IMPLEMENTATION GUIDE

STRMTG
SERVICE TECHNIQUE DES REMONTÉES MÉCANIQUES ET DES TRANSPORTS GUIDÉS

AUTOMATED ROAD TRANSPORT SYSTEMS

« GAME » PRINCIPLE
Globally at least equivalent

MINISTÈRE CHARGÉ DES TRANSPORTS
Liberté
Égalité
Fraternité

Version 1 of December 20, 2021

Purpose - Scope - Intended recipients

This implementation guide explains a demonstration methodology for the “GAME” principle (Globally at least equivalent) provided for by Decree no. 2021-873 of June 29, 2021 implementing Ordinance No. 2021-443 of April 14, 2021 on the type of criminal liability applicable to the operation of an automated road transport vehicle and its conditions of use (French Automated Road Transport System Decree - ARTS Decree).

It applies to automated road transport systems (ARTS), defined by Article R.31151-1 of the French Transport Code (added by Article 6 of the ARTS decree) as *"technical automated road transport systems, 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 concerning guided public transport safety”*.

It is intended for all professionals in the automated public transport sector, including public transport authorities (AOM), project owners, operators, project managers, engineering firms, approved qualified organizations (OQA), automated road transport system designers, and equipment manufacturers.

The purpose of this guide is to clarify and explain applicable safety regulations. It formalizes the agreed expectations of the STRMTG and the profession, thus providing a framework to facilitate the work of professionals. It is not regulatory in nature, but observance of its provisions can be seen as an indication of compliance with the regulatory requirements relating to the GAME principle and/or the suitability of the approach adopted.

These provisions are limited to the safety of the vehicle occupants (passengers, drivers, etc.) and of third parties with regard to system operation.

They do not address:

- issues related to public safety (suspicious packages, vandalism, etc.) or accessibility of the transportation system itself;
- issues related to health and safety conditions for operating and maintenance staff;
- intervention and rescue procedures defined by emergency services;
- issues related to public access buildings such as stations, except for their interfaces with the transport system;
- issues related to external fire control (DECI);
- the consideration of potential risks generated by project works when they do not impact on an existing automated road transport system.

Revision history

Version number	Author	Date	Description
1	P.Jouve	12/20/2021	Created by GAME working group (ARTS)

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Introduction

Decree no. 2021-873 of June 29, 2021, implementing Ordinance no. 2021-443 of April 14, 2021, on the type of criminal liability applicable in the event of the operation of an automated transport vehicle and its conditions of use, sets out the safety requirements applicable to Automated Road Transport Systems (ARTS) and in particular the “Globally at least equivalent” (GAME) principle. This decree is referred to in the rest of this document as the "ARTS Decree".

Demonstration of compliance with these requirements includes several overlapping demonstrations which are linked between the subsystem and system levels. This document only elaborates on demonstration of the GAME requirements.

Vehicles covered by the Automated Road Transport Systems Decree are first subject to prior approval under the French Traffic Code. Approval (or homologation) is the administrative certification of the conformity of the vehicle to the requirements of the technical regulations in order to allow its registration and operation. This process is not addressed in this guide. Approval is a prerequisite for demonstrating safety, but it is not enough to demonstrate the safety of the systems with respect to all hazardous events. By definition, the scope of the approval is limited to the vehicle. Therefore, while the results of the approval and its associated reference documents serve as input data for the safety demonstration of ARTS, the analyses performed as part of the approval cannot replace the system-level analyses described in this guide.

Demonstration of compliance with the safety requirements applicable to the ARTS is performed at the system level. It is carried out for each system in its operational domain and for a predefined route or area and aims to ensure safe operation under reasonably foreseeable traffic conditions. Approval of ARTS safety is a complex process in which several overlapping and complementary approaches coexist.

- The aim of the safety demonstration, under the GAME approach, is to show that the overall level of safety with regard to users, operating staff and third parties is at least equivalent to the existing level of safety or to that resulting from the implementation of systems or subsystems providing comparable services or functions, taking into account current practices, field experience concerning them, and the reasonably foreseeable traffic conditions on the route or traffic area in question.
This demonstration can combine several types of approaches for the systems or subsystems considered, including compliance with existing regulations and technical standards, comparison with existing reference systems (difference-based approach), detailed risk analysis combining inductive and deductive analysis.
GAME demonstration concerns the overall scope of the system and aims to cover all risks related to the safety of vehicle occupants and third parties, without being limited to those related to vehicle collision or system malfunctions. It defines both quantitative and qualitative requirements for the design and operation of the system. These requirements are then applied to the various subsystems and components as well as in the safety management system (SMS). Only this demonstration covered in this implementation guide.

- The purpose of the "scenario-based approach" is to develop a set of traffic scenarios which are representative of the system's operational domain. It provides a basis for certain steps of the GAME safety demonstration, which use or generate scenarios. The scenario-based approach seeks first to harmonize the descriptors of the driving contexts as well as the objects and traffic events potentially encountered in the technical system's operational domain. By combining the descriptors of driving environments and hazards, and, if applicable, additional hazards as systematically as possible, the scenario-based approach can help minimize the risk of omitting critical scenarios in the safety demonstration. For the operational design domain

(ODD) of the system, the scenario-based approach can also extract a set of traffic scenarios which the safety demonstration might need to identify, or the reasons why that scenario is not relevant to the system in question, which would provide useful information on how the risk of scenario omission has been addressed. The scenario-based approach has yet to be developed at the time of writing and is therefore not described in this guide.

- The purpose of the route safety analysis is to demonstrate the compatibility of the route with the system technical design domain and the ability of the technical system to operate safely on the route in the traffic situations it may encounter. Since each route on which an ARTS is deployed is unique and has its own risks, a safety analysis of each route is systematically required. This analysis is used to identify specific traffic scenarios for each route, which are complementary to the GAME approach and the scenario-based approach. Requirements specific to the route safety analysis are not described in this guide.

- The cybersecurity analysis defines the requirements for the protection of digital systems against attacks, which must be taken into account at the various stages of design of the systems, as well as during their various life phases. Cybersecurity is not addressed in this guide.

The safety demonstration of an ARTS is therefore a set of demonstrations interfaced with each other. While this implementation guide defines the general framework for demonstration, it does not describe all aspects of the demonstration.

Finally, the demonstration methodology for the GAME principle presented in this implementation guide is by no means exclusive. For any new system or for any modified part of an existing system, other demonstration methodologies may be used, as long as they have similar objectives. In this case, the alternative demonstration methodology will also be evaluated by the approved qualified organization (OQA).

Definitions

The definitions below are taken from Article R.3151-1 of the Transport Code created by Article 6 of the ARTS Decree:

“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 Traffic Code, and technical installations used for remote intervention or 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 concerning guided public transport safety;

“Operational domain”: the conditions of use of an automated road transport technical system associated with specific routes or traffic areas consistent with its system technical design domain;

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

“Substantial modification”: any modification to an existing automated road transport system or part of a system, where the modification alters the safety assessment;

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

In addition, clarification of the following terms is provided on the basis of definitions from existing publications or those developed within the specific framework of this guide:

“Hazard”: a condition that could lead to an accident (EU Regulation 402/2013 of 30 April 2013).

“Fault/failure”: abnormal condition that may cause a reduction in, or loss of, the capability of a functional unit to perform a required function (IEC 61508-4:2010).

“Risk”: the combination of the likelihood of damage and its severity.

Abbreviations

AOM: Public transport authority (*Autorité organisatrice de la mobilité*)
DCST: Technical system design file (*Dossier de conception du système technique*)
DECI: External fire defense (*Défense extérieure contre l’incendie*)
DPS: Preliminary safety file (*Dossier préliminaire de sécurité*)
DS: Safety file (*Dossier de sécurité*)
ERP: Public access building (*Etablissement recevant du public*)
GAME: Globally at least equivalent (*Globalement au moins équivalent*)
ODD: Operational Design Domain
OQA: Approved qualified organization (*Organisme qualifié agréé*)
SMS: Safety Management System
SOTIF: Safety of the intended functionality
ARTS: Automated Road Transport System

1. Scope

This guide applies to transport systems covered by Article R.3152-2. of the French Transport Code created by Article 6 of ARTS Decree No. 2021-873 of June 29, 2021. It therefore applies to automated road transport technical systems deployed on predefined routes or traffic areas, 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 concerning guided public transport safety.

The ARTS Decree introduces the obligation for automated road transport systems to comply with the "GAME" principle (Globally at least equivalent principle) with regard to their safety level.

This requirement is introduced in the following terms in Article R.3152-2 of the Transport Code created by Article 6 of the ARTS Decree:

“Art. R. 3152-2. – I. - For the purposes of Article L. 3151-1, any automated road transport system or any part of an existing transport system shall be designed, commissioned and, where appropriate, modified in such a way that the overall level of safety with regard to users, operating personnel and third parties is at least equivalent to the existing level of safety or to that resulting from the implementation of systems or sub-systems providing comparable services or functions, taking into account the current practices, field experience concerning them, and reasonably foreseeable traffic conditions on the route or traffic area in question.”

The GAME concept takes into account:

- the different parts of an existing system;
- changing practices (standards, technical guides, recommendations, etc.);
- field experience.

The same Article R.3152-2 addresses the case where a comparative analysis cannot be conducted with an existing system:

"When it is established that there is no comparable system for assessing the safety of the system in question or of one of its subsystems, the level of safety may be established on the basis of a specific safety study for the system or subsystem concerned, conducted in accordance with good engineering practice.”

The purpose of this guide is therefore to explain the conditions of the demonstration by comparison with a reference system and its connection with cases where there is no reference system.

Before presenting the methodology for demonstrating compliance with this principle, the scope of application of this principle should be clarified.

1.1. Scope of the system under analysis

The methodology proposed in the following chapters is based on the following findings and analyses:

An automated road transport system comprises various interfaced structural and operational subsystems.

Each subsystem is itself made up of different subsystems, which may be interfaced.

As systems mature, an automated road transport system may be made up of “standard” sub-assemblies already used on similar systems. Some sub-assemblies may therefore have already been demonstrated to be safe, at least for given usage and environmental conditions.

However, each automated road transport system is unique. The interfaces between the system’s different sub-assemblies, the characteristics of its environment, the route or the predefined area where it operates are therefore specific. This observation justifies the development of safety demonstrations and their evaluation on a case-by-case basis, prior to the decision to commission an ARTS, in addition to the logic of national type approval implemented in the road vehicle sector for example.

It is therefore necessary to check the ability of the various sub-assemblies to operate safely together and the ability of the system to operate safely in its environment on its predefined route (or area).

The level of safety at the system level cannot therefore be substantiated by the demonstration alone, without any other form of guarantee, of the level of safety of its various sub-assemblies.

Therefore, the ARTS Decree defines the notion of automated road transport system as including the vehicles and non-vehicle technical installations, the route or area where these components are deployed and the operating and maintenance rules.

For the purposes of this document, the term “system” is used generically. It can therefore refer to a complete automated road transport system, a technical system, a subsystem or a component.

The GAME principle therefore applies to the system under consideration, but it must be regarded as part of the complete automated road transport system. This means that the safety demonstration must be conducted for the entire automated road transport system in question, i.e. a technical system deployed on a given route and subject to operating and maintenance rules.

As a result, even if a modification only concerns one component of an automated road transport system, the GAME demonstration must be conducted for the complete automated road transport system in question.

1.2. Operations concerned

The GAME principle is a general principle which, according to the terms of the decree, must be implemented for any new automated road transport system or any modification, even if not substantial, of an existing system.

The GAME principle must therefore be complied with at all times.

If a modification is not substantial (i.e. the safety assessment of the system is unchanged), the safety level of the system is not impacted by the modification. The analysis showing that the modification is not substantial therefore demonstrates compliance with the GAME principle.

As soon as a modification leads to a change in the safety assessment of the system, the modification is considered substantial.

1.3. Safety scope

Article R.3152-2. of the French Transport Code created by Article 6 of the ARTS decree, defines 3 major “populations”:

- users of the transportation system,
- operating personnel,
- third parties,

for which the GAME principle must be complied with for any new system or modification of an existing system.

In the context of the decision process for commissioning automated road transport systems (and the related safety files), without prejudice to the safety requirements deriving from other regulations, the demonstration of GAME is only explained in this guide with reference to the safety of the vehicle occupants (including operating staff when they are passengers in the system) and third parties with regard to the operation of the system.

2. Objectives and limits of the GAME principle

2.1. Notion of “globally”

The notion of “globally” associated with the GAME principle can be understood at different levels (complete system, subsystem, by hazardous event, for a set of hazardous events, for all hazardous events, etc.).

It implies that a structural “deficiency” of the system can, subject to substantiation, be “compensated” by a “gain” in one (or more) other structural provision(s) or be made “acceptable” by means of one (or more) operational measure(s) (e.g., specific maintenance or operating criteria).

In any case, any safety gains due to modal shifts (from conventional road transport modes to automated transport in particular) linked to the introduction of the new transport system cannot be included in the GAME demonstration.

In conclusion, while the GAME principle introduces a certain flexibility through the possibility of pursuing a "system" approach to safety, the notion of "globally" associated with it must be understood within the limits mentioned above.

2.2. Notion of “equivalence”

The notion of “equivalence” introduced by the decree reflects the objective of not reducing the level of safety with respect to the level of safety of comparable existing systems.

It should be noted that this equivalence, when demonstrated in relation to a comparable system or subsystem, must also take into account the evolution of industry practices and field experience on the system or subsystem in question, in accordance with Article R.3152-2 of the Transport Code created by Article 6 of the ARTS decree. Therefore, if part of a system is modified, changes to industry practices and field experience will only be taken into account for the modified part of the system.

2.3. Relationship between the different demonstration approaches

Schematically, there are three applicable safety demonstration approaches, applied hazard by hazard:

- Type 1 approach: compliance with technical and safety regulations or compliance with a technical standard;
- Type 2 approach: comparison with an existing system, also known as the “difference-based approach”;
- Type 3 approach: detailed risk analysis for each hazardous event using a recognized method.

The safety demonstration should be based on one or a combination of these approaches, with priority given to the Type 1 approach:

Type 1	Firstly, if there is an applicable regulatory framework, it applies. The reference is therefore based on and imposed by the regulatory provisions in force. Along the same lines, although at another level (since it is not legally enforceable), the issue of the reference is resolved if there is a recognized and relevant technical standard (e.g.,: standard, STRMTG technical guide, recommendation, etc.). The standard taken into account must be that in force when the methodology for demonstrating safety for the route or area in which the technical system is deployed is adopted (i.e. on the date of the OQA's favorable opinion on the DPS, provided that the commissioning decision is made within a reasonable time following this date). These technical standards constitute the minimum safety level allowed without substantiation. However, other demonstrations can be proposed, as long as the equivalence of the requirements to the standard set out in the second paragraph is substantiated.
Type 2	When there is neither an applicable regulatory standard nor an applicable technical standard, comparison with an existing reference system, called “difference-based approach”, can be considered. The system used as a reference must then meet the various criteria explained in Section 3. Changes to industry practices in relation to those of the reference system and field experience must be taken into account when the standards are adopted, at the date of the favorable opinion of the OQA concerning the DPS.
Type 3	When there is neither an applicable regulatory standard nor an applicable technical standard, the Type 2 approach may be rejected, either by choice or because the criteria associated with it cannot be met and therefore there is no reference system (e.g., in the case of innovations and new designs). A detailed risk analysis must then be performed. This may lead to the definition of safety objectives for the system's functions and/or the implementation of recognized standards in other fields, in force at the date of the OQA's favorable opinion on the DPS.

For Type 2 and 3 approaches, several analysis methodologies are possible (quantitative, qualitative, etc.). The nature of the analysis depends directly on the specificities and the scope of the project (at a system, sub-system, function, component level, etc.). Therefore, it is impossible to define an absolute rule in this regard.

In any case, for operations that are subject to a commissioning decision, the safety demonstration methodologies are evaluated by an OQA, as provided for in the ARTS Decree, during evaluation of the safety files (DCST, DPS and DS).

Specificity of the route analysis

Regardless of the approach taken, analysis of the route on which the ARTS is deployed is necessary and is a required component of the system's safety demonstration. Each route is unique and the risks associated with an urban development depend on various factors often linked to the local context (traffic, speeds, types of road users). A safety analysis of each route is therefore necessary to demonstrate the compatibility of the route with the system technical design domain and the ability of the technical system to operate safely on the route in the situations it may encounter.

For example, this demonstration may require the creation of improvements on the route, the adaptation of traffic conditions at certain points on the route, or even modifications to the technical system.

In all cases, field experience associated with a clearly identified risk on a given traffic configuration must be taken into account.

3. Requirements specific to the difference-based approach (Type 2)

3.1. Overview

A new system can (except for innovations or new designs) be made up of several “standard” sub-assemblies, which may have been modified and/or adapted, already in place on other systems in operation.

This observation legitimately leads technical system designers and transport authorities to want to implement a “difference-based” approach to safety, so that safety demonstrations are not repeated when they have already been performed.

This type of approach is entirely feasible, but only under the following conditions:

- the reference system must meet the conditions in Section 3.2;
- the reference system must be perfectly understood (configuration, identification, etc.), along with its limits (in particular the system technical design domain) and conditions of use (required operating conditions, exported requirements, etc.), so as to identify the possible differences with the new system, from a technical standpoint and in terms of the conditions of use and maintenance;
- the exhaustive identification of the differences between the new system and the reference system must be substantiated;
- for each difference identified, it must be demonstrated that the measures implemented guarantee that the safety level of the new system is not lower than the system used as a benchmark.

Notwithstanding the foregoing, use of the difference-based approach to demonstrate safety does not negate the need to provide descriptive information about the system under consideration nor of substantiations relating to the safety of the reference system and, if applicable, the system in question.

The documentation concerning the demonstration and the description of the system considered as requested in the safety files (DCST, DPS, DS) should not be limited to the differences with the reference system.

3.2. Choosing the reference system

If the comparison with an existing system is chosen, the choice of the reference is essential insofar as it establishes the level of safety that needs to be achieved.

This may be the case, for example, when there is no applicable technical standard or when a system already in operation is renewed in an identical (or almost identical) manner.

The ARTS Decree requires that any new system (or modification of an existing system) provide a level of safety that is at least equivalent to the level of safety of systems providing comparable services. The requirement of the decree is therefore to compare levels of safety and not (necessarily) to compare systems with each other.

3.2.1. Multiple reference systems

The ARTS Decree defines as a general reference the safety level of existing systems providing comparable services.

Therefore, it does not impose a single reference system, which can be chosen based on the different subsystems of the transport system. If there are several reference systems, the compatibility between the subsystems and management of the interfaces require special attention.

However, when the safety of a new or modified existing system is demonstrated by comparison with existing systems, it is best to limit the number of reference systems as much as possible.

3.2.2. Rules for choosing the reference system

While it is difficult to define absolute rules for choosing the reference system, a number of principles must be followed:

- In accordance with the ARTS Decree, the reference system may be the system concerned (in the case of a system modification) or an existing system providing comparable services. In all cases, the system must have been in operation for at least two years or have previously been in operation for at least two years with positive field experience. The reference system must be identified at the stage when the safety demonstration principles are decided (at the DPS or DCST stage).

- At the stage when the reference system is identified, changes to best practices with respect to the best practices used for design of the reference system must also be taken into account. Deviations from these best practices (standards, technical guides, recommendations, etc.) must be identified and their acceptability justified.

- The reference system must be a system that exists in France or, alternatively, a country of the European Union (or a state which applies technical and safety rules equivalent to those of the European Union).

    - A - If the reference system is in France:

The system has been assessed in accordance with Section 3 of the ARTS Decree and is deemed to be an acceptable safety reference, provided that no safety deficiencies have been identified from field experience.

Demonstrating that the safety level of a new system is equivalent to that of a system that is not satisfactory in terms of safety would prevent the new system from being put into operation.

Therefore, compliance of a new system with a system already in operation is not necessarily a sufficient condition for obtaining the authorization to operate.

    - B- If the reference system is in another country of the European Union (or a state which applies technical and safety rules equivalent to those of the European Union):

There are two possible scenarios:

Case 1:	The proposed reference system meets the following conditions:

	• it has been assessed (in accordance with the assessment mission provided for in Section 3 of the ARTS Decree); • the assessment was conducted by an organization which is: ◦ independent (as defined in Section 3 of the ARTS Decree); ◦ approved by STRMTG as a Qualified Organization (OQA); • the assessment standards are recognized by STRMTG In this case, the proposed system is an acceptable reference, unless a safety deficiency is identified through field experience on the system.
Case 2:	The proposed system does not meet one (or more) of the above conditions. In this case, the acceptability of the system as a reference for demonstrating safety is assessed on a case-by-case basis by the OQA.

- The reference system must be the same type as the system being assessed. The safety of an ARTS system must therefore be demonstrated by comparison with a reference ARTS system. Adaptations are possible for functions that are common to a different transport system. In this case, the acceptability of the reference system will need to be reviewed by the OQA.

- The reference system must be comparable to the system under assessment, both functionally and in its operating conditions.

- The reference system must be relevant in terms of the safety objective.

- For routes or areas where a technical system is deployed, the notion of a comparable system does not really make sense. As explained in Section 2.3, each route is unique and therefore it is always necessary to analyze the route where a technical system is deployed in order to demonstrate the compatibility of the route with the system technical design domain of the technical system in question.

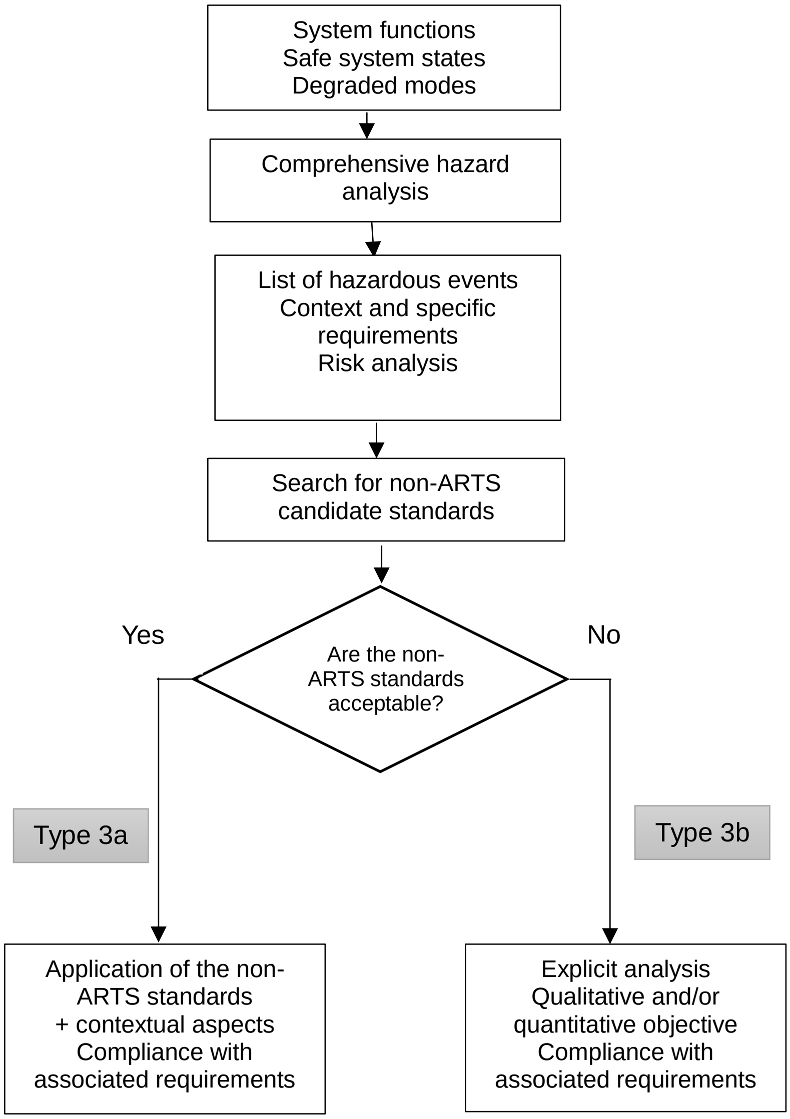
- In any case, the choice of the reference system is subject to an assessment by the qualified organization in charge of the assessment. This assessment will be formalized in the opinion of the approved qualified organization sent to STRMTG, as provided for by the ARTS Decree.

4. Requirements specific to the detailed risk analysis (Type 3)

4.1. Overview

In the case of a system integrating innovative equipment or functions, the difference-based approach may not be possible if there are neither regulatory or technical standards applicable to the complete system, nor an acceptable reference system. It is then necessary to analyze the risks induced by these new functions or this new equipment, in the context of the system in a precise and global way (in accordance with the 2nd paragraph of Art. R. 3152-2. – I. of the Transport Code).
Furthermore, even if there is an acceptable reference system, this same approach, called detailed risk analysis (Type 3), can be chosen instead of the difference-based approach (Type 2).

In order to lighten this analysis work, it is important to be able to use existing technical standards for systems that are not automated road transport systems ("non-ARTS") in this detailed analysis. For example, a designer might find it interesting to analyze the relevance for ARTS of a recognized fire protection standard from the railway sector.



In order to use these non-ARTS standards, the analysis must be made at the hazards level to analyze if there is a recognized non-ARTS standard able to deal with each hazard, in the context of the overall system.

The detailed analysis approach includes several steps:

- Determination of system functions, safe system states, potential degraded modes and maneuvers to achieve safe states.

- Comprehensive analysis of hazards associated with functions and equipment in the context of the overall system. This analysis is broad and aimed at analyzing all the hazards that the system can generate (for example, the families of hazards analyzed at this stage can lead to fires, collisions, derailments, trapping, etc.). This analysis can be based on
  - a deductive approach such as a preliminary hazard analysis performed at the system level analyzing the different causes that can lead to the same hazard;
  - inductive approaches such as the functional FMECA of the system, analyzing the possible failures of each function and the associated potential hazard.

- For each hazard identified in the previous step,
  - Analysis of its potential impacts on the overall system
  - Definition of safety measures to make the risk arising from the hazard acceptable, in the context of the overall system, particularly taking into account:
    - the expected behavior of the system in the hazardous situation;
    - potential aggravating factors such as the absence of drivers and staff and the collective nature of the transport system.

  - If there a system outside the ARTS domain that offers a recognized technical standard that can substantiate these safety measures:
    - Rigorous verification of the acceptability of the non-ARTS standards (See Section 4.2).

  - If the non-ARTS standards are deemed acceptable (Type 3a):
    - Formalization of any exported constraints (limitations, exclusions, conditions, assumptions, etc.) related to application of the non-ARTS standards;
    - Verification of compliance with the various requirements of the non-ARTS standard, supplemented by any contextual aspects.

  - If there are no non-ARTS technical standards, or none deemed acceptable under Section 4.2 (type 3b):
    - Conducting an explicit analysis to determine the qualitative and quantitative measures applicable for this hazard (See Section 4.3);
    - Verification of the implementation of measures stemming from this explicit analysis.

The documentation concerning the demonstration and the description of the system in question as required in the safety files (DCST, DPS, DS) must explain the analysis carried out and its conclusions for each hazard, as well as consideration of any exported constraints.

4.2. Acceptability of standards/reference documents outside the ARTS field

While it is difficult to define absolute rules concerning the acceptability criteria for non-ARTS standards or reference documents, a number of principles can be established:

- The non-ARTS standard under consideration must be recognized for the field it covers in terms of the safety objective.
- The scope of the non-ARTS standard must be compatible with the field of the ARTS systems for the hazard being analyzed. This must be demonstrated by analyzing the commonalities between the fields for this particular hazard, and by showing that there are no points that make the non-ARTS standard incompatible.
- The non-ARTS standard must specifically cover the hazard resulting from the analysis of the hazards specific to the ARTS system, through all the requirements resulting from the analysis of the hazards in the ARTS context, and in particular its potential severity, potential aggravating factors, requirements related to the expected behavior of the system, etc.
- Each standard represents a consistent set of requirements and it is important to apply each non-ARTS standard in its entirety as much as possible.
  However, it is possible that due to the wide scope covered by the non-ARTS standard, only a part of the non-ARTS standard is applicable and suitable for the hazard considered in the analysis.
  In this case, it is necessary to determine and take into account all the contextual aspects and assumptions related to the applicable part of the non-ARTS standard.
- Each standard is based on application assumptions, constraints or conditions. These various constraints must be formalized and taken into account for each non-ARTS standard applied. The compatibility of each of these exported constraints with each other and with the specificities of the ARTS system must be verified.
- As explained above, the non-ARTS standard is chosen on a per-hazard basis, which results in a demonstration which juxtaposes several different non-ARTS standards. Therefore:
  - Compatibility between the different non-ARTS standards requires special attention;
  - In order to facilitate this analysis, it is best to limit the number of non-ARTS standards as much as possible.

Special attention should be paid to demonstrating the acceptability of non-ARTS standards. In particular, it will be necessary to rigorously explain why each standard was chosen, the analyses conducted to demonstrate the compatibility between the different standards, and the method used to take into account the exported constraints.

This demonstration will need to be evaluated by the OQA. This assessment will be formalized in the opinion of the approved qualified organization sent to STRMTG, as provided for by the “ARTS Decree”.

4.3. Principles of the explicit analysis

The explicit analysis is based on an analysis of the hazardous situation in order to determine a safety objective suitable for the situation and the system, then to apply this objective:

- to operational safety;
- and the “safety of the expected function”, in order to address functional deficiencies or reasonably foreseeable misuses (in the absence of any failure);

by means of demonstration frameworks from recognized safety standards (e.g., EN 50126, IEC 61508, ISO 26262, ISO PAS21448 “SOTIF”, ISO/TR 4804, etc.)

The process is broken down into several steps:

- Definition of an overall safety objective based on the accident analysis and field experience from different "target" transport systems (or combinations of systems) already in service, taking into account the specificities of ARTS systems
    - Qualitative and/or quantitative objective such as “number of events per km” or “number of events per hour”, which can also be applied for each level of severity for each scenario,
    - Taking into account a safety margin linked to the innovative nature of ARTS systems and social sensitivity towards any event associated with these systems (automated driving, public transport).

- Successive allocation of the safety objective to the different levels based on the principle of recognized standards in the safety field
    - for macro-functions based on the comprehensive hazard analysis prepared in the initial step, for system functions based on the functional architecture of the system,
    - for subsystems and components based on the hardware architecture of the functions.

5. Methodology

The GAME demonstration must be carried out for each hazardous event.

If necessary, in particular when safety is not ensured for one or more hazardous events, “arbitrations” for a whole set of hazardous events can be implemented within the limits stated in Section 2.1, taking into account the social acceptability of certain types of events.

The methodology is based on the following general 2-level structure:

Globally	1. Substantiation of an overall approach to safety: • A "system" approach to safety based on the generic list of hazardous events, enabling identification of risks linked to the operation of the system as a whole and the definition of safety requirements to be followed for each sub-assembly and each internal interface (between sub-assemblies) or external interface (constraints exported to the environment), • Justification of the implementation of provisions to meet each of the safety requirements defined to ensure the overall safety of the system, • Implementation of a system-wide safety management process to ensure traceability of these requirements throughout the development of the system (including requirements exported to operations and maintenance), • Justification of the appropriateness of the construction and safety demonstration process for the whole system in relation to the applicable standards and best practice, assessed by the OQA.
At Least Equivalent	2. Justification of risk management measures (= "at least equivalent" to): • Justification of the "sufficiency" of each measure implemented to meet the safety requirements defined for each sub-assembly and each interface by demonstrating their compliance: o Preferably with a recognized, relevant technical reference documents (technical regulations, standards, STRMTG technical guides, recommendations, etc.). This is the Type 1 approach, or if there is no recognized and relevant technical standard, o with technical or operational provisions already implemented on similar existing systems and justified from a safety standpoint. This approach can be useful in globally justifying the safety of a given sub-assembly operated identically (or almost identically) on a similar system. The conditions guiding this "difference-based" or Type 2 approach are specified in Section 3, o or with the safety levels and requirements identified by a detailed risk analysis. This approach can be applied to the case of an innovative piece of equipment or function. The conditions for this "detailed risk analysis" or Type 3 approach are specified in Section 4.

These two demonstration levels are inseparable, in the sense that they are both necessary but not individually sufficient to substantiate the safety of the system.

Demonstration that the system in question is “GAME” will be established when:

- implementation of a global approach to safety that complies with the standards and best practices in force can be substantiated

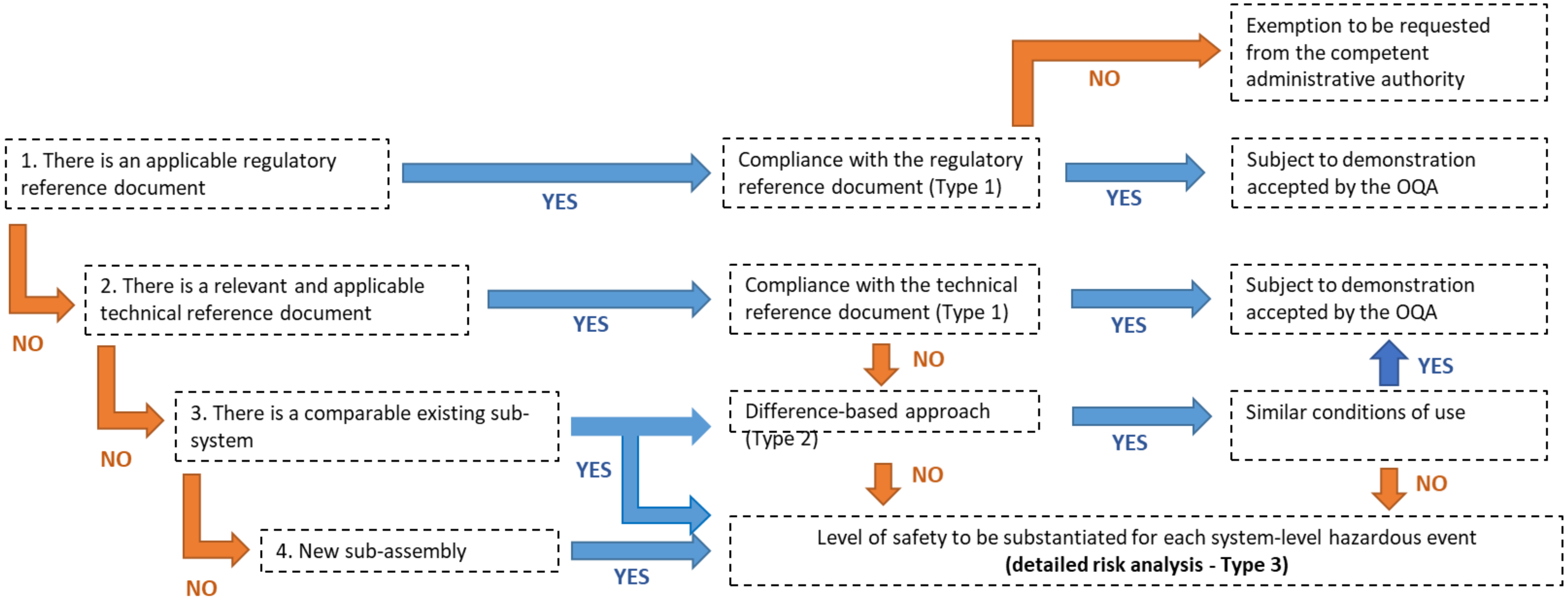
and

- implementation of suitable measures to cover all identified risks can be substantiated.

Otherwise, compensatory measures must be taken to demonstrate the safety of the system with respect to each of the "generic" hazardous events.

In any case, the GAME demonstration must be documented in documents presenting the various aspects substantiating that risks have been managed for the system.

Schematic diagram of the safety demonstration for a sub-assembly:



Annex - Preparation of the guide

In accordance with Decree no. 2010-1580 of December 17, 2010, creating the Technical Service in Charge of Safety for Ropeways and Guided Transport (STRMTG), STRMTG is responsible for producing guides and standards/reference documents.

This document was prepared by the national GAME ARTS working group created by STRMTG.

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Mr Ludovic Brun, STRMTG legal advisor, also contributed to the review of the guide