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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Table of Contents

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 a reported problem or issue, 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. Experience with a broken loop can occur far too often, and can lead to organizations implementing 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 action 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 products and processes, 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?

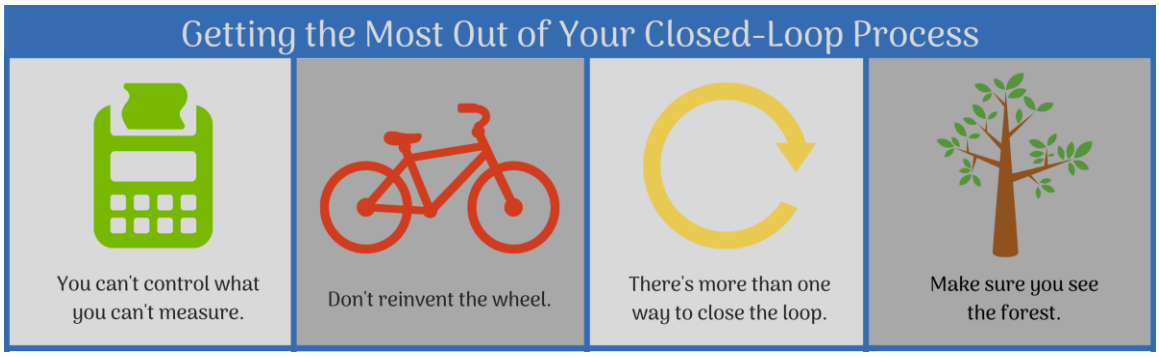
If you are new to FRACAS and have not yet implemented a structured process management system, you can review a number of articles posted on the Relyence web site. You can also learn how you can benefit from using a FRACAS software tool to manage your process. Read more at New to FRACAS?, What is FRACAS?, 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. As expected, FRACAS is used primarily for its main purpose – as an issue tracking mechanism. However, due to all the data captured and available in FRACAS, there are many different lessons and metrics that can be extracted 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 four key concepts:

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



1

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 and collecting a few more data parameters, you can enhance your ability to track and measure a number of metrics.

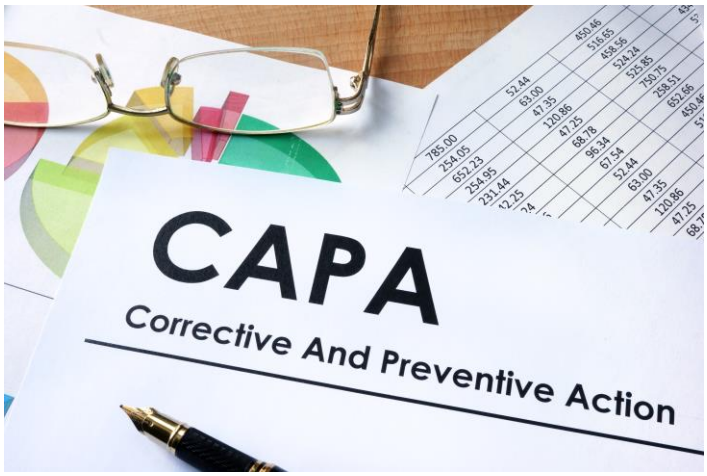
Is Your Process Effective?

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.

2

Don't Reinvent the Wheel

Most commonly, the FRACAS process takes place after a product has been designed and is in use in the field. Because the team members involved in early product design are usually not part of the team responsible for FRACAS, it makes knowledge sharing between the two a challenge. To efficiently retain and share critical knowledge, it is advantageous if the two teams can share data with each other. By pairing your FRACAS process with data from your design team, a more cohesive closed-loop process can be obtained.

There are two main scenarios that arise when a field failure occurs – either the failure has been accounted for by the design team or it is a newly discovered failure. In both cases, the design and FRACAS teams mutually benefit from sharing information with each other.

Was this Failure Anticipated?

During the product design phase, engineers often perform FMEA (Failure Mode and Effects Analysis) to identify potential system failures and design ways to eliminate or mitigate critical failures. Having this list of anticipated failures available to the FRACAS team during incident logging can be very beneficial to avoid reinventing the wheel when it comes to failure data within an analysis.

First, if the FRACAS team can access already identified failure modes, data logging is quicker. Secondly, using this shared data allows for much needed issue reporting consistency. Additionally, failures logged by the FRACAS team can then be shared back with the design team. This information can be used to verify the risk elimination or mitigation efforts are successful, or if not, how they can be improved upon.

Some questions that may arise from failure information from FRACAS:

- Are failures occurring more frequently than anticipated? In this case, the design team could suggest additional measures to mitigate future failures. For example, implementing more frequent maintenance checks.

- Are failures occurring too frequently? Are failures more costly to repair than anticipated? The design team could suggest a redesign of the product with a bigger emphasis on correcting the problematic failures that were uncovered from FRACAS data.

- Were the recommended actions completed from your FMEA insufficient to handle the failure? In this case, the design team can add to or update the recommended actions to better manage future failures.

In addition to the above questions, there is one other common scenario that may arise when sharing data between FMEA and FRACAS teams. For failure modes or causes previously accounted for in FMEA, there are cases where a FRACAS team member may be unaware or miss the appropriate FMEA data and will log new failure information where it is unnecessary. By sharing this information with the FMEA team, they may see that the new failure data fits within the existing FMEA document. For cohesive and precise failure tracking, the FMEA team can update this data and share back with the FRACAS team. This ensures failure information remains consistent and critical failure metrics are accurate.

Was this Failure Unforeseen?

Ideally, all potential failures would be identified during the design process and properly accounted for prior to manufacture or release. Unfortunately, that is rarely the case and there are new failures that are discovered once a product or system is in the field. This could be completely new failures that are uncovered in your FRACAS process or new consequences of failures that were not identified in the

design stage. At this point, the question becomes – does the design team need to go back and update the FMEA with the newly captured data?

In an effective FRACAS process, the new failure data will be recorded with appropriate field details such as how the failure occurred, its severity, how long the repair took, etc. This is all important information to share with the design team. From there, the design team can choose to:

- Add new failures that were uncovered during the FRACAS process and determine appropriate recommended actions.

- Update existing failures with new consequences that were uncovered during the FRACAS process and determine if additional work needs to be done.

If the design team has visibility into the FRACAS data, redesign or product improvement efforts will achieve their maximum benefit.

Closing the Loop with FMEA-FRACAS Integration

As mentioned, a common tool used during product design or process creation is FMEA. When performing any type of FMEA, including DFMEA (Design FMEA), PFMEA (Process FMEA), FMECA (Failure Mode, Effects, and Criticality Analysis), and AIAG & VDA FMEA, you can integrate your failure mode analyses with FRACAS to maximize the benefits of both. Oftentimes, the interaction of these two tools – FMEA and FRACAS - is overlooked. However, by reviewing the data captured in the two analyses, their commonality is revealed. Some examples:

- Failure Mode: Failure modes are 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 identifying a clear failure mode of a reported incident. This enables you to more easily connect similar incident reports so that all those with the same underlying failure mode can be grouped for common analysis and resolution.

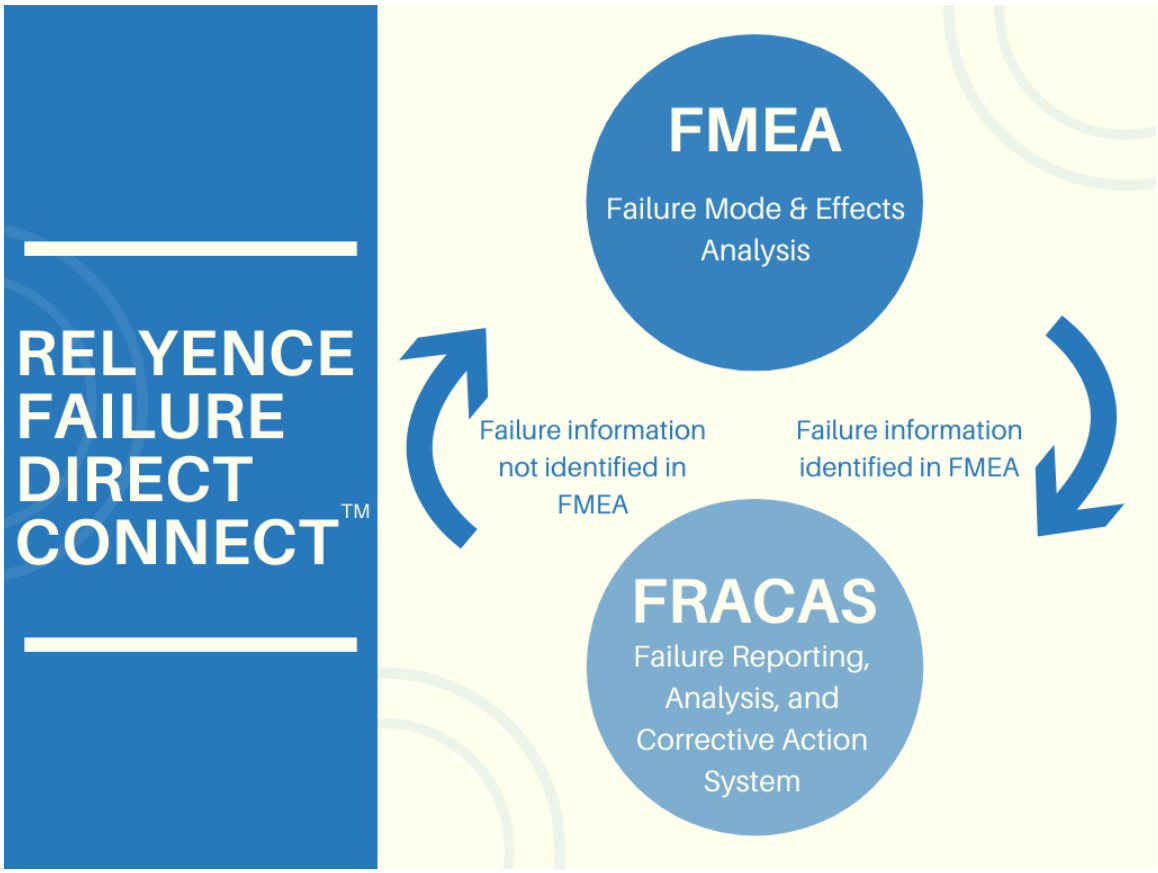
- Cause: Cause is typically a data field logged in both FMEA and FRACAS. It is meant to be a descriptive field that denotes the root cause of failure.

Sharing this data provides for more consistency across your analyses and allows for more cohesive product improvement planning.

- 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. Once again, sharing this information can aid both teams in developing more effective corrective action plans.

By sharing the appropriate data between FMEA and FRACAS, you establish a process where your design and field teams are communicating directly with each other. You are able to leverage knowledge from both teams to create a more effective risk management and failure tracking system. It's a clear way to avoid reinventing the wheel!

Closing the loop between your FMEA and FRACAS using capabilities such as Relyence Failure Direct Connect™ is a powerful way to ensure you are getting the most out of your analyses – essentially ensuring lessons learned are not lost. 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.



By keeping your FMEA and FRACAS data in sync, you not only create a closed-loop system for failure analysis, but also gain an invaluable tool for future design revisions and products. You will no longer need to start from scratch for new product designs, but instead you can leverage the lessons previously learned as a starting point. You can be confident that you will be starting on a solid foundation for your next FMEA by knowing which design aspects previously worked, what failures modes to focus on, and which recommended actions were most effective.

3

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" that can be closed once a FRACAS is in place. When thinking of a FRACAS as a part of your reliability and quality continuous improvement 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, FTA (Fault Tree Analysis), Weibull analysis, and RBD (Reliability Block Diagram) analysis.

Reliability Prediction

If you perform Reliability Prediction, you have a valuable set of metrics: 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

In cases where you employ 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 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.

Fault Tree Analysis

When Fault Tree analysis (FTA) is part of your reliability and quality analysis protocol, you have a powerful tool that can be used as part of your Root Cause Analysis in the FRACAS process. FTA is most-often used as a predictive tool during a product's design stage to analyze critical events and develop risk-mitigation strategies, however it can also be integrated with field failure data from FRACAS to serve as a Root Cause Analysis tool.

In many FRACAS processes, issue management is a two-step process. In the first, customer issues and associated field failure data are logged in a database. If enough issues from the same cause arise, the second step, which involves Root Cause Analysis and Corrective Action Implementation, is initiated. It is at this point where well-known FRACAS methodologies, such as 8D, DMAIC, and PDCA are often employed. To implement FTA as a Root Cause Analysis tool, the field failure can be treated as the top-level event in the diagram. Using the collected field information, Root Cause can be determined using Fault Tree's top-down, deductive risk analysis approach.

If used as a predictive tool in a similar fashion to Reliability and Maintainability Prediction, predicted values for Failure Rate, MTTR, MTBF, etc. of certain Fault Tree events can be compared with field-based metrics from FRACAS. Closing the loop in this manner enables you to start with FTA, capture field failure and repair metrics in FRACAS, then feed those back into the bottom-level Event data from your original FTA. This ensures that your most system critical events are identified for detailed analysis and that risk mitigation strategies are correctly targeted.

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 employ corrective and/or preventive action plans.

RBD Analysis

Many reliability and quality teams utilize Reliability Block Diagram (RBD) analysis, especially in cases where the system includes redundancy. In this case, you have a similar situation as described in Fault Tree Analysis. In your RBD, you have a model of your complete system including any redundancies with predicted failure and repair data. From your FRACAS, if you have implemented the repair and time-based data collection strategies 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 predicted metrics from RBD, capture field failure and repair metrics, then feed those back into the block failure and repair information in RBD. This ensures that your system model is accurate and can help identify high-risk items to better target your continuous improvement efforts.

Additionally, pairing RBD and FRACAS with a Weibull analysis tool can provide an even more powerful closed-loop tool suite. Closing the loop in this manner is a similar process to what is outlined above. After field failure and repair information is collected from FRACAS, that data is fed into Weibull's curve-fitting computations to output best-fit distributions that are then used to model the performance of component blocks in RBD, thus ensuring your model reflects actual field behavior.

4

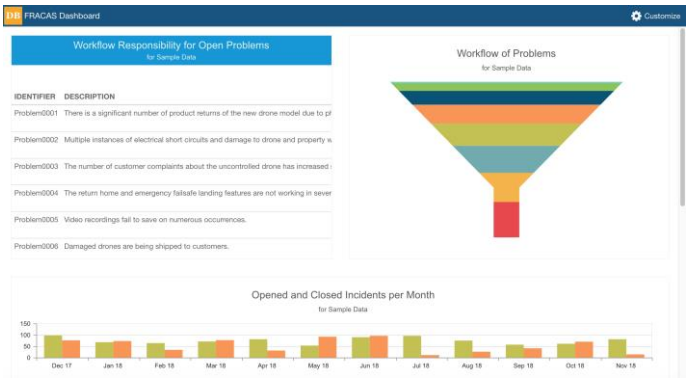
Make Sure You See the Forest

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.