Transmitted by the expert from Japan Document ADS-07-12

Proposals to amend

Consolidated Draft of Common Provisions on ADS Safety
(Version 1.3: 3 February 2025)

This document consolidates the ADS IWG work up to and including the 5th meeting in Seoul in December 2024. This consolidated document will act as the base document going forward until separated into a draft GTR and a draft UNR (currently foreseen for the July ADS IWG meeting).

Cross-references highlighted in yellow for visibility during updating of text.
Revision 1: Correction of numbering error under section 5.2.

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- In-Service Reporting Templates

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1. Purpose

1.1. (*GTR)* This Global Technical Regulation (GTR) provides worldwide harmonised procedures to set and verify compliance with minimum requirements for the safety of Automated Driving Systems (ADS) and vehicles equipped with ADS.

(*UNR)* This Regulation establishes uniform provisions concerning the approval of motor vehicles with regard to their Automated Driving Systems (ADS).

2. Scope

2.1. *(GTR)* This GTR applies to the Automated Driving Systems of vehicles of categories 1 and 2.

(UNR) This Regulation applies to the approval of vehicles of categories M and N with regard to their Automated Driving Systems.

3. Definitions[1]

Terms not found in the draft text have been omitted.

3.1. "*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. [2]

3.2. *"ADS fallback response"* means a system-initiated deactivation of the ADS or an ADS-controlled procedure to place the vehicle in a minimal risk condition.

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

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

3.4.1. *"Strategic function"* means a capability to issue commands, instructions, or guidance for execution by an ADS.[3]

3.4.2. *"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.[4]

3.4.3. *"Operational function"* means a capability to control the real-time motion of the vehicle.[5]

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1 Definitions for terms used in the document.

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.

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

4 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.

5 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.

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3.5. "*ADS user"* means a human user of an ADS vehicle.[6]

3.5.1. *"Driver"* means a human user who performs in real time part or all of the DDT and/or DDT fallback for a particular vehicle.

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

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

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

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

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 necessary to operate the vehicle (i.e., the ADS performs "the entire DDT" as stated in the definition of an "Automated Driving System" under para. 3.2.). These functions can be grouped into three interdependent categories: sensing and perception, planning and decision, and control.

3.8.1. 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.

(d) Positional awareness.

3.8.2. Planning and decision include:

(a) Predicting actions of other road users.

(b) Response preparation.

(c) Manoeuvre planning.

3.8.3. Control includes:

(a) Object and event response execution.

(b) Lateral vehicle motion control.

(c) Longitudinal vehicle motion control.

(d) Enhancing conspicuity via lighting and signalling.

3.8.4. The DDT excludes strategic functions.

[6] All the variations on "user" roles have been group under the "ADS user" definition. This might prove beneficial in the future development of ADS requirements (i.e., introduction of new "user" definitions).

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3.9. *"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.

3.10. *"Event"* means any situation happening in a given time and location.

3.10.1. *"Safety-relevant event"* means an event which is relevant for the evaluation of the safe operation of the ADS Vehicle. These events also include normal operation which are relevant to argument specific ADS design choices and/or the safety case. (e.g., fallback user unavailability, MRM).

3.11. *"Failure"* means the termination of an intended behaviour of an element or an item.

3.12. *"Fault"* means an abnormal condition that can cause an element (system, component, software) or an item (system or combination of systems that implement a function of a vehicles) to fail.

3.13. *"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).

"Manufacturer" means the manufacturer of the ADS vehicle. However, in case that the ADS is not manufactured by the vehicle manufacturer itself, as long as the manufacturer of the ADS is responsible for the safety of the entire ADS vehicle including cybersecurity, this manufacturer of the ADS is also deemed as the manufacturer of the ADS vehicle.

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

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

3.16. *"Occurrence"* means a safety-relevant event during which at least one of the following criteria is fulfilled:

a) Collision involving the ADS vehicle

b) ADS vehicle system/component failure

c) ADS vehicle produces a noncompliance with respect to the requirements of this regulation.

3.16.1. *"Non-critical Occurrence"* means [all occurrences which are not "Critical Occurrences"] [an operational interruption, defect, fault, or other circumstance that influenced or may have influenced ADS safety but did not result in a collision or serious incident.]

3.16.2. *"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.

(c) Any vehicle involved in the event experiences a deployment of any non-reversible restraint system.

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

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Commented [昂樺1]: (Japan) Proposal and comments for the newly proposed definition of "Manufacturer" by SAE (Daniel Smith-san)

Justification;
We **agree with** the proposal by SAE to add the definition of the ADS manufacturer because there are various business models for the development of ADS vehicles.
We think, however, that in any case, **the safety of the entire vehicle has to be ensured**.
Therefore, our proposal intends to clarify that **the manufacture of the ADS would be required to establish a system of responsibility for the safety of the "entire" ADS vehicle,** not limited to that of the ADS only.

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3.17.1. *"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.

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

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

3.20. *"Post-production phase"* means the period in which an ADS vehicle is no longer produced until the end-of-life of all ADS vehicles of the same type. The phase ends when there are no longer any operational ADS vehicles of a specific ADS type.

3.21. *"Priority vehicle"* means a vehicle [operated while making use of] [subject to] exemptions, authorizations, and/or right-of-way under traffic laws [while performing a specified function].

3.22. *"Proving ground"* and "*Test track*" mean a facility 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.

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

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

3.25. *"Road-safety agent"* means a human being engaged in directing traffic, enforcing traffic laws, maintaining/constructing roadways, and/or responding to traffic incidents.

3.26. "*Safety case"* means a structured argument supported by a body of evidence that provides a compelling, comprehensible, and valid case that the ADS is or will be free from unreasonable risk for a given application in a given environment.

[3.26.1. *"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.

[3.26.2. *"Claim"* means a high-level assertion that the behaviour competencies of an ADS will satisfy the DDT performance requirements applicable to one or more scenarios.]

[3.26.3. *"Evidence"* means a set of results of analyses, simulations, and physical testing pertinent to demonstrating the validity of an argument within a safety case.]

3.27. *"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.

3.28. "*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.

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(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.

(c) Technical component using appropriate tools and equipment.

3.29. *"(Traffic) Scenario"* means a description of a sequence of driving situations that may occur during a given trip.[7]

3.29.1. *"Nominal scenario"* means [any scenario that is not a critical or failure scenario].

3.29.2. *"Critical scenario"* means a traffic scenario [where the operating conditions or behaviour of other road users requires a prompt action of the ADS to avoid or mitigate a collision with adverse consequences on human health or property damage].

3.29.3. *"Failure scenario"* means a traffic scenario representing a system failure that compromises the capability of the ADS to perform the entire DDT.

3.29.4. *"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.[8]

3.29.5. *"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.

3.29.6. *"Complex scenario"* means a traffic scenario containing one or more situations that involve [partly dependent parameters that must be taken into account by the ADS to execute the DDT of the ADS (]e.g., a large number of other road users, unlikely road infrastructure, or abnormal geographic/environmental conditions[)].

3.30. *"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.

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

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

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

3.34. *"System-initiated deactivation of the ADS"* means a procedure by which the ADS initiates the transfer of performance of the DDT from the ADS to a vehicle fallback user.

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[7] Scenarios include a driving manoeuvre or sequence of driving manoeuvres. Scenarios can also involve a wide range of elements, such as some or all portions of the DDT, different roadway layouts, different types of road users and objects exhibiting static or diverse dynamic behaviours, and diverse environmental conditions (among many other factors).

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

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3.35. *"Test method"* means a structured approach to consistently derive knowledge about the performance of an ADS by means of executing tests.[9]

3.36. *"Useful life (of an ADS vehicle)"* means the duration during which an ADS vehicle is in an operational state under which it may be driven on public roads regardless of the operational state of the ADS.

3.37. *"User-initiated deactivation of the ADS"* means a procedure by which the user initiates the transfer of performance of the DDT from the ADS to the vehicle user.

3.38. *"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.

3.39. *"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.

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

4. General Requirements

4.1. ADS Requirements

4.1.1. This regulation establishes performance requirements for the evaluation of ADS driving behaviours:

(a) Under nominal scenarios

(b) Under critical scenarios

(c) Under failure scenarios

(d) At ODD boundaries

(e) In fallbacks to an MRC.

4.1.2. [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.]

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Commented [昂榊2]: (Japan) Support to keep.

Justification;
This "C&C human driver" concept is a fundamental concept for ensuring the safety of ADS. Japan strongly supports to maintain the provision.

4.1.3. The requirements for DDT performance under nominal scenarios shall continue to apply during critical scenarios as far as is reasonably practicable under the specific circumstances with the aim of minimising overall [safety] risk[s].

4.2. Manufacturer Documentation

4.2.1. Manufacturer's Safety Management System

[9] For example, virtual testing in simulated environments, physical, structured testing in controlled test-facility environments, and real-world on-road conditions.

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4.2.1.1. This Regulation requires the manufacturer to document its processes for ensuring that the ADS is free of unreasonable safety risks.[10]

4.2.1.2. The Regulation establishes requirements for managing safety throughout the useful life of the ADS vehicle, including the following stages:

(a) Development

(b) Production

(c) Operational

(d) Decommissioning.

4.2.1.3. The Regulation requires these processes, collectively known as the Safety Management System (SMS), to address safety risks associated with organisational, human, and technical factors.[11]

(a) Organisational factors concern procedures and methods to manage identified risks, understand their relationships and interactions with other risks and mitigation measures, and reduce the risk of unforeseen consequences.[12]

(b) Human factors concern the roles of personnel, their skills, training, and understanding to identify risks and mitigation measures, and processes to control for the possibility of human error. [13]

(c) Technical factors concern the tools and equipment used to identify risks and evaluate mitigation measures.[14]

4.2.1.4. The Regulation requires the manufacturer's documentation to cover the following aspects:[15]

(a) Safety policy (para. 6.1.1.)

(b) Risk management (para. 6.1.2.)

(c) Design and development (para. 6.1.3.)

(d) Production (para. 6.1.4.)

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[10] Paras. 4.2.1. is based on ADS-05-13: "In respect of ADS, the manufacture shall establish a SMS with robust processes to manage safety risks and to ensure safety throughout the ADS lifecycle (development, production, operation and decommissioning) including in the event of discontinued production, support, or maintenance." The stages have been merged with para. 4.5.1. of the ISMR OPI proposal in para. 4.2.1.4 below.

[11] Based on ADS-05-13: "The SMS shall manage and improve safety by considering organizational, human and technical risk factors."

[12] ADS-05-13: "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"

[13] ADS-05-13: "Human component ensuring the ADS lifecycle is monitored by personnel with appropriate skills, training, and understanding to identify risks and appropriate mitigation measures while accounting for the possibility of human errors"

[14] ADS-05-13: "Technical component using appropriate tools and equipment."

[15] These are the section headings in ADS-05-13. The word "process" has been dropped as unnecessary (and possibly misleading since these management aspects can involve many processes, not just one). Cross-references are added to guide the reader to the corresponding sections.

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(e) Post-deployment (para. 6.1.5)

(f) Safety assurance (para. 6.1.6.)

(g) Safety promotion (para. 6.1.7.).

4.2.2. Manufacturer Testing of the ADS

4.2.3. Safety Case for the ADS

4.2.3.1. The Regulation requires the manufacturer to produce a safety case for the ADS and its feature(s) in a manner that demonstrates the application of the SMS to the ADS under assessment, including the following aspects:

a) The safety concept, which describes the hazard identification and mitigation measures designed into the ADS to meet the requirements of this regulation and achieve the goal of avoidance of unreasonable risk with regard to functional and operational safety,

b) Information and documentation necessary to describe the ADS covered by the safety case, including the intended use, the operating environment, the interactions with humans, sub-systems and components, control strategies,

c) Structured claims, argumentation, and evidence (including validation tests) that affirm and demonstrate that the ADS meets the requirements in Section 5 and is free from unreasonable risks to the ADS vehicle user(s) and other road users,

d) Demonstration of credibility and suitability of test tools used in generating evidence, and

e) Explanation of the processes for reinforcing ADS safety throughout the life of the ADS.

4.2.4. Post-deployment Safety

4.2.4.1. The Regulation requires the manufacturer to put in place a fleet monitoring mechanism to collect information from the ADS vehicle in accordance with the requirements listed in the 6.1:

(a) GTR: to confirm the safety case and confirm the validation carried out by the manufacturer before market introduction.

UNR: to confirm the safety case and confirm the validation carried out by the manufacturer before the granting of the approval

(b) to enable the identification of unreasonable risks related to the use of an ADS on public roads and the evaluation of its safety performance during real-world operation.

(c) to enable the identification of unanticipated situations, hazards, and risks that lead to unexpected behaviour of the ADS. This information shall be assessed by the Manufacturer and where appropriate be used to develop new or revise existing scenarios derived from ISMR activities.

4.2.4.2. The Regulation requires the manufacturer to have mechanisms for receiving and analysing safety-relevant feedback and reports from other sources, in accordance with the requirement listed in 6.1, to complement the data collected from ADS vehicles.

4.3. Compliance Assessment

4.3.1. Audit of the Safety Management System

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4.3.2. Credibility of the Testing of the ADS

4.3.3. Safety Case for the ADS

4.3.4. Post-Deployment Safety Capabilities

5. ADS Requirements[16]

5.1. ADS Performance of the DDT

5.1.1. The ADS shall be capable of performing the entire Dynamic Driving Task (DDT) within the ODD of its feature(s).

The manufacturer shall use a process to derive behavioural competencies and scenarios that are ODD-relevant. The methodology used in Annex [x] can be used or alternative methods providing they are equally comprehensive.

5.1.2. ADS Performance of the DDT under Nominal Traffic Scenarios

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

5.1.2.2. The ADS shall adapt its speed in line with safety risks.

5.1.2.3. The ADS shall maintain appropriate distances from other road users by controlling the longitudinal and lateral motion of the vehicle.

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

5.1.2.5. The ADS shall adapt its driving behaviour in line with safety risks.

5.1.2.5.1. [The ADS shall demonstrate anticipatory behaviour to reduce the risk of encountering a critical scenario].

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

5.1.2.7. The ADS shall detect and respond to priority vehicles in accordance with the [applicable/relevant] traffic law(s).

5.1.2.8. [The ADS shall not force other road users to take evasive action to avoid a collision with the ADS vehicle.]

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

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

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

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

5.1.2.13. Pursuant to a passenger request under para. [5.3.3.1], the ADS shall bring the vehicle to a safe stop.

Commented [昂榊3]: (Japan) Support to keep.

Justification;
This is a fundamental requirement for ensuring the safety of ADS. With a simple description, it doesn't seem that it needs any further modification.

[16] Anything setting functional or performance requirements for an ADS and/or ADS vehicle. This section is based on "Consolidated DDT section 1.1." as provided by the OPI in his email of 19 December 2024 (The 5th ADS IWG session did not receive a consolidated text for the section).

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

5.1.3. ADS Performance of the DDT under Critical Traffic Scenarios

5.1.3.1. The requirements for DDT performance under nominal scenarios shall continue to apply during critical scenarios as far as is reasonably practicable under the specific circumstances with the aim of minimising overall [safety] risk[s].

5.1.3.2. In the event of a collision involving the ADS vehicle, if required to stop by applicable law, the ADS shall [stop or] fallback to an MRC [as appropriate].

5.1.3.2.1. The ADS shall not resume travel until:

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

(b) It is permissible under the applicable law.

5.1.3.2.2. Notwithstanding 5.1.3.2.1., if possible, the ADS [may move the vehicle if this is required/ shall move the vehicle, if technically possible and safe] in order to appropriately respond to a road safety agent.

5.1.4. ADS Performance of the DDT under Failure Scenarios

5.1.4.1. The requirements for DDT performance under nominal scenarios shall continue to apply during failure scenarios as far as is reasonably practicable under the specific circumstances with the aim of minimising overall [safety] risk[s].

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

5.1.4.3. 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 of [5.1.], or

b) Adapt its performance of the DDT in accordance with the severity of the fault provided the resulting performance complies with the requirements of section [5.1.]

5.1.4.4. Remote termination by the manufacturer [and/or service operator] shall be possible [when requested by Authorities].

5.1.4.4.1. Remote termination for an ADS performing the DDT shall be capable of triggering an ADS fallback response.

5.1.4.4.2. 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.

5.1.5. ADS Performance of the DDT at ODD Boundaries

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

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

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

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

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

5.1.6. Minimal Risk Condition Requirements

5.1.6.1. The ADS shall signal [to other road users] its intention to place the vehicle in an MRC.

5.1.6.2. In the absence of a fallback user, the ADS fallback response shall be to place the vehicle in an MRC.

5.1.6.3. If the ADS feature is designed to request and enable intervention by a fallback user, the ADS shall execute a fallback to an MRC in the event of a failure in the [transition of control] to the user.

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

5.2. Safety of ADS User Interactions with the ADS

5.2.1. General requirements

5.2.1.1. At each initiation of the powertrain, the ADS shall signal the presence of a failure that prevents or limits the operation of a feature.

5.2.1.2. The ADS shall signal its intention to place the vehicle in an MRC to the ADS user(s).

5.2.1.3. An ADS that controls the operation of doors shall provide an emergency override to the user.

5.2.1.4. The ADS HMI shall provide safety relevant information and signals clearly noticeable to the target user(s) under all operating conditions, multimodal (e.g., optical, acoustic, haptic) if needed, simply and unambiguously.

5.2.2. ADS features that allow a user to take over manual-control of the DDT.

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

5.2.2.2. When an ADS feature is active, the vehicle driving controls, direct vision, devices for indirect vision, indicators, tell-tales, and DDT-related warnings may be disabled, suppressed, de-activated, inhibited or by other means made unavailable.

5.2.2.3. The vehicle controls dedicated to the ADS shall be clearly identified and distinguishable to accommodate only the appropriate interactions.[17]

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

(a) ADS status information.

(b) The role of the fallback user, if applicable.

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

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

5.2.2.6. While active, features that have a system-initiated deactivation of the ADS to a fallback user shall:

[17] Through size, form, location, colour, type, action, spacing and/or control shape. The provision aims to promote correct use and is not intended to prohibit multifunction controls.

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(a) Continuously assess whether the fallback user is available to assume the role of driver at the end of the deactivation procedure.

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

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

5.2.2.7. ADS feature activation

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

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

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

5.2.2.7.4. An ADS feature activation resulting in a user becoming a fallback user 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.

5.2.3. ADS feature deactivation to manual driving

5.2.3.1. In a nominal scenario, the beginning of a system-initiated deactivation process shall be indicated in a timely manner to support the fallback user re-engaging to the driving task.

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

5.2.3.3. The ADS feature shall only respond to the user request to initiate a system deactivation process, if the ADS verifies that the user is in a position to assume the role of the driver.

5.2.3.4. 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.

5.2.3.5. The ADS feature shall remain active until the system deactivation process has been completed or the ADS vehicle reaches a minimal risk condition.

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

5.2.3.7. The ADS shall assess if the user is suitably engaged to resume the DDT before completion of the deactivation process.

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

5.2.3.9. At the completion of the deactivation process, control shall be returned to the driver without any continuous lateral or longitudinal control assistance active.

5.2.3.10. If applicable, during the deactivation procedure, the vehicle controls, direct vision, devices for indirect vision, indicators, warnings, and tell-tales shall be set to an appropriate state for manual driving.

Transmitted by the expert from Japan Document ADS-07-12

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

5.2.4. ADS features that do not allow a user to take manual control of the DDT

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

5.2.4.X If remote supervision and remote monitoring by a remote supervision centre are operated, the ADS shall provide the passenger(s) with means to communicate between the ADS and the remote supervision centre.

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

5.2.4.3. The ADS shall not initiate motion unless the safety risks to the passenger(s) have been mitigated.

5.2.4.4. Controls provided for manual driving (e.g., steering, service brake, parking brake, accelerator, lighting) shall be designed to prevent any effect on the DDT whilst the ADS is performing the DDT, or reasonable safeguards shall be put in place to prevent access to controls.

5.2.5. Information Provision to Users (as appropriate: owners, users, operators, etc.)

5.2.5.1. For the ADS users, means shall be provided that facilitates user understanding of the functionality and operation of the system covering at least:

(a) An operational description of the ADS features, capabilities, and limitations (the information should also refer to specific use cases and/or ODD)

(b) The correct use of the ADS and its feature(s)

(c) Instructions for the activation and deactivation of the ADS, with clear explanations of the distinctions between user-initiated deactivation and system-initiated deactivation where applicable

[(d) A description of the responsibilities of the user and ADS when an ADS (feature) is active

(e) Information on ADS responses to ADS vehicle user interventions in the dynamic control of the vehicle

(f) A description of the permitted transitions of roles and the procedure for those transitions

(g) A general overview of non-driving-related activities (NDRA) allowed when an ADS feature is active where applicable

(h) Safety precautions and safety-relevant information for the user

(i) Information related to the HMI of the ADS feature(s) e.g.:

(i) Visual tell-tales, icons

(ii) Auditory signals

(iii) Haptic signals

[(j) Instructions on safety and non-safety measures to be taken when there is a malfunction of the ADS]

(k) Extent, timing and frequency of maintenance operations where applicable

Commented [昂榊4]: (Japan) Proposal to add a new provision 5.2.4.X.

Justification;
For an operation with a remote supervision centre, it would be required to provide the passenger(s) means to communicate with the centre in terms of ensuring the passenger safety (e.g., informing the remote supervision centre of severe failure of ADS).

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(l) Data protection and data security functionalities.

5.3. Other Requirements

5.3.1. [Cyber Security provisions]

5.3.2. The manufacturer shall include a robust process in the SMS to ensure that post-deployment software updates are properly validated and distributed and downloading is confirmed.

6. Manufacturer Requirements[18]

Other requirements (need decisions on how to integrate into the regulations)

The manufacturer shall provide the specific documentation to facilitate the audit and safety assessment.[19]

The manufacturer shall make additional confidential material and analysis data available for on-site inspection (e.g., at a manufacturer facility) as needed for the process audit and/or safety assessment.[20]

The manufacturer shall ensure that this material and analysis data remains available for a period of 10 years counted from the time when production of the ADS is discontinued.

Any changes to ADS safety design shall be communicated as required to the relevant authority.

6.1. Safety Management System[21]

6.1.1. Safety Policy

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

6.1.1.2. The manufacturer shall provide evidence that its safety policy implements the following aspects:[22]

(a) Safety policies and principles (e.g., ISO 21434, para. 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 SMS, taking into account regulation, standards, best practice guidance and the use-case of the vehicle and mapping its organization structure, processes, and work products onto the SMS.

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

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[18] Anything requiring documentation by the manufacturer.
[19] ADS-05-14
[20] ADS-05-14: If required by the auditor, the manufacture shall made additional confidential material and analysis data (e.g. intellectual property) open for inspection (e.g. on-site in the engineering facilities of the manufacturer) at the time of the product assessment/process audit.
[21] ADS-05-13/Rev.1.
[22] The manufacturer shall provide evidence it has implemented the following as part of its SMS:

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(e) Safety Governance elements including management commitment (e.g., ISO 21434, para. 5.4.1 and ISO 9001 Automotive 5.1) and roles and responsibilities (e.g., ISO 26262-2, para. 6.4.2, this relates to the organizational and project dependent activities).

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

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

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

6.1.2. Risk Management

6.1.2.1. The SMS shall include a management process to identify, assess, and mitigate organisational, human, and technical risks.[23]

6.1.2.1.1. The ADS manufacturer shall then be able to show the link between the overall risk management process, the mitigations, and the resulting operational risks.

6.1.2.2. 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 para. 6.2).

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

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

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

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

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

6.1.2.3. This process shall include Failure Mode and Effect Analysis (FMEA), Fault Tree Analysis (FTA), System-Theoretic Process Analysis (STPA) or any similar process appropriate to system functional and operational safety.[24]

[23] ADS-05-13: "The manufacturer shall include in the SMS a Safety risk management process to identify and assess the risks associated to the three SMS factors (i.e., human, organizational, and technical). Any operational risk identified in the product shall, where appropriate, have mitigations implemented. The ADS manufacturer shall then be able to show the link between the overall risk management process, the mitigations, and the resulting operational risks." The first two sentences can be combined for brevity as "identify, assess, and mitigate". The risk management process applies to the ADS under assessment, so the specific risks identified and their mitigations would be provided under the safety case [6.2.7.].

[24] ADS-05-06-Rev.2: "This shall be based on a Failure Mode and Effect Analysis (FMEA), a Fault Tree Analysis (FTA) and a System-Theoretic Process Analysis (STPA) or any similar process appropriate to system functional and operational safety."

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6.1.2.4. The manufacturer shall demonstrate its use of a top down (from possible hazard to design) and a bottom-up approach (from design to possible hazards) in its identification of hazards.[25]

6.1.3. ADS Design and Development

6.1.3.1. This documentation shall include risk management, requirements management, requirements' implementation, testing, failure tracking, remedial actions, and release management [including the following aspects:

(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.

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

6.1.3.2. The manufacturer shall document 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 development, integration, and implementation:

(i) Requirements management (e.g. Requirement capture and validation)

(ii) Validation strategies, including but not limited to:

a. Assessment of the physical testing environment

b. Credibility assessment for virtual tool chain

c. System integration

d. Software

e. Hardware.

(iii) Management of functional safety and safety of the intended functionality (e.g., ISO 13407), including the ongoing evaluation and update of risk assessments and interactions.

(iv) Management of human factors, including human-centred design processes.

(c) Design and change management, including but not limited to:

(i) The major design decisions.

(ii) The relevant design modifications to the ADS.

(iii) Changes to key persons responsible for making decisions that affect safety.

(iv) The tools and thresholds adopted for the ADS safety verification.

6.1.3.3. The manufacturer shall institute and maintain effective communication channels between the departments and third-party organizations responsible for functional/operational safety, cybersecurity,

[25] ADS-05-06-Rev.2: "The manufacturer shall demonstrate how it has taken both a top down (from possible hazard to design) and bottom-up approach (from design to possible hazards) in its identification of hazards."

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and any other relevant disciplines related to the achievement of vehicle safety. These processes and activities shall be documented considering relevant standards and best practice.

6.1.4. Production management

6.1.4.1. The manufacturer shall establish and document the production process in the SMS. The manufacturer shall document its processes and activities to ensure the robustness of the production phase. This documentation shall cover, at least, the following aspects:

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

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

6.1.4.2. 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 vehicle and/or ADS manufacturer and all other manufacturers (partners or subcontractors) involved.

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

(c) Confirmation that safety risk including cybersecurity related to all concerned components/systems of the vehicle are managed

6.1.5. Post-deployment safety

6.1.5.1. The manufacturer shall establish processes to demonstrate its capabilities to execute an effective ISMR and to take the corrective remedial action when necessary.

6.1.5.2. 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 to 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

(h) To share learnings derived from occurrence analysis

(i) To contribute to the continuous improvement of automotive safety.

Commented [昂榊5]: (Japan) Proposal to add a new provision (c)

Justification;
It would be necessary for the manufacturer to identify and manage the risk of all concerned components/systems of the entire vehicle in the process of production.

Transmitted by the expert from Japan Document ADS-07-12

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6.1.5.3. 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.

6.1.5.4. The manufacturer shall collect and analyse vehicle data, and data from other sources to achieve the ISMR objectives.

6.1.5.4.1. The manufacturer shall have a data acquisition strategy, data retention strategy, data access, and security and protection policy.

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

6.1.5.4.3. The 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) The retention of the data for longer-term trend analysis (i.e. subset of the collected data).

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

6.1.5.4.5. 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)

(x) Identify the influence of change of traffic rules on the ADS

(d) Characterize 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.

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

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

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

(a) Routine measurements: a selection of parameters shall be collected to characterize 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.

Commented [昂榊6]: (Japan) Proposal to add one objective

Justification;
The manufacturer would be required to **identify the influence of change of traffic rule** regarding the operation of the ADS as part of the monitoring activity (cf: 5.1.2.9.)

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(b) Exceedance detection: a set of "core values" shall be selected to cover the main areas of interest for the ADS operation with aim at 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 characterize and investigate all the occurrences and safety relevant events [listed in the occurrence list/annex/appendix] 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.

6.1.5.5. The manufacturer shall have a 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.

6.1.5.5.1. The feedback and reports from other sources shall include:

(a) ADS related maintenance and inspection feedback

(b) Enforcers (including the police) and other authorities' reports

(c) Service operator, customer, public and dealer feedback.

6.1.5.6. 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

(c) The outcome of remedial actions.

6.1.5.7. The manufacturer shall include a robust process in the SMS to ensure that post-deployment software updates are properly validated and distributed and downloading is confirmed.

6.1.6. Safety Assurance

6.1.6.1. 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.

6.1.6.2. The manufacturer shall put in place suitable arrangements (e.g., contractual arrangements, clear interfaces, quality management system) with any organization involved in the development, manufacturing, or in-use deployment of its vehicles (e.g., contracted suppliers, service providers, or manufacturers' sub-organizations) The manufacturer shall document its processes and activities, including the following aspects:

(a) Organizational policy for supply chain

(b) Incorporation of risks originating from supply chain

(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-production

(e) Processes for distributed safety activities.

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6.1.6.3. SMS documentation shall be regularly updated in line with any relevant changes to the SMS processes. It is required that 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.

6.1.6.4. 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 person creating the compliance data);

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

6.1.6.5. 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).

6.1.7. Safety Promotion

6.1.7.1. 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.

6.2. Testing of the ADS

6.2.1. The manufacturer shall demonstrate that the approach to testing is suitable for the demonstration of the safety case and the compliance with performance/functional requirements.

6.2.1.1. The manufacturer shall demonstrate that the physical testing (proving ground and/or public road) facilities and environment are suitable for the tests that are being conducted.

6.2.1.2. The manufacturer shall demonstrate that the simulation toolchain(s) is suitable for conducting virtual tests. The requirements for the simulation toolchain(s) are listed in 6.2.2.

6.2.2. Virtual Testing and Simulation Toolchain Credibility Requirements

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

6.2.2.2. The manufacturer shall demonstrate that the simulation toolchain(s) is suitable to use for virtual testing by:

a) performing a criticality analysis that evaluates the potential risk and consequences of using the simulation toolchain(s) for the assessment of the ADS safety case and functional/user requirements.

b) demonstrating that the simulation toolchain(s) fulfils the credibility requirements corresponding to the identified criticality as per the requirements listed in this section.

6.2.2.3. Simulation Toolchain Data Management

6.2.2.3.1. The manufacturer shall manage the data used to develop, verify, validate and update the simulation toolchain(s) throughout its lifetime. The manufacturer shall consider the completeness, accuracy and consistency of this data.

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

6.2.2.3.3. If the simulation toolchain(s) incorporates or relies upon data/tools from other organizations which are not under the control of the manufacturer, the manufacturer shall demonstrate the measures taken to manage the quality and integrity of that data/tools.

6.2.2.3.4. With regards to input data management and parameters associated with the simulation toolchain(s), the manufacturer shall:

a) document the data used to develop, verify and validate the simulation toolchain(s) and note important quality characteristics

b) provide documentation showing that the data used to develop, verify and validate the simulation toolchain(s) covers the intended functionalities that the virtual testing aims to assess

c) document the data and the calibration procedures employed to fit any parameters associated with the simulation toolchain(s)

d) explain the reasons for data or parameters changing between releases.

6.2.2.3.5. 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).

6.2.2.3.6. With regards to the data that is produced by the simulation toolchain(s) and its components, the manufacturer shall:

a) maintain a record of the output from the simulation toolchain(s) during its validation and ensure that they are traceable to the input data that produced them.

b) document the output data and note any important quality characteristics that can be deduced from analysis of the data, e.g. applying statistical methodologies.

6.2.2.3.7. With regards to the quality of the data that is produced by the simulation toolchain(s) and its components, the manufacturer shall:

a) ensure it is sufficient to undertake any validation activity

b) ensure it is sufficient to allow consistency/sanity check of the simulation toolchain(s), possibly by exploiting redundant information

c) ensure it is sufficient to justify manufacturer's claims about their safety case.

6.2.2.3.8. With regards to the management of stochastic models, the manufacturer shall:

a) characterize the variance in the simulation toolchain(s)'s output

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

6.2.2.4. Competency of Personnel

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

a) the personnel that developed the simulation toolchain(s) and its components

b) the personnel that assessed the simulation toolchain(s) and its components

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

6.2.2.4.2. The manufacturer shall have processes and procedures that identify and maintain the skills, knowledge, and experience needed to perform the various activities. 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

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

6.2.2.4.3. The manufacturer shall maintain records of the personnel in the various teams showing they have received the necessary training and have been deemed competent to perform the modelling and simulation activities assigned to those personnel.

6.2.2.4.4. The manufacturer shall set up suitable arrangements with third-party organisations to ensure that the competency of their personnel is adequate to demonstrate the credibility of the simulation toolchain(s).

6.2.2.5. Simulation Toolchain Release Management

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

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

6.2.2.5.2. The manufacturer shall manage and document the simulation toolchain(s) release management process. The simulation toolchain(s) release management activity shall include:

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)

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

6.2.2.6. Description of the Simulation Toolchain

6.2.2.6.1. 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.

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

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

6.2.2.6.4. The manufacturer shall provide a description of the acceptance tests and criteria that will be used to determine if a simulation toolchain is considered credible based on the credibility framework.

6.2.2.7. Simulation Toolchain Assumptions, Known Limitations, and Uncertainty Quantification

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

6.2.2.7.2. The manufacturer shall provide information on:

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

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

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

6.2.2.7.4. 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.

6.2.2.8. Simulation Toolchain Scope

6.2.2.8.1. The manufacturer shall document the scope of each simulation toolchain and identify its limitations.

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

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

6.2.2.8.3. The manufacturer shall demonstrate that the test selection is sufficient to justify the claim that the simulation toolchain(s) can be used within the defined scope.

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

6.2.2.9. Simulation Toolchain Criticality Analysis

6.2.2.9.1. 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.

6.2.2.10. Simulation Toolchain Verification

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

6.2.2.11. Simulation Toolchain Code Verification

6.2.2.11.1. 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).

6.2.2.11.2. 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(s) shows unstable or unrealistic behaviour.

6.2.2.11.3. The manufacturer shall provide information on any sanity/consistency checking procedures that are used.

6.2.2.12. Simulation Toolchain Calculation Verification

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

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6.2.2.12.2 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.

6.2.2.13. Simulation Toolchain Sensitivity Analysis

6.2.2.13.1. 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.

6.2.2.13.2. 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.

6.2.2.13.3. 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 characterize the uncertainty of the overall simulation toolchain outputs.

6.2.2.14. Simulation Toolchain Validation

6.2.2.14.1. 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.

6.2.2.14.2. The manufacturer shall provide evidence that the simulation toolchain(s) results are consistent and correlated with the results of the physical tests.

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

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

6.2.2.14.5. 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.

6.2.2.14.6. 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.

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

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

6.2.2.14.7.2. 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);

d) integrated system validation (sensor model together with the environment model with influences form vehicle model).

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

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

6.2.2.14.10. 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.

6.2.2.14.11. The manufacturer shall demonstrate it has techniques to estimate each simulation toolchain's critical inputs.

6.2.2.14.12. 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.

6.2.2.14.13. The manufacturer shall provide evidence that a proper characterization of the uncertainty of the results of each simulation toolchain and its components, because of any assumptions therein, has been made.

6.2.2.14.14. The manufacturer shall demonstrate the that they have differentiated between the aleatory and epistemic uncertainties associated with each simulation toolchain.

6.2.3. Track testing

6.2.3.1. The manufacturer shall demonstrate that the facilities and environments used to conduct testing on tracks, proving grounds, and/or closed roads are suitable for the purposes of the testing.

6.2.4. Real-world testing

6.3. ADS Safety Case (based on ADS-05-06/Rev.2)

6.3.1. Safety Concept

6.3.1.1. The safety case shall describe each component of the ADS and any other vehicle systems that are relevant to meeting the requirements of this regulation.

6.3.1.1.1. The description shall include an outline schematic of the ADS illustrating the equipment distribution and the interconnections among the components and systems.

6.3.1.1.2. The outline shall include how the following elements are addressed:

(a) Perception and objects detection including mapping and positioning

(b) Characterisation of decision – making

(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., DSSAD)

(f) Redundancies of components and/or connections

6.3.1.2. The safety case shall outline the function of each component of the ADS.

6.3.1.2.1. The outline shall show the signals linking each function with other components or with other vehicle systems. This may be provided by a labelled block diagram or other schematic, or by a description aided by such a diagram.

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6.3.1.2.2. Interconnections within the ADS shall be shown by a circuit diagram for the electric transmission links, by a piping diagram for pneumatic or hydraulic transmission equipment and by a simplified diagrammatic layout for mechanical linkages.

6.3.1.2.3. The transmission links both to and from other systems shall be shown.

6.3.1.2.4. There shall be a clear correspondence between transmission links and the signals carried between components and systems.

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

6.3.1.3. Each component shall be clearly and unambiguously identifiable (e.g. by marking for hardware, and by marking or software identification for software content).

6.3.1.3.1. This will provide a clear method for identifying the hardware and software in the associated documentation.

6.3.1.3.2. Where the software version can be changed without requiring replacement of the marking or component, the software identification must be updated by means of the newly released software.

6.3.1.3.3. Where functions are combined within a single control unit or within a single computer, but shown in multiple blocks in the diagram, then for clarity and ease of explanation, only a single hardware identification marking shall be used.

6.3.1.3.3.1. The identification defines the hardware and software version and, where the software changes and alters the function of the unit, the identifier associated with that software shall also be changed.

6.3.1.4. The manufacturer shall provide information regarding the installation options that will be employed for the individual components that comprise the sensing system.

6.3.1.4.1. 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.

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

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

6.3.1.5. A list of all input and sensed variables 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.

6.3.1.6. A list of all of the ADS output variables 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.

6.3.1.7. The manufacturer shall demonstrate how their SMS processes with regards to functional and operational safety with regards to risk identification, risk analysis, risk evaluation, risk treatment

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(including acceptance) and keeping the risk assessments up to date have been applied to the ADS according to [SMS section 5.6 Risk Management and SMS section 5.7 Design and Development Process].

Text from the SMS (ADS-05-13): Any operational risk identified in the product shall, where appropriate, have mitigations implemented. The ADS manufacturer shall then be able to show the link between the overall risk management process, the mitigations, and the resulting operational risks.

6.3.1.8. The manufacturer 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 functional and operational safety (e.g. redundancies),

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

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

6.3.1.9. The manufacturer shall describe measures taken to assure the cybersecurity of the ADS and the analysis performed to identify and disposition likely security threats. Where UN R 155 applies, the manufacturer shall describe how the ADS meets the requirements of that regulation.

6.3.1.10. The manufacturer shall document measures it has implemented to prevent or deter abuse or misuse of the ADS or its occupants which may normally be performed by a driver. (e.g. unauthorised persons attempting to access a vehicle with occupants, occupant attempting to access driving controls, objects placed on vehicles during operation, attempts to damage a vehicle).

6.3.1.11. [Software updates & Safety Case updates as per 6.1.5.2]

6.3.1.12. The manufacturer shall demonstrate that software updates are validated and confirmed in accordance with SMS section [6.1.5.5] [UNR156].

6.3.1.13. The manufacturer shall describe the following aspects of the data storage system:

(a) Storage location and crash survivability,

(b) Data recorded during vehicle operation and occurrences,

(c) Data security and protection against unauthorized access or use, and

(d) Means and tools to carry out authorized access to data.

6.3.1.14. The safety case provided by the ADS manufacturer 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.

6.3.1.15. The manufacturer shall document how it has defined the Operational Design Domain for the ADS feature and the boundaries within which it is designed to operate. The manufacturer shall document how the ADS determines the presence/absence of the conditions and any linked/dependent conditions (e.g. reduced speed in icy weather). This shall include at least the following characteristics:

(a) Road speed limits,

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(b) Road type and roadway characteristics,

(c) Intended area of operation (e.g. Jurisdictions),

(d) Any geographic limitations,

(e) Environment (e.g. Weather conditions, surroundings), and

f) Road conditions.

6.3.1.16. The manufacturer shall describe the conditions that the driving automation 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.

6.3.1.17. The manufacturer will explain the type of use(s) for which the ADS is intended, such as personal car ownership, urban taxi fleet, goods transportation, highway use, etc.

6.3.1.18. The manufacturer shall document:

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

(b) The conditions that trigger an ADS fallback response,

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

(d) The conditions which may prompt the user to voluntarily take back control, if applicable

6.3.1.19. The manufacturer shall identify the other road users with whom it is designed to interact.

6.3.1.20. The manufacturer shall identify the ADS users, including remote users with whom it is designed to interact.

6.3.1.21. The manufacturer shall describe the methods of activating, overriding, or deactivating the ADS feature by any or all of: the ADS user (where relevant), the remote assistant or operator (where relevant), passengers (where relevant) or other road users (where relevant).

6.3.1.22. The manufacturer shall describe the range of end states constituting a minimal risk condition that can be achieved by the ADS feature. This shall include:

a) The conditions which may trigger an attempt to reach a minimal risk condition,

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

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

6.3.1.23. The manufacturer shall describe how the ADS detects and responds to approaching and crossing of ODD boundaries. This shall include strategies to limit sudden ODD exits and frequent activation/deactivation situations.

6.3.1.24. The manufacturer shall describe how the ADS feature responds to failure situations, including:

(a) Fallback (or fail safe) operation using a partial system,

(b) Redundancy using separate systems,

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

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(d) Removal of some or all automated driving function(s),

(e) Failure of a vehicle system or component other than the ADS that precludes the ADS from performing the DDT.

6.3.1.25. If a partial performance mode of operation is used under certain fault conditions (e.g. in case of severe failures), The manufacture shall describe:

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

(b) the resulting ADS feature behaviour and capabilities (e.g. achievement of a minimal risk condition immediately), and

(c) the warning strategy to the driver/remote supervision centre (if applicable).

6.3.1.26. If a second (backup) means to realize the performance of the dynamic driving task is used, the manufacturer shall describe:

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

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

(c) the resulting limits of backup effectiveness.

6.3.1.27. If the chosen provision selects the removal of an ADS function, it shall be done in compliance with the relevant provisions of this regulation. In this case, all the corresponding output control signals associated with this function shall also be inhibited.

6.3.1.28. The manufacturer shall provide the following information as part of its safety case:

(a) Validation/verification plans including appropriate acceptance criteria,

(b) Analysis of coverage of the different tests and setting minimal ODD coverage thresholds for various metrics and includes ODD boundaries [reference to DDT Annex],

(c) Validation/verification results including evidence that the Validation targets (i.e., validation acceptance criteria) are met,

(d) Evidence that the scenarios tested provide reasonable coverage of the ODD,

(e) How it assesses that the validation methods are robust [reference to Credibility section],

(f) Scenario selection process is reasonably designed to provide reasonable coverage of the ODD and its boundaries, and

(g) Any comparisons drawn between the performance of an ADS feature and that of a manually driven vehicle reflect comparable vehicle categories (e.g. category M1 or category 1-1) and situations.

6.3.1.29. The manufacturer shall state how it has determined that the acceptance criteria it has used in its safety case is deemed to be sufficient, including

(a) Identification of metrics used in evaluating the safety case,

(b) Justification of the chosen acceptance criteria for those metrics, and

(c) The scoring/evaluation of the evidence in generating metrics.

Transmitted by the expert from Japan Document ADS-07-12

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6.3.2. Safety case

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

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

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

6.3.2.2. The safety case shall include claims, arguments and evidence that are understandable, logical, correct and robust and that demonstrate that:

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

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

(i) DDT requirements (5.1)

(ii) User Interactions (5.2)

(iii) Other Requirements (5.3)

6.3.2.3. The manufacturer shall provide the following summary information with regards to its safety case:

(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.

6.3.2.4. The manufacturer shall demonstrate through the safety case that the application of the SMS is suitable for managing ADS safety throughout the lifecycle of the system in accordance with [SMS section]

6.3.2.5. The manufacturer shall demonstrate through the safety case its ability to monitor the ADS over its lifetime in accordance with [ISMR section]

6.3.2.6. The manufacturer shall state relevant assumptions it has made in relation to claims, arguments and evidence.

6.3.2.7. The manufacturer shall demonstrate that the credibility of the simulation toolchain in accordance with" X" [Credibility section] and that the credibility of physical testing used for the generation of evidence with regards to safety have been assessed.

6.3.2.7.1. The manufacturer shall demonstrate that the approach to testing is suitable for the demonstration of the safety case and the compliance with performance/functional requirements.

6.3.2.8. There shall be at least one claim for each goal or regulatory requirement.

6.3.2.8.1. The manufacturer may create multiple sub-claims for a claim, 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.

6.3.2.9. 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.

Transmitted by the expert from Japan Document ADS-07-12

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6.3.2.10. Evidence supporting argumentation shall consist of test results or analysis (e.g. source code, engineering drawings, photographs, required documentation etc.) as appropriate.

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

6.3.2.10.2. 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.).

6.3.2.10.3. 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.

6.3.2.11. As part of the manufacturer's demonstration of compliance to [6.1.6.8 b)], the manufacturer shall review its safety case prior to certification/approval and is encouraged do so during the development process.

6.3.2.11.1. The reviewer(s) chosen for this internal review shall not be a significant contributor of the ADS design team and may be internal or external to the manufacturer.

6.3.2.11.2. 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

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

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

Text from the SMS (ADS-05-13): Any operational risk identified in the product shall, where appropriate, have mitigations implemented. The ADS manufacturer shall then be able to show the link between the overall risk management process, the mitigations, and the resulting operational risks.

6.4. Post-deployment Safety

6.4.1. The manufacturer shall report, as required by the relevant Authority, on the in-service safety performance of the ADS vehicle and provide confirmatory evidence of the audit results of the Safety Management System.

6.4.2. The reporting shall be carried out according to the laws applicable in each contracting party and according to the information available to the manufacturers.

6.4.3. The reporting shall include:

(a) Initial notifications

(b) Short-term reports

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(c) Periodic reports.

6.4.4. The manufacturer shall provide the short term and periodic reports to the relevant Authority in a report (according to reporting templates in the Annex X), that contains a summary and the information relevant to the requirements for reporting.

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

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

6.4.7. The following table provides the list of occurrences and safety relevant event to be reported by the manufacturer. For each occurrence and safety relevant event its relevance to the short-term and/or periodic reporting has been flagged.

Occurrences and safety relevant events	Reporting Type	
	Short-term	Periodic
1. Critical occurrences known to the manufacturer[1]	X	X
2. Noncritical occurrences		
Occurrences related to ADS operation outside its ODD	X	X
ADS failure to achieve a minimal risk condition when necessary	X	X
Occurrences related to Transfer of Control failure		X
Occurrences related to communication-related occurrences issues		X
Occurrences related to cybersecurity-related occurrences issues		X
Occurrences related to failure scenarios		X
Maintenance and repair problems to ADS and its components[2]		X
Occurrences related to unauthorized modifications		X
[Unknown scenarios encountered by the ADS]		X
Other Indications of failure to meet safety requirements	X	X
Occurrences related to safety-relevant performance issues constituting an unreasonable risk to safety.	X	X
3. Safety-relevant events		
Events where an activated ADS feature required interaction with a remote assistant to navigate a driving situation (if applicable)[3]		X
Fallback user unavailability (where applicable) [4]		X
Prevention of takeover under unsafe conditions (where applicable)[5]		X

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[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 This occurrence captures systematic problems due to a maintenance/repair/service action discovered during the ADS operations

3 This event does not cover remote driving, but rather events in which the ADS will require remote assistance to cope with very specific situations.

4 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 fall-back user available.

5 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.

6.4.8. [Initial notifications]

6.4.8.1. 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.

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

6.4.9. Short-term reporting

6.4.9.1. The manufacturer shall report on occurrences and safety-relevant events when at least one of the following is fulfilled:

(a) The ADS feature was active when the ADS vehicle was involved in the occurrence/safety-relevant events, or

(b) The ADS feature was active up to 30 seconds prior to the ADS vehicle experiencing the occurrence/safety-relevant events.

6.4.9.2. The manufacturer shall report on short term basis for the following occurrences:

(a) Indications of failure to meet requirements

(b) Critical occurrences known to the manufacturer where the ADS was involved

(c) Other occurrences listed in [reference annex of occurrences—template annex?]

(d) Other performance issues constituting an unreasonable risk to safety.

6.4.9.3. The manufacturer shall issue a short-term report within 30 days from the knowledge of the matter.

6.4.9.4. The manufacturer shall report in accordance to the short term template in Annex [X], as required by the relevant Authority, following the occurrences flagged under the “Short term reporting” in [5.7.3.14.]

6.4.10. Periodic reporting

6.4.10.1. The manufacturer shall undertake periodic reporting of safety-relevant events and occurrences to the relevant authority.

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6.4.10.2. 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. (e.g. assessment of safety relevant events)

(b) No inconsistencies have been detected compared to the ADS safety performance declared prior to market introduction. (e.g. assessment of occurrences)

(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.

6.4.10.3. 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.

6.4.10.4. The manufacturer shall report occurrences and safety relevant events in accordance with to the periodic reporting template in Annex X, as required by the relevant Authority, for the occurrences and safety relevant events flagged under “Periodic reporting” in [5.7.3.14.]

7. Compliance Assessment[26]

7.1. SMS Audit[27]

7.1.1. Objectives of the SMS audit

7.1.1.1. The documentation of the manufacturer’s safety management system shall be audited for compliance with the provisions under section 6.2.[28]

7.1.1.2. The audit of the manufacturer’s safety management system shall provide confirmatory evidence on the robustness of the manufacturer’s processes to manage safety risks and to ensure safety throughout the ADS lifecycle (development, production, operation and decommissioning).

7.1.1.3. 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.

7.1.1.4. The audit of the safety management system shall only 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.

7.1.2. The auditor shall verify that the manufacturer has used suitable and documented processes to derive behavioural competencies and scenarios that are ODD-relevant and are relevant to the ADS safety case.[29]

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[26] Anything regarding procedures for the independent assessment of the manufacturer’s documentation.
[27] Uniform procedures for verifying compliance of the manufacturer’s SMS with the requirements for documentation of the SMS.
[28] ADS-05-14: The auditor shall audit the manufacturer’s safety management system in respect to the requirements in the section 6.1. of this regulation.
[29] ADS-05-16.

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7.1.2.1. The auditor may refer to the methodology outlined in the Annex [ODD framework annex] as a suitable approach against which to review the approach adopted by the manufacturer.[30]

7.1.2.2. The auditor shall verify that the manufacturer's approach and processes to identify and generate scenarios:[31]

(a) covers the necessary nominal, critical and failure scenarios

(b) takes into account data driven, knowledge driven and stochastic approaches to systematically identify hazardous events and other occurrences used to develop scenarios

(c) properly maps and characterises the behaviour of all the elements included in the scenarios.

7.1.2.3. The auditor shall verify that the manufacturer has used sampling techniques when selecting parameters to be used in creating logical and concrete scenarios used as evidence supporting the ADS safety case to avoid the ADS being optimized for a set of known test cases.[32]

7.1.3. The auditor shall verify that the manufacturer has suitable processes, resources and competent personnel in place for the testing that has been undertaken to demonstrate the ADS safety case.

7.1.3.1. The auditor shall verify that the manufacturer has suitable processes and competent personnel to assess the behavioural competencies demonstrated by the ADS under each scenario against requirements for performance of the Dynamic Driving Task (DDT).[33]

7.1.3.2. The auditor verify that the manufacturer has suitable processes and competent personnel to assess the capability of the ADS to ensure the safety of users and their use of ADS vehicles.[34]

7.1.3.3. The auditor shall verify that the manufacturer has suitable processes in place to identify the set of scenarios to be tested via track-testing.[35]

7.1.3.4. The auditor 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 scenarios (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 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.[36]

7.1.4. [In-service monitoring and reporting]

7.1.4.1. [UNR] The Type Approval Authority or the Assessor in its behalf shall review the manufacturer's documentation to ensure the suitability of ISMR practices for the ADS under evaluation.

[GTR] The Assessor shall review the manufacture's documentation to ensure the suitability of ISMR practices for the ADS under evaluation.

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30 Ibid.
31 Ibid.
32 Ibid.
33 Ibid.
34 Ibid.
35 Ibid.
36 Ibid.

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7.1.4.2. 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

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

7.1.4.3. (UNR) The Type Approval Authority or the Assessor in its behalf shall evaluate the manufacturer's capability to monitor the ADS under evaluation as per the requirement listed in the X [Monitoring section].

(GTR) The Assessor shall evaluate the manufacturer's capability to monitor the ADS under evaluation as per the requirement listed in the X [Monitoring section].

7.1.4.4. (UNR) The Type Approval Authority or the Assessor in its behalf shall evaluate the manufacturer's approach/methods:

(a) To verify the safety performance of the ADS [documented in its Safety case] during the operation and

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

(GTR) The Assessor shall evaluate the manufacturer's approach/methods to verify the safety performance of the ADS [documented in its Safety case] during the operation and to ensure the effectiveness of their safety risk controls.

7.1.4.5. (UNR) The Type Approval Authority or the Assessor in its behalf shall verify and evaluate that the Manufacturer has a mechanism in place:

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

(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.

(GTR) The Assessor shall verify and evaluate that the Manufacturer has a mechanism in place:

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

(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.

7.1.4.6. 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) Evidence that the risk assessment, including residual risks, will be evaluated regularly through the information coming from the monitoring activities.

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(e) Evidence that the monitoring takes into account feedback and report from other sources than the ADS vehicle data

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

7.1.4.7. (UNR) The Type Approval Authority or the Assessor in its behalf shall evaluate the manufacturer's capability to report the occurrences and the safety relevant events during the ADS operation as per the requirement listed in the X [Reporting section].

(GTR) The Assessor in its behalf shall evaluate the manufacturer's capability to report the occurrences and the safety relevant events during the ADS operation as per the requirement listed in the X [Reporting section].

7.1.4.8. (UNR) The Type Approval Authority or the Assessor in its behalf shall evaluate the manufacturer approach/methods for reporting the occurrences and the safety relevant events experienced by the ADS during the operation and for assessing the cause of such events.

(GTR) The assessor shall evaluate the manufacturer approach/methods for reporting the occurrences and the safety relevant events experienced by the ADS during the operation and for assessing the cause of such events.

7.1.4.9. (UNR) The Type Approval Authority or the Assessor shall verify that the manufacturer utilizes the templates in the Annex X. (Note: Not all the data elements included in the template are mandatory. However, the assessor shall evaluate the rationale provided by the manufacturer when:

(a) not mandatory data are not included,

(b) not mandatory data will be included, but in a later stage

(GTR) The Assessor shall verify that the manufacturer utilizes the templates in the Annex X. (Note: Not all the data elements included in the template are mandatory. However, the assessor shall evaluate the rationale provided by the manufacturer when:

(a) not mandatory data are not included,

(b) not mandatory data will be included, but in a later stage.

7.1.4.10. (UNR) The Type Approval Authority or the Assessor shall evaluate the adequacy of the information that the manufacturer intends to use for the characterisation of the occurrences and the safety relevant events (e.g. data elements and metrics).

(GTR) The Assessor shall evaluate the adequacy of the information that the manufacturer intends to use for the characterisation of the occurrences and the safety relevant events (e.g. data elements and metrics).

[Post-deployment—Assessment of ISMR]

7.1.4.11. (UNR) The Type Approval Authority or the Assessor in its behalf shall receive confirmatory evidence that the information provided by the manufacturer during the ADS operations (e.g. Notification, short term and periodic reports) is in compliance with the 6.3* [Pre deployment assessment].

(GTR) The Assessor shall receive confirmatory evidence that the information provided by the manufacturer during the ADS operations (e.g. Notification, short term and periodic reports) is in compliance with the 6.3 [Pre deployment assessment].

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**Note: Not all the data elements included in the template are mandatory. However, the assessor shall evaluate the rationale provided by the manufacturer when:*

1) not mandatory data are not included,

2) not mandatory data will be included, but in a later stage

7.1.4.12. (UNR) The Type Approval Authority or the Assessor in its behalf shall review the information provided by the manufacturer on the ADS operations (e.g. Notification, short term and periodic reports):

(a) to receive confirmatory evidence on the ADS manufacturer's 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 variations of existing scenarios included in the Safety case' evidence.

(d) to ensure the effectiveness of the implemented corrective actions.

(GTR) The Assessor shall review the information provided by the manufacturer on the ADS operations (e.g. Notification, short term and periodic reports):

(a) to receive confirmatory evidence on the ADS manufacturer's 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 variations of existing scenarios included in the Safety case' evidence.

(d) to ensure the effectiveness of the implemented corrective actions.

7.1.4.13. (UNR) The Type Approval Authority or the Assessor in its behalf shall review 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.

(GTR) The Assessor shall review 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.

7.1.4.14. (UNR) The Type Approval Authority or the Assessor in its behalf shall ensure the confidentiality of IP-sensitive reported information in the short-term template.

(GTR) The Assessor ensure the confidentiality of IP-sensitive reported information in the short term template.

7.1.4.15. (UNR) The Type Approval Authority or the Assessor in its behalf, where necessary, may verify the information provided and, if needed, the Type Approval Authority or the Assessor in its behalf may require further investigations and evidence, including test, before closing the occurrence.

(GTR) The Assessor, where necessary, may verify the information provided and, if needed, the assessor may require further investigations and evidence, including test, before closing the occurrence.

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7.1.4.16. (UNR) If a serious safety risk is identified, the Type Approval Authority may recommend temporary safety measures, including immediately restricting or suspending the relevant operations via remote termination, and require actions to restore an acceptable level of safety as per the applicable laws.

(GTR) If a serious safety risk is identified, the Competent Authority may recommend temporary safety measures, including immediately restricting or suspending the relevant operations via remote termination, and require actions to restore an acceptable level of safety as per the applicable laws.

7.2. Testing Credibility Assessment

7.2.1. The assessor 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.[37]

7.2.1.1. The assessor shall verify that the physical testing (proving ground and/or public road) facilities and environment used by the manufacturer in the assessment of the safety case are suitable for the tests that are being conducted.[38]

7.2.1.2. The assessor shall verify that the simulation toolchain(s) used by the manufacturer in the assessment of the safety case is suitable for conducting virtual tests and in compliance with requirements listed in 6.2.2.[39]

7.2.1.3. The assessor shall assess the results of the tests for meaningfulness and consistency.

7.2.1.3.1. The assessor 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 are able to demonstrate the performance of the ADS:

(a) in nominal, critical and failure scenarios

(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.

7.2.2. The assessor shall review the manufacturer's use of the different test methods:[40]

(a) Virtual testing

(b) Track testing

(c) Real-world testing.

7.2.2.1. The assessor shall verify the suitability of the set of tests carried out as evidence to support the safety case, in particular in the terms of coverage and relevance.

7.2.3. Scenario coverage and selection

7.2.3.1. The assessor shall verify that the set of scenarios resulting from the manufacturer scenario generation and identification process is suitable to demonstrate the ADS safety case and are able to cover the space of reasonably foreseeable situations and conditions that the ADS will encounter during its real-world

[37] Duplicated in ADS-05-07 and ADS-05-16. Corresponds with para. 6.2.1.
[38] Duplicated in ADS-05-07 and ADS-05-16.
[39] ADS-05-16.
[40] Ibid.

operations. In particular the assessor shall verify that the set of scenarios selected as evidence to support the ADS safety case includes:[41]

(a) a sufficient number of situations in which the ADS approaches and crosses its ODD boundaries

(b) reasonably foreseeable scenarios that are not deemed to be preventable by the ADS (e.g. related to unsafe behaviour by other road users or to inappropriate infrastructural elements)

7.2.4. Virtual Testing Credibility Assessment

7.2.4.1. The assessor shall review the manufacturer's credibility framework to determine whether the simulation the toolchain(s) is suitable to undertake virtual testing.[42]

7.2.4.2. The assessor shall review the documentation and evidence supporting the manufacturer's claims.

a) A successful outcome of the assessment will be a confirmation that the claims of the manufacturer about the capability of the simulation toolchain(s), including its scope, are correct and that it can be used to perform the virtual testing as part of the ADS assessment.

b) The simulation toolchain(s) can only be used to undertake virtual testing once the credibility of the same has been established.

7.2.4.3. The assessor shall audit the information provided by the manufacturer and may request or carry out additional tests of the simulation toolchain(s) or physical tests. The outcome of the tests shall be reviewed and concerns or discrepancies shall be raised and reviewed with the manufacturer.[43]

7.2.4.4. The manufacturer shall provide an explanation of the discrepancies in the results. If the results from the simulation toolchain(s) do not sufficiently replicate the output of physical test or does not have sufficient scope the assessor shall inform the manufacturer.

7.2.4.4.1. The manufacturer shall conduct extra validation activity and resubmit their information for further assessment.

7.2.4.5. The assessor 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) and hence in the results in line with the requirements laid down in [6.2.2. virtual testing credibility].[44]

7.2.4.6. The assessor shall verify that any virtual test using simulation toolchain(s) containing stochastic elements has taken account of possible uncertainty in the results.[45]

7.2.4.7. The assessor shall verify that virtual testing has been used to vary test parameters and perform a large number of tests to support efficient scenario coverage including critical and unpreventable scenarios as well as low probability events.

7.2.4.8. The assessor shall review the evidence from virtual testing that is provided by the manufacturer to support the ADS safety case. In particular the assessor shall verify that the evidence from virtual testing shows that the ADS complies with the requirements laid down in [the DDT section 5.1.].

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41 ADS-05-16.
42 Duplicated in ADS-05-07 and ADS-05-16.
43 Duplicated in ADS-05-07 and ADS-05-16.
44 ADS-05-16.
45 Ibid.

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7.2.5. Track testing

7.2.5.1. The assessor shall verify that the results of track testing are consistent with the results of virtual testing executed considering the same scenarios in similar conditions.

7.2.5.2. The assessor shall review the evidence from track-testing that is provided by the manufacturer to support the ADS' safety case. In particular the assessor shall verify that the evidence from track testing shows that the ADS complies with the requirements of [the DDT section 5.1.].

7.2.6. Real-world testing

7.2.6.1. The assessor shall review the evidence from real-world testing that is provided by the manufacturer to support the ADS safety case. In particular the assessor shall verify that the evidence from real-world testing shows that the ADS complies with the requirements laid down in [the DDT section 5.1.].

7.2.6.2. The assessor shall verify that the results of real-world testing are consistent with the results of virtual testing and track-testing executed considering the same scenarios in similar conditions.

7.2.7. Confirmatory Testing (based on ADS-05-16)

7.2.7.1. The assessor shall review the documents and the evidence provided by the manufacturer to support their safety case claims. Once the assessor is satisfied with the safety case and the supporting evidence, they shall undertake their own testing using the various methods to confirm that the evidence provided by the manufacturer is representative.

7.2.7.2. The assessor shall use track testing to assess the performance of the ADS in a number of selected important nominal, critical, and failure scenarios.

7.2.7.2.1. Track testing shall be conducted on a testing ground that is part of, or suitably represents, the ODD of the ADS including its physical boundaries to verify that the ADS safely responds to [crossing] ODD boundaries, or that the ADS cannot be activated outside its ODD, where applicable.

7.2.7.2.2. Real-world variation shall be included in the test parameters instead of limiting the test parameters to standardised parameters, standardised test objects and standardised test environments. The test parameters shall therefore go beyond available standards but shall remain within the ODD of the ADS.

7.2.7.2.3. The test track, the test environment and the test objects may also be virtual elements part of a simulation toolchain, provided that the assessor is able to guarantee their credibility is in line with the requirements laid down in [6.2.2.] The ADS or the component being tested shall not be virtual elements or part of a simulation toolchain.

7.2.7.2.4. The test equipment, the test set-up, and the test environment, as well as alterations made to those, shall be recorded with sufficient detail to allow the tests to be reproduced.

7.2.7.2.5. The selection of scenarios to be conducted on a test track shall be appropriate to the ODD, where possible.

7.2.7.2.6. The behaviour of the ADS towards other road users shall be verified on a test track using several scenarios.

7.2.7.2.7. With regards to human factors, the human machine interaction shall be is tested with the ADS user(s) under different scenarios to ensure safe use of the ADS.

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7.2.7.2.8. For track testing a protocol shall be is developed containing minimum requirements that standardise how for 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).]

[7.2.7.2.9. The track tests shall be executed in line with the approach set out in Annex [].]

7.2.7.2.10. Information generated during the track test shall be used as additional data to validate the virtual tests by comparing an ADS' performance between a virtual test and a test track on the same scenario in line with the requirements laid down in [6.2.]

7.2.7.3. Real-world testing shall assess ADS compliance with performance requirements under nominal scenarios.

7.2.7.3.1. Real world testing shall always be conducted with other road users. Tests on public roads that are closed to other traffic shall be considered as track tests.

7.2.7.3.2. It is acknowledged that critical and/or failure scenarios may occur during real-world testing, but they generally shall not be tested on purpose.

7.2.7.3.3. In case such scenario would occur, it shall not be excluded from the assessment.

To the extent that an ADS encounters critical or failure situations during a real-world test drive, the response of the ADS, including exceptions to the nominal performance requirements, shall be considered by the assessor in conjunction with the outcomes of track and virtual testing.

7.2.7.3.4. Real world testing shall be done safely. It is therefore required, if applicable to the ADS use case, that the test supervisor has the possibility to end the real world test at any point. In addition, it is also required that any inappropriate behaviour observed and/or the reason for the forced end is investigated in detail later.

7.2.7.3.5. Real world testing is shall only be conducted if a minimum level of safety of the other road users on public roads and of in-vehicle users of the ADS can be ensured by considering the validation methods of simulation, audit, and track testing as well as the manufacturer's prior real-world testing of the ADS.

7.2.7.3.6. Real world testing shall be considered for assessing aspects of the ADS performance related to its capability to drive in real traffic conditions such as:

(a) Behavioural competencies

(b) Interactions with other road users

(c) Safe and anticipatory behaviour

(d) Smooth driving

(e) Capability to deal with dense traffic

(f) Maintaining flow of traffic, and

(g) Being considerate and courteous to other vehicles.

7.2.7.3.7 Real world testing shall be considered for assessing aspects of the ADS performance at some ODD boundaries (nominal and complex scenarios), i.e. is the system triggering transition demands to the driver when it is supposed to (e.g. end of the ODD, weather conditions). The same testing shall be used to confirm the performances related to human factors under these conditions

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7.2.7.3.8. Real world testing shall be considered for detecting issues that might not be well captured by track tests and simulation, such as perception quality limitation (e.g. due to light conditions, rain, etc.).

7.2.7.3.9. Real world testing shall be considered for assessing aspects relating to human factors, such as user-initiated deactivation, system-initiated deactivation (not leading to a minimal risk condition), audibility of messages in real world conditions, if applicable to the ADS.

7.2.7.3.10. The environment and conditions of the selected test routes shall reflect the applicable ODD's environment and conditions. In addition, the selected test routes shall ensure that the ADS under test is expected to experience complex scenarios.

7.2.7.3.11. Real-world testing shall be developed in line with the approach set out in [Annex].

7.2.7.3.12. For real world testing a protocol shall be developed containing minimum requirements that standardise how for 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).

7.2.7.3.13. While the ADS is designed to perform the DDT only within the conditions represented by its ODD, it is recommended that real world testing shall assess the ADS both within its ODD and outside its ODD (e.g. to determine the ADS's appropriate recognition and response when not in its ODD) on public roads.

7.2.7.3.14. Although it may not be possible to encounter all traffic scenarios during a real-world test, the likelihood of covering specific complex scenarios could shall be increased by selecting a specific type of ODD (e.g., highway) and examining when and where specific elements (e.g., high- or low-density traffic) typically occur.

7.2.7.3.15. Specific infractions identified during real-world testing may shall be reviewed and/or assessed by evaluating the data gathered during that test and any data gathered during additional virtual, track and real-world testing.

7.2.7.3.16. Data generated during real-world testing may shall be used as additional data to validate whether portions of a virtual and/or track-testing environment were modelled properly by comparing an ADS' performance within a simulation and/or track test with its performance in a real-world environment when executing the same test scenario.

7.2.7.3.17. Data collected during real world tests shall be used to support the development of new traffic scenarios for track and virtual testing, allowing for the identification of edge cases and other unanticipated hazardous situations that could challenge the ADS.

7.2.7.3.18. The information gathered from real world testing shall also support improvements in the hazard and risk analysis and to the design of ADS.

7.3. Assessment of the Safety Case for the ADS[46]

7.3.1 [The safety case shall be assessed by an assessor, or team of assessors meeting [Competence & Independence] in order to determine if the Safety Case is complete and robust.

[46] Uniform procedures for assessing the manufacturer's documentation of the safety case for the ADS.

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7.3.2. [The assessor may request that the manufacturer provide supporting documentation, assist in repeating/reproducing evidence or subject the ADS to tests the assessor deems necessary for this task.]

7.3.3. [The assessor shall review the manufacturer's safety case for completeness ensuring that at least the following criteria have been met:

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

(b) each requirement in the regulation has been addressed by one or more claims,

(c) the cumulation of claims would yield a system absent of unreasonable risk,

(d) each claim is supported by one or more arguments,

(e) each argument is supported by a non-zero set of evidence,

(f) the manufacturer has documented metrics and acceptance criteria related to their claims].

7.3.4. [The assessor shall review the manufacturer's safety case for robustness ensuring that at least the following criteria have been met:

(a) All identified risks in the Safety Concept are either reduced, mitigated or accepted and the sum of risk (quantitative or qualitative) is below the unreasonable risk threshold,

(b) Testing evidence and the tools by which they are obtained achieve an acceptable level of credibility and demonstrate stability of performance when subjected to variations [As per Assessment of testing activities],

(c) [Acceptable mix of physical, track and virtual testing – as part of credibility? Manufacturer justification?],

(d) Evidence provided can be repeated and reproduced with consistency of safety objectives [As per [Verification] Testing],

(e) The manufacturer has justified that its evidence provides reasonable coverage of foreseeable operating conditions within the ODD of the system, and

(f) The manufacturer has conducted one or more self-assessments and has taken steps to remediate any findings.]

7.3.5. [The assessor shall prepare a report of its assessment in such a manner that allows traceability, e.g. versions of documents inspected are coded and listed in the records of the Assessor. The report shall include any identified discrepancies/gaps and remediations undertaken by the manufacturer.]

7.3.6. [The assessment shall be conducted by assessors with the technical and administrative knowledge necessary for such purposes. They shall be competent as assessor for ISO 26262-2018 (Functional

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Safety - Road Vehicles), and ISO/PAS 21448 (Safety of the Intended Functionality of road vehicles); and shall be able to make the necessary link with cybersecurity aspects such as those within UN Regulation No 155 and ISO/SAE 21434. This competence should be demonstrated by appropriate qualifications or other equivalent training records.]

7.3.7. [The assessment shall be conducted by assessors who:

(a) have not contributed to the development of the ADS system or it's safety case other than in an assessment capacity

(b) do not have financial incentives linked to the approval of the Safety Case

(c) do not report to the same director as the ADS development team]

7.4. Post-deployment safety

7.4.1 [UNR] The Type Approval Authority or the Technical Service in its behalf shall review the manufacturer's documentation to ensure the suitability of ISMR practices for the ADS under evaluation. "Assessor" is not a term used under the 1958. ECE/TRANS/WP.29/1059 uses the term "technical service".

[GTR] The Assessor shall review the manufacture's documentation to ensure the suitability of ISMR practices for the ADS under evaluation.

7.4.2 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.

7.4.3 (UNR) The Type Approval Authority or the Assessor in its behalf shall evaluate the manufacturer's capability to monitor the ADS under evaluation as per the requirement listed in the 6.1.5.

(GTR) The Assessor shall evaluate the manufacturer's capability to monitor the ADS under evaluation as per the requirement listed 6.1.5.

7.4.4 (UNR) The Type Approval Authority or the Assessor in its behalf shall evaluate the manufacturer's approach/methods:

(a) To verify the safety performance of the ADS [documented in its Safety case] during the operation and

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

(GTR) The Assessor shall evaluate the manufacturer's approach/methods to verify the safety performance of the ADS [documented in its Safety case] during the operation and to ensure the effectiveness of their safety risk controls.

7.4.5. (UNR) The Type Approval Authority or the Assessor in its behalf shall verify and evaluate that the Manufacturer has a mechanism in place:

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(a) To collect data from the vehicle and 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.

(GTR) The Assessor shall verify and evaluate that the Manufacturer has a mechanism in place:

(a) To collect data from the vehicle and 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.

7.4.6. 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) Evidence that the risk assessment, including residual risks, will be evaluated regularly through the information coming from the monitoring activities,

(e) Evidence that the monitoring takes into account feedback and report from other sources than the ADS vehicle data, and

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

7.4.7. (UNR) The Type Approval Authority or the Assessor in its behalf shall evaluate the manufacturer's capability to report the occurrences and the safety relevant events during the ADS operation as per the requirement listed in the 6.1.5 and 6.4.

(GTR) The Assessor in its behalf shall evaluate the manufacturer's capability to report the occurrences and the safety relevant events during the ADS operation as per the requirement listed in the 6.1.5 and 6.4.

7.4.8. (UNR) The Type Approval Authority or the Assessor in its behalf shall evaluate the manufacturer approach/methods for reporting the occurrences and the safety relevant events experienced by the ADS during the operation and for assessing the cause of such events.

(GTR) The assessor shall evaluate the manufacturer approach/methods for reporting the occurrences and the safety relevant events experienced by the ADS during the operation and for assessing the cause of such events.

7.4.9. (UNR) The Type Approval Authority or the Assessor shall verify that the manufacturer utilizes the templates in the Annex X. (Note: Not all the data elements included in the template are mandatory. However, the assessor shall evaluate the rationale provided by the manufacturer when:

(a) non-mandatory data are not included,

(b) non-mandatory data will be included, but in a later stage.

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(GTR) The Assessor shall verify that the manufacturer utilizes the templates in the Annex X. (Note: Not all the data elements included in the template are mandatory. However, the assessor shall evaluate the rationale provided by the manufacturer when:

(a) not mandatory data are not included,

(b) not mandatory data will be included, but in a later stage.

7.4.10. (UNR) The Type Approval Authority or the Assessor shall evaluate the adequacy of the information that the manufacturer intends to use for the characterisation of the occurrences and the safety relevant events (e.g. data elements and metrics).

(GTR) The Assessor shall evaluate the adequacy of the information that the manufacturer intends to use for the characterisation of the occurrences and the safety relevant events (e.g. data elements and metrics).

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Annexes[47]

Annex [] In-Service Reporting Templates

The reporting templates included in this annex aim at assuring the harmonization of the information to be reported and facilitating the information sharing. However, the reporting shall be carried out according to the laws applicable in each contracting party and according to the information available to manufacturer.

Short-term Reporting

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 short-term reporting scheme.

The data elements marked with an asterisk (*) represent information immediately available to the manufacturers and that shall be reported as part of the mandatory reporting requirements in 5.X.Y. It is advised that the remaining applicable data elements are made available to the relevant authority via collaboration with third-party stakeholders.

The data elements potentially containing intellectual property or sensitive data are marked with an "(IP/S)" indicator and shall remain confidential.

WHAT		
Entry name	*Field to be filled*	*Type/size*
Headline*		Text(200)
OCCURRENCE CLASSIFICATION*		
Occurrence/event class[48]		Text(50)
Occurrence/event type[49]		Text(200)
OCCURRENCE DETAILS		
Weather conditions*		Text(20)
Lighting conditions*		Text(20)
ADS vehicle pre-occurrence speed*		Number(3) – [km/h]
ADS vehicle post-occurrence max deceleration*		Number(3) – [m/s^2]
ADS vehicle estimated pre-occurrence mass		Number(5) – [kg]
ADS vehicle telematics provided*		[Y/N]

[47] Extensions of the above where useful to facilitate understanding and use of the regulations.
[48] Those can be: critical occurrence/non-critical occurrence. If deemed, the manufacturer can use the short term template also for safety-relevant events to make sure that Authority is informed about the nature of the event.
[49] Ref Table X

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[ADS vehicle EDR data provided]*		[Y/N]
[ADS vehicle DSSAD data provided]*		[Y/N]
ADS vehicle media provided[50]		[Y/N]
Third-party sources media/telematics provided		[Y/N]
Occurrence reported to the police		[Y/N]
Police report available		[Y/N]
[ADS feature type at occurrence]		Text(50)
(ADS) users available at occurrence		[Y/N]
[(ADS) users attempted takeover]		[Y/N]
WHEN*		
UTC date		[YYYY/MM/DD]
UTC time		[HH:mm]
Local date		[YYYY/MM/DD]
Local time		[HH:mm]
WHERE		
Country		Text(50)
State/Province		Text(50)
City		Text(50)
ZIP code (if applicable)		Number(10)
Street/Intersection		Text(50)
GNSS coordinates[51]* (IP/S)		[longitude, latitude] [Decimal degree]
Scenario within ODD*		[Y/N]
Speed limit at location*		Number(3) – [km/h]
Roadway type*		Text(50)
Roadway surface*		Text(50)
Roadway description*		Text(100)

[50] Those can include dash-cam or other recording systems
[51] GNSS coordinates, if available and applicable, can be used instead of country/state/city/ZIP/street localization.

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DAMAGE[52]		
Highest damage		Text(20)
ADS vehicle damage level		Text(20)
ADS vehicle damage location		Text(20)
Highest damage to other object		Text(20)
Object damaged (level)		Text(50)
		Text(50)
		Text(50)
		Text(50)

INJURY[53]		
Maximum Injury level		Text(50)
Total fatalities ADS vehicle		Number(3)
Total fatalities other road user		Number(3)
Injured road user type		Text(50)
Total serious injuries ADS vehicle		Number(3)
Total serious injuries other road user		Number(3)
Road user type		Text(50)
Total minor injuries ADS vehicle		Number(3)
Total minor injuries other road user		Number(3)
Road user type		Text(50)
Total unknown injuries ADS vehicle		Number(3)
Total unknown injuries other road user		Number(3)

VEHICLE		
Vehicle Identification Number* (IP/S)		Text(17)
Serial number (IP/S)		Text(50)
License plate (IP/S)		Text(10)

[52] Collision Deformation Classification (CDC) or the Vehicle Damage Index (VDI) shall be provided if applicable

[53] 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/)

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State/Country/Province of registry		Text(50)
Vehicle category*		Text(50)
Manufacturer*		Text(50)
Model*		Text(50)
Model Year*		Number(4)
Mileage		Number(9)
ADS version* (IP/S)		Text(50)
ADS licensing		Text(50)
Operator (if any)		Text(50)
Other ADS features type		Text(50)

NARRATIVE*	
Description of the event and post-crash behaviour[54]	
Post-crash behaviour	

ANALYSIS*	
Root cause analysis	
Corrective implementing action	

REPORT MANAGEMENT*		
Reporting entity		Text(100)
Report ID		Text(240)
Report version		Number(10)
Report status		Text(100)
Report date		[YYYY/MM/DD]

[54] If possible digital reconstruction files shall be provided (e.g. PC CRASH files, etc.).

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Parties informed		Text(100)

Periodic Reporting

The periodic templates provide a list of information with corresponding specifications that should be made available to the authority on a yearly basis.

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.

The data elements marked with an asterisk (*) represent information retrievable by the manufacturer on a periodic basis and that shall be reported as part of the mandatory reporting provisions in 5.X.Y. It is advised that the remaining applicable data elements are made available to the relevant authority via collaboration with third-party stakeholders.

ADS IDENTIFICATION*		
Entry name	Field to be filled	Type/size
ADS manufacturer		Text(50)
ADS licensing authority(ies) (if applicable)		Text(50)
ADS version		Text(50)
[ADS feature type]		Text(50)
Vehicle model		Text(50)
Model year		Text(50)
ADS OPERATION INFORMATION*		
Number of vehicles featuring ADS		Number(10)
Cumulative distance travelled by operational ADS		Number(10)
Cumulative time travelled by operational ADS		Number(10)
Average ADS time engagement		Number(10)
OCCURRENCES AND SAFETY RELEVANT EVENTS ASSESSMENT*		
Cumulative number of occurrences		Number(10)
Occurrences covered under the short-term reporting provisions		Number(10)
• Critical occurrences known to the manufacturer		Number(10)
• Occurrences related to ADS operation outside its ODD		Number(10)

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• ADS failure to achieve a minimal risk condition when necessary		Number(10)
• Other Indications of failure to meet safety requirements		Number(10)
• Occurrences related to safety-relevant performance issues constituting an unreasonable risk to safety.		Number(10)
Occurrences covered under the periodic reporting provisions		
• Occurrences related to Transfer of Control failure		Number(10)
• Occurrences related to communication issues		Number(10)
• Occurrences related to cybersecurity issues		Number(10)
• Occurrences related to failure scenarios		Number(10)
• Maintenance and repair problems to ADS and its components		Number(10)
• Occurrences related to unauthorized modifications		Number(10)
• Unknown scenarios encountered by the ADS		Number(10)
Safety relevant events covered under the periodic reporting provisions		Number(10)
• Events where an activated ADS feature required interaction with a remote assistant to navigate a driving situation (if applicable)		Number(10)
• Fallback user unavailability (where applicable)		Number(10)
• Prevention of takeover under unsafe conditions (where applicable)		Number(10)
OCCURRENCES SAFETY OUTCOME*		
Fatalities		Number(10)
• ADS vehicle occupants		Number(10)
• Other road users		Number(10)
Serious injuries		Number(10)

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• ADS vehicle occupants		Number(10)
• Other road users		Number(10)
Minor injuries		Number(10)
• ADS vehicle occupants		Number(10)
• Other road users		Number(10)
Unknown injuries		Number(10)
• ADS vehicle occupants		Number(10)
• Other road users		Number(10)
Accidents and serious incidents		Number(10)
Minor incidents		Number(10)
OCCURRENCES AGGREGATE DESCRIPTION*		
Collision with:		-
• Passenger car		Number(10)
• VAN		Number(10)
• Truck		Number(10)
• Bus		Number(10)
• Other: Vehicle		Number(10)
• Motorcycle		Number(10)
• Cyclist		Number(10)
• Pedestrian		Number(10)
• Other: VRU		Number(10)
• Animal		Number(10)
• Fixed object		Number(10)
• Unknown		Number(10)
• ADS vehicle damage level		-
• Destroyed		Number(10)
• Substantial		Number(10)
• Minor		Number(10)
• Unknown		Number(10)
ADS vehicle damaged area		-
• Front		Number(10)
• Front-left		Number(10)

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• Front-right		Number(10)
• Rear		Number(10)
• Rear-left		Number(10)
• Rear-right		Number(10)
• Left		Number(10)
• Right		Number(10)
• Top		Number(10)
• Bottom		Number(10)
• Unknown		Number(10)
ADS SAFETY GAP*		
ADS discovered safety gaps		Number(10)
Gap #1:		Text(500)
Gap #2:		Text(500)
ADS status of addressed safety gaps (if any)		Number(10)
Gap #1:		Text(500)
Gap #2:		Text(500)
ADS how safety gaps ~~are~~ have been addressed ~~and how~~		Number(10)
Gap #1:		Text(500)
Gap #2:		Text(500)
REPORT MANAGEMENT*		
Reporting entity		Text(100)
Report ID		Text(240)
Report version		Number(10)
Report status		Text(100)
Report date		[YYYY/MM/DD]
• Parties informed	•	• Text(100)