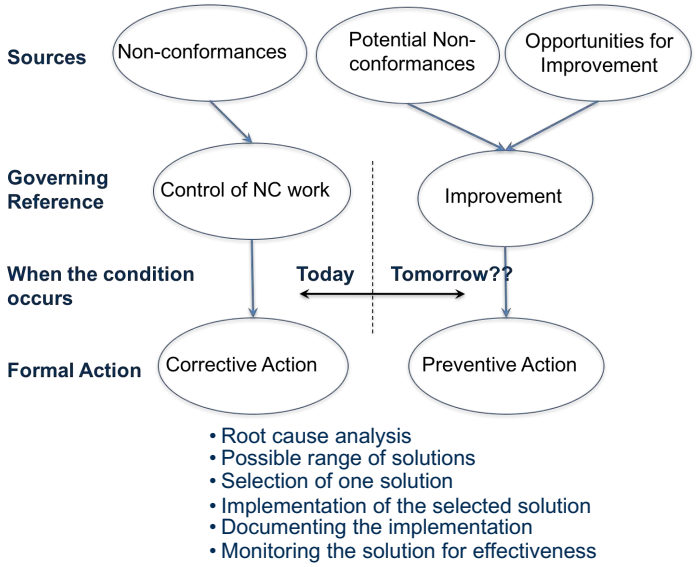
10

Departures from procedures



11

From Identification to Action



- Root cause analysis
- Possible range of solutions
- Selection of one solution
- Implementation of the selected solution
- Documenting the implementation
- Monitoring the solution for effectiveness

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Continual Improvement

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8.9 – Management Review

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Feedback is about Perception

- Understand that 17025 requires a laboratory to **actively seek feedback** regarding all of its activities.
- Understand that feedback is only about how other parties (customers, regulators, the public, stakeholders) perceive the laboratory and should not be confused with actual performance until an investigation is complete. In other words, a complaint cannot be treated as a non-conformance until an investigation indicates (validates) this.

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17025 Continual Improvement

1. There are 9 questions in this Chapter.
2. What does the standard require?
3. Participants select their own answers.
4. The whole group is balloted for the most appropriate response.
5. Clapping indicates a correctly answered question. Buzzer indicates an incorrectly answered question.
6. The citation from the standard is displayed next to the most correct answer.
7. The quiz then advances to the next question.

Press Continue

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17025 Continual Improvement

8.6 Improvement (including Feedback)

Labs **MUST** seek feedback.

A. TRUE
B. FALSE
C. NOT APPLICABLE

16

Continual Improvement

These seven clauses in 17025 provide some direction on the search for non-conformities and potential non-conformities.

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17025 Continual Improvement

Complaints

- 17025 now requires a lab to receive (record), evaluate, and decide (adjudicate) complaints.
- Best practice is to investigate and determine if non-conformance or potential non-conformance exists.
- If yes, do something – treat as non-conformance.
- If no, at least respond to complainant.
- Best practice also includes making the system congruent for both positive (compliment) and negative (complaint) feedback.

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17025 Continual Improvement

7.9 Complaints

Following receipt of a complaint, the laboratory **MUST** determine its validity.

A. TRUE
B. FALSE
C. NOT APPLICABLE

20

Continual Improvement

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Ensuring the validity of test and calibration results

7.7.1.

- QA trend data must now be analyzed and, where found to be outside limits, action must be taken to correct the problem and to prevent incorrect results from being reported.
- Easiest tool is the “second set of eyes.”

7.7.2

- Best tools for laboratory QC is a good PT program. But it must be monitored to be effective.

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17025 Continual Improvement

7.7 Ensuring the validity of results

The laboratory **MUST** track trends in test and calibration results to monitor their continuing validity.

A. TRUE
B. FALSE
C. NOT APPLICABLE

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Continual Improvement

These seven clauses in 17025 provide some direction on the search for non-conformities and potential non-conformities.

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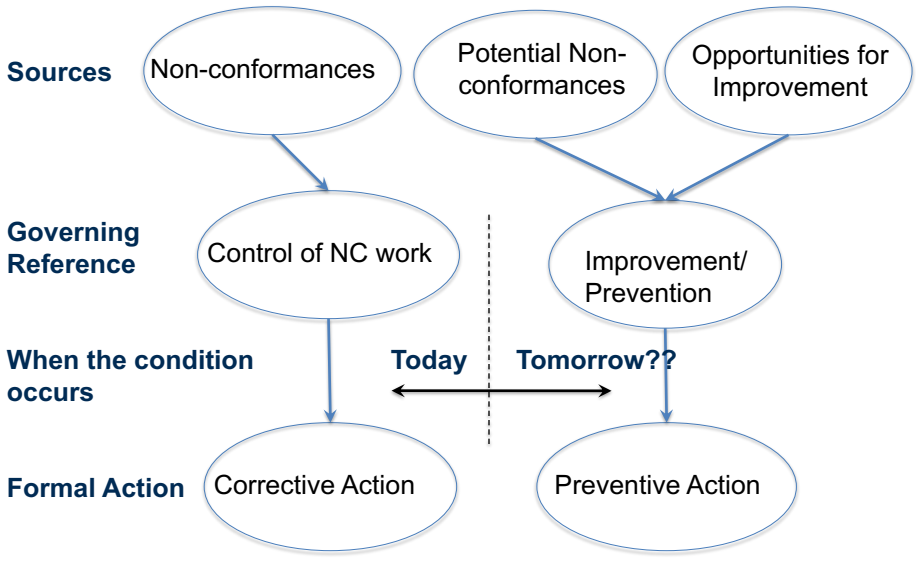
Impediments to Competence

Clauses 8.5 and 8.6 capture most of the instances of conditions in the laboratory that have (or may) impede the consistent production of technically valid results. The processes for capturing both identified non-conformances and potential non-conformances can be the same…same procedures, same forms, and same approach. The only stipulated difference is Time.

27

Departures from procedures



28

17025 Continual Improvement

8.5 Actions to address risks and opportunities

The laboratory **MUST** consider both potentially undesirable (bad) and potentially desirable (improvement) conditions in their continual improvement efforts.

A. TRUE
B. FALSE
C. NOT APPLICABLE

29

17025 Continual Improvement

8.6 Improvement

The laboratory **MUST** identify desirable (improvement) conditions in their continual improvement efforts and **DO SOMETHING ABOUT THEM**.

A. TRUE
B. FALSE
C. NOT APPLICABLE

31

17025 Continual Improvement

8.7 Corrective Action

The laboratory **MUST** determine the need to eliminate the root cause of identified non-conformities as part of undertaking any permanent resolution.

A. TRUE
B. FALSE
C. NOT APPLICABLE

33

17025 Continual Improvement

8.7 Corrective Action

The laboratory **DOES NOT NEED** to review the effectiveness of any corrective action taken.

A. TRUE
B. FALSE
C. NOT APPLICABLE

35

Continual Improvement

These seven clauses in 17025 provide some direction on the search for non-conformities and potential non-conformities.

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8.9 – Management Review

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17025 Continual Improvement

INTERNAL AUDITS

- To audit ALL laboratory activities
- Some Accreditation Bodies specify one year between audits.

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17025 Continual Improvement

8.8 Internal Audits

The laboratory **MUST** use only certified auditors to conduct their internal audits.

A. TRUE
B. FALSE
C. NOT APPLICABLE

39

Continual Improvement

These seven clauses in 17025 provide some direction on the search for non-conformities and potential non-conformities.

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8.9 – Management Review

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Management Reviews

- Some Accreditation Bodies require a one-year Management Review cycle.
- ALL of the (applicable) elements given in this clause **must** appear in the minutes of a management review meeting.

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17025 Continual Improvement

8.9 Management reviews

Management review **REQUIRES** discussion of the following number of issues/topics.

A. 15
B. 4
C. 19

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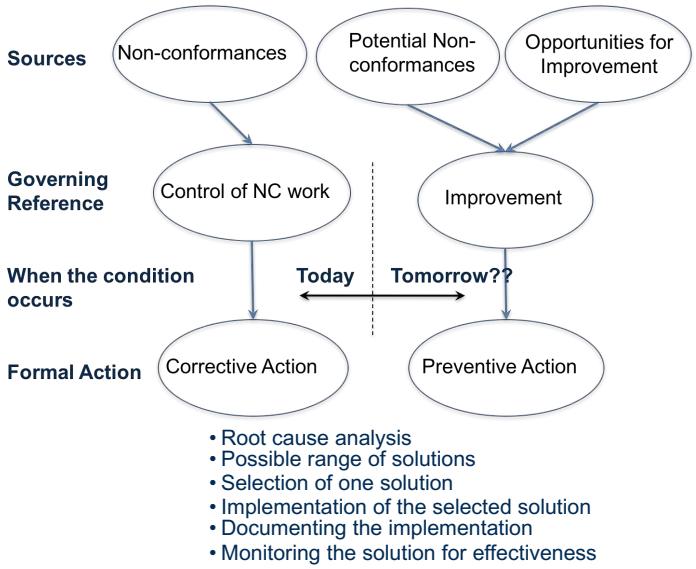
Holistic Continual Improvement Program



- Root cause analysis
- Possible range of solutions
- Selection of one solution
- Implementation of the selected solution
- Documenting the implementation
- Monitoring the solution for effectiveness

45

What Continual Improvement means to the lab

- The processes for capturing and addressing both identified non-conformances and potential non-conformances is the same (procedures, forms, and approach). The only difference is Time.
- Everyone can more easily identify potential non-conformances.
- Implementing this approach in a formal manner also allows the laboratory to pro-actively implement continual improvement.

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Continual Improvement Steps

Step 1 – Identify and Document Departures and Potential Benefits
Step 2 – Remediate them and Document it
Step 3 – Determine the Need for Formal Action and Document it
Step 4 – Implement Formal Action (including Documenting it)
Step 5 – Follow up for Effectiveness and Document it

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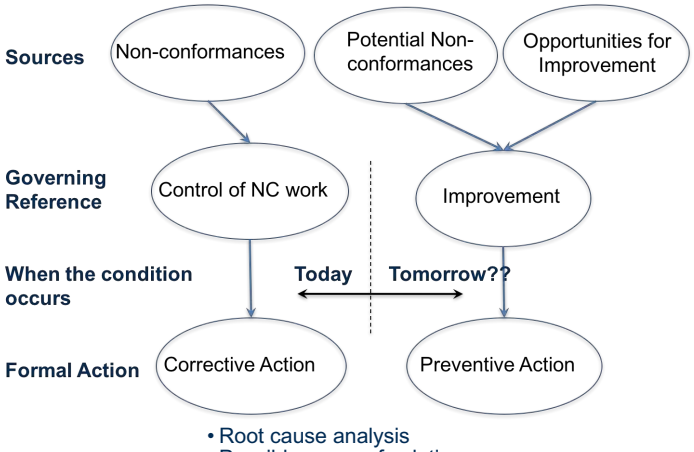
From Identification to Action



- Root cause analysis
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48

Step 1 - Identify

Identify the problem from Injury, Hazardous Condition/Near Miss, Environmental Incident, Motor Vehicle Accident, or from Deviation (or Potential Deviation) or Opportunities for Improvement that adversely affects (or benefits) technical validity of laboratory results.

Create a record and write it down!!!!

NOTE: ISO/IEC 17025 is silent on the issue of risks to the health and safety of the people who work in the lab or visit it.

49

Identify – 1 (HSE)

Injury (to a person): any event in which a person has suffered pain or distress AND where a minimum of first aid treatment is required (including eye wash). Injury types include Lost Time Injury, Medical Aid Injury, Modified Work Injury, and First Aid Injury. Each type calls for a different level of medical treatment and produces different work-related results for the injured person. Very minor incidents such as paper cuts and stubbed toes need not be recorded unless associated with a Hazardous Condition (defined later). First Aid Injuries do not result in lost time.

50

Identify – 2 (HSE)

NOTE: ISO/IEC 17025 is silent on the issue of risks to the health and safety of the people who work in the lab or visit it.

Near Miss: an event in which a person would have suffered pain or distress AND where a minimum of first aid treatment would have been required (including eye wash).

51

Identify – 3 (HSE)

Hazardous Condition: condition that could potentially cause injury to persons or damage to property. Oil leaking from machines, obstructed walkways, dangerous conditions, and unguarded machinery are examples of hazardous conditions.

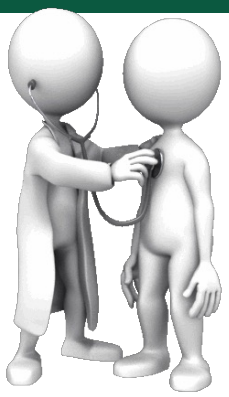
Water and electricity do not mix.

NOTE: ISO/IEC 17025 is silent on the issue of risks to the health and safety of the people who work in the lab or visit it.

52

Identify – 4 (HSE)

Occupational Disease: a disease or illness which has occurred as a result of working conditions. This includes: allergic reactions, dermatitis, infections, cancer, hand / arm vibration syndrome etc.



NOTE: ISO/IEC 17025 is silent on the issue of risks to the health and safety of the people who work in the lab or visit it.

53

Identify – 5 (HSE)

Environmental Incident: release of hazardous materials. Examples are emissions into the atmosphere, waterways, drains or soil. This includes the release of toxic smoke or gas, liquid chemicals, radioactive materials, contaminate water, biohazards, or oil.

NOTE: ISO/IEC 17025 is silent on the issue of risks to the health and safety of the people who work in the lab or visit it.

54

Identify – 6 (HSE)

Motor Vehicle Incident: a company vehicle is involved in an accident resulting in damage to the vehicle or injury to the occupants. This includes all other motor vehicles being driven by a company driver of a company car or van while traveling to and from work.

NOTE: ISO/IEC 17025 is silent on the issue of risks to the health and safety of the people who work in the lab or visit it.

55

Identify – 6 (HSE)

Motor Vehicle Incident: a company vehicle is involved in an accident resulting in damage to the vehicle or injury to the occupants. This includes all other motor vehicles being driven by a company driver of a company car or van while traveling to and from work.

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56

Identify – 7 (Quality)

Deviation: a perceived or actual departure from policies, procedures or processes in our management system or technical operations, or from a requirement from an external specification such as a standard. Note: This term encompasses all concepts also known as "non-conformance" or "anomaly." It includes the concepts behind other, more specific terms, such as "finding," or "issue," or "condition."

57

Identify – 8 (Quality)

Potential Deviation: a potential departure from policies, procedures or processes in our management system or technical operations, or from a requirement from an external specification such as a standard. Note: This term encompasses all concepts also known as "potential non-conformance" or "potential anomaly." It includes the concepts behind other, more specific terms that deal with future events, such as "finding," or "issue," or "condition."

58

Identify – 9 (Quality)

Opportunity for Improvement: a potential improvement in some aspect of laboratory operations in terms of a savings in time or effort, a reduction in complexity, an enhancement to health and safety, an expansion of scope, or other measurable advantage to the business itself or the people working in the laboratory.

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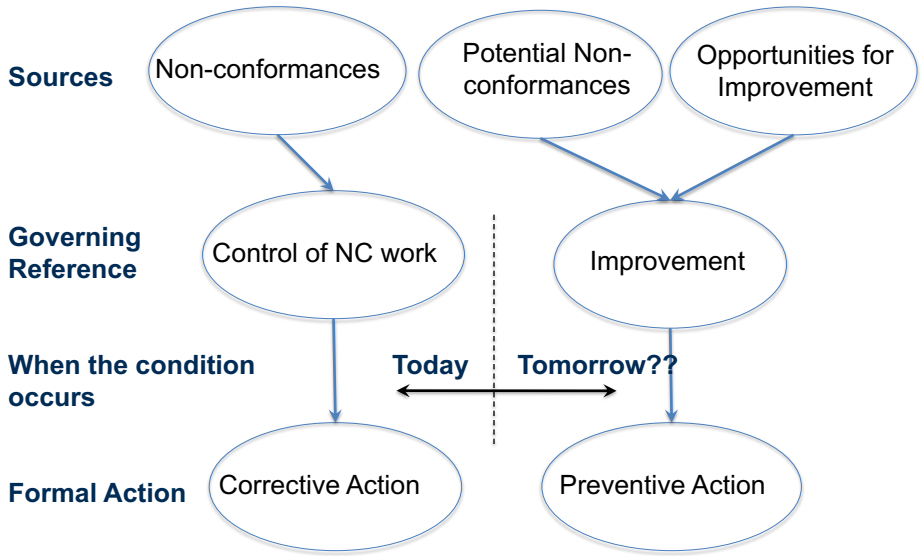
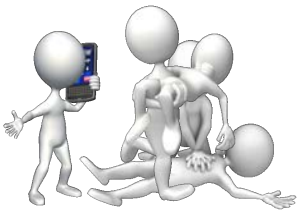
Departures from desired procedures



60

Step 2 - Remediate

Remediate (Correct or Prevent) the problem from continuing (Right Now!!)



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Step 2 - Remediate

Remediate (Correct or Prevent) the problem from continuing (Right Now!!);

Write that down in the record created under the Identify step

62

Step 3 – Determine need for Formal Action, Including RCA

Determine if root cause analysis is required. Ask the "Three Questions."

If the results do not require root cause analysis, stop and submit the record created in the Identify and Remediate steps.

63

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If the results do not require root cause analysis, stop and submit the record created in the Identify and Remediate steps.

64

Is RCA Necessary? - Questions

Three Questions:	Answers:
1. Does this condition (or might it) present unacceptable risk to organisation (or its people or visitors) or provide significant benefit? (Risk/Benefit = IMPACT X Probability of occurrence)	Yes/No?
2. Has this condition (or might it) prevent the organisation from producing technically valid results or making technically valid decisions or significantly enhance its ability to produce technically valid decision?	Yes/No?
3. Is permanent prevention easier than repeated remediation?	Yes/No?

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Is RCA Necessary? - Questions

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3. Is permanent prevention easier than repeated remediation?	Yes/No?

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Is RCA Necessary? - Questions

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2. Has this condition (or might it) prevent the organisation from producing technically valid results or making technically valid decisions or significantly enhance its ability to produce technically valid decision?	Yes/No?
3. Is permanent prevention easier than repeated remediation?	Yes/No?

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Is RCA Necessary? - Answers

Results of the Three Questions:

1. If ALL answers are “no,” then root cause is not required and only remediation (correction or prevention) is needed. Submit the record created in the Identify and Remediate steps. Your job is done!!

1. ANY “yes” answers means a full root cause analysis is REQUIRED. Continue the record created in the Identify and Remediate steps.

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Step 4 – Formal Action

- Identify the underlying Root Cause
- Eliminate the Root Cause or the problem will return.
- Involve all stakeholders of the process under examination in the development of a solution.
- People provide solutions.
- Record implementation.

70

Step 4 – Formal Action

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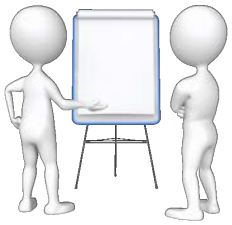

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72

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- Eliminate the Root Cause or the problem will return.
- Involve all stakeholders of the process under examination in the development of a solution.
- People provide solutions.
- Record implementation.

73

Step 4 – Formal Action

Corrective Action

- Corrective Action: *Action to eliminate the cause of a **detected** nonconformity or other undesirable situation*
  - Addresses the CAUSE and not the SITUATION (or condition)
  - If it just addresses the situation or condition it is called *CORRECTION* and not *CORRECTIVE ACTION.*
- Has six basic components:
  - Root cause analysis
  - Possible range of solutions
  - Selection of one solution
  - Implementation of the selected solution
  - Documenting the implementation
  - Monitoring the solution for effectiveness

Correction only and not necessarily formal

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Step 4 – Formal Action

Preventive Action

- Preventive Action: *Action to eliminate the cause of a **potential** nonconformity or other undesirable situation*
  - Addresses the CAUSE and not the SITUATION (or condition)
  - If it just addresses the situation or condition it is called *PREVENTION* and not *PREVENTIVE ACTION.*
- Has six basic components:
  - Root cause analysis
  - Possible range of solutions
  - Selection of one solution
  - Implementation of the selected solution
  - Documenting the implementation
  - Monitoring the solution for effectiveness

Prevention only and not necessarily formal

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Step 4 – Formal Action

Corrective- vs. Preventive- Action

- Non-conformance has already occurred.
  - Corrective Action is to prevent recurrence.
- Potential non-conformance has not already occurred.
  - Preventive Action is to prevent its FIRST occurrence.
- They differ only in TIME
  - Today vs tomorrow
- In ALL other aspects, they are identical.

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Step 4 – Formal Action

Implement the Selected Solution

- Address the Root Cause
- Implement where the root cause exists
- Communicate the solution to all concerned

77

Step 4 – Formal Action

Implement the Selected Solution

- Address the Root Cause
- Implement where the root cause exists
- Communicate the solution to all concerned

78

Step 4 – Formal Action

Document it – Write it Down

Create a record and write it down!!!!

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Step 5 – Follow Up for Effectiveness

- This is the easiest part of Continual Improvement
- Go and look at the Continual Improvement Logs in three or six months and see if the problem has occurred (again)
- If not – good.
- If so – then start back at Root Cause Analysis and select either another Root Cause or another Solution – or both.

80

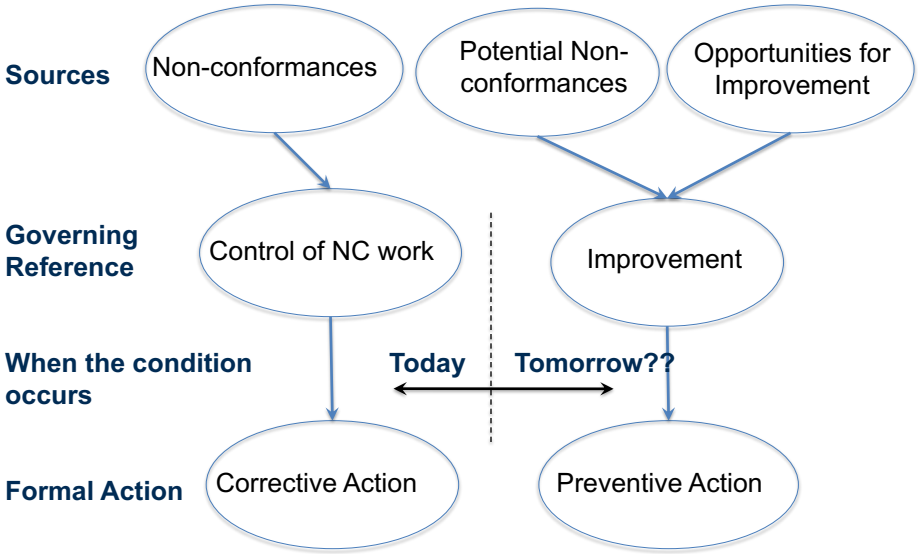
Step 5 – Follow Up for Effectiveness

Document it – Write it Down

Create a record and write it down!!!!

81

Departures from desired procedures



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Healthy Continual Improvement

- Feedback obtained and tracked
- Complaints addressed/using the Compliments
- Non-conformances and potential non-conformances and opportunities for improvement identified and tracked
- Corrective and preventive action taken
- Thorough internal audit
- Good management review

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