Consolidated working draft text for the ADS GTR and UN Regulation

The following table provides current draft provisions in the first column, proposals for revision and comments for consideration in the middle column, and the right column for noting discussion and/or outcomes during the session. Rows highlighted in yellow indicate proposals for amendments, questions or comments for discussion, and other matters requiring IWG attention and decision. Rows highlighted in blue and purple indicate major sections for ease in navigating the document. Links are provided for ease in navigating between related provisions.

Current Text	Proposals and comments	Session discussion and outcomes
1. Purpose		
	Versions differ. 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 Automated Driving Systems (ADS).	
2. Scope		
	Versions differ. GTR: This GTR applies to the ADS of vehicles of categories 1 and 2. UNR: This Regulation applies to the ADS of vehicles of categories M and N.	

3.	Definitions		
3.1.	*"Abstraction"* means a process of selecting relevant aspects of a source or referent system to be represented in a model or simulation.[1]		
3.2.	*"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]		
3.3.	*"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.		
3.5.	*"ADS vehicle"* means a vehicle equipped with an ADS.		
3.6.	*"Behavioural competency"* means an expected and verifiable capability of an ADS feature to operate a vehicle within the ODD of the feature.		

[1] Any modelling abstraction carries with it the assumption that it should not significantly affect the intended uses of the simulation tool.

[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.

3.7.	*"Closed-loop testing*" means testing in an environment in which actions of the ADS hardware, software, or other element(s) in the loop influence the actions of other objects in the simulation.[3]		
3.8.	*"Open-loop testing*" means testing in an environment in which the actions of the ADS hardware, software, or other element(s) in the loop do not affect the actions of other objects in the simulation.[4]		
3.9.	*"Stochastic*" means a process involving or containing a random variable or variables pertaining to chance or probability.	(Germany) Propose to delete. The document makes only use of the phrase "stochastic model". Shift this definition on "Stochastic" to "Model" having a subcategory "Stochastic model: means a model involving or containing a random variable or variables pertaining to chance or probability"	
3.10.	*"Driver"* means a human user who performs in real time part or all of the DDT and/or DDT fallback for a particular vehicle.		
3.11.	*"Dynamic Driving Task (DDT)"* means the real-time operational and tactical functions required to operate the vehicle.		

[3] For example, evaluating ADS interactions with other objects that respond to the actions of the ADS within a traffic model.
[4] For example, evaluating ADS interaction with a recorded traffic situation.

3.11.1.	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.		
3.11.2.	Sensing and perception include:		
	(a) Monitoring the driving environment via object and event detection, recognition, and classification.		
	(b) Perceiving other vehicles and road users, the roadway and its fixtures, objects in the vehicle’s driving environment and relevant environmental conditions.		
	(c) Sensing the ODD boundaries, if any, of the ADS feature.		
	(d) Positional awareness.		
3.11.3.	Planning and decision include:		
	(a) Predicting actions of other road users.		
	(b) Response preparation.		
	(c) Manoeuvre planning.		

3.11.4.	Control includes:		
	(a) Object and event response execution.		
	(b) Lateral vehicle motion control.	(Germany) Propose to merge b) and c) to "vehicle motion control" because b) and c) are not independent.	
	(c) Longitudinal vehicle motion control.		
	(d) Enhancing conspicuity via lighting and signalling.		
3.11.5.	The DDT excludes strategic functions.		
3.12.	*"Strategic function"* means a capability to issue commands, instructions, or guidance for execution by an ADS.[5]		
3.13.	*"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.[6]		
3.14.	*"Operational function"* means a capability to control the real-time motion of the vehicle.[7]		

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

[6] 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.

[7] 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.

3.15.	*"Edge Case*" means a **low-frequency** occurrence that might arise within the ODD of an ADS and warrants specific design attention due to the potential severity of outcomes that might result from encountering such a situation or condition ~~across a full-scale deployed fleet of such ADS vehicles~~.[8]	(Germany) Propose to replace "low-frequency" with "low-probability". (Germany) Propose to delete "across a full-scale deployed fleet of such ADS vehicles". "full scale deployed" remains unclear as a measure of exposure.	
3.16.	*"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.		
3.17.	*"Fallback user"* means a user designated to perform the DDT pursuant to an ADS fallback response.		
3.18.	*"Minimal Risk Condition (MRC)"* means a stable and stopped state of the vehicle that reduces the risk of a crash.	(Germany) Propose: *"Minimal Risk Condition (MRC)"* means a stable and stopped state of the vehicle in such a way that risks in traffic (e.g. collisions) are minimized to the extent possible.	
3.19.	*"Model*" means a description or representation of a system, entity, phenomenon, or process.		
3.19.1.	***"Stochastic model"* means a model involving or containing a random variable or variables pertaining to chance or probability.**	(Germany) Propose to add per the comments under 3.9. deleting "stochastic".	
3.20.	*"Model calibration*" means a process of adjusting numerical or modelling parameters in a model to improve agreement with a referent.		

[8] Examples include a unique road sign or an unusual animal type in the roadway.

3.21.	*"Model parameter"* means a numerical value inferred from real-world data and used to characterise a system functionality.	(Germany) *"Model parameter"* means a numerical value inferred from real-world data and used to represent a system characteristic.	
3.22.	"*Occurrence*" means a safety-relevant event involving an ADS vehicle.		

3.22.1.	"*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~~.[9]	(Germany) "Critical" and "Non-critical" occurrences necessarily need to be complementary. Because of this, the definition of non-critical occurrences might also be deleted.	
3.22.2.	"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 **occurrence** ~~event~~.	(Germany) Propose to replace "event" by "occurrence" for consistency.	
	(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 an airbag deployment.		

[9] Examples include minor incidents, safety degradation not preventing normal operation, emergency/complex manoeuvres to prevent a collision, and more generally all occurrences relevant to the safety performance of the in-service ADS (like transfer of control, interaction with remote operator, etc.).

3.23.	"*Operational Design Domain (ODD)*" means the operating conditions under which an ADS feature is specifically designed to function.		
3.24.	"*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.[10]		
3.25.	*"Other road user (ORU)"* means any entity making use of publicly accessible road infrastructure.		
3.26.	*"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~~.	(Germany) Avoiding misinterpretations. "A specified function" would need further specification.	
3.27.	*"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.		

[10] ODD conditions are distinct from ADS capabilities. An ADS may be designed to manage transient changes in the operating environment where such transient changes do not represent an ODD exit.

3.28.	*"Real time"* means the actual time during which a process or event occurs.		
3.29.	*"Road-safety agent"* means a **non-motorised** human being engaged in directing traffic, enforcing traffic laws, maintaining/constructing roadways, and/or responding to traffic incidents.	(Germany) Expecting that only "non-motorized" road users are being meant. Also the term "Road-safety agent" as it is stated here is currently not being used in any other instance of this document. If there will be no additions using term, it could be deleted.	
3.30.	*"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.		
3.31.	*"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.		
3.32.	*"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.		
3.33.	*"Simulation"* means the imitation of the operation of a real-world process or system over time.		
3.34.	*"Simulation toolchain*" means a combination of simulation tools that are used to support the validation of an ADS.		

3.35.	*"Test case specification"* means the detailed specifications of what must be done by the tester to prepare for the test.		

3.36.	*"Test method"* means a structured approach to consistently derive knowledge about the **performance of an** ADS by means of executing tests.[11]	(Germany) Performance based regulations. In general: We need to come back to para. 3.1.37 and subparagraphs once we have (re-) discussed/confirmed the corresponding requirements (in particular, DDT).	
3.37.	*"Traffic scenario"* means a description of a sequence of driving situations that may occur during a given trip.[12]		
3.37.1.	*"Nominal scenario"* means a traffic scenario representing usual and/or **expectable** ~~expected~~ objects, object behaviours and/or road conditions.	(Germany) "expected" might induce that the ADS must have expected the conditions. (Secy) Open issue: subjective—propose clarification based on alignment with Annex 3.	
3.37.2.	*"Critical scenario"* means a traffic scenario representing unusual and/or **unexpectable** ~~unexpected~~ objects, object behaviours, and/or road conditions.	(Germany) "unexpected" might induce that the ADS need not have expected the conditions. (Secy) Open issue: subjective—propose clarification based on alignment with Annex 3.	
3.37.3.	*"Failure scenario"* means a traffic scenario representing a system failure that compromises the capability of the ADS to perform the entire DDT.	(Secy) What is a "system failure"? Propose clarification based on alignment with Annex 3.	

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

[12] 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).

3.37.4.	*"Functional scenario*" means a basic traffic scenario describing a situation and its corresponding elements at the highest level of abstraction in natural, non-technical language.[13]		
3.37.5.	*"Abstract scenario"* means a formalized, declarative description of a scenario derived from a functional scenario.[14] The specification on the abstract level enables highlighting of the relevant aspects of the scenario while focusing on efficient description of relations (cause-effect).		
3.37.6.	*"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.[15]		
3.37.7.	*"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.		

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

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

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

3.37.8.	*"Complex scenario"* means a traffic scenario containing one or more situations that involve **of partly dependent parameters that must be taken into account by the ADS to determine the control execute the DDT of the ADS (e.g.,** a large number of other road users, unlikely road infrastructure, or abnormal geographic/environmental conditions**)**.	(Germany) Increase abstraction level. Extend proposal to include the entire DDT.	

3.38.	*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.	(Germany) Not applicable to any user.	
3.39.	*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 a vehicle **fallback** user.	(Germany) Not applicable to any user.	
3.40.	*"(ADS) User"* means a human user of an ADS vehicle.		
3.41.	*"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.		
3.42.	*"Validation of the 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** ~~the~~ intended uses ~~of the tool~~.	(Germany)	

3.43.	*"Verification of the 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.		
3.44.	*"Virtual testing*" means the process of testing a system using one or more simulation models.		
3.45.	*"Driver-In-the-Loop*" *(DIL*) means a driving simulator with components to enable the driver to operate in and communicate with the virtual environment and used to assess the human-automation interaction design.		
3.46.	"*Hardware-In-the-Loop*" (HIL) means the hardware of a specific vehicle subsystem running the software with input and output connected to a simulation environment to replicate sensors, actuators, and/or mechanical components in a way that connects all the I/O of the Electronic Control Units (ECU) before the final system is integrated.		
3.47.	*"Model-In-the-Loop*" (MIL) means high-level-of-abstraction software frameworks running on general-purpose computing systems to enable quick algorithmic development without involving dedicated hardware.		

3.48.	*"Software-In-the-Loop"* (SIL) means a methodology where executable code such as algorithms, an entire controller strategy, or a complete software implementation is assessed within a modelling environment on general-purpose computing systems.		
3.49.	*"Vehicle -In-the-Loop"* (VIL) means a fusion of real-world and virtual environments to assess the dynamics of a physical ADS vehicle on a vehicle test bed or a test track at the same level as real-world testing.		
4.	General requirements		
4.1.	Safety Management System		
4.2.	ADS performance of the DDT		
4.2.1.	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.	(OPI) Open item: Significant further discussion is required to explain what is meant by competent and careful human driver in this context	
4.2.2.	The ADS shall be capable of performing the entire Dynamic Driving Task (DDT) within the ODD of its feature(s).		
4.2.3.	New provision (based on guidelines text on "Scenario generation and behavioural competencies")	(OPI) Open item: Further discussion needed on this issue, particularly whether the use of behavioural competencies is mandated. Proposal: 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.	OPI: changed the reference to regulatory language to refer to the ODD Framework (Integration document Annex 3)

4.3.	ADS interactions with user(s)		
4.4.	Safety Assessment		

4.5.	In-Service Monitoring and Reporting	*(Reference ADS-03-09/Rev.1)*	
4.5.1.	The ADS's safety performance remains the responsibility of the manufacturer throughout the lifetime of the ADS.	(OPI) Proposal for changing the text (note: The proposed text requires discussion within the ADS IWG and with the ADS Workshop): *UNR:* While based on the documentation provided by the manufacturer and evidence resulting from testing by the TAA (or the TS acting on behalf of the TAA) the ADS is deemed to be free from unreasonable risk, the ADS's safety performance remains the responsibility of the manufacturer throughout the lifetime of the ADS. *GTR:* While based on the documentation completed prior to self-certification, the ADS is deemed to be free from unreasonable risk, the ADS's safety performance remains the responsibility of the manufacturer throughout the lifetime of the ADS. (Secy) 1. Reasons for workshop involvement unclear. Workshop mandate to address provisions unique to GTR or UNR. IWG mandate to develop common provisions and draft the GTR and UNR based on the common provisions with modifications where necessary. 2. GTR do not refer to specific regulatory frameworks (e.g., "self-certification"). 3. The defined term in the guidelines is "useful life of the ADS vehicle". 4. The provision states a principle rather than a requirement and should be rephrased (e.g., This Regulation establishes requirements to ensure safety throughout the useful life of the ADS vehicle. These requirements include [list of relevant subsections with cross-references].) "General requirements" is an overview and guide to the Regulation.	

4.5.2.	The manufacturer shall put in place a feedback loop (fleet monitoring) to confirm the safety argument and confirm the validation carried out by the manufacturer before market introduction.	(OPI) OPI: Proposal for changing the text (note: The proposed text requires discussion within the ADS IWG and with the ADS Workshop): *UNR*: The manufacturer shall put in place a feedback loop (fleet monitoring) to confirm the safety argument and confirm the validation carried out by the manufacturer ~~before market introduction~~ **the granting of the approval**. *GTR*: The manufacturer shall put in place a feedback loop (fleet monitoring) to confirm the safety argument and confirm the validation carried out by the manufacturer before ~~before market introduction~~ **the self-certification**. (Secy) See comments 1 and 2 under 4.5.1. 1. Is “feedback loop” the same as ISMR? 2. “Safety argument” undefined. Current definitions include to “safety concept” and “safety case”. 3. Is “validation” the same as “safety assessment” (e.g., para. 4.4.)?	

4.5.2.1.	This information shall 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.		
4.5.2.2.	This information shall enable the identification of unanticipated situations, risks, and hazards during real-world ADS operation, and this information shall be used to develop new scenarios.	(Canada) Open issue: Scenario characterization from ISMR data.	
4.5.2.3.	The manufacturer shall also put in place a mechanism that allows information from the ISMR and recommendations from its analysis to be shared with the relevant authority.	(OPI) Discussion on Relevant Authority could be needed.	
4.5.2.4. (Alt)	In this regard, ADS manufacturers shall collect and analyse the safety-relevant information related to their in-service ADS' operation and report data on safety related concerns, occurrences and performance metrics to the relevant authority (i.e. carry-out the In-Service Monitoring and Reporting (ISMR)). ADS manufacturers shall collect and analyse the safety-relevant information related to their in-service ADS' operation and report data that identifies situations which fall into the cases specified for short term and periodic reporting.	(OPI) Open Item, this point (others as well) is linked to Annex 10 of GRVA-19-15r1e "Consideration of data recording under ISMR and the activities of the EDR/DSSAD informal group" OPI: Discussion on Relevant Authority could be needed.	
4.5.3.	~~Before the deployment of the ADS, the manufacturer shall establish processes~~	(OPI) Propose to delete.	

	~~to demonstrate its capabilities to execute an effective ISMR.~~		

4.5.4.	The ISMR shall fulfil three main objectives: (a) Identify safety risks related to ADS performance that need to be addressed, including instances of non-compliance with ADS safety requirements. (b) Support the development of testable traffic scenarios through capturing information when the ADS does not perform safely in unanticipated situations. (c) Share information and recommendations to promote continuous improvement of ADS safety performance.		
4.5.5.	Manufacturers may be expected to collect data relevant to typical operations such as dealer reports, customer reports, etc. to complement the data that shall be collected and uploaded by the manufacturer from ADS vehicles.	(OPI) Data collected from other sources is an open item.	
ISMR specifications			

5.	Requirements/specifications		

5.1.	Safety Management System	*Source: ADS-03-03 (for 5.1.-5.1.7.8.)*	
5.1.1.	In respect of ADS, the manufacture shall have robust processes to manage safety risks and to ensure safety throughout the ADS lifecycle (development, production, operation and decommissioning). It shall include taking appropriate measures to monitor the vehicle during the in-service operation and to take the corrective remedial action when necessary.	(OPI) General Open Item 1: SMS typically targets "organisation". What does the word "organization" mean? Can be replaced with the word "manufacturer" or what else. Manufacturer and organization appear to have been used interchangeably. General Open Item 2: "May" or "Shall". "May" was used in the ALKS reg, so using it here in appropriate contexts is probably fine or not. General Open Item 3: References to ISO standards were all removed. We may not necessarily need to mandate them, but we need to find a suitable way to show the ISO standard as an example. (OPI)Proposal: *In respect of ADS, the manufacture shall ~~have~~ establish a SMS with robust processes to manage safety risks and to ensure safety throughout the ADS lifecycle (development, production, operation and decommissioning). ~~It shall include taking appropriate measures to monitor the vehicle during the in-service operation and to take the corrective remedial action when necessary~~*. The ISMR processed should be included in the SMS part in a dedicated requirement. (Secy) Should "ADS lifecycle" be defined (especially given "useful life of ADS vehicle" definition)? Relates to comment at para. 6.2.1.6.	

5.1.2.	An SMS is a systematic approach to managing safety, which encompasses and integrates organizational, 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; (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.	(OPI) Agreed that this part can be moved in the definitions section. About (a), Suggestion to change as : *…to identify risks and appropriate mitigation measures while accounting for the possibility of human errors*	

5.1.3.	An SMS incorporating all three factors to monitor and improve safety and helping to control the identified risks may be evaluated as adequate. The SMS evaluation may be based on automotive (or other industry) engineering standards, guidebooks, and best practice documents relevant to safety.	(OPI)Proposal: In case we remove the previous point, the 3 SMS factors are not mentioned anymore. So, we will suggest to change the text as: *"the SMS shall manage safety by considering organizational, human and technical risk factors."*	
5.1.4.	Safety Policy		
5.1.4.1.	It is required that a safety policy be included in the SMS to outline the aims and objectives that the organisation uses to achieve the desired safety outcomes. The policy shall declare the principles and philosophies that lay the foundation for the organisation's safety culture and be communicated to all staff throughout the organisation.	(OPI) General Open Item 1: SMS typically targets "organisation". What does the word "organization" mean? (OPI)Proposal: The text can be simplified, we suggest changing as: *"The safety policy shall outline the aims and objectives that the organization uses to achieve the desired safety outcomes."*	

5.1.4.2.	The manufacturer shall document following contents for the sake of implementing SMS: (a) Safety policies and principles (b) Organisation 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 organisation structure, processes, and work products onto the SMS; (d) Safety culture (e) Safety Governance elements including: (i) Management commitment (ii) Roles and responsibilities (f) Effective communications within the organization on safety issues (g) Information sharing outside of the organization (h) Quality Management System to support safety engineering, including change management, configuration management, requirement management, tool management etc.	(OPI) Paragraphs 5.1.4.2. to 5.1.7.8. are still under discussion within OPI.	

5.1.5.	Risk Management		
5.1.5.1.	It is required to 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 during the Design and Development phase. The ADS manufacturer shall then be able to show the link between the overall risk management process, the mitigations, and the resulting operational risks.		
5.1.5.2.	The manufacturer shall document its risk management processes and activities which may include the following aspects: (a) Risk identification (b) Risk analysis (c) Risk evaluation (d) Risk treatment (e) Processes for keeping the risk assessments up to date; (f) Review of safety performance of the organization and effectiveness of safety risk controls.		

5.1.6.	Design and Development Process		
5.1.6.1.	It is required that the design and development process is well established and documented in the SMS. It shall include risk management, requirements management, requirements' implementation, testing, failure tracking, remedial actions, and release management which may include 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.		

5.1.6.2.	The manufacturer shall document its processes and activities which may include the following aspects to ensure the robustness of the design and development phase; (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 operational safety, including the ongoing evaluation and update of risk assessments and interactions; (iv) Management of Human Factors (e.g. 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) The personnel involved in the design; (iv) The tools and thresholds adopted for the ADS safety verification.		
5.1.6.3.	It is required that the manufacturer institutes and maintains effective communication channels between the departments responsible for functional/operational safety, cybersecurity and any other relevant disciplines related to the achievement of vehicle safety.		

5.1.7.	Production and Deployment Process		
5.1.7.1.	It is required that the production process shall be well established and documented in the SMS. The manufacturer shall document its processes and activities which may include the following aspects to ensure the robustness of the development and the production phase; (a) Quality Management System accreditation (b) A description of the way in which the organisation performs all the production functions including management of working conditions, working environment, equipment and tools.		
5.1.7.2.	The manufacturer shall document its processes and activities which may include the following aspects to ensure the robustness of the development and distributed production; (a) Liaison between the vehicle and/or ADS manufacturer and all other organisations (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).		

5.1.7.3.	It is required that the manufacturer demonstrate that periodic independent internal audits and external audits are carried out to ensure that the processes established for the Safety Management System are implemented consistently.		
5.1.7.4.	It is required that the SMS include a robust process to ensure that post-deployment software updates are properly validated and distributed and downloading is confirmed.		
5.1.7.5.	It is required that the manufacturer 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 which may include 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.		

5.1.7.6.	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. The SMS shall be subject to a process of continual improvement. Any changes to SMS documentation shall be communicated as required to the relevant authority.		
5.1.7.7.	It is required that the SMS address measures to be taken to ensure ADS safety in the event of discontinued production, support, or maintenance of the ADS.		
5.1.7.8.	It is required that the manufacturer has 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.		

5.2.	ADS performance of the DDT		
5.2.1.	ADS Performance of the DDT under Nominal Traffic Scenarios		
5.2.1.1.	The ADS shall operate the vehicle at safe speeds.	(OPI) Open issue: Clarify meaning of "safe speeds".	
5.2.1.2.	The ADS shall maintain appropriate distances from other road users by controlling the longitudinal and lateral motion of the vehicle.		
5.2.1.3.	The ADS shall adapt its driving behaviour to the surrounding traffic conditions in order to avoid disruption to the flow of traffic.	(OPI) Open issue A: What should be done when nominal requirements conflict (e.g. other traffic is speeding and the ADS avoiding doing so would disrupt the flow of traffic)? Open issue B: Clarity on definitions of nominal and critical scenarios is needed to be clear which requirements apply (e.g. would the above scenario be critical?).	
5.2.1.4.	The ADS shall adapt its driving behaviour in line with safety risks.		
5.2.1.5.	The ADS shall detect and respond to objects and events relevant to its performance of the DDT;		
5.2.1.6.	The ADS shall detect and respond to priority vehicles ~~**in service**~~ in accordance with the relevant traffic law(s).	(OPI) Proposal to delete "in-service". Concept of "in service" is covered by the definition of priority vehicles (""Priority vehicle" means a vehicle subject to exemptions, authorizations, and/or right-of-way under traffic laws while performing a specified function.")	
5.2.1.7.	~~**Under nominal traffic scenarios, the driving behaviour of**~~ the ADS shall not force other road users to take evasive action to avoid a collision with the ADS vehicle.	(OPI) Proposal: *The ADS shall not force other road users to take evasive action to avoid a collision with the ADS vehicle.* Reference to nominal scenarios redundant as this is the	

		"nominal scenarios" section. Otherwise, remove unnecessary verbiage.	
5.2.1.8.	~~Under nominal traffic scenarios,~~ the driving behaviour of the ADS shall not cause a collision.	(OPI) Proposal: *The driving behaviour of the ADS shall not cause a collision.* Brevity.	
5.2.1.9.	The ADS shall comply with traffic rules in accordance with application of relevant law within the area of operation.		
5.2.1.10.	The ADS shall interact safely with other road users.		
5.2.1.11.	The ADS shall avoid collisions with safety-relevant objects where possible.	(OPI) Consider with para. 5.2.1.8.	
5.2.1.12.	The ADS shall signal intended changes of direction.	(OPI) Open item: Clarity required on whether this is talking about more than just indicators (if not then is it necessary given 5.2.1.9?)	
5.2.1.13.	The ADS shall signal its operational status in accordance with national rules.	(OPI) Clarity required on meaning, could use "if required by" to replace "with".	
5.2.1.14.	Pursuant to a passenger request under para. [7.5.5 a)], the ADS shall bring the vehicle to a safe stop.		
5.2.2.	ADS Performance of the DDT under Critical Traffic Scenarios		
5.2.2.1.	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 risk.		

5.2.2.2.	In the event of a collision, the ADS shall stop the vehicle in an MRC and/or in accordance with applicable traffic laws.	(OPI) Open item: Define collision thresholds, consider "in the event of a collision" is not specific to the ADS	
5.2.2.2.1.	The ADS shall not resume travel until: a) the safe operational state of the ADS vehicle has been verified, b) it is permissible under the applicable law / traffic rule(s), c) there are no other safety considerations.	(OPI) Grouped into one requirement to avoid inconsistent wording. (OPI) Open Item: Is b necessary given 5.2.1.9.? What other safety considerations does c refer to?	
~~5.2.2.2.2~~	~~The ADS may resume the trip where permissible under the applicable traffic rule(s) and other safety considerations.~~	(OPI) Merged into 5.2.2.2.1.	
5.2.3.	ADS Performance of the DDT under Failure Scenarios	(OPI) There should be a link from this section to the relevant safety concept section for failure analysis.	
5.2.3.1.	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 risk.		
5.2.3.2.	The ADS shall detect faults, malfunctions, and abnormalities that compromise its capability to perform the ~~entire~~ DDT within the ODD~~of its feature(s) per the manufacturer's documentation under Section [] above;~~	(OPI) ODD is not linked to documentation elsewhere. According to the definition 3.11.1 whenever DDT is mentioned it refers to the entire DDT so no need to specify here.[16]	

[16] 3.11.1.: 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.

5.2.3.3.	The ADS shall execute a fallback response in the event of a failure in the ADS and/or other vehicle system that prevents the ADS from meeting the requirements of this regulation ~~performing the DDT.~~	(OPI) Open Item: There are a variety of ways that the concept of the ADS being unable to perform the DDT anymore is described. Consistent language should be used.	
5.2.3.4.	The ADS may continue to operate in the presence of faults that do not prevent ~~that~~ the ADS from fulfilling the ~~safety~~ requirements of this regulation ~~applicable to the ADS~~;	(OPI) Open Item: There are a variety of ways that the concept of the ADS being unable to perform the DDT anymore is described. Consistent language should be used.	
5.2.3.4.1.	In response to a fault, the ADS may permit activation and use of a feature impacted by the fault provided that the ADS continues to provide the functions necessary to perform the entire DDT.	(OICA-CLEPA) Prefer this wording to the above 'meeting requirements of the regulation'.	
5.2.3.4.2.	The ADS shall adapt its performance of the DDT in accordance with the severity of the fault to ensure road safety.	(OPI) Open item: Some of the subpoints to 5.2.3.4 seem redundant, perhaps this requirement should be rewritten to avoid duplication	
5.2.3.4.3.	The limited operation of the ADS ~~should~~ shall comply with the ~~normally applicable safety~~ requirements of this regulation.	(OPI) Open Item: There are a variety of ways that the concept of the ADS being unable to perform the DDT anymore is described. Consistent language should be used.	
5.2.3.4.4.	The ADS shall prohibit activation of an ADS feature in the presence of a fault ~~in an ADS function~~ that compromises the ADS capability to comply with the requirements of this regulation. ~~perform the entire DDT within the ODD of the feature.~~	(OPI) Open Item: There are a variety of ways that the concept of the ADS being unable to perform the DDT anymore is described. Consistent language should be used.	
5.2.3.5.	Remote termination of individual or multiple ADS or feature(s) by the manufacturer and/or service operator		

	shall be possible when requested by Authorities.		
5.2.3.5.1.	Remote termination for an ADS performing the DDT shall ~~be capable of~~ trigger~~ing~~ an ADS fallback response.	(OPI) OPI: Open item: Should it be be capable of vs shall trigger? Consider connectivity issues.	
5.2.3.5.2.	Remote termination of an ADS or ADS feature(s) shall render ~~them~~ **it** unable to be activated by **a** user.		
5.2.4.	ADS Performance of the DDT at ODD Boundaries:		
5.2.4.1.	The ADS shall recognise the conditions and boundaries of the ODD of its feature(s) ~~pursuant to the manufacturer's description of the ODD as described under [Documentation requirement ref]Chapter 5.~~	(OPI) ODD will be defined in the documentation section.	
5.2.4.2.	The ADS shall be able to determine when the conditions are met for activation of each feature.		
5.2.4.3.	The ADS shall prevent activation of a feature unless the ODD conditions of the feature are met.		
5.2.4.4.	The ADS shall execute a fallback response when one or more ODD conditions of the feature in use are no longer met.		
5.2.4.5.	The ADS shall be able to anticipate **and safely respond to** foreseeable exits from the ODD of each feature.	(OPI) Without "respond" this is not requiring the ADS to do anything.	
5.2.5.	Minimal Risk Condition Requirements		
5.2.5.1.	The ADS shall signal its intention to place the vehicle in an MRC.	(OPI) Clarify does this refer to ORU?	

5.2.5.2.	In the absence of a fallback-~~ready~~ user, the ADS fallback response shall be to ~~fall back directly to an~~ place the vehicle in a MRC.	(OPI) Fallback-ready user is not a defined term.	
5.2.5.3.	If the ADS **feature** is designed to request and enable intervention by a **fallback user** ~~human driver~~, the ADS shall execute a fallback to an MRC in the event of a failure in the transition of control to the user;	(OPI) Open Item: It would be useful to have a term to refer to these systems without having to explain them every time, suggest this is covered by user group and TF AVC	
5.2.5.4.	Upon completion of a fallback to an MRC, a user may be permitted to assume control of the vehicle.		

5.3.	Interactions between users and ADS		
5.3.1.	General requirements		
5.3.1.1.	The ADS shall signal the presence of any failure that limits the operation of an available feature.		
5.3.1.2.	The ADS shall signal its intention to place the vehicle in an MRC to the ADS user(s).		
5.3.1.3.	An ADS that controls the operation of doors shall provide an emergency override to the user.		
5.3.1.4.	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.		
5.3.2.	ADS features that allow a user to take over manual control of the DDT		
5.3.2.1.	General requirements		
5.3.2.1.1.	The ADS shall be designed to prevent misuse and errors in operation by the user.		
5.3.2.1.2.	When the ADS is active, the vehicle driving controls, indicators, tell-tales, and DDT-related warnings may be disabled, suppressed, de-activated, inhibited or by other means made unavailable, as needed to mitigate the risk of errors in operation, misuse and reduce ambiguous states of vehicle control.		

5.3.2.1.3.	The vehicle controls dedicated to the ADS shall be clearly identified and distinguishable to accommodate only the appropriate interactions.[17]		
5.3.2.1.4.	While an ADS feature is active, it shall inform the user on: (a) ADS status information. (b) The role of the fallback user, if applicable. (c) Any failure of the ADS that limits the operation of an available feature. (d) The ADS shall indicate the availability of a feature for activation.	(OPI) Open issue with regards to system status (active, standby, on/off, engaged/disengaged).	
5.3.2.1.5.	**While active, features that have a system-initiated deactivation of** the ADS **to a fallback user** shall: (a) Continuously assess **through a user-monitoring system** whether the fallback user is available **and in a position to resume the role of driver**. (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.	(OPI) Proposal to amend the wording. (Secy) neutrality issue: "user-monitoring system" prescribes an additional system separate from the ADS and the proposal does not provide objective performance specifications for this system. To ensure neutrality, the proposal should provide performance requirements with a justification explaining how the requirements address the identified safety risk(s). The means to fulfil the requirements should be left to the manufacturer's discretion.	
5.3.2.2.	Requirements on ADS feature activation		

[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.

5.3.2.2.1.	The ADS shall ensure a safe ADS feature activation.		
5.3.2.2.2.	The ADS shall provide ~~immediate~~ **prompt** feedback to indicate success or failure when the user attempts to enable an ADS feature.	(OPI) Proposal to replace “prompt” by “immediate”.	
5.3.2.2.3.	The feature activation process (e.g., sequence of actions and states) shall take into account relevant recommendations or standards.		
5.3.2.2.4.	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 resume the DDT].**	(OPI) Proposal to introduce new wording.	
5.3.2.3.	Requirements on ADS feature deactivation to manual driving		
5.3.2.3.1.	A system-initiated deactivation in nominal situations shall be indicated in a timely manner to support the fallback user re-engaging to the driving task; **Where appropriate, the process (e.g, timing, levels of warnings) may be adapted according to the current circumstances (e.g., the engagement of the fallback user, the status of the ADS and vehicle, the current road traffic situation).**	(OPI) Consolidates wording of several paragraphs in the guidelines to combine all deactivation requirements and remove duplication and misalignment between the sections.	
5.3.2.3.2.	The ADS shall only allow the user to initiate a system deactivation process if the ADS verifies that the user is in a position to resume the role of the driver.		

5.3.2.3.3.	The ADS shall remain active until the system deactivation process has been completed **and the driver is in control** or the ADS vehicle reaches a minimal risk condition.	(OPI) Proposal to introduce new wording. (Scey) Subjectivity: what objective criteria would constitute "in control"?	
5.3.2.3.4.	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** ~~(e.g., due to the current situation being unsuitable or unsafe for the subsequent mode of operation)~~	(OPI) Proposal to introduce new wording and delete "e.g." example.	
5.3.2.3.5.	The ~~user initiated system~~ deactivation process (e.g., sequence of actions and states) shall take into account relevant recommendations or standards.	(OPI) Delete words.	
5.3.2.3.6.	The ADS shall assess the user is suitably engaged to resume the DDT before completion of the deactivation process.		
5.3.2.3.7.	The ADS shall provide a specific indication of the completion of the deactivation of the ADS.		
5.3.2.3.8.	At the completion of the deactivation process, control shall be returned to the driver without any continuous lateral or longitudinal control assistance active.[18~~19~~]	(OPI) Delete footnote.	

[18] ~~This provision may be changed pursuant to evidence from manufacturers demonstrating assurance of the safety of continuous control assistance pursuant to ADS deactivation~~.

5.3.2.3.9.	If applicable upon ADS deactivation, the vehicle controls, indicators, warnings, and tell-tales shall be set to an appropriate state for manual driving.		
5.3.2.3.10.	If applicable, ADS features operating control of closures shall no longer influence closures or the controls associated with closures.		
5.3.2.4.	ADS features that do not allow a user to take manual control of the DDT		
5.3.2.4.1.	The ADS shall provide the passenger(s) with means to request to stop the vehicle.		
5.3.2.4.2.	The ADS vehicle shall provide safety-related information to the passengers.		
5.3.2.4.3.	The ADS shall not initiate motion unless the safety risks to the passenger(s) have been mitigated.		
5.3.2.4.4.	The ADS may provide the user(s) with information related to ongoing operations (e.g., destination, upcoming stops, route progress).		
5.3.2.4.5.	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.		

5.4.	Safety Assessment		
5.4.1.	ADS general description		
5.4.1.1.	The safety case provided by the ADS manufacturer shall include a description of the ADS configuration and the intended uses and limitations on the use of its features, which gives a simple explanation of the operational characteristics of the ADS and ADS features: (a) Operational Design Domain (e.g., road speed limits, road type and roadway characteristics, country, environment, road conditions, etc.) and including the ODD conditions and boundaries of each ADS feature in measurable and/or verifiable terms; (b) Basic performance (e.g. Object and Event Detection and Response (OEDR), etc.); (c) Interactions with other road users; (d) Main conditions for achievement of a minimal risk condition; (e) Interaction with the driver (if relevant) including the transition of control procedures, ADS notifications and fallback user responses; (f) Supervision centre (if relevant); (g) The method of activating, overriding, or deactivating the ADS by any or all of: the ADS user (where relevant), the human supervision centre (where relevant), passengers (where		

	relevant) or other road users (where relevant).		
5.4.2.	Description of the functions of the ADS		
5.4.2.1.	A description shall be provided which gives a clear explanation of all the functions including control strategies of the ADS and the methods employed to perform the dynamic driving tasks within the ODD and the boundaries under which the ADS is designed to operate, including a statement of the mechanism(s) by which control is exercised. aA list of all input and sensed variables shall beis provided and the working range of these defined, along with a description of how each variable affects system behaviour. A list of all output variables which are controlled by the ADS shall be provided and an explanation given, in each case, of whether the control is direct or via another vehicle system. The range of control exercised on each variable shall be defined.		
5.4.3.	ADS Layout and Schematics		
	(a) Inventory of components A list shall be provided, including all the units of the ADS and mentioning the other vehicle systems which are needed to achieve the control function in question. An outline schematic showing these units and their relationships shall be provided, with both the equipment		

distribution and the interconnections made clear. The outline shall include: (i) Perception and objects detection including mapping and positioning (ii) Characterization of decision-making (iii) Remote supervision and remote monitoring by a remote supervision centre (if applicable). (iv) Information display/user interface (v) The data storage system (e.g., DSSAD).		
(b) Functions of the units The function of each unit of the ADS shall be outlined and the signals linking it with other units or with other vehicle systems shall be shown. This may be provided by a labelled block diagram or other schematic, or by a description aided by such a diagram. 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. The transmission links both to and from other systems shall also be shown. There shall be a clear correspondence between		

	transmission links and the signals carried between units. Priorities of signals on multiplexed data paths shall be stated wherever priority may be an issue affecting performance or safety.		
(c)	Identification of units Each unit shall be clearly and unambiguously identifiable (e.g. by marking for hardware, and by marking or software identification for software content). This will provide a clear method for identifying the hardware and software in the associated documentation. 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. Where functions are combined within a single control unit or indeed 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. 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.		

(d) Installation of sensing system components The manufacturer shall provide information regarding the installation options that will be employed for the individual components that comprise the sensing system. 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. The information shall also include installation specifications that are critical to the ADS's performance, e.g., tolerances on installation angle. Any changes to the individual components of the sensing system, or the installation options, shall be updated in the documentation.		
(e) ADS specifications: (i) Description of ADS specifications in nominal, critical, and failure situations, acceptance criteria and the demonstration of compliance with those criteria;		

(ii) List of applied regulations, codes, and standards		
(f) Maintenance and repair interface; protection against unauthorized access: (i) The ADS shall provide an interface for the purposes of maintenance and repair by authorized persons; (ii) The ADS shall be designed to protect against unauthorized access to and modification of the ADS functions; (iii) The measures ensuring protection from unauthorized access shall be provided in alignment with engineering best practices.		

5.4.4.	Safety Concept and Validation of the Safety Concept by the Manufacturer		
5.4.4.1.	The manufacturer shall provide a safety case that affirms and provides evidence to demonstrate that the ADS is free from unreasonable risks for the ADS vehicle user(s) and other road users. This shall include the safety concept, which describes measures designed into the ADS to achieve the goal of avoidance of unreasonable risk with regard to functional and operational safety. The safety case shall also includes a structured demonstration supported by evidence, including validation tests, that the ADS will be free from unreasonable risk. In respect of software employed in the ADS, the outline architecture shall be explained and the design methods and tools used shall be identified. The manufacturer shall show evidence of how the ADS capabilities were realized and checked during the design and development process.	(Secy) Related to comment at 6.2.1.6.	

5.4.4.2.	The safety concept element of the safety case shall provide an explanation of the design provisions built into the ADS to ensure functional and operational safety. Possible design provisions in the ADS include: (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; (d) Removal of some or all automated driving function(s).		
	If a chosen provision utilizes a partial performance mode of operation under certain fault conditions (e.g. in case of severe failures), then these conditions shall be stated (e.g. type of failure). The resulting ADS behaviour and capabilities shall be defined (e.g. achievement of a minimal risk condition immediately) as well as the warning strategy to the driver/remote supervision centre (if applicable). If the chosen provision selects a second (back-up) means to realize the performance of the dynamic driving task, the principles of the change-over mechanism, the logic and level of redundancy and any built-in back-up checking features shall be explained and the resulting limits of back-up effectiveness defined. If the chosen provision selects the removal of an automated driving 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.		

5.4.4.3.	The documentation shall be supported by an analysis which shows how the ADS will behave to mitigate or avoid hazards which can have a bearing on the safety of the ADS vehicle user(s) and other road users. It shall show how unknown hazardous scenarios will be managed by the manufacturer to keep the residual risk level under control. The chosen analytical approach(es) shall be established by the manufacturer and made available for assessment to the relevant authority before market introduction.		
5.4.4.4.	The auditor shall perform an assessment of the application of these analytical approaches, including:		
	(a) Inspection of the safety approach at the concept (vehicle) level;		
	(b) This approach shall be based on a Hazard/Risk analysis appropriate to system safety;		

(c) Inspection of the safety approach at the ADS level including a top down (from possible hazard to design) and bottom-up approach (from design to possible hazards). The safety assessment may be based on a Failure Mode and Effect Analysis (FMEA), a Fault Tree Analysis (FTA), a System-Theoretic Process Analysis (STPA) or any similar process appropriate to system functional and operational safety.	OPI: "…assessment ~~may~~ **shall** be based on a Failure Mode and Effect Analysis (FMEA)… OPI: … a System-Theoretic Process Analysis (STPA) or any similar process appropriate to system functional and operational safety **provided the appropriateness of this process is demonstrated**	

(d) Inspection of the documentation that demonstrates the validation/verification plans and results including appropriate acceptance criteria. It shall include testing appropriate for validation, for example, Hardware in the Loop (HIL) testing, vehicle on-road operational testing, testing with real end users, or any other testing appropriate for validation/verification. The auditor/assessor shall perform an assessment of the physical testing (proving ground and/or public road) environment and shall assess the documentation of the virtual tool chain provided by the manufacturer. The auditor/assessor may decide to carry out tests of the complete integrated tool to assess the credibility of the virtual tool chain. The documentation provided shall demonstrate adherence to and be in the form prescribed in Annex 5 or explain the basis for any deviation from the principles set out in Annex 5. Results of validation and verification may be assessed by analysing coverage of the different tests and setting minimal coverage thresholds for various metrics.	OPI: The auditor/assessor ~~may decide to carry out~~ **shall oversee** tests of…. OPI: Results of validation and verification ~~may~~ **shall** be assessed by analysing coverage of the different tests and setting minimal coverage thresholds for various metrics.	

5.4.4.5.	The documentation shall demonstrate that at least the following items have been covered where applicable:		
	(a) Issues linked to interactions with other vehicle systems (e.g., braking, steering)		
	(b) Failures of the automated driving system and the resulting risk mitigation strategy;		
	(c) Situations within the ODD when a system may create unreasonable safety risks to the ADS vehicle user(s) and other road users due to operational disturbances, for instance: (i) Lack of or wrong comprehension of the vehicle environment; (ii) Lack of understanding of the reaction from the driver the ADS vehicle user(s) or other road users; (iii) Inadequate control; (iv) Challenging scenarios;		
	(d) Identification of the relevant scenarios within the ODD boundaries and the methodology used to select scenarios and choose the validation methodology and approach;		
	(e) Decision-making process for the performance of the dynamic driving tasks (e.g. emergency manoeuvres), the interaction with other road users and the compliance with traffic rules;		

	(f) Cyber-attacks that may have an impact on the safety of the vehicle;		
	(g) Reasonably foreseeable misuse by the driver (if applicable) (e.g., the use of a driver availability recognition system and an explanation on how the availability criteria were established), mistakes or misunderstanding by the driver if applicable (e.g., unintentional override) and intentional tampering of the ADS.		
5.4.4.6.	The safety case shall include arguments and evidence supporting the implementation of the safety concept that is understandable and logical and cover all the different functions of the ADS. The documentation shall also demonstrate that validation measures are robust enough to demonstrate safety (e.g., reasonable coverage of chosen scenarios as part of the validation methodology chosen) and have been completed.		

5.4.4.7.	The documentation shall provide evidence that the vehicle is free from unreasonable risks to the ADS vehicle user(s) and other road users in the operational design domain. This may be achieved through:	OPI: This ~~may~~ **shall** be achieved through:	
	(a) Overall validation targets (i.e., validation acceptance criteria) supported by validation results demonstrating that entry into service of the ADS will not increase the overall level of risk to the ADS vehicle user(s) and other road users compared to manually driven vehicles within the ODD; and	OPI: manually driven vehicles within the ODD; and/**or**	
	(b) A scenario-specific approach showing that the ADS will not increase the overall level of risk to the ADS vehicle user(s) and other road users compared to a manually driven vehicles within the ODD for each of the safety relevant scenarios.		

5.4.4.8.	The safety case shall provide documentation sufficient to allow the relevant authority to verify through assessment of the case and possible testing by the authority that the manufacturer has successfully implemented the safety concept applicable to the ADS. The documentation shall itemizes the parameters being monitored on the vehicle and shall set out evidence supporting the argument that applicable safety requirements have been met. This documentation shall also describe the measures in place to ensure the ADS is free from unreasonable risks to the ADS user(s) and other road users when the performance of the ADS is affected by environmental conditions (e.g., climatic, temperature, dust ingress, water ingress, ice packing).		
5.4.4.9.	Information Provision to Users (as appropriate: owners, users, operators, etc.)	OPI: Propose to move provision to "User safety" section.	
	For the ADS users, documentation shall be provided that facilitates user understanding of the functionality and operation of the system covering at least:	OPI: For the ADS users, documentation **and delivery** ~~should~~ **shall** be provided ~~that facilitates~~ **to the users to facilitate** user understanding of….	
	(a) An operational description of the ADS features, capabilities, and limitations (the information should also refer to specific scenarios and/or ODD);		
	(b) Terms for 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;		
(d) A description of the roles and responsibilities of the driver/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;		
(h) Safety precautions and safety-relevant information for the user;		
(i) Information related to the HMI's indications: (i) Visual tell-tales, icons; (ii) Auditory signals; (iii) Haptic signals;		
(j) Safety measures to be taken in the event of malfunctioning of the ADS;		
(k) Extent, timing and frequency of maintenance operations;		

(l) Means to enable a periodical technical inspection	OPI: Means to enable a periodical technical inspection**, if applicable**	
(m) Documents and templates for maintenance, repair and periodical technical inspection;	OPI: Documents and templates for maintenance, repair and**, if applicable,** periodical technical inspection	
(n) Precautionary statements in the sense of compliance with limit values for the technical functions;		
(o) Data protection and data security functionalities.		

5.5.	Cybersecurity and software updates management		
5.6.	Data storage system		
5.7.	In service monitoring and reporting	*(Reference ADS-03-09/Rev.1)*	
5.7.1.	ISMR processes		
5.7.1.1.	Before the deployment of the ADS, the manufacturer shall establish processes to demonstrate its capabilities to execute an effective ISMR.	(OPI) Proposal (note: The proposed text requires discussion within the ADS IWG and with the ADS Workshop): *UNR:* ~~Before the deployment of the ADS,~~ **Before the granting of the approval,** the manufacturer shall establish processes to demonstrate its capabilities to execute an effective ISMR. *GTR:* ~~Before the deployment of the ADS,~~ **Prior to self-certification of the ADS,** the manufacturer shall establish processes to demonstrate its capabilities to execute an effective ISMR. (Secy) GTR do not refer to regulatory frameworks. Reason for workshop involvement unclear. In principle, a UN Regulation stipulates the requirements and testing to be conducted prior to granting an approval. This Regulation requires the manufacturer to have the ISMR capabilities in place as a condition for receiving an approval of the ADS. The ISMR provisions should be written within this context.	
5.7.1.2.	The ISMR processes shall be part of the SMS of the manufacturer.	(Secy) This provision means that ISMR is integral to the audit of the SMS (i.e., an SMS is not compliant with the Regulations if it does not satisfy the requirements for performing ISMR). The structure of the Regulations should reflect this.	

5.7.1.3.	The processes for ISMR shall demonstrate the capabilities: (a) To monitor critical and non-critical occurrences caused by the ADS. (b) To manage potential safety-relevant gaps during the in-service operation phase **and to update the ADS accordingly.** (c) To perform event investigation. (d) To report safety-relevant occurrences to the **relevant** authority when they occur. (e) To confirm the compliance with the defined safety case. (f) To share learnings derived from incidents and near-miss analysis. (g) To contribute to the continuous improvement of automotive safety.	(OPI) Discussion on Relevant Authority could be needed. (OICA/CLEPA) Open issue: "Near misses" (Secy) 1. For consistency, is the correct term "occurrence" rather than "event", "incident", etc.? 2. Undefined term/procedure: "near-miss analysis".	
5.7.1.4.	The manufacturer shall define appropriate key performance indicators (KPI) to measure the effectiveness of ISMR activities for the ADS operations.		
5.7.2.	In-service monitoring		
5.7.2.1.	The manufacturer ~~and (where applicable) the fleet operator~~ shall set up a monitoring program aimed at collecting and analysing vehicle data, and data from other sources.		

5.7.2.2.	The manufacturer shall provide evidence of the in-service safety performance of the ADS and confirmatory evidence of the audit results of the Safety Management System ~~requirements established by the Audit Pillar~~. (Note: The in-service monitoring is intended to be applicable to all individual ADS types, not to a subset selected by the manufacturer ~~or where applicable, by the fleet operator~~).	(Secy) 1. Please clarify requirements and intent. 2. "type" undefined and possibly term specific to UNR. 3. It might be clearer to stipulate the note as a requirement concerning the scope of ISMR such *as the manufacturer shall monitor the performance of its in-service ADS vehicles*.	
5.7.2.2.	The monitoring program shall include a data acquisition strategy, data retention strategy, data access, security and protection policy.	(OPI) included in the Open Item related to EDR/DSSAD	
5.7.2.2.1.	The data acquisition strategy shall ensure a representative collection of data to monitor the ADS in service performance.		
5.7.2.2.2.	The retention strategy shall ensure that the dataset is retained until the corrective action and review processes are complete. In addition, the strategy shall ensure the retention of the data for longer-term trend analysis (i.e. subset of the collected data).	(OPI) Discuss with EDR/DSSAD IWG.	
5.7.2.2.3.	The data access, security and protection policies shall ensure that information access is allowed only to authorised persons and contains safeguards to ensure the security and protection of the data.	(OPI) included in the Open Item related to EDR/DSSAD	

5.7.2.3.	The data monitoring program shall allow the manufacturer ~~and (where applicable) the fleet operator~~ to: (a) Identify areas of operational risk and quantify current safety margins (e.g. ~~in service safety performance monitoring~~ **safety performance indicator**). (b) Identify when the ADS prevents incidents/accidents (e.g., MRC fallbacks, collision avoidance, emergency manoeuvres). (c) Identify and quantify operational risks by collecting data to characterize and analyse occurrences. (d) Use metrics and thresholds to assess safety risks and discover trends that suggest the emergence of unacceptable risks ~~if that trend continues~~. (e) Put in place procedures for remedial action when an unacceptable risk is discovered or predicted by trends. (f) Confirm the in-service safety level and effectiveness of any remedial action.	(OPI) Proposal to amend.	

5.7.2.4.	The data monitoring program shall ensure that the data analysis is performed with sufficient frequency so that remedial action can be taken promptly and in line with reporting requirements.		

5.7.2.4.1. The analysis techniques shall comprise the following: (a) Routine measurements: a selection of parameters shall be collected to characterise ~~each~~ trip 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. (e.g. vehicle performance monitoring). (b) Exceedance detection: a set of core "value" shall be selected to cover the main areas of interest for the ADS operation with aim at searching for deviations from ~~vehicle~~ **safety** performance and limits. Typically, the main areas of interest are derived from the assessment of the most significant risks before the market introduction. However, they shall be continuously reviewed to reflect the current operations. (e.g., speed limits exceedance, near misses, harsh braking, etc.). (c) Occurrence analysis: ~~recorded data shall be able to characterize and investigate all the occurrences listed in the Annex 8.~~ (d) Statistics: Data Series shall be collected to support the analysis process with additional information. These data shall provide information to generate rate and trends. (e.g. driven km, operating hours).	(OICA/CLEPA) Open issue: "near misses" (0PI) Proposal to replace (c) with "**It shall be possible to characterise and investigate all the occurrences listed in this section using the recorded data.**"	

5.7.2.5.	The data monitoring programme shall identify KPIs to assure that the monitoring is performing at an optimal level, and address any issues affecting the effectiveness of the monitoring program ~~(e.g., data corruption or loss, or result in delayed or degraded event detection). Examples of KPIs for monitoring are trip collection rate, i.e. time between actual safety occurrence and detection of the occurrence (Date of detection of the occurrence by the In-service Monitoring – Date of the actual occurrence of the event)~~.	(OPI) Proposal to delete text.	
5.7.3.	Monitoring of performance		
5.7.3.1.	The monitoring of the ADS performance shall: (a) Provide evidence of in-service safety performance of the ADS **as per the objectives of the periodic reporting**. (b) Enable the identification of a drift or deviation from the ~~demonstrated~~ **declared** performance including the ones that end in an occurrence.	(OPI) OPI: Open Item-This point is linked to Annex 10 of GRVA-19-15r1e (Relationship between In-Service Monitoring and Reporting (ISMR) and the behavioural competencies demonstrated during the original ADS assessment).	
5.7.3.2.	Following the results obtained from the monitoring, the manufacturer shall evaluate: (a) In-service safety performance. (b) The adequacy of the metrics and thresholds. (c) Any remedial actions.		
5.7.4.	Reporting by the manufacturer		
5.7.4.1.	The manufacturer shall report, as required by the relevant authority, in accordance with this section ~~and the subsections~~		

	~~below on "Occurrence reporting" and "Tools for reporting".~~ Two types of reports on the in-service safety performance shall be produced. These are short-term and periodic.		
5.7.4.2.	Short term reporting of occurrences and safety concerns is required for matters of such safety importance that they may require the manufacturer to take remedial action, including: (a) Indications of failure to meet safety requirements. (b) Critical occurrence where the ADS was involved known to the ADS manufacturer or OEM. (c) Other safety-relevant performance issues.		
5.7.4.3.	~~At national level, there may be further requirements for immediate reporting/notification to the authority~~ **The manufacturer shall notify the relevant Authority as soon as practical about any critical occurrence the manufacturer becomes aware of or** in the event the ~~ADS~~ manufacturer becomes aware of a failure/defect which poses an immediate risk to public safety.	(OPI) Proposal for amended wording.	
5.7.4.4.	The manufacturer shall also undertake periodic reporting of performance metrics and occurrences to the ~~safety~~ **relevant** authority.	(OPI) Discussion on "relevant authority" could be needed.	

5.7.4.5.	The periodic report shall provide evidence of the in-service ADS safety performance. In particular, it shall demonstrate that: (a) No inconsistencies have been detected compared to the ADS safety performance declared prior to market introduction. (b) The ADS fulfils the performance requirements as evaluated in the test methods. (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 modifications made by the ADS manufacturer.**	(OPI) This point is linked to ADS performance of the DDT and ADS interactions with user(s) sections. OPI: This point is linked to Annex 7 of GRVA-19-15r1e "ISMR and safety requirements matrix". OPI: this requirement has been modified according to the proposal included in the GRVA-19-13e	
5.7.4.6.	During the **occurrence** investigation, the **relevant** authority shall be informed about the data processing (for example: filtering and conditioning) procedure and agree on the steps undertaken to deliver the data supporting the report.	(OPI) Discussion on "relevant authority" could be needed.	
5.7.3.7.	The **relevant** authority, ~~where necessary~~ **if deemed necessary**, may verify the information provided and, if needed, may make recommendations to the enforcement authority and/or to the ~~ADS~~ manufacturer to remedy any detected conditions constituting an unreasonable risk to safety.	(OPI) Discussion on "relevant authority" could be needed.	
5.7.3.8.	If a serious safety risk is identified, the ~~safety~~ **relevant** authority may recommend temporary safety measures, including immediately restricting or suspending the relevant operations, and require actions to restore an acceptable level of safety.	(OPI) Discussion on "relevant authority" could be needed.	

5.7.3.9.	The short term and periodic reports shall be made available~~, as required by~~ **to** the **relevant** authority, in two parts: (a) A report (according to **the reporting template in** Annex [x]), that contains a summary and the information relevant to the requirements for reporting. (b) The data underpinning the report, exchanged with the **relevant** authority by means of an agreed data exchange file.	(OPI) the template should be included in a dedicated annex to ensure harmonization and sharing of information OPI: Open item-This point is linked to Annex 10 of GRVA-19-15r1e "Consideration of ISMR templates and reporting from other stakeholders." (OPI) Discussion on "relevant authority" could be needed.	
5.7.3.10.	Short term reporting shall be submitted for each critical occurrence.		
5.7.3.11.	Short term reporting is due within one month of the manufacturer's knowledge of the matter. Short term reporting is needed to provide awareness of situations in which the ADS may be or is posing an unreasonable risk to safety in-service.		
5.7.3.12.	Manufacturers shall notify such concerns promptly upon their identification and to issue a report within 30 days form the knowledge of the matter.		
5.7.3.13.	The reporting scheme applies to automated vehicle features of an ADS which was active during a critical occurrence or up to 30 seconds prior to the critical occurrence.		
5.7.3.14.	Periodic reporting shall be submitted 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 (i.e., when ADS is activated).		

5.7.3.15.	The following is a list of occurrences ~~that have been derived from the ADS safety requirements~~ **to be reported by the manufacturer**. ~~It is recommended that these form the basis of the reporting requirements.~~ For each occurrence, its relevance to the short-term and/or periodic reporting has been flagged in the table below.		

Occurrence	Short term reporting [~~1 Month~~ **30 days**]	Periodic Reporting [1 Year]		
1) Occurrence related to ADS performance of the DDT				
1.a. ~~Safety~~ critical occurrences known to the ADS manufacturer or OEM	X	X	(OPI) Propose to delete word "Safety" and add footnote: "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."	
1.b. Occurrences related to ADS operation outside its ODD	X	X		
1.c. ADS failure to achieve a minimal risk condition when necessary	X	X		
1.d. Communication-related occurrences		X		
1.e. Cybersecurity-related occurrences		X		

1.f. ~~Interaction with remote operator if applicable~~		X	(OPI) Proposal to replace provision with "Events where an activated ADS feature required interaction with a remote assistant to navigate a driving situation (if applicable)" and annotate with footnote: "This occurrence does not cover remote driving, but rather events in which the ADS will require remote assistance to cope with very specific situations." (Secy) 1. "Events" or "occurrences"? 2. "required" unclear. 3. "interaction" unclear. 4. "remote assistant" undefined. 5. "navigate" unclear. 6. Is there a safety rationale for this provision?	
2) Occurrences related to ADS interaction with ADS vehicle users				
2.a. ~~Driver~~ **Fallback-user** unavailability (where applicable).		X	(OPI) Proposal to amend wording and add footnote: "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."	
2.b. Occurrences related to Transfer of Control failure		X		
2.c. Prevention of takeover under unsafe conditions **(where applicable)**		X	(OPI) Proposal to amend wording and add footnote: "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.”	
3.a. Occurrences related ADS failure		X		

3.b. Maintenance and repair problems **to ADS and its components.**		X	(OPI) Add wording.	
3.c. Occurrences related to unauthorized modifications		X		
~~3.d. Modifications made by the ADS manufacturer or OEM to address an identified and significant ADS safety issue~~	~~X (if the issue presented an unreasonable risk to safety)~~	~~X~~	(OPI) Proposal to delete.	
4. Occurrences related to the identification of new safety-relevant scenarios	(already covered under 1.a, 1.b, 1.c and 3,d)	X		
5.7.3.16. The reporting shall be carried out according to the laws applicable in each Contracting Party and according to the information available to the ~~reporting actors (~~manufacturers ~~and/or operators)~~.				
5.7.3.17. The short term template (Annex [x]) provides a list of information with corresponding specifications that shall be made available to the **relevant** authority following the occurrence of an event flagged under the "Short term reporting".			(OPI) Open Item, this point is linked to Annex 10 of GRVA-19-15r1e "Consideration of ISMR templates and reporting from other stakeholders." (OPI) Discussion on "relevant authority" could be needed.	

5.7.3.18.	In particular, the short-term reporting provisions shall contribute to identify: (a) Safety-relevant occurrences caused by an ADS. (b) Traffic situations unforeseen in the original validation that resulted in ADS behaviours inconsistent with the expected behavioural competencies. (c) ADS noncompliance with the ADS safety requirements. (d) Safety concerns in need of remedy.	(OPI) Text could be aligned with 8.5.2.2.2.	
5.7.3.19.	The information reported in the short term template will remain confidential.	(OPI) Further discussion on confidentiality is needed.	
5.7.3.20.	The periodic reporting template (Annex [x]) provides a list of information with corresponding specifications that shall be made available to the **relevant** authority on a yearly basis in accordance with the occurrences under the "Periodic reporting".	(OPI) Open Item, this point is linked to Annex 10 of GRVA-19-15r1e "Consideration of ISMR templates and reporting from other stakeholders." (OPI) Discussion on "relevant authority" could be needed.	
6.	Assessment and Test Methods		
6.1.	Audit		

6.2.	Virtual testing		
6.2.1.	Virtual testing credibility assessment	*(reference ADS-03-11)* (Secy) Current structure results in deep numbering.	
6.2.1.1.	Virtual testing uses different types of simulation toolchains to assess compliance of an ADS with safety requirements across a wide range of traffic scenarios, including some of which would be difficult (if not impossible) to reproduce in physical settings.		
6.2.1.2.	Having determined performance boundaries and identified situations involving ADS responses to manage conflicts and mitigate risks under the virtual testing, concrete test scenarios shall be defined for track testing based on the parameters of the corresponding virtual scenarios. Comparison of performance between a virtual test and a track test when executing the same scenario enables assessment of the accuracy of the virtual testing toolchain.		
6.2.1.3.	The auditor shall perform an assessment of the application of these analytical approaches, including:		

6.2.1.3.1.	Inspection of the documentation that shall demonstrate the validation/verification plans and results including appropriate acceptance criteria. It shall include testing appropriate for validation, for example, Hardware in the Loop (HIL) testing, vehicle on-road operational testing, testing with real end users, or any other testing appropriate for validation/verification. The auditor/assessor shall perform an assessment of the physical testing (proving ground and/or public road) environment and should assess the documentation of the virtual toolchain(s) provided by the manufacturer. The auditor/assessor shall carry out tests of the complete integrated tool to assess the credibility of the virtual toolchain. Results of validation and verification shall be assessed by analysing coverage of the different tests and setting minimal coverage thresholds for various metrics. See Annex 5-Appendix 1 for more information on the credibility assessment.		
	~~Types of simulation toolchain approaches~~		
	~~The simulation toolchain used for virtual testing may result in the combination of different approaches. In particular, there are many ways that tests can be performed:~~		

~~(a) Entirely inside a computer (referred to as Model or Software in the Loop testing, MIL/SIL), with the model of the elements involved (e.g., a simple representation of the control logic of an ADS) interacting in a simulated environment; and/or~~ ~~(b) With a sensor, a subsystem, or the whole vehicle interacting with a virtual environment (Hardware or Vehicle in the Loop testing, HIL/VIL). For VIL testing, the vehicle can either be in:~~ ~~(i) A laboratory where the vehicle would be standing still or moving on a chassis dynamometer or on a powertrain test bed and is connected to the environment model by wire or by direct stimulation of its sensors; or~~ ~~(ii) A proving ground where the vehicle would be connected to an environment model and would interact with virtual objects by physically moving on the test track.~~ ~~(c) With a subsystem interacting with a real driver (Driver in the Loop testing, DIL).~~		
~~Interaction between the system and the environment~~		
~~The interaction between the system under the test and the environment can either be an open- or closed-loop.~~		

~~In open-loop virtual testing a data provision unit provides input stimuli to an ADS. The data provision unit can provide data that was collected from a real-world drive or from a different data source. For example, data can be generated during a test using an environment simulator. In any case, the provided data establishes an environment for the ADS. Compared to closed-loop testing there is no feedback between the data provision unit and the ADS. As a common use case is the re-computation of recorded drives, open-loop testing is sometimes referred to as re-compute, replay or re-simulation. A useful property of open-loop testing is the inherent small gap between a virtual test and a corresponding collected real-world situation, as the open-loop test can be as realistic as the used collection mechanism allowed for, with, under ideal circumstances, no additional error introduced by the open-loop approach.~~		
~~Potential applications of open-loop testing include:~~ • ~~Regression tests for previously resolved issues as well as tests for newly introduced ADS features.~~ • ~~Re-validation of previously validated features, e.g., as part of the validation of an improved ADS, especially for features that have no associated functional change.~~ • ~~The testing of non-functional properties of the ADS. For example, evaluating scheduling or timing behavior of executables.~~		

~~In shadow mode testing, an ADS that is subject to testing is connected to a data provision unit. However, the ADS tested is not controlling the vehicle itself. Indeed, it has no effect on the state or behavior of the controlling unit of the vehicle. This approach enables realistic large-scale testing with a fleet of vehicles as test platforms. Since the ADS that is subject to testing has no effect on the vehicle, using a shadow mode can be categorized as open-loop testing.~~		
~~Closed-loop virtual tests include a feedback loop that continuously sends information from the "closed-loop" controller back to the ADS when the ADS takes an action. Within these test systems, the digital objects in the environment could react in different ways depending on the action of the system under test.~~		
~~Selecting an open- or closed-loop test could depend on factors such as the objectives of the virtual testing activity and the status of development of the system under test.~~		

~~The flexibility of simulation makes it a standard test method during a vehicle's design and the development of this pillar will also make it part of the ADS validation process. For an ADS, it will be impossible to test the vehicle's behaviour in the real world for all possible situations as well as for any subsequent change in the ADS' driving logic. Virtual testing will therefore become an indispensable tool to verify the capability of the automated system to deal with a wide variety of possible scenarios. In addition, virtual testing can be beneficial in replacing real world and proving ground testing where there are concerns over safety-critical traffic scenarios. It is recommended therefore that virtual testing be used to test the ADS under safety critical scenarios that would be difficult and/or unsafe to reproduce on test tracks or public roads.~~		
~~Virtual tests used for ADS validation can achieve different objectives depending on the overall validation strategy and the accuracy of the underlying simulation and models.~~ ~~(a) Provide qualitative confidence in the safety of the full system;~~ ~~(b) Contribute directly to statistical confidence in the safety of the full system (caveats apply);~~ ~~(c) Provide qualitative or statistical confidence in the performance of specific subsystems or components;~~ ~~(d) Discover challenging scenarios that can be tested in the real world.~~		

6.2.1.4.	In contrast to all its potential benefits, a limitation, of this approach, is in its intrinsic **potential** limited fidelity. As models provide a representation of the reality, the suitability of a model to satisfactorily replace the real world for validating the safety of an ADS has to be carefully assessed. Therefore, the validation of the simulation and models used in virtual testing is essential to determine the quality and reliability of the results compared to real-world performance.		
6.2.1.5.	A certain number of virtual tests of the ADS' performance shall be compared with its performance in the real world when executing the same scenarios. This will provide the opportunity to assess the accuracy of the virtual testing toolchain that is used. Given the high number of scenarios that virtual testing can perform compared to track testing, the validation will ~~probably~~ need to be performed on a ~~smaller but still~~ sufficiently representative subset of the relevant scenarios in order to substantiate any extrapolation beyond the scenarios used for the ADS' validation.		

~~In the short-term, virtual testing might only be conducted using simulation toolchains developed and maintained by the ADS manufacturer. Since their design depends on the validation and verification strategies implemented by the manufacturer, it is recommended that simulation toolchains are not subject to regulation or standardization at this time. Rather, simulation toolchains should be explained and documented by the ADS manufacturer and its suitability assessed during the certification process. For this reason, the output of the NATM related to virtual testing ensures that documentation and data provided by the manufacturer is appropriate. Furthermore, virtual testing using modelling and simulation should be credible enough for an assessor to make sound decisions. Credibility is discussed further below.~~		
~~It is recommended that when validating the safety of the ADS, particular attention should be placed on the interaction between virtual testing and the other test methods. Virtual testing will have strong relationships with all the pillars of the NATM guidelines. In particular:~~		

~~(a) Virtual testing supplements physical testing to account for the quantity and diversity of ADS configurations, intended uses and limitations on use. One of the strengths of virtual testing is its capacity to assess the ADS performance across multiple scenarios and across ranges of parameters within scenarios in a cost-effective manner. Virtual testing enables results of limited physical tests to be supplemented by verifiable data covering numerous instances of the test scenario, by varying parameters. Using this approach, virtual testing can demonstrate ADS coverage of safety-critical scenarios, and hence provide evidence that an ADS will perform as intended for that type of scenario in the real world. These advantages reduce the burden on physical tests (offsetting their weaknesses) and help to improve the efficiency of the overall assessment process across the pillars. Virtual testing can also be effectively used to identify and cover edge cases and other low-probability scenarios to increase confidence on the ADS' likely performances.~~		
~~(b) Virtual testing can play an important role in the development of traffic scenarios.~~		

~~(c) Virtual testing enables assessment of ADS performance boundaries, enabling precise definition of the boundaries between collision avoidance and crash mitigation. Through methods of randomization and scenario compositions, virtual testing enables the developer or the assessor to challenge the ADS and increase confidence in its performance when challenged with low probability events.~~		
~~(d) Virtual testing will be a key element in the audit assessment. Results of virtual testing carried out both during vehicle development and in the verification and validation phase will provide valuable evidence supporting the safety audit. The manufacturers will need to provide evidence and documentation about how the virtual testing is carried out and how the underlying simulation toolchain has been validated.~~		
~~(e) Results from real-world tests can improve the accuracy of simulation and models.~~		

~~(f) Virtual testing can play an important role in responding to concerns identified through in-use monitoring of ADS performance. Virtual testing provides a quick and flexible approach to analyse ADS performance based on real-world events. It allows manufacturers to understand and verify the ADS behaviour and to understand why an issue may have occurred. It may identify an untested scenario, or a set of untried parameters. It may also identify the "scale" of any issue. If the virtual testing does identify unsafe behaviour it can then also help to assess the efficacy of modifications to the ADS and ultimately to improve the overall ADS performance. Where appropriate, the information and scenario descriptions can be shared and integrated into scenarios and testing regimes worldwide.~~		
~~It is recognised that specific regulatory functional safety requirements are still under development. Virtual testing however, using a validated simulation toolchain, shows promise for assessing the following general safety requirements that are currently under consideration:~~		
~~(a) The ADS should drive safely and manage safety critical situations. These are the requirements where virtual testing can play a prominent role. MIL/SIL, HIL and VIL virtual testing can all be used to assess these requirements at different stages of vehicle verification and validation.~~		

	~~(b) The ADS should interact safely with the user. DIL virtual testing can be helpful to support the assessment of this category of safety requirement by analysing the interaction between the driver and the ADS in a safe and controlled environment.~~		
	~~(c) The ADS should safely manage failure modes and ADS should ensure a safe operational state. The use of virtual testing in these two categories is also very promising but would probably require further research work. SIL virtual testing could include simulated failures and maintenance requests. HIL and VIL virtual testing could be used to assess how the system would react to the occurrence of a malfunctioning induced into the real system.~~		
6.2.1.6.	Credibility assessment for using virtual toolchain in ADS validation	(Secy) Structure: Is this assessment an integral part of the SMS? This section has content on the management of virtual testing and on verifying that the evidence generated by virtual testing is credible for the purposes of validating compliance with the safety requirements. Para. 5.1.1. says that SMS concerns "processes to manage safety risks and to ensure safety throughout the ADS lifecycle (development, production, operation and decommissioning)". Para. 6.2.1.8.1. describes a "dynamic process" involving "management" of "frequent changes". Would maintaining the toolchains be relevant to ADS lifecycle safety? Would virtual testing be used in investigations of ISMR safety concerns?	

		Para. 5.4.4.1. of the Safety Assessment requires the manufacturer to "provide a safety case that affirms and provides evidence to demonstrate that the ADS is free from unreasonable risks for the ADS vehicle user(s) and other road users." Would virtual testing be a source of such evidence? Neither the SMS, Safety Assessment, nor ISMR requirements refer to virtual testing. Given the importance of virtual testing to the assessment of ADS performance, is this a gap?	
6.2.1.6.1.	Introduction, motivation, and scope		
6.2.1.6.1.1.	The use of ~~Modelling and Simulation (M&S) is becoming widespread thanks to the increasing computational capabilities, accuracy, usability, and availability of M&S software packages. M&S~~ **virtual testing** can be beneficial for ADS safety validation because it provides an opportunity to overcome some of the limitations of real testing and to increase the number of testing scenarios. Nonetheless, ~~M&S~~ **virtual testing** can also lead to erroneous/seemingly correct results, especially in relation to complex simulations not adequately supported by robust practices addressing all ~~M&S~~ **modelling and simulations** aspects beyond pure validation. Therefore, ~~higher~~ confidence in ~~M&S~~ **the** credibility **of the virtual** toolchain**(s) used for ADS assessment** is needed so that virtual testing can be used instead of and in conjunction with the other pillars. In other words, ~~M&S~~ **a virtual toolchain** can be used for virtual testing if an assessor is		

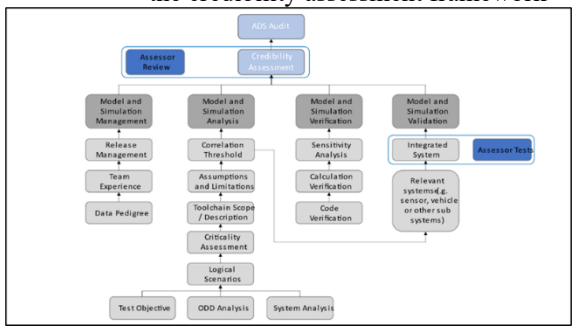
	able to consider the simulation results credible enough to make sound decisions taking into account the potential uncertainties of ~~M&S~~ **the same toolchain.**		
	~~If M&S is to be credible it needs to be validated. Validating the models and the simulation tools and process that make up M&S toolchain is difficult and there are limitations, which include the limited scope of the validation tests and the difficulty in gathering data to support the validation procedures. The use of M&S requires attention to all the factors influencing the quality and validity of M&S toolchain and all its separate components. The aim is to:~~		
	~~(a) Identify a common framework to determine, justify, assess and report the overall credibility of the M&S toolchain.~~		
	~~(b) Identify a way to indicate the levels of confidence in the results when a validation assessment takes place and also to determine the associated domains of applicability for the toolchain.~~		
	~~This framework should be general enough to be used for different M&S types and applications. Unfortunately, the goal is further complicated by the range and differences of ADS features and the variety of simulation tools and toolchains that are used. These considerations lead to the decision to use an (risk based/ informed) credibility assessment framework that can be applied to all M&S applications.~~		

~~The proposed credibility assessment framework provides a general description of the main aspects needed for assessing the credibility of an M&S solution toolchain together with guidelines of the role played by the relevant assessor in the validation process with respect to credibility. The assessor should investigate the documentation and evidence supporting credibility during the audit phase. It is understood that the actual validation tests will take place once there is sufficient evidence that a simulation tool or toolchain produces credible results.~~		
~~The outcome of the current credibility assessment will define the envelope in which the virtual toolchain can be used to support the ADS assessment.~~		
~~Components of the credibility assessment framework~~		

6.2.1.6.1.2.	~~The M&S~~ **A virtual** toolchain could be used for virtual testing if its credibility is established by evaluating its fitness for the intended purpose. It is recommended that credibility is achieved by investigating and assessing five ~~M&S~~ properties **of the virtual toolchain**: (a) Capability—What the ~~M&S~~ **virtual** toolchain can do, and what are the associated risks. (b) Accuracy—How well ~~M&S~~ **virtual** toolchain does reproduce the target data. (c) Correctness—How sound and robust is the ~~M&S~~ data and the algorithms in the tools. (d) Usability—What training and experience is needed and what is the quality of the processes that manage its use. (e) Fit for Purpose—How suitable is the ~~M&S~~ **virtual** toolchain for the assessment of the ADS within its ODD.		
6.2.1.6.1.3.	This framework should be general enough to be used for different ~~M&S~~ **virtual** toolchains types and applications. The goal is complicated by the range and differences of ADS features and the variety of simulation tools and toolchains that are used. A (risk-based/informed) credibility assessment framework that can be applied to all ~~M&S~~ **virtual** testing applications is therefore defined here.		

6.2.1.6.1.4.	The credibility assessment framework provides a general description of the main aspects considered for assessing the credibility of a virtual toolchain together with principles on the role of third parties assessors in the validation process with respect to credibility. The assessor shall investigate the documentation and evidence supporting credibility during the audit phase. It is understood that the actual validation tests will take place once there is sufficient evidence that a simulation tool or toolchain produces credible results.	(OPI) When referring to the assessor, the appropriateness for type-approval and self-certification shall be checked.	
6.2.1.6.1.5.	The outcome of the credibility assessment defines the envelope in which the virtual toolchain(s) can be used to support the ADS assessment.		
6.2.1.7.	Components of the credibility assessment framework and related documentation requirements		

6.2.1.7.1.	~~Therefore, credibility requires a unified method to investigate these properties and get confidence in the M&s results.~~ The ~~Credibility Assessment~~ **credibility assessment** framework introduces a way to assess and report the credibility of ~~M&S~~ **a virtual toolchain** based on quality assurance criteria that allow an ~~indication~~ **estimation** of the levels of confidence in results. In other words, the credibility is established by evaluating the ~~key~~ influencing factors that are **considered** the main contributors to the **performance of the virtual toolchain** ~~behaviour of the models and simulation tools~~ and therefore affect its overall ~~M&S toolchain~~ credibility: ~~The following all have an influence on the overall M&S credibility; organizational management of the M&S activity, team's experience and expertise, the analysis and description of the chosen M&S toolset, the pedigree of the data and inputs, verification, validation, uncertainty characterization.~~ How well each of these factors is addressed indicates the level of quality achieved by ~~M&S~~ **the** toolchain, and the comparison between the obtained levels and the required levels provides a qualitative measure of the ~~M&S's~~ **toolchain** credibility and fitness for its use in virtual testing. A graphical representation of the relationship among the components of the credibility assessment framework is reported in the following figure.		

Graphical representation of the relationships between the components of the credibility assessment framework 		
6.2.1.8. Models and Simulation Management	(Secy) Structure • Release management • Team management • Data management	
6.2.1.8.1. The ~~M&S~~ **toolchain** lifecycle is a dynamic process with frequent releases that shall be monitored and documented. Management activities shall be established to support the ~~M&S~~ **virtual toolchain(s)** through typical product management processes. Relevant information on the following aspects shall be provided.		

6.2.1.8.2.	The models and simulation management shall: (a) Describe the modifications within the ~~M&S~~ toolchain**(s)** releases. (b) Designate the corresponding software (e.g., specific software product and version) and hardware arrangement (e.g., XiL configuration). (c) Record the internal review processes that accepted the new releases. (d) Be supported throughout the full duration of the virtual testing utilization.	(Secy) Structure: this provision appears to describe requirements for release management.	
6.2.1.8.3.	Release management		
6.2.1.8.3.1.	Any **virtual** toolchain's version used to release data for certification purposes shall be stored. The virtual models constituting the testing tool**chain(s)** shall be documented in terms of the corresponding validation methods and acceptance thresholds to support the overall credibility of the toolchain. The developer shall establish and enforce a method to trace generated data to the corresponding toolchain version.		
6.2.1.8.3.2.	Quality check of virtual data. Data completeness, accuracy, and consistency shall be ensured throughout the releases and lifetime of a tool or toolchain to support the verification and validation procedures.		
6.2.1.8.4.	Team's Experience and Expertise	(Secy) This section appears to address management of the virtual testing personnel/organisation.	

6.2.1.8.4.1.	Even though Experience and Expertise (E&E) are already covered in a general sense within the organization, it is important to establish the basis for confidence on the specific experience and expertise for ~~M&S~~ **modelling and simulation** activities.		
6.2.1.8.4.2.	The credibility of the ~~M&S~~ **toolchain** depends not only on the quality of the simulation models but also on the E&E of the personnel involved in its validation and usage ~~of the M&S~~. For instance, a proper understanding of the limitations and validation domain will prevent possible misuse of the ~~M&S~~ **virtual toolchain** or misinterpretation of its results.		
6.2.1.8.4.3.	It is **therefore** ~~important~~ **necessary** to establish the basis for the ADS manufacturer's confidence in the experience and expertise of: (a) The teams that will internally assess and validate the ~~M&S~~ toolchain**(s)** and, (b) The teams that will use the validated ~~simulation~~ **toolchain** for the execution of virtual testing with the purpose of validating the ADS.		

6.2.1.8.4.4. **A proper management of the** team's E&E increases the level of confidence on the credibility of the ~~M&S~~ **virtual toolchain(s)** and its ~~results~~ **outcomes** by ensuring that the human elements underpinning the ~~M&S~~ **modelling and simulation** activities are taken into consideration and **any possible human component** risk~~s from the human aspect of the activity can be~~ **is** controlled~~, through its Management System~~.		
6.2.1.8.4.5. If the ADS manufacturer's toolchain incorporates or relies upon inputs from organizations or products outside of the manufacturer's own team, the ADS manufacturer shall provide an explanation of measures it has taken to manage and develop confidence in the quality and integrity of those inputs.		
6.2.1.8.4.6. The team's Experience and Expertise ~~includes~~ **consists of** two ~~aspects~~ **levels**:		
(a) Organizational level The credibility is established by setting up processes and procedures to identify and maintain the skills, knowledge, and experience to perform ~~M&S~~ **modelling and simulation** activities. The following processes shall be established, maintained and documented: (i) Process to identify and evaluate the individual's competence and skills. (ii) Process for training personnel to be competent to perform ~~M&S~~ **modelling and simulation**-related duties.		

(b) Team level Once a toolchain has been finalized, its credibility is mainly dictated by the skills and knowledge of the teams that will ~~first~~ validate ~~the M&S~~ **it** and then use it for the validation of ADS. The credibility is established by documenting that these teams have received adequate training to fulfil their duties.		
6.2.1.8.4.7. The ADS manufacturer shall: (a) Provide the basis for the ADS manufacturer's confidence in the Experience and Expertise of the individual/team that validates the ~~M&S~~ toolchain. (b) Provide the basis for the ADS manufacturer's confidence in the Experience and Expertise of the individual/team that uses the ~~simulation~~ **toolchain(s)** to execute virtual testing to validate the ADS.		
6.2.1.8.4.8. The ADS manufacturer shall demonstrate how it applies the principles of its Management Systems, e.g. ISO 9001 or a similar best practice or standard, with regard to the competence of its ~~M&S~~ organization and the individuals in that organization and the basis for this determination. The **independent** assessor shall not substitute its judgment for that of the ADS manufacturer regarding the experience and expertise of the organization or its members.		

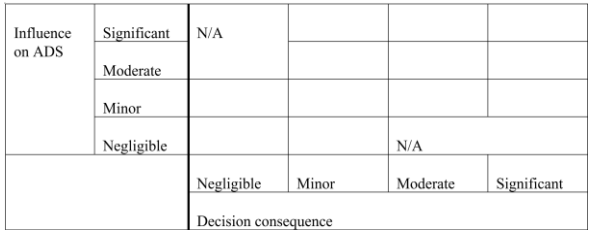
6.2.1.8.5.	Data/input pedigree		
6.2.1.8.5.1.	The **data/input** pedigree shall **contain a record of** traceability of the data and inputs used **by the manufacturer** in the validation of the ~~M&S~~ **toolchain**. ~~The manufacturer should have a record of these that allows the assessor to verify their quality and appropriateness.~~		
6.2.1.8.5.2.	Description of the data used for the ~~M&S~~ **toolchain** validation		
6.2.1.8.5.2.1.	The ADS manufacturer shall document the data used to validate the models included in the tool or toolchain and note important quality characteristics.		
6.2.1.8.5.2.2.	The ADS manufacturer shall provide documentation showing that the data used to validate the models covers the intended functionalities that the toolchain aims at virtualizing		
6.2.1.8.5.2.3.	The ADS manufacturer shall document the calibration procedures employed to fit the virtual models' parameters to the collected input data.		
6.2.1.8.5.3.	**The manufacturer shall quantify the** effect of the data quality (e.g. data coverage, signal to noise ratio, and sensors' uncertainty/bias/sampling rate) on model parameters uncertainty**. This will be an input to the** ~~The quality of the data used to develop the model will have an impact on model parameters' estimation and calibration. Uncertainty in model parameters will be another important aspect in the~~ final uncertainty analysis **of the virtual toolchain**.		

6.2.1.8.6. Data/output pedigree		
6.2.1.8.6.1. The **data/outp**ut pedigree **shall contain** ~~of the output data is important. The manufacturer should keep~~ a record of the **toolchain** outputs ~~of the M&S toolchain~~ **used for its validation** and ensure that it is traceable to the inputs and the ~~M&S~~ toolchain that produced it. ~~This will form part of the evidence trail for the ADS validation.~~		
6.2.1.8.6.2. Description of the data generated by the ~~M&S~~ **toolchain**		
6.2.1.8.6.2.1. The ADS manufacturer shall provide information on any data and scenarios used for virtual testing toolchain validation.		
6.2.1.8.6.2.2. The ADS manufacturer shall document the exported data and note important quality characteristics e.g. using the correlation methodologies.		
6.2.1.8.6.2.3. The ADS manufacturer shall trace ~~M&S~~ **the toolchain(s)** outputs to the corresponding ~~M&S~~ setup:		
(a) Effect of the data quality **on** ~~M&S~~ **toolchain** credibility: (i) The ~~M&S~~ **toolchain** output data shall be sufficient to ensure the correct execution of the validation exercise. The data shall sufficiently reflect the ODD relevant to the virtual assessment of the ADS. (ii) The output data shall allow consistency/sanity check of the virtual models, possibly by exploiting redundant information.		

	(b) Managing stochastic models (i) Stochastic models shall be characterized in terms of their variance. (ii) The use of a stochastic models shall not prohibit the possibility of deterministic re-execution.		
6.2.1.9.	~~M&S~~ **Toolchain(s)** Analysis and Description		
6.2.1.9.1.	The ~~M&S~~ **toolchain(s)** analysis and description aim to define the whole toolchain and identify the parameter space that can be assessed via virtual testing. It defines the scope and limitations of the models and simulation tools and the uncertainty sources that can affect its results.		
6.2.1.9.2.	General description		
6.2.1.9.2.1.	The ADS manufacturer shall provide a description of the complete toolchain along with how the ~~M&S~~ data will be used to support the ADS validation strategy.		
6.2.1.9.2.2.	The ADS manufacturer shall provide a clear description of the test objective.		
6.2.1.9.3.	Assumptions, known limitations, and uncertainty sources		
6.2.1.9.3.1.	The ADS manufacturer shall ~~motivate~~ **describe** the modelling assumptions which guided the design of the ~~M&S~~ toolchain. The ADS manufacturer shall provide evidence on:		

a)	How the manufacturer-defined assumptions play a role in defining the limitations of the toolchain		
(b)	The level of fidelity required for the simulation models.		
6.2.1.9.3.2.	The ADS manufacturer shall provide justification that the tolerance for ~~M&S~~ **toolchain** versus real-world correlation is acceptable for the test objectives.		
6.2.1.9.3.3.	Finally, this section shall include information about the sources of uncertainty in the model. This will represent an important input to final uncertainty analysis, which will define how the ~~M&S~~ toolchain outputs can be affected by the different sources of uncertainty of the ~~M&S~~ toolchain used.		
6.2.1.9.4.	Scope (it defines how the ~~M&S~~ **toolchain** is used in the ADS validation)		
6.2.1.9.4.1.	The credibility of virtual tool shall be enforced by a clearly defined scope for the utilization of the developed ~~M&S~~ toolchains.		
6.2.1.9.4.2.	The ~~mature M&S~~ **toolchain(s)** shall allow a virtualization of the physical phenomena to a degree of accuracy which matches the fidelity level required for certification. ~~Thus, the M&S environment will act as a "virtual proving ground" for ADS testing.~~		

6.2.1.9.4.3.	~~M&S~~ **The** toolchains need dedicated scenarios and metrics for validation. The scenario selection used for validation shall be sufficient to achieve confidence that the toolchain will perform in the same manner in scenarios ~~that were not included in~~ **outside of** the validation scope.		
6.2.1.9.4.4.	ADS manufacturers shall provide a list of validation scenarios together with the corresponding parameter description limitations.		
6.2.1.9.4.5.	The ODD analysis is a crucial input to derive requirements, scope and the effects that the ~~M&S~~ toolchain**(s)** must consider to support ADS validation.		
6.2.1.9.4.6.	Parameters generated for the scenarios will define extrinsic and intrinsic data for the toolchain and the simulation models.		
6.2.1.9.5.	Criticality assessment		
6.2.1.9.5.1.	The simulation models and the simulation tools used in the overall toolchain shall be investigated in terms of their impact in case of a safety error in the final product. The proposed approach for criticality analysis is derived from ISO 26262, which requires qualification for some of the tools used in the development process. In order to derive how critical the simulated data are, the criticality assessment shall consider the following parameters: (a) The consequences on human safety e.g. severity classes in ISO 26262; (b) The degree to which the ~~M&S~~ toolchain**(s)** results influence the ADS.		

6.2.1.9.5.2. The table below provides an example criticality assessment matrix to demonstrate this analysis. ADS manufacturers may adjust this matrix to their particular use case.		
Table 4. Criticality assessment matrix		
		
6.2.1.9.5.3. From the perspective of the criticality assessment, the three possible cases for assessment are: (a) Those models or tools that are clear candidates for following a full credibility assessment. (b) Those models or tools that may or may not be candidates for following the full credibility assessment at the discretion of the assessor. (c) Those models or tools that are not required to follow the credibility assessment.		

6.2.1.10	Verification		
6.2.1.10.	The **toolchain(s)** verification ~~of M&S~~ deals with the analysis of the correct implementation of the conceptual/mathematical models that create and build up the overall toolchain**(s)**. Verification contributes to the ~~M&S~~ **toolchain's** credibility via providing assurance that the individual tools will not exhibit unrealistic behaviour for a set of inputs which cannot be tested. The procedure is ~~grounded~~ **based** in a multi-step approach described below, which includes code verification, calculation verification and sensitivity analysis.		
6.2.1.10.1.	Code verification		
6.2.1.10.1.1.	Code verification concerns the execution of tests to demonstrate that no numerical/logical flaws affect the virtual models.		
6.2.1.10.1.2.	The ADS manufacturer shall document the execution of proper code verification techniques, e.g. static/dynamic code verification, convergence analysis and comparison with exact solutions if applicable.		

6.2.1.10.1.3.	The ADS manufacturer shall provide documentation showing that the exploration in the domain of the input parameters was sufficiently wide to identify parameter combinations for which the ~~M&S~~ **toolchain(s)** ~~tools~~ show unstable or unrealistic behaviour. Coverage metrics of parameters combinations ~~may~~ **shall** be used to demonstrate the required exploration of the model**s'** ~~behaviours~~ **performances**.		
6.2.1.10.1.4.	The ADS manufacturer shall adopt sanity/consistency checking procedures whenever data allows		
6.2.1.10.2.	Calculation verification		
6.2.1.10.2.1.	Calculation verification deals with the estimation of numerical errors affecting the ~~M&S~~ **toolchain(s)**. The ADS manufacturer shall document numerical error estimates (e.g. discretization error, rounding error, iterative procedures convergence). The numerical errors shall be kept sufficiently bounded to not affect validation.		

6.2.1.10.3.	Sensitivity analysis		
6.2.1.10.3.1.	Sensitivity analysis aims to quantify how model output values are affected by changes in the model input values and thus identify the parameters having the greatest impact on the ~~simulation model~~ **toolchain** ~~results~~ **outputs**. The sensitivity study also provides the opportunity to determine the extent to which the simulation model satisfies the validation thresholds when it is subjected to small variations of the parameters, thus it plays a fundamental role to support the credibility of the simulation results.		
6.2.1.10.3.2.	The ADS manufacturer shall provide supporting documentation demonstrating that the most critical parameters influencing the ~~simulation~~ **toolchain(s)** output**s** have been identified by means of **global** sensitivity analysis techniques ~~such~~ as by perturbing the model's parameters.		
6.2.1.10.3.3.	The ADS manufacturer shall demonstrate that robust calibration procedures have been adopted ~~and that this has identified and calibrated~~ **for assigning an appropriate value** to the most critical parameters, leading to an increase in the credibility of the developed toolchain.		
6.2.1.10.3.4.	Ultimately, the sensitivity analysis results will also help to define the inputs and parameters whose uncertainty characterization needs particular attention in order to characterize the uncertainty of the simulation results.		

6.2.1.10.4. Validation		
6.2.1.10.4.1. The quantitative process of determining the degree to which a model or a simulation is an accurate representation of the real world from the perspective of the intended uses of the ~~M&S~~ **toolchain**. The following elements shall be considered when **validating** ~~assessing the validity of a model or simulation~~ **the toolchain**:		
(a) Measures of Performance (metrics) The Measures of Performance are metrics that are used to compare the ADS's performance within a virtual test with its performance in the real world. The Measures of Performance are defined during the ~~M&S~~ **toolchain** analysis. Metrics for validation may include: (i) Discrete value analysis e.g. detection rate, firing rate. (ii) Time evolution e.g. positions, speeds, acceleration. (iii) Analysis of state changes e.g. distance/speed calculations, TTC calculation, brake initiation.		
(b) Goodness of Fit measures The analytical frameworks used to compare real world and ~~simulation~~ **simulated** metrics are generally derived as Key Performance Indicators (KPIs) indicating the statistical comparability between two sets of data. The validation shall show that these KPIs are met.		

(c) Validation methodology The ADS manufacturer shall define the logical scenarios used for virtual testing toolchain validation. They shall be able to cover, to the maximum possible extent, the ODD of virtual testing for ADS validation. The exact methodology depends on the structure and purpose of the toolchain. The validation may consist of one or more of the following:		
(i) Validate subsystem models e.g. environment model (road network, weather conditions, road user interaction), sensor models (Radio Detection And Ranging (RADAR), Light Detection And Ranging (LiDARs), Camera), vehicle model (steering, braking, powertrain).		
(ii) Validate vehicle system (vehicle dynamics model together with the environment model).		
(iii) Validate sensor system (sensor model together with the environment model).		
(iv) Validate integrated system (sensor model together with the environment model with influences from vehicle model).		
(d) Accuracy requirement The requirements for the correlation threshold are defined during the ~~M&S~~ **toolchain** analysis. The validation shall show that ~~these KPIs are~~ **the necessary accuracy is** met.		

(e) Validation scope (the part of the toolchain to be validated) A toolchain consists of multiple tools, and each tool will use several models. The validation scope includes all tools and their relevant models **that require validation**.		
(f) Internal validation results The documentation shall not only provide evidence of the ~~M&S~~ **toolchain** validation but also shall provide sufficient information related to the processes and products that demonstrate the overall credibility of the toolchain used. Documentation/results may be carried over from previous credibility assessments.		
(g) Independent Validation of Results The assessor shall audit the documentation provided by the manufacturer and ~~may~~ **shall** carry out tests of the complete integrated tool. If the output of the virtual tests does not sufficiently replicate the output of physical tests, the assessor ~~may~~ **shall** request that the virtual and/or physical tests to be repeated. The outcome of the tests will be reviewed and any deviation in the results shall be reviewed with the manufacturer. Sufficient explanation is required to justify why the test configuration caused deviation in results.		

(h) Uncertainty characterisation This section is concerned with characterizing the expected variability of the virtual toolchain results. The assessment shall be made up of two phases. In a first phase the information collected from the "~~M&S~~ **toolchain** analysis and description" section and the "data/input pedigree" are used to characterise the uncertainty in the input data, in the model parameters and in the modelling structure. Then, by propagating all of the uncertainties through the virtual toolchain, the uncertainty **in the toolchain output** ~~of the model results~~ is quantified. Depending on the uncertainty of the ~~model results~~ **outputs**, proper safety margins shall be introduced by the ADS manufacturer in the use of virtual testing as part of the ADS validation.		
(i) Characterization of the uncertainty in the input data The ADS manufacturer shall demonstrate they have estimated the model's critical inputs by means of robust techniques such as providing multiple repetitions for their assessment.		

(ii) Characterization of the uncertainty in the model parameters (following calibration). The ADS manufacturer shall demonstrate that when the critical parameters of a model cannot be fully determined they are characterized by means of a distribution and/or confidence intervals.		
(iii) Characterization of the uncertainty in the ~~M&S~~ **toolchain** structure The ADS manufacturer shall provide evidence that **a proper** ~~the modelling assumptions are given a~~ quantitative characterization ~~by assessing the generated~~ uncertainty **generated by the modelling assumptions has been performed** (e.g. comparing the output of different modelling approaches whenever possible).		
(iv) Characterization of aleatory vs. epistemic uncertainty The ADS manufacturer shall aim to distinguish between the aleatory component of the uncertainty (which can only be estimated but not reduced) and the epistemic uncertainty **(which instead cannot be reduced)** deriving from the lack of knowledge in the virtualization of the **physical** process.		

6.2.2.	Documentation structure		
6.2.2.1.	This section **sets out** will define how the ~~aforementioned~~ **above** information will be collected and organized in the documentation provided by the ADS manufacturer to the relevant authority.		
6.2.2.2.	The ADS manufacturer shall produce a document (a “simulation handbook”) structured using this outline to provide evidence for the topics presented.		
6.2.2.3.	The documentation shall be delivered together with the corresponding release of the toolchain and appropriate supporting data.		
6.2.2.4	The ADS manufacturer shall provide clear reference that allows tracing the documentation to the corresponding parts of the toolchain and the data.		
6.2.2.5.	The documentation shall be maintained throughout the whole lifecycle of the toolchain utilization. The assessor ~~may~~ **shall** audit the ADS manufacturer through assessment of their documentation and~~/or~~ by conducting physical tests.		
6.3.	Track		
6.4.	Real-World		
7.	Annexes		