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1 Scope of this Sub guideline

As indicated in article 1 point 4 of regulation (EU) 2019/554, “one or several RUs in cooperation with one or several IMs (“the applicants”) may carry out pilot projects to test alternative means of ensuring the effective communication required by paragraph 1”.

The purpose of this document is to provide guidelines to facilitate the risk analysis by RUs and IMs.

To verify the safety impact on their organisation of the changes linked to the communication methods, each railway operator can rely on the documents drafted as part of deliverable D2.1.

2 Abbreviations and acronyms

Abbreviation / Acronyms	Description
EC	European Commission
GDPR	General Data Policy Regulation
IM	Infrastructure Manager
LP	Language Programme; the dedicated RNE work structure
LT	Prototype of a Language Tool
NSA	National Safety Agency
PDM	Predefined message
RFF	Rail Freight Forward
RNE	RailNetEurope
RU	Railway Undertaking
SMS	Safety-Management System
sWG	sub-Working group
TSI OPE	Technical specification for Interoperability – Operation and traffic management subsystem
T4R	Translate4Rail
UIC	International Union of Railways
WO	Written orders
Xborder	UIC project and work structure dedicated to the issue of improving cross border operation

3 Content of this guideline

This sub guideline contains all information necessary to carry a risk assessment for pilot testing in the first phase (with train drivers who fulfil the requirements under point 8 of Annex VI to Directive 2007/59/EC) and the second phase pilot (with drivers with reduced linguistic skills than what is stipulated by regulation).

4 Reference documents

DOCUMENT REFERENCE	OFFICIAL JOURNAL
Directive 2004/49/EC of the European Parliament and of the Council on Safety on the Community's railways and amending Council Directive 95/18/EC on the licensing of railway undertakings and Directive 2001/14/EC on the allocation of railway infrastructure capacity and the levying of charges for the use of railway infrastructure and safety certification (Railway Safety Directive)	OJ L 164, 30.4.2004, p. 44–113
Directive 2007/59/EC of the European Parliament and of the Council of 23 October 2007 on the certification of train drivers operating locomotives and trains on the railway system in the Community	OJ L 315, 3.12.2007, pp. 51-78.
Commission Directive 2014/82/EU of 24 June 2014 amending Directive 2007/59/EC of the European Parliament and of the Council as regards general professional knowledge and medical and licence requirements	OJ L 184, 25.6.2014, pp. 11-15.
Commission Implementing Regulation (EU) No 402/2013 of 30 April 2013 on the common safety method for risk evaluation and assessment and repealing Regulation (EC) No 352/2009	OJ L 121, 3.5.2013, p. 8–25
Commission Regulation (EU) 2015/995 of 8 June 2015 amending Decision 2012/757/EU concerning the technical specification for interoperability relating to the 'operation and traffic management' subsystem of the rail system in the European Union	OJ L 165, 30.6.2015, p. 1–69
Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016	OJ L 138, 26.5.2016, p. 44–101

DOCUMENT REFERENCE	OFFICIAL JOURNAL
on the interoperability of the rail system within the European Union	
Directive (EU) 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety	OJ L 138, 26.5.2016, p. 102–149

5 Guideline on the application of REGULATION (EU) 2013/402

5.1 Introduction

This guide is articulated so to help the reader understand how regulation (EU) 2013/402 shall be applied.

The proposed change has an impact on safety and, the proposer¹ shall decide including safety expert judgement in the assessment process, on the significance of the change based on the following criteria:

- failure consequence: credible worst-case scenario in the event of failure of the system under assessment, considering the existence of safety barriers outside the system under assessment;
- novelty used in implementing the change: this concerns both what is innovative in the railway sector, and what is new for the organisation implementing the change;
- complexity of the change;
- monitoring: the inability to monitor the implemented change throughout the system life cycle and intervene appropriately;
- reversibility: the inability to revert to the system before the change;
- additionality: assessment of the significance of the change considering all recent safety-related changes to the system under assessment and which were not judged to be significant.

This part must be verified by each RU and IM involved in the pilot testing, on the basis of the particularities of their organization and their SMS. RUs and IMs involved in the pilot will assess the risk within their communication procedures besides the risk assessment performed by the proposer.

The risk analysis prepared in dedicated safety workshops for T4R led by UIC feeding into Deliverable 3.1 Report on safety aspects, is confidential and the result of this significance audit constitutes a recommendation and is not binding.

An assessment body shall carry out an independent assessment of the suitability of both the

¹ According to (EU) regulation 2013/402 article 3 (11)

'proposer' means one of the following:

(a) a railway undertaking or an infrastructure manager which implements risk control measures in accordance with Article 4 of Directive 2004/49/EC;

(b) an entity in charge of maintenance which implements measures in accordance with Article 14a(3) of Directive 2004/49/EC;

(c) a contracting entity or a manufacturer which invites a notified body to apply the 'EC' verification procedure in accordance with Article 18(1) of Directive 2008/57/EC or a designated body according to Article 17(3) of that Directive;

(d) an applicant for an authorisation for the placing in service of structural sub-systems;

application of the risk management process and of its results in case the assessment made identifies a significant change for the purpose of the pilot according to regulation (EU) 2013/402.

Based on the results of the application of risk assessment, the proposer shall produce a written declaration that all identified hazards and associated risks are controlled to an acceptable level and he shall keep adequate documentation to justify its decision.

5.2 General principles applicable to the risk management process

The risk management process shall start from a definition of the system under assessment and comprises the following activities:

- the risk assessment process, which shall identify the hazards, the risks, the associated safety measures and the resulting safety requirements to be fulfilled;
- demonstration of the compliance of the system with the identified safety requirements;
- management of all identified hazards and the associated safety measures.

The proposer in charge of the risk management process shall update the hazard record.

The first step of the risk management process shall be to identify the different actors' tasks, and their risk management activities.

The proposer is responsible for coordinating close collaboration between the different actors involved, according to their respective tasks, in order to manage the hazards and their associated safety measures.

Evaluation of the correct application of the risk management process falls within the responsibility of the assessment body.

5.3 Interfaces management

RUs and IMs concerned shall cooperate in order to identify and manage jointly the hazards and related safety measures that need to be handled at these interfaces. The management of shared risks at the interfaces shall be coordinated by the proposer.

Considering that the communication process needs safety measures that every actor cannot implement by itself, after agreement with another actor, the initial actor transfers the management of the related hazard to the other party. At the stage an RU identifies a hazard in case there is an interface to an IM they need to share this information and vice versa.

When a requirement in a notified national rule cannot be fulfilled by an actor, the proposer shall seek advice from the competent NSA.

6 Description of the risk assessment process

6.1 General description

The risk assessment process is the overall iterative process that comprises:

- the system definition;
- the risk analysis including the hazard identification;
- the risk evaluation.

The risk assessment process shall interact with hazard management.

6.1.1 System definition

The system definition structure needs to be prepared analogous to Annex I, no. 2.1.2 of Regulation (EU) 402/2013, the proposer may use other suitable forms of presentation to satisfy the system definition requirements (see also CG 451.0100A01, section 3.1).

The risk analysis analysed the system in six points:

- 1) System objective;
- 2) System functions and components;
- 3) System limits, including other interacting systems;
- 4) System limits and interfaces;
- 5) Physical and functional interfaces (System environment Safety measures and requirements);
- 6) Limits of risk assessment.

6.1.2 Hazard identification

The hazard identification needs to be prepared analogous to Annex I, no. 2.2.1 of Regulation (EU) 402/2013, the aim is defined as it is "*The proposer must systematically identify all reasonably foreseeable hazards for the entire system undergoing assessment and, if applicable, for its relevant functions and their interfaces, using the comprehensive specialist knowledge of a qualified team. All the hazards identified must be logged in the hazard record*".

All hazards arising from the change need to be systematically identified.

For hazard identification several tools can be used: simple brainstorming, Ishikawa-diagram, HAZOP (analysis of hazards using keywords), event-tree analysis, failure mode and effect analysis etc. according to the Applicant's Management System.

Following this, they had estimated or calculated the probability of occurrence of the hazards, and finally identified for each hazard the damage it can cause.

The respective risk category emerges from the combination of the frequency of occurrence of accidents (arising from hazards), incidents leading to damage and the extent of said damage.

The proposer must verify within his organization that there are no other identified hazards.

The proposer, in addition to the provisions of his SMS, must ensure the presence in the working group of IT specialist, and a train driver instructor (for the RU) and a signaller instructor (for the IM).

6.1.3 Risk analysis

Risks determined and their allocation to a risk acceptance principle (RAP) need to be evaluated, as well as residual risks and measures to overcome them, determining the mitigating measures and the related responsibilities.

The risk acceptability of the system under assessment shall be evaluated by the proponent using one or more of the following risk acceptance principles:

- The application of codes of good practices;
- A comparison with similar systems;
- An explicit risk estimation.

In accordance with the principle referred to in point 5.1, the assessment body shall refrain from imposing the risk acceptance principle to be used by the proposer.

Any inadequacy of safety measures expected to fulfil the safety requirements, or any hazards discovered during the demonstration of compliance with the safety requirements shall lead to reassessment and evaluation of the associated risks by the proposer.

The new hazards shall be registered in the hazard identification table.

6.1.3.1 Information for Risk Analysis

Following the description of the process defined in Sub guide “Communication and testing” a list of functional requirements has been elaborated which the system must fulfil:

PDMs	They must cover all operational situations; Their translation must be controlled by language experts to avoid any misinterpretation.
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<p>The Language tool</p>	<p>The personalized voice recognition must be of high quality and extremely reliable;</p> <p>The recognition of the key words in the sender speech must lead to very few choice of message;</p> <p>The neutral voice reading the messages in various languages must be assessed by drivers and signallers speaking in these foreign languages;</p> <p>The free speech quality of the translation must be high even if the messages are not impacting safety.</p>
<p>The tablet</p>	<p>The tablet must have a sufficient size to be read easily by the driver;</p> <p>The tablet must have a sufficient size to avoid choosing the wrong message displayed in case of some unexpected movement of the locomotive;</p> <p>The tablet must have an electric charger compatible with electricity available in the driver cabin;</p> <p>If possible, the tablet must have an audio output socket to convey by wire the voice directly to a line input on the GSM-R radio;</p> <p>The tablet must have a sufficiently powerful loudspeaker to cover the background noise in the cabin.</p>

6.1.4 Demonstration of compliance with safety requirements

To prepare a train run through the cross-border section some operational requirements are to be fulfilled, which need to be investigated within each company.

RUs and IMs will carry out their own risk assessment (apart from the risk assessment that is performed by the proposer) on integration of the tool within their communication and safe operational procedures because they are in charge of fulfilling the safety requirements.

In case of a consortium such as Translate4Rail for demonstrating a Language Tool prototype the responsibility would remain the same (with involved RUs and IMs) under the umbrella of the consortium.

Before the starting of the Pilot on field, fulfilment of the safety requirements resulting from the risk assessment phase done by RUs and IMs shall be demonstrated under the supervision of the proposer, also based on data from the previous stages in the laboratory. This demonstration shall be carried out by each of the actors responsible for fulfilling the safety requirements. In the second phase pilot (called pilot project with drivers with reduced linguistic skills than what is stipulated by the Regulation 2019/554) the approach chosen for demonstrating compliance with the safety requirements as well as the demonstration itself shall be independently assessed by an assessment body.

Any inadequacy of safety measures expected to fulfil the safety requirements, or any hazards discovered during the demonstration of compliance and the laboratory phase with the safety requirements, which is not covered by a mitigation measure or a combination of mitigation measures, shall lead to reassessment and evaluation of the associated risks by the proposer.

6.1.5 Exchange of information

All hazards and related safety requirements that cannot be fulfilled by one actor alone shall be communicated to another relevant actor in order to find jointly an adequate mitigation measure.

The hazards registered in the hazard record of the actor who transfers them shall only be regarded as controlled when the evaluation of the risks associated with these hazards is made by the other actor and the mitigation measure is agreed by all concerned at the Pilot testing team.

6.1.6 Evidence from the application of the risk management process

Evidence of the risk analysis application process should be sent to the corresponding NSA for evaluation at least three months before the starting of the Pilot by the RU and IM concerned with the Pilot Sheet. (Reference to Annex II Deliverable 2.1 part 1: “Guidelines for implementation and description of T4R pilot”.)