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Root cause analysis: Enhancing event response and corrective action

» Identifying the underlying root causes or system-related factors at play will help determine the proper corrective actions.

» Systemic flaws need to be addressed to prevent recurrence of an incident.

» Using multiple approaches allows leaders to get different perspectives that could expose more than one root cause of a problem.

» Using a graphic depiction of the problem, such as a fishbone diagram, logic tree, or fault tree, can help uncover an explanation of the event.

» Be sure to document and validate the results and collect metrics to be presented to the Audit Committee and board of directors.

Successful implementation of the corrective action cycle can help organizations find and fix systemic problems to either mitigate or prevent negative business results. The following five important considerations can help organizations as they begin to implement the cycle:

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▶ **Implementing the full corrective action cycle**—identifying an issue, determining the root causes, preparing a plan that addresses the root causes, implementing the plan, and following up to ensure the issue has been resolved—is essential for the corrective action cycle to be successful (see Figure 1).

▶ **Applying the discipline of root cause identification** enables more effective action planning and associated implementation.

Hrubey

▶ **Identifying the source of problems** rarely yields only one root cause and can take many forms; organizations may want to try more than one root cause identification approach, depending on the nature of the problem, to increase the likelihood that all root causes are identified.

Figure 1: The corrective action cycle

Observation

Root cause analysis

Develop plan

Implement plan

Validate solution effectiveness
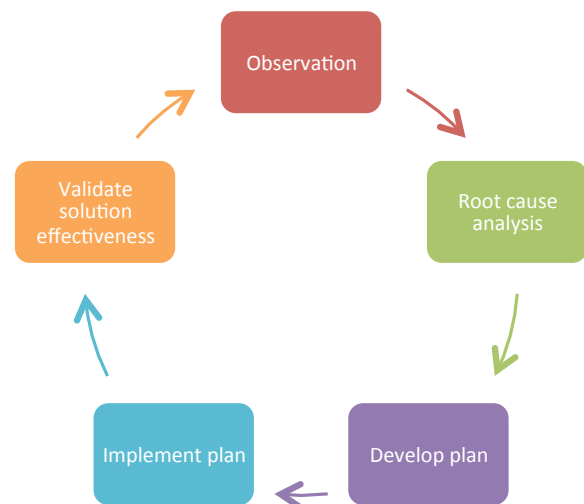
- **Completing the corrective action cycle** requires following up via audit, monitoring events, or doing an assessment to ensure issue resolution.
- **Using technology** can help organizations track and report the corrective action cycle steps and can facilitate information sharing with internal and external stakeholders, including Internal Audit and the board of directors.

Many organizations find themselves in high pressure environments with tight regulations and increasingly intense external scrutiny, raising the bar on expectations to improve their ability to find and fix problems to prevent negative business results.

Implementing the corrective action cycle is challenging for organizations to accomplish practically and efficiently. For example, organizations can complete an investigation and find an individual at fault, but may fail to recognize that systemic issues also contributed to the situation. This failure can lead to a lack of ethics and compliance program effectiveness.

Limitations associated with corrective action

Corrective action is one element of an effective compliance program and is often tied closely to investigation and disciplinary action. It is relatively easy to identify the individuals involved in possible misconduct when a report is received through an organization's compliance reporting process.

> Implementing the corrective action cycle is challenging for organizations to accomplish practically and efficiently.

More challenging, however, is identifying the underlying root cause or system-related factors at play in the situation. Perhaps management communications created an impression that employees should "do whatever it takes to get the sale," and this drove employees to operate out of compliance with company expectations. Maybe policies and procedures were unclear, training was unavailable or ineffective, or the organization's culture fosters an entrepreneurial approach that eschews following the rules.

Numerous barriers can have an impact on an organization's ability to identify the root causes of a systemic failure. Perhaps time pressures, a lack of training, or a lack of awareness prevents investigators from seeing the potential for a systemic cause. Perhaps the problem is misinterpreted, or there is insufficient or unreliable information.

Root cause analysis

Root cause analysis is a logical approach to problem solving because, if carried out effectively, it can help identify systemic flaws that need to be addressed. A well-performed root cause analysis considers the potential multiple root causes across an organization's people, processes, and technology, but an inadequate root cause analysis misses one of these components or ends abruptly at the identification of a single root cause without considering the potential for additional causes of the same problem.

Root cause analysis can take many forms. Every organization, function, and problem is unique, and the approach chosen for performing a root cause analysis will be equally unique. To determine what approach to take, management should consider:

▶ The nature of the problem
▶ The organization's past experience with root cause analysis approaches
▶ The culture of the organization and of the function or functions involved in the analysis

These considerations may help leaders determine that they want to use multiple methods or approaches to look at an issue. Using multiple approaches allows leaders to get different perspectives that could expose more root causes of a problem.

To illustrate a root cause analysis, we will apply four methods that are commonly used to support implementation of corrective action to a fictional scenario. The methods used in this article are:

▶ Five whys
▶ Ishikawa diagram (or fishbone diagram)
▶ Logic tree (or issue tree)
▶ Fault tree

We have simplified each analysis for illustrative purposes. In a real root cause analysis, the approach would be more thorough and would include additional steps, including documentation and validation of results.

Illustrative case study
A global organization has developed a new product for the Asian, European,

and North American markets. In order to be customer-centric, the organization decides to manufacture the product regionally to meet product demand and to prepare customer support materials in local languages.

Once production has begun, demand unexpectedly rises in North America, because of competitor quality challenges. The organization decides to source products for the North American market from Asia and Europe to minimize delay in meeting the rising demand.

Unfortunately, shortly after implementation of the new sourcing plan, customer complaints around the world soar. The organization fires the product manager, blaming her for a failure to prepare for the sourcing transition. In spite of this action, customer complaints continue to flood the organization.

Five Whys
Sakichi Toyoda, founder of Toyota Industries Co., Ltd., developed the Five Whys method in the 1930s. The Five Whys involve:

▶ Asking "why" five or more times
▶ Drilling down to identify the root cause of a problem with each why
▶ Repeating the process as many times as necessary with a different sequence of questions to uncover all of the root causes of a problem

The Five Whys method is often used in conjunction with the other methods outlined in this article.

> Sakichi Toyoda, founder of Toyota Industries Co., Ltd., developed the Five Whys method in the 1930s.

In the case study example, implementing the Five Whys might result in the following.

1. Why has there been an increase in customer complaints?
North American consumers have received products with package instructions written in Kanji. Asian consumers have received products with English package instructions. European customers have received products without package instructions.

2. Why are these package instruction issues occurring?
Packaging and instruction production and manufacturing processes were not set up to handle unique requirements of global customers.

3. Why are these variable instruction and packaging requirements not integrated into the manufacturing processes?
Policies and procedures do not consider the need for package instructions to meet variable regional specifications.

4. Why didn't management's policies and procedures include instructional and packaging considerations for regions in which manufacturing occurs for a different region?
The company has never had to manufacture products in one region for sales and distribution in another region, nor has it ever experienced sudden spikes in demand in a given region that require using manufacturing capacity in other regions.

5. Why hasn't management considered and planned for the regional manufacturing facilities to make products for different regions or for sudden spikes in demand for other regions?
The company does not have a business continuity plan, nor has it planned for sudden changes in market demand.

In this analysis, and when applying any root cause method, the answer to the last question in the string of whys is not the only answer or root cause requiring a corrective action; often multiple answers to questions in the string of whys require corrective action. Additionally, the whys could potentially continue or branch off at any point, extending beyond the five in this simplified example.

Ishikawa diagram
Ishikawa diagrams, also known as fishbone or cause-and-effect diagrams, were developed in the 1960s by Kaoru Ishikawa to show the specific causes of an event. Ishikawa diagrams are often used during product design to identify, in progressive levels of detail, the possible causes of quality defects as well as to identify causes of problems during investigations. Causes are grouped into categories including people, methods, tools, materials, and environment. Organizational leaders ask questions for each category to generate an understanding of the factors associated with a problem. Questions include:
- What happened, or what was the problem?
- Why did it happen?
- How can it be corrected to stop it from happening again?
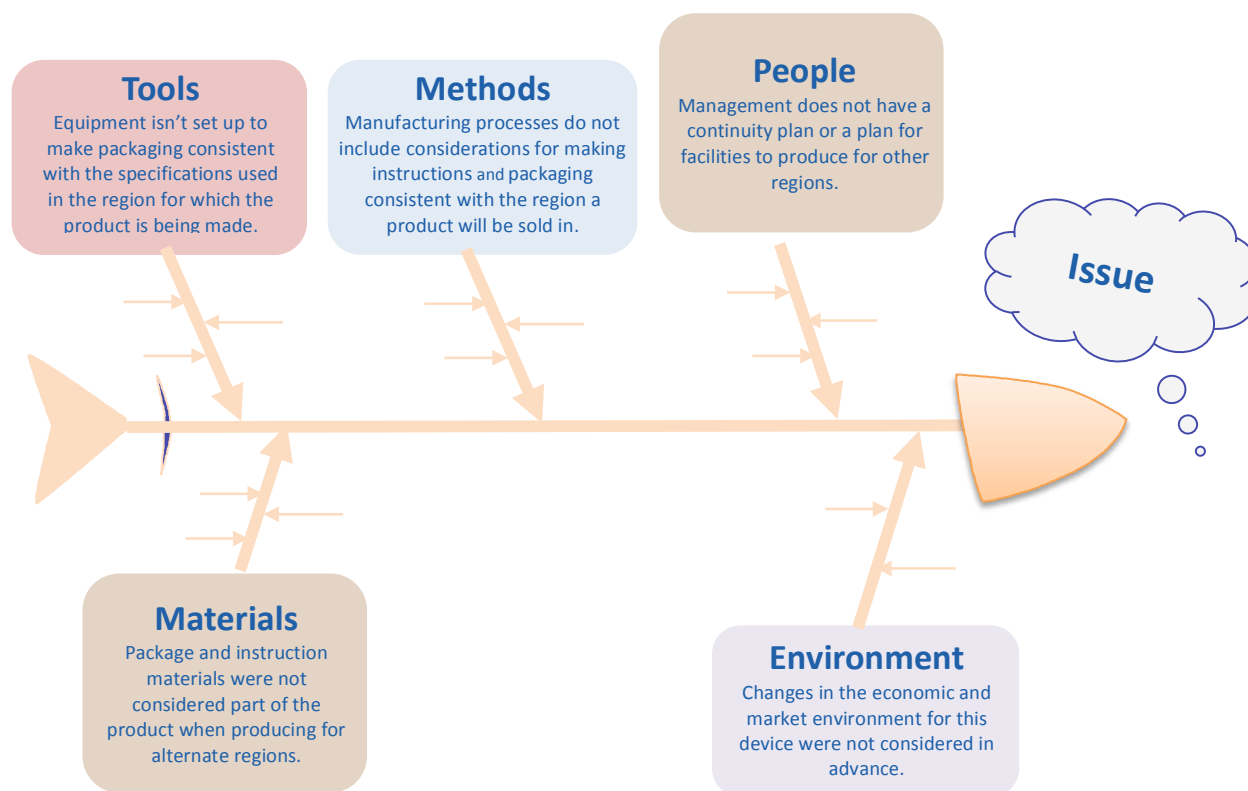
> Ishikawa diagrams, also known as fishbone or cause-and-effect diagrams, were developed in the 1960s by Kaoru Ishikawa to show the specific causes of an event.

Figure 2: Example of an Ishikawa diagram

Tools
Equipment isn't set up to make packaging consistent with the specifications used in the region for which the product is being made.

Methods
Manufacturing processes do not include considerations for making instructions and packaging consistent with the region a product will be sold in.

People
Management does not have a continuity plan or a plan for facilities to produce for other regions.

Issue

Materials
Package and instruction materials were not considered part of the product when producing for alternate regions.

Environment
Changes in the economic and market environment for this device were not considered in advance.

The questions for each category are shown as a diagram that resembles a fish skeleton (see Figure 2). Each bone shows the contributing causes of each category. To expand the analysis, additional categories could be added to the diagram or a branching set of bones could expand out from a cursory cause identified for a given category. When developing the corrective action plan, it is likely that management will find issues that need to be corrected in each category of the diagram.
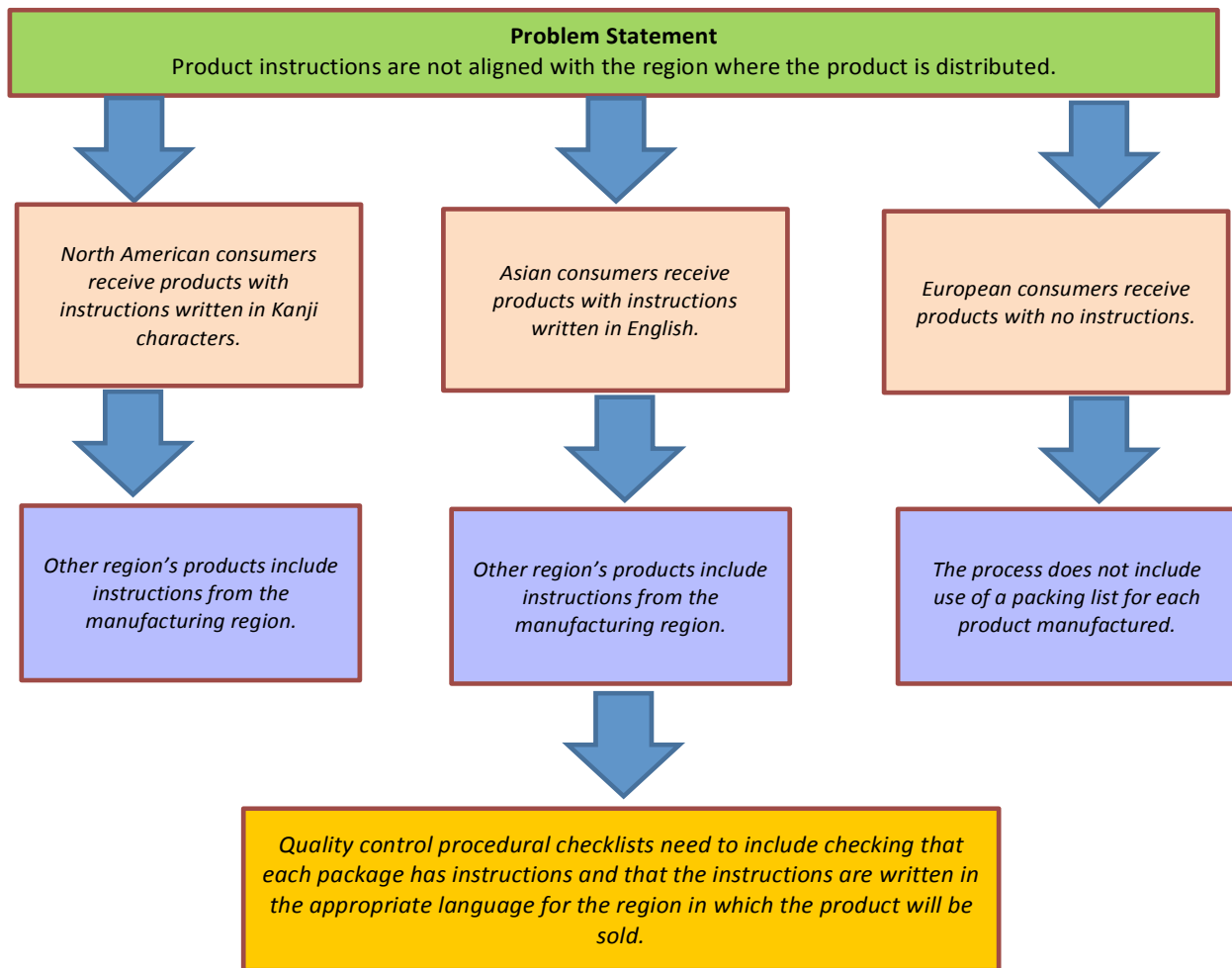
Logic tree

A logic tree (or issue tree) is a visual problem-solving tool that breaks down a situation into discrete pieces to make it easier to search for all possible causes of a problem. The logic tree is named for the graphical depiction of a tree (i.e., a problem is broken down into component parts and then it branches out as details are added). Using a logic tree helps to simplify complex problems and to see the logic behind the root causes of each component of a problem. A logic tree can also be used for determining lead indicators for lag measures to solve for a specific objective, such as how to increase productivity.

For our case study, we broke the initial problem into component parts based on the different issues that were identified in different geographies (See page 80). As with other methods of root cause analysis outlined in this article, it is likely that a real analysis of a situation would involve components branching out and perhaps going into further detail about the cause to get to the end roots of the problem.

Figure 3: Example of a logic tree

Problem Statement
Product instructions are not aligned with the region where the product is distributed.

North American consumers receive products with instructions written in Kanji characters.

Asian consumers receive products with instructions written in English.

European consumers receive products with no instructions.

Other region's products include instructions from the manufacturing region.

Other region's products include instructions from the manufacturing region.

The process does not include use of a packing list for each product manufactured.

Quality control procedural checklists need to include checking that each package has instructions and that the instructions are written in the appropriate language for the region in which the product will be sold.

Fault tree

The fault tree method was developed in the early 1960s by Bell Laboratories to test the U.S. Air Force's Minuteman missile system. The fault tree approach uses a top-down view to help identify potential causes of a system failure. Used frequently to anticipate and prevent non-compliance, the fault tree method also is used to identify weaknesses in planned corrective actions or to identify issues with implementation plans associated with new requirements or regulations.
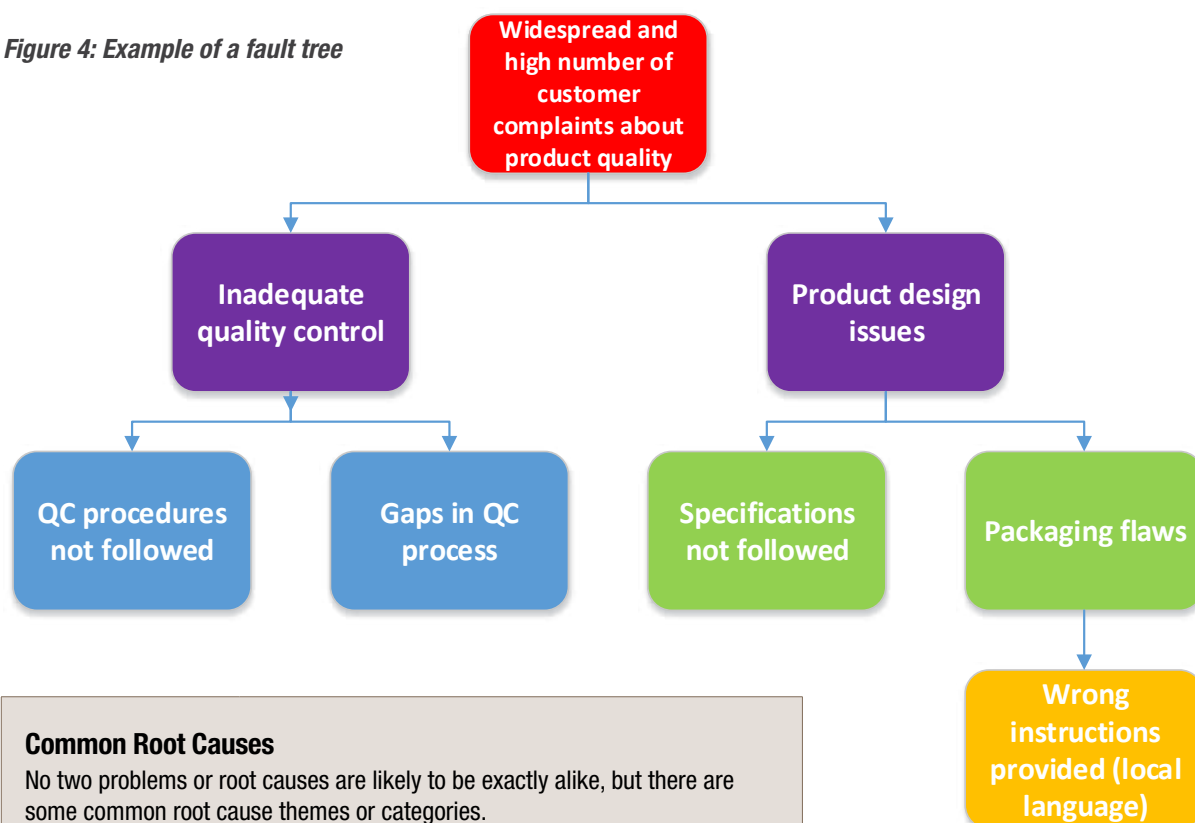
Using the fault tree involves five steps:
1. Define what went wrong or could go wrong
2. Understand the system in which the undesired event occurs
3. Construct the fault tree
4. Evaluate the fault tree
5. Design and implement controls for the identified hazards

Applying the case study in the fault tree (see Figure 4), the top of the tree describes the product quality complaints by customers. Separate branches of the tree identify possible causes for the quality complaints, and each of those branches divides into a second, and even a third, level of cause for the preceding branch. If a company is able to do this exercise in advance of a failure, it can hopefully identify the potential causes of a negative business result and put appropriate measures and controls in place to prevent it.

Figure 4: Example of a fault tree

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                    ┌─────────────────────┐
                    │   Widespread and    │
                    │  high number of     │
                    │     customer        │
                    │ complaints about    │
                    │  product quality    │
                    └─────────────────────┘
           ┌───────────────┴───────────────────┐
  ┌─────────────────┐               ┌─────────────────┐
  │   Inadequate    │               │  Product design │
  │ quality control │               │     issues      │
  └─────────────────┘               └─────────────────┘
     ┌──────┴──────┐                  ┌──────┴──────┐
┌──────────┐ ┌──────────┐      ┌──────────┐ ┌──────────┐
│    QC    │ │  Gaps in │      │Specifica-│ │ Packaging│
│procedures│ │    QC    │      │tions not │ │  flaws   │
│not       │ │ process  │      │ followed │ │          │
│followed  │ │          │      │          │ │          │
└──────────┘ └──────────┘      └──────────┘ └──────────┘
                                                   │
                                            ┌──────────┐
                                            │  Wrong   │
                                            │instruc-  │
                                            │tions     │
                                            │provided  │
                                            │(local    │
                                            │language) │
                                            └──────────┘
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Common Root Causes

No two problems or root causes are likely to be exactly alike, but there are some common root cause themes or categories.

Accountability	Ownership is unclear, leading to oversight failures.
Documentation	Required information is incomplete, missing, or inadequately recorded.
Fraud	Facts are intentionally misrepresented or assets are stolen.
Human Error	Intended activities are not executed or performed properly.
Inefficiency	Formal steps are not taken to define and routinely adjust processes to maintain efficiency and/or best practices.
Misaligned Operations	People, processes, and technology are not effectively aligned to achieve the common objective.
Monitoring and Oversight	Activities necessary to accomplish objectives are not monitored adequately.
Personnel Capabilities	People assigned do not have skills or training that match the expectations of the assigned role.
Physical Safeguards	Lack of physical safeguards over assets, including cash, inventory, controlled substances, or physical security like doors, windows, and fencing.
Policies and Procedures	Written, formal directions designed to enforce organizational behavior in a fashion that is aligned with the organization's goals and values is missing, outdated, or inadequate.
Segregation of Duties	Responsibilities are not split appropriately, creating a lack of checks and balances.
Strategic Miscalculation	Unanticipated event; miscalculation of environmental or other factors.
System Access	Access is not aligned with role because of inadequacies in set up, removal, or ongoing monitoring of users.
Technology Alignment, Design, Configuration	Systems implemented do not improve process efficiency and/or are difficult for untrained users to operate; systems are not configured to provide checks and balances.

Developing and implementing corrective actions

The purpose of root cause analysis is to establish or recommend corrective actions to mitigate the real problem and not just the symptoms of the problem. Clear and precise identification of a root cause or causes adds value by supporting effective corrective action, because it can educate management about why a problem exists and promote consensus for a corrective action.

Although quality root cause analysis can help prevent the recurrence of a problem when effective corrective action is taken, it will be clear that not all root causes were adequately identified or addressed if the problem recurs.

Once a problem's root causes have been identified, it is important to move quickly to develop and implement solutions to reduce the likelihood a problem will recur. The following questions should be considered during the development and implementation of a corrective action:

- Who should be involved?
- How much time will be needed to plan, develop, and implement a solution?
- Do the circumstances warrant redesigning the process, refreshing process documentation, or purchasing new equipment or technology?
- Who is responsible for making key decisions?
- Is there a timeline for the corrective action?
- Who will approve plans?
- Who will pay the bill, and how much will the solution cost?
- Who is keeping track of the budget and the planning and implementation timelines, as well as maintaining communication about the corrective action?

During the planning and implementation phases of the corrective action cycle, it is important to think broadly and strategically about who needs to be involved in the process. Planning and implementation are both activities that require ongoing, transparent communications with broad groups of stakeholders.

It is also valuable to keep a record of the team's decisions. A decision log is helpful if regulators, partners, or other external parties demand information about what was done, when, and why, as well as information about costs associated with the corrective action.

Validating solution effectiveness

After developing and implementing a plan that addresses the root causes associated with the identified problem, it is time to verify that the implemented solution has fixed the problem. Validating solution effectiveness requires three types of actions that occur at different times during the corrective action cycle:

1. During the root cause analysis, the team should verify that the analysis makes sense based on what is known about the specific situation.
2. During development and implementation, the team must verify that a robust plan is developed to address the root causes of the problem. A robust plan will include information such as who is responsible, who is accountable, what resources are required, what milestones are anticipated, and what new behaviors are expected.
3. To complete the corrective action cycle, the team needs to verify that the plan is implemented in a way to sustain the solution over time.

In our case study example, it may make sense to ask the Internal Audit team to include a periodic check into the sustainability of any solutions implemented to address the product quality gaps experienced after demand unexpectedly increased in North America.

It is important to keep track of the implemented solutions and the associated validation of the solution's effectiveness. This can be done through auditing, monitoring, or assessment. You may also wish to keep track of corrective actions taken across your organization on a more comprehensive level. Follow-up can be a challenge for organizations, especially when multiple corrective actions are underway. Technology can help to track corrective actions during and after plan implementation. Using technology allows an organization to track corrective actions more easily by step in the cycle, by due date, by issue type, by responsible party, and by business area.

If an outside regulator or other stakeholder requests an explanation of what happened, documentation will increase your credibility. You will be able to quickly and accurately describe the root causes of the problem, the fixes implemented to resolve the root causes, and the validation you did to make sure the problem was fixed. It also may be important to get advice from your legal counsel about documentation requirements, depending on the industry you are in and the specific lines of business of your organization. The Audit Committee and the board of directors also are interested in metrics associated with corrective action.

How to get started

Successful implementation of the corrective action cycle can help organizations find and fix systemic problems to either mitigate or prevent negative business results. After an issue has been identified, a thorough investigation with input from several perspectives should uncover the root causes.

Involve both key experts and individuals who may not consider themselves experts, but who routinely use the business process, in the evaluation of the associated issues. It is critical to understand how work is actually being done, since it is possible that employees are following a process other than what may be documented in the organization's records. As a part of the mitigation effort, take the time to update process documentation, if necessary.

Remember, regulators and key stakeholders expect organizations to be in a position to find and fix problems, and then to ensure that those problems do not recur. Be sure to evaluate the corrective action over time to make certain that the problem has not recurred. Routinely practicing root cause analysis is one way to increase the likelihood that your ethics and compliance program is effective over time. ✳

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