Provisions of Guidelines	Provisions of GTR/UN Regulations	OPI Comments, etc.
5.4. Safety Management System	5.4. Safety Management System	**Canada:** General comment - Noted in other sections but we will have to check if we can regulate the manufacturer vs regulating the vehicle under the 1958/1998 agreements. We may need to re-word so that it applies to a vehicle instead of applying to a manufacturer - This could be problematic if there are multiple subsidiaries in each country to know who actually responsible e.g. Company X, Company X Canada, Company X Japan, Company X Europe... Canada proposes the following text for section 5.4.1: The purpose of the audit of the ~~manufacturer's~~ safety management system is to confirm that ~~the manufacturer~~ the appropriate responsible entities ~~has~~ have 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. Rationale for change: This recognizes that there may be different parties involved based on the business model used to develop and maintain the ADS feature during its lifecycle (e.g. ADS developer and/or vehicle OEM and/or fleet operator) **UK**: (general comments) "May" was used in the ALKS reg, so using it here in appropriate contexts is probably fine.

		Manufacturer and organization appear to have been used interchangeably. I suggest replacing organization with manufacturer. A few typos across the document. In 5.5.2. 'the' is missing in the first line. References to standards were all removed. I think standards could be added as a way of meeting a requirement. We may not necessarily need to mandate them. However, for consideration, there have been cases where a regulation required compliance with a standard (or an aspect of it). For example, from R 157: "They shall in particular be competent as auditor/assessor for ISO 26262-2018 (Functional Safety - Road Vehicles), and ISO/PAS 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 ISO/SAE 21434)." VCA: The main comment I have on this section is "who's SMS is this". It comes across that there is one organization, but there will be two main organizations involved – vehicle manufacturer and ADS developer. The interactions and responsibilities between these two needs to be made clear. With type approval the focused on vehicle manufacturer the section on "third parties" needs to be made its own section. . Are there fail safes for disabling activation of the system if the manufacturer no longer supports its safety (e.g. insolvency, which is

		different from a managed decommissioning) or safety critical updates are not installed? **Ross:** some (3) refences to "ADS manufacturer" - should the ADS be removed **Results of the small meeting on July 1st.** (OPI) General Open Item 1: SMS typically targets "organization". What does the word "organization" mean? Can be replaced with the word "manufacturer" or what else. Manufacturer and organization appear to have been used interchangeably. General Open Item 2: "May" or "Shall". "May" was used in the ALKS reg, so using it here in appropriate contexts is probably fine or not. General Open Item 3: References to ISO standards were all removed. We may not necessarily need to mandate them, but we need to find a suitable way to show the ISO standard as an example. **Results of ADS IWG #3.** Tentative Agreement: Use "manufacturer". UK: "ADS manufacturer" or "manufacturer" Decision use mfr. "May" or "Shall". "May" was used in the ALKS reg, so using it here in appropriate contexts is probably fine or not. Decision: both will be used but attention to communicating intent (e.g., permission vs. requirement).

		Use of industry standards: References to ISO standards were all removed. We may not necessarily need to mandate them, but we need to find a suitable way to show the ISO standard as an example. Decision: reference permissible under some conditions and prohibited under others. Proposals should be brought to IWG for consideration.
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 establish a SMS with robust processes to manage safety risks and to ensure safety throughout the ADS lifecycle (development, production, operation and decommissioning) including in the event of discontinued production, support, or maintenance. ~~It should include taking appropriate measures to monitor the vehicle during the in-service operation and to take the corrective remedial action when necessary~~.	**EC:** Considering that the SMS in not introduced yet, I suggest to change as: "the manufacture shall establish a SMS with robust processes…." **EC:** "It shall include …when necessary." This part can be removed. The ISMR processed should be included in the SMS part in a dedicated requirement. **Ross:** In R155 we use development, production & post-production (and there were definitions) **Results of the small meeting on July 1st.** (OPI)Proposal: *In respect of ADS, the manufacture shall ~~have~~ establish a SMS with 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~~.* The ISMR processed should be included in the SMS part in a dedicated requirement. **Results of ADS IWG #3.**

		EC: SMS overlaps with ISMR during "operation" phase. So "operation phase" should be specified under requirements. SAE: SMS aspect about "monitoring". Sound SMS includes monitoring for risks just as required under ISMR provisions. Integrity of SMS important (splitting provisions counterproductive). EC: should have what is needed for "operation" just as specifications for development, production, etc. Each phase should have own section with specifications. Decision: remains yellow pending further elaboration. For the 240912 small meeting. Clarify overlap between SMS and ISMR in the "operation" phase. Canada: General comment - Noted in other sections but we will have to check if we can regulate the manufacturer vs regulating the vehicle under the 1958/1998 agreements. We may need to re-word so that it applies to a vehicle instead of applying to a manufacturer - This could be problematic if there are multiple subsidiaries in each country to know who is actually responsible Ie. Company X, Company X Canada, Company X Japan, Company X Europe... Canada proposes the following text for section 5.4.1: The purpose of the audit of the ~~manufacturer's~~ safety management system is to confirm that ~~the manufacturer~~ the appropriate responsible entities ~~has~~ have 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. Rationale for change: This recognizes that there may be different parties involved based on the business model used to develop and maintain the ADS feature during its lifecycle (e.g. ADS developer and/or vehicle OEM and/or fleet operator) **EC/JRC:** Second sentence moved in the operation phase
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.	**Agree to move this paragraph to definition section.** 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 while accounting for the possibility of human errors; (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. **Canada:** Agree to the above. **EC:** Agreed that this part can be moved in the definition. **EC:** About (a), Suggestion to change as : …to identify risks and appropriate mitigation measures while accounting for the possibility of human errors **Results of the small meeting on July 1st:** (OPI) Agreed that this part can be moved in the definitions section. About (a), Suggestion to change as : *…to identify risks and appropriate mitigation measures while accounting for the possibility of human errors* **Results of ADS IWG #3.**

		SAE: SMS more comprehensive than single ADS. Manufacturer's overall approach to safety covering all ADS. Agree that provides a definition, but should not imply a specific SMS for each ADS. Japan: Agree SMS not exclusive to single ADS. Decision: Agree to move to definition. Agree not specific to each ADS.
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.	The SMS shall manage safety by considering organizational, human and technical risk factors.	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.) **Canada:** Agree to the above. **EC:** In case we remove the previous point, the 3 SMS factors are not mentioned anymore. So, I will suggest to change the text as: *"the SMS shall manage safety by considering organizational, human and technical risk factors."* **Results of the small meeting on July 1st:** (OPI)Proposal: In case we remove the previous point, the 3 SMS factors are not mentioned anymore. So, we will suggest to change the text as: *"the SMS shall manage safety by considering organizational, human and technical risk factors."* **Results of ADS IWG #3.**

		(Germany) is this a lower-limit requirement or a not more than requirement? (OPI) seems lower limit requirement. (NL) Is this "shall" or "may": original provision uses "may" twice. Decision: Support in principle with some refinement in revised proposal.
5.5. Safety Policy	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 recommended that a~~ The safety policy ~~be included in the SMS to~~ shall outline the aims and objectives that the organisation ~~will~~ uses 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.~~	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? **Canada:** Agree, in our regulations we use "Company" when this is referenced as it represents the legal entity in operation (that imports/manufactures) in our jurisdiction. We should review the text in the document to be consistent with whatever is chosen. **EC:** The text can be simplified, I do suggest to change as: "The safety policy shall outline the aims and objectives that the organization uses to achieve the desired safety outcomes. " **EC:** SMS typically targets "organisation". To be discussed with the broader group which formulation to use **Results of the small meeting on July 1st:**

		(OPI) General Open Item 1: SMS typically targets "organization". What does the word "organization" mean? (OPI)Proposal: The text can be simplified, we suggest changing as: *"The safety policy shall outline the aims and objectives that the organization uses to achieve the desired safety outcomes."*
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);	~~The processes and activities that are recommended to be documented by the manufacturer include:~~ The manufacturer shall provide evidence it has implemented the following as part of its SMS: (a) Safety policies and principles (~~in line with the concept stated in~~ e.g., ISO 21434, para. 5.4.1 and ISO 9001 Automotive 5.2); (b) Organization 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 organization structure, processes, and work products onto the SMS; (d) Safety culture (e.g., ISO 26262-2, para. 5.4.2); (e) Safety Governance elements including: (i) Management commitment (~~in line with the concept stated in~~ e.g., ISO 21434, para. 5.4.1 and ISO 9001 Automotive 5.1); (ii) Roles and responsibilities (e.g., ISO 26262-2, para. 6.4.2, this relates to the	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.) **Canada:** Wondering if document is the right word here as it may be a paper exercise. Would suggest something like "The manufacturer shall provide evidence it has implemented the following as part of its SMS:" Agree other documents are possible but having an example may be very useful and may set minimum expectations. Without an example standard, we may have some implementations that are inadequate. I think the difficulty is to give an example without making it restrictive to that particular standard. - Perhaps this could be explained in the interpretation document, or additional examples added here to allow more flexibility?

(g) Information sharing outside of the organization (in line with the concept stated in ISO 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.	organizational and project dependent activities); (f) Effective communications within the organization on safety issues (e.g., ISO 26262-2, para. 5.4.2.3); (g) Information sharing outside of the organization (~~in line with the concept stated in~~ e.g., ISO 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.	**UK**: (5.5.2.) I think this would better read as the manufacturer shall document the following to support implementing the SMS: (5.5.2.f) I suggest editing to 'processes' for effective communication within the organization on safety issues. (5.5.2.g) I suggest editing to 'processes' for information sharing outside of the organization. (5.5.2.h) I think the standard examples listed could stay **Results of the small meeting on July 1st:** (OPI) Paragraphs 5.1.4.2. to 5.1.7.8. are still under discussion within OPI.
5.6. Risk Management	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 recommended to~~ The manufacturer shall 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 ~~should~~ shall then be able to show the link between the overall risk management process, the mitigations, and the resulting operational risks.	**Canada:** Regarding to "Design and Development phase", This should perhaps be extended to operations - ie identifying new found risks and process for mitigating them
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.	5.6.2. ~~Examples of~~ Risk management processes and activities ~~that are recommended to~~ shall be documented ~~by the manufacturer~~ considering relevant standards and best practice. They shall include: (a) Risk identification (~~in line with~~ e.g., ISO 31000 para. 6.4.2 ~~standard or equivalent~~); (b) Risk analysis (~~in line with~~ e.g., ISO 31000 para. 6.4.3 ~~standard or equivalent~~); (c) Risk evaluation (~~in line with~~ e.g., ISO 31000 para. 6.4.4 ~~standard or equivalent~~); (d) Risk treatment (~~in line with~~ e.g., 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. **Canada:** Same as comment above, I believe they should be kept but make sure they are examples with flexibility **EC:** Suggest to delete may and use shall even though the list cannot be exhaustive. They are 4 common and standard steps for risk management **UK:** (5.6.2.) I suggest rewriting the 1st line: "The risk management processes and activities shall be documented considering

		relevant standards and best practice. They shall include:..." **UK**: I suggest rewriting it as: "The process for reviewing and documenting the organizational effectiveness of their risk controls and safety performance shall be documented."
5.7. Design and Development Process	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;	The manufacturer shall document its processes and activities to ensure proper deployment of the SMS principles during the design and development phase. ~~It is recommended that the design and development process is well established and documented in the SMS.~~ This documentation shall ~~It should~~ 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:~~	**GER:** Propose to formulate as "The design and development process shall be established and documented including safety management system, requirements management, requirements' implementation, testing, failure tracking, remedial action and release management." **EC:** I suggest to move in dedicated raw/requirement. This part is related to the process needed to ensure a proper deployment of the SMS during the D&D phase. The requirement could be: "The manufacturer shall document its processes and activities to ensure proper deployment

(c) Coordination of roles, responsibilities and information transfer between design and production activities.	(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.	of the SMS principles during the D&D phase. This documentation shall cover, at least, the following aspects; UK: "Well established" may be subjective. I suggest rewriting it as: "The design and development processes shall be established and documented." UK: The following content has been removed from 5.7.1 it should be added back here or as another requirement "It shall include risk management, requirements management, requirements implementation, testing, failure tracking,

		remedial actions, and release management” as otherwise these are not covered.
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; 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;	~~Examples of~~ The manufacturer shall document its processes and activities ~~that should be documented~~ to ensure the robustness of the design and development phase. This documentation shall cover, at least, 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: a. Assessment of the physical testing environment; b. Credibility assessment for virtual tool chain; 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;	**Canada:** I think the may here might give too much leeway to not implement these things. Would prefer a "shall" **EC:** Suggest to delete may and use shall even though the list cannot be exhaustive. These elements shall be documented. We suggest to rephrase like: “The manufacturer shall document its processes and activities to ensure the robustness of the design and development phase. This documentation shall cover, at least, the following aspects; **UK**: I don’t think we need justifications for regulatory requirements (correct me if I am wrong); hence, I suggest we delete: "to ensure the robustness of the design and development phase." **VCA:** Can we move away from using the term ‘operational safety’ here as a reference to SOTIF. This confuses with the more industry recognised term for ‘operational safety’ to relate to safety when operated, as seen in PAS 1881:2022 Operational Safety of Automated Vehicles. I can think of an

(iii) The personnel involved in the design; (iv) The tools and thresholds adopted for the ADS safety verification.	(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.	alternative that isnt a reference to SOTIF, but given there is reference to functional safety (implicitly considered as ISO26262) then why can't we do the same and call it SOTIF. **VCA:** I would prefer to see b. as – Credibility framework (and assessment). depends what comes out of the work on that topic. The manufacturer should put together a credibility framework and then provide evidence that they have addressed the requirements. That evidence and manufacturer review might be the "assessment" or that might more usefully be reserved for the 3rd party review activity. **Canada:** This may have overlap with some of the other section and/or requirements in the safety Case. Is this best placed at the manufacturer level (SMS), the ADS level or both? The rest of the text seems to allude to processes/activities for design and development vs the end product so perhaps both is the answer but should be careful to have complementary requirements vs overlapping.
5.7.3. It is recommended that the manufacturer institutes and maintains effective communication channels between the departments responsible for functional/operational safety, cybersecurity	~~It is recommended that~~ The manufacturer shall institute~~s~~ and maintain~~s~~ effective communication channels between the departments and third-party organizations responsible for functional/operational safety, cybersecurity and any other relevant	R155 and Technical Requirements under the 1998 Agreement (Recommendation document) covers there. This para. May not be necessary. **Canada:**

and any other relevant disciplines related to the achievement of vehicle safety.	disciplines related to the achievement of vehicle safety. These processes and activities shall be documented considering relevant standards and best practice.	Without further specifications, this would be very hard to enforce. Ie. What is an effective communication channel, how does it need to be used? EC: I think is necessary in the frame of the SMS compliance even if the R155 already has the same provisions. UK: could also include "third-party organizations" and "These processes and activities shall be documented considering relevant standards and best practice".
5.8. Production and Deployment Process	5.8. Production ~~and Deployment~~ Process Note: Create a dedicated subsection 5.9. "Post Deployment Process".	GER: Propose to include SMS process aimed at collection vehicle data and data from other sources to monitor and analyse safety-relevant incidents/accidents caused by the engaged ADS. The manufacturer shall report to authorities, market surveillance authorities and the Commission the relevant occurrences. This is also in reference to Field monitoring process (ISO26262 2 7.4.2.3, ISO21448 13.1).
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	~~It is recommended that~~ The manufacturer shall establish and document the production process ~~is well established and documented~~ in the SMS. ~~Examples of~~ The manufacturer shall document its processes and activities	The reference to specific standards should be deleted. Canada:

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.	~~that are recommended to be documented~~ to ensure the robustness of ~~the development and~~ the production phase ~~include~~. This documentation shall cover, at least, the following aspects: (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 organization performs all the production functions including management of working conditions, working environment, equipment and tools.	As above with regards to standards as examples with flexibility **EC:** Suggest to delete may and use shall even though the list cannot be exhaustive. These elements shall be documented. We suggest the rephrase as: "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; **UK:** 5.8.1 should use the term "established" instead of "well established" inline with elsewhere in the document
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).	The manufacturer shall establish and document their distributed production processes and activities in the SMS. ~~Examples of~~ The processes and activities may include ~~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).	**UK:** I suggest rewriting it as "The manufacturer shall establish and document their development and distributed production processes and activities in the SMS. The processes and activities may include:..." I don't think we need justifications for regulatory requirements (correct me if I am wrong); hence, I suggest we delete "to ensure the robustness of the development and distributed production." 5.8.2 appears to cover third-party interaction, but we may want to include the following, although it could be argued that it is implicitly covered by 5.8.2. The manufacturer shall have processes in place for updating and making available

		information to the relevant parties throughout the ADS lifecycle, including owners, transport service operators, assistants and emergency services. **VCA:** I'd agree with UK comments. This section should be beefed up to reflect management of suppliers used in the development, but also how their SMS interacts with organsations responsbile for the deployment.
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.	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. Note: Move to a new section 5.10. "Safety Assurance Process".	**UK:** Another justification - possibly delete General requirement
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.	The manufacturer shall include a robust process in the SMS to ensure that post-deployment software updates are properly validated and distributed and downloading is confirmed. Note: Move to a new section 5.9. "Post Deployment Process".	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) **EC:** Same as 5.7.3 **UK:** Perhaps a hard sell considering that only para from the VMAD doc is to be considered. However, we may want to consider including the following text to elaborate on 5.8.4.

		7.2. The manufacturer shall conduct and document compliance assessment audits against applicable standards and regulations. These shall be conducted by independent personnel, i.e., not by the personnel that created the evidence. 7.3. Examples of processes and activities that should be documented to assure independent design audit and assessment are: 7.3.1. Assurance that all practices and procedure applied during the vehicle / system development are followed. 7.3.2. Assurance that an independent checking of compliance with the applicable requirements and regulations is performed. 7.3.3. Process to assure the continuing evaluation of the Safety management system to ensure that it remains effective. **Canada:** we do not have UNR156 as a requirement at this time. The recommendation document does not have any 'legal standing' for us so would prefer to keep this in. However, this may also be covered in the safety case at the product-level. Move to 5.9

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 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.	~~It is recommended that~~ 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) ~~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~~ 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. Note: Move to a new section 5.10. "Safety Assurance Process".	[FR] to ensure that their approaches to safety management related to the committed activities comply with the safety policy of the manufacture Moved to 5.10
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	SMS documentation shall be regularly updated in line with any relevant changes to the SMS processes. It is ~~recommended~~ required that gap analysis ~~should~~ shall be used when auditing and updating the SMS, examining the current safety culture before	Required gap analysis? Revisit after December meeting EC: This part of the requirement applies to the entire lifecycle. My suggestion is to

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.	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. Note: Move to a new sub-section 5.10. "Safety Assurance Process" except the third sentence. Note: The last two sentences would be moved to a new section 5.11. "Safety Promotion"	create a section 5.10 "safety assurance process" Last sentence will move to 5.11 safety promotion.
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 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.~~ Note: Due to overlap, delete this text. Add "including in the event of discontinued production, support, or maintenance." to the end of 5.4.1..	Paragraph 5.8.7. can be combined with paragraph 5.4.1. Due to overlap, delete this text. complete 5.4.1 "In respect of ADS, the manufacture shall have establish a SMS with robust processes to manage safety risks and to ensure safety throughout the ADS lifecycle (development, production, operation and decommissioning), **including in the event of discontinued production, support, or maintenance**. "
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; (b) Assuring that an independent check of compliance with the applicable requirements is performed. (i.e., not from person creating the compliance data);	~~It is recommended that~~ The manufacturer shall have ~~has~~ 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);	Paragraph 5.8.8. can be combined with paragraph 5.8.3. **Canada:** There are a number of things in ISMR/Safety assessment that may be better placed in the SMS section. The SMS seems to be focused a lot on documentation and implementation of process but it does not seem to require any

(c) Assuring the continued evaluation of the Safety Management System so that it remains effective.	(c) Assuring the continued evaluation of the Safety Management System so that it remains effective. Note: Move to a new sub-section 5.10. "Safety Assurance Process".	action be taken from its implementation. I fear it may be put in place to meet the requirements but not actually implemented as it should be. (ie check in the box) It is not clear what happens if an issue is found, who can flag there is an issue and what happens once an issue is identified. Moved to 5.10, as it is.
	5.9. Post deployment process	**OPI ISMR:** proposal to introduce the following requirement which merges the contents of the 5.4.1(black text) and the content of a similar requirement from the ISMR section(red text): "The manufacturer shall establish processes to demonstrate its capabilities to execute an effective ISMR ~~It shall include taking appropriate measures to monitor the vehicle during the in-service operation~~ and to take the corrective remedial action when necessary.
	5.9.1. The manufacturer shall establish processes to demonstrate its capabilities to execute an effective ISMR and to take the corrective remedial action when necessary. 5.9.2. The processes for ISMR shall demonstrate the capabilities: (a)To monitor ADS operations; (b)To confirm the compliance with the defined safety case and 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	**OPI ISMR:** proposal to introduce the following text taken from the ISMR section: "The processes for ISMR shall demonstrate the capabilities: (a)To monitor ADS operations; (b)To confirm the compliance with the defined safety case and 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 (g)To report occurrences to the relevant authority when they occur; (h) To share learnings derived from occurrence analysis; (i) To contribute to the continuous improvement of automotive safety	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 (g)To report occurrences to the relevant authority when they occur; (h) To share learnings derived from occurrence analysis; (i) To contribute to the continuous improvement of automotive safety.
	5.9.3. The process for ISMR shall demonstrate the capabilities for handling the reports received from other sources, including distinguishing false reports from actual events and conducting thorough investigations when necessary."	**OPI ISMR:** proposal to introduce the following text taken from the ISMR section: "The process for ISMR shall demonstrate the capabilities for handling the reports received from other sources, including distinguishing false reports from actual events and conducting thorough investigations when necessary."
	5.9.4. The manufacturer shall include a robust process in the SMS to ensure that post-deployment software updates are properly validated and distributed and downloading is confirmed.	Note: Move from 5.8.4..
	5.10. Safety Assurance Process	
	5.10.1. The manufacturer shall define appropriate Key Performance Indicators	**OPI ISMR:** proposal to introduce the following text taken from the ISMR section:

	(KPI) to measure the effectiveness of ISMR activities for the ADS operations.	"The manufacturer shall define appropriate Key Performance Indicators (KPI) to measure the effectiveness of ISMR activities for the ADS operations." This requirement can be generalised to make it applicable for the entire SMS
	5.10.2. 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.	Note: Move from 5.8.3..
	5.10.3. ~~It is recommended that~~ 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) ~~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~~ The manufacturer shall document its processes and activities which may include the following aspects: (a) Organizational policy for supply chain;	Note: Move from 5.8.5..

	(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.	
	5.10.4. SMS documentation shall be regularly updated in line with any relevant changes to the SMS processes. It is ~~recommended~~ required that gap analysis ~~should~~ 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.	Note: Move from 5.8.6..
	5.10.5. ~~It is recommended that~~ The manufacturer shall have ~~has~~ 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); (c) Assuring the continued evaluation of the Safety Management System so that it remains effective.	Note: Move from 5.8.8..
	5.11 Safety Promotion Process	
	5.11.1. 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	Note: Move from 5.8.6..

	be communicated as required to the relevant authority.	