

Improvements, Benefits & Financial Impact of the AIAG & VDA FMEA Handbook





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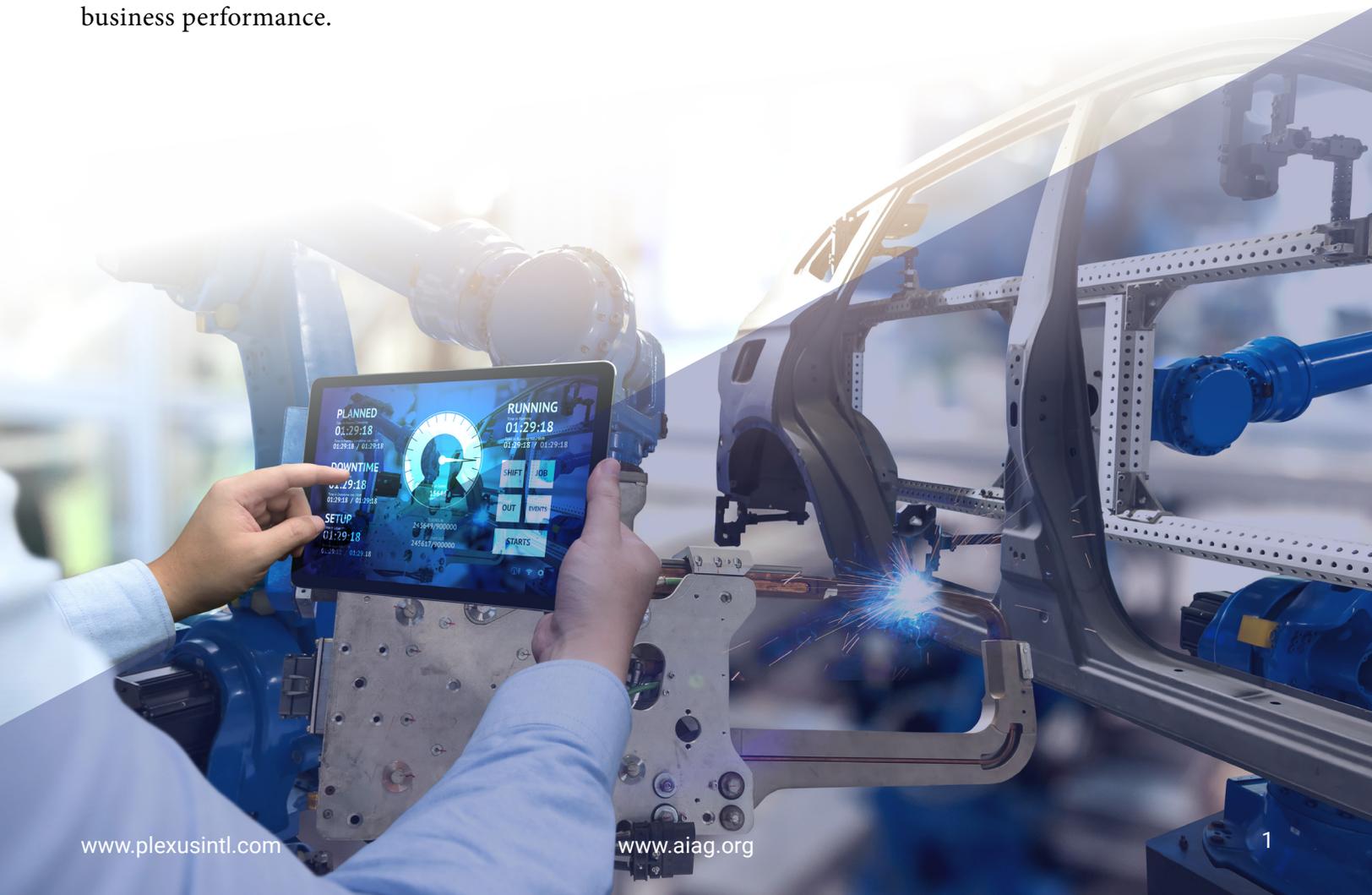
7 steps for properly implementing the AIAG & VDA FMEA development process within your organization.

INTRODUCTION

To improve the FMEA development process and make it easier for automotive manufacturing suppliers to meet the needs of their customers during the Failure Mode and Effects Analysis (FMEA) development process, AIAG and VDA have harmonized their previous “regional” FMEA manuals into a single, co-copyrighted handbook. This handbook uses best practices from each manual, and a process-oriented approach to meet the requirements of both industry groups.

The AIAG & VDA FMEA Handbook is set to launch soon, replacing the previous version (AIAG FMEA Manual 4th Edition). With the official release of the new handbook just around the corner, organizations within the automotive supply chain are questioning the significance of the changes and how they will impact their organization—if at all. The truth is, when correctly implemented, some of the changes will impact your organization both in terms of performance, and ultimately, your organization’s bottom line.

This whitepaper highlights some of most important improvements you can expect to see in the AIAG & VDA FMEA Handbook and explains the benefit of these changes in terms of FMEA robustness, performance, effectiveness and efficiency. But before diving into these improvements and comprehending their impact, it’s important that you know how to determine if your FMEA development process is performing as it should through the linkage between FMEA and the Cost of Quality (COQ) which indicates the financial impact FMEA inevitably has on business performance.





FMEA Helps Mitigate Risk & Balance Cost

Failure Mode and Effects Analysis (FMEA) is a team-oriented, systematic, qualitative, and analytical method intended to identify, analyze, and mitigate technical risks related to product and manufacturing process design. It supports the five Advanced Product Quality Planning (APQP) phases to improve customer satisfaction by emphasizing defect prevention.

When used correctly, a major benefit of the FMEA is being able to mitigate risk while balancing costs leading to organizational stability and growth. To achieve this, you should be able to connect the FMEA to the Cost of Quality (COQ).

Measuring FMEA Effectiveness & Efficiency

Through Connection to the Cost of Quality

The FMEA development process is a deep-dive analysis of the potential for both internal and external failures. As such, the quality of the FMEA affects an organization's success in keeping its Cost of the Poor Quality (COPQ) low. While COPQ seeks to translate the concept of quality failures into terms of time and money, the FMEA is a tool in identifying the source of the failures that contribute to COPQ, allowing an organization to take the right preventive actions.

So how do you determine if your FMEA development process is performing as it should? Improvement of overall business performance can be a good indication, especially in terms of lower Cost of Poor Quality (COPQ).

Objectives of the FMEA Development Process



Clearly identify the function that an item, or activity, should perform.



Identify what would cause that item or activity NOT to perform its intended function.



Develop a realistic risk profile by evaluating how bad each failure mode would be, and the robustness of current prevention and detection controls.



Use the risk profile as a basis for better decision making and taking appropriate actions to meet the intended expectations.

Learning to see the Interdependency

Between Cost of Quality and FMEA

FMEA Effectiveness

The ability to provide information that indicates FMEA performance is critical to obtain management commitment in the FMEA development process. If the main purpose of FMEA is to mitigate technical risks to an acceptable level, we can then affirm that the organizational effort to develop the FMEA will only be valid if incidents of internal and external failures remain within the acceptable limits after the new product or process launch. Consider a simple analogy comparing the effort made to prepare FMEAs with a student who studies hard but still receives poor scores; at the end of the day, poor scores indicate that the studying was not effective. The same goes for FMEA development. We can evaluate FMEA effectiveness by monitoring the reduction of internal and external failures. If there isn't an acceptable reduction in failures, the FMEA was not effective.

FMEA Efficiency

In addition to the effectiveness of your FMEA, it's important that you also consider its efficiency. For managers, another critical aspect of FMEA performance is the level of effort required to prepare effective FMEAs. In order to balance cost, you should consider the resources allocated to prepare FMEAs. For example:

- The time it takes a multidisciplinary team to conduct design reviews and document results in the FMEA form
- Investments in qualification of the multidisciplinary team
- Investments in the improvement of prevention and detection control methods to achieve the expected quality performance targets.

The level of effort required to prepare an effective FMEA relates to the cost of appraisal and prevention, as previously described. Overall COQ is used to show the balance between prevention/appraisal costs and the reduction of internal and external failure costs.

The Cost of Quality

Traditionally, there are four categories within the Cost of Quality (COQ), two of which fall under COPQ:



Prevention Costs

Prevention costs are associated with any activity that prevents failures. Some examples of prevention activities include training, auditing and FMEA development process efforts.



Appraisal Costs

Appraisal costs are associated with the testing and monitoring of items, or activities. Examples of appraisal costs include routine testing costs, lab costs, external lab costs, etc.



Internal Failure Costs

Internal failure costs are the result of failures that exist inside of the organization. This is another area of cost categorized under COPQ. Examples include scrap costs, rework costs, sort costs, and overtime for machines to run on weekends due to poor uptime or high scrap.



External Failure Costs

External failure costs are the result of failures that exist outside of the organization, such as failing to meet a requirement. This area of cost can be categorized under COPQ. Examples include warranty costs, customer returns, sorts, and fines.

Evaluating Similar Products & Processes

FMEA Effectiveness, and Efficiency

Evaluating FMEA effectiveness and efficiency of new product and process development can be accomplished by monitoring the COQ of similar products and process. Current COQ will be the baseline of the new generation of products and processes and the critical question to answer is “Do we expect the same levels of COQ / COPQ in this new product and/or process development?” The answer most likely is, “No, we want lower COPQ.” But even if the answer is “yes” the game is not over. The multidisciplinary team will need to consider if the new product or process has new functions and requirements that will lead to new failure modes or causes, therefore, an evaluation of how robust the current prevention and detection controls are to ensure that quality performance targets are achieved.

The Essential Link Between COQ and FMEAs:

- You will need the FMEA to make sure COQ / COPQ performance targets are met, and
- You will need COQ / COPQ actual performance on similar products and/or process to make sure the FMEA risk evaluation of the new product and/or process is realistic.

The AIAG & VDA FMEA Handbook is strongly rooted with the purpose of increasing FMEA robustness. In the next section we present some of the major improvements, benefits, and changes in the AIAG & VDA FMEA Handbook that will bring your organization to the next level of business performance in the automotive supply chain.



AIAG & VDA FMEA Handbook

Changes & Benefits at a Glance



Why has the FMEA Manual been revised?

The FMEA manual has been revised with the sustainability of the automotive supply chain in mind. The purpose of the development of the new AIAG & VDA FMEA Handbook is to apply a more robust methodology to address product and manufacturing process risks, while considering the complexities of multiple OEM-specific and regulatory requirements, and demanding consumers expectations for better and more innovative products. AIAG and VDA FMEA manuals have been harmonized in a joint publication to take these factors into account.

This new FMEA method is described in a single co-copyrighted handbook that takes the best practices from AIAG and VDA using a process-oriented approach to develop Design and Process FMEAs that meet requirements for both industry groups. Therefore, the application of the AIAG & VDA FMEA Handbook will enable suppliers to effectively address technical risks during the Product and Process Development process by developing a robust, accurate, and complete DFMEA and PFMEA that will meet the needs of all customers.



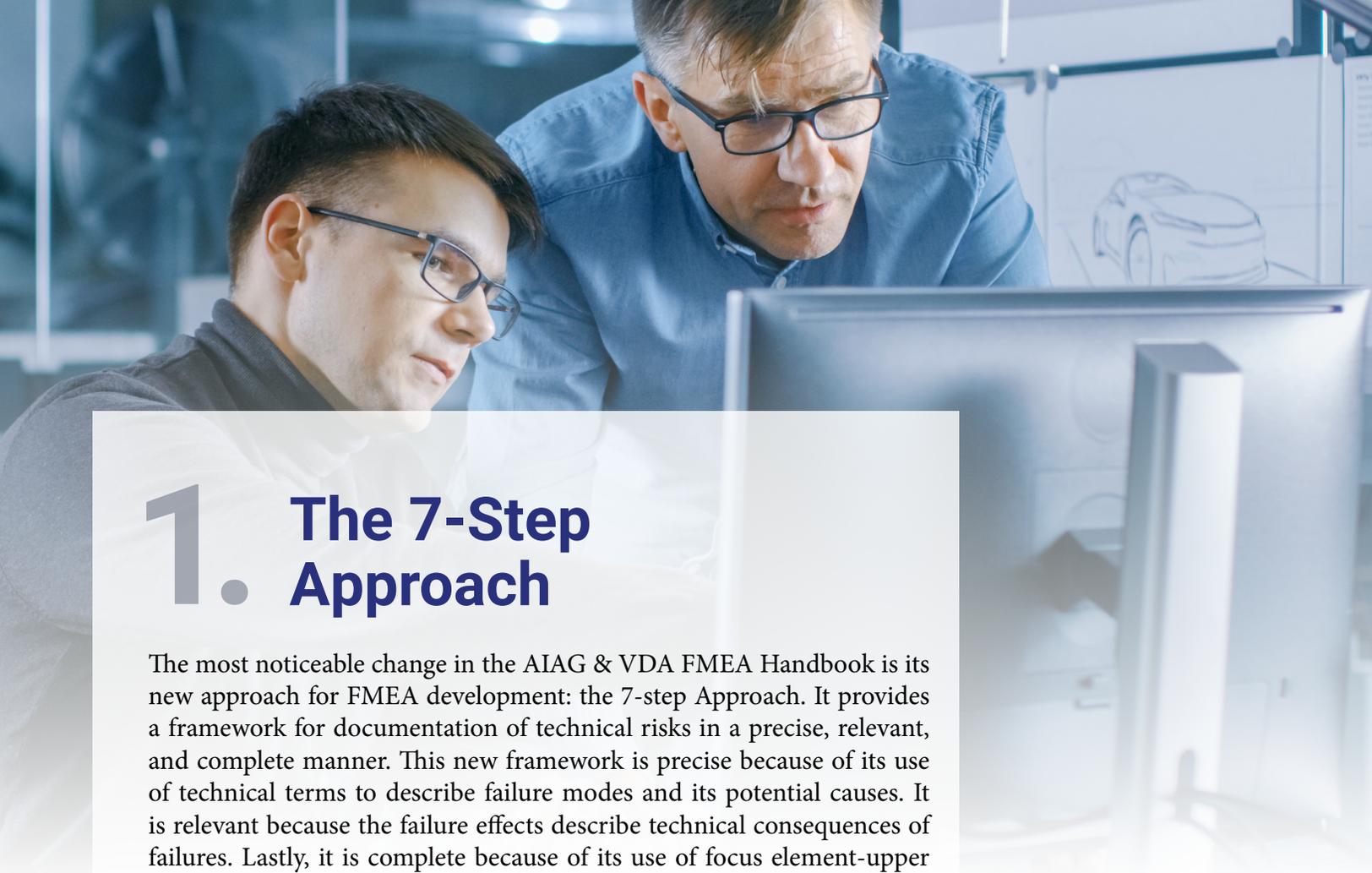
More structured approach



Leverages lessons learned



Error-proofing driven



1. The 7-Step Approach

The most noticeable change in the AIAG & VDA FMEA Handbook is its new approach for FMEA development: the 7-step Approach. It provides a framework for documentation of technical risks in a precise, relevant, and complete manner. This new framework is precise because of its use of technical terms to describe failure modes and its potential causes. It is relevant because the failure effects describe technical consequences of failures. Lastly, it is complete because of its use of focus element-upper level-lower level approach enabling a comprehensive review of the risks.

System Analysis			Failure Analysis & Risk Mitigation			Risk Communication
1 st Step	2 nd Step	3 rd Step	4 th Step	5 th Step	6 th Step	7 th Step
Planning & Preparation	Structure Analysis	Function Analysis	Failure Analysis	Risk Analysis	Optimization	Results Documentation

The Benefit:

The 7-step Approach is more structured, and highly instrumental in increasing a multidisciplinary team's effectiveness and efficiency:

- More risks can be addressed in a comprehensive manner
- Multidisciplinary reviews of the FMEA become engaging “technical guided reflections” instead of an “unfocused brainstorm”, avoiding a discouragement attitude related to FMEA
- Enables senior management to comprehend and review necessary actions and resources to mitigate technical risks



2.

Enhanced FMEA Planning & Preparation

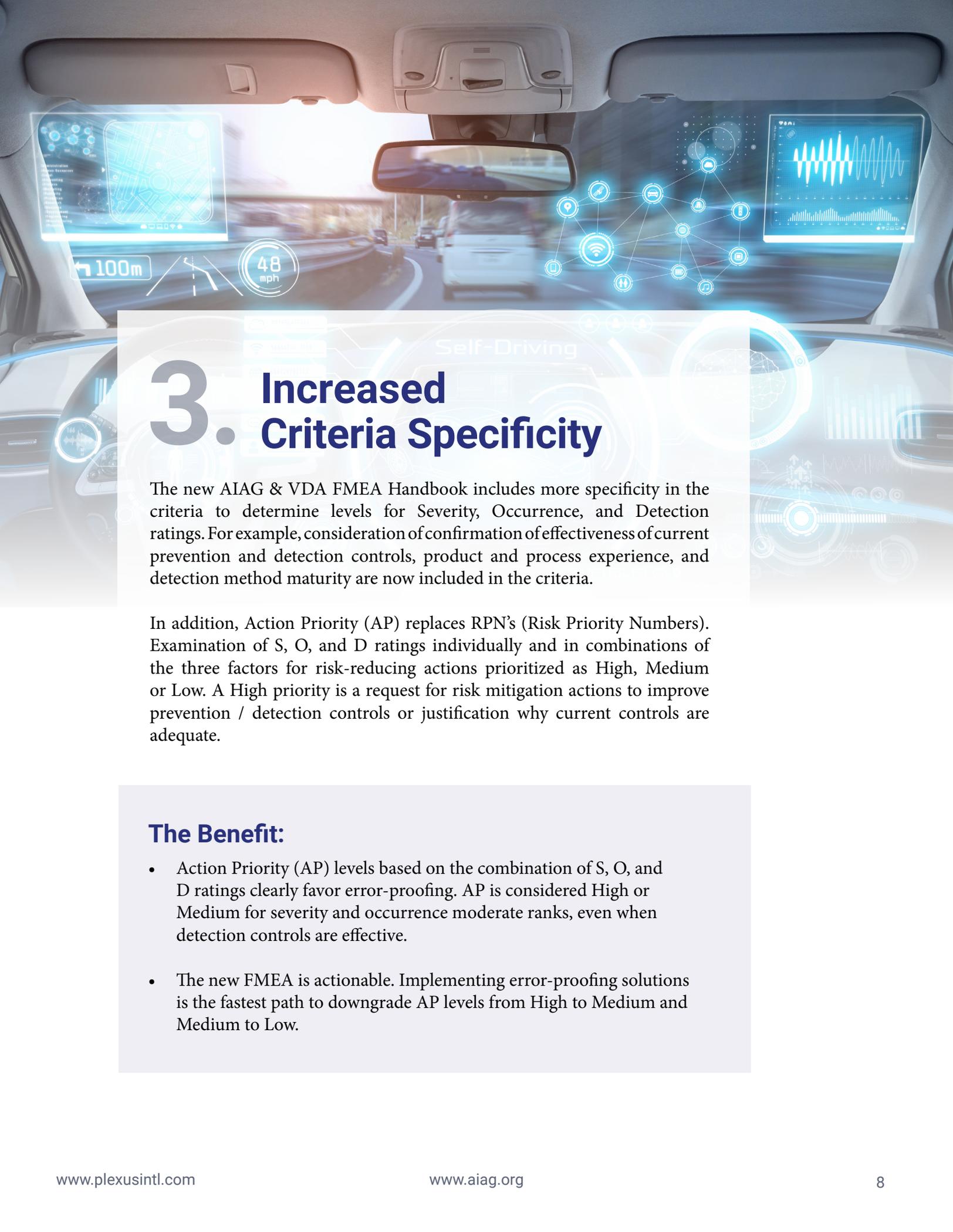
Another major difference is the enhanced direction of FMEA Planning and Preparation; the 1st step of FMEA development. While defining the scope has always been part of the FMEA development, the AIAG & VDA FMEA Handbook gives it increased prominence. For example, determining analysis boundaries (what is included and what is excluded), application of 5T's (FMEA InTent, Timing, Team, Tasks, Tools), preparation of baseline FMEAs with lessons learned, and clear definition of roles and responsibilities (management, technical lead, facilitator, team members) are now more explicitly included in FMEA preparation.

The Benefit:

Enhanced planning and preparation will allow you to avoid wasting time of the multidisciplinary team due to lack of focus (Why are we here? What is the technical risk in discussion now? Who should do what?) and relevant information availability.

The benefits of organizing lessons learned into baseline FMEAs are:

- Mitigate the risk of past failures recurrences due to loss of knowledge related to turnover and retirement
- Save time in FMEA preparation as the baseline FMEA is a robust starting point for FMEA in similar products and processes
- Enable practicality in the concept of “FMEA as a living document”
- Clarity for management to estimate and allocate resources to standardize lessons learned



3. Increased Criteria Specificity

The new AIAG & VDA FMEA Handbook includes more specificity in the criteria to determine levels for Severity, Occurrence, and Detection ratings. For example, consideration of confirmation of effectiveness of current prevention and detection controls, product and process experience, and detection method maturity are now included in the criteria.

In addition, Action Priority (AP) replaces RPN's (Risk Priority Numbers). Examination of S, O, and D ratings individually and in combinations of the three factors for risk-reducing actions prioritized as High, Medium or Low. A High priority is a request for risk mitigation actions to improve prevention / detection controls or justification why current controls are adequate.

The Benefit:

- Action Priority (AP) levels based on the combination of S, O, and D ratings clearly favor error-proofing. AP is considered High or Medium for severity and occurrence moderate ranks, even when detection controls are effective.
- The new FMEA is actionable. Implementing error-proofing solutions is the fastest path to downgrade AP levels from High to Medium and Medium to Low.

ADDITIONAL MAJOR CHANGES

In addition to the major changes explained above, here are other changes you can expect to see:

- Detailed introduction chapter emphasizing and clarifying the foundations necessary to develop a robust FMEA. For example:
 - purpose, objectives, and limits of FMEA
 - norms for documentation of technical risks (clear, true, realistic, and complete)
 - greater emphasis in senior management commitment with FMEA development process
 - clarifications related to know-how protection
 - directions on the transition strategy to the new AIAG & VDA FMEA Handbook
 - use of baseline FMEAs to preserve organizational knowledge and lessons learned
 - correlation between DFMEAs and PFMEAs by considering the same failure effects for the same feature analyzed in both FMEAs
 - Use of 5Ts (Intent-engaging the team by clarifying purpose and scope of work, Timing-alignment with APQP Phases, Team-defining typical roles and responsibilities, Task-use of 7 Step Approach, Tool-FMEA examples include software and traditional spreadsheets) as a project planning approach for FMEA development
- Inclusion of DFMEA 1st Step – Planning and Preparation.
- DFMEA 2nd Step – Structure Analysis. DFMEA form starts with the understanding of the system structure. After the breakdown of the design into system, sub-system, and component the Focus Element, the Next Higher Level, and Next Lower Level is described in the form. Additional clarification on tools to support the structure analysis before completing the DFMEA is provided (Block Diagram, Structure Tree).
- DFMEA 3rd Step – Function Analysis. Deeper explanation on how to describe properly a function, including tools to support the function analysis (P-Diagram).
- DFMEA 4th Step – Failure Analysis. Concepts of types of failures and failure chain model are described to support a more comprehensive (more failures described) and consistent (internal consistency between FE, FM, FC) failure description.
- DFMEA 5th Step – Risk Analysis. Further differentiation between Prevention Controls (PC) and Detection Controls (DC). The confirmation of PC and DC effectiveness needs to be considered before selecting the Occurrence and Detection ratings. More specificity in the criteria to determine levels for Severity, Occurrence, and Detection ratings and the replacement of RPN to DFMEA Action Priority (AP). Low, Medium, and High AP levels drive the determination of action priority.
- DFMEA 6th Step – Optimization. Recommended Action replaced with Prevention Action and Detection Action. Added the columns: Status (planned, decision / implementation pending, completed, discarded), and Action Taken with pointer to evidence.

- DFMEA 7th Step – Results Documentation. Internal reporting to management and customer reporting.
- Added a completely new section called Supplemental FMEA for Monitoring and System Response (FMEA-MSR). MSR can detect failures during end-user operation (driver) and avoid an original High Priority failure effect described in the DFMEA by switching to a degraded operation state (from traditional light or sound alarms to disabling the vehicle).
- Inclusion of PFMEA 1st Step – Planning and Preparation.
- PFMEA 2nd Step – Structure Analysis. Added a more detailed breakdown of the manufacturing process:
 - Focus Element of the PFMEA: the process step station number and name under review
 - Next Higher Level: process item system (the overall manufacturing process)
 - Next Lower Level process: work element 4M type (based on Ishikawa approach). This drives the users to consider the categories of Man, Machine, Material, Method, etc., leading to a more complete list of Failure Cause (FC).
- PFMEA 3rd Step – Function Analysis. Added the description of functions and requirements related to the Next Higher Level and Next Lower Level. This supports a clear and complete description of the Failure Effects (FE) and Failure Causes (FC).
- PFMEA 4th Step – Failure Analysis. Potential Failure Mode is replaced with Failure Mode (FM) of the Focus Element. Potential Effect(s) of Failure is replaced with “Failure Effects (FE) to the Next Higher-Level Element and / or Vehicle End User. Potential Cause of Failure is replaced with Failure Cause (FC) of the Work Element.
- PFMEA 5th Step – Risk Analysis. Classification is replaced with Special Characteristics and Filter Code. Occurrence is replaced with Occurrence of the FC. The Occurrence rating now is based on “prediction of FC occurring”, which leads to determining the actual robustness of the Prevention Controls (PC). Current Process Control – Prevention is replaced with Current Prevention Control (PC) of the Failure Cause (FC). Current Process Control – Detection is replaced with Current Detection Control (DC) of the Failure Cause (FC) or the Failure Mode (FM). Detection is replaced with Detection of the FC or FM. Detection is now based on three factors: detection method maturity, opportunity for detection, and ability to detect. RPN is replaced with PFMEA Action Priority (AP). Low, Medium, and High AP levels drive the determination of action priority.
- PFMEA 6th Step – Optimization. Recommended Action replaced with Prevention Action and Detection Action. Added the columns: Status (planned, decision / implementation pending, completed, discarded), Action Taken with pointer to evidence, Special characteristic, and Remarks.
- PFMEA 7th Step – Results Documentation. Internal reporting to management and customer reporting.

NEXT STEPS

If you're currently using the AIAG FMEA 4th Edition or have yet to properly implement the FMEA development process within your organization, there are important steps to follow once the new AIAG & VDA FMEA Handbook is released. Keep in mind that every organization is different, so the steps needed to adjust your FMEA development process are likely to be unique to your situation. However, here are some steps that will help you get started on the journey:

1

Familiarize yourself with the new AIAG & VDA FMEA Handbook. While many things have indeed changed, some remain the same.

2

Identify any gaps within your current FMEA development process which need to be addressed to meet the new requirements of the new handbook.

3

Provide appropriate training for all parties that have an impact on the development and support of FMEAs (multidisciplinary team, practitioners, managers, auditors).

4

Revisit and update the gap analysis and develop an implementation plan for a specific "new FMEA pilot project".

5

Implement the "new FMEA pilot project" and record lessons learned on the use of the new methodology. Measure your FMEA pilot project financial impact in terms of COQ.

6

Standardize business processes to support the application of the new FMEA Handbook. Professional FMEA Transition coaching and consulting is a cost-effective option in most cases.

7

Finally, adopt a continual improvement approach to make your FMEAs living documents.



TRAINING OPPORTUNITIES

AIAG's training courses for the new AIAG & VDA FMEA Handbook will be provided by Plexus International, a certified global provider for AIAG quality products and services and will be offered to the industry after the official launch of the publication. Any training offered prior to the actual publication date may be quite inaccurate as it is based on the first draft version of the document. Supplier efforts to implement or transition to the new AIAG & VDA FMEA methodology should only occur after the new handbook is published.

For more information visit www.aiag.org or www.plexusintl.com.

