Submitted by the OPI on safety case and assessment

Document ADS-08-34/Rev.1
8th ADS IWG session
14-18 April 2025

OPI update of ADS-08-04/Rev.1/Add.10 pursuant to discussions before the 8th ADS IWG session.

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

Blue means a structural change such as splitting a provision, renumbering, etc.

Orange means an editorial change

ADS-08-04r1	**Suggested changes**	**Comments**
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.		**Secretary:** 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.	7.3.1.2. The assessor may request that the manufacturer provide supporting documentation, assist in repeating/reproducing evidence or subject the ADS to **confirmatory** tests the assessor deems necessary for this task.	**SAE:** We should discuss what this [last part of sentence] means in practice. The review of testing, above, should determine if the set of tests done by the manufacturer were sufficient. **OICA/CLEPA:** Agree, additional material shall only be required if the review of testing clearly indicates that **OPI:** Discussed in meeting, addition of confirmatory addresses intention/meaning
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,		**Secretary:** 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 the risk below the unreasonable risk threshold	(b) The integrity level used for development, verification, and validation of the ADS and its features is appropriate to reduce the risk below the unreasonable risk threshold	**China:** reverse order of "verification" and "validation".

(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?],		**SAE:** What's "acceptable"? This should be explored in the testing section, and there is no metric for what mix is acceptable as long as the cumulative evidence supports the dual claims of absence of unreasonable risk and compliance with the rule's requirements. **China**: delete "track" – Redundant since track testing is a form of physical testing **OPI:** This is still in discussion amongst OPI for correct location - proposal to follow
(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.		**OPI:** Need alignment with ADS workshop - existing text is taken from UNR157 and modified
7.3.1.7. (UNR) The assessor shall be independent and external in accordance with Schedule 2 part 1.4 of the 1958 agreement		
(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		