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Committee of Technical Experts**

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DRAFT EXPLANATORY DOCUMENT: UTP GEN-G

Common Safety Method on Risk Evaluation and Assessment

1. INTRODUCTION

Uniform Technical Prescriptions (UTP) are adopted specifications and are therefore part of COTIF. In principle, each subsystem is subject to one UTP. Where relevant, a subsystem may be covered by several UTP and one UTP may cover several subsystems.

This explanatory document deals with the UTP GEN-G in the version of 1.1.2016, which lays down the common safety method (CSM) on risk evaluation and assessment of safety risks of subsystems and the integration of these subsystems into their environment. .

This document explains when the UTP GEN-G should be applied, and by whom, as this may sometimes differ between COTIF and EU legislation. This document does not go into detail on how risk analysis and risk evaluation should be performed, as this is similar in COTIF and EU legislation. This is comprehensively documented on the website of the European Union Agency for Railways and that guidance can be used within the scope of COTIF as well. Guidance on assessment bodies by the EU Agency for Railways is also available on the OTIF website.

2. SCOPE

UTP GEN-G contains provisions for a harmonised procedure to manage risks relating to significant changes to the rail system or, if the UTP so require, structural subsystems.

The risk management procedure has to be carried out by the proposer and is subject to the independent assessment of its correct application and its results.

The UTP also governs requirements applicable to the independent CSM assessment body.

Changes may be of a technical, operational or organisational nature. A change within the meaning of the UTP takes place if a system, procedure, process, or the like is redesigned, redeveloped or relinquished. If systems, procedures, processes, or the like that have already been assessed are used under other system conditions or in a new combination, this is also regarded as a change within the meaning of the UTP. The extent to which this constitutes a significant change must then be assessed.

The UTP was transposed from equivalent provisions applicable in the European Union. The UTP, as indicated in its scope, concerns the railway system and can be used at system level. The technical provisions of COTIF, to which UTP GEN-G belongs, do not regulate the railways as a complete system. The COTIF technical provisions harmonise the admission, maintenance and use of vehicles, but do not fully regulate operational safety, which remains subject to national or regional provisions. It is for this reason that the practical application of UTP GEN-G may be limited compared to its use in the European Union. This document will therefore focus on the use of UTP GEN-G in the context of COTIF, in particular:

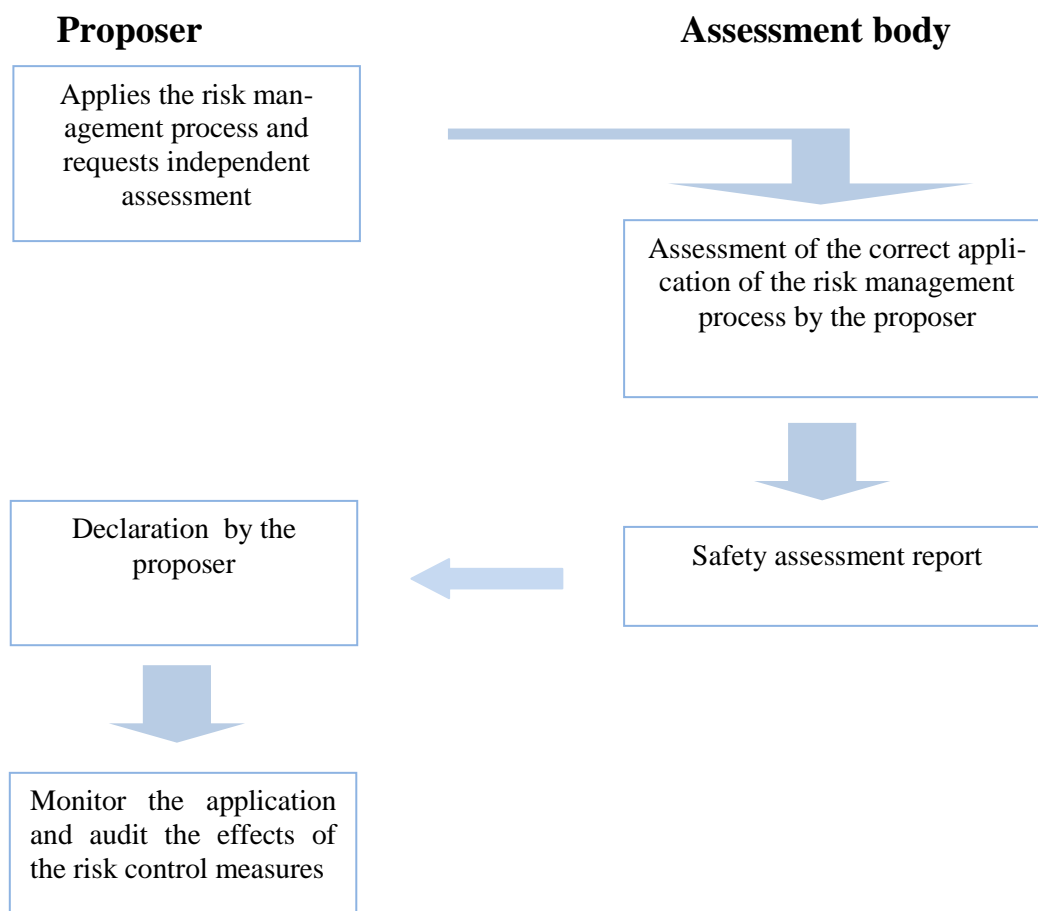
1. The risk management procedure to be carried out for existing, upgraded or renewed vehicles, for instance if there are significant changes to their construction or maintenance which do not require re-admission.
2. In the case of admissions of new vehicles, if the CSM must be applied because a UTP concerning the vehicle so requires.
3. In the case of admissions of new vehicles, to check safe integration between subsystems within a vehicle (i.e. rolling stock and the on-board part of the signalling system), but only when there are no mandatory rules in the UTP or in national rules concerning this safe integration.

4. In the case of admissions of new vehicles, to check safe integration between a vehicle and a particular network. However, this is only mandatory if required by a UTP or by national technical requirements (NTR) in force in accordance with Article 12 APTU and only relates to risks that are not already covered by UTP or NTR.

Application of the CSM must not lead to requirements that are contradictory to those of the UTP and NTR.

3. GENERAL SEQUENCE

The following diagram shows the general sequence of the UTP verification procedure, illustrating that the proposer applies the risk management process and the assessment body checks if the process is correctly applied:



4. PROPOSER

It is the proposer's responsibility to ensure that the risk assessment procedure, including the assessment of the significance of the change, is applied in accordance with point 5.1 of the UTP. The proposer can be any party that is involved in the application of the UTP, for example an ECM, a manufacturer or a railway undertaking.

The proposer must consider for any change if it has an impact on the safety of the railway system. If there is an impact on safety, the proposer must decide, by expert judgement and by applying the criteria in point 4.2, whether the change is significant. The proposer must apply the risk assessment procedure in the event of a significant change.

With regard to the significance of the change, the proposer must always document his decision in accordance with section 4.2. This means that even if the change is deemed not to be significant, this must be documented and kept.

The proposer appoints the assessment body to check and ensure independently that he conducted the risk assessment and risk management activities properly. If the assessment body is not already designated by national legislation, the proposer may select an assessment body in accordance with point 6.1.

Where relevant, the proposer is responsible for coordinating cooperation between the various actors involved. He must keep a hazard record in accordance with Annex I, section 4, in order to identify hazards and the related safety measures.

After the application of the CSM, the proposer is responsible for monitoring the application of the risk control measures and for checking the consequences of the application and its integration into the railway system as a whole.

The proposer must keep any relevant documents that help him to keep a record of the reasons for his decision.

According to the definition in section 3 of the UTP, a “proposer” may be:

- a railway undertaking,
- an infrastructure manager,
- an entity in charge of maintenance which implements measures in accordance with ATMF Article 15 and Annex A to ATMF (ECM Uniform Rules),
- a contracting entity or a manufacturer which invites an assessing entity to assess a subsystem in accordance with UTP GEN-D,
- an applicant for a technical admission.

5. ASSESSMENT BODY

Section 6 of the UTP sets out that the application of the risk management procedure by the proposer must be subject to an independent assessment by an assessment body.

The CSM assessment body neither performs the risk assessment required in Annex I of the CSM for risk assessment, nor provides advice or solutions that could compromise its independence. Section 3 of the UTP defines the term “assessment body” as “*an independent and competent external or internal individual, organisation or entity which undertakes investigation to provide a judgement, based on evidence, of the suitability of a system to fulfil its safety requirements.*” In addition, Section 6 stipulates that this assessment body must meet the criteria set out in Annex II. In order to do this, the assessment body is accredited or recognised by, or on behalf of, a State in accordance with Annex II. The national authority responsible for technical approval may also act as an assessment body if it meets the requirement of Annex II.

Note:

In addition to the criteria for the assessment body currently specified in Annex II of the UTP, an accreditation and recognition scheme for these assessment bodies is also being developed in the EU. This will include more details on accreditation and recognition and may also become relevant for CO-TIF.

The aim is also to administer the accredited and recognised assessment bodies in a database shared with the EU.

Detailed guidance on the tasks of the assessment body are provided in the *Explanatory Note on the CSM Assessment Body in Regulation (EU) N°402/2013 and in OTIF UTP GEN-G of 1.1.2014 on the CSM for risk assessment*, which is available on the OTIF website.

6. DOCUMENTATION

Annex I, section 3 of the UTP says that the proposer must document the risk management procedure used to assess the safety level and compliance with the safety requirements. It must be documented in such a way as to enable an assessment body to have access to all the necessary evidence for the suitability and application of the risk management procedure and its results.

The assessment body must record its conclusions of the assessment in a safety assessment report.

In accordance with section 15 of the UTP, the assessment body then sends the proposer the safety assessment report in line with the requirements set out in Annex III of the UTP. It is the proposer's responsibility to decide whether and how the conclusions of the safety assessment report are to be taken into account when certifying that the change assessed is safe. If the proposer disagrees with part of the safety assessment report, he must justify and substantiate his position.

So not only the application, but also documentation of the process is primarily the obligation of the proposer.

According to section 15 of the UTP the proposer must record in a written declaration the results of the UTP that has been applied, as well as the safety report submitted by the assessment body. By means of this declaration the proposer confirms that all the hazards detected and the associated risks will be kept at a reasonable level. If technical approval becomes necessary, this declaration is sent to the competent authority for technical approvals for decision.

7. RISK MANAGEMENT PROCESS

Annex I of UTP GEN-G sets out the risk management process, breaks it down into more specific elements and provides a comprehensive description of what should be done and by whom. This section provides an overview of the elements which together form the risk management process.

As indicated under the scope of this document, the risk management process is applicable to significant changes and is applied by the proposer.

If a change is significant, the **risk management process** is applied. It consists of the following:

1. Assessment of the risk

- a. System definition, in which the system under evaluation is defined, as well as its boundaries, interfaces and other relevant elements;
- b. Risk analysis, including hazard identification, so as to identify what can happen, how likely it is to happen and how critical that would be;
- c. Risk estimation and evaluation, by means of a description of how the risk will be brought to an acceptable level:
 - i. By applying a code of practice, for example a standard;

- ii. By comparing the system with similar reference systems that are known and understood;
- iii. By explicit risk estimation, which is an expert analysis - either qualitative or quantitative. If hazards cannot be covered by i. or ii., explicit risk estimation should be used. The UTP contains harmonised design targets for technical systems.

In order to reduce a risk to an acceptable level, it might be the case that phases b) and c) have to be repeated several times until suitable safety methods can finally be found.

2. **Demonstration of compliance** with the safety requirements by which the results of the risk assessment are checked for compliance with the safety requirements. These requirements should in principle be governed by regulations;
3. **Hazard management, risk control management and audits.** This concerns monitoring whether and ensuring that the system and its safety measures function as intended in the application of the CSM and meet the safety requirements.

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

Section 18 of the UTP provides for a sequence of reporting which aims at gathering information about the application of the CSM that could be used to improve them.

The proposer is required to report to the competent authority in the case of significant deviations from the presumptions on which the CSM conclusions were based.

Entities in charge of maintenance should report on their activities at least once a year in accordance with ATMF Annex A. This report should include information on application of the CSM.

If the CSM have been applied in the context of vehicle admission, the competent authority which granted the admission should report its experience at least annually (or immediately in case of serious consequences) to the Committee of Technical Experts and may make recommendations for improving the CSM.

The safety measures selected become part of the safety requirements for the system.
