PRACTICAL APPLICATION OF THE NEW APPROACH TO FMEA METHOD ACCORDING TO AIAG AND VDA REFERENCE MANUAL

Dariusz Plinta*, Ewa Golinska, Ľuboslav Dulina

Department of Industrial Engineering, Faculty of Mechanical Engineering, University of Bielsko-Biala, Bielsko-Biala, Poland

*E-mail of corresponding author: dplinta@ath.bielsko.pl

Resume

System requirements in the automotive industry are constantly evolving and being improved. Currently, the entire supply chain, related to the automotive industry, is subject to the fourth amendment to the technical automotive standard - IATF 16949: 2016 Quality management systems - Detailed requirements for the use of ISO 9001: 2015 in serial production and production of spare parts in the automotive industry. In IATF standard, there are advices called reference manuals that provide important guidance on the quality system in this industry - one of them is the FMEA manual. The new guidelines in this regard, developed jointly by AIAG and VDA, entered into force in June 2019. Presentation of the most important changes introduced, as well as presentation of a practical example of the conducted analysis is the purpose of the article.

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1 Introduction

System quality management according to used standards has been used in organizations for over 30 years. During that time, those standards, primarily ISO 9000 series standards, have gained tremendous popularity and have also standardized business language around the world. In Poland, interest in certification of management systems appeared in the 1990s and is constantly popular. The popularity of certification for compliance with requirements of the ISO 9001 standard has become particularly important after Poland's accession to the European Union [1-2]. The first norm related to quality was developed in 1986 by International Organization for Standardisation (ISO) - it was the ISO 8402 norm Quality. Terminology. Over the years, standardized requirements in quality areas have evolved and in 2015 we saw the fourth revision of the ISO 9001 standard.

Quality management plays a special role in production management processes in the automotive industry. In this innovative industry, quality standards, based on the ISO 9000 series standards, are used. The best-known quality management standard in the automotive industry is QS, which is based on the now outdated ISO 9001: 1994 standard, extended by additional industry requirements, 9000 (Quality System Requirements). This standard was created in 1994 on the initiative of the so-called The Big Three of the US automotive industry - Chrysler Corporation, Ford Motor Company and General Motors Corporation. The emergence of this standard was a response to the lack of a standard adapted to requirements of the automotive industry. The above-mentioned car manufacturers jointly recognized that certified quality systems in accordance with requirements of the ISO 9000 series of standards allowed too much freedom for organizations applying them and there was a need to implement a uniform standard that would place higher requirements on suppliers and co-operators of the automotive industry. (Critics of ISO 9001 claim that the standard is too general and therefore useless for specific industries. Moreover, its usage may lead to abandoning creative thinking, inhibiting this way quality development [3-5]. They pointed out, among others, the lack of requirements regarding continuous improvement, application of problem-solving methods, approval of individual stages of project work or strategic quality planning. Votes of criticism in the abovementioned areas have been appearing consistently for years, regardless of any subsequent amendment to the standard.) Such behaviour of the automotive market leaders, ultimately responsible for product quality, was focused on providing supply facilities of the expected quality and was aimed at minimizing the nuisance of multiple assessments of current and potential suppliers and consequently meeting the expectations of the final customer [6-9].

The QS 9000 standard developed into ISO TS 16949

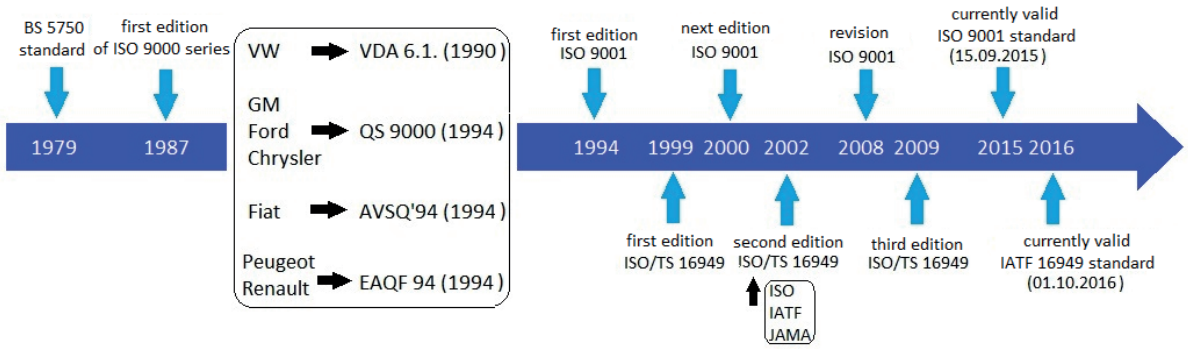

Figure 1 *Evolution of the ISO 9000 series standards and quality systems in the automotive industry, based on [13]*

standard; the design of the standard was approved in 1999. This standard contains a set of requirements that includes, in addition to the requirements of the previously mentioned Big Three (QS 9000), the requirements of the quality systems of the Italian, French and German automotive industry, as well [4], which were born in the process of evolution of quality improvement programs. The most popular of them, which are the sources of today's technical specification IATF 16949, are the following:

- QS 9000 - quality systems requirements of the Big Three of the American car industry (Quality System Requirements, Third Edition, March 1998).
- AVSQ'94 ANFIA - quality systems requirements of the Italian car industry (Valutazione Sistemi Qualita, Edizione 3, Febbraio 1995 + Addendum QS 9000 all' AVSQ, Edizione Marzo 1997).
- EAQF 94 - quality systems requirements of the French car industry (Evaluation Qualite Fournisseur, 1994 Edition plus QS 9000 Appendix to EAQF March 1997 Edition).
- VDA 6.1 - quality systems requirements of the German car industry (Qualitatsmanagement in der Automobilindustrie - QM - Systemaudit 4. vollstandig uberarbeitete Auflage 1998).

The above-mentioned standards, i. e. EAQF (France), VDA 6.1 (Germany), AVSQ (Italy), are recognized in the automotive market, although their universality is disproportionate to the QS 9000 (USA) standard (VDA 6.1 standard is also a commonly used norm for quality management, particularly in Europe, including Poland). However, a smaller number of certifications in the field of these systems or a smaller number of OEMs (Original Equipment Manufacturers) who put these systems as the required basis for management systems, in no way diminish the role, they played in the process of qualifying suppliers or shaping the IATF 16949 global standard [10-11].

It may seem that the QS 9000 standard is only slightly different from the ISO 9001 standard. However, this is not the case, also because in its content, QS 9000 repeatedly refers to the so-called manuals. Knowledge of these manuals is key in this standard and there is a need to include this information in the quality system. Although the QS 9000 standard ceased to be required in December 2006, the related manuals are constantly updated and recalled by many car manufacturers and certification body auditors as manuals with guidelines for meeting the IATF 16949 requirements.

As a part of the QS 9000 standard and today IATF 16949, a manufacturer can use the following manuals:

- APQP - Advanced Product Quality Planning and Control Plan.
- PPAP - Production Part Approval Process.
- SPC - Statistical Process Control.
- MSA - Measurement System Assessment.
- FMEA - Failure Mode and Effects Analysis.
- QSA - Quality System Assessment.

The present elaboration refers to analysing the changes in the area of the requirements included in the reference manuals. Two reference manuals have been analysed for this purpose - the manuals according to AIAG (*Automotive Industry Action Group*) and VDA (from German: *Verband der Automobilindustrie)* requirements, as well as their integration in form of a common, first edition of the FMEA manual [12].

The second edition of ISO / TS 16949: 2002 was developed in 2002 in cooperation of three organizations:

- ISO - International Organization for Standardization.
- IATF - International Automotive Task Force.
- JAMA - Japan Automobile Manufacturers Association.

Technical specifications in the automotive industry, just like the ISO 9000 series standards, are constantly evolving (Figure 1). Currently, the entire supply chain related to the automotive industry (not only suppliers, but also sub-suppliers, even when only a small part of their production is intended for the automotive industry) is obliged to apply the fourth amendment to the technical automotive standard IATF 16949 from 2016 - IATF 16949: 2016 Quality management systems - Detailed requirements for the use of ISO 9001: 2015 in series production and the production of spare parts in the automotive industry. Until today, it is the basic, though voluntary, standard in the automotive industry.

The reason for its issue was issuing the new ISO 9001: 2015 standards, which are the system basis for this technical specification. IATF 16949: 2016 is an automotive standard that is based on the structure

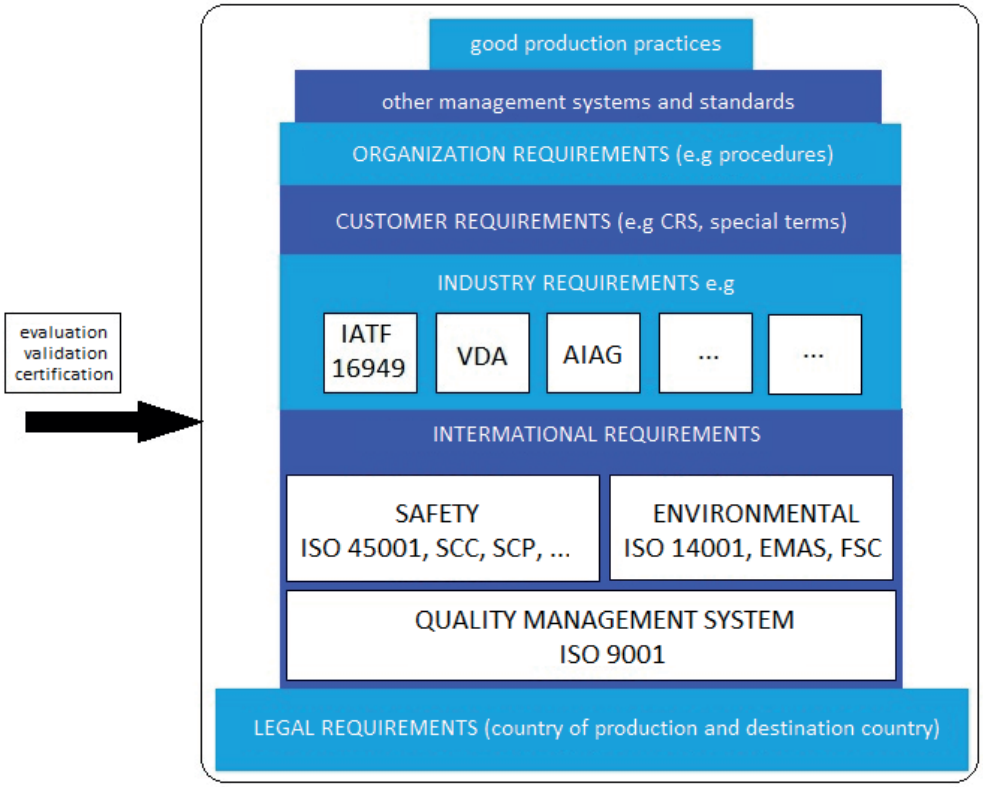

Figure 2 *A model of current requirements towards car manufacturers*

and requirements of ISO 9001: 2015, supplemented with specific technical issues specific to the automotive industry (mainly obligatory system documentation, i. e. procedures, instructions and records and requirements in the field of statistical process control or risk analyses).

Summarizing, IATF 16949 can be described as a compromise among car manufacturers. Therefore, it does not take into account all the requirements of each manufacturer, but only emphasizes the fulfilment of individual customer requirements. That is why a customer and his requirements determine the shape of the quality management system implemented in the company. This applies, for example, to the need or lack of need to use QS 9000 standard manuals. A simplified model of requirements for today's car manufacturers is shown in Figure 2.

The IATF 16949 standard has gained international significance - primarily due to its dynamically growing coverage, involving suppliers around the world. Currently, more than twenty years after the technical specification was introduced for the first time on the automotive market, it is widely recognized and absolutely required in North America and is increasingly common in Europe, South America, Australia and Asia. It should also be remembered that the group of enterprises that have implemented and require the IATF 16949 standard from their suppliers is growing. It is also significant that a company that builds the quality system according to IATF 16949 must require its subcontractors to meet the requirements of this standard, which, in turn, significantly expands the circle of companies interested in it.

However, compliance with restrictive requirements resulting from the IATF 16949 standard is often not sufficient for entrepreneurs in the logistics chain of the automotive industry. It is worth noting that organization-specific sets of requirements (CSR - Customer Specific Requirements) have emerged that extend the standard requirements. Due to the multitude of individual customer requirements, the set of the requirements placed on automotive suppliers is not limited (A part of the CSR requirements is described in the so- called Manuals - briefly mentioned in the introduction to this paper). The main requirements of the CSR include the FMEA analysis presented later in the article.

2 FMEA in the automotive industry

FMEA is a commonly applied, obligatory method in the automotive industry, therefore a unified approach to conducting this analysis seems necessary, but - as practice shows - this approach differs in different organizations and is usually carried out according with the CSR requirements.

Historically, the FMEA (Failure Mode, Effects and Criticality Analysis) method was born in the 1950s for the needs of the arms industry and received the greatest publicity when NASA used it in the Apollo space program. The next milestone in development of this approach was the first application of FMEA (Nowadays FMEA is used as an equivalent to FMECA. Both, Mode and Effects Analysis (FMEA) and Failure

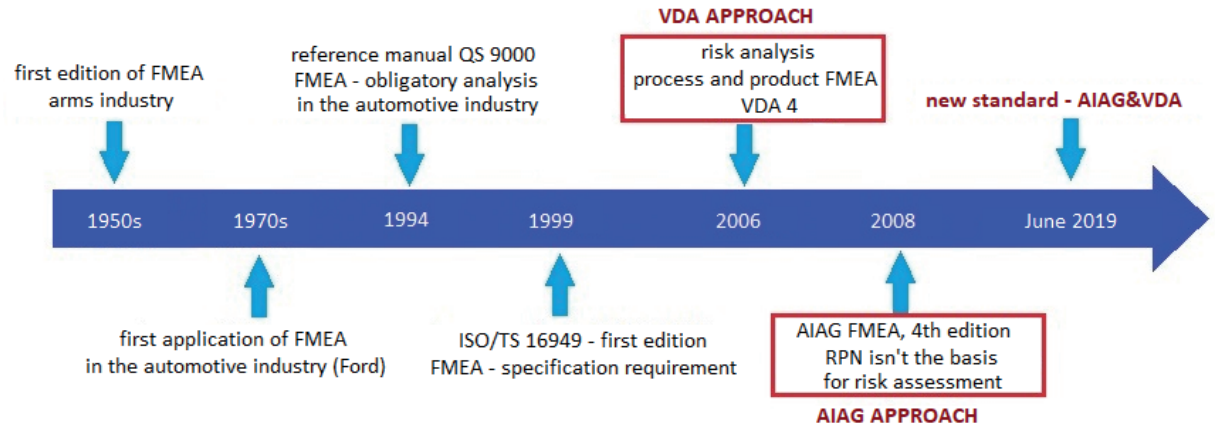

Figure 3 *Evolution of the approach to FMEA*

Modes, Effects and Criticality Analysis (FMECA) are methodologies designed to identify potential failure modes for a product or process, to assess the risk associated with those failure modes, to rank the issues in terms of importance and to identify and carry out corrective actions to address the most serious problems in the automotive industry by the Ford Motor Company (after the so-called Pinto scandal) and the analysis included meeting the requirements in terms of the car safety and compliance with legal requirements [14-16]. The FMEA became an obligatory analysis in the automotive industry only in 1994 (reference manual QS 9000). In addition, the first automotive standard (ISO / TS 16949 from 1999) maintained the obligation to conduct the FMEA analyses. Further on, the FMEA approach has had two important elaborations - from the VDA standard and the AIAG standard (Figure 3).

Since then, the AIAG has developed its requirements dedicated to automotive manufacturers in the United States (the last revision was the fourth edition of the 2008 manual) and VDA issued the VDA 4 standard, which showed a risk analysis from the point of view of the German car market (latest edition - second amended, updated in June 2012). The consequence of this was often the need to use a different approach to FMEA analysis in one organization, when it implemented projects for companies requiring opposite approaches (e. g. for Ford and VW - each of these clients expected to document the analysis in accordance with their requirements; Ford according to AIAG FMEA, whereas VW according to VDA 4), which led to chaos. Currently, a new standard has been released for conducting the FMEA analysis, which was based on a consensus regarding different expectations of AIAG and VDA as to the shape of FMEA. The changes in the manual can be considered revolutionary - for example, in relation to the resignation from the RPN (Risk Priority Number) indicator, however, looking from a wider perspective it can be safely stated that the guidelines of the new manual follow good practices in running the FMEA in organizations. A detailed description of differences and their summary in relation to both the AIAG and VDA requirements, can be found in Annex F of the FMEA Handbuch manual published jointly by AIAG & VDA in June 2019. The manual is a result of three years of cooperation between the OEMs and first-order suppliers belonging to AIAG and VDA and it replaces the AIAG FMEA edition 4, as well as VDA volume 4 FMEA Product and process manuals [16].

Discussing the detailed differences between standards is not within the scope of this study and will not be cited because of its extensiveness. Later in the paper, only the new FMEA procedure and a practical application of the approach are presented. The main purpose is to present a way of the risk assessment in accordance with the new demands and comparing it to results of the traditionally conducted FMEA, which were based on assessing the RPN.

3 The FMEA procedure according to coherent AIAG&VDA requirements

The new AIAG&VDA FMEA method is described in 7 steps, which are elaborated in detail and presented on examples in Section 4 of the present paper. The steps in order are the following:

- Step 1 - Planning and preparation
- Step 2 - Structure analysis
- Step 3 - Functional analysis
- Step 4 - Failure analysis
- Step 5 - Risk analysis
- Step 6 - Optimization
- Step 7 - Documenting results.

Irrespective of the fact whether the FMEA relates to the product (DFMEA - design FMEA) or a process (PFMEA - process FMEA,) the procedure is realized in analogical steps - the first 3 steps relate to system analysis, the following 3 steps are connected with failure analysis and limiting risk and the step number 7 is communicating the risk in an organization [12]. The main difference regarding the conducted analyses is the difference in the elements analysed during the method application - DFMEA analyses the features, functions and product requirements and in the case of PFMEA the analysis relates to operations included in the process.

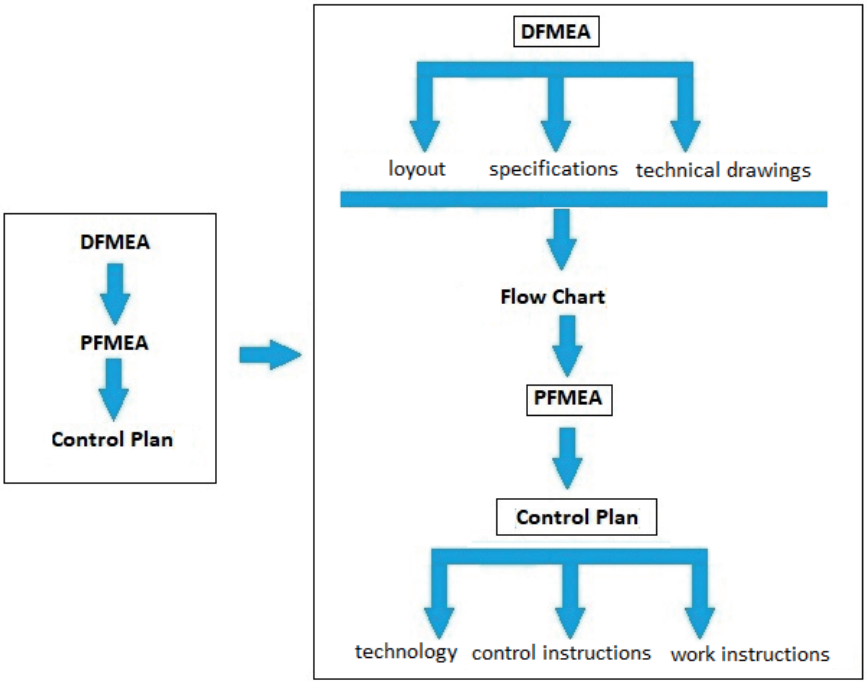

Figure 4 *Connections of DFMEA, PFMEA and other documents in an organization*

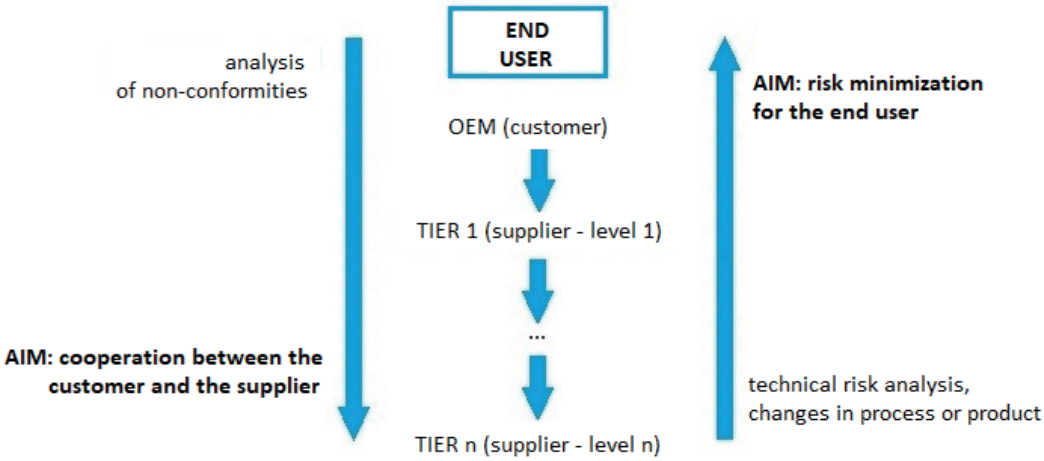

Figure 5 *Cooperation in creating FMEA in supply chain in the automotive industry (TIER - direct supplier for OEM, TIER 2 - second supplier in the logistics chain, etc.*

Accordingly, the FMEA sheets for design and process will be different. In the first case, the resulting sheet will be a combination of all the FMEA sheets for individual functions specified for the product, whereas in the second case it will include the FMEA sheets for all the operations of the analysed process.

Important changes in the new approach to FMEA concern step 5, where the commonly known RPN (Risk Priority Number) was replaced by AP (Action Priority). According to the guidelines, the AP is estimated on three levels: AP H - a high priority, AP M - medium priority, AP L - low priority of action; however, actions must be performed only in the case of AP H. Action priority was developed during the preparation of the new AIAG manual and presented in form of tables from which it is possible to read the action priority for risk reduction both for DFMEA and PFMEA. The AP, similarly, to RPN, is a combination of assessments related to the non-compliance significance, occurrence and detectability, however, the detail of the assessment proposed in the tables developed in the new manual significantly reduces the subjectivity of the expert assessment, which considerably affects improvement activities in the organization.

In production practice, the input document is the DFMEA and only then, on its basis, the PFMEA is created (according to Figure 4). Since October 2013, the FMEA rank has increased due to an update of Rules for achieving and maintaining IATF recognition [17]. The amendment introduced a point about connections between the Control Plans and FMEA and effective implementation of the changes introduced in the above documents - changes in FMEA should be reflected in Control Plans (Figure 4). Adding requirements in the

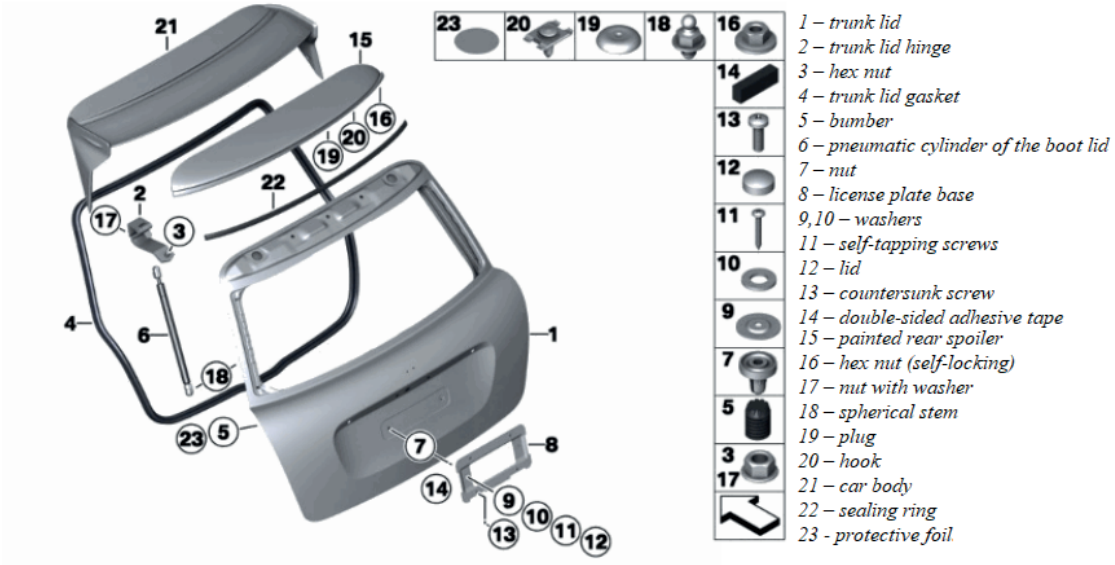

Figure 6 *A fragment of the workstation instruction related to operations conducted at workstation 9.8., source: authors on the basis of materials from production practice*

area of risk management to Rules for achieving and maintaining the IATF recognition is consistent with one of the basic principles of quality management - continuous improvement.

It should also be remembered that FMEA analyses are carried out at various levels in the supply chain in the automotive industry. First of all, from the OEM level, and from the point of view of different suppliers, as well. Until recently (before the introduction of the new approach to FMEA), multi-level assessment (from the point of view of the final, external and internal customer at every stage of this chain) were only good manufacturing practice. At present, they are already included in the new FMEA procedure and require close cooperation between organizations in the supply chain (Figure 5).

4 PFMEA for the assembly process of a spoiler in a passenger car - problem statement and a fragment of analysis

The process FMEA is aimed at analysing potential (or real) failures in the processes of production, assembly, logistics, etc. so as to manufacture products in accordance with the design intentions and meeting all the requirements of interested parties. The failures analysed in PFMEA are different from those analysed in DFMEA. By means of the FMEA, processes occurring in an enterprise are analysed taking into account (potential or actual) non-conformities that may arise due to process variability. Thanks to the PFMEA analyses, it is possible to prioritize preventive (corrective) actions and - if necessary - to improve control activities in an enterprise.

The process FMEA is carried out mainly before production starts, to prevent the occurrence of non-compliances associated with product manufacture, as well as the consequences of those defects. In the production practice, PFMEA is, however, conducted at cyclical intervals and constitutes the so-called Live document - during the course of the project, in which information on internal and external complaints, information from customers, information on process changes is supplemented. The FMEA sheet presents how the project is evaluated and constitutes a company's knowledge base.

The research was carried out at an automotive industry enterprise on the passenger car assembly line and concerned the workstation at which a car spoiler is mounted. The process of installing the spoiler at this workstation includes three basic variants - installing the spoiler in the classic, city and sport versions. Models that are not equipped with a spoiler are also produced. In production practice, individual parts, listed in workstation instructions, are provided in a coded version, enabling for their unambiguous identification (RFID codes). Figure 6 shows a fragment of the instruction for the analysed workstation. The document specifies a proper conduct of the installer at this workstation related to installing the license plate base and the spoiler.

All steps of the PFMEA analysis were carried out respectively.

1st Step - Planning and preparation.

At this stage, the project was identified, including its boundaries. According to the 5T method, the goal (Target) and project schedule (Timing) were developed, a team was appointed (Team), the tasks were distributed (Tasks) and quality management tools were selected to be applied in the project (Tools).

PFMEA was conducted for an existing process of spoiler mounting on workstation 9.8. In determining

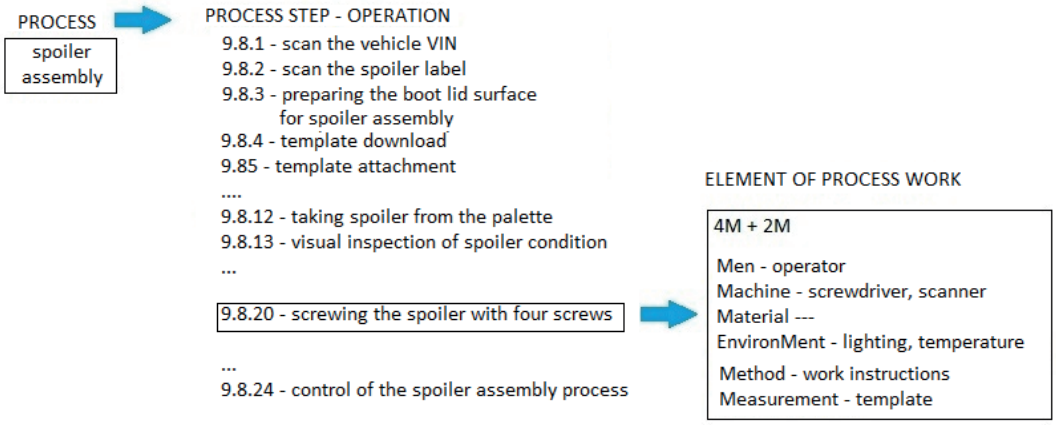

Figure 7 *A fragment of a structure tree for the analysed process*

the scope of the analysis, the team takes into account previous PFMEAs that have already been performed. It also takes into account the DFMEAs that have been received from suppliers. The requirements of all the interested parties were considered, with particular emphasis on legal requirements. At this point, it is worth noting that mounting a spoiler does not affect operation safety of the vehicle or pose a threat to the driver or passengers of the car, but it is a threat to other road users. That is why the assembly at this workstation is provided with safety characteristics (SC).

2nd Step - Structure analysis.

In this step, the team developed a process structure analysis using a structure tree. The new release of PFMEA also allows process diagram analysis in this step. Due to the documentation used in the company, the team could use ready-made flow diagrams (spoiler assembly process, workstation 9.8, activities 9.8.1-9.8.24); however, this solution is only seemingly easier. As production practice shows, the analyses carried out on defect trees effectively limit the possibility of overlooking a failure in the process [16, 18-19]. By using the structure tree analysis, the team organized the hierarchy of system components and illustrated relationships by means of structural connections. Thanks to such activities it was possible to understand the relationship between process elements, operations and process work elements (Figure 7).

The analysis presented in Figure 7 was carried out for all the operations related to this process and concerned all the elements of this process, which constitute the lowest level in this flow. The categories included by the team are not only standard 4M (man, machine, material, environment). In addition, when analysing work process elements, the team included two additional categories (method, measurement).

3rd Step - Functional analysis.

At this stage, the key is to link the requirements or process characteristics with the functions. The team did not identify characteristics other than those resulting from the DFMEA. Safety characteristics appear in the spoiler assembly process, so, in order to ensure that these characteristics are achieved through the process, they should be monitored. A fitter uses a template to measure the size of the gap after installing the spoiler. The durability of the connection is also verified (assessment of the supply of double-sided tape used in the process), as well as the tightening of the bolts fixing the spoiler (torque read by the IT system connected to the screwdriver).

4th Step - Failure analysis.

The main goal of this stage is to develop a failure chain by the team, i. e. the relationship between:

- A failure that occurred in the analysed element - determination of the FM (Failure Mode) in the sheet FMEA.
- The reason for this failure - FC (Failure Cause) designation in the FMEA sheet.
- The result of this failure - FE (Failure Effect) designation in the FMEA sheet.

Figure 8 shows a fragment of the team's work during step 4.

The most important guidelines that the team followed when analysing failures were:

- For FM - each fault was analysed separately, the possibility of detecting the fault during the inspections/tests was analysed.
- For FC - the causes of failures were analysed from the two levels perspective: the direct cause of the fault and the source fault, the reasons were considered in categories 4M + 2M using the Ishikawa diagram.
- For FE - the failures' results were analysed from the perspective of the internal and external customer (i. e. the user of the product), including the legal consequences.

5th Step - Risk assessment and analysis.

Step 5 is a basis for the process optimization. In the first stage, the team measures which preventive controls

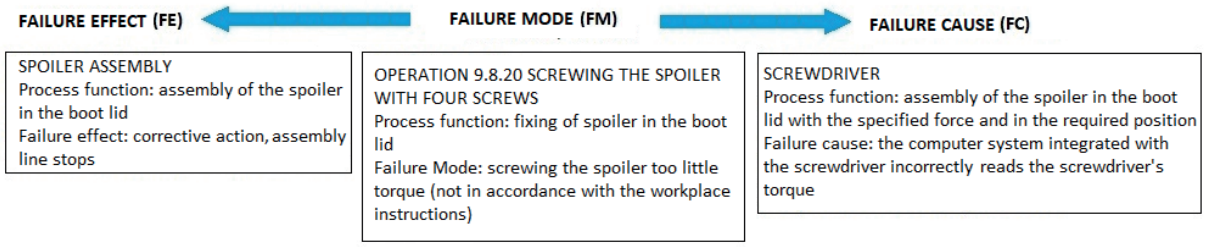

Figure 8 *An exemplary failure chain*

Table 1 *Risk assessment - AP activities prioritization according to guidelines from the new AIAG and VDA manuals (excerpt); AP assessment for the analysed case in bold in the table, based on [12]*

AP activities prioritization						
significance	S	occurrence	O	detection	D	AP
very high effect	9-10	very high	8-10	very low - low	7-10	H
				moderate	5-6	H
				high	2-4	H
				very high	1	H
		high	6-7	very low - low	7-10	H
				moderate	5-6	H
				high	2-4	H
				very high	1	H
		moderate	4-5	very low - low	7-10	H
				moderate	5-6	H
				high	2-4	H
				very high	1	M
		low	2-3	very low - low	7-10	H
				moderate	5-6	M
				high	2-4	L
				very high	1	L
		very low	1	very high - very low	1-10	L

(PC) and detecting controls (DC) are currently used in the process. For the presented example, for the needs of the article, the team identified: template-dependent spoiler position (PC), workstation instruction (PC), visual control (DC), control at the end of the analysed line section (DC) and random control (DC).

At a later stage, the team analysed independent risk factors for all the failure chains identified in step 4. As in previous approaches to FMEA, three criteria were considered: significance of the failure effect (S), occurrence of the failure cause (O) and detectability the failure or its cause (D). During the risk assessment, ready-made, very precisely prepared lists, indicating the level of all the criteria, were used. For example, by analysing the failure chain shown in Figure 8, according to the AIAG + VDA manual, the criterion significance was assessed at a moderate level (S = 8), because the manual determines the impact at level 8 when for an internal customer "a failure can cause deviations in the primary process, deterioration in the speed of the production line, a need to hire extra workforce." The team considered this failure not only in the context of its impact on its own production facility but looked at the problem from a wider perspective. Analysing the impact of this incompatibility on the final user, S = 10 and thus reaches the maximum in the analysed method. The manual describes failure significance determined at level 10 as follows: "the failure affects the safety of ae vehicle and/or other vehicles, the health of the driver and /or passengers or other road users, including pedestrians".

The other two criteria were assessed similarly. When assessing the occurrence (O), the following were taken into account: the type of control in the process (behavioural or technical - according to the manual), preventive control (preventive control partially effective in preventing the failure causes), the level of incidents per 1000 vehicles was rated as 1 / 500. Hence, reading from the Table 1, O = 6, which is high. In assessing detection (D), the team considered two areas: the maturity of the detection method (the control method has not been confirmed as effective and reliable) and the detection capability (human or manual control); hence D was estimated at level 8.

Table 2 *FMEA form - part 1; According to guidelines from the new AIAG and VDA manuals; the case analysed in the paper, based on [12]*

failure analysis - step 4				risk analysis - step 5					
FE	S	FM	FC	PC	O	DC	D	AP	SC
the need to conduct corrective action, assembly line standstills	8	screwing the spoiler with too little torque	the computer system incorrectly read the torque of the screwdriver	workstation instruction, the template of the spoiler's position	6	visual control, random check, end of line control	8	H	Δ
the product influences the safety of other road users	10	screwing the spoiler too little torque	the computer system incorrectly read the torque of the screwdriver	workstation instruction, the template of the spoiler's position	6	visual control, random check, end of line control	8	H	Δ

For the analysed failure chain S = 10, O = 6, D = 8. Based on that estimation, the team was able to proceed to prioritising AP activities and determined the highest priority for review and action (H), according to Table 1.

At this stage, the first part of the PFMEA form is also created. The fragment described in the article is presented in Table 2.

6th Step - Optimization

The main purpose of this stage was to identify the actions necessary to reduce the risk, including determining the scope of responsibility, deadlines for introducing actions and assessing their effectiveness, as well as re-assessing the risk after the actions are introduced. In both cases presented in the article, AP was estimated at a high level (priority H). In such a situation, taking action is obligatory. If the AP is estimated at level M or L, the FMEA only recommends taking action.

In this step, the team decided to take corrective actions. As the root cause of the problem, an unprotected computer program was identified that verified the torque at which the screwdriver fastened the bolts securing the spoiler to the boot lid. The cause has been eliminated and changes were documented. Although in the case presented in the paper the implemented actions did not affect the AP PFMEA result itself - priority is still at level H, the team managed to improve the process.

7th Step - Documenting results.

The last step of the analysis was to prepare an FMEA report and to communicate the results within the organization.

5 Comparing the analyses' results carried out under the old and new approach

While discussing the changes in the approach of risk assessment according to different approaches, it is important to analyse briefly the evolution of e approaches to the risk assessment in the automotive industry (Figure 9).

The initial indications for the FMEA analyses clearly informed the organization about the level of risk that should be accepted by it (RPN range 1 - 100, first column in Figure 9). Above this level, the risk associated with the analysed process, design, structure was unacceptable and it was absolutely necessary to take actions aimed at minimizing this risk. The next stage (column 2 in Figure 9) took into account the individual risk appetite of the organization. Each enterprise established its own, acceptable risk level above which it took corrective or preventive actions. The last stage of the risk analyses based on the FMEA method with the use of RPN (column 3 in Figure 9) took into account not only the individual approach to the acceptable risk level, but the organizational context, as well. In this situation, the risk area appeared, which was conditionally acceptable for the organization (depending on the favourable or not influences of the environment, as well as the analysis of the organization's own capabilities).

In the company presented in the study, the FMEA evolved in accordance with the presented diagram. In the final phase of the analyses carried out with use of the RPN, the following values were established for the measures: RPN at the level of 1 - 80 was an acceptable risk, up to 300 - conditionally acceptable risk and above 300 - unacceptable risk.

When assessing the risk associated with the process (presented and analysed in Section 4 of this study), according to the new and the old approach (in the old approach for O and D, the same results were obtained):

- Assessment of occurrence (O) included: type of control in the process (behavioural or technical - according to the manual), preventive controls (preventive controls partially effective in preventing the causes of error), the level of incidents was assessed as 1 / 500. Therefore - reading from the table, O = 6 that is moderate.
- Detection (D) was assessed - the team looked at two

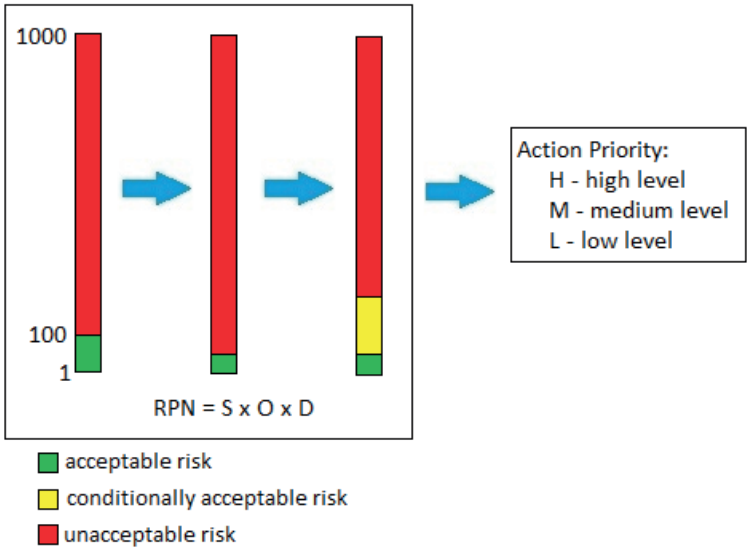

Figure 9 *Evolution of risk analysis in the automotive industry*

areas: the maturity of the detection method (the control method has not been proven effective and reliable) and ability to detect (human or hand-held inspection); therefore, D was estimated at 8.

- The severity (S) of the non-compliance was assessed. In the new approach, the assessment team considered this inconsistency not only in terms of its impact on its own production facility, but also looked at the problem more broadly.

The impact of non-compliance on the end user is S = 10, so it reaches its maximum with the analysed method. The manual book in the column Severity of error in assessment 10 has the following description: The error affects the operational safety of a vehicle and / or other vehicles, the health of the driver and / or passengers or other road users, including pedestrians (critical characteristics).

On the other hand, according to the old approach, in relation to the analysis of the severity of non-compliance, considerations were made only in the intra-organizational system, therefore S = 6. An error may cause deviations in the basic process, deterioration of the speed of the production line, the need to employ additional labour.

The following results were obtained:

- RPN estimated according to the old method was RPN = 288 (O = 6, D = 8, S = 6, RPN = 288) - the level of risk was conditionally acceptable. This means that with a favourable organizational context, the enterprise was not procedurally obliged to take actions to minimize the risk associated with the process.
- AP estimated according to the new method received the highest priority of actions (O = 6, D = 8, S = 10, AP at H level). This means that the organization is obliged to take actions with the identified risk.

The presented comparison illustrates the beneficial changes in the FMEA analyses, which, with the new approach developed by AIAG & VDA, consider a broader perspective of the risk assessment related to the organization's operations.

6 Conclusions

The emergence of the new FMEA handbook, developed thanks to the joint efforts of AIAG and VDA, has systematized good practice in risk analysis related to both the process and the product. Thanks to the precisely developed and described procedure for estimating the criteria affecting the risk: S, O, D, as well as the approach to AP estimation, the new method results in the greater repeatability of the assessment performed by various teams of experts. As a result, there is hope that companies from the automotive industry will stop perceiving the FMEA as an uncomfortable requirement of the standard that they must meet, but as a method generating value for the enterprise. It should be remembered that everything that has been or can be identified under the FMEA procedure constitutes its value and also significantly affects the effectiveness of the decision-making process.

Furthermore, properly conducted FMEA forms a strong basis for preparing the efficient control plans and it is a document, which can charge or release the responsibility of one of the parties in the logistics chain for the design and / or product.

The biggest problem in the correct application of the achievements, developed by the representatives of AIAG and VDA, is the time-consuming nature of the procedure, especially at the stage of implementing changes. Another disadvantage of the approach is the difficult access to knowledge - textbooks and training courses in this field are also payable and the participation of a competent consultant is expensive.

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