Forming a Corrective and Preventative Actions (CAPA) Program

A Publication for AGA Members

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Glossary (Key Concepts and Definitions)

Corrective and Preventive Action (CAPA) plan: A CAPA Plan is a collective process, or series of measures, to correct the immediate problem, to determine the cause or causes of the problem, and to develop and implement a plan to prevent the problem from recurring. *(Indiana University Research Guidance)*

Corrective and Preventive Action (CAPA) Program: The purpose of the corrective and preventive action program is to collect information, analyze information, identify, and investigate product and quality problems, and take appropriate and effective corrective and/or preventive action to prevent their recurrence. Verifying or validating corrective and preventive actions, communicating corrective and preventive action activities to responsible people, providing relevant information for management review, and documenting these activities are essential in dealing effectively with product and quality problems, preventing their recurrence, and preventing or minimizing failures. One of the most important quality system elements is the corrective and preventive action program. *(United States Food and Drug Administration, modified)*

Compliance: To meet prescribed acts, laws, and regulations. (Note: A non-compliance is a particular case of a non-conformance). *(AGA Whitepaper: Developing & Implementing a Quality Assurance Program for Natural Gas Operations)*

Conformance: An affirmative indication or judgment that a product or process has met relevant internal and external requirements (e.g., company defined specifications, standards, and contracts; and state and federal regulations). (Note: Conformance includes compliance). *(American Society for Quality (ASQ, modified))*

Correction: An immediate action to eliminate or remediate a detected non-conformance, defect, or other undesirable situation (e.g., if there is a fire in a trashcan, the correction would be to pour water on the flames until the fire is fully extinguished). *(ISO 9000:2015, modified)*

Corrective Action: An action taken, following an issue, to eliminate the cause(s) of an existing non-conformance, defect, or other undesirable situation in order to prevent recurrence. (e.g., if there was a fire that was extinguished in a trashcan, the corrective actions could include removing

the ashes to prevent a flare-up and removing the chemicals that caused the fire initially). *(ISO 9000:2015, modified)*

Effectiveness: 1) The state of having produced a decided upon or desired effect. 2) A measure of the appropriateness of the goals chosen and the degree to which they are achieved. *(ASQ)*

Key Performance Indicator (KPI): A statistical measure of how well an organization is doing in a particular area. A KPI could measure an organization's financial performance or how it is holding up against customer requirements. *(ASQ)*

Nonconformance: A violation of requirements, or the nonfulfillment of a specified requirement. *(ASQ, modified)*

Observation: A statement of fact made during an audit/review and substantiated by objective evidence. *(International Safety Management (ISM), modified)*

Plan-Do-Check-Act Cycle (PDCA): A four-step process for quality improvement. In the first step (plan), a way to effect improvement is developed. In the second step (do), the plan is carried out, preferably on a small scale. In the third step (check), a study takes place between what was predicted, and what was observed in the previous step. In the last step (act), action is taken on the casual system to effect the desired change. The Plan-Do-Check-Act Cycle is sometimes referred to as the Shewhart Cycle. The concept was popularized by W. Edwards Deming as the Plan-Do-Study-Act Cycle. *(ASQ, modified)*

Preventative Action: An action taken to eliminate the cause(s) of potential non-conformities, defects, or other undesirable situations in order to prevent future occurrence (e.g., if there had been a combination of chemicals that caused a fire in a specific trashcan, preventative actions could include ensuring separation of chemicals or a selection of a different model of trashcan to prevent flames). *(ISO 9000:2015, modified))*

Procedure(s): The steps in a process, and how the steps are to be performed for the process to fulfill a customer's requirements, usually documented. *(AGA Whitepaper: Developing & Implementing a Quality Assurance Program for Natural Gas Operations)*

Process: A set of interrelated work activities characterized by a set of specific inputs and value-added tasks which consists of a procedure for a set of specific outputs. *(ASQ, modified)*

Process Improvement: Actions taken to increase the effectiveness or efficiency of a process in meeting specified requirements. *(ASQ)*

Quality: Conformance to requirements. It is the characteristics of a product or service which uphold its ability to satisfy stated or implied needs. *(ASQ, modified)*

Quality Assurance (QA): Comprises those actions necessary to provide adequate confidence that products, processes, or systems comply with requirements such as regulations, internal procedures, and standards. The focus is on providing assurance that processes are adequate and effective. *(AGA Whitepaper: Developing & Implementing a Quality Assurance Program for Natural Gas Operations)*

Quality Control (QC): Comprises operational techniques and activities, including inspections, necessary to control the characteristics of a product or service (i.e., characteristics that can be measured against codes, drawings, specifications). The focus is on preventing defective products or services from being passed on. *(AGA Whitepaper: Developing & Implementing a Quality Assurance Program for Natural Gas Operations)*

Quality Management System: The organizational structure, procedures, processes, controls, and resources needed to achieve stated quality objectives. *(AGA Whitepaper: Developing & Implementing a Quality Assurance Program for Natural Gas Operations)*

Root Cause: An action or activity which results in a fundamental deficiency or non-conformance and must be permanently eliminated to prevent recurrence of the same or similar non-conformance; source where the nonconformance originates. *(AGA Whitepaper: Developing & Implementing a Quality Assurance Program for Natural Gas Operations)*

Root Cause Analysis: A process to identify causal factors, or the root cause. When the root cause is identified and corrected, the problem typically is fixed permanently. Without root cause analysis, solutions to the problem are often erroneous, and the problem could recur.

(AGA Whitepaper: Developing & Implementing a Quality Assurance Program for Natural Gas Operations)

Specific, Measurable, Attainable, Relevant & Time-Based (SMART): A SMART matrix is a communication and planning tool used to identify the specifics of actions or tasks. SMART stands for specific, measurable, attainable, resources, and time. *(ASQ)*

Executive Summary

This white paper aims to aid natural gas utility operators in the creation of a formal Corrective and Preventive Action (CAPA) program, as well as identify several leading practices in managing individual CAPA plans that may be valuable to natural gas utilities seeking to implement or improve their CAPA programs. To that end, this white paper seeks to be a useful resource for utility operators as they develop and implement a CAPA program that produces effective plans or, alternatively, as they seek to better align their current CAPA programs with industry standards and best practices. Properly managed CAPA plans can help ensure operators are effectively addressing pipeline risk while improving or enhancing an operator's safety and quality culture. Per API RP1173 and ISO 9001, CAPA programs and the individual CAPA plans apply the core principle of "Plan-Do-Check-Act" (PDCA) and the continuous improvement life cycle. Although informal processes may have some degree of effectiveness, formalizing and aligning operator processes with industry standards and leading practices can significantly help increase the benefits of CAPA programs.

1. Introduction

A CAPA program can improve productivity and performance by addressing problems identified by an organization utilizing individual CAPA plans which are a series of measures to correct immediate problems and to develop and implement plans to prevent those problems from recurring. The effectiveness of an organization's CAPA program is generally highly dependent on the quality of preceding investigations for each CAPA plan. Root Cause Analysis (RCA) may be done as part of an investigation to identify the underlying causes of a problem, incident, or event. A CAPA plan that addresses the root causes of a problem, incident, or event means actions taken are more likely to prevent recurrence. While a detailed discussion of the various processes and tools available to conduct an RCA is beyond the scope of this white paper, it is important to note that several types exist and vary in complexity. An organization should consider the potential risk of recurrence, as well as the effective use of resources, when deciding when to apply RCA or some other in-depth investigative technique as a precursor to a CAPA plan.

An effective CAPA program should aim to:

- Improve processes or methods.
- Achieve measurable improvement in the highest priority areas.
- Eliminate repeated deficiencies.
- Reduce operational risks.

An effective CAPA program typically achieves these outcomes by defining processes and tools to ensure that each CAPA plan is created using the same operational controls. Outcomes of the CAPA plans are measured for effectiveness and communicated to stakeholders by CAPA administrators. Each CAPA plan may relate to different parts of the process improvement cycle of "Plan-Do-Check-Act" (PDCA). For example, performance monitoring may help ensure that the planned outcome is achieved ("Plan-Do"). Corrective actions and preventative actions may help serve as the "Check-Act" portions of the PDCA cycle. In many ways, a typical CAPA program closely resembles the PDCA cycle:

- Plan – Based on analysis, determine the problem the CAPA plan is intended to address. What actions will be taken? By when? By whom?

- Do – Implement/take action per the CAPA plan.
- Check – Measure to verify that the actions implemented by the CAPA plan were effective at preventing a recurrence of the problem.
- Act – If the actions were not effective, initiate a new CAPA plan. If the plan was effective, the plan is closed or completed.

Effective communication of the CAPA program within the organization can drive further process improvement. When corrective measures or other improvements resulting from a CAPA plan are effectively tracked and monitored, stakeholders can see progress. As a result, silos are diminished and synergies are achieved due to the increased visibility of process improvements. There is also an increased opportunity within the organization for shared learning to occur and greater facilitation in building a culture of quality in which employees drive operational effectiveness through ongoing focus on procedural adherence and quality outcomes.

2. Why CAPA?

A CAPA program can help support the organization's safety and quality culture, help realize the benefits of operational change management, and help enable meaningful collaboration to advance both safety and operational excellence. A CAPA program can help the organization better identify trends, evaluate risk, and identify the appropriate actions to take, as well as helping ensure the effectiveness of recommended actions. A well communicated CAPA program helps enhance visibility across the organization and can help ensure that critical improvements are made and that these improvements have the intended impact.

A well designed CAPA program can be a major catalyst of change and is key to the reduction of operational risk. However, it is important to have guidelines for what the CAPA program covers. Organizations should be careful not to overextend their resources by requiring CAPA plans for every potential nonconformance. Overextending staff and resources may impact the quality, effectiveness, and value of implemented actions. Likewise, organizations should also avoid under-utilizing their CAPA program, which may result in the organization failing to adequately account for and mitigate potential risks.

CAPA programs are often associated with incident reviews along with other organizational programs, such as Damage Prevention. CAPA programs can be managed by a single business unit or by multiple business units. Examples of situations where organizations can utilize a CAPA program include, but are not limited to, event/incidents learnings, emergency drill findings, quality assurance/quality control findings, damage prevention investigation findings, self-assessment findings, and hazard corrections.

3. What Makes an Effective CAPA Program

An effective CAPA program must have strong leadership support and visibility across the organization to be successful. A procedure outlining the program should identify the executive sponsor of the overall program. Additionally, the program may be governed by a cross-functional steering committee, representing the portions of the organization that the CAPA effort is designed to support. The steering committee would oversee the program, including reviewing progress of open CAPA actions, ensuring visibility and transparency to the process, and resolving conflicts and resource constraints related to CAPA plan actions and proposed completion dates.

An effective CAPA program should define the requirements and processes of a formalized tracking system (see Section 6.4 for additional detail about tracking). It should include a reporting mechanism to communicate the status of individual tracked actions and overall CAPA program metrics. The sponsor or oversight committee should determine who in the organization will receive periodic status reports on the CAPA action items and how frequently they will be communicated. Such reports may include the number of open items, average age of open items, or items closed in the past 90 days. Organizations may also consider incorporating these reports into the Management Review cycle of the Pipeline Safety Management System and/or Quality Management System as applicable.

To achieve a proper balance, organizations should align their CAPA program to an organizational risk matrix and determine an appropriate plan deployment based on the level of actual or potential risk. In some cases, a correction may occur without the organization initiating a CAPA plan. However, a CAPA plan should be created for significant events identified by the organization. See

the glossary for further definition on the distinction between correction, corrective action, and preventative actions to ensure appropriate application of the CAPA program.

4. Administration of the CAPA Program

Responsibility for administration of the CAPA program should be clearly identified to ensure successful implementation and sustainment. The program can be administered by one specific business unit or numerous business units which have oversight to their own overall CAPA plan management within a tiered program. The CAPA program documentation should define which business units contribute to or manage the program, including any tools and processes that are required to ensure that the program is used consistently, and data is visible to all necessary stakeholders. A noncomprehensive list of business units that utilize and manage CAPA programs includes:

- Safety Department – For accidents, injuries, driving patterns, near misses, and operational safety field assessments.
- Regulatory Compliance – For Notices of Proposed Violations, findings or other issues identified by public service commission staff, PHMSA, NTSB, OSHA, EPA, etc.
- Office of General Counsel / Legal – For any potential litigation or liability issues.
- Quality Assurance (QA) / Quality Control (QC) – For nonconformances observed during QA or QC activities.
- Asset Protection – For damage prevention efforts.
- Material/Supplier Administration – For defective items, materials, or supplier issues
- Corrosion Control – For cathodic protection issues.
- Engineering – For design errors, or redesigns.
- GIS – For mapping errors, poor data quality, timeliness of mapping, etc.
- Internal Auditing – For processing audit results and findings.
- Operations, and Integrity Management – For additional and accelerated actions resulting from operations reviews and employee interviews.

Administrative duties related to the effective implementation and management of a CAPA program should include, but are not limited to, who can recommend and approve CAPA plan

action items, who can approve assignment to a specific action owner, how a proposed completion date is agreed upon, and whether a post-closure effectiveness evaluation will be required of an implemented action. Additionally, an effective CAPA program should identify who will have responsibility for:

- Generating and maintaining training for CAPA program users.
- Identifying and granting access for users where software programs are used to support the CAPA, in accordance with the administrative procedure controls.
- Supporting questions from users of the CAPA system.
- Closing CAPA plan action items once approved.
- Ensuring appropriate communication when action items are completed.
- Generating and distributing reports of the CAPA program health (number of open items, average age of item, items closed in past 90 days, etc.).
- Accountability for post-closure follow-up or implementation

Training requirements for all stakeholders should also be identified by the CAPA Program administration. Specific requirements will likely vary with the difficulty, importance, and consequence of the CAPA tasks, but should address the following training needs:

- Training on the program's intent, scope, expectations, and available tools.
- Training for those identifying CAPA plan action items on appropriate investigation techniques and risk evaluation.
- Training for issue and action owners on the workflow, resources, process documentation, expected metrics, and other requirements of their roles.
- Training for any approvers/decision makers on CAPA specific requirements that go beyond the minimum requirements of the job.
- Training for CAPA program team on program management, qualitative and quantitative methods for monitoring program effectiveness, CAPA program best practices from inside and outside the industry, and any other core job duties that are beyond the minimum requirements of the job.

5. Implementing a CAPA Program

A CAPA program can be narrow to serve the needs of a specific function or department (such as Pipeline Safety compliance) or have a wider scope to fit the collective needs of an organization. When implementing a CAPA program, the scoping procedure should clearly identify which organizational issues will fall into the program and how continuity will be maintained across all impacted programs. Within the context of natural gas operations, decisions in determining the scope of a CAPA program might include:

- Operational Issues – Staffing, equipment, tools, management initiatives, and management of change program.
- Pipeline Safety Compliance Requirements – Responses to written requests from federal, state, or local regulatory agencies.
- Program Reviews – OQ, Public Awareness, DIMP, TIMP, Drug and Alcohol.
- Safety Assurance Findings – Actions identified in the Pipeline Safety Management System.
- Quality Control/Quality Assurance Findings – Internal QA program, construction inspections, material inspections.
- External / Peer Reviews – External audits, external incidents, NTSB Reports.
- Safety Culture Assessments – Action items from safety culture events, surveys.
- Employee or Contractor Reporting Programs – Items submitted to the program.
- Stakeholder Engagement Surveys – Feedback from emergency responders, public officials, customers, landowners.
- Materials Quality Assessments – Supplier quality audits, failed material investigations, installed components identified as defective or subject to failure.
- Near Miss Reporting.

Once the scope of the CAPA program is defined, an effective CAPA program should have thresholds or triggers set for when a CAPA plan must be initiated. It should also allow for initiation of CAPA plans outside of these thresholds or triggers, as deemed appropriate. This empowers the organization to use the program, to proactively solve problems, and build a quality culture. Without

defined criteria, the organization may fall into the trap of enacting CAPA plans for non-critical problems or anomalies that are best resolved through a simple correction.[1]

The CAPA program should also identify issues that do not meet the scope for inclusion. Where applicable, this should provide line of sight to where these issues are tracked for remediation. For instance, an employee may report that a pressure control station needs to be painted. The CAPA program might indicate that the correction of deficient field conditions is not in scope but should indicate that the report was routed to a work maintenance system for remediation.

To ensure that open CAPA plan action items remain visible to the organization until completed, the CAPA program should include a reporting mechanism to communicate the status of individual tracked actions and overall CAPA program metrics. CAPA plan action owners and other identified management should have clear visibility to the status of items assigned to them, including the identified action, the desired due date, and a current update on the status of work being completed to implement the action.

5.1 Considerations for Implementation

Implementation of a new CAPA program requires the consideration of many factors, including communication about the program, piloting the new program, and training employees. Effective communication should occur in multiple stages and should come from various levels of the organization. In the early stages, communication focuses on the overall goal of the program and how it will benefit the organization. As the program is in development, information should be provided regarding the progress of the program, the requirement to change, and the risk of not changing. As the program moves towards implementation, communications should evolve to identifying roles, responsibilities, and impact to daily work.

Once implemented, communications should begin to incorporate training and information regarding the effectiveness of the CAPA program, as well as any changes to policies or practices. Piloting a new CAPA program is not required but may be useful to operators implementing a CAPA program. Piloting allows the organization to test the program, the procedures, and the

[1] See glossary.

training before rolling it out across the organization. Pilots can be built to test singular or multiple aspects of the program allowing essential feedback to tweak and improve the program. Not only can an organization pilot a newly developed program, but changes made to the program post implementation may also be piloted.

Training should occur throughout the implementation of a new CAPA program in a variety of ways. It should involve interactive sessions tied specifically to roles and responsibilities. It can include hands-on training, team meetings, and one-on-one sessions. An organization may choose to create a training program that incorporates reference materials along with interactive training modules that covers how the program works, explains basic concepts, and describes how to interact with the program. It is also important that training be completed as close as possible to when employees will begin to utilize the system.

Change management concepts with proper engagement and communication channels should be considered, especially when action items require long-term implementation that has impacts, initiates a cultural change or similar unknown opportunities.

6. CAPA Plan Life Cycle

Expectations and controls should be set for each of the steps involved in completing a CAPA plan to ensure consistency and effectiveness. A typical CAPA program may include the steps identified in Figure 1.

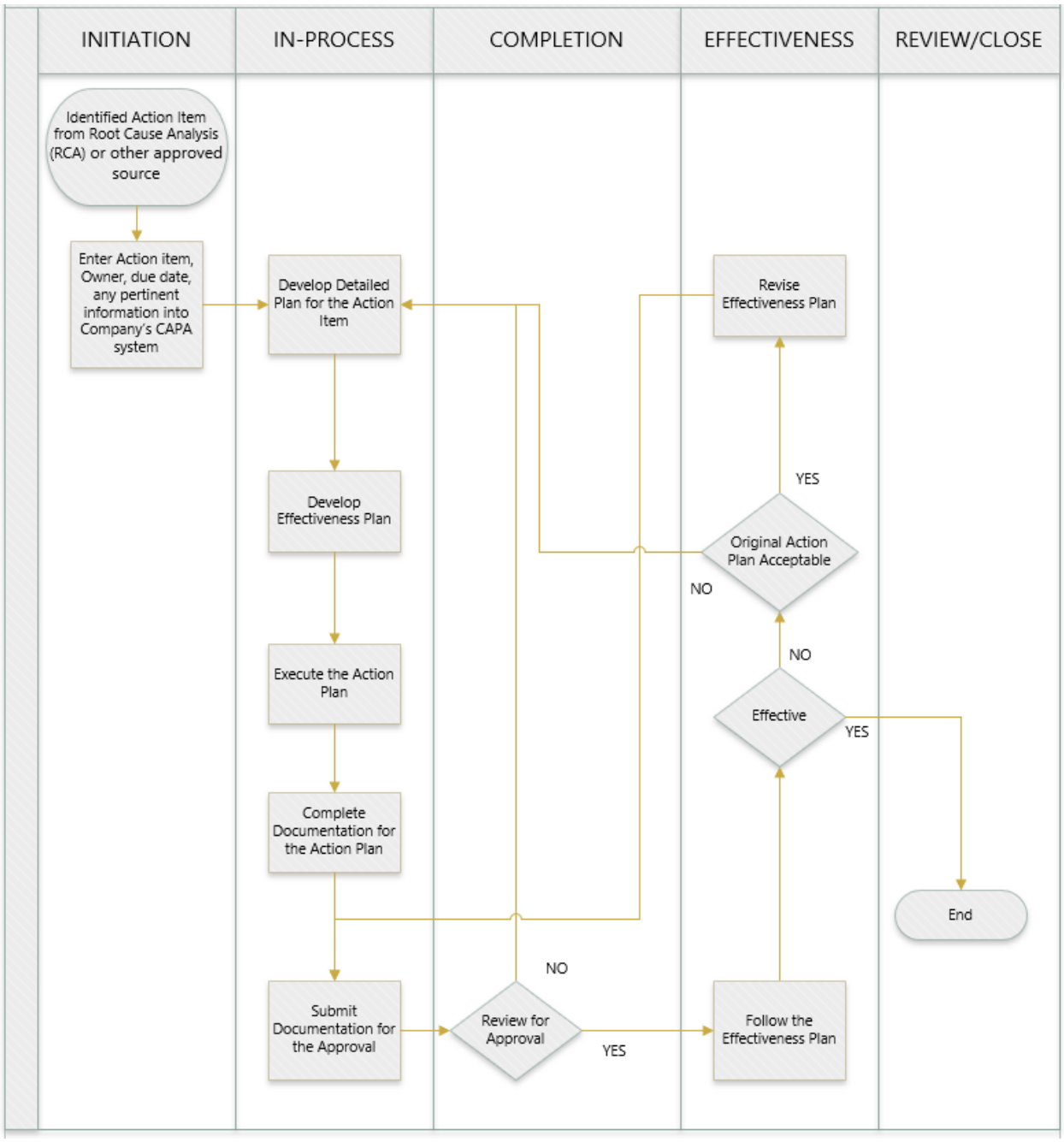


***Figure 1**: CAPA Flow Chart for Individual Action Item.*

Each organization must define their own process and requirements, but each CAPA plan is likely to include several steps.

6.1 Initiating a CAPA Plan

A CAPA plan is initiated in accordance with the defined process triggers. The problem being addressed by the CAPA plan should be clearly stated and defined. The organization should have a formal intake process for documenting the issue that includes a numbering or naming scheme to track/manage CAPA plans. This step also includes assigning an employee or employees to lead the development of the action plan.

The following are some areas that should be considered when establishing triggers to the CAPA program:

- Defect/rework/repair trends.
- Activities should align with defined process for PSMS including Incident investigations and learnings from past and external events.
- Analysis of emergency response activities.
- Identified safety concerns.
- Near misses, human error or identified training deficiency.
- Significant events as defined by the organization.
- Significant customer complaints.
- Internal and external audit findings.

6.2 Creating an Action Plan

The organization should define criteria for what constitutes an adequate action plan. Development of the action plan should be done with input/guidance from an individual knowledgeable with CAPA plan requirements to ensure it meets the defined criteria.

Some measures to consider in reviewing the action plan are:

- The actions are appropriate to the severity of the problem.
- Actions are identified to address the root causes identified (where there is an associated RCA).
- Actions are identified to address the existing problem (correction).

- Actions are identified to prevent the problem from occurring again (corrective).
- Actions are identified for related areas that could also have the same problem occur (preventative).
- Dates are provided for when the actions will be completed and are in line with the risk/severity of the issue being addressed.
- Plan identifies who is accountable for ensuring the actions are completed by the identified due date.
- Identification of what evidence will be provided to demonstrate completion of the actions.
- Identification of organization who is accountable for long term follow-up, implementation plan or support of action beyond the CAPA elements (i.e., new policy/process or updates, training, bulletin, communication).

Some additional guidance on ensuring the effectiveness of the proposed action plan:

- The most effective action plans will focus on elimination of the cause first, before focusing on mitigating the impact of potential reoccurrence.
- Actions should focus on the process, rather than on a specific individual.
- Use the SMART framework (specific, measurable, achievable, realistic, and time-bound) in developing actions to ensure they are clearly understood and easy to monitor.

6.3 Approving an Action Plan

CAPA plans should typically be reviewed and approved by the manager of the individual responsible for completing the action plan. This helps ensure that adequate resources (funding or human) will be available, and that actions and recommendations will be prioritized for completion.

The organization may consider also having plans reviewed by a CAPA review board or other responsible parties to ensure consistency and adequacy in accordance with the measures identified above. A cross-functional team is typically assembled for the CAPA review board, including members such as quality assurance, technical experts, field representation, leadership, and others,

to evaluate the impact of a CAPA plan on the organization. The CAPA review board can also provide input on prioritization and insight into where there may be overlapping action plans that could potentially be consolidated.

6.4 Tracking Completion

As determined in the program, the person(s) responsible for monitoring open action items should ensure they are being resolved in a timely manner. This can be done through dashboards, notifications, and, when necessary, escalation to higher management levels. The program should have a defined escalation process and thresholds for late or incomplete CAPA plans.

The program should also include guidelines for changing or extending action item timelines. Generally, the initial action plan approver and their direct leadership should be informed of any changes to the timeline. The organization should consider risk exposure due to extended time to correct and prevent issues, as well as resource prioritization.

6.5 Performing an Effectiveness Check

When validating the effectiveness of a CAPA plan, an effectiveness check is used to verify that the completed actions resolved the problem. An effectiveness check also minimizes reoccurrence risks and is useful in an organization’s continuous improvement efforts. It is the last step taken after identifying a problem and implementing the CAPA plan actions. If the effectiveness check determines that the problem has not reoccurred, the CAPA plan is considered successful. If, however, the problem has reoccurred, the CAPA plan has not resolved the problem and should be revisited. The effectiveness review should be performed by someone who is independent and unbiased, which may include someone external to the department or external to the company.

For effectiveness checks to provide value, they should be efficient with required resources. This may mean aligning the rigor of the effectiveness check to the risk level of the CAPA plan. In these cases, the changes with the highest risks are subjected to more comprehensive effectiveness checks (both in frequency and resources) and lower risk CAPA plans subjected to lesser or even no effectiveness checks.

Typical data sources that can be used to determine effectiveness of a CAPA plan include inspection reporting, audit results, and/or monitoring metrics that were put in place as a result of the CAPA plan or that originally highlighted the need for a CAPA plan. The intent of the CAPA plan is to significantly reduce the likelihood of the problem reoccurring which should be evident in a downward trend in any process monitoring or key performance indicator trends.

The timeframe for reviewing data trends and/or performing audit or inspection of the impacted process should be determined with consideration for the cycle time of the process. Enough data must be available for meaningful measurements and analysis. Further, the effectiveness check should allow sufficient time for the organization to have completed training on changes instituted as part of the CAPA plan.

Effectiveness checks should be performed in a timely manner. Keeping CAPA plans open for long periods of time due to their effectiveness checks can negatively impact quality indicators that are related to CAPA plan age. If effectiveness checks are not prioritized, this can lead to a CAPA program that appears to be improperly managed as well as disengagement from end users.

6.6 Closure

The CAPA program should define those responsible for closing a CAPA plan and what records must be kept. As CAPA plans are closed, the CAPA program should feed back into any established risk registers. Effective CAPA plans should lower the organization's risk exposure by implementing appropriate controls or by reducing their likelihood. The organization responsible for continuation or implementation of the lessons learned or best practices should be identified when closing a CAPA.

7. CAPA Program Tools & Software

Throughout the CAPA process, the organization may employ various tools and systems to facilitate completion of the plan. Additionally, these tools could include facilitating reporting and information sharing for the overall CAPA program.

7.1 Forms/Templates

The organization should develop standard forms and templates to be used for each CAPA plan. This will ensure that the key deliverables of the program are achieved as defined. For example, see the CAPA plan sample format in Appendix A.

7.2 Software

There are many software solutions available for helping to track and manage CAPA programs. Consideration for ease of use and adaptability to suit established processes of the organization should be included in selecting a software system. Although using established software may help facilitate trend analysis and program oversight, use of software dedicated to this purpose is not required for an organization to implement an effective CAPA program.

7.3 Dashboards/Reporting

The organization should consider development of a programmatic dashboard or centralized reporting system for their CAPA program. The system should provide, at minimum, the necessary information for the various stakeholder groups, including status of open CAPA plans and upcoming due dates. As a CAPA program matures, this may include establishing and monitoring program key performance indices, analysis on recurring issues, common causes, and a tie-in to risk registers.

8. Continuous Improvement of the CAPA Program

Continuous improvement of an organization's CAPA program is critical to the program's effectiveness. As part of the initial program design and development of the CAPA program, key objectives should be defined that correspond to measures of program effectiveness and success. Reviewing those regularly along with other key indicators provides information that can be used for changes to program requirements, procedures, and other program features. In all cases, CAPA program reviews should be conducted formally, including an agenda, objectives, data provided, and decisions and action items documented. The program reviews and updates should also reflect evolving industry standards, technologies, and best practices.

The specific metrics included in a CAPA program review will depend on data availability and the maturity of the program. During CAPA program implementation, the metrics are focused primarily on adoption and ensuring that the program is taking root in the organization. Data insight and visualization is also likely taking shape and will focus on basic but important measures such as:

- How many CAPA plans were initiated and in what distribution. Employee vs. leader vs. contractor, geographic regions, workgroups, number of repeat submitters, etc
- Identification of any CAPA plans routed to other workstreams - Safety issues, IT issues, etc.
- Log of CAPA plan progress - Time between submittal and action, action item due dates/progress, number of CAPA plans in each step of the process, etc.
- Breakdown of individuals involved in each CAPA plan and adherence to the process - Steps followed as required, indicators of competence and confidence in performing CAPA program responsibilities as assigned, etc.

As the CAPA program matures, the organization can shift to focus on the effectiveness of CAPA efforts, first at the item level, and eventually maturing to monitoring the risk and safety impacts of the CAPA program across the organization. At this stage, the data analytics may get more sophisticated, and potential measures may include indicators such as:

- The effectiveness of actions immediately following resolution.
- Ongoing monitoring of the sustainability of actions.
- More detailed review of CAPA plans themselves (trending of causes, key words, suppliers, processes, etc.).
- User experience feedback for those participating in the program to make it more usable, effective, and efficient.
- Review of alignment between CAPA plans being addressed and overall business priorities to ensure the CAPA program is suitable.
- Identification of trends (key words, consistent causes, assets identified, etc.) that may indicate a need for a larger, more global CAPA plan.

The process for reviewing the CAPA program should include monitoring of both tactical and strategic performance. Each organization will need to determine the correct cadence for their organization based on the maturity and scale of the CAPA program. However, there should be regular reviews that ensure the program is tactically functioning as intended. Data shared should include lagging indicators and should be shared with program owners and stakeholders with direct responsibility for the program.

The process of reviewing the strategic performance of the CAPA program should be done consistently. In the review, the performance of the program should evaluate whether the stated objectives are being met, including impact on the risk level of the organization if possible. Organizations should consider a cadence at which the program is reviewed by other qualified individuals external to the program, either internally or by a third-party organization, to provide ongoing alignment to best practices and ensure unbiased feedback.

Appendix A: Sample CAPA Plan Format

CAPA Overview Summary Information

This is a high-level overview of the CAPA activities. It is completed and updated at appropriate points in the CAPA process.

Problem Statement:

CAPA Risk Rating *Align with risk procedures. Keep updated as risk is re-assessed.*

Impact

☐ **Low** ☐ **Medium** ☐ **High**

Impact Description

Severity

☐ **Low** ☐ **Medium** ☐ **High**

Severity Description

Proceed with CAPA?

☐ **Proceed** ☐ **Not Proceed**

Justification for Not Proceeding to CAPA *If not proceeding, document justification and send for approval*

Name/Title Providing Justification: _____ Date: _____

Approval for Closure without CAPA: _____ Date: _____

CAPA Team Members and Responsibilities *If proceeding, assign CAPA owner to begin CAPA activities. Update team members as they are added to the CAPA*

Name/Title	CAPA Team Function
	CAPA Owner

Chronology of activities with dates for the CAPA *Update at a frequency dictated by the work being accomplished.*

Date	*Activity, Decision, or Milestone*

Duplicate the next sections ("ACTION ITEM" & "EFFECTIVENESS CHECK") for each corrective action and preventative action

Action Item

☐ **Corrective Action** ☐ **Preventative Action**

Action Plan #	**Action Responsible Person**	**Action Completion Due Date**

Corrective Action Plan and/or Preventative Action Plan

Objective Evidence of Completion *Provide supporting objective evidence to confirm the corrective action(s) and/or preventative action(s) has been completed*

Approval of Completed Action Item

Name/Title of Approver: _____ Date: _____

Effectiveness Check

EC #	**Effectiveness Check Responsible Person**	**Effectiveness Check Completion Due Date**

Effectiveness Check Plan

Objective Evidence of Effectiveness Check *Describe how effectiveness was verified.*

☐ **Effective**

☐ **Ineffective**

If ineffective, document path forward and rationale.

Approval of Effectiveness Check

Name/Title of Approver: _____ Date: _____