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Toward a More Precise Technical Risk Analysis with FMEA regarding Safety Risks

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Abstract: During product and production development technical risk analysis with the well-known method of FMEA (Failure Mode and Effect Analysis) is an established process. The focal point of the risk analysis is the primary and secondary functions of the product. Of course, one of those functions is to ensure that the user of the product is not endangered. However, FMEA has few granularization options for evaluating this type of risk. Within this paper we will derive an approach to establish a more precise possibility for estimation of safety risks. In order to achieve this objective, the procedure for special characteristics will be combined with the probability specifications from other risk assessments procedures. On the one hand, these will be the specifications for maximum injury probability based on European legislation and the Product Liability Regulation. This regulation, which has undergone revisions since December 2024, is applicable to all products. It stipulates the procedures to be followed and the limit values for risks to persons from products placed on the market. On the other hand, the probability of occurrence will be based on the approaches to functional safety in the automotive sector. ISO 26262 (current version: 2018, first published: 2011) establishes objectives for electronic systems (safety systems) with respect to the probability of faults in the field, considering factors such as injury severity, frequency of the hazardous situation and controllability by the driver. The combination of these two approaches facilitates a more precise and comprehensive evaluation of different safety risks, thereby enabling the derivation of conclusions regarding the acceptance of deviations in production with respect to the objectified safety risk.

Keywords: special characteristics, risk analysis, control strategy

1. Introduction

In the automotive industry, ensuring that only safe products are brought to market is of paramount importance (Silanovska & Vrtanovski, 2022). Therefore, it is necessary to implement processes and procedures that systematically record and evaluate safety-influencing characteristics (Sirbulescu & Severin, 2024) (Tiuc et al., 2015). Within the risk analysis according all potential “safety relevant” failure effects are rated with a 10. This would lead to many special characteristics. The discourse surrounding special characteristics has once again become a focal point among original equipment manufacturers (OEMs) and suppliers to the automotive industry, as evidenced by the VDA volume ”Special Characteristics (SC)” (Verband der Automobilindustrie [VDA], 2020) and also mentioned in the VDA/AIAG standard for FMEA (Automotive Industry Action Group (AIAG) / Verband der Automobilindustrie [VDA], 2019). In the event of non-compliance with stipulated requirements, companies may face product liability consequences. Conversely, over-compliance can incur substantial additional expenses related to inspection costs within production and the necessary documentation and archiving (Kheirkhah, 2021). Special characteristics are product characteristics and/or production process parameters (process characteristics) that may have an impact on safety (operational safety and safety in use), compliance with official regulations, function, performance, fit, appearance, or further processing of the product (VDA, 2020) (SAE International, 2021). Special characteristics that have an impact on safety are often driven by “German Angst” and sometimes subject to disproportionate requirements for safety in production. There is a persistent demand for a capable and controlled process with $c_{pk} \geq 1.67$ or, if this is not possible, for 100% inspection with 0 ppm slip-through. This article focuses on special characteristics relevant to safety and describes an approach for ensuring that these features are implemented in the automotive environment with the necessary care, balancing the requirements for safety and cost-effectiveness in production.

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2. Existing approaches

The underlying concept of special features, in principle, possesses cross-industrial relevance. Nevertheless, it is the automotive industry that is primarily driving forward the guidelines for implementation, as can be seen in early approaches within the technical risk analysis (FMEA – Failure Mode and effect analysis) (see e.g. (SAE International, 2021) (Ford Motor Company, 2011) (FMEA (VDA, 2019)(VDA, 2019))

1.1 Approach according to VDA "Special characteristics"

Special characteristics refers to "consequences with immediate danger to life and limb" in the event of deviations from the characteristic tolerance. "The causal relationships between the characteristic and the consequences must be predictable and must not be beyond the realm of probability.". Special characteristics enable companies to prove to external parties in the event of damage that they have fulfilled their duty of care according to regulations (e.g. (REGULATION (EU) 2023/988 on general product safety, 2023). Documents proving this must be retained for 30 years in accordance with VDA specifications (VDA, 2020). The retention period for specification documents refers to the end of production (EoP), and the retention period for quality records refers to 30 years after the production of the product. According to Ford Manual, the presence of potential critical characteristics in development is indicated by the designation "YC," which signifies the potential for these characteristics to be critical (Ford Motor Company, 2011). In the context of production, these elements are designated with the suffix "CC," which stands for "Critical Characteristic. However, the VDA approach does not distinguish between development and production (VDA, 2020). Potential critical characteristics must be determined during development by development engineers, as only then can the function of the product be assessed in the event of deviations from the characteristic values (Udvuleanu & Nicolae, 2023). This can be supported by function/characteristic nets or failure nets as recommended in the VDA procedure for failure mode and effects analysis (FMEA) (VDA, 2019). Special characteristics are generally communicated to production via markings on the design drawing or other specifications (e.g., lists) (VDA, 2020). The marking informs production or the supplier that special care must be taken here (SAE International, 2021).

1.1.1 Filter Concept

The VDA concept recommends filters in development (concept and design filters) and production (production concept and process filters) for rejecting special characteristics (VDA, 2020). The rejection of special characteristics must be carried out using suitable tests and documented with test reports and comprehensible reasons.

Table 1. filter concept according to VDA special characteristics (VDA, 2020)

	Phase in product development	Filter concept: characteristics can be rejected when…
Concept filter	Design (concept phase)	… the system has been designed as a fail-safe system or if redundancies are present that prevent the error sequence from occurring. The fail-safe system used as justification must in turn be analyzed for its relevance with regard to special characteristics.
Design filter	Design (design detailing phase)	… it can be proven that deviations from the characteristic tolerance do not lead to a functional failure, e.g., due to a high safety factor. An indication of this is provided, by analogy with the functional safety of electronic components, if the required function is still unambiguously guaranteed even if the characteristic value is halved or doubled [ISO 26262]. Robustly designed characteristics are then only considered as inspection characteristics.
Production concept filter	Production process design	… a deviation is not possible from a production perspective, e.g., due to a poka-yoke solution. For the poka-yoke solution, functionality must also be verified (documented provocation attempts).
Process filter	Production process (tryouts)	… the process is capable of manufacturing and is under control (robust process [VDA 2020]), i.e., the characteristic values (mean value and dispersion) do not change over time or only change within known limits. These processes can be controlled using statistical process control (SPC). In this case, verification must

	be carried out using process parameters (e.g., c_p and c_{pk}). Statistical process monitoring is suitable for tool-bound processes (e.g., punching). Here, verification can be carried out using recorded process sequences, short-term capabilities and documented random sampling.

1.2 Hazard analysis and risk assessment (HARA)

Hazard analyses and risk assessments (H&R) can be used to determine the “immediate danger” and the “probability of danger”. Depending on the industry and area of application, there are standards and specific guidelines (ISO 26262-3, 2018) (Mössner, 2012); (EN ISO 12100, 2010). For the approach the guidelines used by the European Union Rapid Information System (RAPEX) (Mössner, 2012) and ISO 26262 for E/E components in the automotive industry (ISO 26262-3, 2018) were employed. The general objective is the systematic identification of potential hazards (foreseeable, permanently present, and unexpected). The unexpected hazards posed by the product can be determined on the basis of the main functions of the product and its intended and foreseeable use. Furthermore, the risk of each identified potential hazard or hazardous situation is assessed based on the extent of damage and the probability of occurrence. The risks identified are then compared with defined limit values or risk criteria and an assessment is made as to whether risk reduction measures are necessary.

1.3 RAPEX

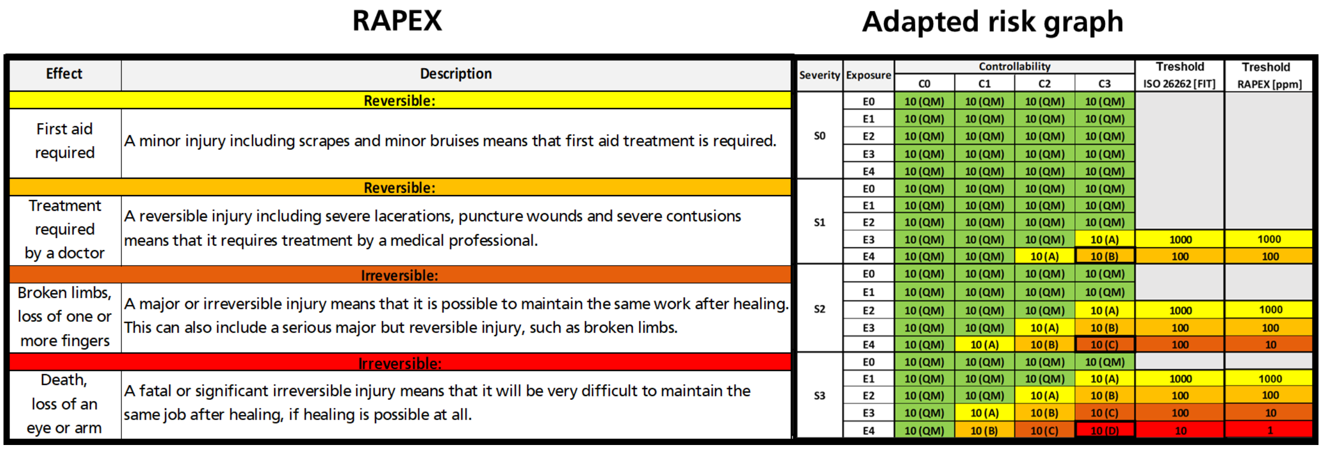
The Rapid Alert System RAPEX (Rapid Exchange of Information System) is a Europe-wide instrument established to protect consumers from consumer products that pose a health risk (COMMISSION IMPLEMENTING DECISION (EU) 2019/417 - Guidelines for the management of the European Union Rapid Information System ‘RAPEX’, 2018). The RAPEX system identifies hazards based on product characteristics (application-related) and takes into account the expected user group (consumer categories). The severity of potential injuries is divided into four categories. The probability of injury is estimated based on the probability of occurrence of the actions that could lead to injury. Based on the severity and probability of occurrence, the inherent hazard of the product is classified into four classes.

1.4 ISO 26262

ISO 26262 is used to validate safety-related electrical and electronic (E/E) components and systems in vehicles. Chapter 3 describes HARA in the concept phase using a risk graph. This risk graph is applied to the application-related hazards of the main functions for all operating states and determines the ASIL (Automotive Safety Integrity Level) based on the three categories of severity of the potential hazard (Severity=S), duration of exposure in the operating situation (Exposure=E), and controllability of the situation by the user (Controllability=C). The ASIL describes the probability of a hazardous situation occurring in the application.

2. Approach to reduce inspection efforts for special characteristics

Given the current state of technology, it is now possible to develop an approach for defining inspection scopes for specific characteristics while considering the application context. To do this, the severity classification from RAPEX is combined with the severity from the ISO 26262 risk graph, and the corresponding ppm limit values from the RAPEX concept are assigned to the ASIL. Furthermore, the global B=10 ratings from the FMEA are converted to B=10 (f:ASIL) (see Figure 1). The characteristics classified as B=10 (QM) are now only (non-special) inspection characteristics, as either the severity is insignificant and/or the occurrence is unlikely and/or control is certain. This makes it unlikely that proof will have to be provided to external parties. The characteristics classified as B=10 (A..D) remain special characteristics. The limit values (in ppm) specified in accordance with RAPEX apply to them.



RAPEX

Effect	Description
Reversible:	
First aid required	A minor injury including scrapes and minor bruises means that first aid treatment is required.
Reversible:	
Treatment required by a doctor	A reversible injury including severe lacerations, puncture wounds and severe contusions means that it requires treatment by a medical professional.
Irreversible:	
Broken limbs, loss of one or more fingers	A major or irreversible injury means that it is possible to maintain the same work after healing. This can also include a serious major but reversible injury, such as broken limbs.
Irreversible:	
Death, loss of an eye or arm	A fatal or significant irreversible injury means that it will be very difficult to maintain the same job after healing, if healing is possible at all.

Adapted risk graph

Severity	Exposure	Controllability				Treshold	Treshold
		C0	C1	C2	C3	ISO 26262 [FIT]	RAPEX [ppm]
S0	E0	10 (QM)	10 (QM)	10 (QM)	10 (QM)		
	E1	10 (QM)	10 (QM)	10 (QM)	10 (QM)		
	E2	10 (QM)	10 (QM)	10 (QM)	10 (QM)		
	E3	10 (QM)	10 (QM)	10 (QM)	10 (QM)		
	E4	10 (QM)	10 (QM)	10 (QM)	10 (QM)		
S1	E0	10 (QM)	10 (QM)	10 (QM)	10 (QM)		
	E1	10 (QM)	10 (QM)	10 (QM)	10 (QM)		
	E2	10 (QM)	10 (QM)	10 (QM)	10 (QM)		
	E3	10 (QM)	10 (QM)	10 (QM)	10 (A)	1000	1000
	E4	10 (QM)	10 (QM)	10 (A)	10 (B)	100	100
S2	E0	10 (QM)	10 (QM)	10 (QM)	10 (QM)		
	E1	10 (QM)	10 (QM)	10 (QM)	10 (QM)		
	E2	10 (QM)	10 (QM)	10 (QM)	10 (A)	1000	1000
	E3	10 (QM)	10 (QM)	10 (A)	10 (B)	100	100
	E4	10 (QM)	10 (A)	10 (B)	10 (C)	100	10
S3	E0	10 (QM)	10 (QM)	10 (QM)	10 (QM)		
	E1	10 (QM)	10 (QM)	10 (QM)	10 (A)	1000	1000
	E2	10 (QM)	10 (QM)	10 (A)	10 (B)	100	100
	E3	10 (QM)	10 (A)	10 (B)	10 (C)	100	10
	E4	10 (QM)	10 (B)	10 (C)	10 (D)	10	1

Figure 1. Relationship between severity S, probability of the hazardous situation occurring via exposure E and controllability C, and associated permissible ppm values according to RAPEX

The following steps are now taken to determine the application-related definition of the scope of inspection for the special characteristics:

Step 1: Determination of potential hazards using HARA based on the main functions of the product and the planned application (usage scenarios).

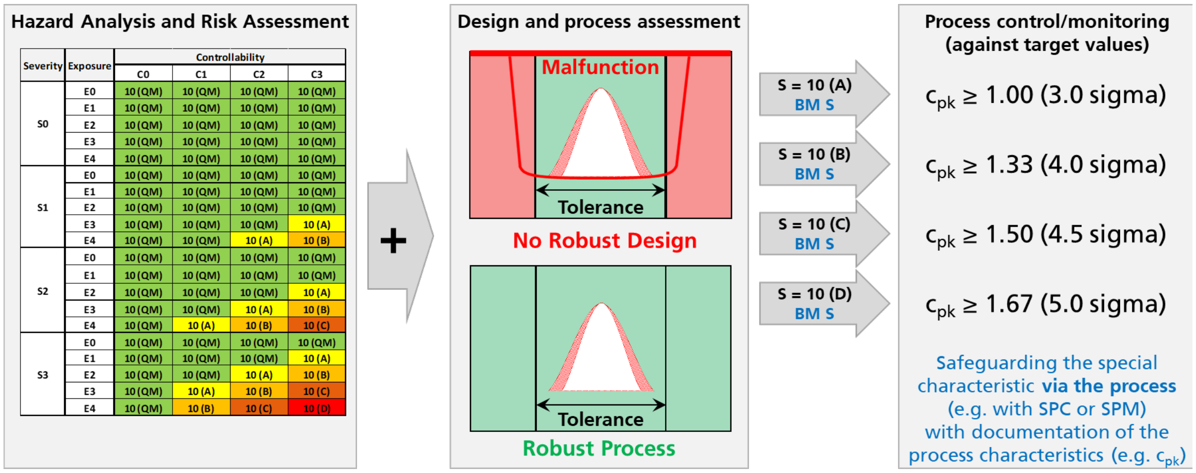
Step 2: Determination of the ASIL based on the severity level S classified according to RAPEX, the duration of exposure in the operating situation (Exposure=E) and the controllability of the situation by the user (Controllability=C) with the aid of the risk graph according to ISO 26262.

Step 3: Determination of the associated characteristics for the hazards of the product using function and characteristic networks or fault networks from the FMEA. Inheritance of the application-related ASIL to the associated special characteristics.

Step 4: Communication of the risk to production by passing on the ASIL in the labeling of the special characteristic (e.g., Zeppelin dimension with ASIL).

Step 5: Define the required c_{pk} limits based on the ASIL classification for the combination of “no robust design” and “robust process” using the RAPEX classification for permissible ppm values (see Figure 2)

Step 6: Definition of the permissible slip-through rate based on the ASIL classification for the combination of “no robust design” and “no robust process” using the RAPEX classification for permissible ppm values (see Figure 3).

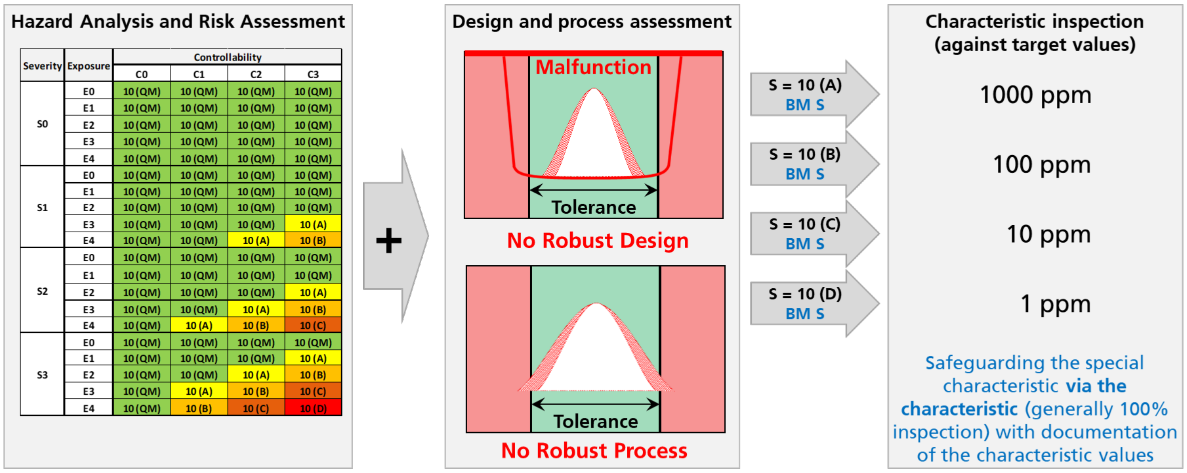


Hazard Analysis and Risk Assessment

Severity	Exposure	Controllability			
		C0	C1	C2	C3
S0	E0	10 (QM)	10 (QM)	10 (QM)	10 (QM)
	E1	10 (QM)	10 (QM)	10 (QM)	10 (QM)
	E2	10 (QM)	10 (QM)	10 (QM)	10 (QM)
	E3	10 (QM)	10 (QM)	10 (QM)	10 (QM)
	E4	10 (QM)	10 (QM)	10 (QM)	10 (QM)
S1	E0	10 (QM)	10 (QM)	10 (QM)	10 (QM)
	E1	10 (QM)	10 (QM)	10 (QM)	10 (QM)
	E2	10 (QM)	10 (QM)	10 (QM)	10 (QM)
	E3	10 (QM)	10 (QM)	10 (QM)	10 (A)
	E4	10 (QM)	10 (QM)	10 (A)	10 (B)
S2	E0	10 (QM)	10 (QM)	10 (QM)	10 (QM)
	E1	10 (QM)	10 (QM)	10 (QM)	10 (QM)
	E2	10 (QM)	10 (QM)	10 (QM)	10 (A)
	E3	10 (QM)	10 (QM)	10 (A)	10 (B)
	E4	10 (QM)	10 (A)	10 (B)	10 (C)
S3	E0	10 (QM)	10 (QM)	10 (QM)	10 (QM)
	E1	10 (QM)	10 (QM)	10 (QM)	10 (A)
	E2	10 (QM)	10 (QM)	10 (A)	10 (B)
	E3	10 (QM)	10 (A)	10 (B)	10 (C)
	E4	10 (QM)	10 (B)	10 (C)	10 (D)

+
Design and process assessment
Malfunction
Tolerance
No Robust Design
Tolerance
Robust Process
S = 10 (A)
BM S
S = 10 (B)
BM S
S = 10 (C)
BM S
S = 10 (D)
BM S
Process control/monitoring (against target values)
$c_{pk} \geq 1.00$ (3.0 sigma)
$c_{pk} \geq 1.33$ (4.0 sigma)
$c_{pk} \geq 1.50$ (4.5 sigma)
$c_{pk} \geq 1.67$ (5.0 sigma)
Safeguarding the special characteristic via the process (e.g. with SPC or SPM) with documentation of the process characteristics (e.g. c_{pk})

Figure 2. Definition of c_{pk} limits based on ASIL classification for the combination of “no robust design” and “robust process.”



Hazard Analysis and Risk Assessment

Severity	Exposure	Controllability			
		C0	C1	C2	C3
S0	E0	10 (QM)	10 (QM)	10 (QM)	10 (QM)
	E1	10 (QM)	10 (QM)	10 (QM)	10 (QM)
	E2	10 (QM)	10 (QM)	10 (QM)	10 (QM)
	E3	10 (QM)	10 (QM)	10 (QM)	10 (QM)
	E4	10 (QM)	10 (QM)	10 (QM)	10 (QM)
S1	E0	10 (QM)	10 (QM)	10 (QM)	10 (QM)
	E1	10 (QM)	10 (QM)	10 (QM)	10 (QM)
	E2	10 (QM)	10 (QM)	10 (QM)	10 (QM)
	E3	10 (QM)	10 (QM)	10 (QM)	10 (A)
	E4	10 (QM)	10 (QM)	10 (A)	10 (B)
S2	E0	10 (QM)	10 (QM)	10 (QM)	10 (QM)
	E1	10 (QM)	10 (QM)	10 (QM)	10 (QM)
	E2	10 (QM)	10 (QM)	10 (QM)	10 (A)
	E3	10 (QM)	10 (QM)	10 (A)	10 (B)
	E4	10 (QM)	10 (A)	10 (B)	10 (C)
S3	E0	10 (QM)	10 (QM)	10 (QM)	10 (QM)
	E1	10 (QM)	10 (QM)	10 (QM)	10 (A)
	E2	10 (QM)	10 (QM)	10 (A)	10 (B)
	E3	10 (QM)	10 (A)	10 (B)	10 (C)
	E4	10 (QM)	10 (B)	10 (C)	10 (D)

Safeguarding the special characteristic **via the characteristic** (generally 100% inspection) with documentation of the characteristic values

Figure 3. Definition of ppm limits for slip-through based on the ASIL classification for the combination of "no robust design" and "no robust process."

The next steps then follow the classical process to derive the inspection plan:

Step 1: Assignment of inspection to the product characteristic, function, or process characteristics

Step 2: Definition of the appropriate inspection strategy depending on a capable and controlled process via SPC or, in the case of a tool-based process, via statistical process monitoring (SPM).

Step 3: Determination of process capabilities for capable and controlled processes or for tool-dependent processes and comparison with the permissible cpk limit values for the application (keep in mind: the documentation of these process capability tests has to be treated equal to a inspection value of a special characteristic – so the documentation requirements (e.g. 30 Years according to [VDA 2020] apply)

Step 4: Definition of inspection strategies based on systematic and random influences to ensure the determined permissible slip for application via occurrence and detection

3. Conclusion

The approach delineated herein demonstrates, in accordance with prevailing guidelines and standards, the potential for a substantial reduction in the scope of inspection for special characteristics pertinent to safety. The VDA concept for special characteristics is supplemented by an application-specific filter for classifying "consequences with immediate danger to life and limb" and for avoiding "causal sequences that are beyond all probability." This approach provides companies with a straightforward and accessible method for the objective selection and classification of special characteristics pertinent to safety.

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