

Guidance Document for the Audit of Safety Management System (SMS)

Location:

- **GTR:** 6.1 to 6.1.11.2.10
- **UNR:** 8.1 to 8.1.11.2.10

Explanation

This text provides guidance concerning the audit section of the SMS. The following information does not create any obligation for Manufacturers and Authorities. It is only intended to provide suggestions on valuable information to support organizations developing, producing, and operating Automated Driving Systems (ADS) as well as those assessing compliance by providing information on:

- SMS design and implementation
- Evidence for auditing the SMS
- Criteria for determining the level of readiness of SMS

Location: 6/8.1.5. Audit of the safety policy

6/8.1.5.1.

The audit shall verify that the safety policy covers the following aspects/The approval authority or its designated technical service shall verify that the safety policy covers following aspects:

- (a) Definition of the principles and objectives upon which the SMS is built, operated, and maintained,*
- (b) General recognition of the inherent risks of ADS-related activities throughout their life cycle, including the risks of the parties involved,*
- (c) Organisational structure and the safety governance elements and their appropriateness for the needs of the organisation,*
- (d) Evidence of the commitment to safety, and*
- (e) Description of the means/approaches to engage people within the organisation in the culture of safety.*

Explanation

The SMS begins with the organisational safety policy and objectives. A policy defines the principles upon which the SMS is built and operated. It outlines the strategy for achieving an acceptable level of safety within the organisation. A Safety Policy can be considered

as the foundation of the SMS. It defines the organization's safety philosophy, commitments, governance, and may state the goal of having sufficient resources to assure safety. A safety policy also helps the organization to engage its people in the culture of safety. The intention of this requirement is to ensure that the safety policy provides a clear, structured, and organisation-wide foundation for the SMS, reflecting both strategic intent and operational realities.

Definition of Safety Objectives (ref. 6/8.1.5.1.a)

This element aims to ensure that the safety policy defines the core principles and objectives that underpin the SMS, providing direction for how safety is managed, measured, and continuously improved. The safety policy is expected to outline safety objectives that support the monitoring of safety performance. These objectives may be measurable where appropriate and may address both organizational performance and the in-service safety of the ADS, while being linked to key SMS activities such as risk management, safety assurance, and safety promotion.

Recognition of risks (ref. 6/8.1.5.1.b)

This element intends to ensure that the organisation acknowledges the inherent risks associated with ADS activities across the lifecycle, including those arising from all involved parties. Thus, the safety policy is expected to acknowledge the safety relevance of organisations involved, including suppliers, software providers, and service providers. It may also recognise potential safety risks associated with ADS operations and the need for appropriate oversight of third-party contributions. This reflects the expectation of a realistic and system-wide understanding of safety risks.

Organizational Structure and Safety Governance (ref. 6/8.1.5.1.c)

This provision highlights the need for a clearly defined governance framework, ensuring that roles, including those of the key people, such as the accountable executive and the SMS manager, their responsibilities, and the decision-making structures are appropriate to the organisation's size and function, and that the governance framework supports effective safety management.

Commitment to Safety (ref. 6/8.1.5.1.d)

The intention is to ensure that safety is visibly supported at the highest organisational level, demonstrating leadership commitment and accountability as a key enabler of an effective SMS. The safety policy is expected to demonstrate management commitment to safety, typically through approval by the accountable executive, and to support the promotion of safety and the continuous improvement of the SMS.

Safety Culture (ref. 6/8.1.5.1.e)

This element emphasises that safety depends on people. The policy may therefore describe how the organisation engages personnel to ensure that safety is actively supported across all relevant safety functions.

The safety policy is expected to promote a positive safety culture, encouraging transparent reporting, learning from safety events, and accountability, while outlining behaviours that are considered unacceptable.

Examples may include, but are not limited to:

- How an organisation defines safety objectives that incorporates their specific structure and activities.
- A safety policy that acknowledges a broad range of hazards, including those arising from software, data or organisational practices.
- How an organisation incorporates safety roles and responsibilities in its organisation structure to support effective governance.
- The way senior leaders demonstrate their commitment to safety, by being visible and actively engaging in review activities and communications.
- The approaches an organisation uses to encourage engagement with safety culture, such as regular discussions, briefings and feedback channels.

References for Implementation

Some useful references in this regard are:

- JRC140978 APPENDIX 1 - Technical Guidance on Safety Management System
- AVSC00007202107 - 5.1,
- ISO 9001:2015 - 5.2, ISO 21434:2021- 5.4.1, ISO 10013:2021 - 4.2.2 and 4.2.3, ISO 26262-2:2018 5.4.2.1, 5.4.2.2, ISO 45001:2018, ISO 55001:2024,
- CAP 795 Ch.3, EASA Management System Assessment Tool, Safety ICAO Doc 9859 AN/474 Safety Management Manual,
- ERA Guide on SMS requirements, Regulation (EU) No 376/2014

Location: 6/8.1.6. Audit of the risk management

6/8.1.6.1. The audit shall verify that the risk-management processes cover the following aspects/The approval authority or its designated technical service shall verify that the risk-management processes cover following aspects:

(a) Reactive and proactive practices for risk management are in place,

(b) The risk management activity is not limited to the ADS itself but includes risk arising from organisation/people which can affect the SMS effectiveness or the safety of the ADS,

(c) The risk management activity includes risks from third parties, and

(d) The risk management activity covers and is performed over the entire lifecycle.

Explanation

Safety risk management is the core activity that supports the SMS and contributes to achieving the safety objectives and the intended results of the Organization, as well as the effectiveness of other organizational processes. The term safety risk management, as opposed to the more generic term risk management, is meant to restrict itself to the management of safety risks (e.g., without consideration of factors such as financial, legal, economic, or reputational risks).

Reactive and proactive practices (ref. 6/8.1.6.1.a)

This provision aims to ensure that organisations do not rely solely on incident response but also implement forward-looking risk identification and prevention mechanisms. The combination of reactive (event-based) and proactive (predictive and preventive) practices reflects the expectation of a mature SMS capable of anticipating risks, not only responding to them.

Other sources of risks (ref. 6/8.1.6.1.b)

The requirement highlights that safety risks are not confined to the ADS technology itself. The intention is to ensure that risk management also addresses organisational structures, human performance, and internal processes, in order to identify hazards, perform risk analysis, design, implement and monitor effective safety controls. Recognising that these factors can significantly influence both SMS effectiveness and operational safety outcomes.

In this perspective, safety risk management covers both organizational safety risks such as process deficiency (i.e., process oriented safety risk) and operational risks (i.e. product and deployment support-oriented safety risk) due to hazards, which could reasonably be encountered during the operations of the ADS.

Third-party risks (ref. 6/8.1.6.1.c)

Risk management is also expected to take into account risks arising from third parties, such as suppliers, software providers, service providers, or other organisations whose activities could influence the safety of the ADS. This reflects the expectation that organisations address risks introduced by external actors, acknowledging that safety depends on the broader ecosystem, not only internal activities.

Lifecycle coverage (ref. 6/8.1.6.1.d)

Risk-management activities are expected to be applied throughout the entire ADS lifecycle, including development, production, deployment, and post-deployment

phases, ensuring that risks are continuously identified, assessed, and managed. The intention is to ensure that risk management is applied consistently across all lifecycle phases, avoiding gaps and ensuring ongoing control of risks.

Examples may include, but are not limited to:

- Proactive practices such as using hazard identification exercises or safety risk assessments.
- Reactive practices like incident reviews are part of the continuous safety improvement processes lifecycle.
- Including risks arising from sources including organisational practices, communication and human performance.
- Partners and suppliers sharing relevant safety information as part of third-party risk management.
- Full lifecycle risk management, including updating risk assessments and when there are new operational contexts and new technologies emerge.

References for Implementation

Some useful references in this regard are:

- JRC140978 APPENDIX 1 - Technical Guidance on Safety Management System
- ISO 31000:2018 6.3-6.6,
- AVSC00007202107 5.2,
- ISO 26262-2:2018 5.4.3,
- CAP 795 Ch.4, EASA,
- Management System Assessment Tool, Regulation (EU) No 748/2012.

Location: 6/8.1.7. Audit of the safety assurance

6/8.1.7.1. The audit shall verify that the safety-assurance processes cover the following aspects/The approval authority or its designated technical service shall verify that the safety-assurance processes cover the following aspects:

- (a) Periodic independent internal audits and external audits,*
- (b) Processes for the management of the supply chain and any other involved organisation(s) that could affect the safety of the ADS,*
- (c) Change management processes are in place,*
- (d) Processes for corrective actions to maintain an acceptable level of safety are in place,*
- (e) The corrective action applies to the ADS as well as SMS,*
- (f) Monitoring practices to measure overall safety performance are in place,*
- (g) The monitoring practices apply to the ADS as well as to the SMS, and*

(h) Independent functions for carrying out the compliance assessment and audit are in place.

Explanation

The intention of this requirement is to ensure that organisations have robust mechanisms to verify, monitor, and continuously improve safety performance. The regulatory text emphasises that Safety assurance is not a one-time verification activity, but a continuous, evidence-based process aimed at ensuring that safety measures remain effective over time.

Safety assurance refers to the set of activities used to monitor whether risk control measures remain effective and whether safety objectives are being met over time. It provides systematic processes that give confidence that organizational activities, and products, continue to meet established safety requirements.

Safety assurance typically includes collecting and analysing safety information, such as through audits, evaluations, employee reporting, and operational data. These activities help organisations identify new hazards, assess system performance, and determine opportunities for safety improvements.

Through regular system assessments and analysis, safety assurance supports the continuous evaluation and improvement of safety performance for both the organisation and the products it provides.

Internal and external audits (ref. 6/8.1.7.1.a)

This element ensures the presence of independent and periodic verification mechanisms to assess compliance and effectiveness of the SMS.

Supply chain and external organisations (ref. 6/8.1.7.1.b)

The requirement highlights that safety assurance is expected to extend beyond the organisation to include involved parties, reflecting a system-of-systems perspective.

Change management (ref. 6/8.1.7.1.c)

This provision ensures that changes are systematically assessed and managed, recognising that modifications can introduce new risks.

Corrective actions (ref. 6/8.1.7.1.d)

The intention is to ensure that organisations have processes to identify, implement, and track corrective actions to maintain safety at an acceptable level.

Scope of corrective actions (ref. 6/8.1.7.1.e)

This clarifies that corrective actions may address both technical aspects (ADS) and organisational/systemic aspects (SMS).

Monitoring of safety performance (ref. 6/8.1.7.1.f)

This element ensures the use of performance monitoring practices to track safety outcomes over time.

Scope of monitoring (ref. 6/8.1.7.1.g)

Monitoring is expected to cover both the ADS and the SMS, ensuring a comprehensive view of safety performance.

Independence of assessment functions (ref. 6/8.1.7.1.h)

The requirement aims to ensure that compliance and audit activities are carried out independently, supporting objectivity and credibility of the assessment.

Examples of good audit practice may include, but are not limited to:

- Examination of both documentation and practical implementation of safety processes.
- Assessment of how organisations coordinate safety information sharing with suppliers and partners.
- Review of change management activities and outcomes triggered by operational issues, software development updates and internal audits, improvements and product reviews.
- Reviews of root cause analysis and corrective actions.
- Review of impact and consequences of revised procedures and updated technical controls.
- Review of the approach and output from various monitoring procedures including operational data, safety reports and performance indicators.

Examples for Implementation

Some useful references in this regard are:

- JRC140978 APPENDIX 1 - Technical Guidance on Safety Management System
- ISO 26262-2/8:2028, ISO 9001 2015,
- AVSC00007202107, 5.3
- EASA Regulation (EU) No 748/2012, CAP 795 ch.5, EASA Management System Assessment Tool

Location: 6/8.1.8. Audit of the Safety Promotion

6/8.1.8.1. The audit shall verify that the safety-promotion processes cover the following aspects/The approval authority or its designated technical service shall verify that the safety-promotion processes cover the following aspects:

(a) There is an appropriate level of competence of the personnel to perform their duties,

(b) The competence is promoted through training,

(c) Means for internal and external safety communications are in place, and

(d) Process for continuous improvement.

Explanation

The intention of this requirement is to ensure that safety is actively supported by people, competencies, and communication, recognising that organisational culture is a key enabler of SMS effectiveness.

The regulatory text aims to highlight that technical measures alone are insufficient to ensure safety, and that a supportive organisational culture is essential.

Safety Promotion focuses on developing and maintaining a positive safety culture across the organisation. It includes activities that raise safety awareness, strengthen safety knowledge, and encourage active participation in safety-related processes.

Typical safety promotion actions may include SMS training, safety communication and awareness initiatives, sharing safety lessons learned, and ensuring that personnel competencies are appropriate for the various activities. ~~match system requirements~~. By promoting open communication and engagement, safety promotion encourages all members of the organisation to contribute to improving safety performance.

Personnel competence (ref. 6/8.1.8.1.a)

This provision ensures that staff have the necessary knowledge and skills to perform their safety-related responsibilities.

Training (ref. 6/8.1.8.1.b)

The requirement highlights that competence is expected to be actively developed and maintained through structured training.

Safety communication (ref. 6/8.1.8.1.c)

This element ensures the existence of effective communication channels, both internally and externally, to support awareness and information sharing.

Continuous improvement (ref. 6/8.1.8.1.d)

The intention is to ensure that safety promotion contributes to ongoing learning and improvement, reinforcing the adaptive nature of the SMS.

Examples may include, but are not limited to:

- How the organisational competency needs differ by role and may be supported through diverse training approaches.
- The range of organisational training using diverse methods and different formats such as written guidance, demonstrations, mentoring and workshop as appropriate.
- Communications that share lessons learned from incidents or audits.
- Mechanisms that enable employees to raise safety concerns or propose improvements.
- How organisations update SMS processes and practices based on practical insights.

Examples for Implementation

Some useful references in this regard are:

- JRC140978 APPENDIX 1 - Technical Guidance on Safety Management System
- ISO 26262-2:2018 5.4.4., ISO 9001:2015 7.2,
- AVSC00007202107 5.4.,
- CAP 795 Ch.6, Regulation (EU) No 748/2012, EASA Management System Assessment Tool