

§6.1. SMS requirements

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.

6.	Manufacturer Requirements	
6.1.	Safety Management System	
6.1.1.	Safety Policy	
6.1.1.1.	The safety policy shall outline the aims and objectives that the manufacturer uses to achieve the desired safety outcomes with regard to any and all ADSs it manufactures and may apply to other products of the manufacturer as well.	SAE: It's important to make clear that there is not a different SMS for each ADS. Sec: The General Requirements should explain that the SMS requirements address management of safety risks across all products, presumably including the expectation of an SMS certification before approval of an ADS safety case.
6.1.1.2.	The manufacturer shall provide evidence that its safety policy implements the following aspects:	Sec: What "evidence" is expected?
	(a) Safety policies and principles (e.g., ISO 21434, para. 5.4.1 and ISO 9001 Automotive 5.2.);	Sec: Can this be improved? It's circular: the safety policy shall implement safety policies.
	(b) Organization safety objectives and the process for creating safety performance indicators used in the safety case;	Sec: Does the safety case mention these "safety performance indicators"? Are these indicators sufficiently explained to know what is expected?

<p>(c) Appropriate structure for SMS, taking into account regulation, standards, best practice guidance and the use-case of the vehicle and mapping its organization structure, processes, and work products onto the SMS;</p>		<p>Sec: What does this provision mean? What is expected? It reads like it has had too many cooks. What exactly is expected? How does a technical service determine compliance?</p>
<p>(d) Safety culture (e.g., ISO 26262-2, para. 5.4.2);</p>		
<p>(e) Safety Governance elements including management commitment (e.g., ISO 21434, para. 5.4.1 and ISO 9001 Automotive 5.1) and roles and responsibilities (e.g., ISO 26262-2, para. 6.4.2, this relates to the organizational and project dependent activities);</p>		
<p>(f) Effective communications within the organization on safety issues (e.g., ISO 26262-2, para. 5.4.2.3);</p>		
<p>(g) Information sharing outside of the organization (e.g., ISO 21434, para. 5.4.5 and ISO 9001, but from a safety perspective)</p>	<p>(g) Information sharing outside of the organization (e.g., ISO 21434, para. 5.4.5 and ISO 9001 from a safety perspective)</p>	
<p>(h) Quality Management System (e.g., IATF 16949 or ISO 9001 to support safety engineering, including change management, configuration management, requirement management, tool management etc.</p>		
<p>6.1.2. Risk Management</p>		

<p>6.1.2.1. The SMS shall include a management process to identify, assess, and mitigate organisational, human, and technical risks.</p>	<p>6.1.2.1. The SMS shall include management processes to identify, assess, and mitigate organisational, human, and technical risks.</p>	<p>Sec: The scope is unlikely to be covered by a single management process.</p>
<p>6.1.2.1.1. The ADS manufacturer shall then be able to show the link between the overall risk management process, the mitigations, and the resulting operational risks.</p>	<p>6.1.2.1.1. The manufacturer shall then be able to show the link between the overall risk management process, the mitigations, and the resulting operational risks.</p>	<p>EC: Delete “ADS” for consistency in references to the manufacturer.</p>
	<p>6.1.2.1.1.1. The processes shall include documentation of identified risks and their mitigation in the safety concept of each ADS as specified under para. 6.3.1.7.</p>	<p>Sec: Proposal to explicitly link para. 6.1.2. to the safety case. Para. 6.3.1.7. requires documentation on how this SMS provision was applied to the ADS under assessment. Therefore, the safety concept documentation shows the link. These provisions provide explicit criteria for assessing the SMS by requiring the process to result in the documentation required under 6.3.1.7.</p>
	<p>6.1.2.1.1.2. The processes shall include testing to demonstrate that the mitigations are effective.</p>	
<p>6.1.2.2. The manufacturer shall document its risk-management processes and activities with consideration of relevant standards and best practices, including:</p>		
<p>(a) Risk identification (e.g., ISO 31000 para. 6.2),</p>		
<p>(b) Risk analysis (e.g., ISO 31000 para. 6.3),</p>		
<p>(c) Risk evaluation (e.g., ISO 31000 para. 6.4),</p>		
<p>(d) Risk treatment (e.g., ISO 31000 para. 6.5),</p>		
<p>(e) Processes for keeping the risk assessments up to date,</p>	<p>(e) Processes for keeping the risk assessments up to date, and</p>	<p>Sec: Add “and” since all the items on the list shall be included in the documentation.</p>

<p>(f) Review of safety performance of the organisation and effectiveness of safety risk controls.</p>		
<p>6.1.2.3. This process shall include Failure Mode and Effect Analysis (FMEA), Fault Tree Analysis (FTA), System-Theoretic Process Analysis (STPA) or any similar process appropriate to system functional and operational safety.</p>	<p>6.1.2.3. This process shall include Failure Mode and Effect Analysis (FMEA), Fault Tree Analysis (FTA), System-Theoretic Process Analysis (STPA) or any similar process appropriate to system functional safety and safety of the intended functionality.</p>	<p>China: Based on the conclusion of the IWG ADS-04 session (London), the operational safety should be replaced by SOTIF.</p>
	<p>6.1.2.3. These processes shall cover system functional safety and safety of the intended functionality such as Failure Mode and Effect Analysis (FMEA), Fault Tree Analysis (FTA), or System-Theoretic Process Analysis (STPA).</p>	<p>Sec: Numbering? This provision refers to a preceding provision. It is not clear whether it refers to 6.1.2.2. or 6.1.2.1. (or even 6.1.2. as a whole). Sec: Rephrased. "process" changed to "processes" since multiple processes cited. FMEA, etc. are examples of "appropriate processes" for addressing functional safety and SOTIF.</p>
<p>6.1.2.4. The manufacturer shall demonstrate its use of a top down (from possible hazard to design) and a bottom-up approach (from design to possible hazards) in its identification of hazards.</p>	<p>6.1.2.4. The manufacturer shall demonstrate its safety approach at the ADS level including a top down (from possible hazard to design) and a bottom-up approach (from design to possible hazards) in its identification of hazards.</p>	<p>China: SMS should focus on the relevant process, approach and activity of the manufacturer concerning the safety management throughout the ADS lifecycle. So refer to the Integration document (GRVA-20-36), it's better to clearly indicate that "safety approach" at the ADS level including ...</p>
<p>6.1.3. ADS Design and Development</p>		
<p>6.1.3.1. This documentation shall include risk management, requirements management, requirements' implementation, testing, failure tracking, remedial actions, and release management [including the following aspects:</p>		<p>Text in brackets.</p>

(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.]		
6.1.3.2. The manufacturer shall document its processes and activities to ensure the robustness of the design and development phase, including the following aspects:		
(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:	(ii) Validation/verification strategies, including but not limited to:	China: Consistency with para. 6.3.1.28. (The manufacturer shall provide the following information as part of its safety case: (a) Validation/verification plans including appropriate acceptance criteria).
a. Assessment of the physical testing environment,		

<p>b. Credibility assessment for virtual tool chain,</p>	<p>Delete.</p>	<p>China: The entire requirements for the credibility assessment of virtual tool chain have been specified in 6.2.2. and its sub paragraphs, including management, analysis, verification and validation. If the manufacturer uses simulation as a test method, the credibility assessment of the toolchain shall fulfill the relevant requirements. So it's not necessary to indicate the credibility assessment in the SMS section</p>
<p>c. System integration,</p>		<p>Sec: Reconsider for clarity. These items are not “validation strategies”.</p>
<p>d. Software,</p>	<p>d. Software, and</p>	
<p>e. Hardware;</p>		
<p>(iii) Management of functional safety and safety of the intended functionality (e.g., ISO 13407), including the ongoing evaluation and update of risk assessments and interactions;</p>	<p>(iii) Management of functional safety and safety of the intended functionality (e.g., ISO 26262, ISO 21448), including the ongoing evaluation and update of risk assessments and interactions; and</p>	<p>China: Correct error in reference to standards.</p>
<p>(iv) Management of human factors, including human-centred design processes.</p>		
<p>(c) Design and change management, including but not limited to:</p>		
<p>(i) The major design decisions,</p>		
<p>(ii) The relevant design modifications to the ADS,</p>		
<p>(iii) Changes to key persons responsible for making decisions that affect safety,</p>	<p>(iii) Changes in personnel responsible for decisions affecting safety,</p>	<p>Sec: Presume the concern is with changes in personnel, not changes to the people themselves.</p>

<p>(iv) The tools and thresholds adopted for the ADS safety verification.</p>	<p>(iv) The tools and thresholds adopted for the ADS safety validation/verification.</p>	<p>China: Consistency with para. 6.3.1.28. (The manufacturer shall provide the following information as part of its safety case: (a) Validation/verification plans including appropriate acceptance criteria).</p>
<p>6.1.3.3. The manufacturer shall institute and maintain effective communication channels between the departments and third-party organizations responsible for functional/operational safety, cybersecurity, and any other relevant disciplines related to the achievement of vehicle safety. These processes and activities shall be documented considering relevant standards and best practice.</p>		
<p>6.1.4. Production management</p>		
<p>6.1.4.1. The manufacturer shall establish and document the production process in the SMS. The manufacturer shall document its processes and activities to ensure the robustness of the production phase. This documentation shall cover, at least, the following aspects:</p>		
<p>(a) Quality Management System accreditation (e.g., IATF 16949 or ISO 9001),</p>	<p>(a) Quality Management System accreditation (e.g., IATF 16949 or ISO 9001), and</p>	<p>Sec: Add “and”.</p>
<p>(b) A description of the way in which the manufacturer performs all the production functions including management of working conditions, working environment, equipment and tools.</p>	<p>(b) A description of the way in which the manufacturer performs all the production functions including management of working conditions, equipment and tools.</p>	<p>Sec: “working conditions” and “working environment” mean the same thing.</p>

<p>6.1.4.2. The manufacturer shall establish and document their distributed production processes and activities in the SMS. The processes and activities shall include:</p>		
<p>(a) Liaison between the vehicle and/or ADS manufacturer and all other manufacturers (partners or subcontractors) involved;</p>	<p>(a) Liaison between the vehicle and/or ADS manufacturer and all other manufacturers (partners or subcontractors) involved; and</p>	<p>Sec: Add “and”.</p>
<p>(b) Criteria for the acceptability of “subsystem/components” manufactured by other partners or subcontractors. (i.e., deployment of production assurance requirements to supply chain).</p>		
<p>6.1.5. Post-deployment safety</p>		
<p>6.1.5.1. The requirements listed in the 6.1.5 are without prejudice to applicable laws governing access to data, availability, and privacy and data protection.</p>		<p>How does the following related to the safety case provision 6.3.2.5. (The manufacturer shall demonstrate through the safety case its ability to monitor the ADS over its lifetime in accordance with the requirement listed in 6.1.5.1-6.1.5.8.)?</p>
<p>6.1.5.2. The manufacturer shall establish processes to demonstrate its capabilities to execute an effective ISMR and to take the corrective remedial action when necessary.</p>		<p>The “shall establish” wording assumes that the manufacturer does not have the processes. The requirement is to have the processes, not to establish the processes. The provision should refer to “post-deployment safety” rather than ISMR (which is part, but not all of the safety requirement).</p>
<p>6.1.5.3. The processes for ISMR shall demonstrate the capabilities:</p>		<p>Check for consistency with §6.4.</p>
<p>(a) To monitor ADS operations;</p>		
<p>(b) To confirm the compliance with the defined safety case and</p>		

	compliance to the performance requirements;		
	(c) To identify safety risks related to ADS performance that need to be addressed in the frame of the SMS activities, including instances of non-compliance with ADS safety requirements;		
	(d) To manage potential safety-relevant gaps during the in-service operation and to provide the information that allows the ADS to be updated according to the appropriate manufacturer processes;		
	(e) To support the development of new or revise existing scenarios;		
	(f) To perform event investigation;	(f) To investigate incidents;	
	(g) To report occurrences to the relevant authority when they occur;	(g) To report occurrences to the relevant authority in accordance with the requirements under para. 6.4.;	Sec: Suggest deleting “when they occur” to avoid risk of confusion: Section 6.4. specifies the reporting frequencies (and all occurrences do not have the same reporting requirements).
	(h) To share learnings derived from occurrence analysis;	(h) To share knowledge from occurrence analysis; and	Sec: Add “and”. Improve wording.
	(i) To contribute to the continuous improvement of automotive safety.		
6.1.5.4.	The process for ISMR shall demonstrate the capabilities for handling the reports received from other sources, including distinguishing false reports from actual events and		

<p>conducting thorough investigations when necessary.</p>		
<p>6.1.5.5. The manufacturer shall demonstrate the capabilities to monitor the performance of all its in-service ADS vehicles.</p>		
<p>6.1.5.6. The manufacturer shall demonstrate the capabilities collect and analyse vehicle data, and data from other sources to achieve the ISMR objectives.</p>	<p>6.1.5.6. The manufacturer shall demonstrate the capabilities to collect and analyse vehicle data and data from other sources to achieve the ISMR objectives.</p>	<p>China: Editorial correction-“to”</p>
<p>6.1.5.6.1. The manufacturer shall have a data acquisition strategy, data retention strategy, data access, and security and protection policy.</p>		
<p>6.1.5.6.2. The data acquisition strategy shall ensure a representative collection of data to monitor the ADS in service performance.</p>		
<p>6.1.5.6.3. The retention strategy shall ensure that:</p>		
<p>(a) Data related to a detected safety issue is retained until any necessary corrective action and review processes are complete, and</p>		
<p>(b) The retention of the data for longer-term trend analysis (i.e. subset of the collected data).</p>		
<p>6.1.5.6.4. The data access, security and protection policies shall ensure that information access is allowed only to authorized persons and contains safeguards to ensure the security and protection of the data in accordance with the data-</p>		<p>Sec: Consider against para. 6.1.5.1. This provision requires compliance with the prevailing laws which raises a question on whether the “without prejudice to national laws” is necessary. This also relates to the DSSAD work so alignment should be addressed.</p>

protection laws of the relevant jurisdiction.		
6.1.5.6.5. The manufacturer shall achieve the following objectives from the monitoring activity:		
(a) Verify the safety performance (i.e., Safety Performance Indicators) and confirm the in-service safety level of the system (i.e. metrics and thresholds);		
(b) Identify areas of operational risk;		
(c) Identify when the ADS prevents incidents/accidents (e.g., MRC fallbacks, collision avoidance, emergency manoeuvres);		
(d) Characterise and analyse occurrences;		
(e) Discover trends that suggest the emergence of unacceptable risks;		
(f) Ensure that remedial actions are put in place when an unacceptable risk is discovered or predicted by trends;		
(g) Confirm the effectiveness of any remedial action;	(g) Confirm the effectiveness of any remedial action; and	Sec: Add “and”.
(h) Enable the development of new or the revision existing scenarios derived from ISMR activities.		
6.1.5.6.6. The manufacturer shall perform a data analysis with sufficient frequency so that remedial action can be taken		

<p>promptly and in line with reporting requirements listed in 6.4.</p>		
<p>6.1.5.6.7. The analysis techniques shall include at least the following:</p>		
<p>(a) Routine measurements: a selection of parameters shall be collected to characterize the performance of ADS and to allow a comparative analysis. These measurements shall aim at identifying and monitoring emerging trends and tendencies before the trigger levels associated with exceedances are reached;</p>		
<p>(b) Exceedance detection: a set of “core values” shall be selected to cover the main areas of interest for the ADS operation with aim at searching for deviations from safety performance and limits. They shall be continuously reviewed to reflect the current operations;</p>		
<p>(c) Occurrence analysis: It shall be possible to characterize and investigate all the occurrences listed in the 6.4.9 using the recorded data;</p>	<p>(c) Occurrence analysis: It shall be possible to characterize and investigate all the occurrences listed in the 6.4.9 using the recorded data; and</p>	<p>Sec: Add “and”.</p>
<p>(d) Statistics: Data series shall be collected to support the analysis process with additional information. These data shall</p>		

provide information to generate rates and trends.		
6.1.5.7. The manufacturer shall have a mechanisms in place for receiving and analysing safety-relevant feedback and reports from other sources to extract safety-relevant information and to review the safety monitoring data.		
6.1.5.7.1. The feedback and reports from other sources shall include at least:		Sec: Rephrase. Manufacturers cannot compel independent third parties to furnish information. For example, law enforcement is under no obligation, and may be prohibited from, sharing information.
(a) ADS related maintenance and inspection feedback;		
(b) Enforcers (including the police) and other authorities' reports	(b) Law enforcement and other authorities;	
(c) Service operator, customer, public and dealer feedback.		
6.1.5.8. The manufacturer shall evaluate the results from the monitoring activity to assess:		
(a) In-service safety performance,		
(b) The adequacy of the metrics and thresholds,	(b) The adequacy of the metrics and thresholds, and	Sec: Add "and".
(c) The outcome of remedial actions.		
6.1.6. Safety Assurance		
6.1.6.1. The manufacturer shall 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.		
6.1.6.2.	The manufacturer shall 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) The manufacturer shall document its processes and activities, including 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,	(d) Processes to establish contracts, agreements for ensuring safety across the phases of development, production, and post-production, and	Sec: Add “and”.
	(e) Processes for distributed safety activities.		
6.1.6.3.	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.		
6.1.6.4.	The manufacturer shall have processes for:		
	(a) Assuring that all practices and activities documented as part of the SMS are followed;		
	(b) Assuring that an independent check of compliance with the applicable requirements is performed. (i.e., not from person creating the compliance data);	(b) Assuring that an independent check of compliance with the applicable requirements is performed. (i.e., not from person creating the compliance data); and	Sec: Add “and”.
	(c) Assuring the continued evaluation of the Safety Management System so that it remains effective.		
6.1.6.5.	The manufacturer shall define appropriate Key Performance Indicators (KPI) to measure the effectiveness of the Safety Management System throughout the ADS lifecycle (development, production, operation and decommissioning).	6.1.6.5. The manufacturer shall define appropriate Key Performance Indicators (KPIs) to measure the effectiveness of the Safety Management System throughout the ADS lifecycle (development, production, operation and decommissioning).	China: Editorial-“KPIs”
6.1.7.	Safety Promotion		
6.1.7.1.	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.		

Prepared by the drafting secretary

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