Getting the Most Out of Your Closed-Loop Corrective Action Process

Whether you have implemented an accepted methodology, such as PDCA, DMAIC, or 8D, or use a custom process tailored to your needs, your CAPA or FRACAS management system contains a wealth of information. Most often, corrective action management tools are not extended beyond their main purpose: process tracking and control. However, due to the breadth of data encompassed, your closed-loop corrective action system can offer a wide range of insights and metrics that add even more benefits. In this article, we will discuss a few that can be discovered.

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What is a Closed-Loop Management System?

A closed-loop management system is a process to manage, track, and correct problems or issues. The process begins with problem report and identification, progresses through identifying a corrective action, and finally to implementing the corrective action to resolve the issue. Product-centered companies, large to small, engage in some type of closed-loop corrective action (CLCA) process. It may be formal or not, tightly controlled or loosely developed, but it exists in some manner.

The core of any closed-loop system is the step-by-step process of problem identification to problem resolution. If any step of the process is not completed – a problem is not recorded, a corrective action is not identified, a corrective action is not implemented – the loop is broken. Far too often, experiences with a broken loop lead organizations to implement a controlled, trackable closed-loop system. Over time, most companies realize the necessity of implementing a system to effectively manage the handling of reported issues. While the processes established vary tremendously, most corporations have settled on some type of software system to track and manage issues as they arise.

Closed-loop processes extend to a wide range of business areas: product testing, non-conformance reporting, compliance requirement tracking, handling product failures in the field, tracking manufacturing defects, and many other examples. In essence, your organization may have various types of processes to track and manage. While the type of issues being managed may vary, the general process remains relatively the same: an issue is reported, and then the problem is corrected in some manner. The number of steps between initial logging and final closure varies depending on your organization, your needs, the complexity of the process, the number of people involved, and, in some cases, compliance requirements. Additionally, the processes often develop and change over time as needs and requirements evolve.

Closed-loop Process Management Methodologies

The most common terms used for this type of process management system are CAPA or FRACAS. CAPA (Corrective and Preventive Action) and FRACAS (Failure Reporting, Analysis, and Corrective Action System) are built on a step-by-step approach to process control. The objective behind CAPA and FRACAS, or any process management methodology, is *quality improvement*. By implementing an effective closed-loop corrective process in your organization, you can be assured that problems are being addressed and corrected. Ultimately, an efficient closed-loop system results in better quality, as well as providing a mechanism for continuous quality improvement.

There are many commonly recognized and accepted methods for control and continual process improvement including 8D, PDCA (Plan-Do-Check-Act), and DMAIC (Define, Measure, Analyze, Improve, Control). For more information about process control methods, and a description of the 8D steps, read more at Relyence FRACAS Process Control.

For this article, we will use the term *FRACAS* to denote any corrective action system for ease of readability, but the concepts apply to whatever system you have in place.

Are You New to FRACAS?

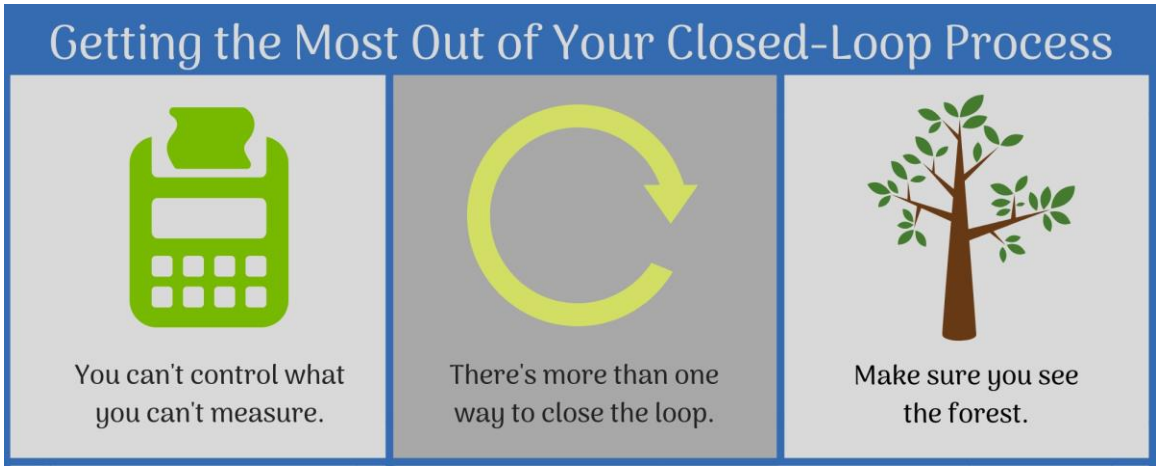
If you are new to FRACAS and have not yet implemented a structured process management system, you can review a number of articles posted on the Relyence web site. You can also learn how you can benefit from using a FRACAS software tool to manage your process. Read more at New to FRACAS?, Is it CAPA or is it FRACAS? , and Relyence FRACAS Product Page.

Discover What's Hiding in Your FRACAS Data

Whether you have implemented a defined methodology, or one customized to suit your needs, your corrective action system contains a wealth of information. Most often, the FRACAS process is viewed based on its main purpose: tracking and control. However, due to all the data captured and available in FRACAS, there are many different lessons and metrics that can be gleaned to gain even more benefits from FRACAS. In this article, we will discuss a few that are often overlooked. There are even more than this, and we encourage you to consider ways to extend your FRACAS information to offer even more insight to further improve quality.

We will delve into three key concepts:

1. You can't control what you can't measure.
2. There's more than one way to close the loop.
3. Make sure you see the forest.



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You Can't Control What You Can't Measure

At its core, FRACAS is a process management system. Because of this, the ability to apply metrics to your data is often overlooked. You may already be tracking valuable data that can offer the ability to measure the effectiveness of your product or system, as well as provide valuable insight into the effectiveness of your FRACAS itself. Or, by making some minor modifications to your FRACAS by collecting a few more data parameters, you can enhance your ability to track and measure a number of metrics.

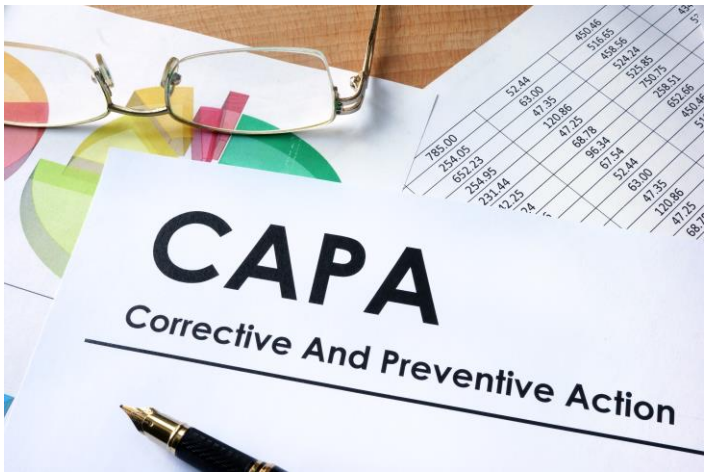
Is Your Process Effective?

First, consider ways to use metrics to assess your process itself. For example, you typically know the date of occurrence, or at least the reported date, of an issue. If you also track the date of close out, you have the ability to measure the length of time it is taking your team to handle issues. Once this is known, you can then augment it with additional measures by asking more probing questions, such as:

- What is the closure interval over time? Are you getting quicker at resolving issues?
- Are certain team members able to close issues faster than others? Do you need more training for some team members?
- Is the number of incidents increasing over time? Do you need more team members to keep your customers happy?
- Are your issues getting held up at a particular process step? Does your process need to be reevaluated?

Can You Improve Your Product?

Secondly, consider ways to use FRACAS information to measure your product or system performance. For example, some FRACAS tools enable you to track time information alongside your FRACAS data. You can include information such as operating units and operating time. Combining time-based data with your incident reports enables you to take your FRACAS to the next level and track and measure your product performance.



For example, your FRACAS can be used to compute field-based failure rate and MTBF (Mean Time Between Failure) values. Over time, these reliability metrics become more refined as your data sample grows and becomes a more accurate reflection of product performance. Having these measures in hand enables you to determine if your product is experiencing more failures than expected. It also allows you to proactively make product adjustments if needed.

Along with incident or failure reports, your associated repair information can be utilized to provide additional insight into corrective actions being taken. With repair data captured in FRACAS, you can compute field-based MTTR (Mean Time to Repair). Combining the repair time with operating time information, you can also compute MTTF (Mean Time to Failure) and even availability. Once again, this valuable insight enables you to get an early assessment of your product's repair related metrics.

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There's More Than One Way to Close the Loop

A closed-loop corrective action system ensures that information is captured so that team members can effectively identify and solve issues. The information logged and the process steps vary, but the main objective of a FRACAS is to ensure the loop is closed and issues are resolved.

Typically, the implementation of a FRACAS is based on the need to close the loop. Perhaps issues are not getting handled, perhaps responsibility is not being appropriately assigned, perhaps there is no mechanism to track that a problem has been resolved. Whatever the reason, a corrective action management system is a widely accepted method in many industries for eliminating these problems.

However, there are yet even more "loops" than can be closed once a FRACAS is in place. When thinking of a FRACAS as a part of your reliability and quality continuous improvements efforts as a whole, you can see how FRACAS can work in conjunction with other tools. For example, your reliability and quality efforts may incorporate Reliability Prediction, Maintainability Prediction, FMEA (Failure Mode and Effects Analysis), and Weibull analysis.

Reliability Prediction

If you perform Reliability Prediction, you have a valuable set of metrics from these tools: predicted reliability values such as MTTF, MTBF, failure rate, and availability. Using FRACAS to evaluate your product metrics as described earlier, you also have a matching set of field-based reliability values. By comparing the two, you have insight into whether your predicted values are in line with your deployed product.

Additionally, some Reliability Prediction standards, such as Telcordia and 217Plus enable you to adjust failure rates using data obtained from testing or from the field, such as that available from data captured in your FRACAS. The ability to augment your Reliability Prediction analyses with this additional information enables you to fine tune your predictive analyses.

Closing the loop in this manner enables you to start with your Reliability Prediction analysis, move onto FRACAS when your product is manufactured and installed, and then finally, go back and evaluate or reassess your prediction based on data captured in the field. This information can help you gain insight into how you can improve your future reliability prediction analyses, as well as improve the reliability of your deployed product.

Maintainability Prediction

If you perform Maintainability Prediction analysis, you have a similar situation as described for Reliability Prediction. From your Maintainability Prediction, you have a set of predicted values related to repair and maintenance, such as MTTR. From your FRACAS, if you have implemented the repair and time-based data collection described earlier, you have a matching set of actual field-based statistics. Once again, you can compare your predicted values to the actual values you are experiencing in the field.

Closing the loop in this manner enables you to start with your Maintainability Prediction analysis, capture repair metrics you see in your fielded product in your FRACAS, and then go back and reevaluate your prediction based on FRACAS-determined repair values. You can then utilize the lessons learned to refine future maintainability prediction analyses, and ultimately improve your repair processes.

Weibull Analysis

If you do not perform predictive analyses, or any type of pre-production analysis, you may only have at your disposal "life data". Life data analysis is evaluation and analysis of actual product operation, or product life. Weibull analysis is also called Life Data Analysis because it analyzes actual product failures over time.

With FRACAS, you have product life information – the performance of your product during operation. FRACAS captures the failures of your product, and can include the associated time data. Using FRACAS, you can use this data to create a Weibull data set. The Weibull data set includes information about failure times, and can include information about units operating without failure as well. The resulting Weibull data set then allows you to evaluate your product using all the techniques available to you with Weibull analysis.

Weibull analysis performs curve-fitting techniques to your data points. Using the resulting plot, you can view the probability curve of your product performance over time, including future time points. In this way, Weibull is used as a predictive tool. The value of using Weibull analysis with your FRACAS data is that you can spot trends, assess the situation before issues become larger problems, and proactively make product corrective plans.

FMEA

If you perform FMEA or FMECA (Failure Mode, Effects, and Criticality Analysis), you can integrate these failure mode assessments with FRACAS to enhance the benefits of both. Oftentimes, the interaction of these two tools – FMEA and FRACAS - is overlooked. This is due to several factors, such as the fact that the analyses are typically done by different team members, or possibly different groups within your organization.

However, by reviewing the data captured in the two analyses, their commonality is revealed. Some examples:

- Failure Mode: Failure Mode is one of the main data elements in a FMEA. Very often, the failure mode is also included in the FRACAS, sometimes even in a data field perhaps broadly labeled "Description of Failure". Including a distinct "Failure Mode" data field in your FRACAS may be helpful to aid team members in evaluating a clear failure mode of a reported incident. The value of this is that it enables you to more clearly connect similar incident

reports – all those with the same underlying failure mode can be grouped for common analysis and resolution.

- Cause: Cause is typically a data field logged in both FMEA and FRACAS. It is meant to be a descriptive field that denotes the root cause of failure.

- Action: "Action" data fields may have various names, and in fact there are different types of actions. In this case, the "Recommended Action" or "Recommended Corrective Action" field is a point of similarity between FMEA and FRACAS. In the case of FMEA, a possible failure mode is identified through design analysis and then a recommended action in order to correct or mitigate the failure is determined. In the case of FRACAS, a failure is logged due to an actual event in the field, and, similarly, the "Action Taken" in order to correct or mitigate the failure is recorded.

Closing the loop between your FMEA and FRACAS is powerful way to ensure you are getting the most out of both your products – essentially ensuring lessons learned are not lost. Questions you can answer by using FMEA and FRACAS in conjunction with each other include:

- Did you capture all possible failure modes in your FMEA? Have new failure modes been identified in your FRACAS? If they have, do you need to go back and update your FMEA with the newly captured data?

- Did your FRACAS uncover new causes of failures that were not identified in your FMEA? Do you need to go back and update your FMEA?

- Were the recommended actions completed from your FMEA sufficient? Are further actions required to more effectively handle a failure uncovered in the field? Do you need to go back and update your FMEA?

Closing the loop between your FMEA and FRACAS using capabilities such as Failure Direct Connect™ from Relyence can be advantageous for all your future design revisions and future products. Start with your FMEA, and then use your FRACAS to identify those failure modes, causes, or actions that were either unaccounted for or insufficiently analyzed in the original FMEA. Then, update your FMEA to capture those lessons learned in FRACAS. Your newly updated FMEA can then be used as a knowledge bank as you move onto your next generation products. You can be confident that you have a solid starting point for your next FMEA.

3

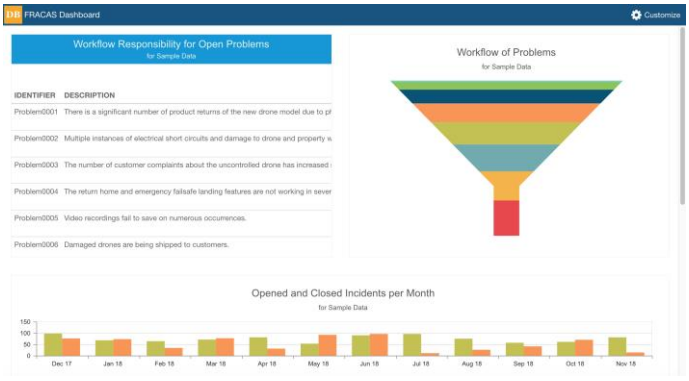
Make Sure You See the Forest

Lastly, one of the most advantageous ways you can capitalize on your FRACAS data is to remember the old adage: Make sure to see the forest through the trees. FRACAS data capture and tracking is a step-by-step controlled process. Team members are focused on the items they are responsible for and then moving the issue through to the next step, all in an effort to ensure incidents are resolved. And, indeed, this is the central role of FRACAS.

Sometimes it is difficult to stop and take a more holistic view of your FRACAS. This means stepping back and reviewing your overall process from a high level. By doing this, you may be pleasantly surprised at your efficiency and effectiveness, which means your team is on task, and capably handling issues. However, you may spot something that stands out as an area in need of improvement, or perhaps even a trend that you want to proactively address.

Dashboard

One method to get a system-wide overview is to use a dashboard. Dashboards provide high-level visual assessments and condense information into an easily digestible format. Oftentimes, dashboards are considered a management-level type of feature. And, this is a true value – managers are able to review overall measures and do not need to get into the details unless they want to.



However, think about using a dashboard at an individual level or a team level. How many issues have I been responsible for? Is my team closing out issues in a reasonable time frame? Are we getting more issues than we can effectively handle? Is one component of our product

more problematic than another? Can I make a recommendation for product improvement based on what I have seen?

Dashboards provide high-level insight that can often go unnoticed when you are dealing with day-to-day tasks and trying to interpret a large amount of data.

Trend Analysis

Trend analysis can provide valuable insight into your product health and performance. A trend score is an indicator of whether your system is improving, remaining stable, or degrading over time. Trend score can be computed based on FRACAS failure reports and operating time information.

A trend score of zero indicates your system is in a relatively steady-state condition, meaning your incident report rate is remaining fairly constant. Negative trend scores indicate a decreasing incident rate, or an improving system. Positive trend scores indicate issues are increasing, or a degrading system.

Trend scores provide a simple, quantitative approach to help you assess and evaluate your system's health, enabling a proactive approach to maintaining your quality goals.

Conclusion

FRACAS is an invaluable tool for corrective action closed-loop process management. All organizations gain tremendously by implementing a FRACAS as a stand-alone tool. The ability to effectively monitor issues from identification through to resolution is vital to business success.

FRACAS can also be used a building block to gain even further benefits for your organization. Your FRACAS contains a wealth of data that can be used for more extensive product evaluation or system performance measurement. Building on information you are already capturing to maximize its use will help you get the most out of your closed-loop corrective action management system. Extending your FRACAS provides you with an even more proactive and powerful approach to fulfilling your quality goals. Relyence FRACAS supports all the techniques presented in this paper. For more information, contact us or try it out for free.