

SPECIAL REPRINT

Improving QS-9000 Audits of Process-FMEAs

Peeking Into the Core of a Quality Management System

by Murray Sittsamer

Process Failure Mode and Effects Analysis (P-FMEA) has become both a popular *and* a controversial tool within QS-9000 compliant companies. There are two elementary reasons why companies are hurriedly generating P-FMEAs:

- It is a required component of Element 4.2, Quality System, and Element 4.9, Process Control, of QS-9000 through Production Part Approval Process (PPAP) requirements and Advanced Product Quality Planning (APQP) guidelines
- P-FMEA plays a key role in complying with Element 4.14, Corrective and Preventive Action.

Beyond its somewhat mystifying name and humdrum reputation, P-FMEA is a logical tool that can be quickly understood. With little training and often with templated starting points, many suppliers to the Big Three and other original equipment manufacturers (OEMs) generate P-FMEAs that presumably satisfy auditor and customer requirements.

However, in many cases P-FMEAs are not so straightforwardly generated. Guidelines for determining which failure modes and what causes to consider are usually lacking in substance—if they are available at all.

The risk ranking scales for Severity, Occurrence and Detection are often applied without consistent logic or are applied without regard for the information that is clearly observable on the plant floor and/or in the quality records. If the three rankings are applied carelessly, the resulting Risk Priority Number (RPN) will be meaningless for quality planning.

When created without sufficient cross-functional input, a P-FMEA will not offer a complete view of the true nature of the manufacturing or service process being analyzed.

The result is that it provides limited guidance on applying quality control methods for driving quality improvement. When P-FMEAs are created by a team that lacks unambiguous guidelines and ranking scales, creating the P-FMEA is a frustrating exercise with no benefit to any team members other than the individual responsible for submitting this required document.

The Core of the Quality System

An effective P-FMEA—one worth more than the paper it is printed on—reflects with high fidelity the true operating characteristics and perils present in the manufacturing process it is evaluating:

- When the process changes, the

P-FMEA will change.

- When the resultant quality level for a specific characteristic worsens, the P-FMEA should change to reflect a higher occurrence frequency for the suspected causes and/or a degraded ability to detect the defect.

At any point in time a P-FMEA should be an honest reflection of a supplier's ability to detect *and prevent* quality defects.

Since the P-FMEA really is the expert system that drives the content of Process Control Plans (PCP) and job instructions through the APQP process, anything short of high fidelity with the real world will leave the customer unprotected against the receipt of potentially defective product.

What Happens—and Should—to P-FMEA in an Audit?

What is likely to happen during a traditional registration assessment—and what should happen to make that audit valuable in assessing your company's use of P-FMEAs? During typical QS-9000 registration assessments, P-FMEAs are rarely a topic of much inspection or discussion.

When reviewed by auditors, P-FMEAs are assumed to have captured some assessment of quality risk. In many cases an auditor might check to ensure that, at a minimum, the highest RPN has an associated corrective action identified.

The highest RPNs for any process represent the weakest links in its chain of process events. It is fair to expect that those processes with the highest risks are candidates for con-

tinuous improvement.

A meticulous auditor will check that none of the committed completion dates for recommended actions are past due. An auditor may test the supplier's document control system to validate the current issue and distribution control of a P-FMEA. Auditors with a basic knowledge of APQP will check that the process steps on the P-FMEA correspond exactly to the process steps specified in the Process Flow Diagram (PFD).

The traditional assessment of a P-FMEA described above could be called a tertiary audit. It is not wrong, but it overlooks the fundamental purpose of the P-FMEA—that is, to protect the customer by assessing and working to reduce the risk of quality defects.

A P-FMEA should be a reflection of the quality control methods within a production process. So, if the auditors are truly working to assess the true effectiveness of your quality system, they will eagerly begin a plant floor audit path with a P-FMEA in hand. Consider these examples:

- “This low Detection ranking indicates you have high confidence that insufficient application of sealant will be caught at your leak tester. Could I see that test station? Also, would you show me your customer complaint and warranty data for this product, by reason code?”
- “You indicate on this P-FMEA that a light screen error-proofs selection of the wrong pin, resulting in a low occurrence and low RPN. Let's take a look at that station and how the operator performs the job.”
- “This P-FMEA indicates that you control a possible out-of-calibration condition on your electronic fastener tools with a daily audit of bolt torque. Where are the records of those audits kept?”

Alternately, while making obser-

vations throughout the bulk of a facility's audit, many audit paths could lead back to the P-FMEA to assure that the P-FMEA is current and accurate. Representative lines of questioning might be:

- “This chart shows an increased trend of scrap generation at operation 40. Is that reflected in your P-FMEA?”
- “I see several customer complaints related to cosmetic defects. Is your potential to not detect occasional escapes properly reflected in your P-FMEA?”
- “I see this model-year's design now has an additional oil passage hole. May I see where that is reflected in your P-FMEA?...”

Improved P-FMEA Audit Techniques

As companies diminish the deficiencies in their quality systems over time, surveillance auditors will be digging deeper and using a variety of techniques to obtain evidence of compliance to QS-9000 and the company's own documented quality procedures.

QS-9000's additions require that P-FMEAs be generated, but the exact method and the subtleties of creating a sufficient P-FMEA are not part of the standard. SAE J-1739 and the *Failure Mode and Effects Analysis Reference Manual* only present what could be considered “guidelines”. Therefore, problems found in areas of a P-FMEA would not necessarily qualify as nonconformances based on these two documents.

However, the problems found may be used by an auditor as audit observations or as evidence leading up to unfavorable findings regarding the overall effectiveness of the audited quality system.

The following are examples of approaches that auditors can take to

deepen their assessment of a P-FMEA while probing the underlying soundness of a supplier's quality system:

1. *Verify that the control schemes specified in the P-FMEA are called out in relevant process control plans, gaging instructions, job instructions, and other quality procedures and ultimately practiced on the plant floor.*

An effective P-FMEA establishes what control should be in place to prevent or detect potential problems. If a control method is assumed in the P-FMEA but not evident on the plant floor, then the P-FMEA is not a true reflection of the process. Conversely, if a control is present on the plant floor but not called out in the P-FMEA, then the P-FMEA does not represent reality within that facility and possibly shows an inflated risk ranking where risk is largely mitigated. Neither situation is desirable when seeking proper identification of risk.

A failure mode in many P-FMEAs is that the Detection ranking is assumed to be very good (a low number) because the potential problem is easy to detect. However, if nothing is actually done on the plant floor to detect the potential problem, the assumption is false and the P-FMEA is misrepresenting reality. In this case, the result is the potential for defects to reach the customer.

For example, a team might use a low detection score for a visual check of “missing” oil dipsticks, because those would be “obvious” errors. However, if no one (or no device) is assigned the task of visually checking that component, there is a high risk that a missing dipstick will “leak out” to the customer.

The value of the Control Plan is to systematically apply the controls

that are called out in the P-FMEA to mathematically reduce risk.

2. Confirm that ranking scores are not compressed; i.e., the team is taking advantage of the broad range of the 1 to 10 ranking scales for Severity, Occurrence and Detection.

The value of the rankings in a P-FMEA is the ability to convey the relative risk for any given "Failure Mode-Cause-Control" combination. If all causes have an Occurrence of either 2 or 3 and never anything higher or lower, it really doesn't indicate which of several causes leading to a particular failure mode might be more likely. Usually a few causes will be the leading contributors to a particular failure mode (pareto principle) and therefore have a higher priority in terms of the need to control.

Similarly, if all Severity rankings were the same, the resulting RPNs will not help a team identify which risk to work on first. And if all Detection scores were the same number, the P-FMEA would not differentiate risk based on the true ability of a control to better detect a problem versus a different control. The value of the 1-to-10 scale is to discriminate between high- and low-risk factors.

An auditor can glean much by skimming down the ranking columns of a P-FMEA. Are the rankings scores compressed? Does the P-FMEA tend to rank everything with lower (optimistic) rankings? A lack of discrimination in the application of rankings leads to RPN values that are not meaningful.

3. Substantiate that the highest RPNs have valid recommended actions.

P-FMEA is a process to identify potential problems before they become a reality. If a potential problem is highlighted by high RPNs but no

action is taken to reduce the risk, then that potential problem will likely become a reality. A high RPN problem can be characterized as having a high severity, a high probability of occurrence and a high chance of escaping detection. If nothing is done about this problem, the team is setting itself up for failure.

Sometimes a company may have valid reasons for not having recommended actions for high RPN items. For example:

- The product is being phased out.
- Technical solutions are cost-prohibitive given the age of the equipment.

Unless business or technological reasons prevent improvement, something should be done to reduce the risk of high RPN items.

Remember, if adequate actions are not in place for these weakest links, the completion date is scheduled too far out, or key dates are often missed, then this evidence might be used to build a case that the supplier is not providing adequate resources to ensure quality.

4. Substantiate that the P-FMEA was created and is maintained with data rather than the judgment of the team (or an individual) alone.

If an effective P-FMEA is to have a high fidelity with the reality, the nuances of the plant floor must be reflected in the P-FMEA. When a problem causes customers to return product on a regular basis, the failure mode must be on the P-FMEA, the Occurrence ranking should be relatively high, and the Detection score should reflect the supplier's inability to consistently detect the defective product.

In the planning stages for a new product, the team should use a similar product's production process as a guide for determining the new

product's risk attributes. Where there are product characteristic or processing differences, the team should use its judgment in making the determinations of risk.

Where actual experience and data are available, they provide the best knowledge base from which to create or update a P-FMEA. Occurrence rankings especially are only an educated guess without quality data—without data, the selected ranking will be subjective. The production manager of a GM-Powertrain plant has a plaque on her desk that tells it like it is: "Without data, it's only another opinion."

A well-maintained P-FMEA will incorporate data generated on the plant floor during regular production as well as data from customer complaints. The P-FMEA should address not only "What might go wrong?", but also "What does go wrong?". It should consider not only "Might we detect the error?", but also "Have we ever had that error escape?".

5. Verify that the customer is protected from likely risks everywhere in the supplier's scope of control.

Many P-FMEAs only consider proprietary manufacturing steps that convert materials into product. While this is usually the most intricate aspect of the supplier's activities, it is not the only realm where errors can lead to nonconformances and customer complaints.

Problematic areas that are often ignored in a P-FMEA include: handling, packing, shipping and rework. Since there are failure modes, effects, causes and controls for these processes, it is a straightforward exercise to create a P-FMEA for these steps.

Where a top-level intuitive analysis suggests a medium-to-high risk of problems, time should be taken to formally think through the

causes and controls to prevent or better detect problems.

Many P-FMEAs also consider only the failure modes for key, or special, characteristics. If control of the non-special, or standard, characteristics is assumed, where are those "assumed" controls communicated to the plant floor?

If the P-FMEA is being used to help prevent and reduce variation and waste in the process, it needs to consider all characteristics that might pose risk. Again, an upfront risk assessment based on the judgment of a qualified team will help prioritize where in the Process Flow Diagram the P-FMEA should be well developed and where it could be developed with less detail and deliberation. Team members will appreciate their time being well-spent.

While the scope and level of detail of a P-FMEA is a controversial topic, it is important to at least consider, with an up-front risk assessment, how you can protect your customer from receiving defective parts. If a potential risk is high, it is inappropriate to let that risk fall through the cracks.

Conclusion

Process Failure Mode and Effects Analysis is truly a window into an implemented quality system. When created with care, it describes what can go wrong and, based on knowledgeable team input, prescribes what care is required to prevent or detect errors. When reviewed with scrutiny, it assesses the method the supplier used to prevent quality problems.

Auditors can learn much when they peek into a P-FMEA. In addition

to it being a good guide to what should be occurring on the plant floor, a well-maintained P-FMEA also reflects a supplier's commitment to continuous improvement and waste reduction.

There is no single way that a P-FMEA must be created or audited. Still, by peeking deeper into the document, a careful auditor can learn much about the thought process that the supplier uses to stipulate quality control methods on the plant floor and to drive quality improvement activities. ###

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