

## A Review of the Evolution of Hazard and Risk Analysis Methods for Automated Driving in the Context of ISO 26262 and ISO 21448

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The increasing level of automation in vehicle systems leads to higher system complexity and challenges for established safety analysis processes. Classical approaches such as Hazard Analysis and Risk Assessment (HARA), central to functional safety under ISO 26262, as well as methods such as Fault Tree Analysis (FTA) and Failure Mode and Effects Analysis (FMEA), show limitations when applied to open and dynamic operational environments with complex interactions. This paper presents a systematic literature review investigating how hazard and risk analysis methods have evolved following the release of ISO 26262 (2nd ed.), with particular consideration of ISO 21448 addressing the safety of the intended functionality (SOTIF). Scientific publications from December 2018 to December 2025 were identified and analyzed using defined selection criteria. The results indicate that current developments primarily extend and combine established methods rather than replacing them. These approaches enhance scenario representation, interaction analysis, and quantitative assessment, but remain heterogeneous and not fully integrated. The paper provides a structured classification of these developments and highlighting the need for systematic integration of complementary methods to address the safety challenges of highly automated vehicle systems.

**Keywords:** Hazard and Risk Analysis, Functional Safety, ISO 26262, ISO 21448, SOTIF, Automated Driving, Safety Analysis Methods.

### 1. Introduction

The increasing level of automation and connectivity in modern vehicles leads to greater system complexity, more intensive interactions between vehicles and infrastructure, and increased operational uncertainty in real-world traffic environments Ji et al. (2024). As a result, established safety analysis processes face limitations when applied to highly automated systems in open and dynamic environments. Deriving and validating appropriate safety goals across a wide range of operating conditions has become a major challenge for functional safety assurance Hawkins et al. (2022). The introduction of ISO 21448 has further highlighted that risks beyond conven-

tional hardware and software failures must be addressed systematically International Organization for Standardization and SAE International (2022). Both ISO 26262 and ISO 21448 define required activities for safe system development but remain method-independent, leaving their practical implementation largely to developers. This has led to numerous methodological extensions aimed at bridging the gap between functional safety and SOTIF in automated driving Burton and McDermid (2023), with System-Theoretic Process Analysis (STPA) being a prominent example that supports the analysis of system interactions and control-related hazards in early development phases Abdulkhaleq et al. (2016). Despite the growing body of research, a structured

overview of these developments and their normative positioning is still lacking. Existing work typically focuses on specific extensions or combinations of individual methods such as HARA, STPA, or FMEA, while a systematic synthesis across methods remains largely absent Li et al. (2024). The remainder of this paper is structured as follows. Section 2 describes the review methodology, Section 3 presents the results, Section 4 evaluates the identified approaches, Section 5 discusses the findings, and Section 6 concludes the paper.

**Related Work** Several review papers address safety processes for highly automated vehicles. Xie et al. (2020) summarize recent advances in functional safety design methodologies across analysis, design, and runtime phases, with a focus on system-level safety processes and future trends related to ISO 21448, but without explicitly addressing hazard and risk analysis methods. Similarly, Gyllenhammar et al. (2025) review methods for safety assurance and identify key challenges such as operational uncertainty, responsibility allocation, and the integration of AI-based components, highlighting gaps in existing design, verification, and runtime approaches. In addition, Chia et al. (2022) compare risk assessment methodologies with respect to ISO 26262 and ISO 21448 and provide recommendations for their application in automated driving systems. However, existing work typically focuses on safety processes, validation strategies, or complete risk assessment frameworks rather than on the methodological development of individual hazard and risk analysis techniques. In contrast, this work systematically examines how classical hazard and risk analysis methods have been extended, adapted, or combined to meet the evolving requirements of functional safety and SOTIF.

## 2. Research Methodology

In this paper, the term ISO 21448 is used consistently to refer to all stages of the standard, including ISO/PAS, ISO/DIS, and ISO/SAE. A systematic literature review was conducted to identify methodological contributions that extend, adapt, or combine classical hazard and risk anal-

ysis methods for highly automated vehicle systems, with a focus on functional safety and SOTIF. Publications from December 2018 to December 2025 were retrieved from IEEE Xplore and Google Scholar using the following search string: ((“hazard analysis” OR “risk assessment”) AND (“HARA” OR “FTA” OR “FMEA” OR “STPA”) AND (“method” OR “methodology”) AND (“ISO 26262” OR “SOTIF”) AND (“extended” OR “novel”)). The search yielded over 1000 results. After applying formal criteria and excluding non-peer-reviewed publications, titles and abstracts were screened, resulting in 61 candidate publications. A subsequent full text review excluded 31 publications due to insufficient relevance to the automotive domain, resulting in a final set of 30 publications. Inclusion criteria ensured methodological relevance and consistency. Publications were included if they (i) presented a methodological contribution to hazard or risk analysis, (ii) addressed ISO 26262 and/or ISO 21448 or were relevant to functional safety or SOTIF, and (iii) were applicable to automated vehicle systems. Exclusion criteria comprised (i) purely descriptive works without methodological contribution, (ii) studies not related to hazard or risk analysis in the context of functional safety or SOTIF, (iii) publications outside the automotive domain, and (iv) studies with a primary focus on cybersecurity rather than safety. Publications addressing cybersecurity aspects in addition to a primary safety contribution were retained.

**Research Questions** Based on the research objectives and the reviewed literature, this review addresses the following research questions:

**RQ1:** What methodological extensions of classic hazard and risk analysis methods have been developed since the release of ISO 26262 (2nd ed., 2018) and ISO 21448 in order to implement their requirements for automated vehicle systems?

**RQ2:** To what extent do these methodological developments address the safety challenges related to highly automated systems?

**RQ3:** Which methodological approaches enable the systematic identification of risks especially in the context of SOTIF?

These research questions form the analytical basis for the presentation of results, the evaluation of the identified approaches, and the discussion of unresolved challenges.

### 3. Results

This chapter presents the results of the review, organizing 30 identified publications into thematic categories based on their primary methodological contribution.

#### 3.1. Model-Based Approaches

The results from this category are aimed at enhancing the consistency and traceability of system models and hazard analysis by employing model-based methods. Jianyu and Zhang (2021) propose a method that combines STPA with model-based systems engineering and aligns this method with the requirements of ISO 26262 and SOTIF. Duan (2022) presents an approach in which STPA is tightly integrated to SysML models to describe control structures and interactions between systems. The work also performs simulation-based quantitative analyses of selected unsafe control actions to demonstrate the applicability of the model-based approaches in system design.

#### 3.2. Integrated Safety Frameworks and Hybrid Methodologies

The results in this category combine multiple analysis techniques to address both technical system behavior and sociotechnical interactions. Thomas and Groth (2023) propose a safety framework based on Hybrid Causal Logic (HCL), combining Event Sequence Diagrams, FTA, and Bayesian networks to address identified limitations of current AV safety methodologies. Li et al. (2024) integrate STPA into the concept phase of ISO 26262 and ISO/SAE 21434 to reduce redundancies and inconsistencies in safety and security requirements, extending the STPA SafeSec method with additional interface elements and introducing a loss scenario tree to describe unsafe and insecure control actions. Going further, El Badaoui et al. (2025) combine STPA with the requirements of ISO 26262 and ISO 21448, presenting an explicitly normative end-to-end inte-

gration approach. Bergenhem et al. (2020) propose a quantitative risk norm and incident classification for analyzing risks in cooperative platooning systems, complemented by a distributed architecture separating strategic, tactical, and operational functions.

#### 3.3. Scenario-Based Approaches

The results in this category focus on evaluating risk in operational scenarios by considering environmental factors and system interactions. Kramer et al. (2020) present an integrated method for identifying and quantifying hazardous scenarios that considers both functional safety and SOTIF and extends existing analysis tools for automated driving. Khatun et al. (2020) propose an extended HARA combining functional safety, SOTIF, and cybersecurity considerations, with a focus on scenario representation and the systematic identification of FuSa and SOTIF interactions. For AI-based components, Zhao et al. (2025) introduce EOS-STPA, extending STPA to external operational scenarios using hierarchical control structures and ontology theory to formalize system interactions and enhance SOTIF coverage. Ercan and Doğan (2025) combine STPA with the Cause Tree Analysis (CTA) recommended in ISO 21448 and ISO/PAS 8800 to derive causal scenarios from unsafe control actions while assessing risks due to perception and performance limitations. Zhu et al. (2022) propose a method for identifying triggering conditions under ISO 21448, providing formal categorizations and structured formulations that require less system insight than existing approaches.

#### 3.4. Quantitative and Data-Driven Approaches

The results in this category seek to enhance the objectivity and reproducibility of expert-based risk assessments. Patel and Liggesmeyer (2021) propose a Dynamic Risk Assessment for runtime use, classifying severity and controllability from on-board sensor data using a support vector machine (SVM). De Gelder et al. (2021) propose a data-driven quantitative risk assessment representing ADS risk as the expected number of injuries,

decomposed into exposure, severity, and controllability to address subjectivity limitations of ISO 26262 and ISO 21448. Hou et al. (2024) introduce Noisy-HBN, a Bayesian network approach integrating noisy nodes and IoV-aggregated factors to assess unknown causes on SOTIF, validated through scenario-based verification on a newly developed virtual dataset. Deng et al. (2025) combine FRAM with Bayesian networks to identify and quantify risks from functional resonance – hazardous interactions among normally operating components not captured by conventional methods such as STPA. Cărlan et al. (2024) propose a SOTIF oriented meta-algorithm integrating qFTA, UL 4600 based safety performance indicators, and statistical hypothesis tests for risk-based deployment decisions under ISO 21448. Putter et al. (2023) propose a K-Means++ and k-NN based unsupervised methodology to generate representative test scenario catalogs from real-world accident data for validating perception-based Pre-Crash systems under ISO 26262 and ISO 21448. Schwalb (2021) address rare hazard test coverage by combining probabilistic hazard analysis with a dynamic monitoring approach and a neural network based scenario sampler to accelerate testing under ISO 26262 and SOTIF. Zheng, Liu, Li, Wang, and Qin (Zheng et al.) propose a quantitative risk assessment method for CAVs combining FTA with a cloud model-based analytic hierarchy process (AHP) to refine ASIL classifications and reduce uncertainty from subjective data, validated through a sensitivity analysis on an AEB system. Finally, Sun et al. (2025) introduce a fusion safety analysis collectively addressing functional safety, SOTIF, and select security considerations by mapping unsafe behaviors to hazardous scenarios and quantitatively assessing integrated risks, demonstrated on an ACC case study.

### **3.5. Operational and Runtime-Oriented Safety Analysis**

The results in this category extend traditional safety analyses, traditionally confined to the development phase, by incorporating methods for assessing risks and hazards during operation. Chia et al. (2021) propose ReRAF, a recursive real-

time risk assessment framework dynamically capturing collision-based risks and controllability in temporal and spatial domains, comparing current hazards with past occurrences to predict safety actions and complement static HARA processes. Correa-Jullian et al. (2025) develop a structured hazard identification methodology for L4 ADS MaaS fleets without safety drivers, combining ESD, CoTA, STPA, and FTA to analyze interactions between multiple human and machine agents including remote and fleet operators.

### **3.6. Vehicle-Level Safety Assessment**

The result in this category extends classic safety analyses beyond individual components by accounting for safety-relevant interactions across subsystem boundaries. Gu (2025) propose VISEF, extending ISO 26262 through vehicle-level hazard integration via similarity-based consolidation and ASIL reallocation, complemented by safety path inspection across ECU control flows, validated through a probabilistic model and an industrial xEV case study.

### **3.7. Automation and Tool Support for Safety Analysis Activities**

The results in this category focus on reducing manual effort in safety analysis activities and increasing the objectivity of results. Sini et al. (2019) propose an approach that uses vehicle simulators at the vehicle-level to test the specification of Advanced Driver Assistance System (ADAS) behavior based on simulated operating situations. Sini and Violante (2020) combine engineering based HARA with vehicle-level simulation to automatically and systematically identify and classify hazards, improving objectivity by capturing complex functional interactions. Oakes et al. (2021) introduce SAHARA, a machine learning based fault injection approach that semi automatically identifies, visualizes, and classifies hazardous situations under ISO 26262 in approximately twenty minutes.

### **3.8. Extensions of Classical Hazard and Risk Analysis Methods**

The results listed here aim to adapt established techniques such as HARA, FMEA, FTA, and

STPA to the increasing complexity of automated, connected, and cooperative vehicle systems. Maier and Mottok (2022) investigate relations between causal models and established safety analysis techniques such as FMEA, FTA, and GSN, extending the concept of Hybrid Causal Logic to develop a causal shell model of automotive system safety. Chen et al. (2020) integrate STPA into an FMEA template through the STPAFT method, combining component-level analysis with system-theoretic causal factors to derive safety goals and functional safety requirements in the ISO 26262 concept phase. Xing et al. (2021) further extend STPA by incorporating finite state machines to explicitly model vehicle states and environmental conditions, enabling the identification of additional hazardous events. Warg et al. (2020) propose a quantitative risk norm with consequence classes as a tailored HARA replacement for ADS, ensuring completeness of safety goals under ISO 26262.

#### **4. Evaluation**

The following evaluation assesses the identified methodological contribution with respect to the research questions defined in section 2.

##### **4.1. Model-Based Approaches**

The identified results show that the integration of model-based approaches and STPA enhances consistency by improving consistency, transparency, and traceability between system architecture and safety analysis. These approaches thus support the structured identification of hazards and the systematic derivation of safety requirements. However, risk assessment is generally only addressed to a limited extent. This means that additional methods such as quantitative risk assessment or scenario-based validation are required to ensure the safety of automated driving functions.

##### **4.2. Integrated Safety Frameworks and Hybrid Methodologies**

Integrated and hybrid approaches show that combining multiple analysis methods improves the understanding of interactions and supports alignment across safety and security domains. This

helps to address limitations of individual methods and improves consistency in safety analyses. However, the diversity of combined approaches indicates challenges for consistent integration in industrial processes.

##### **4.3. Scenario-Based and Interaction-Oriented Approaches**

The results indicate that scenario-based approaches address hazard identification in open and dynamic environments by capturing environmental influences, system interactions, and perception limitations. The extension of STPA to external operational scenarios and its integration with ISO 21448 enable a more structured consideration of performance limitations in automated driving systems. Together, these approaches expand the analysis of risks beyond purely component focused perspectives.

##### **4.4. Quantitative and Data-Driven Approaches**

The results indicate that quantitative and data-driven methods reduce subjectivity in risk assessment by linking safety analysis to statistical evidence, runtime data, and, in some cases, real world observations. Contributions include dynamic risk assessment for runtime use and probabilistic approaches for rare hazard coverage. While these methods support more objective assessment, their validity depends on data availability and scenario coverage. They therefore complement established hazard and risk analysis processes rather than replacing them.

##### **4.5. Operational and Runtime-Oriented Safety Analysis**

The results indicate that operational and runtime-oriented safety analyses extend traditional development phase methods by enabling the assessment of risks under dynamic temporal and spatial conditions and by capturing interactions between multiple human and machine agents during operation. Recursive real time risk assessment and structured multi agent hazard identification demonstrate how operational approaches can complement static HARA processes. However, based on the limited number of identified

contributions, this area remains comparatively underrepresented, indicating a lack of established methodologies for runtime safety analysis.

#### **4.6. Vehicle-Level Safety Assessment**

The result demonstrates that vehicle-level safety analysis extending ISO 26262 through hazard integration and ASIL reallocation enables a more comprehensive consideration of system wide interactions beyond traditional item oriented analyses. However, as this assessment is based on a single identified contribution, broader conclusions remain limited and further validation across different system architectures is required.

#### **4.7. Automation and Tool Support for Safety Analysis Activities**

The results indicate that simulation based and machine learning based tools reduce manual effort and improve objectivity in hazard identification and classification. The combination of engineering based HARA with vehicle-level simulation supports structured hazard identification, while fault injection approaches such as SA-HARA demonstrate reduced analysis effort under ISO 26262. These approaches support safety analysis activities but do not replace expert judgment in safety critical development.

#### **4.8. Extensions of Classical Hazard and Risk Analysis Methods**

The results show that classical hazard and risk analysis methods are extended through the integration of system-theoretic concepts, causal modeling, and state based representations to address the complexity of automated vehicle systems. The combination of STPA with FMEA, the extension of STPA using finite state machines, and the development of causal models demonstrate how established methods can be adapted to capture additional system interactions and states. In addition, the proposal of a quantitative risk norm as an alternative to HARA indicates that, in specific cases, classical methods may require more fundamental adaptation. These contributions reflect ongoing methodological development toward safety analysis approaches suited for automated driving.

### **5. Discussion**

The literature review reveals substantial methodological developments in hazard and risk analysis driven by the increasing complexity of automated vehicle systems and the additional requirements of ISO 26262 and ISO 21448. Addressing RQ1, these developments span model-based, scenario-based, hybrid, quantitative, vehicle-level, and runtime-oriented approaches. Rather than replacing established techniques, most contributions extend classical methods through scenario modeling, interaction analysis, probabilistic assessment, or adaptations to specific standards, thereby preserving compatibility with existing safety processes. This indicates that current developments remain largely incremental and focused on extending existing approaches rather than introducing unified methodological frameworks.

Regarding RQ2, the reviewed methods address safety challenges to varying degrees, but no single approach provides comprehensive coverage. Scenario-based methods improve hazard identification in dynamic environments, quantitative methods reduce subjectivity, and vehicle-level approaches capture dependencies across system components. Runtime-oriented methods further extend safety considerations into operation, suggesting that combinations of complementary methods are often required to address complex safety challenges.

With respect to RQ3, SOTIF specific risk identification is primarily supported by scenario-based methods, STPA extensions, and probabilistic techniques such as Bayesian networks and quantitative fault tree analysis. These approaches address performance limitations, perception uncertainties, and triggering conditions that are not covered by classical fault oriented analyses.

### **6. Conclusion**

The results of this review indicate that the evolution of classical hazard and risk analysis methods for automated vehicle systems has so far been largely incremental and fragmented, as reflected by the predominance of method extensions and combinations rather than the emergence of unified methodological frameworks. Across all

identified categories, a consistent pattern emerges in which scenario-based, system-theoretic, and quantitative approaches are used to complement rather than replace established techniques. This highlights a growing need for structured integration of these methods into coherent safety processes, particularly to address dynamic system behavior, interaction complexity, and performance limitations beyond fault based analysis. In addition, the increasing use of data-driven and probabilistic approaches indicates a shift toward more evidence based risk assessment, while runtime-oriented methods extend safety considerations beyond the development phase into operation. However, the identified approaches remain heterogeneous and only partially aligned with existing standards, limiting their direct applicability in industrial contexts. Overall, the results suggest that future progress in safety assurance will depend less on further isolated method extensions and more on the systematic integration and standardization of complementary approaches to achieve scalable and consistent safety processes for highly automated vehicle systems.

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