IMPLEMENTATION GUIDE



AUTOMATED ROAD TRANSPORT SYSTEMS

Requirements applicable to ARTS operational safety management systems (SMS)



Version 1 of November 6, 2023

Purpose – Scope – Recipients

This document sets out the requirements applicable to safety management systems for automated road transport systems (ARTS).

It applies to ARTS covered by Title V of Book I of Part Three of the Regulatory Part of the French Transport Code (Articles R. 3151-1 to R. 3153-1).

It is intended for all professionals in the sector, including public service organizers, operators, engineering firms, approved qualified organisations (OQA), designers of automated road transport technical systems, and equipment manufacturers.

The provisions of this Guide are intended to clarify and set out the applicable safety regulations. They formalise the agreed expectations of STRMTG and the sector, providing a framework designed to facilitate the work of professionals. They are limited to the safety of occupants and third parties with regard to operation of the system in automated driving mode, i.e. when a human driver is not providing dynamic control of the vehicle on roads open to public traffic (i.e. roads where there is nothing to prevent use by the public). The Guide is not regulatory in nature, but observance of its provisions can be seen as an indication of compliance with regulatory requirements and/or the suitability of the approach adopted.

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A - Introduction

1 - Definitions

The definitions in Article R. 3151-1 of the French Transport Code apply to this Guide, including:

"Automated road transport technical system": a set of highly or fully automated vehicles, as defined in Article R. 311-1, Sections 8.2 and 8.3 of the French Highway Code, and technical installations used for remote intervention or contributing to safety.

"Automated road transport system": automated road transport technical system deployed on predefined routes or traffic areas, and supplemented by operating and maintenance rules, for the purpose of providing a public collective or individual road transport service or private road transport service, excluding transport systems subject to Decree No. 2017-440 of March 30, 2017 regarding guided public transport.

"Operational domain": the operational conditions of use of an automated road transport technical system associated with specific routes or traffic areas consistent with the system technical design domain.

"System technical design domain": the operating conditions under which an automated road transport technical system is specifically designed to operate.

"Preliminary safety file": the file provided for in Article R. 3152-7 of the Transport Code.

"Safety file": the file provided for in Article R. 3152-8 of the Transport Code.

"Substantial modification": any change to an existing automated road transport system or part of a system, where the change alters the safety assessment.

"Qualified organisation": an organisation approved to conduct safety assessment of the design, implementation and operation of automated road transport systems.

"Safety management system": a set of rules, procedures and methods to be implemented to continuously achieve safety objectives.

"Service organizer": for public transport services provided under Article L. 1221-3 of the French Transport Code, the local authority responsible under Article L. 1221-1 or L. 1241-1 of the Transport Code; for public transport services organised under Part III, Book 1, Title 1, Section 3 of the Transport Code, the company referred to in Article L. 3111-17; for private public transport services, the operator under Article L. 3122-1; for private services, the natural or legal persons mentioned in R. 3131-1 and R. 3131-2.

"Operator": a natural or legal person who, directly or at the request of the service organizer, operates the transport system and manages and maintains it. The operator may be the same entity as the service organizer or the designer of the technical system. In the case of multiple operators, the term operator refers to the lead operator.

"Lead operator": an operator designated by the service organizer to coordinate operation of the transport system with the support of the various operators and infrastructure managers.

A lead operator is designated by the service organizer if there are several operators. The lead operator coordinates the day-to-day operation of the system and reports to the service organizer. In particular, it is responsible for establishing the lead operator's safety management system, in particular providing interfaces between the safety management systems of the various operators (Article R. 3152-11, V).

"Road manager": the authority responsible for roadways according to the French Roadway Code.

The following terms and definitions¹ also apply to this Guide:

"Interested party": person or organisation that can affect, be affected by, or perceive itself to be affected by a decision or activity.

"Top management": person or group of people who directs and controls the operator at the highest level.

Note 1: Top management has the power to delegate authority and provide resources within the operator's organisation.

Note 2: If the scope of the safety management system covers only part of the operator, then top management refers to those who direct and control that part of the operator.

"Policy": the operator's intentions and direction, as formally expressed by its top management.

"Objective": result to be achieved.

Note 1: Objectives can relate to different disciplines (such as finance, sales and marketing, purchasing, health and safety, and the environment). They can be, for example, organisation-wide or specific to a project, product, service or process.

Note 2: An objective can be expressed in different ways, for example as an intended result, a requirement, an operational criterion, as a compliance objective or by using other terms with the same meaning (e.g. aim, goal or target).

Note 3: In the context of safety management systems, the safety objectives of the management system are set by the operator, consistent with its safety policy, to achieve specific results.

"Safety objective of the safety management system"²: an objective set by the operator, in line with its safety policy, with a view to maintaining and, where reasonably practicable, improving its safety performance (see Section B - 3.2 -).

"Risk": effect of uncertainty in achieving objectives.

Note 1: An effect is a deviation from the expected - positive or negative.

Note 2: Uncertainty is the state, even partial, of deficiency of information related to, understanding or knowledge of, an event, its consequence, or likelihood.

Note 3: Risk is often characterised by reference to potential events and consequences, or a combination of these.

Note 4: In safety risk assessment, risk is expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the likelihood of its occurrence.

"Process": set of interrelated or interacting activities that uses or transforms inputs to deliver a result.

Note 1: Whether the result of a process is called an "output", "product" or "service" depends on the context of the reference.

"Competence": ability to apply knowledge and skills to achieve intended results.

"Documented information": information required to be controlled and maintained by an operator and the medium on which it is contained.

Note 1: Documented information can be in any format and media and from any source. Note 2: Documented information can refer to:

¹ Unless otherwise stated, terms and definitions are taken from "ISO/IEC Directives, Part 1 - Procedures for the technical work - Consolidated ISO Supplement, 2023 edition, Appendix 2 to Annex SL".

² Term and definition specific to this Guide

- The safety management system, including related processes;
- Information created in order for the operator to operate (documentation);
- Evidence of results achieved (records).

"Performance": measurable result.

Note 1: Performance can relate either to quantitative or qualitative findings. Note 2: Performance can relate to managing activities, processes, products, services, systems or organisations.

"Continual improvement": recurring activity to enhance performance.

"Effectiveness": extent to which planned activities are realised and planned results are achieved.

"Requirement": need or expectation that is stated, generally implied or obligatory.

Note 1: "Generally implied" means that it is custom or common practice for the operator and interested parties that the need or expectation under consideration is implied. Note 2: A specified requirement is one that is stated, for example in documented information.

"Conformity": fulfilment of a requirement.

"Nonconformity": non-fulfilment of a requirement.

"Corrective action": action to eliminate the cause(s) of a nonconformity and to prevent recurrence.

"Audit": systematic and independent process for obtaining evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled.

Note 1: An audit can be an internal audit (first party) or an external audit (second party or third party), and it can be a combined audit (combining two or more disciplines). Note 2: An internal audit is conducted by the operator itself or by an external party on its behalf. Note 3: "Audit evidence" and "audit criteria" are defined in ISO 19011.

"Audit criteria"¹: set of requirements used as a reference against which objective evidence is compared

Note 1: If the audit criteria are legal (including statutory or regulatory) requirements, the terms "compliance" and "non-compliance" are often used in audit findings. Note 2: requirements may include policies, procedures, work instructions, legal requirements, contractual obligations, etc.

"Measurement": process to determine a value.

"Monitoring": determining the status of a system, a process or an activity. Note 1: To determine the status, there can be a need to check, supervise or critically observe.

2 - Acronyms

OQA: Approved qualified organisation (*Organisme qualifié agréé*) ARTS: Automated Road Transport System DPS: Preliminary Safety File (*Dossier préliminaire de sécurité*) DS: Safety file (*Dossier de sécurité*) SMS: Operational safety management system STRMTG: Technical Service in Charge of Safety for Ropeways and Guided Transport (*Service technique des remontées mécaniques et des transports guidés*)

¹ Source ISO 19011

3 - Regulatory provisions

The safety management system is defined in Article R. 3151-1 of the French Transport Code:

"Safety management system": a set of rules, procedures and methods to be implemented to continuously achieve safety objectives.

The DPS describes the draft safety management system (Article R. 3152-7):

"The preliminary safety file describes, with regard to the intended operational domain of the automated road transport system: [...]

The draft operational safety management system which describes:

a) Operating and maintenance rules;

b) Measures for controlling the maintenance of the safety level;

c) Specifications for the performance of safety tasks;

d) Measures relating to work organisation and staff training;"

At the DPS stage, the draft safety management system is drawn up under the responsibility of the service organizer.

The final version of the safety management system forms part of the DS (Article R. 3152-8):

"The safety file, with regard to the intended operational domain of the automated road transport system, must:

1° Incorporate the final versions of the operational safety management system, along with the parts of the preliminary safety file that have changed;"

At the DS stage, Article R. 3152-11, III. gives responsibility for drawing up the safety management system to the ARTS operator:

"The operational safety management system is drawn up by the operator."

Before any decision to commission an ARTS, at the DPS and DS stages, the safety management system is assessed by an OQA, which must be approved for Technical Field No. 6 "Operational safety management systems" (Article R. 3152-11 II and III):

"The qualified organisation referred to in Article R. 3152-23 shall verify that the system described in this file meets the requirements of Articles R. 3152-2 to R. 3152-5 and complies with good practices. This verification is formalised by an Opinion which is attached to the preliminary safety file"

"The qualified organisation referred to in Article R. 3152-23 shall verify that the safety file demonstrates that the system meets the requirements of Articles R. 3152-2 to R. 3152-5 and complies with good practices. This verification is formalised by an Opinion which is attached to the safety file."

Once the ARTS has been commissioned, during the service life of the system, Article R. 3152-15 requires an annual audit of the safety management system to be carried out by an OQA, which must be approved for Technical Field No. 6 "Operational safety management systems":

" I. – The operator shall have an annual external audit carried out by the organisation referred to in Article R. 3152-27 in order to assess:

1° Application of the operational safety management system;

2° Effectiveness of internal control;

3° Adequacy of the safety management system in relation to changes in operational safety issues."

Article R. 3152-19 stipulates that staff responsible for safety tasks must be suitably accredited and trained. The safety management system must set out the content of the training and the procedures for issuing accreditations in accordance with the Order of 2 August 2022 implementing Article R. 3152-3 of the Transport Code, relating to the accreditation of remote operators in automated road transport systems. Article R. 3152-19 also requires the services responsible for safety assessment to be independent of those responsible for implementation.

"No one may be assigned to a safety task for which he or she is not qualified. The staff responsible for assessing safety shall come from departments other than those responsible for implementation and carry out their duties by analysis, monitoring, testing and inspection. Operating staff assigned to safety tasks shall receive appropriate training and accreditation, the content and procedures for which are set out in the safety management system referred to in Article R. 3152-7."

In the event of a change to the safety management system, the service organizer must determine, in conjunction with the operator, whether it is a substantial change to the ARTS, in which case operations must be suspended, a new assessment by an OQA must be carried out and a new decision must be made to commission the ARTS¹ (Article R. 3152-18, V).

If there is a change of operator, the new operator must draw up a safety management system. A change in operator is a substantial change to the ARTS.

¹ The decision to commission the ARTS may immediately follow the suspension of operation if the OQA has carried out its assessment and issued a favourable Opinion.

B - Safety management system requirements

Note on the structure of the requirements in this Guide:

The common framework of the ISO High-Level Structure¹ is used in this Guide to functionally group together the safety management system requirements defined in Article R. 3151-1 of the Transport Code. This alignment is particularly useful for operators who opt to implement a single (sometimes called "integrated") management system, enabling them to meet the requirements of two or more management system standards simultaneously. The framework also makes it easier for ARTS operators to understand and apply a process approach when developing, implementing, updating and continually improving their safety management system.

Note on cybersecurity:

In establishing, implementing, updating and continually improving the safety management system, the operator shall:

- a) Take into account the cybersecurity risks that may affect the safety of occupants and third parties, as defined in the STRMTG Implementation Guide on cybersecurity for ARTS;
- b) Comply with the applicable requirements set out in the Implementation Guide referred to above.

1 - Context of the operator

1.1 - Understanding the operator and its context

The operator shall determine the external and internal issues that are relevant to its purpose and that influence its ability to achieve the expected result(s) of its safety management system.

It shall identify the safety risks posed by ARTS operations, whether implemented by the operator itself or by contractors, partners or suppliers under its control.

It shall take account of the regulations applicable to ARTS (in particular Articles R. 3151-1 to R. 3153-1 of the French Transport Code) and the applicable STRMTG guides (in particular this Guide, the Guide on cybersecurity for ARTS, the Guide on managing safety-related events for ARTS and the Guide for the annual report on ARTS operational safety).

1.2 - Understanding the needs and expectations of interested parties

The operator shall determine:

- a) The interested parties who are relevant to the safety management system (e.g. public authorities, technical system designers, service organizers, road managers, emergency and rescue services, contractors, suppliers, partners, other operators, the lead operator where appropriate);
- b) The safety-related requirements of these interested parties (legal, regulatory or other requirements) to be addressed through the safety management system.

¹ ISO/IEC Directives, Part 1, 2016 Consolidated Supplement, Appendix 2 to Annex SL.

1.3 - Determining the scope of the safety management system

The operator shall determine the boundaries and applicability of the safety management system in order to establish its scope.

When determining this scope, the operator shall take into account:

- a) The external and internal issues and safety risks referred to in 1.1;
- b) The requirements referred to in 1.2.

The scope shall be available as documented information.

1.4 - Safety management system

The operator shall establish, implement, maintain and continually improve a safety management system, including the necessary processes and their interactions, in accordance with the requirements of this Guide.

2 - Leadership

2.1 - Leadership and commitment

The operator's top management shall demonstrate leadership and commitment to the development, implementation, maintenance and continual improvement of the safety management system by:

- a) Taking overall responsibility and accountability for safety within its scope;
- b) Ensuring commitment to safety by management at different levels within the organisation through their activities and in their relationships with staff and contractors;
- c) Ensuring that the safety policy and safety objectives of the safety management system are established, understood and compatible with the strategic direction of the operator;
- d) Ensuring the integration of the safety management system requirements into the operator's operational processes;
- e) Ensuring that the resources needed for the safety management system are available;
- f) Communicating the importance of an effective safety management system and of conforming to its requirements;
- g) Ensuring that the safety management system is effective in controlling the safety risks associated with operation of ARTS;
- h) Leading and encouraging staff to contribute to the effectiveness of the safety management system;
- i) Promoting continual improvement of the safety management system;
- j) Ensuring that safety is considered when identifying and managing risks associated with the operator's activities and explaining how conflict between safety objectives of the safety management system and other objectives associated with the activity will be recognised and resolved.

2.2 - Safety policy

Top management shall establish a safety policy that:

- a) Is consistent with the overall safety level of the ARTS established under the responsibility of the service organizer;
- b) Takes into account the requirements exported from the technical system into the operating and maintenance rules;
- c) Takes into account the measures established between the service organizer and the road managers or project managers, relating to knowledge, management and maintenance of roadways or technical and safety installations during operation of the service;
- d) Is suited to the scale of ARTS operating activities;

- e) Provides a framework for setting safety objectives of the safety management system and evaluating the operator's safety performance against these objectives;
- f) Includes a commitment to comply with all legal and other requirements related to safety;
- g) Includes a commitment to control safety risks which arise from its activities;
- h) Includes a commitment to continual improvement of the safety management system;
- i) Is implemented and applied appropriately, in accordance with the operator's strategy and the operator's safety performance assessment.

The safety policy shall:

- a) Be available as documented information;
- b) Be communicated within the operator's organisation;
- c) Be available to interested parties, as appropriate.

2.3 - Roles, responsibilities and authorities

The operator's top management shall ensure that the roles, responsibilities and authority of staff whose duties affect safety (including management and other staff performing safety-related duties) are defined at all levels within the operator's organisation, documented, assigned and communicated to the staff concerned.

Top management shall assign responsibility and authority for:

- a) Ensuring that the safety management system complies with the requirements of this Guide;
- b) Reporting on safety management system performance to top management.

Top management shall ensure that staff with delegated responsibilities for safety-related tasks have the authority, competence and appropriate resources necessary to perform their tasks without being adversely affected by other activities within the operator's organisation.

Delegation of responsibility for safety-related tasks shall be documented and communicated to the relevant staff, accepted and understood.

The allocation of roles referred to in the first paragraph shall be communicated to operational roles within the operator's organisation and where relevant, outside the operator (see Section 5.4 "Contractors, partners and suppliers").

3 - Planning

3.1 - Actions to address risks

3.1.1 - General

When planning for its safety management system, the operator shall take into account the issues referred to in Section 1.1 and the requirements referred to in Section 1.2, and identify the risks that need to be addressed in order to:

- a) Give assurance that the safety management system can achieve its intended result(s);
- b) Prevent or reduce undesired effects;
- c) Achieve continual improvement.

The operator shall plan:

- a) Actions to address these risks;
- b) How to:
 - i. Integrate and implement these actions into the safety management system processes;

ii. Evaluate the effectiveness of these actions.

3.1.2 - Risk assessment

The operator shall:

- a) Identify and analyse all risks associated with operation, maintenance, organisation and technical aspects corresponding to the type, scale and field of its activities. These risks include those resulting from human and organisational factors such as workload, workstation design, fatigue, and suitability of procedures, as well as those resulting from the activities of other interested parties (see Section 1 "Context of the operator");
- b) Assess the risks referred to in Point a) by applying appropriate risk assessment methods;
- c) Develop and implement safety measures;
- d) Implement a system to monitor the effectiveness of the measures (see Section 6.1 "Monitoring, measurement, analysis and assessment");
- e) Identify and specify the need to collaborate with other interested parties (such as law enforcement, technical system designers, service organizers, road managers, emergency and rescue services, contractors, suppliers, partners, other operators, and the lead operator as appropriate);
- f) Communicate risks to staff and involved external parties (see Section 4.4 "Communication").

Before implementing any modification to an ARTS in operation, the operator shall carry out an assessment of the risks arising from the change (see Section 5.6 "Management of change"), including those arising from the modification process itself.

3.1.3 – Safety tasks

The operator shall define the safety tasks performed by staff assigned to the operation or maintenance of ARTS, including those involved in remote intervention and supervision.

3.2 - Safety objectives of the safety management system and planning to achieve them

The operator shall establish the safety objectives of the safety management system for relevant functions at relevant levels to maintain and, where reasonably practicable, improve its safety performance.

The safety objectives of the safety management system shall:

- a) Be consistent with the safety policy and the organisation's strategic objectives (where applicable);
- b) Be measurable (if feasible);
- c) Take into account applicable legal and other requirements;
- d) Be monitored;
- e) Be communicated;
- f) Be reviewed on the basis of the results achieved and revised as necessary;
- g) Be kept up to date as documented information.

When planning how the safety objectives of the safety management system will be achieved, the operator shall determine:

- a) The actions that will be done;
- b) The resources that will be required;
- c) Who will be responsible;
- d) Deadlines;
- e) How the results will be evaluated.

The operator shall describe the strategy and plan(s) for monitoring achievement of the safety objectives of the safety management system (see Section 6.1 "Monitoring, measurement, analysis and assessment").

3.3 - Planning of changes

When the operator decides that it is necessary to modify the safety management system, the modifications shall be carried out in a planned manner.

4 - Support

4.1 - Resources

The operator shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the safety management system.

4.2 - Competence

4.2.1 - General

The operator shall ensure that staff having a role that affects safety are competent in the safety-related tasks for which they are responsible (see Section 2.3 "Roles, responsibilities and authorities"). To do this, taking into account the applicable regulatory requirements, the operator shall define:

- a) The competencies (including knowledge, qualifications, and non-technical behaviours and attitudes) required for safety-related tasks;
- b) Selection principles (basic educational level, psychological and physical fitness required);
- c) Initial training, experience and qualifications required;
- d) Ongoing training and periodic update of existing competencies;
- e) Periodic assessment of competence and periodic checks on psychological and physical fitness to ensure that these are maintained over time;
- f) Specific training in relevant parts of the safety management system in order to deliver their safetyrelated tasks.

Appropriate documented information shall be available as evidence of these competencies.

4.2.2 - Training

The operator shall provide a training programme, as referred to in points c), d) and f) of Section 4.2.1, for staff performing safety-related tasks, which ensures that:

- a) The training programme meets the identified competency requirements and individual needs of staff;
- b) Where applicable, training ensures that staff can perform their duties under all operating conditions (normal, degraded and emergency);
- c) The duration of training and the frequency of refresher training are appropriate for the training objectives;
- d) Records of training are kept;
- e) The training programme shall be regularly reviewed and audited (see Section 6.2 "Internal auditing") and changes shall be made where necessary (see Section 5.6 "Management of change").

Specific back-to-work arrangements shall be in place for staff following accidents/incidents or long absences from work, including providing additional training where such a need is identified.

4.2.3 – Accreditation of staff assigned to safety tasks

In accordance with Article R. 3152-19 of the French Transport Code, the operator shall:

a) Implement an accreditation system for staff assigned to safety tasks;

- b) Ensure that the staff responsible for these tasks have the necessary competence (see Section 4.2.1 "General") and have received appropriate training (see Section 4.2.2 "Training");
- c) Ensure that no staff are assigned to a safety task for which they are not accredited.

4.2.4 – Remote-intervention operator accreditation

The operator shall ensure that it complies with the requirements relating to the suitability and training of ARTS remote-intervention operators, which are set out in the Order of 2 August 2022 implementing Article R. 3152-3 of the Transport Code, relating to the accreditation of remote-intervention operators for automated road transport systems.

4.3 - Awareness

Staff carrying out work under the authority of the operator and having safety-related tasks shall:

- a) Be made aware of the safety policy;
- b) Be aware of their contribution to the effectiveness of the safety management system, in particular to achievement of the safety objectives of the safety management system (see Section 3.2 "Safety objectives of the safety management system and planning to achieve them");
- c) Be aware of the repercussions and consequences of any failure to meet safety management system requirements.

4.4 - Communication

The operator shall determine the relevant communication needs for the exchange of safety-related information between the different levels of the operator and with external interested parties, including contractors, partners and suppliers.

To ensure that safety information reaches those who issue opinions and make decisions, the operator shall manage the identification, receipt, processing, production and dissemination of safety-related information.

The operator shall ensure that safety-related information is:

- a) Relevant, complete and understandable for the intended users;
- b) Valid;
- c) Accurate;
- d) Consistent;
- e) Controlled (see Section 4.5.3 "Control of documented information");
- f) Communicated before it takes effect;
- g) Received and understood.

4.5 - Documented information

4.5.1 - General

The operator's safety management system shall include:

- a) Documented information required by this Guide;
- b) Documented information that the operator considers necessary for the effectiveness of the safety management system.

4.5.2 - Creating and updating documented information

When creating and updating documented information, the operator shall ensure appropriate:

a) Identification and description of the documented information (e.g. its title, date, author, reference number);

- b) Format (e.g. language, software version, graphics) and media (e.g. paper, electronic, for example);
- c) Review carried out to determine its relevance and adequacy;
- d) Approval.

4.5.3 - Control of documented information

Documented information required by the safety management system and by this Guide shall be controlled to ensure:

- a) That it is available and suitable for use when and where needed;
- b) That it is adequately protected (for example, from any loss of confidentiality, inappropriate use or loss of integrity).

To control documented information, the operator shall implement the following activities, where applicable:

- a) Distribution, access, retrieval and use;
- b) Storage and preservation, including preservation of legibility;
- c) Change management (e.g. version control);
- d) Retention and disposition.

Documented information of external origin determined by the operator to be necessary for the planning and operation of the safety management system shall be identified and controlled.

Documented information required by the safety management system and by this Guide shall be kept for a minimum of 10 years.

Note: access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and modify the documented information.

4.5.4 - Description of the safety management system

The operator shall draw up a document describing the safety management system covering:

- a) The identification and description of the processes and activities related to the safety of operations, including safety-related tasks and associated responsibilities (see Section 2.3 "Roles, responsibilities and authorities");
- b) The interaction between these processes;
- c) The procedures or other documents describing how these processes are implemented;
- d) The identification of contractors, partners and suppliers with a description of the type and extent of services delivered;
- e) The identification of contractual arrangements and other business agreements, concluded between the operator and other parties identified under Point d) necessary to control the safety risks of the operator and those related to the use of contractors;
- f) Reference to the documented information required by this Guide.

4.5.5 - Annual Report on ARTS Operational Safety

In accordance with Article R. 3152-14 of the Transport Code, the operator shall prepare an Annual Report on ARTS Operational Safety and submit it to the service organizer, who in turn submits it to the Prefect and STRMTG.

To prepare the report, the operator shall take into account the STRMTG Implementation Guide for the Annual Report on ARTS Operational Safety.

5 - Operation

5.1 - Operational planning and control (1)

The operator shall plan, implement and control the processes needed to meet requirements and to carry out the actions determined in Section 3, by:

- a) Establishing criteria for these processes;
- b) Implementing control of these processes in accordance with the criteria.

Documented information shall be available to the extent necessary to provide assurance that the processes have been carried out as planned.

The operator shall control planned modifications to the ARTS, analyse the impacts of unforeseen modifications and, if necessary, take action to mitigate any negative effects (see Section 5.6 "Management of change").

The operator shall ensure that outsourced processes, products or services, which are relevant to the safety management system, are controlled.

5.2 - Operational planning and control (2)

When planning, developing, implementing and reviewing its operational processes, the operator shall ensure that during operation:

- a) Safety measures are applied (see Section 3.1.2 "Risk assessment");
- b) Plan(s) to achieve the safety objectives of the safety management system are delivered (see Section 3.2 "Safety objectives of the safety management system and planning to achieve them");
- c) Information is collected to assess the correct application and effectiveness of the operational arrangements (see Section 6.1 "Monitoring, measurement, analysis and assessment").

The operator shall ensure that its operational arrangements conform to the safety-related requirements of the regulations applicable to ARTS and any other relevant requirements (see Section 1 "Context of the operator").

To control risks where relevant for the safety of operational activities (see Section 3.1.2 "Risk assessment"), the operator shall take at least the following into account:

- a) The various operating modes of the system, the conditions for switching from one mode to another and the management of this switch (normal, degraded, emergency modes, start-up or return to operation after, in particular, a prolonged interruption of operation or a collision);
- b) Management of safety-related events (see Section 7.2 "Safety-related events") and the implementation of appropriate precautionary measures when such an event occurs;
- c) Minimal-risk manoeuvres, emergency manoeuvres, remote intervention, passenger evacuation arrangements and on-site intervention;
- d) The conditions required to operate the system and the associated monitoring and alarm devices (e.g. visibility conditions, environmental conditions, traffic conditions (density), connectivity conditions);
- e) Operating conditions related to the ARTS route, in particular: partial services, worksites on and/or near the roadway, obstacles on the route, impact by the environment, areas with particular safety issues, etc.;
- f) The cybersecurity requirements to be applied during the operation-maintenance phases in order to ensure that the level of cybersecurity risks to the system is kept to an acceptable level (see STRMTG Implementation Guide on cybersecurity for ARTS).

To control the allocation of responsibilities where relevant for the safety of operational activities, the operator shall define how relevant tasks affecting the safe delivery of all services are allocated to competent staff within the organisation (see Section 2.3 "Roles, responsibilities and authorities"), and to other external qualified parties when appropriate (see Section 5.4 "Contractors, partners and suppliers").

To control information and communication where relevant for the safety of operational activities (see Section 4.4 "Communication"), relevant staff shall be advised of all specific requirements relating to the operation of ARTS, including any relevant changes which may result in a hazard, and temporary or permanent operational restrictions (e.g. due to roadworks).

To control competence for the safety of operational activities (see Section 4.2 "Competence"), the operator shall ensure that:

- a) Its staff receive training and comply with work instructions, and corrective actions are taken where required;
- b) Its staff receive specific training in case of anticipated changes affecting the running of operations or the tasks assigned to them;
- c) Following a safety-related event, adequate measures are adopted with staff if necessary.

5.3 - Asset management for ARTS technical systems

The operator shall manage the safety risks associated with the assets of ARTS technical systems, hereinafter referred to as "assets" (see Section 3.1.2 "Risk assessment").

The operator shall:

- a) Ensure that the assets are used for the purpose intended while maintaining their safe operational state and expected level of performance in all operating modes;
- b) Detect, as soon as reasonably practicable, instances of nonconformity with operating requirements before or during the operation of the assets, including the application of restrictions of use as appropriate to ensure a safe operational state of the asset (see Section 6.1 "Monitoring, measurement, analysis and assessment").

The operator shall ensure that its asset management arrangements, where applicable, conform to all relevant requirements (see Section 1 "Context of the operator").

To control the risks associated with asset maintenance (see Section 3.1.2 "Risk assessment"), the operator shall at least:

- a) Implement a preventive and corrective maintenance plan, taking into account the requirements of interested parties, to maintain the asset in a safe operational state, based on its planned and actual use and its design characteristics;
- b) Manage the removal of the asset from operation for maintenance, when defects have been identified or when asset condition degrades outside the limits of a safe operational state as referred to in Point a);
- c) Manage the return to operation of the asset with eventual restrictions of use after maintenance has been delivered to ensure it is in a safe operational state;
- d) Manage monitoring and measurement equipment to ensure that it is fit for its intended purpose.

To control information and communication where relevant for the safe management of assets (see Section 4.4 "Communication"), the operator shall take into account:

- a) The exchange of relevant information within the organisation or with external entities responsible for maintenance (see Section 5.4 "Contractors, partners and suppliers"), in particular on safety-related malfunctions, accidents and incidents as well as on eventual restrictions of use of the asset;
- b) The traceability of all necessary information, including information relating to Point a) (see Section 4.4 "Communication" and Section 4.5.5 "Control of documented information");

c) The establishment and maintenance of records, including the management of changes affecting the safety of assets (see Section 5.6 "Management of change").

5.4 - Contractors, partners and suppliers

The operator shall identify and control safety risks arising from outsourced activities, including operation or cooperation with contractors, partners and suppliers.

To control the safety risks referred to in the previous paragraph, the operator shall define the criteria for the selection of contractors, partners and suppliers, and the contract requirements they have to meet, including:

- a) The legal and other requirements related to safety (see Section 1 "Context of the operator");
- b) The level of competence required to deliver the tasks set out in the contract (see Section 4.2 "Competence");
- c) The responsibilities for the tasks to be performed;
- d) The safety performance to be maintained during the contract;
- e) The obligations relating to the exchange of safety-related information (see Section 4.4 "Communication");
- f) The traceability of safety-related documents (see Section 4.5 "Documented information").

The operator shall:

- a) Monitor the safety performance of all activities and operations of contractors, partners and suppliers to ensure that they comply with the requirements set out in the contract;
- b) Ensure that contractors, partners and suppliers are aware of the safety risks they pose to the operator's activities.

5.5 - Management of relations with other external parties

5.5.1 – Management of relations with road managers

The operator shall manage relations with road managers to ensure that road-related information that may impact ARTS operational safety is continuously exchanged between the operator and road managers.

5.5.2 – Management of relations with other external partners who may have information concerning the operational safety of ARTS

The operator shall manage relations with external parties who may have information concerning ARTS operational safety (law enforcement, rescue and emergency services, security services, etc.) in order to ensure that this information is constantly exchanged between the operator and these partners (see also 5.7 "Emergency management and intervention and safety plan").

5.5.3 – Management of relations between the lead operator and other operators (where applicable)

The operator shall manage relations with other operators to ensure day-to-day coordination of the transport system operations.

If the operator is the lead operator, it shall define and implement:

- a) Measures for managing interfaces between the safety management systems of the different operators;
- b) The organisation and resources put in place to prepare the annual report on the system's operational safety (see Section 4.5.5 "Annual Report on ARTS Operational Safety").

If the operator is not the lead operator, it shall manage interactions with the lead operator to ensure dayto-day coordination of ARTS operations.

5.6 - Management of change

The operator shall implement and control changes to the ARTS (including route changes or safety management system changes) to maintain or improve safety performance. This shall include decisions at the different stages of change management and the subsequent review of safety risks (see Section 3.1.2 "Risk assessment").

Before implementing a change to the ARTS (including a change to the route or the safety management system), the operator shall assess whether or not it is substantial and determine how it will be handled, particularly with regard to informing the service organizer.

5.7 - Emergency management and the intervention and safety plan

5.7.1 - Emergency management

The operator shall identify emergency situations and the associated timely measures to be taken to manage them (see Section 3.1.2 "Risk assessment") and to re-establish normal operating conditions.

The operator shall ensure that, for each identified type of emergency:

- a) The emergency services can be promptly contacted;
- b) The emergency services are provided with all relevant information both in advance, to prepare their emergency response, and at the time of an emergency;
- c) First aid is provided internally.

The operator shall identify and document the roles and responsibilities of all parties.

The operator shall have plans for action, alerts and information in case of emergency including arrangements to:

- a) Alert all staff with responsibility for emergency management;
- b) Communicate information to all parties (e.g. infrastructure manager, contractors, authorities, emergency services), including emergency instructions for passengers;
- c) Take any decisions required in accordance with the type of emergency.

The operator shall describe how resources and means for emergency management have been allocated (see Section 4.1 "Resources") and how training requirements have been identified (see Section 4.2 "Competence").

The emergency arrangements shall be regularly tested in cooperation with other interested parties and updated when appropriate.

5.7.2 - Intervention and safety plan

The operator shall prepare an intervention and safety plan in accordance with Article R. 3152-13 of the French Transport Code. This plan shall describe:

- a) The internal organisation put in place to respond without delay in the event of an incident affecting or likely to affect the safety of ARTS or surrounding third parties;
- b) The resources that may be mobilised in this event;
- c) The division of tasks between the operator and road managers;
- d) The procedures for alerting external emergency services and for communicating and coordinating with these services.

6 - Performance evaluation

6.1 - Monitoring, measurement, analysis and assessment

The operator shall determine:

- a) What needs to be monitored and measured;
- b) The monitoring, measurement, analysis and assessment methods, as appropriate, to ensure the validity of the results;
- c) When monitoring and measurement shall be carried out;
- d) When the monitoring and measurement results shall be analysed and assessed.

Documented information shall be available as evidence of these results.

The operator shall evaluate the performance and effectiveness of the safety management system.

The operator shall regularly monitor the performance of safety-related tasks at all levels within the organisation and intervene if they are not being properly performed.

The operator shall implement measures to ensure that safety level of ARTS operation is maintained. To guarantee the ongoing effectiveness of these measures, they shall be periodically monitored, reviewed and tested.

In accordance with Article R. 3152-19 of the French Transport Code, the operator shall ensure that the staff responsible for assessing safety come from departments other than those responsible for implementation and carry out their duties by conducting analysis, monitoring, tests or inspections.

6.2 - Internal auditing

6.2.1 - General

The operator shall conduct internal audits at planned intervals to provide information to determine whether the safety management system:

- a) Complies with:
 - i. The operator's own safety management system requirements;
 - ii. The requirements of this Guide;
- b) Is effectively implemented and kept up to date.

6.2.2 - Internal audit programme

The operator shall plan, establish, implement and maintain one or more audit programmes, including frequency, methods, responsibilities, planning requirements and reporting.

When establishing an internal audit programme or programmes, the operator shall take into account the importance of the relevant processes and the results of previous audits.

The operator shall:

- a) Define audit criteria and the scope of each audit;
- b) Select auditors and carry out audits in such a way as to ensure the objectivity and impartiality of the audit process. In accordance with Article R. 3152-19 of the French Transport Code, the operator shall ensure that the staff responsible for assessing safety come from departments other than those responsible for implementation;
- c) Ensure that the results of audits are reported to the relevant managers and to top management.

Documented information shall be available as evidence of the implementation of the audit programme(s) and audit results.

Note: recommendations for auditing management systems are given in ISO 19011.

6.3 - Management review

6.3.1 - General

At planned intervals, top management shall review the continuing suitability, adequacy and effectiveness of the safety management system implemented by the organisation.

6.3.2 - Management review inputs

The management review shall take into account:

- a) The status of actions from previous management reviews;
- b) Changes in internal and external issues (see Section 1 "Context of the operator");
- c) Changes in the needs and expectations of relevant interested parties regarding the safety management system;
- d) The operator's safety performance related to:
 - i. The achievement of the safety objectives of the safety management system;
 - ii. The results from its monitoring activities, including the internal audit findings, and internal accident/incident investigations and status of their respective actions;
 - iii. The results of external audits of the safety management system (see Section 6.4 "External Auditing");
- e) Opportunities for improvement.

6.3.3 - Management review outputs

The results of the management review shall include decisions on opportunities for continual improvement and on any changes to be made to the safety management system.

Documented information shall be available as evidence of the results of management reviews.

6.4 - External auditing

Every year, the operator shall have an external audit of the safety management system carried out by an OQA approved for Technical Field No. 6 "Operational safety management systems", in accordance with Article R. 3152-15 of the French Transport Code.

The operator shall submit the audit report to the service organizer, together with the OQA's Opinion on the continuation of operations and any action plan that should be implemented.

7 - Improvement

7.1 - Continual improvement

The operator shall continually improve the suitability, adequacy and effectiveness of the safety management system, taking into account, in particular, the outputs of the following activities:

- a) Monitoring, measurement, analysis and assessment (see Section 6.1 "Monitoring, measurement, analysis and assessment");
- b) Internal auditing (see Section 6.2 "Internal auditing");
- c) Management review (see Section 6.3 "Management review");
- d) External auditing (see Section 6.4 "External auditing");

e) Lessons learned from accidents and incidents (see Section 7.2 "Safety-related events").

The operator shall provide means to motivate staff and other interested parties to be active in improving safety as part of its organisational learning.

The operator shall provide a strategy to continually improve its safety culture, relying on the use of expertise and recognised methods to identify behavioural issues affecting the different parts of the safety management system and to put in place measures to address these.

7.2 - Safety-related events

Safety-related events resulting from the operator's automated transport activities shall be:

- Reported, logged and analysed to determine their causes, in accordance with Article R. 3152-22 of the French Transport Code and the STRMTG Implementation Guide on managing safety-related events for ARTS;
- b) Reported to the interested parties in accordance with Article R. 3152-22 of the Transport Code and the STRMTG Implementation Guide on managing safety-related events for ARTS.

The operator shall ensure that recommendations from the authorities or the national investigating body, or internal or industry investigations are evaluated and implemented if appropriate or mandated.

The operator shall:

- a) Use information resulting from event analyses to review the risk assessment (see Section 3.1.2 "Risk assessment");
- b) Learn lessons with the aim of improving safety;
- c) Where applicable, adopt corrective and/or improvement measures (see Section 5.6 "Management of change").

7.3 - Nonconformity and corrective action

When a nonconformity occurs, the operator shall:

- a) React to the nonconformity and, where appropriate:
 - i. Take action to control and correct it;
 - ii. Deal with the consequences;
- b) Evaluate, if necessary with the relevant interested parties, the need for action to eliminate the cause(s) of the nonconformity in order that it does not recur or occur elsewhere, by:
 - i. Reviewing the nonconformity;
 - ii. Determining the causes of the nonconformity;
 - iii. Determining if similar nonconformities exist or can potentially occur;
- c) Implement all actions needed within a timeframe appropriate to the nature of the nonconformity;
- d) Review the effectiveness of any corrective action taken;
- e) Make changes to the safety management system if necessary.

Corrective actions shall be appropriate to the effects of the nonconformities encountered.

Documented information shall be available as evidence of:

- a) The nature of the nonconformities and any subsequent actions taken;
- b) The results of any corrective action.

Note: the nonconformities referred to here are those relating to safety management system requirements.

C - Preparation of the Guide

In accordance with Article R. 3152-1 of the French Transport Code, STRMTG is responsible for preparing and updating ARTS safety assessment and demonstration guidelines.

This document has been prepared on the basis of the work of the "Operational safety management system guidelines for ARTS" working group, led by STRMTG/DTPA, which includes representatives of STRMTG, service organizers, operators, vehicle and ARTS designers and manufacturers, and bodies considering approval as OQAs.

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