Section from guidance document	**Text**	**Comments**
5.2-.5.3	[SMS section]	Elements from this section relate to Safety Assessment, will need to evaluate and coordinate
5.10	Safety Assessment of the ADS	
5.10.1	[removed]	Could be kept/shortened as introduction to section depending on final structure
5.10.2	ADS General Description	
5.10.2.1	~~It is recommended that t~~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).	
5.10.3	Description of the functions of the ADS	

5.10.3.1	A description ~~should~~ 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. ~~It is recommended that a~~A list of all input and sensed variables shall be~~is~~ 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~~should~~ 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~~should~~ be defined.	
5.10.4	ADS Layout and Schematics (a) Inventory of components A list shall~~should~~ 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 ~~should~~ shall be provided, with both the equipment distribution and the interconnections made clear. ~~It is recommended that t~~The outline shall include~~s~~: (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 ~~should~~ shall be outlined and the signals linking it with other units or with other vehicle systems shall~~should~~ be shown. This may be provided by a labelled block diagram or other schematic, or by a description aided by such a diagram. ~~It is recommended that i~~Interconnections within the ADS shall~~should~~ 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~~should~~ also be shown. There shall~~should~~ be a	

	clear correspondence between transmission links and the signals carried between units. Priorities of signals on multiplexed data paths shall ~~should~~ be stated wherever priority may be an issue affecting performance or safety. (c) Identification of units Each unit shall~~should~~ be clearly and unambiguously identifiable (e.g. by marking for hardware, and by marking or software identification for software content). This will~~should~~ 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. ~~It is recommended that w~~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~~should~~ 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~~should~~ also be changed. (d) Installation of sensing system components The manufacturer shall~~should~~ provide information regarding the installation options that will be employed for the individual components that comprise the sensing system. These options shall~~should~~ 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~~should~~ 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~~should~~ 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~~should~~ be provided in alignment with engineering best practices.	
5.10.4 (bis)	Safety Concept and Validation of the Safety Concept by the Manufacturer	
5.10.4.1	The manufacturer shall~~should~~ 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. ~~Part of the safety case is~~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. ~~In addition to this descriptive documentation, the~~The safety case shall also include~~s~~ 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~~should~~ be explained and the design methods and tools used shall~~should~~ be identified. The manufacturer ~~should~~shall show evidence of how the ADS capabilities were realized and checked during the design and development process.	
5.10.4.2	~~It is recommended that t~~The safety concept element of the safety case shall~~should~~ 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~~should~~ be stated (e.g. type of failure). The resulting ADS behaviour and capabilities	

	shall~~should~~ 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, ~~it is recommended that~~ 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 is recommended that this is~~it shall be done in compliance with the relevant provisions of this regulation. In this case, ~~A~~ all the corresponding output control signals associated with this function shall~~should~~ also be inhibited.	
5.10.4.3	The documentation shall~~should~~ 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 ~~should~~ 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~~should~~ be established by the manufacturer and made available for assessment to the relevant authority before market introduction.	
5.10.4.4	The auditor shall~~should~~ perform an assessment of the application of these analytical approaches, including: (a) Inspection of the safety approach at the concept (vehicle) level; (b) ~~It is recommended that t~~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~~ shall be based on a Failure Mode and Effect Analysis (FMEA), a Fault Tree Analysis (FTA), ~~and~~ a System-Theoretic Process Analysis (STPA) or any similar process appropriate to system functional and operational safety provided the appropriateness of this process is ~~;~~demonstrated; (d) Inspection of the documentation that ~~should~~ demonstrates the validation/verification plans and results including appropriate acceptance criteria. It ~~should~~ 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~~should~~ perform an assessment of the physical	Additional requirement added to (d) linking to current annex 5 – will need to point to correct section in final document

	testing (proving ground and/or public road) environment and shall~~should~~ assess the documentation of the virtual tool chain provided by the manufacturer. The auditor/assessor ~~may decide to~~shall oversee~~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 ~~See~~ Annex 5 ~~Appendix 1~~ or explain the basis for any deviation from the principles set out in Annex 5. ~~for more information on the credibility assessment.~~ Results of validation and verification ~~may~~ 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.~~	
5.10.4.5	~~It is recommended that t~~The documentation shall ~~confirms~~ demonstrate that at least each of the following items have been considered~~are 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.	
5.10.4.6	The safety case ~~should~~ 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~~should~~ 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.	
5.10.4.7	~~It is recommended that t~~The documentation shall provide~~s~~ 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 ~~could 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/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.	Dan: I believe this "could" was purposeful and intended not to be prescriptive in terms of having to provide evidence of meeting both aggregate targets and scenario-specific validation criteria. This was a huge debate in the EU reg context because the ODD-specific data needed for this comparison can be very hard to obtain and there is no consensus on what aggregate targets are appropriate for any given ODD. I have suggested a possible approach that retains the requirement for evidence in the first sentence but provides the option of providing evidence at either the aggregate level, scenario level, or both. J-M: In my view "may" could be useful in terms of interpretation but would then not be required. Would it be sufficient to keep it as "shall" with the and/or? Alternative may be to say "This shall be achieved through one or a combination of the following:" - we could also add additional options if required but we may run into issues if we give too much leeway for interpretation.
5.10.4.8	The safety case shall~~should~~ 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. ~~It is recommended that t~~The documentation shall itemize~~s~~ the parameters being monitored	

	on the vehicle and shall~~should~~ set out evidence supporting the argument that applicable safety requirements have been met. This documentation shall~~should~~ 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).	
5.10.5-5.10.6	[out of scope – DSSAD & Cybersecurity]	
5.10.7	Information Provision to Users (as appropriate: owners, users, operators, etc.)	Section 5.10.7 should be reviewed by the OPI on user requirements
5.10.7.1	For the ADS users, documentation and delivery ~~should~~ shall be provided to the users to facilitate user understanding of the functionality and operation of the system covering at least: (a) An operational description of the ADS features, capabilities, and limitations (the information should also refer to specific 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;	I believe the intent was that the delivery of the documentation would support understanding. Providing a very thick owner's manual is unlikely to be useful to a user.

	(k) Extent, timing and frequency of maintenance operations; (l) Means to enable a periodical technical inspection, if applicable; (m) 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.	

Annex 5

Note Annex 5 was included in both the Safety Assessment and Virtual Testing Credibility Assessment items, as such the OPI on Virtual testing and credibility assessment may have duplicate requirements. Only select requirements are listed.

Section from guidance document	**Text**	**Comments**
I.	[no text reproduced]	
II. 7.	~~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 v~~Virtual testing shall 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.	
II. 10.	~~It is recommended that a v~~Virtual test of the ADS' performance ~~is~~ shall be compared with its performance in the real world when executing the same scenario. ~~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~~ shall 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 validation.	Some terms are not well defined (e.g. sufficiently representative)
II. 11.	~~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 sh~~all~~ould 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.~~	
II. 12. (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~~ shall ~~need to~~ provide evidence and documentation about how the virtual testing is carried out and how the underlying simulation toolchain has been validated.	

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Annex 5 – Appendix 1

Note Annex 5 was included in both the Safety Assessment and Virtual Testing Credibility Assessment items, as such the OPI on Virtual testing and credibility assessment may have duplicate requirements. Only select requirements are listed.

Section from guidance document	**Text**	**Comments**
II. 6	~~It is recommended that t~~The ~~M&S~~modelling and simulation toolchain ~~could~~ shall only be used for virtual testing if its credibility is established by evaluating its fitness for the intended purpose. ~~It is recommended that~~ The credibility ~~is~~ shall be determined ~~achieved~~ by investigating and assessing five ~~M&S~~modelling and simulation properties: (a) Capability – what the ~~M&S~~model/simulation can do, and what are the associated risks; (b) Accuracy – how well ~~M&S~~the model/simulation ~~does~~ reproduces the target data; (c) Correctness – how sound & robust are~~is~~ the model/simulation~~M&S~~ data and the algorithms in the tools; (d) Usability – what training and experience is needed and what is the quality of the process that manage its use;	Properties are listed here but lack detail and methods to assess/score or obtain pass/fail

	(e) Fit for Purpose – how suitable is the ~~M&S toolchain~~model/simulation for the assessment of the ADS within its ODD.	
II. 9	~~It is recommended that this part should:~~The developer shall: (a) Describe the modifications when an update to a ~~within the M&S~~model/simulation ~~toolchain~~ is release~~s~~d; (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.	Bullet c) – while the process is recorded, it may not be valid, perhaps need further expansion
II. A. 1. 10.	~~It is recommended that a~~Any ~~toolchain's~~model/simulation version used ~~to release data~~ for certification purposes ~~should~~ shall be stored so that it can be operated at a later date. ~~The virtual models constituting the testing tool should be documented in terms of t~~The corresponding validation methods and acceptance thresholds to support the overall credibility of the toolchain shall be documented. The developer ~~should~~ shall establish and enforce a method to trace generated data to the corresponding toolchain version.	
II. A. 2. 16.	If the ADS manufacturer's toolchain incorporates or relies upon inputs from organizations or products outside of the manufacturer's own team, ~~it is recommended that~~ the ADS manufacturer shall include~~s~~ an explanation of measures it has taken to manage and develop confidence in the quality and integrity of those inputs.	
II. A. 2. 18.	The ADS manufacturer ~~should~~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 to execute virtual testing with the purpose of validating the ADS.	

II. A. 2. 19.	The ADS manufacturer ~~should~~ shall demonstrate of 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. ~~It is recommended that the assessor not substitute its judgment for that of the ADS manufacturer regarding the experience and expertise of the organization or its members.~~	Dan: Should keep deleted text in some form. Otherwise, a perfectly valid simulation (which will be a huge proportion of validation evidence) could be rejected because the assessor doesn't like the quals of the sim team. J-M: From my point of view, if there is an issue the assessor finds they should have some sort of say (provided they are adequately versed/ skillful/ knowledgeable). Certain options to try and balance: 1. preface with "Under usual circumstances, [...]" 2. reword: "In case of ambiguity, the assessor may request additional justification with regards to the approach taken and/or the experience or expertise of the organization or its members. The assessor shall endeavour to respect innovative approaches that may have been chosen by the manufacturer."
II. A. 3. 20.	~~The pedigree and traceability of the data and inputs used in the validation of the M&S is important.~~ The manufacturer ~~should~~ shall have a record of these that allows the assessor to verify their quality and appropriateness. **(a)Description of the data used for the M&S validation** (i) The ADS manufacturer ~~should~~ shall document the data used to validate the models included in the tool or toolchain and note important quality characteristics; (ii) The ADS manufacturer ~~should~~ shall provide documentation showing that the data used to validate the models covers the intended functionalities that the toolchain aims at virtualizing; (iii) The ADS manufacturer ~~should~~ shall document the calibration procedures employed to fit the	An additional requirement for a sensitivity analysis may be warranted

	virtual models' parameters to the collected input data. **(b) Effect of the data quality (e.g. data coverage, signal to noise ratio, and sensors' uncertainty/bias/sampling rate) on model parameters uncertainty** ~~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.~~	
II. A. 4. 19	~~The pedigree of the output data is important.~~ The manufacturer ~~should~~ shall keep a record of the outputs of the M&S toolchain 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.~~ **(a) Description of the data generated by the M&S** (a) The ADS manufacturer ~~should~~ shall provide information on any data and scenarios used for virtual testing toolchain validation; (b) The ADS manufacturer ~~should~~ shall document the exported data and note important quality characteristics e.g. using the correlation methodologies; (c) The ADS manufacturer ~~should~~ shall trace M&S outputs to the corresponding M&S setup: (i) Effect of the data quality M&S credibility: (a) The M&S output data ~~should~~ shall be sufficient to ensure the correct execution of the validation exercise. The data ~~should~~ shall sufficiently reflect the ODD relevant to the virtual assessment of the ADS. (b) The output data ~~should~~ shall allow consistency/sanity check of the virtual models, possibly by exploiting redundant information. (ii) Managing stochastic models (c) Stochastic models ~~should~~ shall be characterized in terms of their variance; (d) The use of a stochastic models ~~should~~ shall not prohibit the	

	possibility of deterministic re-execution.	
II. B. 1. 21.	The ADS manufacturer ~~should~~ shall provide a description of the complete toolchain along with how the M&S data will be used to support the ADS validation strategy.r The ADS manufacturer ~~should~~ shall provide a clear description of the test objective.	
II. B. 2. 22.	The ADS manufacturer ~~should~~ shall motivate the modelling assumptions which guided the design of the M&S toolchain. The ADS manufacturer ~~should~~ 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.	
II. B. 2. 22.	The ADS manufacturer ~~should~~ shall provide justification that the tolerance for M&S versus real-world correlation is acceptable for the test objective	
II. B. 2. 23.	Finally, this section ~~should~~ 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~~	
II. B. 3. 24.	The credibility of virtual tool ~~should~~ shall be enforced by a clearly defined scope for the utilization of the developed M&S toolchains.	
II. B. 3. 25.	The ~~mature~~ M&S ~~should~~ 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.~~	
II. B. 3. 26.	~~M&S toolchains need dedicated scenarios and metrics for validation.~~ The scenario selection used for validation ~~should~~ shall be sufficient such that there is confidence that the toolchain will perform in the same manner in scenarios that were not included in the validation scope.	
II. B. 3. 27.	ADS manufacturers ~~should~~ shall provide a list of validation scenarios together with the corresponding parameter description limitations.	
II. B. 4. 30.	The simulation models and the simulation tools used in the overall toolchain shall~~should~~ 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 is, the	

	criticality assessment shall considers at least the following parameters: (a) The consequences on human safety e.g. severity classes in ISO 26262; (b) The degree in which the M&S toolchain results influence's the ADS.	
II. C. 1. 35.	The ADS manufacturer ~~should~~ shall document the execution of proper code verification techniques, e.g. static/dynamic code verification, convergence analysis and comparison with exact solutions if applicable	
II. C. 1. 36.	The ADS manufacturer ~~should~~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 tools show unstable or unrealistic behaviour. Coverage metrics of parameters combinations may be used to demonstrate the required exploration of the model's behaviours.	
II. C. 1. 37.	The ADS manufacturer ~~should~~ shall adopt sanity/consistency checking procedures whenever data allows	
II. C. 2. 38.	Calculation verification deals with the estimation of numerical errors affecting the M&S. The ADS manufacturer ~~should~~ shall document numerical error estimates (e.g. discretization error, rounding error, iterative procedures convergence). The numerical errors shall~~should~~ be kept sufficiently bounded to not affect validation.	
II. C. 3. 40.	The ADS manufacturer ~~should~~ shall provide supporting documentation demonstrating that the most critical parameters influencing the simulation output have been identified by means of sensitivity analysis techniques such as by perturbing the model's parameters;	
II. C. 3. 41.	The ADS manufacturer ~~should~~ shall demonstrate that robust calibration procedures have been adopted and that this has identified and calibrated the most critical parameters leading to an increase in the credibility of the developed toolchain.	
II. C. 4. 43	~~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. It is recommended that the~~ The following items shall be considered when assessing the validity of a model or simulation: (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 analysis. Metrics for validation may~~ shall 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 metrics are generally derived as Key Performance Indicators (KPIs) indicating the statistical comparability between two sets of data.~~ The validation ~~should~~ shall show that ~~these~~ KPIs indicating statistical comparibility are met. (c) Validation methodology The ADS manufacturer ~~should~~ shall define the logical scenarios used for virtual testing toolchain validation. They ~~should~~ 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~~ shall 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 + environment model with influences form vehicle model). (d) Accuracy requirement ~~Requirement for the correlation threshold is defined during the M&S analysis.~~ The validation ~~should~~ shall show that the~~se~~ KPIs for correlation thresholds are met. (e) Validation scope (what part of the toolchain to be validated) ~~A toolchain consists of multiple tools, and each tool will use several models.~~ The validation scope shall include~~s~~ all tools and their relevant models. (f) Internal validation results	

	The documentation ~~should~~ shall ~~not only~~ provide evidence of the M&S validation ~~but also should~~and 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 ~~should~~ shall audit the documentation provided by the manufacturer and ~~may~~ 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~~ shall be reviewed and any deviation in the results ~~should~~ 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 ~~should~~ shall be made up of two phases. In a first phase the information collected from the "M&S Analysis and Description" section and the "Data/Input Pedigree" ~~are~~ shall be used to characterise the uncertainty in the input data, in the model parameters and in the modelling structure. In a second phase~~Then,~~ by propagating all of the uncertainties through the virtual toolchain, the uncertainty of the model results ~~is~~ shall be quantified. Depending on the uncertainty of the model results, proper safety margins will need to 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 ~~should~~ 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 ~~should~~ shall demonstrate that when a model's critical parameters 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 structure The ADS manufacturer ~~should~~ shall provide evidence that the modelling assumptions are given	

	a quantitative characterization by assessing the generated uncertainty (e.g. comparing the output of different modelling approaches whenever possible).); (iv) Characterization of aleatory vs. epistemic uncertainty The ADS manufacturer ~~should~~ shall aim to distinguish between the ~~aleatory~~ random component of the uncertainty (which can only be estimated but not reduced) and the epistemic uncertainty deriving from the lack of knowledge in the virtualization of the process.	

Annex 5 – Appendix 2

Note Annex 5 was included in both the Safety Assessment and Virtual Testing Credibility Assessment items, as such the OPI on Virtual testing and credibility assessment may have duplicate requirements. Only select requirements are listed.

Section from guidance document	**Text**	**Comments**
2.	The ADS manufacturer shallould produce a document (a "simulation handbook") structured using this outline to provide evidence for the topics presented.	
3.	The documentation ~~should~~ shall be delivered together with the corresponding release of the toolchain and appropriate supporting data.	
4.	The ADS manufacturer ~~should~~ shall provide clear reference that allows tracing the documentation to the corresponding parts of the toolchain and the data.	
5.	The documentation ~~should~~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 or requesting the manufacturer to conduct physical tests.	