Document ADS-18-04/Rev.1
18th ADS IWG session
14 January 2026, Web conference

United Nations

Economic and Social Council

Distr.: General
10 November 2025

Original: English

Economic Commission for Europe

Inland Transport Committee

World Forum for Harmonization of Vehicle Regulations

Working Party on Automated/Autonomous and Connected Vehicles

Twenty-fourth session
Geneva, 19-23 January 2026
Item 4(a) of the provisional agenda
Automated/Autonomous and Connected Vehicles:
Informal Working Group on Automated Driving System

Proposal for a new United Nations Global Technical Regulation on Automated Driving Systems (ADS)

Submitted by the Informal Working Group on Automated Driving Systems*

The text reproduced below was prepared by the Informal Working Group on Automated Driving Systems to propose the establishment of a new United Nations Global Technical Regulation providing worldwide harmonised provisions for the safety of Automated Driving Systems on Category 1 and 2 vehicles. This document is based on informal document GRVA-23-23 and submitted pursuant to ECE/TRANS/WP.29/**2019**/39/Rev.2 as amended by ECE/TRANS/WP.29/2021/151, ECE/TRANS/WP.29/2023/43, and ECE/TRANS/WP.29/2024/33 ("AV Framework Document"), ECE/TRANS/WP.29/2019/34 ("Guidelines and recommendations for Automated Driving System safety requirements, assessments and test methods"), and ECE/TRANS/WP.29/AC.3/62 ("Authorization to develop a new UN GTR on Automated Driving Systems").

* In accordance with the programme of work of the Inland Transport Committee for 2026 as outlined in proposed programme budget for 2026 (A/80/6 (Sect. 20), table 20.7), the World Forum will develop, harmonize and update UN Regulations in order to enhance the performance of vehicles. The present document is submitted in conformity with that mandate.

United Nations Global Technical Regulation on Automated Driving Systems (ADS)

Contents

I. Statement of technical rationale and justification

A. Introduction

1. With the rapid development of Automated Driving System (ADS) technology, ADS vehicles hold great potential to improve road safety and enhance mobility options for numerous road users. ADS are poised to significantly change the nature of road transport. They also pose many novel safety risks that must be effectively addressed by manufacturers and the international regulatory community.

2. The introduction of ADS presents many new and unique challenges for the development of vehicle regulations. Governments around the world are facing the problem of how to formulate effective regulatory measures. To ensure ADS safety, the safety regulators require new concepts, tools, and methodologies in addition to those historically used for previous vehicle technologies and systems.[1]

3. WP.29 recognizes that for automated vehicles to fulfil their potential, in particular to improve road transport, they must be placed on the market in a way that reassures road users of their safety. If automated vehicles confuse users, disrupt road traffic, or otherwise perform poorly, then they will fail to improve road transport outcomes.[2] Therefore, there is an urgent need for regulatory measures, to ensure the safety of automated vehicles that are deployed on public roads, and to promote collaboration and communication amongst those involved in their development and oversight.

4. Technical provisions, guidance resolutions and evaluation criteria for automated vehicles will, to the best extent possible, be performance based, technology neutral, and based on state-of-the-art technology, while avoiding restricting future innovation. [3] Automated vehicle systems, operating in automated mode in their respective Operational Design Domain (ODD) shall not cause any traffic accidents resulting in injury or death that are reasonably foreseeable and preventable. Based on these principles, this GTR sets out a series of vehicle safety provisions to address the safe deployment of ADS equipped vehicles.[4]

5. It is important to note that the diversity of ADS vehicle configurations and the characteristics and constraints of their ODD present challenges in establishing harmonized requirements for worldwide use. At the same time, the complexity of driving also presents challenges to the assessment of ADS performance across the diversity of ODDs.[5]

6. This GTR aims to provide a harmonized methodology, incorporating high-level requirements that address the unique nature and safety challenges associated with ADS technology as well as a multi-pillar approach to ensure comprehensive, effective and efficient validation of ADS safety.[6]

7. This GTR is based on the collaborative efforts of the Informal Working Group on Automated Driving Systems (IWG on ADS) and the Working Party on automated and Connected Vehicles (GRVA) workshops on Automated Driving Systems.

B. Procedural background

8. In 2015, the World Forum for Harmonization of Vehicle Regulations (WP.29) established a programme under the Intelligent Transport Systems (ITS) Informal Working Group (IWG) to focus on automated driving (ITS/AD).

(a) During its 174th (March 2018) session, WP.29 approved a ITS/AD proposal for a “Reference document with definitions of Automated Driving under

1 ECE/TRANS/WP.29/2024/39
2 ECE/TRANS/WP.29/2019/34/Rev.2.
3 ECE/TRANS/WP.29/2019/34/Rev.2.
4 ECE/TRANS/WP.29/2019/34/Rev.2.
5 GRVA-18-50.
6 GRVA-18-50.

WP.29 and the General Principles for developing a UN Regulation on automated vehicles".

(b) In March 2018, ITS/AD established a Task Force on Automated Vehicle Testing (TFAV) "to develop a regulatory testing regime that assesses a vehicle's automated systems so as to realise the potential road safety and associated benefits under real life traffic conditions".

(c) TFAV established subgroups to consider AV assessment methods:

(i) Physical certification tests and audit, and

(ii) Real-world test drive.

9. At the 178th session, WP29 adopted the Framework document on automated vehicles (ECE/TRANS/WP.29/2019/34/Rev.2), herein referred to as the Framework document and the Terms of Reference (ToRs) (ECE/TRANS/WP.29/1147, Annex VI). The Framework Document provides "guidance to WP.29 subsidiary Working Parties (GRs) by identifying key principles for the safety and security of automated vehicles of levels 3 and higher". [7] The Framework Document allocated work on these WP.29 priorities across several informal working groups, including Functional Requirements for Automated Vehicles (FRAV) and Validation Methods for Automated Driving (VMAD). The Framework document instructed VMAD and FRAV to develop a 'new assessment/test method for automated driving' (NATM) for consideration during the 183rd (March 2021) session of WP.29.

10. The VMAD Terms of Reference (ToR) mandated the group to develop assessment methods, including scenarios, to validate the safety of automated systems based on a multi-pillar approach including audit, simulation/virtual testing, test track, and real-world testing. FRAV developed functional (performance) requirements for automated vehicles. Based on the work of both groups the NATM master document, which outlines a conceptual framework for validating the safety of automated driving systems, was developed. The first version of this document was adopted at the 184th session (June 2021) of WP29 (ECE/TRANS/WP.29/1159). The second version was submitted to the 12th session (January 2022) of GRVA[8].

11. Building on this conceptual work, VMAD and FRAV were instructed by WP29 to undertake the development of the NATM guidelines. This document was developed to provide direction to developers and contracting parties of the 1958 and the 1998 UN vehicle regulations agreements on recommended procedures for validating the safety of ADS.[9]

12. WP.29 further directed FRAV and VMAD to collaborate and deliver a consolidated FRAV/VMAD submission (requirements and assessment methods) for its June 2024 session. WP.29 approved the integrated FRAV/VMAD guidelines during the June 2024 session.[10]

13. At the 191st WP.29 session and the sixty-eighth Executive Committee of the 1998 Agreement (AC.3) session in November 2023, WP.29 adopted a proposal for the regulatory approach for Automated Driving Systems (WP.29-191-30/Rev.1). This proposal included the creation of (i) a new IWG on ADS and (ii) GRVA workshops to launch and undertake the work on regulatory activities for such systems. This decision was documented in the report of the 191st WP.29 session.[11] AC.3 approved the request for authorization of a new UN GTR on ADS in March 2024 as documented in Annex IV of the report on the 192nd WP.29 session.[12]

[7] ECE/TRANS/WP.29/2019/34/Rev.2 and ECE/TRANS/WP.29/1147 Annexes V and VI. 4. The Framework Document refers back to the Automated Driving definitions provided in the reference document ECE/TRANS/WP.29/1140 noted in para. 1.2. The reference document cites SAE J3016:2016 as its source for establishing levels of driving automation (1-5).

[8] ECE/TRANS/WP29/GRVA/2022/2

[9] ECE/TRANS/WP.29/1159

[10] ECE/TRANS/WP.29/2024/39

[11] ECE/TRANS/WP.29/1175

[12] ECE/TRANS/WP.29/1177

14. At its eighteenth session, GRVA discussed the regulatory approach for Automated Driving Systems, as adopted by WP.29. It deliberated on the establishment of a bureau composed of representatives from Canada, China, the European Commission, the United Kingdom of Great Britain and Northern Ireland, Japan, and the United States of America to lead the activity. GRVA adopted the draft ToR for the IWG on ADS and the organization of GRVA workshops on ADS and submitted them to WP.29.[13]

15. At the 192nd WP.29 session and the sixty-ninth AC.3 session in March 2024, WP.29 agreed that the IWG on ADS would be sponsored and led by Canada, China, European Commission, Japan, United Kingdom of Great Britain and Northern Ireland and the United States of America. WP.29 noted that the secretariat would be supported by representatives of the American Automotive Policy Council (AAPC), the International Organization of Motor Vehicle Manufacturers (OICA), the Japan Automobile Standards Internationalization Center (JASIC), and SAE International (formerly the Society of Automotive Engineers). The IWG on ADS was tasked with developing the technical requirements for the ADS regulation for Contracting Parties under the 1958 and 1998 Agreements. The GRVA workshops focused on the development of the administrative requirements for the ADS regulations, as well as an interpretation document to assist in the implementation of these regulations. Two ambassadors (the experts from Australia and the Netherlands) between the IWG on ADS and the GRVA Workshops were tasked to align the activities of the two groups and evaluate the progress of both activities.[14] During that session, WP.29 adopted an amendment to the Framework Document on Automated Vehicles to take into account these new activities.[15]

16. During its first session of the IWG on ADS reviewed its the work plan and a draft structural framework for the UN GTR and UN Regulation content. It included specific sections, namely “General requirements,” “Performance requirements/Test specifications,” and “Assessment/Test procedures.”[16] It was agreed to appoint “Officers of Principal Interest” (OPI) for each section, who would act as points of contact and coordinators, receiving assistance from IWG on ADS experts. During the first session of the ADS workshop OPIs were also selected to develop the text for the administrative provisions for the ADS GTR and UN Regulation.

17. The initial objective of the IWG was transposition of the ADS guidelines (1958 and 1998 Agreements) into common regulatory provisions, focusing first on requirements and then on assessment methods/processes.[17] This text is derived from the specific provisions and annexes received from the June 2024 Functional Requirements for Automated Vehicles (FRAV) - Validation Method for Automated Driving (VMAD) Informal Working Group Integrated Document[18] under the Working Party on automated and Connected Vehicles (GRVA) and workshops for the generation of the draft UN Global Technical Regulation on ADS. The second phase involved transposing the common provisions into UN GTR and UN Regulation texts and integrating the GRVA ADS workshop outcomes into the text.

18. The IWG also received reports on the work of other informal groups, including Automated Vehicle Categorisation (AVC), Event Data Recorders and Data Storage Systems for Automated Driving (EDR/DSSAD), Regulation Fitness for Automated Driving Systems (FADS), and the GRVA ADS WS. The IWG noted the need for consistency across all these activities with the ADS regulations.[19]

19. The text was further refined from subsequent discussions at multiple IWG on ADS sessions and GRVA workshops. This included consolidation of common provisions of the text based on the work of the IWG OPIs. The consolidated common provisions document provided a baseline document that was then separated into a draft GTR and a draft UN Regulation.

[13] GRVA-18-41/Rev.2 and GRVA-18-42/Rev.2.
[14] ECE/TRANS/WP.29/2024/38 and ECE/TRANS/WP.29/AC.3/62
[15] ECE/TRANS/WP.29/2024/33 based on informal document WP.29-191-31
[16] ADS-01-03
[17] WP.29-194-ADS/Add.1
[18] ECE/TRANS/WP.29/2024/39
[19] GRVA-21-44/Add.1

C. Technical background

20. The key subject of this GTR is ADS. The definition of ADS "means the vehicle hardware and software that are collectively capable of performing the entire Dynamic Driving Task (DDT) on a sustained basis." [20] When the ADS is in operation, the DDT is "always performed in its entirety by the ADS, which means the whole of the tactical and operational functions required to operate the vehicle". [21] Section 1 describes what the DDT consists of. Section 2 describe the need to demonstrate the technical competency of the ADS. Section 3 describes the various methods used to validate the safety of the ADS.

1. ADS performs all tactical and operational functions of driving

21. Driving consists of three categories of functions: strategic, tactical, and operational. The real-time tactical and operational functions required to operate a vehicle in on-road traffic are collectively known as the DDT, which does not include strategic functions. Strategic functions include activities such as determining a trip destination that do not involve vehicle dynamic control.

22. The tactical level involves manoeuvring the vehicle in traffic during a trip, including perceiving and assessing the driving environment, deciding and planning on a specific manoeuvre. Tactical functions include but are not limited to manoeuvre planning and execution, enhancing conspicuity (lighting, signalling, gesturing, etc.), and managing interactions with other road users. Tactical functions generally occur over a period of seconds.

23. Operational functions include but are not limited to lateral vehicle motion control (steering) and longitudinal vehicle motion control (acceleration and deceleration). This operational effort involves split-second reactions, such as making micro-corrections while driving. [22]

24. The DDT definition explains that these functions can be grouped into three interdependent categories: sensing and perception, planning and decision, and control. [23]

25. Sensing and perception include: (a) monitoring the driving environment via object and event detection, recognition, and classification, (b) perceiving other vehicles and road users, the roadway and its fixtures, objects in the vehicle's driving environment and relevant environmental conditions, (c) sensing the ODD boundaries (if any) of the ADS feature, and (d) positional awareness.

26. Planning and decision include: (a) predicting actions of other road users, (b) response preparation, and (c) manoeuvre planning.

27. Control includes: (a) object and event response execution, (b) lateral vehicle motion control, (c) longitudinal vehicle motion control, and (d) enhancing conspicuity via lighting and signalling.

2. ADS needs to demonstrate the competency of vehicle safety

28. An ADS must demonstrate the competency to operate the vehicle safely, to respond to external conditions, and to manage internal failures.

29. Moreover, the ADS must be designed to ensure safe use and the safety of its users throughout the useful life of the vehicle.

---

[20] ECE/TRANS/WP.29/2024/39 paragraph 3.1.2. This definition is based on SAE J3016 and ISO/PAS 22736 (Taxonomy and Definitions for Terms Related to Driving Automation Systems for On-Road Motor Vehicles). These standards define levels of driving automation based on the functionality of the driving automation system feature as determined by an allocation of roles in DDT and DDT fallback performance between that feature and the (human) user (if any). The term "Automated Driving System" is used specifically to describe a Level 3, 4, or 5 driving automation system.

[21] ECE/TRANS/WP.29/2024/39 paragraph 3.1.11.1.

[22] ECE/TRANS/WP.29/2024/39 Annex 1 paragraph 6, 8, 9, 11-15.

[23] ECE/TRANS/WP.29/2024/39 paragraph 3.1.11.1.

30. To ensure that the safety competency is demonstrated, an ADS might be expected to be assessed via a framework for the development of traffic scenarios.

31. The framework would include nominal, critical and failure scenarios. The requirements of the rule intentionally avoid technical specifications and performance limits for specific scenarios because each traffic situation requires a response appropriate to its combination of elements, risks, and available options.

32. Defining the performance criteria in critical scenarios could be difficult. In these cases, this could be done by using appropriate safety models to enable assessment of ADS performance within the limits of the safety models.

33. As a general concept, the safety level an ADS should be at least the same or greater than a competent and careful human driver. This concept is important minimizing unreasonable safety risks to the ADS vehicle user(s) and other road users . The manufacturer's safety case for the ADS and its features will include a description of the design processes used to implement the safety concept, and a structured presentation demonstrating through a body of evidence that the ADS and its features have undergone sufficient safety validation to ensure an absence of unreasonable risk in the ADS's performance.

3. Validating the safety of ADS

34. Validating the ADS's capabilities is a highly complex task which cannot be done comprehensively nor effectively through one validation methodology alone. As a result, it is necessary to adopt a multi-pillar approach for the validation of ADS.

35. These various methodologies are intended for use in combination(s) to produce an efficient, comprehensive, and coherent assessment of ADS safety performance. Each of the testing methodologies possess their own strengths and limitations, such as differing levels of environmental control, environmental fidelity, scalability, and cost, which should be considered. In some cases, the application of more than one method could be necessary to assess the capability of an ADS to cope with range of situations that can arise in real-world traffic. The use of multiple methods allows for flexibility in the composition, sequencing, and application of testing across the diversity of ADS, while avoiding unnecessary redundancies and overlaps. Figure 1 below illustrates relationships across the ADS safety requirements, ODD analysis and scenario generation, and the validation pillars.

36. Virtual testing uses different types of simulation toolchains to assess the compliance of an ADS with the safety requirements on a wide range of virtual scenarios including some which would be extremely difficult if not impossible to test in real-world settings. The aspect of credibility of simulation/virtual testing is included in this topic. [24]

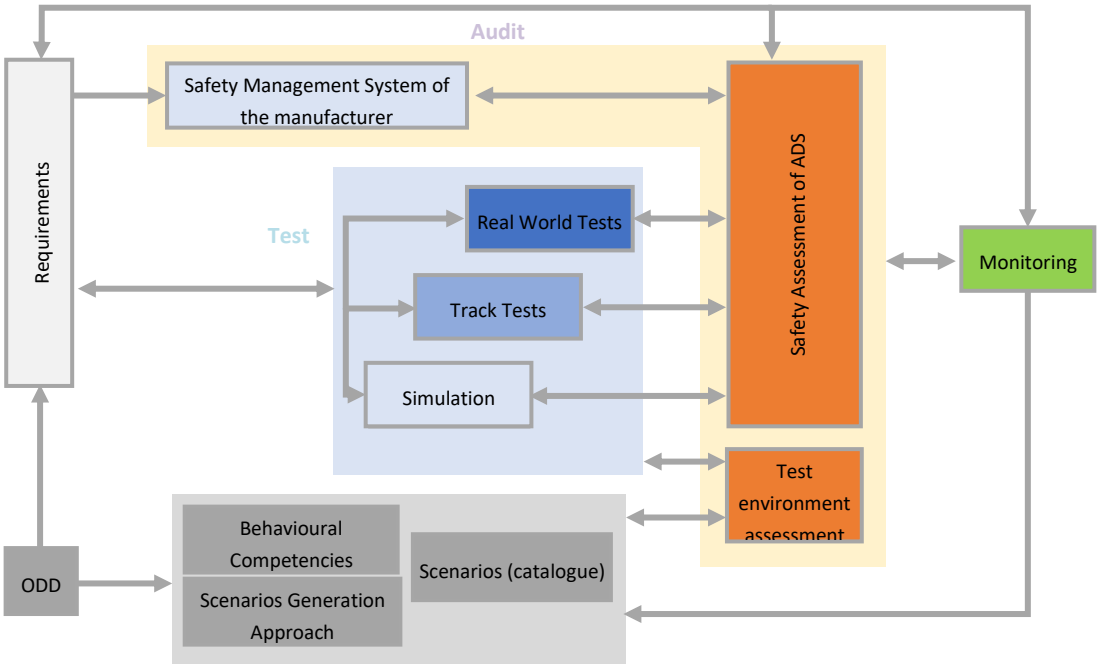
37. Track testing uses a closed-access testing ground with various scenario elements to test the capabilities and functioning of an ADS.[25]

38. Real-world testing uses public roads to test and evaluate the performance of ADS related to its capacity to drive in real traffic conditions.[26]

39. The audit and assessment procedures establish how manufacturers will be required to demonstrate to safety authorities using documentation, their simulation, test-track, and/or real-world testing of the capabilities of an ADS. The audit will validate that hazards and risks relevant for the system have been identified and that a consistent safety-by-design concept has been put in place. The audit will also verify that robust processes/mechanisms/strategies (i.e., safety management system) that are in place to ensure the ADS meets the relevant safety requirements throughout the vehicle lifecycle. It shall also assess the complementarity between the different pillars of the assessment and the overall scenario coverage.[27]

[24] ECE/TRANS/WP.29/2022/57, para. 15.
[25] ECE/TRANS/WP.29/2022/57, para. 16.
[26] ECE/TRANS/WP.29/2022/57, para. 17.
[27] ECE/TRANS/WP.29/2022/57, para. 18.

Relationships across safety requirements, ODD analysis, scenario generation, and validation pillars



4. Common Issues and Principles

40. The following list of issues and principles guided discussions and activities on automated vehicles within WP.29 and each of its relevant subsidiary Working Parties. The aim was to capture the shared interests and concerns of regulatory authorities, provide the general parameters for work, and to provide common definitions and guidance.

41. The following is a list of common principles with brief descriptions and explanations. It is expected these would form the basis for further development. Except for items (n) and (o), all these items have been identified in ECE/TRANS/WP.29/**2019**~~202~~9/34/Rev.2:

(a) System Safety: When in the automated mode, the automated vehicle should be free of unreasonable safety risks to the driver and other road users and ensure compliance with road traffic regulations.

(b) Failsafe Response: The automated vehicle should be able to detect its failures or when the conditions for the ODD are not met. In such a case, the vehicle should be able to transition automatically to a mitigated risk condition.

(c) Human Machine Interface (HMI) /Operator information: Automated vehicle should include driver engagement monitoring in cases where drivers could be involved (e.g., takeover requests) in the driving task to assess driver awareness and readiness to perform the full driving task. The vehicle should request the driver to hand over the driving tasks in case that the driver needs to regain proper control of the vehicle. In addition, automated vehicles should allow interaction with other road users (e.g., by means of external HMI on operational status of the vehicle, etc.).

(d) Object Event Detection and Response (OEDR): The automated vehicles shall be able to detect and respond to objects/events that may be reasonably expected in the ODD.

(e) Operational Design Domain (ODD) (automated mode): Manufacturers should document the ODD available on their vehicles and the functionality of the vehicle within the prescribed ODD. The ODD should describe the specific conditions under which the automated vehicle is intended to drive in the automated mode. The ODD should include the following information at a minimum: roadway types, geographic area, speed range, environmental

conditions (weather as well as daytime/nighttime), and other domain constraints.

(f) Validation for System Safety: Manufacturers should demonstrate a robust design and validation process based on a systems-engineering approach with the goal of designing ADS free of unreasonable safety risks and ensuring compliance with road traffic regulations and the principles listed in this document. Design and validation methods should include a hazard analysis and safety risk assessment for the ADS, OEDR, as well as the overall vehicle design into which the ADS is being integrated. When applicable, the broader transport ecosystem should be included in this analysis. Design and validation methods should demonstrate the behavioural competencies an automated vehicle would be expected to perform during normal operation, the performance during crash avoidance situations, and the performance of **fallback**~~fall-back~~ strategies. Test approaches may include a combination of simulation, test track, and on-road testing.

(g) Cybersecurity: The automated vehicle should be protected against cyber-attacks in accordance with established best practices for cyber vehicle physical systems. Manufacturers shall demonstrate how they incorporated vehicle cybersecurity considerations into ADSs, including all actions, changes, design choices, analyses, and associated testing, and ensure that data is traceable within a robust document version control environment.

(h) Software Updates: Manufacturers should ensure system updates occur as needed in a safe and secure way and provide for after-market repairs and modifications as needed.

(i) Event data recorder (EDR) and Data Storage System for Automated Driving vehicles (DSSAD): The automated vehicles should have an ability to collect and record the necessary data related to the system status, occurrence of malfunctions, degradations or failures in a way that can be used to establish the cause of any crash and to identify the status of the automated driving system and the status of the driver.

Additional issues not listed in the currently agreed WP.29 priorities

(j) Vehicle maintenance and inspection: Vehicle safety of in-use vehicles should be ensured through measures such as those related to maintenance and the inspection of automated vehicles, etc. Additionally, manufacturers are encouraged to have documentation available that facilitates the maintenance and repair of ADSs after a crash. Such documentation would likely identify the equipment and the processes necessary to ensure safe operation of the automated vehicle after repair.

(k) Consumer Education and Training: Manufacturers should develop, document, and maintain employee, dealer, distributor, and consumer education and training programs to address the anticipated differences in the use and operation of automated vehicles from those of conventional vehicles.

(l) Crashworthiness and Compatibility: Given that a mix of automated vehicles and conventional vehicles will be operating on public roadways, automated vehicle occupants should be protected against crashes with other vehicles.

(m) Post-crash AV behaviour: automated vehicles should be able to return to a safe state immediately after being involved in a crash. Bringing the vehicle to a safe state includes considerations such as shutting off the fuel pump, removing motive power, moving the vehicle to a safe position off the roadway, and disengaging electrical power. It is vital that the ADS have the capability to engage with an operations centre or collision notification centre.

(n) ~~Artificial Intelligence: vehicle automation is based on a combination of hardware and software. The requirements in this regulation are based on the condition that this software does not include the use of online in vehicle~~

~~learning Artificial Intelligence. Artificial Intelligence can be used to analyse and improve ADS software in an engineering environment. By means of a software update (over the air or connected) this update can be installed in the vehicle, again without in vehicle learning features during operation of this version.~~ **The requirements of this regulation are written with the expectation that ADS software does not include the use of online in-vehicle learning that self-modifies system behaviour.**

(o) ADS vehicles shall be in conformity with regional legislation (e.g. data protection, privacy).

D. Principles for developing the global technical regulation

42. The GTR provides a necessary first step to the safe deployment of ADS equipped vehicles on public roads as there are no existing global regulations nor regulations established in the Compendium of Regulations of the 1998 Agreement to support ADS deployment.

43. Furthermore, industry has repeatedly indicated the need for regulations to be developed to support the deployment of vehicles equipped with ADS. This is necessary to prevent the fragmentation of regulatory approaches and avoid delaying the deployment of new technologies with the potential of improving road safety, promoting cleaner and greener transport, promoting social inclusion, and supporting economic growth.

44. This GTR was developed on the principal of being performance-based and technology-neutral. The regulations have been developed in a manner that can be adapted to accommodate different types of vehicle certification processes.

45. There are several GRVA subgroups active in the field of vehicle automation (EDR/DSSAD, TF on AVC, TF on FADS, Cybersecurity /Over-the-Air software updates). This first GTR is based on the information currently available from these subgroups. It provides worldwide harmonised procedures to set and verify compliance with minimum requirements for the safety of ~~ADS and~~ vehicles **with regard to their**~~equipped with~~ ADS, with the notion that future improvements of the GTR are expected as ADS technologies continue to evolve. It takes into consideration existing and new data, research, and standards proposed by the contracting parties and industry.

E. Technical rationale and justification

1. Application/scope

46. This UN GTR applies to vehicles of Category 1 and Category 2 based on the vehicle classification and definitions outlined in the 1998 Global Agreement Special Resolution No. 1 (S.R.1) with regard to their Automated Driving System.

47. Given that high potential of the improvement for road traffic safety is expected for the vehicles equipped with ADS, this regulation will help to establish the minimum safety requirements for the manufacturers developing ADS and the adequate validation requirements for the approval authorities[28].

48. Considering the diversity of ADS vehicle configurations, use cases, and the characteristics of their ODDs (e.g., highway, urban, parking), this regulation will provide generic and high-level requirements to support the harmonization for ADS regulatory development worldwide and to support the introduction of innovations, allowing the industry

[28] Throughout this document, the term '**a**~~A~~pproval **a**~~A~~uthority' is used to denote the competent authority of a Contracting Party to the 1958 Agreement that grants approval or refuses approval or withdraws approval or grants extension of approval or refuses extension of approval or suspends approval. The reference to the type approval authority is solely for the purpose of better illustrating the relevant background of the GTR (Global Technical Regulation) development and does not involve any type access requirements.

to use state-of-the-art technologies. At the same time, it will offer approval authorities a way to harmonize the safety level of ADS vehicles in the market.

49. The generic requirements framework of this regulation will also allow further development of additional requirements for specific use cases or ADS features in the future.

50. The safety case also includes requirements that the manufacturer review its safety case and remediate issues prior to certification/approval.

2. Rationale for requirements concerning performance of the dynamic driving task

51. As a general concept, the safety level of ADS shall be at least to the level at which a competent and careful human driver could minimize the unreasonable safety risks to the ADS vehicle user(s) and other road users.

52. Driving involves real-time risk management under prevailing traffic scenarios, which means a description of a sequence of driving situations that may occur during a given trip. Therefore, safe ADS performance of the dynamic driving task (DDT) depends upon the situations presented under each individual scenario and each scenario is associated with one or more behavioural competencies.

53. This UN GTR establishes requirements for ADS driving behaviours under relevant traffic situations (nominal situations, critical situations, failure situations), at ODD boundaries, and in fallbacks to an MRC.

54. The broad objectives are that the ADS operates safely in all traffic situations. To do this, the ADS must be able to recognize the ODD of its features and prevent activation of its features outside their ODD. While a feature is active, the ADS should not cause traffic accidents or unreasonably disrupt the flow of traffic and should obey traffic rules in nominal situations. Under critical traffic situations or failure situations, the ADS may need to diverge from its behaviour in nominal situations and prioritise safety over other aspects.

3. Rationale for requirements concerning ADS user interactions with the ADS

55. The requirements for safe interactions between users and ADS vary depending on user role, system design and tasks to be performed by the user during the use of the ADS-equipped vehicle, such as:

(a) ADS features that permit a user to take over the performance of the DDT, and

(b) ADS features that do not permit a user to take over the performance of the DDT.

56. There is significant concern that unclear procedures for the safe deactivation of ADS features could lead to mode confusion – where the user does not know if the ADS or the user is in control of the DDT. Several requirements are included for these transitions, including the use of a driver monitoring system to verify that fallback users remain able to take control when requested, and that control of the DDT is only given to a user if they are in a position to safely assume the driving task.

57. In addition to the requirements for the ADS, this UN GTR requires the manufacturer to provide appropriate means to facilitate user understanding of the functionality and operation of the ADS. The means shall cover relevant aspects, such as operational description of the ADS features, capabilities, and limitations, instructions for the activation and deactivation of the ADS, general overview of non-driving-related activities (NDRA) allowed when an ADS feature is active where applicable, etc.

4. Rational for other ADS requirements

58. Other requirements are necessary to ensure overall safety of the ADS. This includes installation of a DSSAD to monitor the performance of the ADS, cyber security requirements, protection from unauthorised access to the ADS and the ability to conduct necessary maintenance. While not specific to the testing and validation of the ADS these provisions have been deemed as playing an important role to ensure that the manufacturer takes a holistic approach to ensuring the safety of the ADS throughout its lifecycle.

5. Rationale for safety management system

59. The safety management system (SMS) is a systematic approach of the manufacturer to manage safety that encompasses and integrates human, organisational, and technical factors:

(a) The human component ensures the ADS lifecycle is monitored by personnel with appropriate skills, training, and understanding to identify risks and appropriate mitigation measures.

(b) The organisational component procedures and methods that help to manage the identified risks, understand their relationships and interactions with other risks and mitigation measures, and help to ensure that there are no unforeseen consequences.

(c) The technical component using appropriate tools and equipment.

60. An adequate SMS will incorporate all three factors to monitor and improve safety and help to control the identified risks. It should also include taking measures to monitor the vehicle during the in-service operation and to take corrective remedial action when necessary.

61. To facilitate auditing, the manufacturer should provide certain specific documentation to demonstrate that an SMS with robust processes to manage safety risks and to ensure safety throughout the ADS lifecycle (development, production, operational, decommissioning) has been established.

62. This UN GTR requires the manufacturer's documentation to cover relevant aspects, including safety policy, risk management, safety assurance, safety promotion, management of design and development, management of production, and management of post-deployment safety.

6. Rationale for Assessment of Test Environments

63. The use of new tools for testing introduces some uncertainty about whether the tools themselves adequately represent the environments in which the ADS will operate. Manufacturers will need to use a combination of testing methods (virtual testing, track testing, and real-world testing) during the development and validation of their ADS. Due to the large number of potential scenarios to replicate, virtual testing will likely be thoroughly used in this process.

64. The manufacturer should demonstrate that the approach to testing (virtual testing, track testing, real-world testing) and the scenario coverage/selection are suitable to validate/verify the safety case and compliance with the associated performance/functional requirements specified in this UN GTR.

65. High confidence in simulation toolchain credibility is needed so that virtual testing can be used by the manufacturer to validate the safety of their ADS on its own and in conjunction with the other testing methods. This requires that the simulation tool or a combination of simulation tools provide an accurate representation of the real-world system where the ADS operates. The validity and credibility of the simulation toolchain(s) may vary depending on the environment and operating parameters. It is critical to determine in which scenarios the results of the simulation toolchain(s) can be relied upon. Therefore, it is essential to set up a harmonized credibility framework as part of this UN GTR. The framework includes requirements for the simulation toolchain, including information on assumptions, limitations, quantification of uncertainty, scope, criticality analysis, sensitivity analysis, verification, and validation.

66. Regarding the assessment aspect, there are two main parts outlined in this UN GTR. One component is for the assessment of the safety case testing activities and the other is for confirmatory testing.

7. Rationale for drafting a safety case

67. A complete safety case for the ADS and its features is required to be documented by the manufacturer. This includes a description of the system, the design processes used to

implement the safety concept, and a structured presentation demonstrating through a body of evidence that the ADS and its feature(s) meet the requirements in the regulation and have undergone sufficient safety validation to ensure there are no unreasonable risks in the ADS's performance.

68. The safety case by the manufacturer demonstrates the application of the SMS to the ADS under assessment, including its design and intended uses (safety concept) and an evidence-based structured argument (safety claim, argument, evidence) that the ADS meets the safety requirements specified in this UN GTR.

69. The safety case allows the relevant authority to determine whether the manufacturer has the capability to manage ADS safety throughout the lifecycle of the system.

70. The safety case also includes requirements that the manufacturer review its safety case and remediate issues prior to certification/approval.

8. Rationale for assessment of the safety case

71. The evaluation (i.e., safety assessment) of the safety case provided by the manufacturer, including the safety of the ADS design, is essential to determine whether the vehicle's ADS is safe by design and whether the ADS has been sufficiently validated before market introduction.

9. Rationale for post-deployment safety

72. In addition to the pre-deployment assessment of ADS safety, verification that the processes and capabilities to perform post-deployment assessment of ADS performance is required. The purpose of post-deployment safety is to confirm the manufacturer's safety case and safety during real-world operation. The reporting requirements for post-deployment safety will also help to identify unanticipated situations encountered in the real world, which can then be used to develop new or revise existing scenarios.

73. Before the deployment of the ADS, the manufacturer should demonstrate that it has processes in place and is capable of performing the post-deployment safety tasks. These processes should be documented as part of the manufacturer's SMS.

74. The monitoring program established by the manufacturer should collect and analyse vehicle data, and data from other sources. Manufacturers are required notify the relevant authority of a critical occurrence without unreasonable delay to allow the relevant authority to take any necessary actions to ensure public safety. Furthermore, two types of reports are required as part of post-deployment safety: short-term reports for specific significant and critical occurrences and periodic reports focus on more general statistics and other occurrences experienced by deployed vehicles.

10. Rationale for Other Manufacturer Requirements

75. Besides requirements that are focused on validating the safety of the ADS, the manufacturer will be required to provide owners and operators with necessary information on any required maintenance to ensure that the ADS can continue to operate safely once it is deployed.

11. Rationale for audit of SMS

76. The purpose of the SMS audit pillar is to allow the relevant authority to determine that the manufacturer has established robust processes to manage safety risks, manage safety throughout the ADS lifecycle, and that the manufacturer is compliant with the requirements as outlined in this UN GTR.

77. Given that the post-deployment safety is also included in the SMS, the audit of the SMS should review the manufacturer's documentation to ensure the suitability of post-deployment safety practices (processes, tools, personnel) for the ADS and evaluate the manufacturer's capability to monitor the ADS and to report any occurrences/safety-relevant events during the ADS operation. Documentation should also note the manufacturer's

approach/methods to verify the safety performance of the ADS and for reporting the occurrences/safety-relevant events experienced by the ADS during the operation.

78. This UN GTR specifies the requirements for the audit of SMS, including the audit of the manufacturer's post-deployment safety mechanism.

12. Rationale for post-deployment safety assessment

79. The evaluation of the ADS post-deployment is necessary to assess evidence as to whether the safety management system and the safety case are sufficient or if any changes are necessary to ensure the safety of the ADS.

F. Existing regulations, directives, and international voluntary standards

80. The purpose of compiling this list of existing regulations and standards is to provide a comprehensive overview of the current landscape governing automated driving systems. The list categorizes these into three main sections:

(a) UN guidance used as a basis for the development of the GTR/UNR.

(b) Standards and regulations referenced in the GTR/UNR.

(c) Other standards and regulations identified.

This compilation aims to facilitate better understanding, comparison, and alignment of ADS regulatory practices globally, reflecting the foundational work accomplished by the groups from the UN and highlighting the current regulatory status of contracting parties.

(a) The following documents reflect the technical progress made by WP.29 before starting to draft the ADS regulation, these technical documents come from informal working groups such as FRAV and VMAD, which are not only "existing regulations or technical documents", but also the basis for the preparation of this regulation, which was compiled on the basis of the conversion of the above technical documents.

- (UN) Guidelines and Recommendations concerning Safety Requirements for Automated Driving Systems
- (UN) New Assessment/Test Method for Automated Driving (NATM) Guidelines for Validating Automated Driving System (ADS)
- (UN) Guidelines and recommendations for ADS safety requirements, assessments, and test methods to inform regulatory development

(b) The following documents consist of regulations, directives, and international voluntary standards that were already in effect prior to the development of this regulation. These documents were referenced or quoted during the development process of the ADS regulation (GTR/UNR).

United Nations:

- (UN) UN Regulation No. 157 (Automated Lane-Keeping System)

International Organization for Standardization (ISO):

- ISO/SAE 21434:2021 - Road Vehicles - Cybersecurity engineering
- ISO/SAE PAS 22736:2021 Taxonomy and Definitions for Terms Related to Driving Automation Systems for On-Road Motor Vehicles
- ISO 26262: 2018 - Road vehicles – Functional safety – From Part1 to Part 10
- ISO 9001 - Quality management systems
- ISO 31000 - Risk management
- ISO 21448: 2022 - Road vehicles — Safety of the intended functionality
- ISO 9241-210:2019 Ergonomics of human-system interaction Part 210: Human-centred design for interactive systems

- ISO PAS 8800 : 2024- Road vehicles — Safety and artificial intelligence
- ISO/TS 5083:2025 Road vehicles — Safety for automated driving systems — Design, verification and validation

International Automotive Task Force (IATF):

- IATF 16949 - Quality management systems (automotive)

(c) Although not explicitly referenced in the ADS regulations, the following documents submitted by contracting parties and relevant organizations (as of September 2025) are recognized as relevant to the development and deployment of automated vehicles.

United Nations:

- UN Regulation No. 155 (Cyber Security and Cyber Security Management System)
- UN Regulation No. 156 (Software Updates and Software Updates Management System)

International Organization for Standardization (ISO):

- ISO 34501:2022 Road vehicles - Test scenarios for automated driving systems — Vocabulary
- ISO 34502:2022 Road vehicles - Test scenarios for automated driving systems- Scenario based safety evaluation framework
- ISO 34503:2023 Road Vehicles - Test scenarios for automated driving systems - Specification for operational design domain
- ISO 34504:2024 Road vehicles - Test scenarios for automated driving systems - Scenario categorization
- ISO/TR 21959-1:2020 Road vehicles - Human performance and state in the context of automated driving
- ISO 24089:2023 - Road Vehicles - Software update engineering

Society of Automotive Engineers (SAE):

- SAE J3208-Taxonomy and Definitions of ADS Verification & Validation
- SAE J3237-Operational Safety Metrics for Verification & Validation of Automated Driving Systems (ADS)
- SAE J3279-Best Practices for Applying Simulations in Driving Automation System Development
- SAE 3259-Taxonomy & Definitions for ODD for Driving Automation Systems
- SAE J3016-Taxonomy and Definitions for Terms Related to Driving Automation Systems for On-Road Motor Vehicles

Institute of Electrical and Electronics Engineers (IEEE):

- IEEE 2846 2022 Assumptions for Models in Safety Related Automated Vehicle Behavior

5G Automotive Association (5GAA）:

- TR T-210009 1.0 Safety Treatment in Connected and Automated Driving Functions

Association for Standardization of Automation and Measuring Systems(ASAM):

- OpenSCENARIO DSL V2.1.0
- OpenSCENARIO XML V1.3.1
- OpenDRIVE V1.8.1
- OpenODD V1.0

European Union:

- Regulation 2022/1426

- Regulation 2019/2144
- ELKS Regulation 2021/646

The United Kingdom:

- BSI PAS 1884 Safety operators in automated vehicle testing and trialling
- Automated Vehicles Act (2024)

The United States of America:

- NHTSA DOT HS 812 083 Advanced Test Tools for ADAS and ADS
- NASA-STD-7009A - Standard for models and simulations

China：

- GB/T 40429-2022 Taxonomy of driving automation for vehicles
- GB/T 41798-2022 Intelligent and connected vehicles—Track testing methods and requirements for automated driving functions
- GB 44497-2024 Intelligent and connected vehicle—Data storage system for automated driving
- GB/T 44721-2024 Intelligent and connected vehicle—General technical requirements for automated driving system
- GB/T 44719-2024 Intelligent and connected vehicle—Methods and requirements of road test for automated driving functions
- GB/T 45312-2025 Intelligent and connected vehicles—Operational design condition for automated driving system

France:

- Ordonnance no. 2021-443 of April 14, 2021 on the criminal liability regime applicable in the event of the circulation of a vehicle with driver delegation and its conditions of use.

Japan:

- JIS D 6805 Testing Method of the Characteristics and Functions of Automatic Guided Vehicles

Germany：

- Act on Autonomous Driving (Section 1a - 1l Road Traffic Act, StVG), 2021
- Ordinance on Approval and Operation of Autonomous Vehicles (AFGBV), 2022

G. Benefits and costs

81. For the time being, ADS will not be mandatory for vehicles. Currently, there is only one specific ADS application for which a UN ADS regulation has been developed (ALKS/R157). Consequently, for all other ADS applications except ALKS, there is no clear regulation that helps manufacturers in developing their ADS and authorities in validating the related products and processes. This GTR is an important prerequisite to support the process of harmonization of engineering and validation requirements.

82. For ADS technology, the issue of responsibility attribution is one of the core challenges on its development path. Based on the authoritative platform of WP.29, formulating a comprehensive set of global technical regulations for ADS with international consensus is an important step in improving the relevant legal environment, while also clarifying the current capabilities and limitations of ADS technology. In this way, provisions can be built upon the existing technological conditions through a regulation that establishes a clear and reasonable framework for responsibility attribution. This framework establishes traceable technical parameters and system behaviour logging requirements for manufacturers

and software developers. In accident scenarios, the documented technical evidence provides an auditable basis for accountability determination processes while maintaining adaptability for evolving ADS verification methodologies. The standardized technical benchmarks support alignment with legal proceedings without constituting legal judgments.

83. Social trust and acceptance are key to the widespread integration of ADS technology into people's daily lives. The formulation and subsequent use of ADS regulations can play an important role in enhancing public awareness, dispelling misunderstandings, and fostering trust. These processes not only provide the public with a more comprehensive and in-depth understanding of ADS technology but also, through legal commitments and safeguards, might alleviate people's uncertainties and fears about the new technology. In the long run, this could create a positive and open social environment for realizing the grand vision of intelligent transport.

84. At this stage of ADS development, there is no quantitative data to support a thorough cost-benefit analysis. With the accumulation of data from various deployments and testing, the GTR might help quantify both the costs and benefits of ADS regulation. A globally harmonized regulation may potentially reduce costs and increase efficiencies for manufacturers. Such benefits may stem from streamlined production processes as well as the resources required to adapt to different regulatory regimes. For example, manufacturers may not be required to retool production facilities to comply with different regulations in different countries. With the wider application of ADS, more data will become available to improve the cost/benefit analysis.

85. Empirical data from ADS demonstration zones and research institutions worldwide highlight the potential benefits and challenges of ADS technology across diverse traffic environments. Statistical analyses of passenger vehicles indicate that accident rates in ADS modes are consistently lower than in manual driving. ~~[According to the data shared by the GRVA experts, there is an average of 18.5 accidents per million kilometres in manual driving (10.2 at-fault accidents), compared to 7.1 accidents in automated driving (2.8 at-fault accidents). Notably, some leading technology providers have achieved zero at-fault accidents per million kilometres in automated mode.~~

~~86. [However, according to the data shared by the GRVA experts, challenges to traffic efficiency persist, particularly during peak hours or in complex scenarios. Studies suggest automated vehicles may experience a 5–15 per cent reduction in average speed compared to human drivers, primarily due to conservative following distance decisions, suboptimal route planning, and delayed responses to dynamic environments. For example, pilot projects in multiple urban areas reported peak-hour automated vehicle speeds of 22–28 km/h, 10–18 per cent lower than manual driving, with travel times increasing by 8–12 per cent on average.]~~

86~~7~~. This regulation's development, while resource-intensive, promises safety improvements. The collaborative process has enhanced knowledge-sharing between automakers, governments, and research bodies, creating transferable insights for future regulatory work, including ADAS standards. Notably, this marks the first simultaneous development of a UN GTR and corresponding UN Regulation for shared safety goals, setting a new benchmark for international regulatory cooperation. Key technical elements from this GTR also demonstrate broader applicability, potentially informing updates to existing driver assistance regulations. The established framework may accelerate future rulemaking processes in evolving automotive technologies.

87~~8~~. At the same time, qualitative analysis remains equally important. Factors such as user acceptance, public perception, and regulatory adaptability cannot be fully captured through numbers alone. A deeper examination is required to ensure comprehensive regulation. By combining both quantitative and qualitative analyses, decision-making for future regulation development can be optimized. This regulation provides important sources for these analyses, such as In-Service Monitoring and Reporting (ISMR). This ISMR element helps to balance supporting innovation with controlling the safety level. The output of ISMR can be used to further improve ADS regulation where needed.

II. Text of the Regulation

1. Scope

1.1. This global technical regulation applies to the Automated Driving Systems of vehicles of categories 1 and 2.

2. Definitions

2.1. "*Automated Driving System (ADS)"* means the vehicle hardware and software that are collectively capable of performing the entire Dynamic Driving Task (DDT) on a sustained basis. [29]

2.2. *"ADS vehicle"* means a vehicle equipped with an ADS.

2.3. *"Dynamic Driving Task (DDT)"* means the real-time operational and tactical functions required to operate the vehicle.

2.3.1. When the ADS feature is active, the DDT is always performed in its entirety by the ADS which means the whole of the tactical and operational functions necessary to operate the vehicle (i.e., the ADS performs "the entire DDT" as stated in the definition of an "Automated Driving System" under paragraph 2.1.). These functions can be grouped into three interdependent categories: sensing and perception, planning and decision, and control.

2.3.2. Sensing and perception include:

(a) Monitoring the driving environment via object and event detection, recognition, and classification,

(b) Perceiving other vehicles and road users, the roadway and its fixtures, objects in the vehicle's driving environment and relevant environmental conditions,

(c) Sensing the ODD boundaries, if any, of the ADS feature, and

(d) Positional awareness.

2.3.3. Planning and decision include:

(a) Predicting actions of other road users,

(b) Response preparation, and

(c) Manoeuvre planning.

2.3.4. Control includes:

(a) Object and event response execution,

(b) Lateral vehicle motion control,

(c) Longitudinal vehicle motion control, and

(d) Enhancing conspicuity via lighting and signalling.

2.3.5. The DDT excludes strategic functions.

2.4. *"Real time"* means the actual time during which a process or event occurs.

[29] This definition is based on SAE J3016 and ISO/PAS 22736 (Taxonomy and Definitions for Terms Related to Driving Automation Systems for On-Road Motor Vehicles). These standards define levels of driving automation based on the functionality of the driving automation system feature as determined by an allocation of roles in DDT and DDT fallback performance between that feature and the (human) user (if any). The term "Automated Driving System" is used specifically to describe a Level 3, 4, or 5 driving automation system.

2.5. *"(ADS) function"* means an ADS hardware and software capability designed to perform a specific portion of the DDT.

2.5.1. *"Operational function"* means a capability to control the real-time motion of the vehicle.[30]

2.5.2. *"Tactical function"* means a capability to perceive the vehicle environment and control real-time planning, decision, and execution of manoeuvres, including conspicuity of the vehicle and its motion.[31]

2.5.3. *"Strategic function"* means a capability to issue commands, instructions, or guidance for execution by an ADS.[32]

2.6. *"(ADS) feature"* means an application of an ADS designed specifically for use within an Operational Design Domain (ODD).

2.6.1. *"ADS feature of type 1 (ADSF-1)"* means an ADS feature which includes an ADS fallback response requiring a fallback user.

2.6.2. *"ADS feature of type 2 (ADSF-2)"* means an ADS feature which does not include an ADS fallback response requiring a fallback user.

2.7. *"(ADS feature) active"* means the operational state in which an ADS feature is performing the DDT.

2.8. *"(ADS feature) activation"* means the act of changing the operational state of an ADS feature, from available to active.

2.9. *"(ADS feature) available"* means the operational state of an ADS feature pursuant to the ADS verification that the ODD conditions of the feature have been met at a time prior to activation of the feature when it is not performing any part of the DDT.

2.10. *"(ADS feature) deactivation"* means the change of the operational state of the ADS feature from the state in which it is performing all of the DDT to the state in which it is performing none of the DDT.

2.11. ~~[~~*"Data Storage System for Automated Driving (DSSAD)"*~~]~~ **means the capability to record and store data concerning the safety performance of a vehicle's ADS.**

2.11.1. *"(DSSAD) triggering event"* means a time-stamped data element that triggers the recording and storing of time-series data elements.

2.11.2. *"Emergency manoeuvre"* means a manoeuvre performed by the system in case of an event in which the vehicle is at imminent collision risk and has the purpose of avoiding or mitigating a collision.

2.11.3. *"Imminent collision risk"* means a situation or an event that leads to a collision of the vehicle with another road user or an obstacle that cannot be avoided by a braking demand lower than 5 m/s^2.

[2.11.4. *"Detected objects"* shall mean objects detected by the perception system of the vehicle and classified by the ADS as relevant for the purpose of performing a dynamic driving task. Objects with a negative relative velocity shall be deemed relevant.]

2.12. *"Operational Design Domain (ODD)"* means the operating conditions under which an ADS feature is specifically designed to function.

[30] Operational functions involve executing micro-changes in steering, braking, and accelerating to maintain lane position or proper vehicle separation and immediate responsive actions to avoid crashes in critical driving situations.

[31] Examples include deciding whether to overtake a vehicle or change lanes, signalling intended manoeuvres, deciding when to initiate the manoeuvre, choosing the proper speed, and executing the manoeuvre.

[32] Examples include setting the starting point, destination, route, and way points to be used by an ADS during a trip.

2.12.1. *"ODD exit"* means:

(a) the presence of one or more ODD conditions outside the limits defined for use of the ADS feature, and/or

(b) the absence of one or more conditions required to fulfil the ODD conditions of the ADS feature.

2.13. "*Occurrence"* means a safety-relevant event involving an ADS vehicle.[33]

2.13.1. *"Critical Occurrence"* means an occurrence during which at least one of the following criteria is fulfilled:

(a) At least one person suffers an injury that requires medical attention or dies as a result of being in the vehicle or being involved in the event,

(b) The ADS vehicle, other vehicles, or stationary objects sustain physical damage that exceeds a certain threshold, or

(c) Any vehicle involved in the event experiences a deployment of any non-reversible occupant restraint system, vulnerable road user secondary safety system, or the delta-V thresholds to be met, whichever occurs first.

2.13.2. *"Significant Occurrence"* means occurrences that are not "Critical Occurrences" but are required to be reported on a short-term basis due to their relevance to safety.

2.13.3. *"Vulnerable road user secondary safety system"* means a deployable vehicle system outside the occupant compartment designed to mitigate injury consequences to vulnerable road users during a collision.

2.14. *"(ADS) user"* means a human user of an ADS vehicle.

2.14.1. *"Occupant"* means an ADS user located inside an ADS vehicle.

2.14.2. *"Driver"* means an ADS user who performs in real time part or all of the DDT for a particular ADS vehicle.

2.14.3. *"Fallback user"* means an occupant designated to perform the DDT pursuant to an ADS fallback response.

2.14.4. *"(ADS vehicle) Passenger"* means an occupant who is not a driver or fallback user.

2.15. *"ADS fallback response"* means a system-initiated deactivation procedure or an ADS-controlled procedure to place the vehicle in a mitigated risk condition (MRC).

2.16. *"System-initiated deactivation of the ADS"* means a procedure by which the ADS initiates the transfer of performance of the DDT from an ADSF-1 to a fallback user.

2.17. *"User-initiated deactivation of the ADS"* means a procedure by which the user initiates the transfer of performance of the DDT from an ADS feature to the user.[34]

2.18. *"Suppressed"*, in relation to manual controls, means a condition, in which a control function is limited or has limited effect until a threshold is exceeded.

2.19. *"Remote termination"* means the act of remotely disabling one or more ADS features of one or more vehicles.

2.20. *"Mitigated Risk Condition (MRC)"* means a stable and stopped state of the vehicle that reduces the risk of a crash.

---

[33] The occurrences to be reported are listed in Annex 3.

[34] ~~Where an ADSF-2 suggests that a user might optionally take control, this shall be considered a user-initiated deactivation if the user accepts the suggestion.~~

2.21. *"Other road user (ORU)"* means any entity making use of publicly accessible road infrastructure.

2.21.1. *"Road-safety agent"* means a human engaged in directing traffic, enforcing traffic laws, and/or responding to traffic incidents.

2.21.2. *"Priority vehicle"* means a vehicle subject to exemptions, authorisations, and/or right-of-way under traffic laws while performing a specified function.

2.22. *"Behavioural competency"* means an expected and verifiable capability of an ADS feature to operate a vehicle within the ODD of the feature.

2.23. *"Failure"* means the termination of an intended behaviour of a system or component due to fault manifestation.

2.24. *"Fault"* means an abnormal condition that can cause a system or component to fail.

2.25. *"Functional safety"* means the absence of unreasonable risks under the occurrence of hazards caused by a malfunctioning behaviour of electric/electronic systems (safety hazards resulting from system faults).

2.26. *"Safety of the intended functionality (SOTIF)"* means the absence of unreasonable risk due to hazards resulting from functional insufficiencies of the intended functionality or reasonably foreseeable misuse.

2.27. *"Safety Management System (SMS)"* means a systematic approach to managing safety that encompasses and integrates organisational, human, and technical factors:

(a) Human component ensuring the ADS lifecycle is monitored by personnel with appropriate skills, training, and understanding to identify risks and appropriate mitigation measures ~~to identify risks and appropriate mitigation measures~~ while accounting for the possibility of human errors.

(b) Organisational component procedures and methods that help to manage the identified risks, understand their relationships and interactions with other risks and mitigation measures, and help to ensure that there are no unforeseen consequences, and

(c) Technical component using appropriate tools and equipment.

2.28. *"Test method"* means a structured approach to consistently derive knowledge about the performance of an ADS by means of executing tests.

2.29. *"Virtual testing"* means a type of testing that uses a simulation toolchain(s) to generate evidence for the manufacturer's safety case.

2.29.1. *"Simulation"* means the imitation of the operation of a real-world process or system over time, utilising a software implementation for some (or all) of the models, tools, or test environment.

2.29.2. *"Simulation toolchain"* means a simulation tool or a combination of simulation tools that are used to generate evidence for the manufacturer's safety case.

2.29.3. *"Model"* means a description or representation of a system, entity, phenomenon, or process.

2.29.4. *"(Model) parameter"* means a numerical value inferred from real-world data and used to represent a system characteristic.

2.29.5. *"Stochastic model"* means a model involving or containing a random variable or variables pertaining to chance or probability.

2.29.6. *"Validation (of a simulation model)"* means the process of determining the degree to which a simulation model is an accurate representation of the real world from the perspective of its intended uses.

2.29.7. *"Verification (of a simulation model)"* means the process of determining the extent to which a simulation model or a virtual testing tool is compliant with its requirements and specifications as detailed in its conceptual models, mathematical models, or other constructs.

2.29.8. *"Sensor Stimulation*" means a technique whereby artificially generated signals are provided to trigger the element under testing in order to produce the result required for evaluation of the element.

2.30. *"Test track"* means a facility, including a proving ground or roadway, closed to public traffic and designed to enable physical assessment of an ADS and/or ADS vehicle performance, e.g., via sensor stimulation and/or the use of dummy devices.

~~2.31. *"Edge Case"* means a low-probability occurrence that might arise within the ODD of an ADS and that warrants specific design attention due to the potential severity of outcomes that might result from encountering such a situation or condition.~~

2.31~~2~~. *"Safety case"* means structured documentation that provides a compelling, comprehensible, and valid case that the ADS meets the relevant ADS requirements of this regulation and is free from unreasonable risks to the ADS vehicle user(s) and other road users.

2.31~~2~~.1. *"Argument"* means a written explanation within a safety case that captures the logical connections between a claim and the evidence for achievement of that claim.

2.31~~2~~.2. *"Claim"* means a verifiable statement within a safety case.

2.31~~2~~.3. *"Evidence"* means material pertinent to demonstrating the validity of a claim, such as physical test results, simulation results, analyses with supporting data, etc.

2.32~~3~~. *"Safety concept"* means a description of the measures designed into the ADS so that it operates in such a way that it is free of unreasonable safety risks to the ADS vehicle user(s) and other road users in every operating condition relevant to the ODD.

2.33~~4~~. *"(Driving) situation"* means the conditions surrounding a vehicle (including other road users).

2.33~~4~~.1. *"Nominal situation"* means a driving situation that is neither a critical nor a failure situation.

2.33~~4~~.2. *"Critical situation"* means a driving situation that requires prompt action by the ADS to avoid or mitigate the risk of a crash that could result in adverse consequences on human health or property damage.

2.33~~4~~.3. *"Failure situation"* means a driving situation where a failure compromises the capability of the ADS to perform the entire DDT.

2.34~~5~~. *"Traffic scenario"* means a representation of a sequence of driving situations that can occur during a given trip.

2.34~~5~~.1. *"Nominal scenario"* means a traffic scenario representing one or more nominal driving situations.

2.34~~5~~.2. *"Critical scenario"* means a traffic scenario representing one or more critical situations.

2.34~~5~~.3. *"Failure scenario"* means a traffic scenario representing one or more failure situations.

2.345.4. *"Functional scenario"* means a basic traffic scenario describing a situation and its corresponding elements at the highest level of abstraction in natural, non-technical language.[35]

2.345.5. *"Abstract scenario"* means a formalized, declarative description of a scenario derived from a functional scenario.[35] [36] The specification on the abstract level enables highlighting of the relevant aspects of the scenario while focusing on efficient description of relations (cause-effect).

2.345.65. *"Logical scenario"* means a traffic scenario elaborated at a lower level of abstraction to include value ranges or probability distributions for each element of the corresponding functional scenario.[37]

2.345.76. *"Concrete scenario*" means a traffic scenario at a level of abstraction in which specific values have been selected for each element from the continuous ranges as may be defined in the corresponding logical scenario.

2.356. *"Safety-relevant object"* means an object that, if collided with, is likely to cause non-trivial damage to the vehicle or that is likely to pose a safety risk to other road users, vehicle occupants, or infrastructure.

3. General requirements

3.1. As a general concept, the safety level of ADS shall be at least to the level of a competent and careful human driver.

3.2. The ADS shall be free from unreasonable risk.

3.3. The requirements of this regulation are without prejudice to applicable laws governing:

(a) Access to data,

(b) Availability of data,

(c) Data privacy,

(d) Data protection, and

(e) Provision of data to other authorities.

4. ADS requirements

4.1. Performance of the DDT

4.1.1. The ADS shall be capable of performing the entire DDT within the ODD of its feature(s).

4.1.2. ADS Performance of the DDT in Nominal Situations

4.1.2.1. The driving behaviour of the ADS shall not cause a collision.[38]

4.1.2.2. The ADS shall adapt its driving behaviour in line with safety risks: this shall at least include:

---

[34][35] For example, a description of the ego vehicle's actions, the interactions of the ego vehicle with other road users and objects, and other elements that compose the scenario such as environmental conditions.

[35][36] **Declarative descriptions can include structured natural language, programming language or other forms of languages that meet the required criteria (formalized and declarative).**

[36][37] For example, elaborating the lane element to cover possible lane widths.

[37][38] It is acknowledged that establishing causation can be complex, and not always possible. However, where it is established that the behaviour of an ADS caused a collision, this is a non-compliance with this requirement.

(a) Anticipating the risks in the driving environment to reduce the likelihood of encountering a critical situation,

(b) Adapting its speed in line with safety risks, and

(c) Maintaining appropriate distances from other road users by controlling the longitudinal and lateral motion of the vehicle.

4.1.2.3. The ADS shall avoid unreasonable disruption to the flow of traffic in line with safety risks.

4.1.2.4. The ADS shall detect and respond to objects and events relevant to its performance of the DDT.

4.1.2.5. The ADS shall detect and respond to priority vehicles in accordance with the applicable traffic law(s).

4.1.2.6. The ADS shall comply with traffic rules in accordance with the application of relevant law within the area of operation.

4.1.2.7. The ADS shall interact safely with other road users.

4.1.2.8. The ADS shall avoid collisions with safety-relevant objects.

4.1.2.9. The ADS shall signal its operational status if required by applicable laws.

4.1.2.10. Pursuant to a passenger request under paragraph 4.2.3.1., the ADS shall bring the vehicle to a safe stop.

4.1.2.11. The ADS shall have strategies in place to appropriately detect and respond to instructions from road safety agents.

4.1.3. ADS Performance of the DDT in Critical Situations

4.1.3.1. The requirements for DDT performance under nominal situations shall continue to apply during critical situations as far as is reasonably practicable under the specific circumstances with the aim of minimising overall safety risks.

4.1.3.2. When a collision cannot be avoided, the ADS shall aim to mitigate its severity.

4.1.3.3. In the event of a collision involving the ADS vehicle, if required to stop by applicable law, the ADS shall fall back to an MRC or bring the vehicle to a standstill as appropriate. During this process, the user may initiate deactivation of the ADS if the design of the ADS allows.

4.1.3.3.1. The ADS shall not resume travel unless:

(a) The safe operational state of the ADS vehicle has been verified, and

(b) It is permissible under the applicable laws.

4.1.3.3.2. Notwithstanding paragraph 4.1.3.3.1.(a), if the collision occurred while an ADSF-2 was active, when directed by a road safety agent, the ADS shall move the vehicle unless the ADS determines that the manoeuvre poses an unreasonable safety risk or is not technically possible due to damage. Alternatively, the safety case shall describe how the road safety agent's instructions will be complied with in such circumstances.

4.1.4. ADS Performance of the DDT in Failure Situations

4.1.4.1. The requirements for DDT performance in nominal situations shall continue to apply during failure situations as far as is reasonably practicable under the specific circumstances with the aim of minimising overall safety risks.

4.1.4.2. The ADS shall detect faults, malfunctions, and abnormalities that compromise its capability to perform the DDT within the ODD.

4.1.4.3. In response to a fault, the ADS shall either:

(a) Execute a fallback response and prohibit activation of the impacted feature(s) if the fault prevents the ADS from performing the DDT in accordance with the requirements under paragraph 4.1., or

(b) Adapt its performance of the DDT in accordance with the severity of the fault, provided the resulting performance complies with the requirements under paragraph 4.1.

4.1.4.4. The ADS shall be capable of remote termination.

4.1.4.4.1. **The procedure for remote termination of an ADS performing the DDT shall include the capability to perform an ADS fallback response.** ~~Remote termination for an ADS performing the DDT shall be capable of triggering an ADS fallback response.~~

4.1.4.4.2. **The remote**~~Remote~~ termination of an ADS or ADS feature(s) shall render it unable to be activated by a user until such time as the remote termination is rescinded.

4.1.5. ADS Performance of the DDT at ODD Boundaries

4.1.5.1. The ADS shall recognise the conditions and boundaries of the ODD of its feature(s).

4.1.5.2. The ADS shall be able to determine when the conditions are met for activation of each feature.

4.1.5.3. The ADS shall prevent activation of a feature unless the ODD conditions of the feature are met.

4.1.5.4. The ADS shall execute a fallback response when one or more ODD conditions of the feature in use are no longer met.

4.1.5.4.1. In response to an ODD exit, ADSF-2 shall aim to bring the ADS vehicle to a stop in a safe location that complies with traffic rules (e.g., a parking space).

4.1.5.5. The ADS shall be able to anticipate and safely respond to foreseeable exits from the ODD of each feature.

4.1.6. Fallbacks to a Mitigated Risk Condition (MRC)

4.1.6.1. For ADSF-2, the ADS fallback response shall be to place the vehicle in an MRC. The ADS feature may permit a user-initiated deactivation to interrupt the fallback to an MRC.

4.1.6.2. For ADSF-1, if it has not been possible to complete a system-initiated deactivation procedure, the ADS shall execute a fallback to an MRC. During the fallback to the MRC, the user may initiate the deactivation of the ADS.

4.1.6.3. Upon completion of an ADS fallback to an MRC, a user may be permitted to assume control of the vehicle.

4.2. Interactions between the ADS and its User(s)

4.2.1. General requirements

4.2.1.1. Safety-relevant information and signals shall be:

(a) Noticeable by the target user(s) under all operating conditions,

(b) Comprehensible and unambiguous, and

(c) Multi-modal (e.g., optical, auditory, haptic) if needed.

4.2.1.2. The ADS shall signal initiation of a fallback to an MRC to the ADS user(s).

4.2.1.3. The ADS shall permit a user to override ADS operation of doors in the event of an emergency.

4.2.2. ADS features that permit a user to take over the performance of the DDT.

4.2.2.1 General requirements

4.2.2.1.1 The ADS feature shall be designed to prevent misuse and errors in operation by the user.

4.2.2.1.2. While an ADS feature is active:

(a) The controls related to manual performance of the DDT shall be disabled, suppressed, or, by other means, made unavailable in a manner that prevents unsafe interference with the ADS performance of the DDT:

(i) In the case these controls are suppressed, the ADS shall have strategies in place to prevent ambiguous states of control or unintentional effect on the DDT,

(ii) When a user overcomes a suppression threshold, a user-initiated deactivation procedure shall commence and must follow the requirements of 4.2.2.3. Overcoming the suppression threshold shall not be the primary means to request a user-initiated deactivation,

(b) Devices for indirect vision, tell-tales, and non-ADS-related warnings may be disabled, suppressed, or, by other means, made unavailable, and

(c) In the case of an ADSF-2, the direct view to the outside environment may be reduced or compromised. Direct view shall be restored immediately upon the passenger requesting deactivation.

4.2.2.1.3. The vehicle controls dedicated to the ADS shall be clearly identified and distinguishable to accommodate only the appropriate interactions.

4.2.2.1.4. While an ADS feature is active, it shall inform the user of:

(a) ADS status information,

(b) The role of the fallback user in the case of an ADSF-1, and

(c) Adapted performance of the DDT consequent to some failure of the ADS.

4.2.2.1.5. The ADS shall indicate the availability of a feature for activation.

4.2.2.1.6. While active, an ADSF-1 shall:

(a) Continuously assess whether the fallback user is available to assume the role of driver. A fallback user is considered available when

(i) The user is at least awake, and

(ii) Correctly seated in such a way as to enable the fallback user to take control of the DDT at the end of the deactivation procedure,

(b) Provide effective procedures for re-engaging the fallback user who has been detected to be not available.

(c) Trigger a fallback to an MRC where it has not been possible, feasible, and/or safe to re-engage the fallback user.

(d) Ensure the system-initiated deactivation procedure includes sufficient time for the fallback user to perceive the need to take over and to safely re-engage with the driving task.

4.2.2.2. ADS feature activation

4.2.2.2.1. The ADS shall ensure a safe ADS feature activation.

4.2.2.2.2. The ADS shall provide immediate feedback to indicate success or failure when the ADS user attempts to activate an ADS feature.

4.2.2.2.3. The feature activation procedure (e.g., sequence of actions and states) shall take into account relevant recommendations or standards.

4.2.2.2.4. Upon activation of an ADSF-1, the ADS shall immediately and explicitly inform the fallback user of the consequent expectations on them to be ready to respond to a request to resume the DDT.

4.2.2.2.5. The ADS shall obtain the passenger’s consent to perform the role of fallback user before executing a transition from an ADSF-2 to an ADSF-1.

4.2.2.3. ADS feature deactivation to manual driving

4.2.2.3.1. The ADS shall follow a safe ADS feature deactivation procedure.

4.2.2.3.2 A suggestion from an ADSF-2 that a user might optionally take control shall be considered a user-initiated deactivation if the user accepts the suggestion.

4.2.2.3.3. Following the user requesting deactivation of the ADS feature, the ADS shall follow a deactivation procedure to safely transfer control of the DDT to the user.

4.2.2.3.4. The ADS shall respond when the user requests to initiate a system deactivation procedure. The ADS shall only initiate the system deactivation procedure if the ADS verifies that the user is in a position to assume the role of the driver.

4.2.2.3.5. ADS feature deactivation may be delayed if it is assessed by the ADS that the situation is unsuitable or unsafe for the subsequent mode of vehicle operation. In this case, the user shall be informed of this circumstance.

4.2.2.3.6. The ADS feature shall remain active until the system deactivation procedure has been completed or the ADS vehicle reaches a mitigated risk condition.

4.2.2.3.7. The deactivation procedure (e.g., sequence of actions and states) shall take into account relevant recommendations or standards.

4.2.2.3.8. The ADS shall assess if the fallback user or the passenger assuming the role of the driver is suitably engaged to resume the DDT before completion of the deactivation procedure.

4.2.2.3.8.1 A user is considered suitably engaged to resume the DDT when they are at least:

(a) In contact with the steering control and,

(b) Their gaze has been primarily directed to a driving task-relevant area long enough to be able to resume the DDT safely.

4.2.2.3.8.2. If gaze monitoring is momentarily unavailable, other user-engagement monitoring measures may be used. Such measures shall be described in the safety concept.

4.2.2.3.9. The ADS shall provide a specific indication of the completion of the deactivation of the ADS.

4.2.2.3.10. At the completion of the deactivation procedure, control shall be returned to the driver without any **sustained** ~~continuous~~ lateral or longitudinal control assistance active. **However, any sustained lateral assistance system that is permitted or required to be automatically enabled at the initiation of the power train may be set to the same state as it was prior to ADS activation.**

4.2.2.3.11. During the deactivation procedure, controls related to manual performance of the DDT, direct view to the outside environment, devices for indirect vision, indicators, warnings, and tell-tales shall be set to an appropriate state for manual driving.

4.2.2.3.12. If applicable, ADS features operating control of closures shall no longer influence closures or the controls associated with closures.

4.2.3. ADS features that do not permit a user to take over the performance of the DDT

4.2.3.1. The ADS shall provide the passenger(s) with means to request to stop the vehicle.

4.2.3.2. The ADS vehicle shall provide safety-related information to the passengers.

4.2.3.3. If safety risks to passengers arise while an ADS feature is active (e.g., safety belts not fastened, passengers not seated), the ADS shall respond according to the strategies described in paragraph 5.3.2.10.

4.2.3.4. Controls provided for manual driving (e.g., steering, service brake, parking brake, accelerator, lighting) shall be designed to prevent any effect on the DDT

while the ADS is performing the DDT, or reasonable safeguards shall be put in place to prevent access to controls.

4.2.4. Information provision to users who can perform the role of the driver

4.2.4.1. Means shall be provided that facilitate user understanding of the functionality and operation of the system.

4.2.4.1.1. A description of the ADS features and their capabilities and limitations shall be provided.

4.2.4.1.2. Instructions for the activation and deactivation of the ADS feature(s) shall be provided, with clear explanations of the distinctions between user-initiated deactivation and system-initiated deactivation where applicable.

4.2.4.1.3. A description of the transitions of user roles and the procedure for those transitions, for example, reversion to manual driving following deactivation of the ADS feature shall be provided.

4.2.4.1.4. Any expectations on the fallback user to be ready to resume the DDT upon request shall be explained.

4.2.4.1.5. A general overview of non-driving-related activities (NDRA) allowed when an ADS feature is active shall be provided.

4.2.4.1.6. Information related to the signals used by the ADS feature(s) shall be provided, including:

(a) Visual tell-tales, icons,

(b) Acoustic signals, and

(c) Haptic signals.

4.2.4.1.7. Information on possible changes in the performance of the DDT by the ADS features following a failure of the ADS shall be provided.

4.2.4.1.8. Information on how the ADS feature responds to inputs by the user into controls provided for manual driving (e.g., steering, service brake, parking brake, accelerator, lighting), if they are available, shall be provided.

4.2.4.1.9. Information on any additional safety precautions in using an ADS feature to be taken by the user shall be provided, such as that owners, operators, or drivers should check the condition of tyres and lights.

4.3. Other ADS Requirements

4.3.1. Data Storage Systems for Automated Driving

4.3.1.1. The ADS vehicle shall be equipped with a DSSAD capable of monitoring the safety performance of the ADS in accordance with the provisions of this Regulation.

4.3.2. The ADS shall be protected from cyber threats.

4.3.2.1. The manufacturer shall document and implement processes for managing cyber security across the development, production, and post-deployment phases.

4.3.2.2. The manufacturer shall describe its processes for cyber security, including:

(a) Identification, assessment, and treatment of cyber security risks,

(b) Monitoring, detecting, and responding to cyber-attacks, and

(c) Mitigating relevant cyber threats and vulnerabilities.

4.3.3. If the ADS software can be updated, the ADS shall support safe and secure software updates.

4.3.3.1. The manufacturer shall document and implement processes for safely and securely managing ADS software updates, including:

(a) software identification and version control,

(b) Description and notification (e.g., release notes for each software version),

(c) Verification and validation prior to deployment,

(d) Target vehicle identification and compatibility checks, and

(e) Safe and secure delivery and implementation.

4.3.4. The ADS shall be designed to protect against unauthorized access to and modification of the ADS features and functions. The measures ensuring protection from unauthorized access shall be provided in alignment with engineering best practices.

4.3.5. The ADS shall provide an interface for the purposes of maintenance and repair by authorized persons.

4.3.5.1. For vehicles without manual driving controls, suitable means shall be made available, where necessary (e.g., special controls, test modes, ADS functions) to enable the performance of the physical checks required for mandated inspections of other vehicle systems in the jurisdiction of operation (e.g., Periodical Technical Inspection, safety standards inspection, etc.).

4.3.6. The ADS shall receive and appropriately manage all signals received from other **systems of the ADS vehicle** ~~vehicle systems~~. A list of these signals and how they are managed shall be included in the manufacturer's safety case.

4.3.7. While an ADSF-2 is active, the ADS shall manage relevant non-DDT-related tasks (which would otherwise be performed by a driver) in accordance with the manufacturer's safety case. Alternatively, where the ADS does not perform such necessary tasks, the safety case shall describe how these tasks are performed.

4.3.8. The performance of the ADS shall not be adversely affected by magnetic or electrical fields.

4.3.9. If an ADS feature can be activated while the ADS vehicle is operating as a vehicle combination, the ADS shall also meet the requirements of this Regulation with respect to that vehicle combination while that ADS feature is active.

5. Manufacturer requirements

5.1. Safety Management Systems (SMS)

5.1.1. The manufacturer shall establish, implement, and document a Safety Management System (SMS).

5.1.2. Safety policy

5.1.2.1. The safety policy shall outline the aims and objectives that the manufacturer uses to achieve the desired safety outcomes.

5.1.2.2. The manufacturer shall provide evidence that its safety policy implements the following aspects:

(a) Safety policies and principles (e.g., ISO 21434, paragraph 5.4.1 and ISO 9001 Automotive 5.2.),

(b) Organization safety objectives and the process for creating safety performance indicators used in the safety case,

(c) Appropriate structure for the SMS taking into account regulation, standards, best practice guidance, and the use-case of the ADS and its features and mapping its organization structure, processes, and work products onto the SMS,

(d) Safety culture (e.g., ISO 26262-2, paragraph 5.4.2),

(e) Safety governance, including management commitment (e.g., ISO 21434, paragraph 5.4.1 and ISO 9001 Automotive 5.1), clear lines of accountability and roles and responsibilities (e.g., ISO 26262-2, paragraph 6.4.2, this relates to the organizational and project-dependent activities), and

(f) Quality Management System (e.g., IATF 16949 or ISO 9001**)** to support safety engineering, including change management, configuration management, requirement management, tool management, etc.

5.1.3. Risk management

5.1.3.1. The SMS shall include a management process to identify, assess, and mitigate organisational, human, and technical risks.

5.1.3.1.1. The SMS shall show the link between the overall risk management process, the mitigations, and the resulting operational risks.

5.1.3.2. The manufacturer shall document its risk-management processes and activities with consideration of relevant standards and best practices, including:

(a) Risk identification (e.g., ISO 31000 paragraph 6.2),

(b) Risk analysis (e.g., ISO 31000 paragraph 6.3),

(c) Risk evaluation (e.g., ISO 31000 paragraph 6.4),

(d) Risk treatment (e.g., ISO 31000 paragraph 6.5),

(e) Processes for keeping the risk assessments up to date, and

(f) Review of the safety performance of the organisation and the effectiveness of safety risk controls.

5.1.4. Safety assurance

5.1.4.1. The manufacturer shall demonstrate that periodic independent internal audits and external audits are carried out to ensure that the processes established for the Safety Management System are implemented consistently.

5.1.4.2. The manufacturer shall put in place suitable arrangements (e.g., contractual arrangements, clear interfaces, quality management system) with any organisation involved in the development, manufacturing, or in-use deployment of its ADS and its features (e.g., contracted suppliers, service providers, or manufacturers' sub-organisations).

5.1.4.2.1. The manufacturer shall document its processes and activities, including the following aspects:

(a) Organisational policy for supply chains,

(b) Incorporation of risks originating from supply chains,

(c) Evaluation of supplier SMS capability and corresponding audits,

(d) Processes to establish contracts, agreements for ensuring safety across the phases of development, production, and post-deployment,

(e) Processes for distributed safety activities, and

(f) The manufacturer shall have processes for providing safety-relevant information to relevant parties as needed, enabling them to meet their legal obligations.

5.1.4.3. SMS documentation shall be regularly updated in line with any relevant changes to the SMS processes. Gap analysis shall be used when auditing and updating the SMS, examining the current safety culture before formulating new and more appropriate SMS processes to ensure issues are adequately resolved.

5.1.4.4. The manufacturer shall have processes for:

(a) Assuring that all practices and activities documented as part of the SMS are followed,

(b) Assuring that an independent check of compliance with the applicable requirements is performed (i.e., not from the person(s) creating the compliance data), and

(c) Assuring the continued evaluation of the Safety Management System so that it remains effective.

5.1.4.5. The manufacturer shall define appropriate Key Performance Indicators (KPI) to measure the effectiveness of the Safety Management System throughout the ADS lifecycle (development, production, operation, and decommissioning).

5.1.5. Safety promotion

5.1.5.1. The SMS shall be subject to a process of continual improvement (e.g., "Plan, Do, Check, Act" as described in ISO 9001). Any changes to SMS documentation should be communicated as required to the relevant authority.

5.1.5.2. The manufacturer shall institute and maintain:

(a) Effective communications within the organization on safety issues (e.g., ISO 26262-2, paragraph 5.4.2.3),

(b) Information sharing outside of the organization (e.g., ISO 21434, paragraph 5.4.5 and ISO 9001, but from a safety perspective),

(c) SMS training plans.

5.1.6. Management of design and development

5.1.6.1. The SMS shall include evidence of the deployment of the safety policy in the Design and Development phase, including the following:

(a) Roles and responsibilities of the people involved during the design and development phase,

(b) Qualifications and experience of persons responsible for making decisions that affect safety, and

(c) Coordination of roles, responsibilities, and information transfer between design and production activities.

5.1.6.2. The manufacturer shall implement its processes and activities to ensure the robustness of the design and development phase, including the following aspects:

(a) A general description of how the organization performs all the design and development activities,

(b) Vehicle/system design and development, integration, and implementation, and safety case processes and activities, including at least the following:

(i) Requirements management (e.g., requirement capture and validation),

(ii) Suitability of the physical testing environment,

(iii) Credibility of virtual tool chain,

(iv) Tool management,

(v) System integration,

(vi) Software development assurance,

(vii) Hardware development assurance,

(viii) Management of functional safety (e.g., ISO 26262) and SOTIF (e.g., ISO 21448), including the ongoing evaluation and update of risk assessments and interactions,

These processes shall include elements like e.g Failure Mode and Effect Analysis (FMEA), Fault Tree Analysis (FTA), System-Theoretic Process Analysis (STPA) or any similar process appropriate to system functional safety and SOTIF.

(ix) Management of human factors, including human-centred design processes for safety-relevant interactions (e.g., ISO 9241-210).

(c) Change management, including but not limited to:

(i) Major design decisions,

(ii) ADS design modifications,

(iii) Changes in key personnel responsible for making decisions that affect safety, and

(iv) Tools and thresholds adopted for ADS safety verification.

5.1.6.3. The manufacturer shall include effective communication channels between the departments and third-party organizations responsible for functional safety, SOTIF, cybersecurity, and any other relevant disciplines related to the achievement of vehicle safety.

5.1.6.4. The SMS shall include a process for creating safety performance indicators used in the safety case.

5.1.7. Management of production

5.1.7.1. The manufacturer shall establish and document the production process in the SMS. This documentation shall cover at least the following aspects:

(a) Quality Management System (e.g., IATF 16949 or ISO 9001) and

(b) A description of the way in which the manufacturer performs all the production functions, including management of working conditions, working environment, equipment, and tools.

5.1.7.2. The manufacturer shall establish and document their distributed production processes and activities in the SMS. The processes and activities shall include:

(a) Liaison between the manufacturer and all other organisations (e.g., suppliers, partners, or subcontractors) involved in the supply chain and

(b) Criteria for the acceptability of "subsystem/components" manufactured by other partners or subcontractors. (i.e., deployment of production assurance requirements to the supply chain).

5.1.8. Management of post-deployment safety

5.1.8.1. The manufacturer shall establish processes to demonstrate its capabilities to manage safety during the post-deployment phase, including carrying out In-Service Monitoring and Reporting (ISMR) and taking remedial actions when necessary.

5.1.8.2. The processes for ISMR shall demonstrate the capabilities:

(a) To monitor ADS operations,

(b) To confirm the compliance with the defined safety case and compliance with the performance requirements,

(c) To identify safety risks related to ADS performance that need to be addressed in the frame of the SMS activities, including instances of non-compliance with ADS safety requirements,

(d) To manage potential safety-relevant gaps during the in-service operation and to provide the information that allows the ADS to be updated according to the appropriate manufacturer processes,

(e) To support the development of new or revise existing scenarios,

(f) To perform event investigation,

(g) To report occurrences to the relevant authority when they occur, and

(h) To share learnings derived from occurrence analysis which have triggered SMS processes for the continuous improvement of the ADS vehicle safety.

5.1.8.3. The process for ISMR shall demonstrate the capabilities for handling the reports received from other sources, including distinguishing false reports from actual events and conducting thorough investigations when necessary.

5.1.8.4. The manufacturer shall demonstrate the capabilities to monitor the performance of all its in-service ADS vehicles.

5.1.8.5. The manufacturer shall demonstrate the capabilities to collect and analyse vehicle data and data from other sources to achieve the ISMR objectives.

5.1.8.5.1. The manufacturer shall have:

(a) A data-acquisition strategy,

(b) A data-retention strategy, and

(c) Data access, security, and protection policies.

5.1.8.5.2. The data acquisition strategy shall ensure a representative collection of data to monitor the ADS in service performance.

5.1.8.5.3. The data retention strategy shall ensure that:

(a) Data related to a detected safety issue is retained until any necessary corrective action and review processes are complete, and

(b) **A subset of the collected data is retained to enable longer-term trend analysis** ~~The retention of the data for longer-term trend analysis (i.e., subset of the collected data)~~.

5.1.8.5.4. The data access, security, and protection policies shall ensure that information access is allowed only to authorised persons and contains safeguards to ensure the security and protection of the data in accordance with the data-protection laws of the relevant jurisdiction.

5.1.8.5.5. The manufacturer shall achieve the following objectives from the monitoring activity:

(a) Verify the safety performance (i.e., Safety Performance Indicators) and confirm the in-service safety level of the system (i.e., ~~–~~metrics and thresholds),

(b) Identify areas of operational risk,

(c) Identify when the ADS prevents incidents/accidents (e.g., MRC fallbacks, collision avoidance, emergency manoeuvres),

(d) Characterise and analyse occurrences,

(e) Discover trends that suggest the emergence of unacceptable risks,

(f) Ensure that remedial actions are put in place when an unacceptable risk is discovered or predicted by trends,

(g) Confirm the effectiveness of any remedial action, and

(h) Enable the development of new or the revision of existing scenarios derived from ISMR activities.

5.1.8.5.6. The manufacturer shall perform a data analysis with sufficient frequency so that remedial action can be taken promptly and in line with reporting requirements listed under paragraph 5.4.

5.1.8.5.7. The analysis techniques shall include at least the following:

(a) Routine measurements: A selection of parameters shall be collected to characterise the performance of ADS and to allow a comparative analysis. These measurements shall aim at identifying and monitoring

emerging trends and tendencies before the trigger levels associated with exceedances are reached.

(b) Exceedance detection: A set of safety performance indicators shall be selected to cover the main areas of interest for the ADS operation with the aim of searching for deviations from safety performance and limits. They shall be continuously reviewed to reflect the current operations.

(c) Occurrence analysis: It shall be possible to characterise and investigate all the occurrences listed in Annex 1 using the recorded data.

(d) Statistics: Data series shall be collected to support the analysis process with additional information. These data shall provide information to generate rates and trends.

5.1.8.6. The manufacturer shall have mechanisms in place for receiving and analysing safety-relevant feedback and reports from other sources to extract safety-relevant information and to review the safety monitoring data.

5.1.8.6.1. The other sources shall include at least:

(a) ADS-related vehicle maintenance and inspection feedback,

(b) Law enforcement and other road-safety authorities,

(c) Service operators, customers, public and dealer feedback.

5.1.8.7. The manufacturer shall evaluate the results from the monitoring activity to assess:

(a) In-service safety performance,

(b) The adequacy of the metrics and thresholds, and

(c) The outcome of remedial actions.

5.2. Test environments

5.2.1. Virtual testing

5.2.1.1. The manufacturer shall describe the intended use(s) of virtual testing and its role in the overall testing strategy.

5.2.1.2. The manufacturer shall demonstrate that each simulation toolchain is suitable to use for virtual testing by showing that they fulfil the requirements laid down in the present section.

5.2.1.2.1. In performing this assessment, the manufacturer shall take into account the results of the simulation toolchain criticality analysis as described under paragraph 5.2.1.9. below to produce evidence to support the safety case and for the assessment of ADS compliance with functional/user requirements.

5.2.1.3. Data management

5.2.1.3.1. The manufacturer shall manage the **relevant** data used to ~~develop,~~ verify, validate**,** and update the simulation toolchain(s) **until the ADS has been decommissioned**~~throughout its lifecycle~~. The manufacturer shall consider the completeness, accuracy and consistency of this data.

5.2.1.3.2. The manufacturer shall maintain a record of the data used in the validation of the toolchain(s).

5.2.1.3.3. The manufacturer shall describe the measures taken to ensure the quality and integrity of data or tools integrated into the simulation toolchain(s) from organisations that are not under the control of the manufacturer.

5.2.1.3.4. Management of input data and simulation toolchain(s) parameters

5.2.1.3.4.1. The manufacturer shall document the input data used to verify and validate the simulation toolchain(s).

5.2.1.3.4.2. The documentation shall note important quality characteristics of the input data.

5.2.1.3.4.3. The documentation shall show that the input data covers the intended ADS functionalities that the virtual testing aims to assess.

5.2.1.3.4.4. The documentation shall describe the calibration procedures used to fit parameters associated with the simulation toolchain(s).

5.2.1.3.4.5. The documentation shall explain the reasons for any changes to the data or parameters that occur when a new version of a simulation toolchain(s) is released.

5.2.1.3.5. The manufacturer shall quantify the uncertainty in the simulation toolchain(s) and its outputs that occur because of the quality of the data (e.g. data coverage, signal-to-noise ratio, and sensors' uncertainty/bias/sampling rate).

5.2.1.3.6. Management of output data

5.2.1.3.6.1. The manufacturer shall record the output data from the simulation toolchain(s) used for its validation.

5.2.1.3.6.2. Each output record shall be traceable to the input data that produced the output.

5.2.1.3.6.3. The manufacturer shall conduct statistical analysis of the output data and note any important quality characteristics deduced from this analysis.

5.2.1.3.6.4. The manufacturer shall show that the quality of the output data is sufficient to:

(a) Validate the simulation toolchain(s) and its components;

(b) Allow consistency/sanity check of the simulation toolchain(s) and its components; and

(c) Produce evidence to support the ADS safety case.

5.2.1.3.6.5. If stochastic models exist in the simulation toolchain(s), with regard to the data generated by these models, the manufacturer shall:

(a) Characterise the variance in the output of the simulation toolchain(s), and;

(b) Ensure the possibility of a deterministic re-execution of the simulation toolchain(s).

Where determinism cannot be guaranteed, the manufacturer shall provide evidence that its impact on the credibility of the simulation toolchain is acceptable.

5.2.1.4. Competency of personnel

5.2.1.4.1. The manufacturer shall document and provide the rationale for their confidence in the competency of:

(a) The personnel who developed the simulation toolchain(s) and its components,~~;~~

(b) The personnel who assessed the simulation toolchain(s) and its components,~~;~~ and

(c) The personnel who used the simulation toolchain(s) to perform the testing with the purpose of validating the system.

5.2.1.4.2. The manufacturer shall have processes and procedures that identify and maintain the skills, knowledge, and experience needed to develop, assess, and use the simulation toolchain(s). The following processes shall be established, maintained, and documented:

(a) Process to identify and evaluate the necessary competencies that are required to perform the modelling and simulation activities identified by the manufacturer,~~;~~ and

(b) Process for training personnel to be competent to perform the modelling and simulation activities.

5.2.1.4.3. The manufacturer shall maintain records of the personnel involved in the development, assessment, and use of the simulation toolchain(s) showing they have received the necessary training and have been deemed competent to perform the requested modelling and simulation activities.

5.2.1.4.4. The manufacturer shall set up suitable arrangements with third-party organisations linked to the simulation toolchain(s), to ensure that the competency of the third-party personnel is adequate to perform the tasks assigned to those personnel.

5.2.1.4.5. The arrangements with third-party organisations shall be aligned with the SMS provisions reported in paras. 5.1.4.2. and 5.1.6.3.

5.2.1.5. Release management

5.2.1.5.1. The manufacturer shall manage and support the simulation toolchain(s) used for virtual testing throughout the lifecycle of the simulation toolchain(s).

5.2.1.5.1.1. This management and support shall also continue until the end of the post-deployment phase of the ADS.

5.2.1.5.2. The manufacturer shall manage and document the simulation toolchain(s) release management process, including:

(a) A description of the modifications associated with each toolchain(s) release,

(b) A record of any associated software (e.g., specific software product, designations, and version) and hardware arrangements (e.g., XiL configuration), and

(c) A record of the internal review activities that supported the toolchain(s) acceptance and release.

5.2.1.6. Description of the simulation toolchain

5.2.1.6.1. The manufacturer shall describe the simulation toolchain(s) and identify its scope of applicability, its limitations, assumptions and the sources of uncertainty that can affect results.

5.2.1.6.2. The manufacturer shall provide a description of the simulation toolchain(s) and its components.

5.2.1.6.3. The manufacturer shall provide a description of the approach adopted in the simulation toolchain(s) validation.

5.2.1.6.4. The manufacturer shall provide a description of the acceptance tests and criteria that will be used to determine that the simulation toolchain(s) can be used to produce the evidence needed to support the ADS safety case.

5.2.1.7. Simulation toolchain assumptions, known limitations, and uncertainty quantification

5.2.1.7.1. The manufacturer shall describe the modelling assumptions and considerations that guided the design of the toolchain(s).

5.2.1.7.2. The manufacturer shall provide information on:

(a) Assumptions made during the development of each simulation toolchain and its components, and the limitations that these assumptions impose on its scope and applicability, and

(b) The rationale for choices made about the level of fidelity of each simulation toolchain and its components.

5.2.1.7.3. The manufacturer shall provide justification that the tolerances associated with the simulation toolchain(s) are appropriate and meet the acceptance tests and criteria.

5.2.1.7.4. The manufacturer shall provide details of the sources of uncertainty in each simulation toolchain and its components, and the assessment of their impact on the results.

5.2.1.8. Simulation toolchain scope

5.2.1.8.1.1. The scope shall refer to the ODD and identify any limitations about its applicability to the ODD.

5.2.1.8.2. The manufacturer shall demonstrate how each simulation toolchain imitates the relevant physical phenomena and meets the necessary level of accuracy.

5.2.1.8.3. The manufacturer shall provide sufficient evidence to justify the claim that the simulation toolchain(s) can be used within the defined scope.

5.2.1.8.4. The manufacturer shall provide a list of tests used for validation and the corresponding parameters and any known limitations.

5.2.1.9. Simulation toolchain criticality analysis

5.2.1.9.1. The manufacturer shall review the error estimates of the simulation toolchain(s) to assess their criticality and the effect these would have on the manufacturer's claims about their safety case.

5.2.1.10. Simulation toolchain verification

5.2.1.10.1. The manufacturer shall demonstrate that the simulation toolchain(s) will not exhibit unrealistic behaviour for valid inputs which have not been explicitly tested.

5.2.1.11. Simulation toolchain code verification

5.2.1.11.1. The manufacturer shall document the execution of proper code verification techniques used in evaluating each simulation toolchain and its components (e.g., static/dynamic code verification, convergence analysis and comparison with exact solutions if applicable).

5.2.1.11.2. The manufacturer shall provide evidence that the input parameter space was sufficiently explored to identify if there are any parameter combinations for which the simulation toolchain shows unstable or unrealistic behaviour.

5.2.1.11.3. The manufacturer shall undertake sanity and consistency checking procedures and provide information on the results to show that the simulation toolchain(s) are robust.

5.2.1.12. Simulation toolchain calculation verification

5.2.1.12.1. The manufacturer shall document numerical error estimates (e.g., discretisation error, rounding error, iterative procedures, and convergence).

5.2.1.12.2. The manufacturer shall review the analysis and demonstrate that the numerical errors are understood and sufficiently bounded to allow the simulation toolchain(s) to be used for virtual testing.

5.2.1.13. Simulation toolchain sensitivity analysis

5.2.1.13.1. The manufacturer shall provide documentation demonstrating that the input data and parameters that most critically influence the toolchain outputs have been identified by means of appropriate sensitivity analysis techniques.

5.2.1.13.2. The manufacturer shall demonstrate that robust calibration procedures have been adopted for assigning appropriate value(s) to all the simulation parameters while ensuring that special attention is taken for the most critical parameters. ~~This is to ensure that the simulation toolchain can be used to emulate the relevant real-world system.~~

5.2.1.13.3. The manufacturer shall demonstrate that sensitivity analysis has been used to identify the critical input data and parameters that need particular attention in order to characterise the uncertainty of the overall simulation toolchain outputs.

5.2.1.14. Simulation toolchain validation

5.2.1.14.1. The manufacturer shall perform a validation analysis based on quantitative metrics to determine the degree to which each simulation toolchain is an accurate representation of the real-world system.

5.2.1.14.2. The manufacturer shall provide evidence that each simulation toolchain's results are consistent and correlate with the results of physical tests.

5.2.1.14.7. The manufacturer shall define the methodology and tests used for each simulation toolchain validation.

5.2.1.14.3. The validation shall be performed on a sufficiently representative set of tests in order to substantiate the claims that the simulation toolchain(s) are suitable and can be used within their scope.

5.2.1.14.4. The manufacturer shall define the measures of performance (metrics) that will be used when comparing the results of physical tests and the output of the simulation toolchain(s).

5.2.1.14.5. The manufacturer shall use appropriate statistical techniques when comparing the results of physical tests and the corresponding output of the simulation toolchain and its components.

5.2.1.14.6. The manufacturer shall specify acceptance tests and criteria during the development of each simulation toolchain and its components and demonstrate that they have been achieved.

5.2.1.14.7.1. It should be clear whether the full ODD is within the scope of the toolchain(s) or only part of it.

5.2.1.14.7.2. The validation strategy may consist of one or more of the following:

(a) Subsystem model validation (e.g., environment models, sensor models, and vehicle models);

(b) Vehicle system model validation (vehicle dynamics model together with the environment model);

(c) Sensor system validation (sensor model together with the environment model); and

(d) Integrated system validation (sensor model together with the environment model with influences from the vehicle model).

5.2.1.14.8. The manufacturer shall demonstrate that the accuracy criteria defined during each simulation toolchain development have been met.

5.2.1.14.9. The manufacturer shall provide evidence that the processes related to the validation activity have been followed.

5.2.1.14.10. The manufacturer shall document their uncertainty characterisation analysis and provide information about how the simulation toolchain(s) should be used and any safety margins that should be applied when it is used for virtual testing.

5.2.1.14.11. The manufacturer shall demonstrate that it has techniques to estimate each simulation toolchain's critical inputs and that they have been applied, and the results documented.

5.2.1.14.12. The manufacturer shall demonstrate that they have characterised the critical parameters used in each simulation toolchain and its components, and where appropriate, have identified these as distributions with confidence intervals.

5.2.1.14.13. The manufacturer shall demonstrate that they have achieved a proper characterisation of the uncertainty of the results of each simulation toolchain and its components, because of any assumptions therein.

5.2.1.14.14. The manufacturer shall demonstrate that they have differentiated between the aleatory and epistemic uncertainties associated with each simulation toolchain.[39] [38]

5.2.2. Track testing

[38] [39] **"Aleatory u~~U~~ncertainty" means the portion of uncertainty deriving from a random process that cannot be reduced.~~, while~~ "Epistemic u~~U~~ncertainty" means the portion of uncertainty deriving from a lack of knowledge about a process that can be reduced via observations.**

5.2.2.1. The manufacturer shall demonstrate that the track testing environment and capabilities are suitable to conduct testing and gather evidence to support the safety case. In particular, the manufacturer shall demonstrate that:

(a) The track testing conducted includes static and dynamic elements representative of the ODD and of the expected operating conditions, and

(b) The equipment used during track testing undergoes periodic inspection, maintenance, and calibrations to ensure that the measurements are characterised by sufficient accuracy and precision.

5.2.3. Real-world testing

5.2.3.1. The manufacturer shall demonstrate that the real-world testing facilities (public roads), environment, and capabilities are suitable to conduct testing and gather evidence to support the safety case. In particular, the manufacturer shall demonstrate that:

(a) The selected test routes hold a sufficient probability for the ADS to encounter situations that involve a large number of other road users, unlikely road infrastructure, or abnormal geographic/environmental conditions, and

(b) The equipment used during real-world testing undergoes periodic inspection, maintenance, and calibrations to ensure that the measurements are characterised by sufficient accuracy and precision.

5.3. Safety case for an ADS

5.3.1. System Description

5.3.1.1. The manufacturer shall provide a system description.

5.3.1.2. The system description shall describe the type(s) of use(s) for which the ADS is intended, such as personal car ownership, urban taxi fleet, goods transportation, highway use, etc.

5.3.1.2.1. This shall include a description of each ADS feature configuration, including ADS functions applicable to that specific feature, the intended uses and limitations on the use of the feature, which gives a simple explanation of its operational characteristics.

5.3.1.3. The system description shall describe how the Operational Design Domain has been defined for each ADS feature and explain the boundaries of each of the conditions in which the feature is designed to operate. This shall include at least the following:

(a) **Geographic limitations**~~Intended area of operation (e.g., jurisdictions, geographic limitations)~~,

(b) Roadway characteristics (e.g., road type, road conditions, speed limit),

(c) Environmental conditions (e.g., weather, illumination), and

(d) Dynamic elements (e.g., kinds of other road users).

5.3.1.4. The system description shall include outlines of the following elements of the ADS and their relationships to other vehicle systems:

(a) Hardware components and their functions, and

(b) Software components and their functions.

5.3.1.4.1. The outlines shall include block diagrams and/or schematics.

5.3.1.4.1.1. The hardware components outline shall include a schematic of the ADS illustrating the equipment distribution.

5.3.1.4.1.2. The outlines shall integrate the hardware identification markings of the ADS components in their diagrams and/or schematics, and a table shall be provided to link the hardware identification to the software identification.

5.3.1.4.1.3. A single hardware identification marking shall be used for functions that are combined within a single component (e.g., control unit or single computer) but are shown in multiple blocks in a block diagram.

~~5.3.1.4.1.4. [The table specified in paragraph 5.3.1.4.1.2. of this Regulation shall be kept up to date with software and hardware updates.]~~

5.3.1.4.2. The outlines shall include the components/functions of the ADS and other vehicle systems that are relevant to meeting the requirements of this Regulation.

5.3.1.4.2.1. The outlines shall show interconnections between the components/functions of the ADS and those components/functions and other systems via:

(a) A circuit diagram for the electrical transmission links,

(b) A piping diagram for pneumatic and/or hydraulic transmission equipment, and

(c) A simplified diagrammatic layout for mechanical linkages.

5.3.1.4.2.2. There shall be a clear correspondence between transmission links in the hardware and software components outline, schematics, and/or diagrams and the signals carried between components and systems of the corresponding functions outline, schematics, and/or diagrams.

5.3.1.4.2.3 Priorities of signals on multiplexed data paths shall be stated wherever priority can be an issue affecting performance or safety.

5.3.1.4.3. The outlines shall include how the following functions and aspects are addressed:

(a) Sensing and perception of events and objects,

(b) Decision-making and planning,

(c) Remote supervision and remote monitoring by a remote supervision centre (if applicable),

(d) Information display/user interface,

(e) The data storage system (e.g., Data Storage System for Automated Driving), and

(f) Redundancies of relevant components and/or connections.

5.3.1.4.4. The hardware components outline shall provide information regarding the installation options that will be employed for the individual components that comprise the sensing system.

5.3.1.4.4.1. These options shall include, but are not limited to, the location of the component in/on the vehicle, the material(s) surrounding the component, the dimensioning and geometry of the material surrounding the component, and the surface finish of the materials surrounding the component, once installed in the vehicle.

5.3.1.4.4.2. The information shall also include installation specifications that are critical to the ADS's performance, such as tolerances on installation angle.

5.3.1.4.4.3. Any changes to the individual components of the sensing system or the installation options shall be updated in the documentation.

5.3.1.5. A list of all inputs relevant to/for the ADS, including those from sensors, shall be provided, and the working range of these defined, along with a description of how each variable is linked to the control functions of the ADS and potential impacts on system behaviour. This shall include the nominal range and coverage area of each sensor.

5.3.1.6. A list of all of the ADS outputs shall be provided and an explanation given, in each case, of whether the output directly controls the vehicle or is processed via another vehicle system. The range of control exercised on each variable shall be defined as well as the nominal capabilities of control actuators.

5.3.1.7. The system description shall describe how the ADS detects and responds to approaching and crossing of ODD boundaries.

5.3.1.8. The system description shall document:

(a) The conditions that must be present to permit activation of the feature,

(b) The conditions that trigger a fallback response,

(c) The conditions that must be present to permit deactivation of the feature, and

(d) The conditions that might prompt the user to voluntarily take back control, if applicable.

5.3.1.9. The system description shall indicate the categories of other road users with whom the ADS is designed to interact (e.g., pedestrians, cyclists, etc).

5.3.1.10. The system description shall identify the ADS users with whom the ADS is designed to interact and describe the nature of their interactions with the ADS.

5.3.1.11. If the ADS can request a remote intervention, the system description shall describe the nature and process for such interaction.

5.3.1.12. The system description shall describe the methods of activating, overriding, or deactivating the ADS feature by any or all of: the ADS user (where relevant), remote intervention (where relevant), passengers (where relevant), or other road users (where relevant).

5.3.1.13. Data Storage Systems for Automated Driving

5.3.1.13.1. In accordance with Annex 6, the manufacturer shall describe the DSSAD installed on the ADS vehicle, including:

(a) Capability to record time-stamped data,

(b) Capability to record time-series data,

(c) List of recordable data elements,

(d) Means for enabling access to stored data, and

(e) Means for protecting data against unauthorized access and manipulation.

5.3.1.13.2. ~~[~~The manufacturer shall justify the use of data elements provided by an alternative format listed in Annex 6.~~]~~

5.3.1.14. The system description shall describe the range of end states constituting a mitigated risk condition that can be achieved by the ADS feature, including:

(a) The conditions that might trigger an attempt to reach a mitigated risk condition,

(b) The processes by which the ADS feature attempts to reach a mitigated risk condition, and

(c) The evaluation of risk related to mitigated risk condition end states.

5.3.1.15. The **system description** ~~safety concept~~ shall include the following information:

(a) A list of the potential faults identifiable by the diagnostic system(s) of the ADS feature, and

(b) A list of vehicle system(s) and/or component(s) other than the ADS whose failure would preclude the ADS from performing the DDT.

5.3.1.16. The system description shall describe how the ADS feature responds to failure situations, including at least one or more following means (as applicable):

5.3.1.16.1. If a partial performance mode of operation is used under certain fault conditions (e.g., in case of severe failures), the system description shall describe:

(a) Conditions for activation of that mode (e.g., type of failure),

(b) Resulting ADS feature behaviour and capabilities (e.g., achievement of a mitigated risk condition immediately), and

(c) Warning strategy to the user/remote supervision centre (if applicable).

5.3.1.16.2. If a second (backup) or a diverse means to realize the performance of the dynamic driving task is used, the system description shall describe:

(a) The principles of the change-over mechanism,

(b) The logic and level of redundancy and any built-in checking features, and

(c) The resulting limits of effectiveness.

5.3.1.16.3. If the chosen response to a system failure entails the removal of an ADS function, the system description shall describe how it is done in compliance with the relevant provisions of this regulation. It shall also describe how all the corresponding output control signals associated with this function are inhibited.

5.3.1.17. The system description shall describe how user gaze is monitored, how the ADS determines that gaze is directed to a driving task-relevant area, and what parameters are used by the ADS for gaze duration in those areas for the purposes of paragraph 4.2.2.3.8.1.(b).

5.3.2. Safety concept

5.3.2.1. The manufacturer shall document its safety concept, which shall include the risks identified according to the SMS processes relevant to the ADS under paragraph 5.1.3**.** ~~of this Regulation relevant to the ADS~~ and shall include how those risks have been reduced, mitigated, or accepted.

5.3.2.1.1. The safety concept shall demonstrate the manufacturer's use of processes with top-down (from possible hazard to design) and bottom-up approaches (from design to possible hazards) in its identification of hazards.

5.3.2.2. The safety concept shall describe how the ADS features detect, identify, and respond to hazards, including the following:

(a) Detection and identification of hazards,

(b) Design provisions for SOTIF and functional safety (e.g., redundancies),

(c) An analysis that shows how the ADS will behave (e.g., control strategies) to mitigate or avoid hazards that can have a bearing on the safety of the ADS user(s) and other road users, and

(d) An analysis that shows how unknown hazardous scenarios and situations will be managed.

5.3.2.3. The safety concept shall describe the process the ADS uses to determine if a collision with an object would cause non-trivial damage.

5.3.2.4. The safety concept shall describe the ADS's strategy for determining if the ADS vehicle has collided with a safety-relevant object.

~~[5.3.2.5. The safety concept shall describe how software updates are validated and confirmed in accordance with paragraph [5.1.4.3.] of this Regulation.]~~

5.3.2.6. The safety concept shall describe how the ADS determines the presence/absence of the conditions stated in 5.3.1.3. and any linked/dependent conditions (e.g., reduced speed in icy weather).

5.3.2.7. The safety concept shall describe the conditions that the automated driving system is reasonably likely to encounter on its trip(s), including, but not limited to, environmental and geographical conditions, and/or the presence or absence of certain traffic or roadway characteristics, and explain how those expected conditions compare to the ODD of the ADS as described pursuant to paragraph 5.3.1.3. of this Regulation.

5.3.2.8. The safety concept shall describe measures or strategies, where applicable, implemented to:

(a) Prevent or mitigate abuse, misuse, and errors by occupants that could affect safe performance of the DDT (e.g., occupants attempting to access driving controls),

(b) Prevent, mitigate, or deter harm to occupants caused by external sources (e.g., unauthorised persons attempting to access a vehicle with occupants), and

(c) Prevent, mitigate, or deter abuse and misuse of the vehicle or its systems from external sources. (e.g., objects placed on vehicles during operation, attempts to damage a vehicle).

5.3.2.9. The safety concept shall describe strategies to limit sudden ODD exits and frequent activation and deactivation situations.

5.3.2.10. The safety **concept** ~~case~~ shall include a list of safety risks to passengers (e.g., safety belts not fastened, passengers not seated) and a description of how they are managed for all passengers while an ADS feature is active.

5.3.2.11. The safety concept shall describe the strategies in place to avoid operating the vehicle when the general working condition of the vehicle is not satisfactory (e.g., condition of tyres, brakes, lighting, status of external loads, steering). These strategies may include technological solutions, physical inspections, or other relevant solutions.

5.3.2.12. Data Storage System for Automated Driving

5.3.2.12.1. The manufacturer shall provide evidence demonstrating the following:

(a) Recording of the data elements listed under paragraph 5.3.1.13.1.(c); and

(b) Storage of recorded data in accordance with Annex 6.

5.3.2.13. The safety concept shall describe the approach used by the manufacturer to derive behavioural competencies and scenarios that are ODD-relevant.

5.3.2.13.1. The manufacturer may refer to the methodology outlined in Annex 5 as a suitable approach to derive behavioural competencies and scenarios that are ODD-relevant or alternative methods, providing they are equally comprehensive.

5.3.2.14. The safety concept shall describe the scenarios identification and generation approach, and how that approach addresses the following:

(a) Coverage of the appropriate nominal, critical, and failure situations,

(b) Use of data-driven, knowledge-driven, and stochastic approaches to systematically identify hazardous events and other occurrences,

(c) Inclusion of elements (especially dynamic elements) that are representative of existing traffic conditions in the expected operating conditions, and

(d) Incorporate the identified characteristics and behaviours of all the relevant scenario elements.

5.3.2.15. The safety concept shall describe the manufacturer's approach to scenario selection to cover the reasonably foreseeable situations and conditions that the ADS will encounter, including how the following aspects are covered:

(a) The selection of sufficient scenarios in which the ADS needs to initiate a **fallback**~~fall back~~ response (e.g., approaching the ODD **boundaries**~~limits~~),

(b) Reasonably foreseeable situations that are not deemed to be preventable by the ADS (e.g., related to unsafe behaviour by other road users or by infrastructural failures), and

(c) The use of appropriate techniques to explore the parameter space when choosing concrete scenarios.

5.3.2.16. The safety **concept** ~~case~~ shall describe how the manufacturer has determined the suitability of processes, resources, and competent personnel in place to:

(a) Design and undertake the testing that produces the evidence supporting the ADS safety case,

(b) Select scenarios that combine static and dynamic elements of a test track for correctly reproducing the situations selected for track testing,

(c) Identify test routes that capture predictable aspects of the ODD (e.g., road types and geometries), elements found in the related nominal situations (e.g., other road users, signs, and signals), and typical dynamic conditions (e.g., high/low traffic densities),

(d) **Ensure that the** ~~The~~ test routes ~~shall also~~ enable verification of nominal requirements for the safety of user interactions, including prior to, at the time of, and after entering and exiting the ODD of an ADS feature,

(e) **Assess** ~~To assess~~ the behavioural competencies demonstrated by the ADS for each scenario against the DDT performance requirements under paragraph 4.1. of this Regulation, and

(f) **Assess** ~~To assess~~ the capability of the ADS to ensure the safety of users and the safe use of the ADS.

5.3.2.17. The safety concept shall include the following information:

(a) Verification and validation plans, including metrics and targets:

(i) An explanation of how scenarios and situations are selected as part of verification and validation to provide reasonable coverage of the ODD and its boundaries,

(ii) Methodology, metrics, and targets used to determine reasonable ODD coverage,

(iii) Any analysis comparing the performance of an ADS feature to that of a manually driven vehicle of comparable category (e.g., Category 1-1) in situations within the ODD of the feature and,

(iv) Identification of any metrics or targets resulting from the analysis in (iii).

(b) Scoring/evaluation methodology to obtain metrics,

(c) Justification of the chosen acceptance criteria for metrics,

(d) Verification and validation results, including evidence that the targets have been met (i.e., metrics meet acceptance criteria), and

(e) The strategy applied for preventing activation of the ADS or ADS feature(s) after it has been decommissioned.

5.3.3. Claims, arguments, and evidence

5.3.3.1. The safety case shall include a series of claims for each of which there must be at least one supporting argument.

5.3.3.1.1. Each argument shall be supported by at least one piece of evidence.

5.3.3.1.2. Each claim, argument, and piece of evidence shall be uniquely labelled but may be used more than once (i.e., a piece of evidence may support more than one argument).

5.3.3.2. The claims, arguments, and evidence shall be understandable, logical, correct, and robust and shall demonstrate that:

(a) The ADS is free of unreasonable risk to ADS user(s) and other road users and

(b) The ADS meets the applicable requirements of this regulation in each of the following areas:

(i) Performance of the DDT (paragraph 4.1.).

(ii) User interactions (paragraph 4.2), except for the user information requirements under paragraph 4.2.5., and

(iii) Other requirements (paragraph 4.3.),

5.3.3.3. The following summary information shall be provided with regard to the claims, arguments, and evidence:

(a) A summary identifying the relationships between claims and their supporting argument and evidence, and

(b) A summary identifying each regulatory requirement noted above and the claims that demonstrate the requirement is met.

5.3.3.4. The claims, arguments, and evidence shall describe how the SMS processes (section 5.1) have been applied to manage ADS safety throughout the lifecycle of the system.

5.3.3.5. Relevant assumptions made in relation to claims, arguments, and evidence shall be stated.

5.3.3.6. The claims, arguments, and evidence shall demonstrate that the approach to testing is suitable for the demonstration of the safety case and the compliance with performance/functional requirements.

5.3.3.7. Each requirement defined under paragraphs 5.3.3.2, 5.3.3.4, 5.3.3.6., and as may be defined by the manufacturer shall have at least a claim.

5.3.3.7.1. Multiple sub-claims for a claim may be created, where a broader claim may not be sufficient or where additional justification is warranted, as long as said sub-claims are sequenced logically and their relationships are included in the summary documents.

5.3.3.8. Each argument supporting a claim shall provide contextual information and supporting information that explains how a claim is met based on an appropriate set of evidence.

5.3.3.9. Evidence supporting argumentation shall consist of test results or analysis (e.g., system layout and schematics, photographs, required documentation, etc.) as appropriate.

5.3.3.9.1 The virtual, track, and real-world test environments used to generate evidence shall satisfy the requirements under paragraphs 5.2.1., 5.2.2., and 5.2.3. respectively.

5.3.3.9.2. Testing results may be provided individually or on aggregate and shall include appropriate acceptance criteria.

5.3.3.9.3. Each test shall include enough information or be recorded in such a way that it may be reproduced upon request (e.g., same software/hardware versions, same tool versions, same scenario, same parameters, etc.).

5.3.3.9.3.1. The manufacturer shall facilitate access and execution of the necessary tools and analysis software upon request by the authority for the purpose of reproducing this evidence as part of the approval process or during compliance verification.

5.3.4. Manufacturer’s review of its safety case

5.3.4.1. As part of the manufacturer’s demonstration of compliance with the specifications of paragraph 5.1.4., the manufacturer shall review its safety case prior to certification/approval and is encouraged to do so during the development process.

5.3.4.2. The reviewer(s) shall be independent, meaning that they are free from conditions that would threaten their ability to review the safety case without bias.

5.3.4.3. The reviewer(s) may be internal or external to the manufacturer.

5.3.4.4. The review shall be documented, available for inspection, and include:

(a) Qualifications of the reviewer/ review team,

(b) Date/period of review, version of the safety case, tools, and ADS reviewed,

(c) Methods used to review the safety case,

(d) Listing of any evidence repeated/reproduced, and

(e) Identified gaps, questions, or areas of lower confidence or unknowns.

5.3.4.5. Following each review, and after a time of the manufacturer's choice but before assessment of compliance, the manufacturer shall include in their review documentation the steps taken to remediate or improve upon any findings (e.g., release notes).

5.4. Post-deployment safety

5.4.1. The manufacturer shall provide reports on the in-service safety performance of its ADS vehicles to enable:

(a) Monitoring implementation of the SMS processes required under paragraphs 5.1.4. and 5.1.8. of this Regulation,

(b) Monitoring of ADS performance for consistency with the claims evidenced in the safety case of the ADS under paragraph 5.3.3. of this Regulation, and

(c) Identification of safety concerns in need of remedy.

5.4.2. The reporting by the manufacturer shall be based upon information known to the manufacturer.

5.4.3. The manufacturer shall provide initial notifications, short-term reports, and periodic reports to the relevant authority.

5.4.4. The manufacturer shall provide the supporting data underpinning the report by means of an agreed data exchange mechanism upon request by the relevant authority.

5.4.5. The manufacturer shall provide the relevant authority with a description of the data processing (for example: filtering and conditioning) procedure and agree on the steps undertaken to deliver the data supporting the report.

5.4.6. The manufacturer shall report occurrences when at least one of the following is fulfilled:

(a) An ADS feature was active when the ADS vehicle was involved in the occurrence, or

(b) An ADS feature was active up to 30 seconds prior to the ADS vehicle experiencing the occurrence.

5.4.7. Initial notifications

5.4.7.1. The manufacturer shall notify the relevant authority of a critical occurrence without unreasonable delay in accordance with the applicable laws after becoming aware of it.

5.4.7.2. The initial notification may be limited to high-level data (e.g., location, time, type of accident).

5.4.8. Short-term reporting

5.4.8.1. The manufacturer shall provide short-term reports for the significant and critical occurrences listed in Annex 1 of this Regulation.

5.4.8.2. The manufacturer shall issue each short-term report within 30 days from its knowledge of the occurrence.

5.4.8.3. The manufacturer shall report the occurrences in accordance with the template provided in Annex 2 of this Regulation.

5.4.9. Periodic reporting

5.4.9.1. The manufacturer shall provide periodic reports for the occurrences listed in Annex 1.

5.4.9.2. The periodic report shall provide evidence of the in-service ADS safety performance. In particular, it shall demonstrate that:

(a) The ADS fulfils the performance requirements as evaluated in the test methods and/or declared in the safety case,

(b) No inconsistencies have been detected compared to the ADS safety performance declared prior to market introduction, and

(c) Any newly discovered significant ADS safety performance issues that pose an unreasonable risk to safety have been adequately addressed, and how this was achieved, including how they were addressed.

5.4.9.3. The manufacturer shall submit periodic reporting regularly, at least every year, in the form of aggregated data (e.g., per hour of operation and distance driven) for ADS-vehicle type and related to ADS operation.

5.4.9.4. The manufacturer shall provide the periodic report in accordance with the template provided in Annex 3.

5.5. Other manufacturer requirements

5.5.1 The manufacturer shall make available the extent, timing, and frequency of maintenance operations necessary for safe ADS performance to the vehicle owner or operator.

6. Compliance assessments

6.1. Audit of the Safety Management System

6.1.1. The documentation of the manufacturer’s safety management system shall be audited for compliance with the requirements under paragraph 5.1. of this Regulation.

6.1.2. The audit of the manufacturer’s safety management system shall provide evidence on the robustness of the manufacturer’s processes to manage safety risks and to ensure safety throughout the ADS lifecycle (development, production, deployment, and post-deployment).

6.1.3. The auditor shall evaluate the robustness of the manufacturer’s processes to monitor the safety management system activities (KPIs) and to take appropriate (corrective or preventive) action to address any issue.

6.1.4. The audit of the safety management system shall be conducted by auditors with the technical and administrative knowledge necessary for such purposes. This competence shall be demonstrated by appropriate qualifications or other equivalent training records.

6.1.5. Audit of the safety policy

6.1.5.1. The audit shall verify that the safety policy covers the following aspects:

(a) Definition of the principles and objectives upon which the SMS is built, operated, and maintained,

(b) General recognition of the inherent risks of ADS-related activities throughout their life cycle, including the risks of the parties involved,

(c) Organisational structure and the safety governance elements and their appropriateness for the needs of the organisation,

(d) Evidence of the commitment to safety, and

(e) Description of the means/approaches to engage people within the organisation in the culture of safety.

6.1.6. Audit of the risk management

6.1.6.1. The audit shall verify that the risk-management processes cover the following aspects:

(a) Reactive and proactive practices for risk management are in place,

(b) The risk management activity is not limited to the ADS itself but includes risk arising from the organisation/people which can affect the SMS effectiveness or the safety of the ADS,

(c) The risk management activity includes risks from third parties, and

(d) The risk management activity covers and is performed over the entire lifecycle.

6.1.7. Audit of the safety assurance

6.1.7.1. The audit shall verify that the safety-assurance processes cover the following aspects:

(a) Periodic independent internal audits and external audits,

(b) Processes for the management of the supply chain and any other involved organisation(s) that could affect the safety of the ADS,

(c) Change management processes are in place,

(d) Processes for corrective actions to maintain an acceptable level of safety are in place,

(e) The corrective action applies to the ADS as well as SMS,

(f) Monitoring practices to measure overall safety performance are in place,

(g) The monitoring practices apply to the ADS as well as to the SMS, and

(h) Independent functions for carrying out the compliance assessment and audit are in place.

6.1.8. Audit of safety promotion

6.1.8.1. The audit shall verify that the safety-promotion processes cover the following aspects:

(a) There is an appropriate level of competence of the personnel to perform their duties,

(b) The competence is promoted through training,

(c) Means for internal and external safety communications are in place, and

(d) Process for continuous improvement.

6.1.9. Audit of design and development processes

6.1.9.1. The audit shall verify that the design and development process covers the following aspects:

(a) Management of the design and development phase, and

(b) Evidence of the embodiment of the safety policy, risk management, safety assurance, and safety promotion aspects in the design and development.

6.1.10. Audit of production processes

6.1.10.1. The audit shall verify that the production processes cover the following aspects:

(a) Management of the production phase, and

(b) Evidence of the embodiment of the safety policy, risk management, safety assurance, and safety promotion aspects in the production.

6.1.11. Audit post-deployment processes

6.1.11.1. The audit shall verify that the post-deployment safety processes cover the following aspects:

(a) Management of the post-deployment phase, and

(b) Evidence of the embodiment of the safety policy, risk management, safety assurance, and safety promotion aspects in the post-deployment phase.

6.1.11.2 Audit of In-Service Monitoring and Reporting (ISMR)

6.1.11.2.1. The manufacturer's documentation shall be reviewed to verify the suitability of ISMR practices for the ADS.

6.1.11.2.2. The documentation review shall provide evidence that:

(a) The processes for ISMR are suitable for the ADS,

(b) The tools used for ISMR are suitable for the ADS, and

(c) The personnel for ISMR have an adequate level of competence.

6.1.11.2.3. The manufacturer's capability to monitor the ADS shall be evaluated for compliance with the requirements under paragraphs 5.1.8.1. through 5.1.8.7.

6.1.11.2.4. The manufacturer's methods shall be evaluated:

(a) To verify the safety performance of the ADS during the operation, and

(b) To ensure the effectiveness of their safety risk controls.

6.1.11.2.5. The audit shall verify and evaluate that the manufacturer has a mechanism in place:

(a) To collect data from the vehicle and to receive data from other sources, and

(b) To utilize all relevant data feeding sources in order to assess the ADS safety risks, evaluate its safety performance, and, in time, take appropriate actions and check their effectiveness.

6.1.11.2.6. The documentation review shall provide evidence that, at least:

(a) Responsibilities and timelines are defined to ensure that the monitoring is applied and effective,

(b) Methods for data collection and analysis are adequate to ensure monitoring objectives are fulfilled,

(c) ADS safety performance will be verified in reference to the safety performance indicators and safety performance targets as indicated in the safety case,

(d) The risks are managed and controlled based on the information coming from the monitoring activities,

(e) The monitoring takes into account feedback and information received from sources other than the ADS vehicle data, and

(f) The effectiveness of the monitoring activity will be regularly reviewed.

6.1.11.2.7. The manufacturer's capability to report the occurrences listed in Annex 1 shall be verified.

6.1.11.2.8. The manufacturer's approach/methods for reporting the occurrences experienced by the ADS during the operation and for assessing the cause of such events shall be evaluated.

6.1.11.2.9. Use of the reporting templates in Annex **2**~~4~~ and Annex **3**~~5~~ by the manufacturer shall be verified.

6.1.11.2.10. The data, metrics, and other information that the manufacturer intends to use for the characterisation of the occurrences shall be evaluated for adequacy.

6.2. Assessment of the test environments

6.2.1. Virtual testing environments

6.2.1.1. Each simulation toolchain used by the manufacturer shall be verified for its suitability to conduct virtual testing in compliance with the requirements under paragraph 5.2.1. of this Regulation.

6.2.1.2. The assessment shall review the documentation provided by the manufacturer to determine whether the simulation toolchain(s) is suitable to undertake virtual testing.

6.2.1.2.1. The assessor shall review the documentation and evidence supporting the manufacturer's claims about the simulation toolchain(s) capability and its scope.

6.2.1.2.2. The manufacturer may be required to demonstrate the execution of the simulation toolchain(s) and the generation of results to verify that the evidence complies with the provisions under paragraph 5.2.1 of the Regulation and to ensure understanding of the use of the simulation toolchain(s).

6.2.1.2.3. The information provided by the manufacturer shall be audited and additional testing may be required to verify its claims. The results of the audit and of any additional tests shall be reviewed and any concerns or discrepancies shall be documented and reviewed with the manufacturer.

6.2.1.2.3.1. If the process in 6.2.1.2.3 is unable to confirm an appropriate level of consistency between the information provided by the results of additional testing and those of the manufacturer or raises other concerns for which the manufacturer cannot provide a reasonable explanation of the discrepancies, then the manufacturer shall undertake a review to identify the reasons for those discrepancies.

6.2.1.2.3.2. After the discrepancies under paragraph 6.2.1.2.3.1. above have been identified and resolved, the manufacturer shall explain its findings and impact. The manufacturer shall add this new information and associated updates to the material being assessed. Updated material shall be assessed.

6.2.1.2.4. The assessment shall determine and document if the simulation toolchains are suitable for virtual testing.

6.2.2. Track testing

6.2.2.1. The track testing facilities, environment, and capabilities used to generate the evidence to support the safety case claims shall be assessed for compliance with the provisions under paragraph 5.2.2. and sub-paragraphs.

6.2.2.2. The manufacturer may be required to demonstrate the execution of its track tests to verify that the evidence complies with the provisions under paragraph 5.2.2.

6.2.3. Real-world testing

6.2.3.1. The real-world testing facilities, environment, and capabilities used to generate the evidence to support the safety case claims shall be assessed for compliance with the provisions under paragraph 5.2.3.

6.2.3.2. The manufacturer may be required to demonstrate the execution of its real-world tests to verify that the evidence complies with the provisions under paragraph 5.2.3.

6.3. Assessment of the safety case

6.3.1. Assessment of the safety-case content

~~[~~6.3.1.1. **An assessment shall be conducted by competent personnel to verify the completeness and robustness of the safety case in accordance with the provisions of paragraphs 6.3.1.3. and 6.3.1.4.** ~~The safety case shall be assessed by an assessor, or team of assessors meeting 6.3.1.6. and 6.3.1.7. in order to determine if the safety case is complete and robust.]~~

6.3.1.2. The manufacturer may be required to provide supporting documentation and assist in reproducing evidence or to subject the ADS to confirmatory tests.

6.3.1.3. The assessment shall include a review of the manufacturer's safety case for completeness to ensure that at least the following criteria have been met:

(a) The manufacturer's safety concept is consistent and complete,

(b) Each requirement of this Regulation has been addressed by one or more claims in accordance with paragraph 5.3.3.7 of this Regulation,

(c) The cumulation of claims would yield a system absent of unreasonable risk pursuant to paragraphs 5.3.2.1, 5.3.2.17. and 5.3.3.2. of this Regulation,

(d) Each claim is supported by one or more arguments in accordance with paragraph 5.3.3.1. of this Regulation,

(e) Each argument is supported by a non-zero set of evidence in accordance with paragraph 5.3.3.1.1. of this Regulation,

(f) The manufacturer has documented metrics and acceptance criteria related to their claims in accordance with paragraph 5.3.2.17., and

(g) **Unique labelling of claims, arguments and evidence in accordance with paragraph 5.3.3.1.2., and backward and forward traceability from requirements to evidence in accordance with paragraph 5.3.3.3.** ~~backwards and forward traceability from requirements to evidence as per 5.3.3.3.~~

6.3.1.4. The assessment shall review the manufacturer's safety case for robustness to verify that at least the following criteria have been met:

(a) All identified risks in the safety concept have been reduced, mitigated, or accepted and the aggregate residual risk (quantitative or qualitative) is below the unreasonable risk threshold,

(b) The integrity level used for development, verification, and validation of the ADS and its features is appropriate to reduce the risk below the unreasonable risk threshold,

(c) The tools by which testing evidence is obtained achieve an acceptable level of credibility and demonstrate stability of performance when subjected to variations in accordance with paragraph 6.2.,

(d) Testing evidence was obtained from an adequately explained combination of virtual, track, and real-world testing and shows consistency of results between those test methods,

(e) The manufacturer has taken steps to limit the potential for unintended functions in the ADS or for unintended functions to be induced in interfacing systems,

(f) Testing evidence provided can be repeated and reproduced with consistency of safety objectives in accordance with paragraph 6.3.2.,

(g) The testing evidence demonstrated by the manufacturer provides reasonable coverage of foreseeable operating conditions and events in the intended area of operation in alignment with the approaches described in paragraphs 5.3.2.14. and 5.3.2.15., including conditions

consistent with the ODD of the ADS and conditions that may involve ODD exit, and

(h) The manufacturer has conducted one or more self-assessments and has taken steps to remediate any findings as per 5.3.4.

6.3.1.5. A report of the assessment shall be prepared that allows traceability (e.g., versions of documents inspected are coded and listed in the records). The report shall include any identified discrepancies/gaps and remediations undertaken by the manufacturer.

6.3.1.6. Assessment of the DSSAD

6.3.1.6.1. The documentation provided under paragraph 5.3.1.13. shall be verified for consistency with the provisions of Annex 6.

6.3.2. Assessment of safety-case testing activities

6.3.2.1. General provisions

6.3.2.1.1. The assessment shall verify that the approach to testing adopted by the manufacturer is suitable for the demonstration of the safety case and the compliance with performance/functional requirements.

6.3.2.1.2. The assessment shall verify that the combined coverage of the testing results from all pillars (virtual, track, real world) is sufficient to support the ADS safety case claims.

6.3.2.2. Assessment of the scenarios and their management

6.3.2.2.1. The assessment shall verify that the manufacturer has used suitable and documented processes to derive behavioural competencies **and scenarios** that are relevant to both the ODD and the ADS safety case.[40]

6.3.2.2.2. The assessment shall verify that the manufacturer's approach and processes to identify and generate scenarios are appropriate. In particular, the resulting scenarios shall:

(a) Cover the appropriate nominal, critical, and failure situations,

(b) Use data-driven, knowledge-driven, and stochastic approaches to systematically identify hazardous events and other occurrences,

(c) Include elements (especially dynamic elements) that are representative of existing traffic conditions in the expected operating conditions, and

(d) Incorporate the identified characteristics and behaviours of all the relevant scenario elements.

6.3.2.2.3. The assessment shall verify that the set of scenarios and situations resulting from the manufacturer's scenario generation and identification process is suitable for demonstrating the ADS safety case. This includes covering reasonably foreseeable situations and conditions that the ADS will encounter during its real-world operations. In particular, the approval authority or its designated technical service shall verify that the set of scenarios and situations selected as evidence to support the ADS safety case includes:

(a) Scenarios and situations in which the ADS needs to initiate a **fallback**~~fall back~~ response (e.g., approaching the ODD **boundaries**~~limits~~), and

(b) Reasonably foreseeable situations that are not deemed to be preventable by the ADS (e.g., related to unsafe behaviour by other road users or by infrastructural failures).

6.3.2.2.4. The assessment shall verify that the manufacturer has adopted appropriate techniques to explore the parameter space when choosing concrete scenarios.

[40] The methodology in the Annex **5**~~[X]~~ is one suitable process against which to review the process adopted by the manufacturer.

6.3.2.3. Assessment of the processes in place for testing

6.3.2.3.1. The assessment shall verify that the manufacturer has suitable processes, resources, and competent personnel who can design the testing that produces the evidence supporting the ADS safety case.

6.3.2.3.1.1. The assessment shall verify that the manufacturer has suitable processes in place to select and combine static and dynamic elements of a test track for correctly reproducing the conditions of the scenarios selected to track testing.

6.3.2.3.1.2. The assessment shall verify that the manufacturer has suitable processes in place to identify test routes that capture predictable aspects of the ODD (e.g., road types and geometries), elements found in the related nominal situations (e.g., other road users, signs, and signals), and typical dynamic conditions (e.g., high/low traffic densities). The test routes shall also enable verification of requirements for the safety of user interactions, including prior to, at the time of, and after entering and exiting the ODD of an ADS feature.

6.3.2.3.2. The assessment shall verify that the manufacturer has suitable processes, resources, and competent personnel to undertake the testing that produces the evidence supporting the ADS safety case.

6.3.2.3.2.1. The assessment shall verify that the manufacturer has suitable processes, resources, and competent personnel to assess the behavioural competencies demonstrated by the ADS for each scenario and situation against the requirements for performance of the DDT.

6.3.2.3.2.2. The assessment shall verify that the manufacturer has suitable processes, resources, and competent personnel who can assess the capability of the ADS to ensure the safety of users and the safe use of the ADS.

6.3.2.3.3. The assessment shall verify that the manufacturer has not optimised the ADS for a set of known test cases.

6.3.2.4. Assessment of testing evidence

6.3.2.4.1. The assessment shall include a review of the evidence produced by the manufacturer in demonstrating the ADS safety case using the different test methods:

(a) Virtual testing.

(b) Track testing.

(c) Real-world testing.

6.3.2.4.1.1. The assessment shall review the evidence produced by the manufacturer in demonstrating the capability of the ADS to perform the DDT.

6.3.2.4.1.2. The assessment shall review the evidence produced by the manufacturer to demonstrate the capability of the ADS to interact with users in compliance with the requirements under paragraph 4.2. of this Regulation.

6.3.2.4.1.3. The assessment shall verify that the procedures and data collection associated with testing are in line with established scientific and engineering practice.

6.3.2.4.1.4. For the specific case of ADS interaction testing, the assessment shall:

(a) Verify that the people involved are representative of the expected general population of ADS users and other road users, where applicable, and

(b) Verify that the results achieved can be considered statistically significant.

6.3.2.4.1.5. The assessment shall verify the suitability of the set of tests carried out as evidence to support the safety case, in particular in terms of coverage, consistency, and relevance.

6.3.2.4.1.6. The assessment shall verify that the results of the tests are able to demonstrate the behavioural competencies of the ADS when performing the DDT. In

particular, the assessor shall verify that the test results confirm the claims and arguments in the ADS safety case:

(a) In nominal, critical, and failure situations,

(b) While approaching and crossing the ODD boundaries, and

(c) In the case that collisions with other road users are not deemed to be preventable.

6.3.2.4.1.7. The assessment shall verify that the manufacturer has suitable processes in place to identify the set of scenarios to be tested using the different testing methods.

6.3.2.4.1.8. The assessment shall verify that the manufacturer has suitable processes in place to verify the consistency of the test results across the different testing methods adopted.

6.3.2.4.2. Assessment of virtual testing evidence

6.3.2.4.2.1. The assessment shall verify that the manufacturer's virtual testing has been carried out, incorporating proper consideration of the assumptions, accuracy, and uncertainty in the simulation toolchain(s) in accordance with the requirements under paragraph 5.2.1. The reviewer shall verify that the use of the results from the virtual testing reflects these considerations.

6.3.2.4.2.2. The assessment shall verify that any virtual test using a simulation toolchain containing stochastic elements has taken account of the possible uncertainty in the results.

6.3.2.4.2.3. If the manufacturer uses virtual testing to demonstrate scenario coverage, the assessment shall verify that they have included critical scenarios and low probability events. The critical scenarios shall include unavoidable collision scenarios.

6.3.2.4.3. Assessment of track testing evidence

6.3.2.4.3.1. The assessment shall review the evidence from track testing that is provided by the manufacturer to support the safety case of the ADS.

6.3.2.4.3.2. The assessment shall verify that at least part of the scenario tested via track testing includes critical scenarios replicating conditions that could result in a collision.

6.3.2.4.4. Assessment of real-world testing evidence

6.3.2.4.4.1. The assessment shall review the evidence from real-world testing that is provided by the manufacturer to support the ADS safety case.

6.3.2.4.4.2. The assessor shall verify that the evidence collected via real-world testing by the manufacturer covers a wide variety of situations and conditions that the ADS may encounter during its real-world operations.

6.3.2.4.4.3. To the extent that an ADS encounters critical or failure situations during a real-world test drive, the response of the ADS, including any discrepancies with the nominal performance requirements, shall be considered by the assessor in conjunction with the outcomes of track and virtual testing.

6.3.3. Confirmatory testing

6.3.3.1. At the option of the Contracting Party, confirmatory testing may be required to use one or more test methods and pre-defined and repeatable test protocols to confirm that the evidence provided by the manufacturer accurately represents the ADS performance. The confirmatory tests shall cover a range of driving conditions representative of the ODD, including at least and as appropriate: [41]

[41 The information reported in Annex 5 may be used to extend the list of scenarios that can be selected for confirmatory testing.]

(a) Failure situations,

(b) Behaviours in the presence of vulnerable road users,

(c) Situations with a large number of other road users, traffic disturbance, unlikely road infrastructure, uncommon road conditions, and/or atypical environmental conditions,

(d) User interactions,

(e) Compliance with traffic rules,

(f) Collision avoidance and mitigation,

(g) ODD boundaries and fallbacks to MRC, and

(h) Conditions that trigger DSSAD and ISMR functions.

6.3.3.1.1. The assessment shall ensure that the physical testing (proving ground and/or public road) facilities and environment and the virtual testing environment as applicable are suitable to conduct the testing and confirm the evidence provided by the manufacturer to support the safety case in accordance with the requirements under paragraph **5**~~6~~.2. of this Regulation.

6.3.3.1.2. The assessment shall compare the information generated by the confirmatory testing with the evidence produced by the manufacturer to check that there is an appropriate level of consistency between them.

6.3.3.1.2.1. The assessment's confirmatory testing strategy may identify a test case that is within the ODD but not easily compared to an existing result provided by the manufacturer. This case should still be considered and the results compared with the expected behaviour of the ADS. The expected behaviour should be determined in discussion with the manufacturer.

6.3.3.1.2.2. If the assessment is unable to confirm that there is an appropriate level of consistency between the results, the manufacturer shall review the alleged discrepancies and take appropriate action to resolve them.

6.3.3.2. Virtual testing

6.3.3.2.1. The provisions included in the following paragraphs **up to and including 6.3.3.2.4. shall** ~~until 6.3.3.2.~~ apply in the case that confirmatory virtual testing is conducted or required.

6.3.3.2.2. The confirmatory testing shall demonstrate that the simulation toolchain used for virtual testing complies with the requirements under paragraph 5.2.1. of this Regulation.

6.3.3.2.3. The confirmatory testing shall document the choices for the scenarios selected.

6.3.3.2.4. The manufacturer may be required to make available the virtual testing environment it has used to produce evidence in its safety case to carry out confirmatory virtual testing.

6.3.3.3. Track testing

6.3.3.3.1. The provisions included in the following paragraphs until 6.3.3.4. apply in the case that confirmatory track testing is conducted or required.

6.3.3.3.2. The confirmatory testing shall explain and document the choices for the scenarios used to test the ADS.

6.3.3.3.3. Any track testing shall be conducted on a testing ground that is part of, or suitably represents, the ODD of the ADS and complies with the requirements under paragraph 5.2.2. of this Regulation.

6.3.3.3.3.1. The manufacturer may be required to make available the testing grounds it has used to produce evidence in its safety case to carry out confirmatory track testing.

6.3.3.3.4. Track testing may be conducted to verify that ADS responds safely to situations:

(a) Occurring within the ODD,

(b) Occurring while crossing the ODD boundaries, and

(c) Concerning its activation outside of the ODD.

6.3.3.3.5. The confirmatory testing shall consider how to manage real-world variations. Variations may include, but are not limited to, changes in lighting conditions, weather, road surface conditions, and surrounding traffic behaviour. The assessment shall confirm that the ADS maintains safe performance within its ODD and verify that the ADS responds to approaching and crossing of ODD boundaries in line with the safety case.

6.3.3.3.6. The confirmatory testing shall ensure an appropriate protocol is used for recording the track testing. It will contain at least minimum requirements on test-relevant data collection and analysis, e.g., how the data is recorded, how measurements are derived from the recorded data, and how the measurements are analysed.

6.3.3.3.7. The confirmatory testing shall ensure that the track testing carried out is recorded with sufficient details to allow the tests to be reproduced to a sufficient level of accuracy. The information recorded shall include at least the test equipment, the test set-up, and the test environment, as well as any variations and adjustments.

6.3.3.3.8. The confirmatory testing shall include scenarios where the behaviour or position of other road users requires the ADS to react to their movement or presence.

6.3.3.3.9. The confirmatory testing shall use track testing to also confirm that user(s)-related aspects are in line with the ADS safety case.

6.3.3.4. Real-world testing

6.3.3.4.1. The confirmatory real-world testing shall ensure safety, including the capability to end a test at any point if it becomes unsafe.

6.3.3.4.2. The confirmatory real-world testing shall be demonstrably safe for other road users and for users in the vehicle.

6.3.3.4.3. The real-world confirmatory testing shall demonstrate the claims for ADS performance under real traffic conditions.

6.3.3.4.4. The real-world confirmatory testing shall demonstrate the claimed ADS performance when approaching and crossing ODD boundaries, where appropriate.

6.3.3.4.5. The real-world confirmatory testing shall demonstrate the claimed ADS performance relating to issues that may not be well captured by track tests and simulation, such as perception quality limitation (e.g., due to light and environmental conditions, etc.).

6.3.3.4.6. The real-world confirmatory testing shall demonstrate the claimed ADS performance for aspects relating to human factors, such as user-initiated deactivation, system-initiated deactivation (not leading to a mitigated risk condition), and audibility of messages in real-world conditions, if applicable to the ADS.

6.3.3.4.7. The real-world confirmatory testing shall demonstrate the claimed ADS performance related to the interaction with ADS users and other road users under these conditions.

6.3.3.4.8. The real-world confirmatory testing shall consist of selected test routes that reflect the environment and conditions of the ODD of the ADS feature(s).

6.3.3.4.9. The real-world confirmatory testing shall ensure that the selection of test routes utilises appropriate strategies to enhance the probability of ADS encountering situations that involve a large number of other road users, unlikely road infrastructure, or abnormal geographic/environmental conditions, by examining when and where specific elements (e.g., high- or low-density

traffic) typically occur. It is understood that it may not be possible to encounter all traffic situations during a real-world test.

6.3.3.4.10. The confirmatory testing shall ensure that an appropriate protocol is followed when undertaking real-world testing. It should contain minimum requirements that standardise how the test-relevant data are to be collected and analysed (e.g., how the data is recorded, how measurements are derived from the recorded data, and how the measurements are analysed).

6.3.3.4.11. The real-world confirmatory testing shall demonstrate the claimed ADS performance both within and outside the ODD of its feature(s) (e.g., to determine the ADS's appropriate recognition and response when not in its ODD) on public roads.

6.3.3.4.12. Any failure to meet the requirements of this Regulation identified during real-world testing shall be reviewed and assessed both directly and by evaluation against any other relevant and available evidence (e.g., data gathered during other testing or supplied by the manufacturer).

6.3.3.4.13. In case of track testing according to 6.3.3.3., the assessment shall compare the information generated during real-world testing with the information from track testing to ensure there is an appropriate level of correlation of the results, including the performance of the ADS.

6.3.3.4.13.1. If there is insufficient consistency between the results, then the discrepancies shall be reviewed and action taken to resolve them.

6.3.3.4.14. Test coverage and termination criteria

6.3.3.4.14.1. The real-world test drive shall cover the functions required to perform the entire DDT in the ODD pursuant to the outcomes of the safety case analysis.

6.3.3.4.14.2. The test should be terminated only when all relevant parts of 6.3.3.4.14.1., excluding safety-critical and failure-related scenarios, have been monitored and assessed.

6.4. Post-deployment safety assessment

6.4.1. The assessment shall review the information provided by the manufacturer and assess that it is in accordance with the manufacturer’s SMS.

6.4.2. The information provided by the manufacturer on the ADS operations (e.g., notifications, short-term and periodic reports) shall be reviewed:

(a) To receive confirmatory evidence on the safety case and on the Safety Management System,

(b) To receive information on the ADS safety level and assess whether the ADS continues to be safe when operated on the road,

(c) If applicable, to verify that this information is used to develop new scenarios or variants of existing scenarios used to generate evidence that supported the ADS safety case, and

(d) To assess the effectiveness of the remedial actions.

6.4.3. The assessment shall include a review of the manufacturer’s data processing (for example: filtering and conditioning) procedure during occurrence investigation and agree on the steps undertaken to deliver the data supporting the report.

6.4.4. The confidentiality of sensitive and business confidential information reported in accordance with the short-term template shall be assured.

6.4.5. The assessment may include, where necessary, verification of the information provided and, if needed, the manufacturer may be required to complete further investigations and produce further evidence, before closing the occurrence.

Annex 1

List of Reportable Occurrences by Reporting Type

The following table lists the occurrences to be reported by the manufacturer in accordance with paragraphs 5.4.8.1., 5.4.9.1., and 6.1.11.2.7 of this Regulation. The table indicates the reporting type(s) that apply to each occurrence.

Occurrences	*Reporting Type*		
	Notification	*Short-term*	*Periodic*
1. **Critical occurrences**[1]	X	X	X
2. **Significant occurrences**			
ADS operation outside its ODD		X	X
ADS failure to achieve a ~~[~~mitigated~~]~~ risk condition when necessary		X	X
Failure to meet the ADS requirements as per the Section **4**~~5~~ of this regulation		X	X
Performance issues constituting an unreasonable risk to safety		X	X
3. **Other occurrences**[2]			
Uncompleted system-initiated deactivation processes to manual driving			X
Communication issues affecting the safety of the ADS			X
Cybersecurity issues affecting the safety of the ADS			X
System failures that compromise the capability of the ADS to perform the entire DDT			X
Maintenance or repair issues affecting the ADS's intended functionality [3]			X
Unauthorized modifications to ADS that could affect the intended functionality			X
Manoeuvres performed to reach MRC			X
Emergency Manoeuvres			X
Active ADS feature required remote interaction to navigate a driving situation [4]			X
Fallback user unavailability [5]			X
Prevention of takeover under unsafe conditions[6]			X

[1] If such an occurrence also belongs to one of the remaining sub-categories listed in the occurrence table, the following provisions apply:

- Short-term report: there is no need to double-report such occurrence also as part of one of the remaining categories listed in the table.
- Periodic reporting: the occurrence should be double reported both as part of critical occurrence and as occurrence belonging to one of the remaining categories listed in the table. However, the report shall specifically note this aspect.

[2] The Occurrences of this category could be also reported as critical or significant occurrences. In this case, the periodic report shall specifically note this aspect.

[3] This occurrence captures systematic problems due to a maintenance/repair/service action discovered during the ADS operations.

[4] This occurrence captures events in which the ADS will require a support for “tactical functions” to cope with very specific situations, while the ADS continues to perform the entire dynamic driving task.

[5] At aggregate level, this information can provide useful information on the validity of the HMI concept and on the need to provide more effective procedures for keeping the **fallback**~~fall back~~ user available.

[6] It is acknowledged that there is no obligation to implement such design solution. However, such information can provide useful information to evaluate the safety benefit of implementing such solution.

Annex 2

In-Service Reporting Template: Short-term Reporting

1.1. The following template aims at ensuring that a consistent and comprehensive set of information is delivered to the relevant authority to foster an effective implementation of the short-term reporting ISMR requirements.

1.2. The manufacturer may use the short-term template to also report for other occurrences which are not mandated in Annex 3.

1.3. Depending on the nature of the significant occurrence, non-applicable fields shall be marked N/A.

1.4. The authority may request further information where a field has been marked N/A.

Entry name	*Mandatory ([~~[~~Y/N]~~]~~*	*Field to be filled*	*Type/size*
WHAT			
Headline	Y		Text
OCCURRENCE CLASSIFICATION			
Occurrence class[42]	Y		Text
Occurrence type[43]	Y		Text
OCCURRENCE DETAILS			
Last active / active ADS feature at the time of the occurrence	Y		Text
ODD conditions relevant to the occurrence analysis	Y		Text
Maximum ADS-determined/estimated vehicle speed **during the 10**[~~[10]~~] seconds prior to the collision	Y		Number – (**[**~~[~~km/h~~]~~)
Maximum ADS vehicle longitudinal deceleration **during the 10**[~~[10]~~] seconds after the collision	Y		Number – (**[**~~[~~m/s^2~~]~~)
Availability of EDR data	Y		Y/N
Availability of DSSAD data	Y		Y/N
Additional supporting data available[44]	Y		Y/N
Occurrence reported to the law enforcement known to the manufacturer	N		Y/N
Police report available	N		Y/N

[42] Class can be: critical occurrence/significant occurrence/other occurrence.

[43] Ref Table Annex 3.

[44] Data can include ADS vehicle data (speeds…), ADS vehicle collected media (cameras…) or third-party sources.

Entry name	*Mandatory (~~[~~Y/N)~~]~~*	*Field to be filled*	*Type/size*
VEHICLE DETAILS			
Vehicle Identification Number	Y		Text (17)
Vehicle approval number	Y		Text
Vehicle category	Y		Text
Mileage	N		Number
ADS identifier	Y		Text
ADS licensing authorities	N		Text
Operator (if any/available)	N		Text
Other ADS features	N		Text
WHEN			
UTC date	Y		(~~[~~YYYY/MM/DD)~~]~~
UTC time	Y		(~~[~~HH:mm)~~]~~
Local date	Y		(~~[~~YYYY/MM/DD)~~]~~
Local time	Y		(~~[~~HH:mm)~~]~~
WHERE			
Country	Y		Text
State/Province	N		Text
City	N		Text
Location	Y		Text (~~[~~longitude, latitude)~~]~~
Roadway type	Y		Text
Roadway surface	Y		Text
Roadway description	Y		Text

Entry name	*Mandatory (~~[~~Y/N~~]~~)*	*Field to be filled*				*Type/size*
KNOWN OR ALLEGED DAMAGE						
Description of Damage to the ADS vehicle	N					Text
ADS vehicle damage area(s)	N	Front left	Front centre	Front right	Top	
		Rear left	Rear centre	Rear right	Bottom	
		Right side	Left side	Unknown		
ADS vehicle occupant restraint systems deployed	N					Y/N
ADS vehicle towed	N					Y/N
Any ADS feature no longer able to operate	N					Y/N
Other vehicles damaged	N					Y/N
KNOWN OR ALLEGED INFRASTRUCTURE DAMAGE						
Infrastructure type	N					Text
Detailed description	N					Text
KNOWN OR ALLEGED INJURY[45]						
Injury type	N					(~~[~~Fatal/non-fatal~~]~~)
Fatalities: ADS vehicle user(s)	N					Number
Fatalities: Other road user(s)	N					Number
Injuries: ADS user(s)	N					(~~[~~Number and text~~]~~)
Injuries: Other road user(s)	N					(~~[~~Number and text~~]~~)
DESCRIPTION OF THE OCCURRENCE						
Detailed description[46]	Y					Text
Post-occurrence behaviour	Y					Text

[45] Supporting information can be derived from CADaS taxonomy (https://road-safety.transport.ec.europa.eu/system/files/2021-07/cadas_glossary_v_3_7.pdf) or from Abbreviated Injury Scale (https://www.aaam.org/abbreviated-injury-scale-ais/)

[46] If the ADS did not deviate from its intended functionality or violate safety requirements, the field can provide supporting justification. Otherwise, the root cause analysis will identify and explain the issue.

Entry name	*Mandatory (~~{~~Y/N)~~}~~*	*Field to be filled*	*Type/size*
ANALYSIS			
Root cause analysis	Y		Text
Corrective action needed	Y		Y/N
Corrective action implemented	Y		Y/N
If implemented, description of corrective action	Y		Text
New or variant of an existing scenario encountered	Y		Y/N
Speed limit at location	Y		Number
ADS user(s) available at occurrence, in case of ADSF-1 (~~{~~Y/N)~~}~~	N		Y/N
Attempted (successful/completed) user-initiated deactivation of the ADS feature within 30 seconds prior to the occurrence, if applicable (~~{~~Y/N)~~}~~	N		Y/N
REPORT MANAGEMENT			
Reporting entity	Y		Text
Report ID	Y		Text
Report version	Y		Number
Report status (e.g., initial notification, in progress, closed)	Y		Text
Report date	Y		(~~{~~YYYY/MM/DD)~~}~~
Parties informed	Y		Text

Annex 3

In-Service Reporting Template: Periodic Reporting

1.1. The periodic template provides a list of information with their corresponding reporting specifications that should be made available to the authority on a yearly basis.

1.2. The following template aims at ensuring that a consistent and comprehensive set of information is delivered to the relevant authority to foster an effective application of the periodic reporting scheme. Further granularity of the information can be considered depending on the ADS use cases.

1.3. Where an ADS has more than one feature, the periodic report shall clearly differentiate each feature.

Entry name	*Mandatory (~~[~~Y/N)~~]~~*	*Field to be filled*	*Type/size*
ADS IDENTIFICATION			
Manufacturer	Y		Text
Vehicle/system approval number	Y		
ADS licensing authority(ies) (if applicable)	N		Text
ADS software version/identifier(s)	Y		Text
Applicable SMS	Y		Text
Vehicles equipped with ADS	Y		Number
ADS OPERATION INFORMATION (segmented by ADS feature)			
ADS-equipped vehicles per feature			Number
Cumulative distance travelled by an active ADS feature, optionally segmented by:	Y		Number
Country/province of operation	N		Text
Times of the day	N		Text
Weather conditions	N		Text
Road conditions[47]	N		Text
Cumulative time travelled by an active ADS feature, optionally segmented by:	Y		Number
Country/province of operation	N		Text
Times of the day	N		Text
Weather conditions	N		Text
Road conditions	N		Text
Average ADS time engagement	Y		Number

[47] Those refer to the state of the road at the time of operation, such as: dry, wet, icy, snowy, or muddy.

Entry name	*Mandatory (~~[~~Y/N~~]~~)*	*Field to be filled*	*Type/size*
OCCURRENCES ASSESSMENT (segmented by ADS feature)			
Occurrences covered under the short-term reporting provisions			
Critical occurrences known to the manufacturer	Y		Number
ADS operation outside its ODD	Y		Number
ADS failure to achieve an MRC when necessary	Y		Number
Failure to meet the ADS requirements under paragraph 6 of this Regulation	Y		Number
Performance issues constituting an unreasonable risk to safety	Y		Number
Occurrences covered under the periodic reporting provisions			
Uncompleted system-initiated deactivation process to manual driving			Number
Occurrences safety review			Text
Communication issues affecting the safety of the ADS			Number
Occurrences safety review			Text
Cybersecurity issues affecting the safety of the ADS			Number
Occurrences safety review			Text
System failures that compromise the capability of the ADS to perform the entire DDT			Number
Occurrences safety review			Text
Unauthorized modifications to the ADS that could affect the intended functionality			Number
Occurrences safety review			Text
Manoeuvres performed to reach MRC			Number
Occurrences safety review			Text
Emergency manoeuvres			Number
Occurrences safety review			Text
ADS feature required remote interaction			Number
Occurrences safety review			Text
Fallback user unavailability (where applicable)			Number
Occurrences safety review			Text
Prevention of takeover under unsafe conditions (where applicable)			Number
Occurrences safety review			Text

Entry name	*Mandatory (~~(~~Y/N)~~)~~*	*Field to be filled*	*Type/size*
OCCURRENCES SAFETY OUTCOME (segmented by ADS feature)			
Fatalities	Y		Number
ADS vehicle users	Y		Number
Other road users	Y		Number
Injuries	Y		Number/Text
ADS vehicle users	Y		Number/Text
Other road users	Y		Number/Text
Detected collisions	Y		Number
Collision review	Y		Text
OCCURRENCES AGGREGATE DESCRIPTION (segmented by ADS feature)			
Collision with[48]:	Y		-
Passenger car	N		Number
Van	N		Number
Truck	N		Number
Bus	N		Number
Other vehicle	N		Number
Motorcycle	N		Number
Cyclist	N		Number
Pedestrian	N		Number
Other VRU	N		Number
Animal	N		Number
Fixed object	N		Number
Unknown	N		Number
ADS vehicle damage level			
ADS vehicle no longer able to operate	Y		Number
ADS vehicle needing repairs	Y		Number
Unknown	Y		Number
ADS vehicle damaged area			
Front	Y		Number
Front left	Y		Number
Front right	Y		Number
Rear	Y		Number
Rear left	Y		Number
Rear right	Y		Number
Top	Y		Number
Bottom	Y		Number
Unknown	Y		Number

[48] The following list is provided as an example. Manufacturers may use different categories as long as "vehicle" and "vulnerable road-users" are reported separately.

ADS MONITORING ASSESSMENT (segmented by ADS feature)			
ADS Safety Monitoring manufacturer outcome, including:			Text
SPIs monitoring analysis	Y		Text
Identified operational risks	Y		Text
Identified corrective actions	Y		Text
Implemented corrective actions	Y		Text
REPORT MANAGEMENT			
Reporting entity	Y		Text
Report ID	Y		Text
Report version	Y		Number
Report status (e.g., initial notification, in progress, closed)	Y		Text
Report date	Y		(~~[~~YYYY/MM/DD) ~~]~~
Parties informed	Y		Text

Annex 4

Threshold Definitions

1. General

1.1. This annex defines thresholds for the reporting of critical occurrences as defined under paragraph 3.13.1.

1.2. The timing for the notification of such occurrences starts from the manufacturer's knowledge that the occurrence exceeded the threshold for a critical occurrence.

1.3. The manufacturer shall exert all reasonable efforts to gather the relevant evidence supporting the critical occurrence identification without delays or limitations.

2. Injury level threshold

2.1. The injury level threshold for a critical occurrence aims at promoting the reporting of collisions resulting in a fatality or any person requiring medical attention due to the injury, regardless of whether the person killed or injured was an occupant of the subject vehicle.

2.2. The threshold is triggered by the attendance in the area of the collision of an ambulance.

2.3. The manufacturer shall classify the occurrence as critical if they reasonably believe that there may be an injury requiring medical attention to any person, even if an ambulance has not been detected.

2.4. The manufacturer is expected to fulfil these criteria through one of the following approaches:

(a) ADS strategies in place to appropriately detect such situations, provided that the ADS vehicle is still capable of performing audio/visual sensing capabilities, following the collision or via remote visual check (if applicable),

(b) Processes to receive and analyse information from other sources, or

(c) Combination of (a) and (b).

3. Physical damage threshold

3.1. The physical damage triggering condition for critical occurrence aims at promoting the reporting of collisions that, despite not causing any significant injury or fatality to people, are deemed critical because of the extent of the damage produced on vehicles or stationary objects.

3.2. The concept of "physical damage" is here intended as:

(a) Tow-away, e.g., damage that restricts/prevents regular operation of a vehicle involved in the collision as part of the reported occurrence, or

(b) Importance-based, e.g., damage that affects the safe state of the ADS, critical road infrastructure asset, and other vehicles/road users.

3.3. The manufacturer is expected to fulfil this criterion through one of the following approaches:

(a) ADS strategies in place to appropriately detect such situations, provided that the ADS vehicle is still capable of performing audio/visual sensing capabilities, following the collision or via remote visual check (if applicable),

(b) Processes to receive and analyse information from other sources, or

(c) Combination of (a) and (b).

3.4. Tow-away damage threshold

3.4.1. The tow-away threshold is triggered when the damage occurred to a vehicle involved in the collision is such that the same can no longer be operated either manually or in automated mode requiring specialized equipment for traffic restoration.

3.5. Importance-based damage threshold

3.5.1. Importance-based damage thresholds consider the type of item that was damaged to take into account its relevance and health status.

3.5.2. The importance-based threshold shall be deemed exceeded when one of the following conditions occurs:

(a) Collision with priority vehicles,

(b) Collision rendering traffic lights and/or other safety-relevant road signage no longer operational/visible,

(c) Collision affecting infrastructure communication/connectivity support system,

(d) Collision damaging or rendering a roadway segment impassable,

(e) Collision producing fire, or

(f) Any other collision that requires the attendance of road safety agent.

4. Restraint system and Delta-V threshold

4.1. The restraint system triggering condition and Delta-V threshold aim at promoting the reporting of occurrences in case one of the following applies:

(a) The deployment of any non-reversible deployable occupant restraint systems,

(b) The deployment of vulnerable road user secondary safety system, such as airbags, pretensions, and active bonnet systems, or

(c) The applicable Delta-V thresholds to be met according to the EDR system fitted on the vehicle.

Annex 5

ODD-based Behavioural Competencies and Scenario Identification Approach

1. Introduction

This annex provides an overview on an approach that may be used to derive verifiable performance criteria for the approval or, as relevant, for self-certification of ADS, based on the manufacturer's description of the Operational Design Domain (ODD) of the ADS. Such criteria would be developed by identifying behavioural competencies that embody and correspond to specific ADS safety requirements and relevant ~~[~~scenarios and situations~~]~~ that may be used to validate the ADS's competencies.

The suggested approach includes a description of how such competencies can be classified into nominal, critical and failure and mapped to the relevant ~~[~~scenarios ~~and situations]~~, selected either from existing databases or identified through the application of different approaches.

Different approaches may exist to perform such an activity; therefore, the approach herein presented should be considered as a recommended guideline for both manufacturers and authorities.

1.1. Operational Design Domain

The external conditions constituting the ODD in which the ADS was designed to operate will help determine which ADS competencies are required. For example, if an ADS has an ODD which comprises of roads with non-signalised junctions, one of the required behavioural competencies for the ADS in that ODD could potentially be "unprotected left or right turn". However, the same behaviour competency may not be required if the ODD of an ADS is limited to motorways or highways.

1.2. Behavioural competencies

Behavioural competencies track the three broad categories of driving situations that may be encountered in the performance of the DDT: nominal, critical, and failure.

~~[Nominal driving situations are those in which behaviour of other road users and the operating conditions of the given ODD are reasonably foreseeable (e.g., other traffic participants operating in line with traffic regulations) and no failures occur that are relevant to the ADS's performance of the DDT.]~~

~~[Critical driving situations are those in which the behaviour of one or more road users (e.g., violating traffic regulations) and/or a sudden and not reasonably foreseeable change of the operating conditions of the given ODD (e.g., sudden storm, damaged road infrastructure) creates a situation that requires a prompt action of the ADS to avoid or mitigate a collision. In this case, it is recognised that the ADS may not be able to avoid a collision, but mitigation may be possible.]~~ **Critical situations are those requiring prompt action by the ADS to avoid or mitigate the risk of a collision that could result in adverse consequences on human health or property damage. For example, those in which the behaviour of one or more road users (e.g., violating traffic regulations) and/or a sudden and not reasonably foreseeable change of the operating conditions of the given ODD (e.g., sudden storm, damaged road infrastructure) requires the ADS to take prompt action. In this case, it is recognised that the ADS might not be able to avoid a collision, but that mitigation might nonetheless be possible.**

~~[~~Failure situations involve those in which the ADS or another vehicle system experiences a ~~fault or~~ failure that compromises the ADS's ability to perform the DDT, such as sensor or computer failure or a failed propulsion system.~~]~~

Nominal situations are those that are neither critical nor failure, such as those in which the behaviour of other road users and the operating conditions of the given ODD are reasonably foreseeable (e.g., other traffic participants operating in line with traffic regulations) and no failures occur that are relevant to the ADS's performance of the DDT.

2. Approach Description

The ODD-based behavioural competencies and scenario identification approach is based on the interaction of the following elements:

(a) Behavioural competencies and scenario generation

(b) Competencies and scenario mapping

(c) Assumptions

(d) Performance and acceptance criteria evaluation

Figure 1 describes the overall approach. Once acceptance criteria are defined based on overall requirements, different approaches (described below) are used to generate nominal, critical and failure scenario~~s~~ tests. Testing is performed using various test methods, and the outcome is evaluated to see if there is sufficient evidence to support the safety case claims and the acceptance criteria. The following section describes the different stages and steps.

2.1. Behavioural Competencies Identification

The approach suggests a series of analytical frameworks that could help to derive measurable criteria appropriate for the specific application. These frameworks are divided into:

(a) ODD Analysis

(b) Driving interactions analysis

(c) OEDR analysis

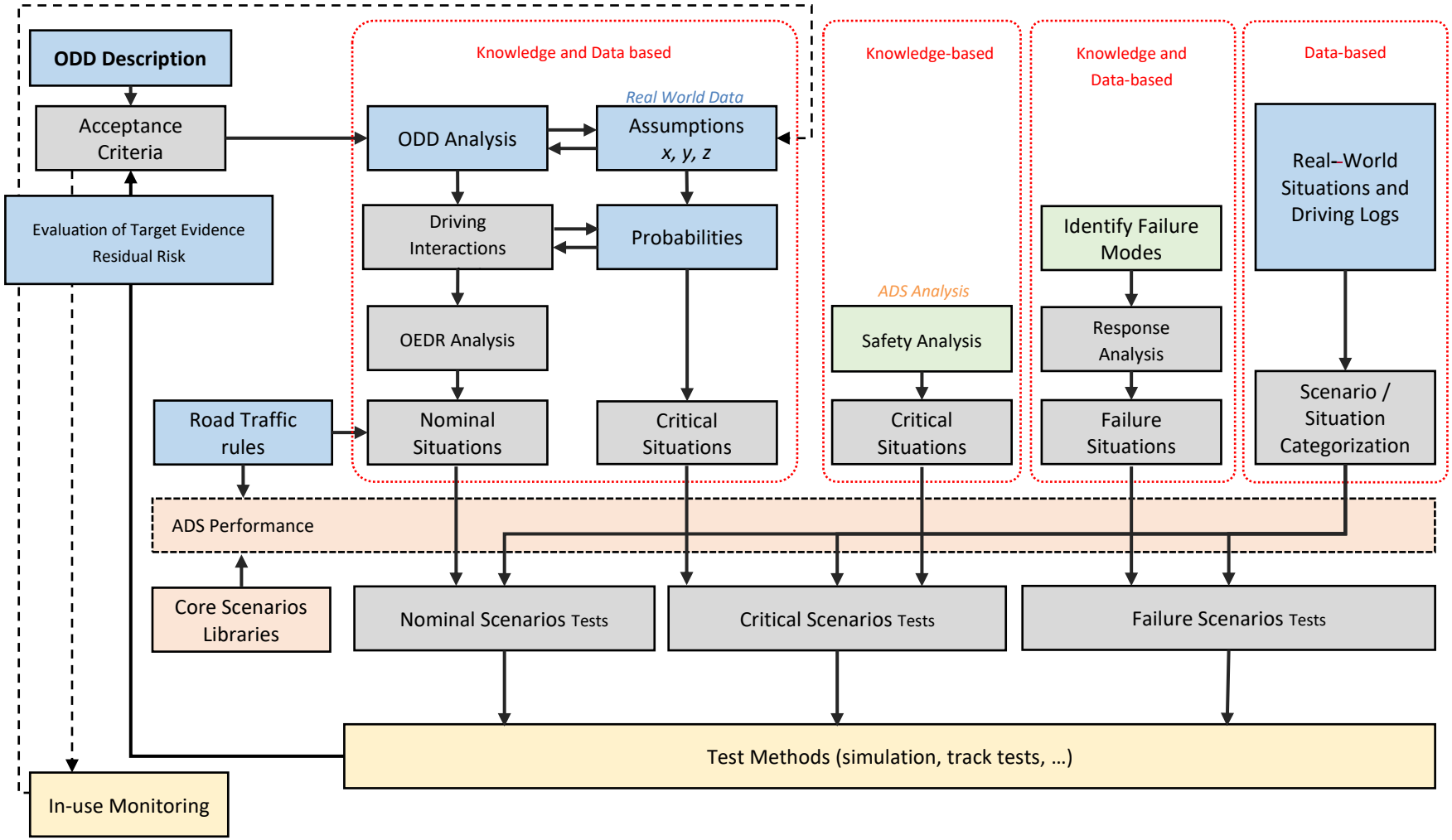
2.1.1. ODD analysis

This analysis represents the first step with the aim to identify the characteristics of the ODD. An ODD ~~[specification/~~description~~]~~ can consist of stationary physical elements (e.g., physical infrastructure), environmental conditions, dynamic elements (e.g., reasonably expected traffic level and composition, vulnerable road users) and operational constraints to the specific ADS application. **The output consists of a list of elements to be considered in the subsequent analysis.** ~~[Various sources provide useful guidance for precisely determining the elements of a particular ODD and their format definition…]~~

2.1.2. Driving interactions analysis

In the driving interactions analysis, the behaviours of other road users that are reasonably expected and the presence of roadway characteristics in the ODD are explored in more detail by mapping actors with appropriate properties and defining interactions between the objects.

Figure 1 - Example of a possible approach to identify behavioural competencies and scenarios



An example of this analysis is given in Table 1, where static and dynamic behaviours of other objects (including other road users) that the ADS is reasonably expected to encounter within the ODD are described. In the case of vehicles, this includes behaviours such as “acceleration”, “deceleration”, “cut-in”; for pedestrians, examples of dynamic behaviours include “crossing road”, “walking on sidewalk”, etc.

The behaviour of other road users and the condition of physical objects within the ODD may fall at any point along a continuum of likelihood. For example, deceleration by other vehicles may range from what is expected and reasonable in the traffic circumstances, to unreasonable but somewhat likely rapid deceleration, to extremely unlikely (e.g., a sudden cut-in combined with full braking on a clear high-speed road). The analysis of the ODD and reasonably expected driving situations within the ODD should make distinctions that include an estimate of the likelihood of situations to ensure that the ADS’s performance is evaluated based on response to reasonably likely occurrences involving nominal, critical, and failure situations but not on the expectation that the ADS will avoid or mitigate the most extremely unlikely occurrences.

2.1.3. Object and Event Detection and Response (OEDR) Analysis: Behavioural competencies identification

Once the objects and their reasonably expected behaviours have been identified, it is possible to map the appropriate ADS response, which can be expressed as a behavioural competency. The detailed response is derived from more general and applicable safety requirements. The acceptable ADS response will vary depending on whether the driving situation involves nominal, critical, or failure characteristics.

The outcome of the analysis is a set of **behavioural** ~~behaviour~~ competencies that can be applied to the events characterizing the ODD. Table 2 provides a qualitative example of a matching event and response.

The combination of objects, events, and their potential interaction, as a function of the ODD, constitutes the set of potential situations pertinent to the ADS under analysis.

2.2. Scenario Identification

To ensure that the behavioural competencies identified in the previous paragraphs are ready to be assessed, ODD-relevant ~~[~~scenarios ~~and situations]~~ must be identified.

Scenarios can be described at different abstraction levels (i.e., functional, abstract, logical, and concrete) by focusing the scenario description on specific aspects, while leaving other details for further processing.

Sampling techniques can be used when selecting parameters to be used in creating logical and concrete scenarios for the ADS validation for a particular ADS and its ODD to avoid the ADS being optimized for a set of known test cases.

Table 1
Examples of static and dynamic objects and their properties

Objects	*Examples of events and interactions*
Vehicles (e.g. cars, light trucks, heavy trucks, buses, motorcycles)	Lead vehicle decelerating Lead vehicle stopped Lead vehicle accelerating Changing lanes Cutting in Turning Encroaching opposite vehicle Encroaching adjacent vehicle Entering roadway Cutting out
Pedestrians	Crossing road: inside crosswalk, Crossing road: outside crosswalk Walking on sidewalk/shoulder
Cyclists	Riding in lane Riding in adjacent lane Riding in dedicated lane Riding on sidewalk/shoulder Crossing road: inside/outside crosswalk
Animals	Static in lane Moving into/out of lane Static/moving in adjacent lane Static/moving on shoulder
Debris	Static in lane
Other dynamic objects (e.g., shopping cart)	Static in lane Moving into/out of lane
Traffic signs	Stop Yield Speed limit Crosswalk Railroad crossing School zone
Vehicle signals	Direction indicators

Table 2
Examples of elementary behavioural competencies for given events

Event	*Response*
Lead vehicle decelerating	Follow vehicle, decelerate, stop
Lead vehicle stopped	Decelerate, stop
Lead vehicle accelerating	Accelerate, follow vehicle
Lead vehicle turning	Decelerate, stop
Vehicle changing lanes	Yield, decelerate, follow vehicle
Vehicle cutting in	Yield, decelerate, stop, follow vehicle
Opposite vehicle encroaching	Decelerate, stop, shift within lane, shift outside lane
Adjacent vehicle encroaching	Yield, decelerate, stop
Lead vehicle cutting out	Accelerate, decelerate, stop
Pedestrian crossing road	Yield, decelerate, stop
Cyclist riding in lane	Yield, follow
Cyclist crossing road	Yield, decelerate, stop

This approach suggests complementary methodologies to derive reasonably expectable scenarios which might occur for a given ODD:

(a) Knowledge-based methods,

(b) Data-based methods, and

(c) Goal-based methods.

A knowledge-driven scenario generation approach utilizes domain specific (or expert) knowledge to identify nominal, critical and failure events systematically and create scenarios. Examples of knowledge-driven scenarios generation approaches include:

(a) Experience acquired during ADS development,

(b) Synthetically generated scenarios from key parameter variations,

(c) Engineered scenarios based on functional safety requirements and safety of intended functionality,

(d) Composing complex scenarios from basic scenarios,

(e) Random variations of scenario parameters, both for the ADS an ORUs.

A data-driven approach utilizes the available data to identify and classify occurring scenarios. Data-driven scenarios generation approaches include:

(a) Analysing human driver behaviour, including evaluating naturalistic driving data,

(b) Collision data from accident databases, insurance records, and law enforcement authorities.

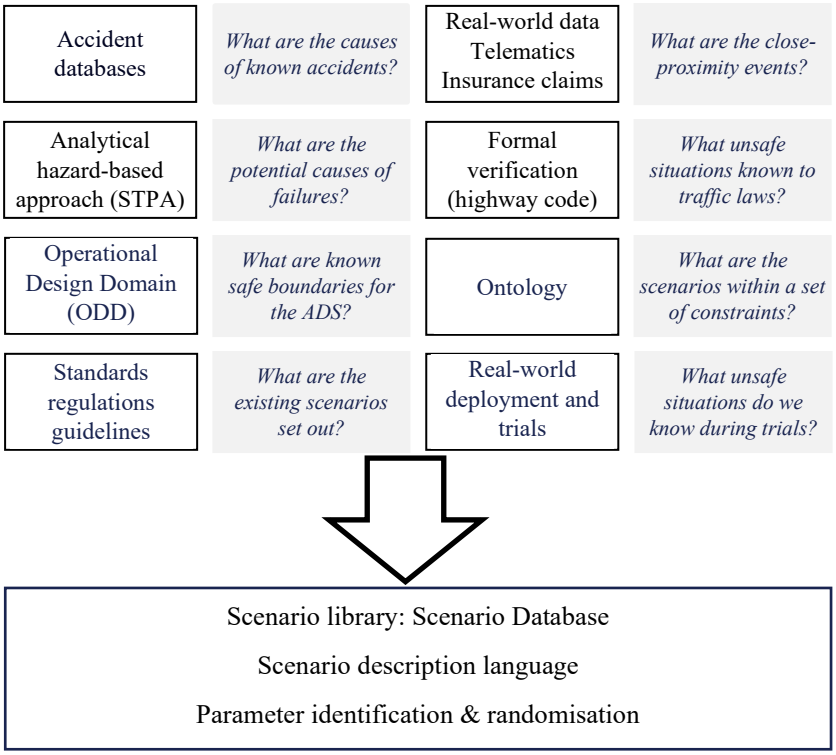
(c) Traffic patterns relevant for the ODD from real-world driving logs;

(d) Situations recorded using instrumented vehicles, the ADS vehicle's sensors, infrastructure or drones.

(e) **In-Service Monitoring and Reporting findings.** ~~[ISMR ref]~~

Figure 2 illustrates various data-based and knowledge-based scenario generation methods.

Figure 2
Examples of data-based and knowledge-based generation methods



While many of the knowledge-based method are looking at existing data and knowledge, a different method is goal based. ~~[While many of the knowledge based methods are looking at existing data and knowledge, a different method is goal based. As the acceptance criteria are defined, they are actually setting the goals that should be demonstrated by testing and coverage and used as evidence for safety claims. Starting from these goals, and looking at the existing status of the evidence, gaps in testing and coverage can be identified, and mapped back to missing scenarios that should be used for testing.~~

~~Furthermore, existing scenarios already defined in standards, regulations or guidelines can also be utilised for the testing of ADSs. Additional scenarios include those that occur during real world trials and deployments. Such scenarios might not have been considered pre deployment but are key learnings. At the time of publishing this text, there is significant experience gathered with existing trials and tests, and thus a significant amount of driving logs and recording can be used.~~

~~For **modern**AI centric ADS systems, training requires usage of a lot of data from driving logs and recordings.~~ **Training of ADS requires large volumes of data from driving logs and recordings.** The same data resources can be used to test the behavioural competencies. The challenge is to map these into the scenario categories, in order to ensure that this testing and its results are counted correctly toward the acceptance criteria evaluation.

One method to categorise these logs and recordings is to match them to existing abstract scenario libraries, and classify them into nominal, critical and failure scenarios. With categorisation and classification, the evaluation of these scenarios, and counting their contribution to the evidence and the success criteria, can take place.

The scenario-generation method should include adequate coverage of relevant nominal, failure, and critical ~~[~~scenarios and situations~~]~~ to effectively validate the ADS. "Coverage" refers to the degree to which scenarios sufficiently incorporate driving situations in order to validate the relevant requirements of this regulation. Sufficient coverage is essential to the overall effectiveness and credibility of these methodologies as a validation approach. Sufficient coverage should be with respect to the ADS feature or ODD. Coverage can be measured across different domains, and metrics can be used to determine sufficiency. **Coverage can be measured both on the test scenarios saving as input to the test, as well as on the behavioural competencies and KPIs demonstrated during testing.**

2.3. Behavioural competencies and scenarios mapping

Once relevant scenarios and behavioural competencies have been identified, it is necessary to link them. The classification in the three broad categories of driving situations an ADS might encounter, such as nominal, critical and failure, serves the purpose.

2.3.1. Nominal Situations Competencies

In these situations, ADS competencies can often be derived by applying traffic laws of the country where the ADS is intended to operate, as well as by applying general safe driving principles for situations not adequately addressed by current traffic laws for human drivers. Examples of such competencies may include adherence to legal requirements to maintain a safe distance from vehicles ahead, provide pedestrians the right of way, obey traffic signs and signals, etc. Of course, some nominal competencies (e.g., safe merging, safely proceeding around road hazards) may not be explicitly articulated or mandated by traffic laws. In some instances, traffic laws may provide wide discretion for the driver to determine the safest response to a particular situation (for example, how to respond to adverse weather conditions). As such, not all traffic laws are stated with sufficient specificity to provide a clear basis for defining a competency.

~~Therefore, an approach to codify rules of the road to provide additional specificity was developed (see Appendix 1)~~. **Therefore, an example approach to codify rules of the road to provide additional specificity is introduced in paragraph 2.5.2. below.** Additionally, application of models involving safe driving behaviour may be needed in addition to reference to codified rules of the road in developing behavioural competencies for nominal driving situations.

Table 3 provides an example of competencies and scenario mapping for nominal situations.

2.3.2. Critical Situations Competencies

The development of these competencies requires analysis of (1) what constitutes such unreasonable behaviour by ORUs and/or a sudden change of the operating conditions that are not reasonably foreseeable and (2) what constitutes an appropriate ADS response to avoid or mitigate the imminent crash. Additionally, it is also important to identify the occurrence of unplanned emergent behaviour**s** in critical situations.

Analysis of the first type **can** ~~may~~ be based on a variety of methodologies, including **reference to existing standards that offer** ~~, e.g., IEEE 2846 (which offers~~ guidance on what behaviours by other road users are reasonably

foreseeable~~)~~ and other models of reasonable driving behaviour. Analysis of the second factor may be based on various models of acceptable human driving behaviour in crash-imminent situations.

Hazard identification methods (**e.g., Systems Theoretic Process Analysis)**~~e.g. STPA as mentioned in SAE J3187), which~~ **that** analyse the system design for functional and operational insufficiencies~~,~~ can help identify the occurrence of emergent behaviour which may lead to critical situations.

The development of behavioural competencies for critical driving situations faces several challenges. No general consensus exists on the appropriate models for the behaviour of ORUs or appropriate responses by the ADS to unreasonable ORU behaviours that make a crash imminent.

Table 4 provides an example of competencies and scenario mapping for critical situations.

Table 3
Example of competencies and scenario mapping in nominal situations

ODD Element	Driving Behaviour	Traffic Rule	ADS Requirements	Behavioural Competency	Test Scenario
Bicycle	Riding in lane		The ADS shall adapt its driving behaviour in line with safety risks	The ADS ensures relative velocity during passing manoeuvre does not exceed [30] km/h	The ADS travels between [30–50]km/h on the centre line of its lane A cyclist travels in the same direction as the ADS between [10–20] km/h, [0.2–1] m away from the lane edge
		Drivers will need to use a minimum passing distance for bicycles of 1.5m in urban areas, and 2m out of town	The ADS shall comply with traffic rules in accordance with application of relevant law within the area of operation.	The ADS shifts in lane to pass by cyclist with 1.5.m lateral distance	
			The ADS shall avoid unreasonable disruption to the flow of traffic in line with safety risks.	The ADS crosses the centre lane marking to ensure the safe passing distance is not violated	
			The ADS shall interact safely with other road users	The ADS activates the turn signal if the centre lane marking is crossed	

Table 4
Example of competencies and scenario mapping in critical situations

Losses	Hazards	Unsafe Control Action	Loss scenario	Causal factors	Behavioural Competency	Test Scenario
Collision with object outside the vehicle	ADS does not maintain a safe distance from the lead motor vehicle	Braking demand is not provided	Object in vehicle trajectory is not detected	Undetected/misclassified object; Obscured object; Incorrect sensor fusion result	The ADS is following behind a lead vehicle, with the headway set by the ADS. The lead vehicle decelerates at the max assumed rate depending on the weather conditions	Lead vehicle decelerated to turn [right/left] or travel straight on a [mini /large] roundabout
			Object is not considered to be in the vehicle trajectory	Localisation issues leading to incorrect positioning of ego vehicle or object		Lead vehicle decelerated whilst shifting lane to avoid a [static object/other road user]

[Critical situation behavioural competencies should provide evidence that an ADS needs to be responsive to actions by other road users, which may make a crash unavoidable. Therefore, critical scenarios should not be limited to those that are deemed preventable by the ADS. Unsafe behaviours of other road users (e.g., vehicle travelling in the wrong direction, sudden un-signalled lane changes, and exceeding the speed limit) — if reasonably foreseeable within the appropriate ODD — should be included as part of validation testing.]

2.3.3. Failure Situations Competencies

The ADS safety requirements include management of various failure modes. As noted above, failure situations involve those in which the ADS or another vehicle system experiences a fault or failure that compromises the ADS's ability to perform the DDT, such as sensor or computer failure or a failed propulsion system.

In developing the behavioural competencies appropriate for failure situations, the objective is to describe the ability of the ADS to detect and respond safely to specific types of faults and failures. Depending upon the nature and extent of the fault or failure, the responses can include identifying a minor fault for immediate repair after trip completion, responding to a significant fault with restrictions (such as limp-home mode) for the remainder of the trip, or responding to major failures by achieving a mitigated risk condition. Communication of the fault or failure condition to vehicle users may also be a desirable ADS behavioural competency.

Table 5 provides an example of competencies and scenario mapping for failure situations.

2.4. Assumptions

Concrete performance requirements depend on the specific situations the ADS encounters, on a reference behaviour that is deemed appropriate for a human driver or a technical system, and on assumptions (e.g., cut-in speed values, reaction times, …) about the behaviour of the vehicle and other road users. Assumptions concerning the actions of other road users may need to account for cultural differences in driving styles in different geolocations, making it impracticable to harmonise these assumptions across different domains. Therefore, evidence should be provided to support the assumptions made. Existing standards, e.g., IEEE 2846-2022 provide a sets of assumptions to be considered by ADS safety-related models for an initial set of driving situations. Additionally, several other tools, including data collection campaigns performed during the development phase, real-world accident analysis and realistic driving behaviour evaluations, constraint randomisation, Bayesian optimisation, among others, can be used to inform values for such assumptions.

2.5. Performance Evaluation

As previously highlighted, nominal situations are considered reasonably foreseeable for a given ODD and therefore, it is expected that the ADS would be capable of handling them without any resulting collision.

Table 5
Example of competencies and scenario mapping in failure situation

Failure Type	Failure Mode	Potential Cause	**Behavioural** ~~Behaviour~~ Competency	ADS Requirements	Test Scenario	Pass/Fail Criteria
Perception	Fail to identify ODD boundary	Failure to detect ODD attribute e.g. heavy rain/fog	Safely stop in lane of travel	The ADS shall recognise the conditions and boundaries of the ODD of its feature(s)	The ADS operates beyond the predicted ODD	The ADS detects the ODD conditions are not met and issues a minimal risk manoeuvre
				In response to a fault, the ADS shall either execute a fallback response and prohibit activation of the impacted feature(s) if the fault prevents the ADS from performing the DDT in accordance with the requirements of **paragraph 4.1. of this Regulation** ~~5.1.,~~ or adapt its performance of the DDT in accordance with the severity of the fault provided the resulting performance complies with the requirements of **paragraph 4.1.** ~~section 5.1~~		The minimum risk manoeuvre should not cause the vehicle to decelerate greater than [4]m/s2

On the other hand, **in** failure situations ~~are performed~~ **the aim is** to assess the ADS ability to recognise faults/failures in the system and safely react to such cases.

For the purpose of defining performance criteria in critical situations, those **situations** where others are at fault, behaving unforeseeably, and the collision might potentially not be prevented have to be analysed further. In these situations, different considerations can be made.

2.5.1. Evaluation of target evidence and residual risk

As testing by the manufacturer is an ongoing process, the outcome of the testing is constantly evaluated. The goal of the evaluation is to assess if sufficient evidence to support the claims of the safety case is achieved, and if an assessment of an acceptable residual risk can be developed. This evaluation is **a** major input to the decision ~~of~~ **on whether the** acceptance criteria are met, or if more scenarios and tests are required. If more are required, then additional effort is invested (by using all methods shown above) ~~in increasing~~ **to increase** the ODD and scenario coverage, until the goals of the acceptance criteria is met.

Another way to look at it is represented by the goal-based methods. As the acceptance criteria are defined, they are actually setting the goals that should be demonstrated by testing and coverage and used as evidence for safety claims. Starting from these goals, and looking at the existing status of the evidence, gaps in testing and coverage can be identified, and mapped back to missing scenarios that should be used for testing.

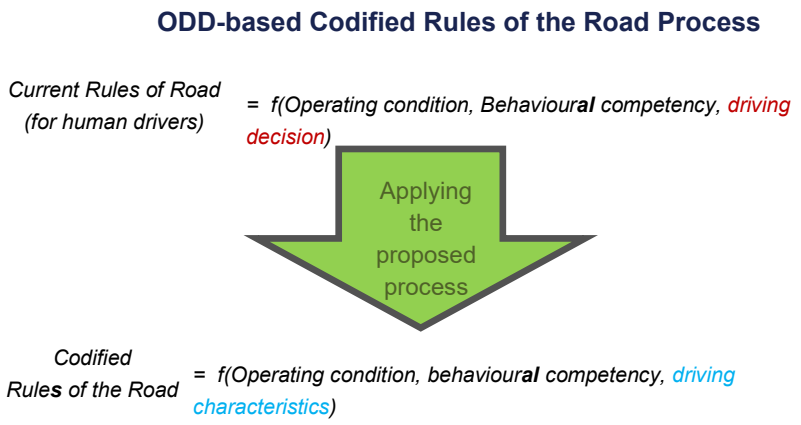
2.5.2. Application of Rules of the Road

An approach to define an acceptance criterion related to nominal driving situations is to evaluate the ADS performance against the rules of the road. Furthermore, ADS safety requirements state that, “The ADS shall comply with traffic rules in accordance with application of relevant law within the area of operation.”

~~It is challenging to test against this requirement in the absence of codified rules of the road.~~

One possible approach is the codification of the “rules of the road”. Figure 3 illustrates the use of rules of the road as pass/fail criteria for individual scenarios. The following approach for codification of Rules of the Road can be used to link individual rules with corresponding scenarios using ODD and behaviour labels.

Figure 3
Rules of the Road to define pass/fail criteria



Current rules of the road (for human drivers) have three components:

Operating conditions include both ODD aspects and vehicle states (e.g., system failures, hardware failures etc.). Every set of traffic laws or behaviour rules (for human drivers) defined in any country are based on an understanding of the expected behaviours of human drivers. As a result, they do not explicitly define all aspects of the expected driving behaviour but can be argued to include "implicit assumptions" based on this understanding.

Following the process, a "codified" rule of the road for an automated driving system will also have three components:

Codified rule = Operating condition + behavioural competency + driving decisions

The process of codification helps identify where "implicit assumptions" about driving behaviour are present in the rules for human drivers. The codified rules of the road help to turn "undefined" attributes in the rules of the road (for human drivers) into "defined" attributes in the codified "rules of the road".

Annex 6

~~[~~Data Storage Systems for Automated Driving~~]~~

1. Purpose

1.1. ~~This annex defines Data Storage System for Automated Driving (DSSAD) as the data storage capability of a vehicle to monitor the safety performance of ADS and establishes requirements to enable the evaluation of ADS safety performance.~~ **This annex provides DSSAD specifications in accordance with paragraphs 6.3.1.1., 7.3.1.13., 8.3.1.6., and 8.3.3.1. The manufacturer shall address these specifications in its description of the DSSAD installed on the ADS in accordance with paragraph 7.3.1.13.**

2. Data storage and security

2.1. The DSSAD shall be capable of recording and storing time-stamped and time-series data elements as defined in paragraph 5 of this annex.

2.2. The DSSAD shall be protected against both unauthorized access and manipulation.

2.3. ~~In the case of the data intended to be stored off-board the vehicle cannot be transmitted, it shall remain stored on the vehicle.~~ **Data elements under paragraph 5 of this annex that may be stored off-board the vehicle shall remain stored on the vehicle until the data has been successfully uploaded to an off-board storage facility.**

3. Data format

3.1. Each data element listed in paragraph 5 of this annex shall be available in accordance with paragraph 4 of this Annex. The output shall be provided in an open standard format (e.g. JSON, CSV, XML), with the exception of 'sensor data', and the data shall be in a readable form, aside from 'sensor data' ~~[~~and 'visual images'~~]~~.[1]

3.2. Information required to interpret the output to correlate it with respect to the data elements required in paragraph 5 of this annex shall be provided by the manufacturer to an authorized entity on request and subject to applicable national law(s).

3.3. Time-stamp data format

3.3.1. Time stamp data shall be recorded in a clearly identifiable way with following data:

(a) The time stamped data element, as listed under paragraph 5.2.1. of this annex.

(b) The additional information noted in the table under paragraph 5.2.1. for each time stamped data element as appropriate.

(c) Date (Resolution: yyyy/mm/dd)

(d) Time stamp

(i) Resolution: hh/mm/ss timezone (e.g., 12:59:59 UTC)

[1] Readable means that the data is of numerical values and natural language which can be understood to represent a specific data point with a value associated with it (e.g. <<speed>>35<<speed/>>, not hexadecimal or binary).

(ii) Accuracy: +/- 1.0 second

(e) Location: global longitude + latitude; shall be recorded in decimal degrees and to at least five (5) decimal places but shall be unrounded.

3.3.2. A single timestamp may be allowed for multiple elements recorded simultaneously within the time resolution of the specific data elements. If more than one element is recorded with the same timestamp, the information from the individual elements shall indicate the chronological order.

4. Data Accessibility

4.1. The DSSAD data (whether stored on or off-board the vehicle) shall be readily available and retrievable through an electronic communication interface that complies with a publicly available interface standard. It is recommended to use an internationally recognized standard.[2]

4.2. Instructions for retrieving the DSSAD data via the electronic communication interface shall be maintained by the manufacturer. [2]

4.3. The stored DSSAD data shall be retrievable even when the main onboard vehicle power supply is not available.

4.4. The DSSAD data shall be retrievable even after an impact to the vehicle of a severity level set by relevant regulations.

4.5. If the DSSAD data is intended to be stored on-board the vehicle, then the following applies.

4.5.1. The data elements concerning the activation and deactivation of the feature in paragraph 5.2.1. of this annex shall be available via the vehicle's information display/user interface where controls related to manual performance of the DDT are provided.

4.5.2. Upon request of an authorized entity, the manufacturer shall make available to them the manufacturer-specific tools, software, webservice interfaces, and/or support to retrieve the DSSAD data.

4.6. If the DSSAD data is intended to be stored off board the vehicle, then the following applies.

4.6.1. An authorized entity shall not have to install any manufacturer specific systems or software to retrieve the DSSAD data.

5. Data elements

5.1. The DSSAD shall record and store the data elements listed under paragraph 5.2. and 5.3. of this annex. This requirement shall be without prejudice to applicable laws governing access to data, availability, privacy and data protection.

5.2. Time-stamp data elements

5.2.1. The following table details the data elements of time-stamp data to be recorded, along with any additional information ~~and recording condition~~.

Event	*Additional Information*	~~*Recording condition*~~
Activation of the feature	ADS feature is activated by the: (a) system, or (b) user	

[2] Contracting parties may further define technical specifications for data accessibility and/or availability of instructions under national law.

The following data elements shall be recorded if they occur while an ADS feature is active.		
Deactivation of the feature	ADS feature is deactivated by the: (a) **Initiated by the** system, or (b) **Initiated by a** user	~~While the feature is active~~
ODD exit		~~While the feature is active~~
Start of ADS fallback to user, if applicable	**ADS fallback to user initiated** ~~Deactivation of the ADS feature initiated~~ due to: (a) Foreseen condition (b) Unforeseen condition (c) Failure (d) Input to the driving controls, or (e) ODD exit.	~~While the feature is active~~
Start of ADS fallback to an MRC	**Fallback to an MRC initiated due to:**~~MRC resulting from:~~ (a) ODD exit (b) ADS failure (c) Collision detected (d) Detection that fallback user is not available when they have no longer met the conditions of paragraph 4.2.2.1.6 of this Regulation (if applicable), or (e) Failure of the fallback user to take control following a system-initiated deactivation of the ADS.	~~While the feature is active~~
User input to the driving controls, if applicable	Application of: (a) brake control, (b) acceleration control, (c) steering control, or (d) direction indicator.	~~While the feature is active~~
Application of the passenger stop request as designated in paragraph 4.2.3.1. of this Regulation		~~While the feature is active~~
Prevention of user takeover, if applicable	Prevention of user takeover (if applicable) due to: (a) Unintentional user input, (b) Current situation unsuitable, (c) Current situation unsafe, or (d) User not suitably engaged.	~~While the feature is active~~

Detection that fallback-user is not available when they have no longer met the conditions of paragraph 4.2.2.1.6. of this Regulation, if applicable		~~While the feature is active~~
Start of Emergency Manoeuvre		~~While the feature is active~~
End of Emergency Manoeuvre		~~While the feature is active~~
Event Data Recorder (EDR) trigger input [3]		~~While the feature is active~~
Detected collision		~~While the feature is active~~
MRC achieved	Indication of end states per paragraph 5.3.1.14. of this regulation	~~While the feature is active~~
Detected failure ~~situation~~ **that compromises the ADS capability to perform the DDT**	~~The failure could include the following:~~ ~~(a) ADS~~ ~~(b) Sensor~~ ~~(c) Other vehicle systems (mechanical, electrical, etc.)~~ **Nature of failure in accordance with para. 7.3.1.15.**	~~While the feature is active~~
Remote intervention in a tactical function, if applicable.		~~While the feature is active~~

5.3. Time series data elements

5.3.1. ~~[~~The data elements shall be recorded ~~in compliance with paragraph 5.3.x~~ if the following thresholds are reached or conditions occur:

(a) Detected collision

(b) EDR trigger input (excluding last stop trigger)~~]~~

5.3.1.1. If there is no system or sensor designed to provide the data element to be recorded and stored under paragraph 5.3, alternative data may be utilized if the data provides equivalent information to the specified data element.

5.3.2. The following table details the data elements of time-series data to be recorded during a triggering event.

Data element	*Condition for requirement*	*Recording interval/time (relative to time stamp)*
Visual images[4]		
Detected object distance, longitudinal	Mandatory, if available	
Detected object distance, lateral	Mandatory, if available	
Detected object relative velocity, longitudinal	Mandatory, if available	
Detected object relative velocity, lateral	Mandatory, if available	

[3] Excluding any last stop trigger.

[4] **This data element is generally represented by a camera image; however, this image may be a construct of other sensor data if camera images are unavailable.**

Detected object classification	Mandatory, if available	
Sensor data[5]	Mandatory if 'Detected object elements' are not available	
ADS-requested accel demand	Mandatory	
ADS-requested service braking demand	Mandatory	
ADS-requested parking brake demand	Mandatory	
ADS-requested steering demand	Mandatory	
Vehicle acceleration, longitudinal	Mandatory	
Vehicle acceleration, lateral	Mandatory	
ADS-determined vehicle speed	Mandatory	

[5] e.g., camera, radar, LiDAR, used by the ADS for decision making. This shall be documented in the information package provided to the Authorised Entity. This shall include a "Visual Representation" submitted to the Authorised Entity at the time of providing the DSSAD Data ~~and shall comply with the requirements of 4.1 and 5.4~~.