Provisions of Guidelines	Provisions of GTR/UN regulations	Comments, Notes
5.1. Introduction	6.1 Audit of the SMS	EC/JRC: We suggest the following structure: 6.1 Audit of the SMS 6.1.1 Objectives of the SMS audit 6.1.2 SMS Audit (Assessor review based on the SMS requirements section) 6.1.3 Audit process (e.g. application, documentation, management of finding/deficiency and not compliance, certificate, validity, frequency of audit and recertification, management of the changes to the SMS) 6.1.3 Assessor competence
5.1.1. An audit of the ADS manufacturer's safety management system and a safety assessment of the ADS manufacturer's safety case, including its safety-by-design concept, referred to hereafter as the "safety concept" (see definition above), are important validation pillars. To enable this audit and safety assessment, the ADS manufacturer might be required to provide certain documentation. In some jurisdictions, the audit and safety assessment will be performed directly by an approval authority, while in other jurisdictions, the relevant authority may enlist an independent entity to conduct these functions.	6.1.1 Objectives of the SMS audit The auditor shall audit the manufacturer's safety management system in respect to the requirements in the section 5.X of this regulation.	OPI: Delete. There are no requirements in paragraph 5.1.1. Canada/TC: Suggest removing Pillar here as it may lead to confusion 5.2. Purpose and Elements of the Audit ~~Pillar~~ 6.1.1. EC/JRC proposal: *The auditor~~/assessor~~ shall audit the manufacturer's safety management system in respect to the requirements in the section 5.X of this regulation* Based on EC/JRC proposal
5.2. Purpose and Elements of the Audit Pillar	Deleted	
5.4.1. The purpose of the audit of the manufacturer's safety management system is to confirm that the manufacturer has robust processes to manage safety risks and to ensure safety throughout the ADS lifecycle (development, production, operation and decommissioning). 5.10.1. The purpose of the safety assessment of the ADS is for the safety authority to determine that	6.1.1.1 The audit of the manufacturer's safety management system shall provide confirmatory evidence on the robustness of the manufacturer's processes to manage safety risks and to ensure safety throughout the ADS lifecycle (development, production, operation and decommissioning).	6.1.1.1. EC/JRC proposal: *The audit of the manufacturer's safety management system shall provide confirmatory evidence on the robustness of the manufacturer's processes to manage safety risks and to ensure safety throughout the ADS lifecycle (development, production, operation and decommissioning).*

hazards and risks relevant to the ADS have been identified by the manufacturer and a consistent safety concept has been implemented to mitigate these risks.		Based on EC/JRC proposal
5.2.1. The purpose of the audit pillar is to facilitate a determination that: (a) The manufacturer has the right processes to ensure operational and functional safety during the vehicle lifecycle; and (b) The vehicle's ADS is safe by design and that the design has been sufficiently validated before market introduction.	Deleted	Canada/TC: I think 5.2.1. (a) is a review of the SMS. EC/JRC: 5.2.1. (a) can be deleted because it is already covered in the previous one Canada/TC: I would position 5.2.1. (b) as the Safety Assessment (ie review of the Safety Case) EC/JRC: Agree.
5.2.2. Therefore, this pillar is composed of two main components: the audit of the manufacturer processes established through a safety management system and the evaluation (i.e., safety assessment) of the safety case provided by the manufacturer, including the safety of the ADS design.	Deleted	Delete. There are no requirements in paragraph 5.2.2. EC/JRC: Agree. Delete.

5.2.3. It is recommended that the manufacturer be required to demonstrate that: (a) Robust processes are in place to ensure safety throughout the vehicle's lifecycle (development, production, operation, and decommissioning). This shall include taking the right measures to monitor the vehicle during the in-service operation and to take appropriate (corrective or preventive) action to address any issues, (b) The hazards and risks of the ADS have been identified and it is clear that the manufacturer's safety concept exists and had been applied to mitigate them through a safety-by-design approach, and (c) The risk assessment and the safety concept have been validated, through testing, by the manufacturer and show that the vehicle meets the safety requirements before market introduction. The vehicle should be free of unreasonable safety risks to the broader transport ecosystem, and in particular, to the ADS vehicle user(s) and other road users. Based on the evidence provided by the manufacturer in its safety case and confirmatory tests conducted by or for the safety authority, authorities will be able to assess whether the processes, the risk assessment, the design, and the validation are robust enough with regard functional and operational safety.	6.1.1.2. The auditor shall evaluate the robustness of the manufacturer's processes to monitor the safety management system activities (KPIs) and to take appropriate (corrective or preventive) action to address any issue.	The third sentence of sub-paragraph (c) should be deleted. Reason) No requirements are included in that sentence. Canada/TC: I would suggest here that the Audit portion be aimed at the authority. Any requirements on the manufacturer should be in the corresponding requirements sections (e.g. SMS, Safety Case, ISMR etc.) EC/JRC 5.2.3. (a) is already included above. Canada/TC: 5.2.3. (a) is part of the SMS. 5.2.3. (b) and (c) are part of the Safety Case (although the processes to do this may be part of the SMS). EC/JRC: 5.2.3. (b) and (c) fall into the Safety Assessment. EC/JRC proposal: 6.1.1.2 The ~~assessor/~~auditor shall evaluate the manufacturer's capability to monitor the safety management system activities (KPIs) and to take appropriate (corrective or preventive) action to address any issue. Based on EC/JRC proposal:
5.3. Documentation to be provided	Move to a general requirement in the documentation section.	EC/JRC: Documentation can be part of the requirement section more than the assessment. Otherwise, we can also have a dedicated section related to the documentation requirements.

5.3.1. To facilitate the approval authority's audit and safety assessment, the ADS manufacturer should provide certain specific documentation.	Move to a general requirement in the documentation section.	Move to General requirement
5.3.2. It is recommended that the documentation package shows that the ADS: (a) Is designed and was developed to operate in such a way that it is free from unreasonable risks for the ADS vehicle user(s) and other road users within the declared ODD; (b) Respects any applicable performance requirements concerning performance of the DDT and interaction with ADS users; (c) Was developed according to the development process/method declared by the manufacturer.	Move to a general requirement in the documentation section.	Canada/TC: 5.3.2. (a), (b) are part of the Safety Case requirements right now. 5.3.2. (c) is intended to be in the safety case - essentially that the SMS processes have been applied to the ADS. EC/JRC: Suggestion to delete, 5.3.2. (a), (b), (c) are related to the safety assessment. Move to General requirement.
5.3.3. Documentation should be made available in three parts: (a) An information document which is submitted to the authority and should contain a brief overview of the separate documents provided; (b) For the purpose of conducting the audit, a complete description of the manufacturer's Safety Management System; (c) For the purpose of conducting the safety assessment, a complete safety case for the ADS and its features, including a description of the design processes used to implement the safety concept, and a structured presentation demonstrating through a body of evidence that the ADS and its feature have undergone sufficient safety validation to ensure an absence of unreasonable risk in the ADS's performance.	Move to a general requirement in the documentation section.	Canada/TC: Perhaps 5.3.3. should be moved into the SMS and Safety Case sections as these are requirements for the manufacturer. I think it is already required in those sections. EC/JRC: 1) We should have a dedicated section concerning the documentation/documentation requirements. 2) Point (a), we should discuss about how the Information document shall look like 3) Point (c), we propose to delete as it is related to the safety assessment. Move to General requirement.

5.3.4. Rather than including such information in the documentation submitted to the approval authority. Additional confidential material and analysis data (intellectual property) should be retained by the manufacturer but made open for inspection (e.g. on-site in the engineering facilities of the manufacturer) at the time of the product assessment/process audit.	~~Rather than including such information in the documentation submitted to the approval authority.~~ If required by the auditor~~/assessor~~, the manufacture shall made ~~A~~additional confidential material and analysis data (**e.g.** intellectual property) ~~should be retained by the manufacturer but made~~ open for inspection (e.g. on-site in the engineering facilities of the manufacturer) at the time of the product assessment/process audit. Note: Move to a general requirement in the documentation section.	More concise expression. EC/JRC: We should have a dedicated section concerning the documentation/documentation requirements. Canada/TC: I think this should be a general requirement in the documentation section (or general requirements) as it applies to the manufacturer OPI: It depends on the restructuring, but if it remains the current structuring, then keep it as it is.
5.3.5. The manufacturer should ensure that this material and analysis data remains available for a period of 10 years counted from the time when production of the ADS is discontinued. Any changes to ADS safety design should be communicated as required to the relevant authority.	The manufacturer ~~should~~ **shall** ensure that this material and analysis data remains available for a period of 10 years counted from the time when production of the ADS is discontinued. Any changes to ADS safety design ~~should~~ **shall** be communicated as required to the relevant authority. Note: Move to a general requirement in the documentation section.	OPI comments: What is the relevant authority? EC/JRC: We should have a dedicated section concerning the documentation/documentation requirements. Canada/TC: I think this should be a general requirement in the documentation section (or general requirements) as it applies to the manufacturer. OPI: It depends on the restructuring, but if it remains the current structuring, then keep it as is. ZF: Adding new requirement on the audit frequency in 5.3.6. and also add 5.3.7., 5.3.8., 5.3.9., 5.3.1..
	Deleted	ZF: 5.3.6 The manufacturer shall demonstrate that periodic independent internal process audits (e.g. every 2 years) are carried out to ensure that the processes established in accordance with points in 5.4. Safety Management System are implemented consistently. EC/JRC:

		This is part of the SMS requirements section. Delete
	New requirement. Revisit at Phase3	ZF: 5.3.7. When this audit of the SMS has been satisfactorily completed and in receipt of a signed declaration from the manufacturer according to the model as defined, a certificate named Certificate of Compliance for SMS (hereinafter the Certificate of Compliance for SMS) shall be granted to the manufacturer. For reference for the model of the Certificate of Compliance for SMS use from the Appendix 3 & 4 of the EU ADS regulation EU Regulation 2022/1426 Publications Office (europa.eu). EC/JRC: 1) Not sure, this is our task or the task of the workshop to identify the need for a certificate 2) The approach can be different between TA and Self certification 3) SMS certificate of compliance is only required for the EU 2022/1426 regulation but not Un regulations Revisit at Phase3
	New requirement. Revisit at Phase3	ZF: 5.3.8. In due time, the manufacturer shall apply for a new or for the extension of the existing Certificate of Compliance for SMS. The type-approval authority shall, subject to a positive audit, issue a new Certificate of Compliance for SMS or extend its validity for a further period of three years. The type-approval authority shall verify that the SMS continue to comply with the requirements of this Regulation. The type-approval authority shall issue a new certificate in cases where changes have been brought to the attention of the type-approval authority or its

		Technical Service and the changes have been positively re-assessed. EC/JRC: As above. Revisit at Phase3
	New requirement. Revisit at Phase3	ZF: 5.3.9. The reporting of the safety assessment of the ADS safety concept as well as the audit of the safety management system of the manufacturer shall be performed in such a manner that allows traceability, e.g. versions of documents inspected are coded and listed in the records of the Technical Service. EC/JRC: This text is generally applicable and should be moved a section related documentation requirements. In addition the text shall be adapted to be applicable to both agreements. New Requirement. Rediscuss at Phase3
	Deleted.	ZF: Competence of the auditors/assessors 5.3.10. The assessment of the ADS safety concept and the audit of the safety management system under this part shall only be conducted by assessors/auditors with the technical and administrative knowledge necessary for such purposes. They shall be competent as auditor/assessor for e.g. ISO 26262-2018 (Functional Safety – Road Vehicles), and ISO 21448 (Safety of the Intended Functionality of road vehicles); and shall be able to make the necessary link with cybersecurity aspects in accordance with UN Regulation No 155 and e.g. ISO/SAE 21434). This competence shall be demonstrated by appropriate qualifications or other equivalent training records. EC/JRC:

		We suggest deleting this point because it is also already included at the end of the document Delete.
5.9. Link with the in-service monitoring/reporting pillar	Deleted.	Tentatively agree to delete and need to cross check.
5.9.1. It is recommended that a manufacturer include in the SMS processes to monitor safety-relevant incidents/ crashes/collisions caused by the ADS. The manufactures should also have a process to manage potential safety-relevant gaps during the in-service operation phase (possibly identified by in-service monitoring) and a process to update those vehicles.	Deleted.	Canada/TC: I think this is covered in SMS or ISMR already and may be covered in the Safety Case Deleted. They are supposed to be stipulated in ISMR or safety case section.
5.9.2. The manufacturer should have processes to report safety relevant occurrences (e.g. collision with another road users and potential safety-relevant gaps, see the In-service Monitoring and Reporting Pillar) to the relevant authority when they occur.	Deleted.	EC/JRC: "Requirements for reporting safety relevant occurrences" can be omitted. They are supposed to be stipulated in ISMR section. Delete
5.9.3. The manufacturers should set up processes for the operational phase to confirm of compliance with the defined safety case. It should include early detection of new unknown situations (in line with SOTIF safety development goal to minimize the unknown scenarios area), event investigation, to share lessons derived from incidents and near-miss analysis to allow the whole community to learn from operational feedback and to contribute to the continuous improvement of automotive safety. Example of guiding principles: Is there a document describing the appropriate procedure of reporting incidents to the management? Is there evidence that the company is complying with that procedure? Is there a document describing the appropriate procedure of investigation and documentation of incidents? Is there evidence that the company is complying with that procedure?	Deleted.	EC/JRC: It is part of the ISMR Canada/TC: I think these sections may be covered in SMS or ISMR (reporting requirements & monitoring requirements) Delete and move to the SMS or ISMR section.

	6.2. The role of the auditor	
5.10.4.4. The auditor 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 this approach 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) and a System-Theoretic Process Analysis (STPA) or any similar process appropriate to system functional and operational safety; (d) Inspection of the documentation that should demonstrate the validation/verification plans and results including appropriate acceptance criteria. It should 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 should perform an assessment of the physical testing (proving ground and/or public road) environment and should 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. Results of validation and verification may be assessed by analyzing 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.	Delete and move to the safety assessment section.	EC/JRC: We suggest moving all the text in 5.10.1 in the safety assessment section Delete and move to the safety assessment section.

	6.2.1. The audit of the safety management system shall only be conducted by auditors with the technical and administrative knowledge necessary for such purposes. This competence shall be demonstrated by appropriate qualifications or other equivalent training records.	UNR157 was used as a reference. "The assessment of the ADS safety concept and the audit of the safety management system under this part shall only be conducted by assessors/auditors with the technical and administrative knowledge necessary for such purposes. They shall be competent as auditor/assessor for e.g. ISO 26262-2018 (Functional Safety – Road Vehicles), and ISO 21448 (Safety of the Intended Functionality of road vehicles); and shall be able to make the necessary link with cybersecurity aspects in accordance with UN Regulation No 155 and e.g. ISO/SAE 21434). This competence shall be demonstrated by appropriate qualifications or other equivalent training records." EC/JRC: *We suggest keeping only this text:* *The audit of the safety management system shall only be conducted by ~~assessors/~~auditors with the technical and administrative knowledge necessary for such purposes.* *~~They shall be competent as auditor/assessor for e.g. ISO 26262-2018 (Functional Safety – Road Vehicles), and ISO 21448 (Safety of the Intended Functionality of road vehicles), and shall be able to make the necessary link with cybersecurity aspects in accordance with UN Regulation No 155 and e.g. ISO/SAE 21434).~~* *This competence shall be demonstrated by appropriate qualifications or other equivalent training records.*