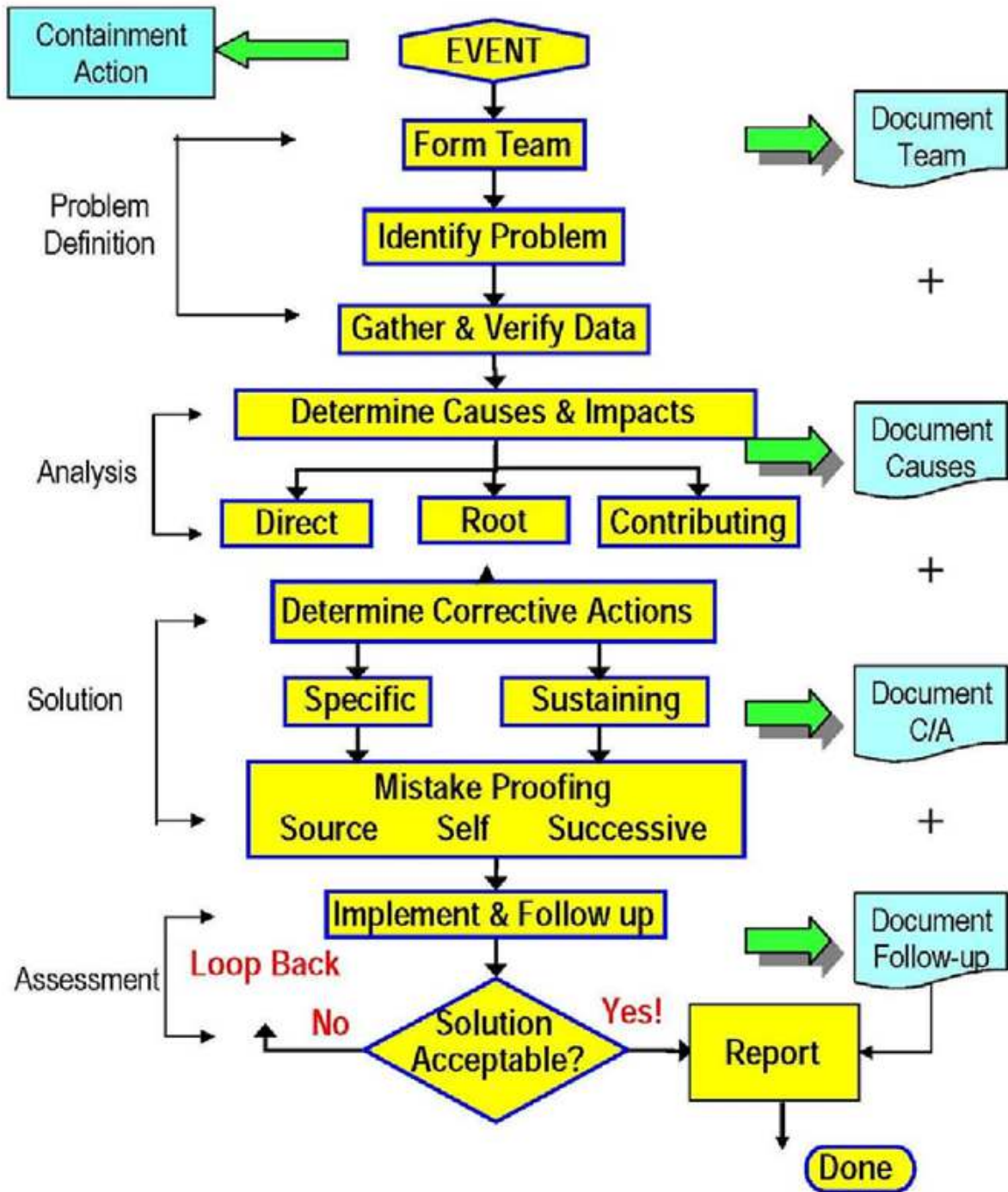


Root Cause Corrective Action For PRI Industry-Managed Programs

This guide has been created to support companies pursuing industry-managed accreditation. It details how to respond to non-conformances in the acceptable way. This approach was initially adopted by Nadcap and other industry-managed programs have since opted to utilize it as well. Nadcap is the leading worldwide cooperative program of major companies designed to manage a cost-effective consensus approach to special processes and products and provide continual improvement within the aerospace and defense industries.





Overview

Root Cause Corrective Action for non-conformances has long been a requirement for those working in industries with critical processes. It is a process of determining the causes that led to a nonconformance or event, and implementing corrective actions to prevent a recurrence of the event.

Submitting full and complete responses will aid in acceptance of your responses, shorten the cycle time for accreditation/approval, and provide you with a powerful continual improvement tool.

While this supplement is called Root Cause Corrective Action for PRI Industry-Managed Programs, there is nothing unique about these expectations for corrective action. The Performance Review Institute will strictly enforce the requirements for corrective action. Quality system requirements, such as AS9100 and AC7004, expect:

- Establishment and maintenance of documented procedures for implementing corrective and preventive action.
- Corrective or preventive action taken to eliminate the causes of actual or potential nonconformities to a degree appropriate to the magnitude of the problems and commensurate with the risks encountered.
- Implementation and recording of changes to the documented procedures resulting from corrective and preventive action.
- Effective handling of customer complaints and reports of product nonconformities.
- Investigation of the cause of nonconformities relating to product, process and quality system, and recording the results of the investigation.
- Determination of the corrective action needed to eliminate the cause of nonconformities.
- Application of controls to ensure that corrective action is taken and that it is effective.

The response submitted must demonstrate compliance with each of these requirements. Following the process described herein and documenting these steps will allow you to demonstrate this compliance. All of these requirements are met within a corrective action process that addresses:

- Containment
- Problem definition
- Analysis
- Solution
- Assessment

Root Cause Corrective Action for PRI Industry-Managed Programs

Industry-managed accreditation requires clear and concise descriptions of actions taken to fully and completely address non-conformances identified during the audit. Frequently, responses to audits describe the steps taken to bring the noncompliance into compliance, or restate the finding as the root cause. Actual action taken to address the issue is often limited to “we retrained the operator”. The industry-managed approach requires you to analyze the cause(s) and take appropriate actions.

There are numerous successful approaches to root cause corrective action and any of them can be used. The requirements for response submittal are:

- Immediate Corrective Action Taken
- Root Cause of the Nonconformance
- Impact of All Identified Causes and the Root Cause
- Actions Taken to Prevent Recurrence
- Define and Attach Objective Evidence

The process described here is “a” process for identifying the information required by industry-managed accreditation programs as well as meeting corrective action requirements. The steps described here encompass essential elements of any corrective action system, but may be accomplished with different tools or called by different names. For our purposes we will use the term “event” to mean any of the following: audit finding, product failure, customer complaint, customer return, scrap, rework, SPC special cause, accident, etc. Whatever process you use, whatever terms you use, make certain you understand how and where your responses fit into the submittal requirements.

Containment Action

Containment action is the first step in this process. These are the actions taken immediately after you become aware of the event to stop the event from occurring and preventing or minimizing any impact from the event. You contain the problem and the effects prior to beginning corrective action. While these actions may be called specific corrective action, please note that there are no actions here to correct the problem, they are just damage control:

- Put out the fire: This step is where you stop the event from occurring.
- Assess the damage: Once you have stopped the event from occurring, determine what and how much damage has been done.
- Contain all effects: Upon determination of the amount and extent of damage, prevent everything that was affected from escaping, and determine if anything has escaped.
- Notify as appropriate: If it is determined that product may have escaped, notify any impacted customers.

These steps are the actions taken to bring the noncompliance into compliance. This is the immediate corrective action constituting the information to be supplied in the Immediate Corrective Action. Each of these steps should be described in detail. Advise exactly what steps you took to stop the event from occurring, what was the impact and how you determined this. Describe in detail the steps you took to contain any effects (while we are critically concerned with hardware, effects may go beyond product). If product has, or may have, been shipped to a customer, advise who and how you notified customers.

Problem Definition

Corrective action begins with clearly defining the actual problem. While this may seem simple, many repetitive non-conformances result because the wrong problem was solved, only the outcome was fixed, or only one problem was corrected when there were really two or more problems. The steps involved in problem definition are:

- Forming the team
- Identifying the problem
- Gathering and verifying data

Forming the Team

Assigning the wrong personnel to corrective action projects is a common problem. Many times, the projects are assigned to Quality, when Quality did not make the error, or it may be assigned to employees in charge of the area where the problem or noncompliance was discovered when the noncompliance resulted from a systemic problem that goes far beyond the area where the noncompliance was discovered.

A team of stakeholders in the problem should be assembled. Who owns the problem? Who has a stake in the outcome and the solution to the problem? Who are the vested owners of both the problem and the solution? These are the people who know the process, have the data and experience, and they are the ones will have to implement the corrective actions. Without the full support of the stakeholders, long-term solutions are not likely.

Once the stakeholders are identified, consider if additional expertise is needed. If so, the team may need to include qualified team members or ad-hoc members who, while not stakeholders, can contribute information, technical expertise, management support, or offer advice.

Please note that the stakeholders and qualified members may change as the team gains more information and data. Clarifying the problem or additional problems may surface involving additional stakeholders or require additional expertise. As the process evolves, continue to assure that your team includes stakeholders and necessary experts and resources.

Identifying the Problem(s)

In order to fix a problem, it must be clearly and appropriately defined. Frequently, the non-conformance identified is not really the problem, but the symptom of the problem. If you have an expired gage, that is a symptom of a problem with your recall system. A flow-down problem is generally a contract review or quality planning issue. Asking questions similar to the following will help you to address the actual problem and not just the symptom that was identified as the event.

- What is the scope of the problem?
- How many problems is it?
- What is affected by the problem?
- What is the impact on the company?
- How often does the problem occur?

Addressing these types of questions will assist you in clarifying and defining the problem(s).

“If you cannot say it simply, you do not understand the problem.”

Once the problem is defined, it must be clearly stated in simple terms. While some problems might be *“the unique, inherent metallurgical properties”*, you aren’t going to be able to fix that, but certainly there is some process variability that contributed to this and can be fixed. Do not allow yourself to hide behind the technical, state-of-the-art nature of industries with critical processes. Very few of our problems are actually technical or high-tech.

When the problem is known, the event question to be answered can be formed. This event question begins the “5-Why” process.

An event question is:

Short
Simple
Concise
Focused on one problem
Is a question starting with Why.....?
Is the first “Why” in the process

An event question does not:

Tell what caused the event
State what to do next
Explain the event

Gather and Verify Data

When the problem is identified, it is time to begin data collection. The factual information and data necessary to assure a thorough cause analysis needs to be collected. Data may have to be collected several times during this process, but the preliminary collection phase occurs now and will guide the analysis process.

Initial data gathering starts at the scene. Data has a shelf life, the longer you wait the more difficult it becomes to obtain good information. When possible, go to the scene and take note of who was present, what is in place, when the event occurred and where the event happened. If the event is in the form of an audit finding, try to recover as much of the scene as possible.

Types of data to collect:

- **Location** -the site, building, department, or field location where the event took place
- **Names of Personnel** -operations personnel, visitors, contractors
- **Date and Time**
- **Specifications** -what are the requirements?
- **Operational Conditions** -start up, shutdown, normal operations
- **Environmental Conditions** -noise levels, visual distractions, lighting, temperature, etc.
- **Communications** -verbal or written, what orders were being followed?
- **Sequence of Events** -in what order did things take place?
- **Equipment** -what was being operated?
- **Physical Evidence** -damaged equipment or parts, medical reports
- **Recent Changes** -in personnel, equipment or procedures
- **Training** -classroom, on-the-job, none
- **Other Events** -have there been similar occurrences?

Once gathered, verify the accuracy of the data. Cause analysis is performed based on fact.

Remember, if you don't look, you will not find the problem. Make sure that gathered data is correct and complete. Then go where the data takes you. Do not take the data where you want it to go.

Analysis

When the problem is identified, and preliminary data has been gathered and verified, the analysis can begin. We will describe a "5-Why" process, but analysis may take other forms. This process uses the Why – Why – etc. method to build a cause chain because it is a natural, logical progression for thinking through a problem. The 5-Why process is called that because, generally speaking, it takes 5 "whys" to get to the logical end of the cause chain. Not all cause chains will be complete in 5 whys, some will take 7 and others will reach their end in 3.

Example of Why-Why Method of Questioning

The Event: I didn't get to work on time.

Event related Question: **Why was I late?** (Simple Question)

Car wouldn't start (Simple Answer)

Why didn't the car start? (Simple Question)

The Battery was dead (Simple Answer)

Why was the battery dead? (Simple Question)

Dome light was on all night (Simple Answer) **Battery was old** (Answer to this chain)

Why was the light on? (Simple Question)

The car door was left open (Simple Answer)

Why was the door open? (Simple Question)

Kids played in car (Simple Answer)

Why were Kids in car? (Simple Question)

Car not locked (Simple Answer)

Why was car unlocked? (Simple Question)

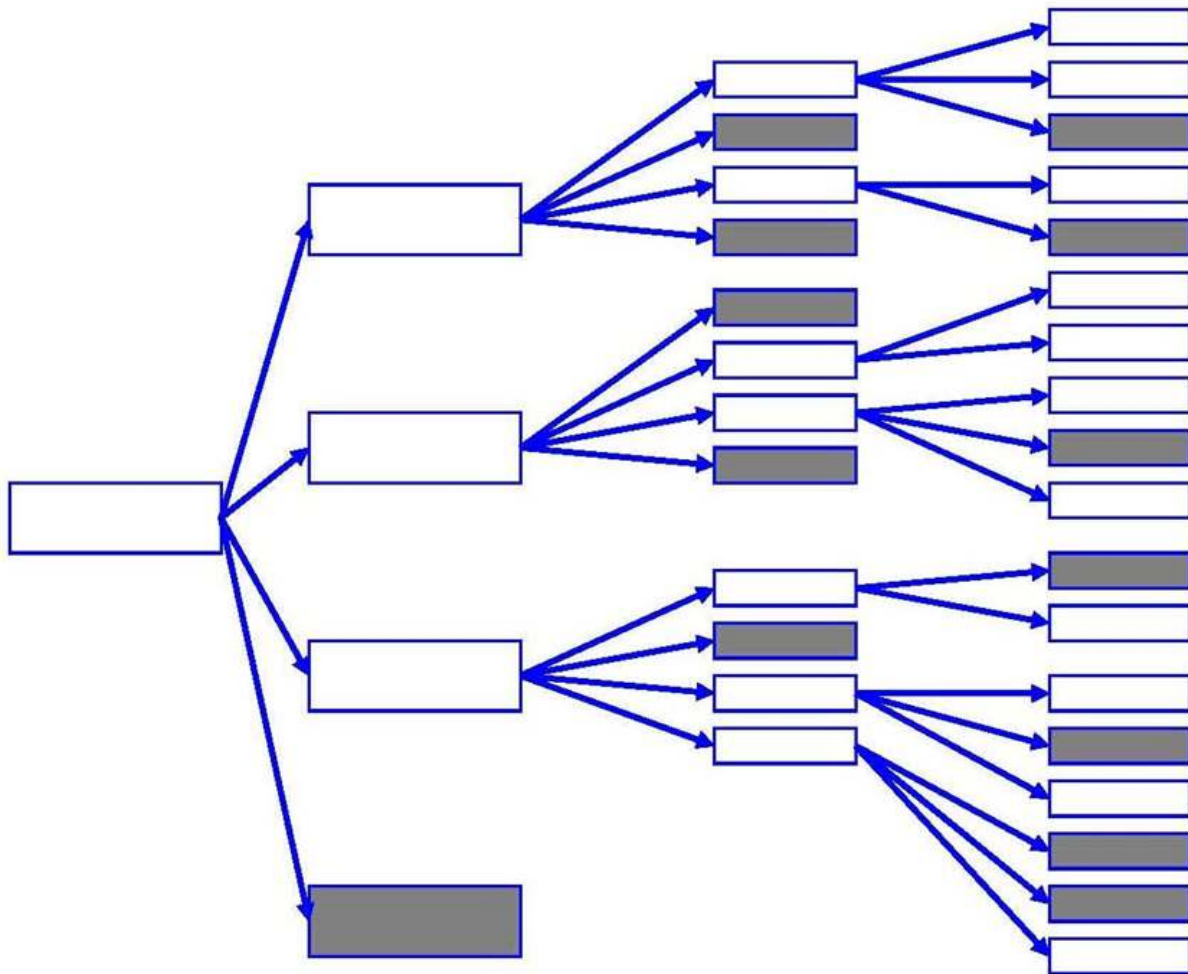
Remote access failed to activate lock. (Simple Answer)

The answers to the "Why" questions form a chain of causes leading to the root cause. The answer to the first Why is the direct cause. The logical end of each chain is a root cause (each chain will have its own root) and the causes in between the direct cause and the root cause are contributing causes. There may be no contributing causes, but there is always a root cause – the best and logical place to stop as identified by the team. This place is where continuing to ask Why adds no value to prevention of recurrence, variability reduction, or cost savings.

For example, if the event is is:

- A procedure does not exist or needs revision -- Why doesn't it exist (and stating that someone did not know is not acceptable) – What was the systemic reason for the lack of knowledge
- Operator (or technician) not trained and/or qualified – Why was the operator not trained (stating that training was not conducted only restates the finding) and Why is an unqualified operator performing work

There may be multiple branches and multiple root causes (each branch having its own root cause). Each branch should be analyzed and worked down to its' logical end. Many of these identified causes, may not directly relate to the problem, but point to issues that still need to be addressed to prevent future problems. Some formal method of prioritizing causes will need to be developed to aid in determining when an identified cause should be worked, as a large number of causes will be generated and not all are worthy of much investment to fix. The figure below demonstrates a complete 5-why analysis with grayed out boxes being either causes not supported by data or causes not to be fixed by some formal prioritization method.



Using the 5-Why approach provides a structured approach to corrective action and can form the basis for a broad-based continual improvement and preventive action plan. This formal process should capture and prioritize causes and address them as the basis for continual improvement efforts. The issues identified through this process are obstacles within the organization that are costing time, money, and frustration. This cause identification process, coupled with a structured prioritization process will also satisfy the requirements for:

- Corrective action to a degree appropriate to the magnitude of the problems and commensurate with the risks encountered
- Effective handling of customer complaints and reports of product nonconformities
- Investigation of the cause of nonconformities relating to product , process and quality system, and recording the results of the investigation

The root cause of the chain with the highest priority should be identified as the Root Cause in the format required. The contributing causes between the root cause and the direct cause may be included to clarify your analysis process.

Impact

You should now re-examine your impact statement. While the impact and effects of the event were addressed as part of your immediate corrective (or containment action), you have now identified numerous causes that may also have impacted your products or processes. Consider the effects that the entire cause chain has had and be certain that they get addressed. If necessary, readdress the Impact statement.

Be certain that this statement addresses:

- Scope of non-conformance – limited to 1 part or 1 lot, or was it systemic and what specific parts were affected
- Description of what was done to review similar product to confirm or reject the possibility of a systemic problem
- Evidence of customer notification and response
- Disposition of any nonconforming parts

Solution

It is now time to begin problem solving, and if you have built a good cause chain, you know what needs to be fixed. Some of the problems have been fixed as part of containment, but now it is time for root cause preventive action.

Preventive Corrective Action can also be thought of as Sustaining, as you cannot prevent the event at this juncture, it has already happened. Actions taken now are to prevent recurrence of the event. They focus on breaking the cause chain completely by fixing the contributing causes and the root cause. A contributing cause, if not addressed, could be a future root cause.

Preventive Action is a series of actions that positively change or modify system performance. It focuses on the systemic change and the places in the process where the potential for failure exists. Preventive Action does not focus on individual mistakes or personnel shortcomings.

In determining solutions consider the following:

- **Feasibility:** The solutions need to be within the company's resources and schedule.
- **Effectiveness:** The solutions need to have a reasonable probability of solving the problem.
- **Budget:** Solution costs must be within the budget of the company and appropriate for the extent of the problem.
- **Employee Involvement:** The departments and personnel affected by the problem need to be involved in creating the solution.
- **Focus on Systems:** The solutions should be focused on systemic issues. Operators do make mistakes, but that is not usually the root cause of the problem.
- **Contingency Planning:** All solutions are developed with a certain expectation of success. Critical elements of the solution should have contingency plans available to prevent failure of the entire solution.

Guidelines for Solution Development:

- There is no absolute correct solution. Other solutions should be ranked based on the degree of effectiveness and suitability for the company.
- Do not rush to a solution, and be willing to think about alternatives over a reasonable period of time.
- Always be willing to challenge the root cause as a symptom of a larger problem.
- Never accept an assumption as fact without significant data.

When devising a corrective action, ask whether they lower the risk of the event recurrence to an acceptable level, and if there are any adverse effects that might be caused to make the action undesirable.

Assessment

The assessment portion of the corrective action process includes both:

- **Follow-Up:** A review done by a team member to ensure all corrective actions are implemented as stated.
- **Assessment:** An independent review to determine if the corrective actions have been effective in preventing recurrence.

Follow-Up

Corrective actions must be accomplished as stated and someone is responsible to assure that the actions were implemented. When verifying implementation, it is important to take things literally. Was everything accomplished as you stated in the report? Were the tasks accomplished according to the established timeline?

Do not commit to actions that the team cannot deliver. Be careful in use of terms, such as everyone or all. Remember, you have to show you have done what you said you would do and be able to show objective evidence.

Assessment

Once the action has been implemented, you are required to determine that the actions taken were effective. In order to determine effectiveness, you must define the criteria by which you measure effectiveness and what is acceptable. Assessing effectiveness of actions taken will be a significant step in reducing non-sustaining corrective actions.

1. Determine the criteria for and the frequency of evaluation
2. Evaluate
3. Close, or return to the cause chain if necessary.

Please note: The effectiveness of your corrective actions will be verified during subsequent audits. Ineffective or non-sustaining corrective action is cause for removal from the Supplier Merit Program, where applicable. Non-sustaining corrective actions are one of the biggest sources of findings across all Task Groups.

Conclusion

Following the process described here and documenting your steps will assure that you comply with requirements, and speed the closure of your audit. An effective and robust Corrective Action program promises significant opportunity for continual improvement and overall organizational success.

PRI offers professional development opportunities at convenient regional locations or at your facility. Root Cause Corrective Action is just one of the training courses on offer.