§7.3. Assessment of the safety case

Green means no change to the text (including no numbering change)

Blue means an editorial proposal.

Orange means an open issue or substantive proposal for amendment.

7.	Compliance Assessment		
7.3.	Assessment of the Safety Case for the ADS		
7.3.1.	Assessment of the Safety Case Content		
7.3.1.1.	The safety case shall be assessed by an assessor, or team of assessors meeting 7.3.6 and 7.3.7 in order to determine if the Safety Case is complete and robust.		Paras. 7.3.1.6. and 7.3.1.7.
7.3.1.2.	The assessor may request that the manufacturer provide supporting documentation, assist in repeating/reproducing evidence or subject the ADS to tests the assessor deems necessary for this task.		
7.3.1.3.	The assessor shall review the manufacturer's safety case for completeness ensuring that at least the following criteria have been met:		
	(a) the manufacturer's safety concept is consistent and complete,		

(b) each requirement in the regulation has been addressed by one or more claims as per 6.3.2.8,		Which requirements? ADS requirements? Manufacturer requirements?
(c) the cumulation of claims would yield a system absent of unreasonable risk as per 6.3.1.30, 6.3.1.31 and 6.3.2.2,		
(d) each claim is supported by one or more arguments as per 6.3.2.1,		
(e) each argument is supported by a non-zero set of evidence as per 6.3.2.1.1,		
(f) the manufacturer has documented metrics and acceptance criteria related to their claims as per 6.3.1.30 and 6.3.1.31.		
(g) backwards and forward traceability from requirements to evidence as per 6.3.2.3.		
7.3.1.4. The assessor shall review the manufacturer's safety case for robustness ensuring that at least the following criteria have been met:		
(a) All identified risks in the Safety Concept are either reduced, mitigated or accepted and the sum of risk (quantitative or qualitative) is below the unreasonable risk threshold,		
(b) The integrity level used for development, validation, and verification of the ADS and its features is appropriate to reduce	(b) The integrity level used for development, verification, and validation of the ADS and its features is appropriate to reduce	China: reverse order of "verification" and "validation".

the risk below the unreasonable risk threshold	the risk below the unreasonable risk threshold	
(c) Testing evidence and the tools by which they are obtained achieve an acceptable level of credibility and demonstrate stability of performance when subjected to variations as per 7.2,		
(d) [Acceptable mix of physical, track and virtual testing – as part of credibility? Manufacturer justification?],	(d) [Acceptable mix of physical and virtual testing – as part of credibility? Manufacturer justification?],	China: delete “track”-Redundant since track testing is a form of physical testing.
(e) The manufacturer has taken steps to limit the potential for unintended functions in the ADS or for unintended functions to be induced in interfacing systems		
(f) Evidence provided can be repeated and reproduced with consistency of safety objectives as per 7.3.9,		
(g) The evidence demonstrated by the manufacturer provides reasonable coverage of foreseeable operating conditions and events in the intended area of operation, including conditions consistent with the ODD of the ADS and conditions that may involve ODD exit, and		
(h) The manufacturer has conducted one or more self-assessments and has taken steps to remediate any findings as per 6.3.2.11.		

7.3.1.5.	The assessor shall prepare a report of its assessment in such a manner that allows traceability, e.g. versions of documents inspected are coded and listed in the records of the Assessor. The report shall include any identified discrepancies/gaps and remediations undertaken by the manufacturer.		
7.3.1.6.	The assessment shall be conducted by assessors with the technical and administrative knowledge necessary for such purposes. They shall be competent as assessor for functional safety (e.g. ISO 26262), safety of the intended functionality (e.g. ISO/PAS 21448), human factors considerations and shall be able to make the necessary link with cybersecurity (e.g. UN R155, ISO/SAE 21434). This competence should be demonstrated by appropriate qualifications or other equivalent training records.		
7.3.1.7.	(UNR) The assessor shall be independent and external in accordance with Schedule 2 part 1.4 of the 1958 agreement		
7.3.1.7.	(GTR) The assessors shall be free from conditions that would threaten their ability to assess the Safety Case without bias including:		
	(a) financial incentives linked to the approval of the Safety Case (excludes incentives for the work undertaken to assess the Safety Case)		

	(b) participated in the development of the Safety Case via creation of evidence, analyses, test tools or other material		
	(c) Potential of reprisals for not approving the Safety Case		
7.3.2.	Assessment of Safety Case Testing Activities		
7.3.2.1.	General provisions		
7.3.2.1.1.	The assessor shall verify that the approach to testing adopted by the manufacturer is suitable for the demonstration of the safety case and the compliance with performance/functional requirements.		
7.3.2.1.2.	The assessor shall verify that the combined coverage of the testing results from all pillars (virtual, track, real world) is sufficient to support the ADS safety case claims.		How is this verified?
7.3.2.2.	Assessment of the scenarios and their management		Sounds like an SMS issue.
7.3.2.2.1.	The assessor shall verify that the manufacturer has used suitable and documented processes to derive behavioural competencies that are relevant to both the ODD and to the ADS safety case		
7.3.2.2.2.	The assessor shall verify that the manufacturer's approach and processes to identify and generate scenarios is appropriate. In particular, the resulting scenarios shall:		Sec: This provision follows with a list, so change items to alpha.

7.3.2.2.2.1. cover the appropriate nominal, critical and failure situations;	(a) Cover the appropriate nominal, critical, and failure situations,	
7.3.2.2.2.2. use data driven, knowledge driven and stochastic approaches to systematically identify hazardous events and other occurrences;	(b) Use data driven, knowledge driven and stochastic approaches to systematically identify hazardous events and other occurrences;	
7.3.2.2.2.3. include elements (especially dynamic elements) that are [representative/consistent] of existing traffic conditions in the target operational domain;	(c) Include elements (especially dynamic elements) that are [representative/consistent] of existing traffic conditions in the target operational domain;	
7.3.2.2.2.4. incorporate the identified characteristics and behaviours of all the relevant scenario elements.	(d) Incorporate the identified characteristics and behaviours of all the relevant scenario elements.	
7.3.2.2.3. The assessor shall verify that the set of scenarios resulting from the manufacturer's scenario generation and identification process is suitable for demonstrating the ADS safety case. This includes covering reasonably foreseeable situations and conditions that the ADS will encounter during its real-world operations . In particular the assessor shall verify that the set of scenarios selected as evidence to support the ADS safety case includes:		This provision follows with a list, so convert to alpha.
7.3.2.2.3.1. a sufficient number of situations in which the ADS needs to initiate a fall-back response (e.g. approaching the ODD limits).	(a) A sufficient number of situations in which the ADS needs to initiate a fallback response (e.g. approaching the ODD limits).	How is "sufficient" determined? "Situations" should be "scenarios" since this relates to testing. China: editorial-"fallback".
7.3.2.2.3.2. reasonably foreseeable scenarios that are not deemed to be preventable by the ADS (e.g. related to unsafe	(b) Reasonably foreseeable scenarios that are not deemed to be preventable by the ADS (e.g.	ADS do not prevent scenarios. ADS can manage situations to mitigate risks. Consider correlation of this provision with definition of "critical scenario".

	behaviour by other road users or by infrastructural failures)	related to unsafe behaviour by other road users or by infrastructural failures)	
7.3.2.2.4.	The assessor shall verify that the manufacturer has adopted appropriate techniques to explore the parameter space when choosing concrete scenarios.		
7.3.2.3.	Assessment of the processes in place for testing		Sounds like SMS.
7.3.2.3.1.	The assessor shall verify that the manufacturer has suitable processes, resources and competent personnel to undertake the testing that produces the evidence supporting the ADS safety case.		
7.3.2.3.1.1.	The assessor shall verify that the manufacturer has suitable processes, resources and competent personnel to assess the behavioural competencies demonstrated by the ADS for each scenario, against the performance requirements of the Dynamic Driving Task (DDT).		
7.3.2.3.1.2.	The assessor shall verify that the manufacturer has suitable processes, resources and competent personnel who can assess the capability of the ADS to ensure the safety of users and the safe use of the ADS.		
7.3.2.3.2.	The assessor shall verify that the manufacture has not optimised the ADS for a set of known test cases.		

7.3.2.4. Assessment of testing evidence		Correlation with 6.3.2. Claims, Arguments and Evidence of the Safety case?
7.3.2.4.1. The assessor shall review the evidence produced by the manufacturer in demonstrating the ADS safety case.		
7.3.2.4.1.1. The assessor shall review the evidence produced by the manufacturer in demonstrating the capability of the ADS to perform its Dynamic Driving Tasks (DDT).		
7.3.2.4.1.2. The assessor shall review the evidence produced by the manufacturer in demonstrating the capability of the ADS to interact safely with users.		
7.3.2.4.1.3. The assessor shall review the manufacturer's use of the different testing methods:		Implicit requirement for testing to include the three pillars. If intended, make use of the three generic methods a requirement.
1. Virtual testing	(a) Virtual testing	
2. Track testing	(b) Track testing	
3. Real world testing	(c) Real-world testing	
7.3.2.4.1.4. The assessor shall verify that the procedures and data collection associated with [user] testing are in line with best established scientific and engineering practice.		Sounds like SMS.
7.3.2.4.1.5. For the specific case of ADS user testing, the assessor shall:		
7.3.2.4.1.5.1. verify that the people involved are representative of the general population of ADS users and other road users where applicable;	(a) Verify that the people involved are representative of the general population of ADS users and other road users where applicable;	Deep numbering.

7.3.2.4.1.5.2 verify that the results achieved can be considered statistically significant.	(b) Verify that the results achieved can be considered statistically significant.	Deep numbering.
7.3.2.4.1.7. The assessor shall verify the suitability of the set of tests carried out as evidence to support the safety case, in particular in terms of coverage and relevance.		Sounds like credibility of the testing.
7.3.2.4.1.8. The assessor shall assess the results of the tests carried out for meaningfulness and consistency.		
7.3.2.4.1.9. The assessor shall verify that the results of the tests are able to demonstrate the behavioural competencies of the ADS when performing the DDT. In particular the assessor shall verify that the test results confirm the claims and arguments in the ADS safety case:		Provision establishes a list: convert to alpha.
7.3.2.4.1.9.1. in nominal, critical and failure scenarios;	(a) In nominal, critical and failure scenarios,	
7.3.2.4.1.9.2. while approaching and crossing the ODD boundaries;	(b) While approaching and crossing the ODD boundaries,	
7.3.2.4.1.9.3. in the case that collisions with other road users are not deemed to be preventable.	(c) In the case that collisions with other road users are not deemed to be preventable.	
7.3.2.4.1.10. The assessor shall verify that the manufacturer has suitable processes in place to identify the set of scenarios to be tested using the different testing methods.		Deep numbering
7.3.2.4.1.11. The assessor shall verify that the manufacturer has suitable processes in place to verify the consistency of the		Deep numbering

	test results across the different testing methods adopted.		
7.3.2.4.2.	Assessment of virtual tests.		Sound like testing credibility.
7.3.2.4.2.1.	The assessor shall verify that the manufacturer's virtual testing has been carried out incorporating proper consideration of the assumptions, accuracy and uncertainty in the simulation toolchain(s) in line with the requirements laid down in 6.2.2. The reviewer shall verify that the use of the results from the virtual testing reflects these considerations.		
7.3.2.4.2.2.	The assessor shall verify that any virtual test using simulation toolchain(s) containing stochastic elements has taken account of the possible uncertainty in the results.		
7.3.2.4.2.3.	If the manufacturer is using virtual testing to demonstrate scenario coverage the assessor shall verify that they have included critical scenarios and low probability events. The critical scenarios shall include those that could result in a collision. [The assessor will also check how the manufacturer has explored the parameter space and identified the number and type of tests to perform.]		
7.3.2.4.3.	Assessment of track testing.		Sounds like testing credibility.
7.3.2.4.3.1	The assessor shall review the evidence from track-testing that is provided by the manufacturer to support the ADS' safety case.		

7.3.2.4.3.2	The assessor shall verify that at least part of the scenario tested via track-testing includes critical scenarios replicating conditions that could result in a collision.		
7.3.2.4.4.	Assessment of real-world testing.		Sounds like testing credibility
7.3.2.4.4.1.	The assessor shall review the evidence from real world testing that is provided by the manufacturer to support the ADS safety case.		
7.3.2.4.4.2.	The assessor shall verify that the manufacturer has suitable processes in place to identify test routes that capture predictable aspects of the ODD (e.g., road types and geometries), elements found in the related nominal scenarios (e.g., other road users, signs, and signals), and typical dynamic conditions (e.g., high/low traffic densities). The test routes shall also enable verification of nominal requirements for the safety of user interactions, including prior to, at the time of, and after entering and exiting the ODD of an ADS feature.		
7.3.2.4.4.3.	The assessor shall verify that the evidence collected via real world testing by the manufacturer covers a wide variety of situations and conditions that the ADS may encounter during its real-world operations.		
7.3.2.4.4.4.	To the extent that an ADS encounters critical or failure situations during a real-world test drive, the response of		

	the ADS, including any discrepancies with the nominal performance requirements, shall be considered by the assessor in conjunction with the outcomes of track and virtual testing.		
7.3.3.	Confirmatory testing by assessor	7.3.3. Confirmatory testing	Define “confirmatory testing” as being some form of independent corroboration of the manufacturer’s testing outcomes (evidence).
7.3.3.1.	The assessor shall undertake physical testing using the various methods to confirm that the evidence provided by the manufacturer is representative.		
7.3.3.1.1.	The assessor shall ensure that the physical testing (proving ground and/or public road) facilities and environment are suitable to conduct the testing and confirm the evidence provided by the manufacturer to support the safety case in line with the provisions laid down in 7.2.1. and sub-paragraphs.		
7.3.3.1.2.	The assessor shall compare the information generated by the confirmatory testing with the evidence produced by the manufacturer to check that there is an appropriate level of correlation between them.		
7.3.3.1.2.1.	If the assessor is unable to confirm that there is an appropriate level of correlation, then the manufacturer should be informed that the results do not correlate. The manufacturer should review the alleged discrepancies and take appropriate action to resolve them.		

7.3.3.2.	Track testing by assessor.		"by assessor" redundant since this is a subsection of "confirmatory testing" which is by definition [assessor]
7.3.3.2.1.	The assessor [shall/may] use track testing to confirm the performance of the ADS in a number of selected relevant nominal, critical, and failure scenarios.		Brackets.
7.3.3.2.1.1.	The assessor shall explain and document their choices for the scenarios used to test the ADS.		
7.3.3.2.2.	Any track testing shall be conducted on a testing ground that is part of, or suitably represents, the ODD of the ADS. Tests may be conducted to verify that the ADS responds safely to situations including, crossing ODD boundaries and activation behaviour outside of the ODD, where applicable.		
7.3.3.2.2.1.	The assessor may use the testing ground used by the manufacturer to carry out confirmatory track testing.		
7.3.3.2.3.	The assessor shall consider how to manage real world variations. Where appropriate such variations should be allowed rather than restricting all tests to standardised parameters, test objects and test environments. The ADS should continue to perform if the tests remain within the ODD or react appropriately if not.		
7.3.3.2.4.	The test track, the test environment and the test objects may also be virtual elements as part of a simulation		

	toolchain, provided that the assessor is able to guarantee their credibility in line with the requirements laid down in 6.2.2. The ADS or the component being tested shall not be virtual elements or part of a simulation toolchain.		
7.3.3.2.5.	The assessor shall ensure an appropriate protocol is used for recording the track testing. It will contain at least minimum requirements on test relevant data collection and analysis, e.g., how the data is recorded, how measurements are derived from the recorded data, and how the measurements are analysed.		
7.3.3.2.6.	The assessor shall ensure that the track testing carried out is recorded with sufficient details to allow the tests to be reproduced to a sufficient level of accuracy. The information recorded shall include at least the test equipment, the test set-up, and the test environment, as well as any variations and adjustments		
7.3.3.2.7.	The assessor shall select scenarios to be conducted on a test track that are appropriate to the ODD.		
7.3.3.2.8.	The assessor shall select scenarios where the behaviour or position of other road users require the ADS to react to their movement or presence.		
7.3.3.2.9.	The assessor shall [verify/confirm] the human factor evidence from the		

	confirmatory tests are correlated with those provided by the manufacturer		
7.3.3.2.10.	The assessor shall ensure the executin of any track tests in line with the approach set out in Appendix 1 to this Annex.		
7.3.3.3.	Real world testing by assessor		
7.3.3.3.1.	The assessor [shall/may] conduct real world testing of the ADS in nominal scenarios. It is acknowledged that critical and/or failure scenarios may occur during real world testing, but generally should not be tested on purpose. If such scenarios occur, they shall not be excluded from the assessment.		Brackets.
7.3.3.3.2.	The assessor shall ensure that real world testing is conducted safely and therefore can end a test at any point if it becomes unsafe.		
7.3.3.3.3.	The assessor shall ensure that real world testing only be conducted if an appropriate level of safety for the other road users and for users in the vehicle can be demonstrated. [This may be provided by considering the audit, virtual testing, and track testing as well as the manufacturer's prior real world testing of the ADS.]		Brackets.
7.3.3.3.4.	The assessor shall ensure that real world testing confirms the claimed ADS performance in real traffic conditions.		

7.3.3.3.5.	The assessor shall ensure that real-world testing confirms the claimed ADS performance when approaching and crossing ODD boundaries, where appropriate. This testing shall include nominal and complex scenarios. The testing shall be used to confirm the claimed ADS performance related to the interaction with users under these conditions		
7.3.3.3.6.	The assessor shall ensure that real world testing confirms the claimed ADS performance relating to issues that may not be well captured by track tests and simulation, such as perception quality limitation (e.g. due to light and environmental conditions, etc.)		
7.3.3.3.7.	The assessor shall ensure that real world testing confirms the claimed ADS performance for aspects relating to human factors, such as user-initiated deactivation, system-initiated deactivation (not leading to a minimal risk condition), audibility of messages in real world conditions, if applicable to the ADS.		
7.3.3.3.8.	The assessor shall review the environment and conditions of the selected test routes to ensure they reflect the environment and conditions of the ADS' ODD.		
7.3.3.3.9.	The assessor shall ensure that the test routes that are selected include complex scenarios that the ADS is expected to encounter.		

7.3.3.3.10.	The assessor shall ensure that an appropriate protocol is followed when undertaking real world testing. It should contain minimum requirements that standardise how the test relevant data are to be collected and analysed (e.g., how the data is recorded, how measurements are derived from the recorded data, and how the measurements are analysed).		
7.3.3.3.11.	The assessor shall ensure that real world testing confirms the claimed ADS performance both within its ODD and outside its ODD (e.g. to determine the ADS's appropriate recognition and response when not in its ODD) on public roads.		
7.3.3.3.12.	The assessor shall attempt to increase the likelihood of encountering specific complex scenarios by selecting an ODD (e.g. highway) and examining when and where specific elements (e.g. high- or low-density traffic) typically occur. It is understood that it may not be possible to encounter all traffic scenarios during a real world test.		
7.3.3.3.13.	The assessor shall review any infractions identified during real world testing and assess it both directly and by evaluating it against any other relevant and available evidence, e.g. the data gathered during other testing or supplied by the manufacturer.		
7.3.3.3.14.	The assessor shall compare the information generated during real		

	world testing with the information from track testing to ensure there is the appropriate level of correlation of the results including the ADS' performance.		
7.3.3.3.14.1.	If there is insufficient correlation then the manufacturer should be informed and should review the alleged discrepancies and take appropriate action to resolve them.		Deep numbering
7.3.3.3.15.	The assessor shall ensure real world testing is undertaken in line with the approach set out in Appendix 1 to this Annex.		