Provisions of Guidelines	Provisions of GTR/UN Regulations	OPI Comments, etc.
5.4. Safety Management System		
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). It should include taking appropriate measures to monitor the vehicle during the in-service operation and to take the corrective remedial action when necessary.	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.	
5.4.2. 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.	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.	It might be more appropriate to move paragraph 5.4.2 to definitions section.
5.4.3. An adequate SMS will incorporate all three factors to monitor and improve safety and help to control the identified risks. The SMS evaluation is based on automotive (or other industry) engineering standards, guidebooks, and best practice documents relevant to safety.	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.	It might be more appropriate to move paragraph 5.4.3 to definitions section together with paragraph 5.4.2. (Paragraph 5.4.3. can be deleted because its content is too general and it would add almost no value.)
5.5. Safety Policy		

5.5.1. It is recommended that a safety policy be included in the SMS to outline the aims and objectives that the organisation will use to achieve the desired safety outcomes. The policy should declare the principles and philosophies that lay the foundation for the organisation's safety culture and be communicated to all staff throughout the organisation. The creation of a positive safety culture begins with clear, unequivocal safety governance.	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. ~~The creation of a positive safety culture begins with clear, unequivocal safety governance.~~	The last sentence should be deleted because it would add no value in regulatory aspect. What does the word "organization" mean? Can be replaced with the word "manufacturer" or what else?
5.5.2. The processes and activities that are recommended to be documented by the manufacturer include: (a) Safety policies and principles (in line with the concept stated in ISO 21434, para. 5.4.1 and ISO 9001 Automotive 5.2); (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 (ISO 26262-2, para. 5.4.2); (e) Safety Governance elements including: (i) Management commitment (in line with the concept stated in ISO 21434, para. 5.4.1 and ISO 9001 Automotive 5.1 (ii) Roles and responsibilities (ISO 26262-2, para. 6.4.2, this relates to the organizational and project dependent activities); (f) Effective communications within the organization on safety issues (ISO 26262-2, para. 5.4.2.3); (g) Information sharing outside of the organization (in line with the concept stated in ISO	The manufacturer shall document following contents for the sake of implementing SMS; (a) Safety policies and principles ~~(in line with the concept stated in ISO 21434, para. 5.4.1 and ISO 9001 Automotive 5.2)~~; (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 ~~(ISO 26262-2, para. 5.4.2)~~; (e) Safety Governance elements including: (i) Management commitment ~~(in line with the concept stated in ISO 21434, para. 5.4.1 and ISO 9001 Automotive 5.1~~ (ii) Roles and responsibilities ~~(ISO 26262-2, para. 6.4.2, this relates to the organizational and project dependent activities~~); (f) Effective communications within the organization on safety issues ~~(ISO 26262-2, para. 5.4.2.3);~~ (g) Information sharing outside of the organization ~~(in line with the concept stated in ISO~~	Reference to ISO standards should be removed. The reference documents would exist not only ISO but also other standards. (Besides, ISO is not free of charge due to copy right.)

21434, para. 5.4.5 and ISO 9001, but from a safety perspective); (h) Quality Management System (e.g., as per IATF 16949 or ISO 9001 or equivalent) to support safety engineering, including change management, configuration management, requirement management, tool management etc.	~~21434, para. 5.4.5 and ISO 9001, but from a safety perspective;~~ (h) Quality Management System ~~(e.g., as per IATF 16949 or ISO 9001 or equivalent~~ to support safety engineering, including change management, configuration management, requirement management, tool management etc.	
5.6. Risk Management		
5.6.1. It is recommended to include in the SMS a Safety risk management process to identify and assess the risks associated to the three SMS factors described above (i.e., human, organizational, and technical). Any operational risk identified in the product should, where appropriate, have mitigations implemented during the Design and Development phase. The ADS manufacturer should then be able to show the link between the overall risk management process, the mitigations, and the resulting operational risks.	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 ~~described above~~ (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.	
5.6.2. Examples of risk management processes and activities that are recommended to be documented by the manufacturer: (a) Risk identification (in line with ISO 31000 para. 6.4.2 standard or equivalent); (b) Risk analysis (in line with ISO 31000 para. 6.4.3 standard or equivalent); (c) Risk evaluation (in line with ISO 31000 para. 6.4.4 standard or equivalent); (d) Risk treatment (in line with ISO 31000 para. 6.4.5 standard or equivalent); (e) Processes for keeping the risk assessments up to date; (f) Review of safety performance of the organization and effectiveness of safety risk controls.	The manufacturer shall document its risk management processes and activities which may include the following aspects: (a) Risk identification ~~(in line with ISO 31000 para. 6.4.2 standard or equivalent)~~; (b) Risk analysis ~~(in line with ISO 31000 para. 6.4.3 standard or equivalent);~~ (c) Risk evaluation ~~(in line with ISO 31000 para. 6.4.4 standard or equivalent);~~ (d) Risk treatment ~~(in line with ISO 31000 para. 6.4.5 standard or equivalent);~~ (e) Processes for keeping the risk assessments up to date; (f) Review of safety performance of the organization and effectiveness of safety risk controls.	The reference to ISO standards should be deleted.
5.7. Design and Development Process		

5.71. It is recommended that the design and development process is well established and documented in the SMS. It should include risk management, requirements management, requirements' implementation, testing, failure tracking, remedial actions, and release management. Examples of processes and activities that should be considered to assure that responsibilities are properly discharged: (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.	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. ~~Examples of processes and activities that should be considered to assure that responsibilities are properly discharged.~~ (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.	
5.7.2. Examples of processes and activities that should be documented 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;	~~Examples of processes and activities that should be documented to ensure the robustness of the design and development phase.~~ 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;	

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.	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.	
5.7.3. It is recommended 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.	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.	R155 and Technical Requirements under the 1998 Agreement (Recommendation document) covers there. This para. May not be necessary.
5.8. Production and Deployment Process		
5.8.1. It is recommended that the production process is well established and documented in the SMS. Examples of processes and activities that are recommended to be documented to ensure the robustness of the development and the production phase include: (a) Quality Management System accreditation (e.g., as per IATF 16949 or ISO 9001 or equivalent); (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.	It is required that the production process shall be well established and documented in the SMS. ~~Following examples of processes and activities that are recommended to be documented to ensure the robustness of the development and the production phase include:~~ 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 ~~(e.g., as per IATF 16949 or ISO 9001 or equivalent),~~ (b) A description of the way in which the organisation performs all the production functions	The reference to specific standards should be deleted.

	including management of working conditions, working environment, equipment and tools.	
5.8.2. Examples of processes and activities to be documented to assure robustness of 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).	~~Examples of processes and activities to be documented to assure robustness of development and distributed production.~~ 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).	
5.8.3. It is recommended 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.	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.	
5.8.4. It is recommended that the SMS include a robust process to ensure that post-deployment software updates are properly validated and distributed and downloading is confirmed.	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.	Paragraph 5.8.4 could be deleted because software updates and software management system are regulated by UN R156 and the technical requirements under the 1998 Agreement (Recommendation document)
5.8.5. It is recommended 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) to ensure that their approaches to safety management related to the committed	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). ~~to ensure that their approaches to safety management related to the committed~~	

activities comply with the recommendations of the present guidelines. Examples of processes and activities that are recommended to be documented: (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.	~~activities comply with the recommendations of the present guidelines. Examples of processes and activities that are recommended to be documented:~~ 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.	
5.8.6. SMS documentation shall be regularly updated in line with any relevant changes to the SMS processes. It is recommended that gap analysis should 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 (e.g. "Plan, Do, Check, Act" as described in ISO 9001). Any changes to SMS documentation should be communicated as required to the relevant authority.	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 ~~(e.g. "Plan, Do, Check, Act" as described in ISO 9001)~~. Any changes to SMS documentation shall be communicated as required to the relevant authority.	
5.8.7. It is recommended that the SMS address measures to be taken to ensure ADS safety in the event of discontinued production, support, or maintenance of the ADS.	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.	Paragraph 5.8.7. can be combined with paragraph 5.4.1.
5.8.8. It is recommended that the manufacturer has processes for: (a) Assuring that all practices and activities documented as part of the SMS are followed;	It is required that the manufacturer has processes for: (a) Assuring that all practices and activities documented as part of the SMS are followed;	Paragraph 5.8.8. can be combined with paragraph 5.8.3.

(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.	(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.	