



Organisation intergouvernementale pour les transports internationaux ferroviaires

Zwischenstaatliche Organisation für den internationalen Eisenbahnverkehr


Intergovernmental Organisation for International Carriage by Rail

Uniform Technical Prescription

**Common Safety Method
on risk evaluation and
assessment**

UTP GEN-G

Applicable from [Click here to enter a date.](#)

 OTIF	GENERAL PROVISIONS Risk evaluation and assessment		UTP GEN-G Page 2 of 30
	Status: ADOPTED		Original: EN

APTU Uniform Rules (Appendix F to COTIF 1999)

Uniform Technical Prescriptions **General provisions** **Common Safety Method on** **risk evaluation and assessment**

(UTP GEN-G)

This UTP has been developed in accordance with COTIF in the version of 1 March 2019 and in particular with Articles 3, 4, 6, 7, 7a and 8 of the APTU Uniform Rules (Appendix F to COTIF).

For definitions, see also Article 2 of the APTU Uniform Rules (Appendix F to COTIF), Article 2 of the ATMF Uniform Rules (Appendix G to COTIF) and Article 2 of the EST Uniform Rules (Appendix H to COTIF).

Footnotes are not legal provisions. They include both explanatory information and references to other regulations.


0. EQUIVALENCE

Following their adoption by the Committee of Technical Experts, the OTIF regulations included in this document are declared equivalent, in the meaning of Article 13 of the APTU Uniform Rules (UR) and Article 3a of the ATMF UR, to the corresponding European Union (EU) regulations, in particular:

- Commission Implementing Regulation (EU) 402/2013 of 30 April 2013, as amended by Commission Implementing Regulation (EU) 2015/1136 of 13 July 2015.

The objectives and scope of COTIF and the EU law concerning railways are not identical and it has therefore been necessary to use different terminology for concepts that have a similar but not identical meaning. The following table lists the terms used in this UTP and the corresponding terms used in the relevant TSI:

This UTP	EU law
This UTP	This Regulation
Contracting State	Member State
Competent authority	National safety authority

 OTIF	GENERAL PROVISIONS Risk evaluation and assessment		UTP GEN-G Page 3 of 30
	Status: ADOPTED		Original: EN

National requirement	Notified national rule
----------------------	------------------------

Where provisions in this UTP and the EU Regulation differ in substance, the respective texts are in a 2-column format. The left-hand column and the full width texts show the UTP provisions (OTIF regulations) and the right-hand column shows the EU texts¹. Texts in the right-hand column are strictly for information only. For EU law, consult the Official Journal of the European Union.

Where differences between texts of this UTP and the EU texts are either editorial, or are not substantive, or concern the list of terms quoted above, the EU texts are not generally reproduced. The EU texts may however be reproduced to improve clarity and readability.


1. SUBJECT MATTER

- 1.1 This UTP establishes a revised common safety method (CSM) for risk evaluation and assessment of safety risks of subsystems and integration into their environment in the scope of the APTU and ATMF UR, as well as risks to be managed by actors in the scope of the EST UR. as referred to in Article 6(3)(a) of Directive 2004/49/EC.
- 1.2 This UTP harmonises: shall facilitate the access to the market for rail transport services through harmonisation of:
- a) the risk management processes used to assess impact of changes on the safety levels and compliance with safety requirements;
 - b) the exchange of safety-relevant information between different actors within the rail sector in order to manage safety across the different interfaces which may exist within this sector;
 - c) the evidence resulting from the application of a risk management process.

2. SCOPE

- 2.1 This UTP shall apply to the proposer as defined in section 3(11) when making any change

¹ In several instances, reference is made in the right-hand column to EU Directives and other EU acts that have been repealed and replaced by newer versions. References to the repealed EU Directives and other EU acts are to be construed as references to the newer versions and are to be read in accordance with the correlation table included in the newer versions.

 OTIF	GENERAL PROVISIONS Risk evaluation and assessment		UTP GEN-G Page 4 of 30
Status: ADOPTED			Original: EN Date: 14.6.2023

that may impact products or activities which fall within the scope² of the APTU, ATMF or EST UR, partially or in full, including:

- activities of organisations that have safety related responsibilities, such as for keeping, maintaining and operating vehicles or trains in international traffic;
- railway vehicles intended to be used in international traffic;
- procedures and activities concerning the maintenance and use of these vehicles.

to the railway system in a Member State.

Such changes may be of a technical, operational or organisational nature. As regards organisational changes, only those changes which could impact operational or maintenance processes shall be subjected to consideration under the rules of section 4.

2.2 When, on the basis of an assessment under the criteria set out in section 4(2) (a) to (f):

- a) the change is considered significant, the risk management process set out in section 5 shall be applied;
- b) the change is considered not significant, keeping adequate documentation to justify the decision shall be sufficient.

2.3 This UTP shall apply also to structural subsystems

in the scope of the ATMF UR, in the following situations:

to which Directive 2008/57/EC applies:

- a) if a risk assessment is required by the relevant UTP; in this case the relevant UTP shall, where appropriate, specify which parts of UTP GEN-G apply;
- b) if the change is significant as set out in section 4.2, the risk management process set out in section 5 shall be applied


to ensure that the structural subsystem is safely integrated into the rail system in which it is intended to be used.

within the placing in service of structural subsystems to ensure their safe integration into an existing system by virtue of Article 15(1) of Directive 2008/57/EC.

2.4 The application of this UTP in the case referred to in paragraph (b) of section 2(3) shall not lead to requirements contradictory to those laid down in the relevant UTPs.

If application of this UTP GEN-G reveals a safety deficiency in other UTPs, this deficiency shall be considered as a contradiction between UTPs.

² The UTP INF defines the extent to which the subsystem infrastructure falls within the scope of the APTU and ATMF UR. Changes to infrastructure should be assessed for significance, in accordance with section 2.2, in relation to elements that fall within the scope of the UTP INF. Changes to elements that do not fall within the scope of the UTP INF should be subject to the rules applicable in the state concerned.

 OTIF	GENERAL PROVISIONS Risk evaluation and assessment		UTP GEN-G Page 5 of 30
	Status: ADOPTED		Original: EN

If such contradictions occur, the proposer shall inform the Contracting State concerned which may then decide to ask for a revision of the UTP in accordance with

Article 8a of the APTU UR.

Permission not to apply particular or any of the provisions of UTP(s) applicable to a structural subsystem or part of it shall be subject to the rules on derogations laid down in Annex B to the ATMF UR.

Article 6(2) or Article 7 of Directive 2008/57/EC or a derogation in accordance with Article 9(2) of that Directive.

2.5 [reserved]

The railway systems excluded from the scope of Directive 2004/49/EC according to its Article 2(2) are excluded from the scope of this Regulation.

2.6 The provisions of

UTP GEN-G, document A 94-01G/1.2012, version 01, dated 01.05.2012

Regulation 352/2009

shall continue to apply in relation to projects which are at an advanced stage of development

as defined in Article 2 b) of the APTU UR on the date of entry into force of this UTP.

within the meaning of Article 2(t) of Directive 2008/57/EC at the date of application of this Regulation.

3. DEFINITIONS

For the purpose of this UTP, the definitions


in Article 2 of the ATMF UR and Article 2 of the APTU UR

in Article 3 of Directive 2004/49/EC

apply.

The following definitions shall also apply:

1. “risk” means the frequency of occurrence of accidents and incidents resulting in harm (caused by a hazard) and the degree of severity of that harm;
2. “risk analysis” means systematic use of all available information to identify hazards and to estimate the risk;
3. “risk evaluation” means a procedure based on the risk analysis to determine whether an acceptable level of risk has been achieved;
4. “risk assessment” means the overall process comprising a risk analysis and a risk evaluation;
5. “safety” means freedom from unacceptable risk of harm;
6. “risk management” means the systematic application of management policies, procedures and practices to the tasks of analysing, evaluating and controlling risks;

 OTIF	GENERAL PROVISIONS Risk evaluation and assessment		UTP GEN-G Page 6 of 30
Status: ADOPTED		Original: EN	Date: 14.6.2023


7. “interfaces” means all points of interaction during a system or subsystem life-cycle, including operation and maintenance where different actors of the rail sector will work together in order to manage the risks;
8. “actors” means all parties which are, directly or through contractual arrangements, involved in the application of this UTP;
9. “safety requirements” means the safety characteristics (qualitative or quantitative, or when needed both qualitative and quantitative) necessary for the design, operation (including operational rules) and maintenance of a system in order to meet legal or company safety targets;
10. “safety measures” means a set of actions either reducing the frequency of occurrence of a hazard or mitigating its consequences in order to achieve and/or maintain an acceptable level of risk;
11. “proposer” means
 - a) a railway undertaking or an infrastructure manager which implements risk control measures in accordance with

national, regional or international regulations, insofar as these make the railway undertakings and infrastructure managers responsible for the safe operation of the railway system and the control of risks associated with it and oblige them to implement necessary risk control measures, where appropriate in cooperation with each other, to apply national safety rules and standards, and to establish safety management systems;	Article 4 of Directive 2004/49/EC;
--	------------------------------------
 - b) an entity in charge of maintenance which implements measures in accordance with


Article 15 of the ATMF UR and Annex A to the ATMF UR (Rules for the certification and auditing of entities in charge of maintenance);	Article 14a(3) of Directive 2004/49/EC;
---	---
 - c) a contracting entity or a manufacturer which invites

an assessing entity in the meaning of Article 5 of the ATMF UR to assess a structural subsystem in accordance with UTP GEN-D;	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 a technical admission of structural sub-systems;	for an authorisation for the placing in service of structural sub-systems;
--	--
12. “safety assessment report” means the document containing the conclusions of the assessment performed by an assessment body on the system under assessment;
13. “hazard” means a condition that could lead to an accident;

 OTIF	GENERAL PROVISIONS Risk evaluation and assessment		UTP GEN-G Page 7 of 30
Status: ADOPTED		Original: EN	Date: 14.6.2023


14. “assessment body” means the 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;
15. “risk acceptance criteria” means the terms of reference by which the acceptability of a specific risk is assessed; these criteria are used to determine that the level of a risk is sufficiently low that it is not necessary to take any immediate action to reduce it further;
16. “hazard record” means the document in which identified hazards, their related measures, their origin and the reference to the organisation which has to manage them are recorded and referenced;
17. “hazard identification” means the process of finding, listing and characterising hazards;
18. “risk acceptance principle” means the rules used in order to arrive at the conclusion whether or not the risk related to one or more specific hazards is acceptable;
19. “code of practice” means a written set of rules that, when correctly applied, can be used to control one or more specific hazards;
20. “reference system” means a system proven in use to have an acceptable safety level and against which the acceptability of the risks from a system under assessment can be evaluated by comparison;
21. “risk estimation” means the process used to produce a measure of the level of risks being analysed, consisting of the following steps: estimation of frequency, consequence analysis and their integration;
22. “technical system” means a product or an assembly of products including the design, implementation and support documentation; the development of a technical system starts with its requirements specification and ends with its acceptance; although the design of relevant interfaces with human behaviour is considered, human operators and their actions are not included in a technical system; the maintenance process is described in the maintenance manuals but is not itself part of the technical system;
23. “catastrophic accident” means an accident typically affecting a large number of people and resulting in multiple fatalities;
24. “safety acceptance” means status given to the change by the proposer based on the safety assessment report provided by the assessment body;
25. “system” means any part of the railway system
(within the scope of this UTP); | ;
which is subjected to a change whereby the change may be of a technical, operational or organisational nature;
26. “national requirement” means any national rule in accordance with Article 12 of the APTU UR, or in accordance with Article 3 § 4 of the EST UR; | “notified national rule” means any national rule notified by Member States under Council Directive 96/48/EC or, Directive 2001/16/ EC of the European Parliament and of the Council and Directives 2004/ 49/EC and 2008/57/EC;
27. “certification body” means a certification body
as defined in Article 2 of Annex A to the ATMF UR (Rules for the certification and | as defined in Article 3 of Regulation (EU) No 445/2011;

 OTIF	GENERAL PROVISIONS Risk evaluation and assessment		UTP GEN-G Page 8 of 30
Status: ADOPTED			Original: EN Date: 14.6.2023

- auditing of entities in charge of maintenance);
28. “conformity assessment body” means a conformity assessment body that performs conformity assessment activities including calibration, testing, certification and inspection; as defined in Article 2 of Regulation (EU) No 765/2008;
29. “accreditation” means accreditation as defined in Article 2 ab) of the ATMF UR; Article 2 of Regulation (EU) No 765/2008;
30. “national accreditation body” means the sole body in a Contracting State that performs accreditation with authority derived from the State; a national accreditation body as defined in Article 2 of Regulation (EU) No 765/2008;
31. “recognition” means an attestation by a national body other than the national accreditation body that the assessment body meets the requirements set out in Annex II of this UTP to carry out the independent assessment activity specified in sections 6.1 and 6.2;
32. “systematic failure” means a failure that occurs repeatedly under some particular combination of inputs or under some particular environmental or application conditions;
33. “systematic fault” means an inherent fault in the specification, design, manufacturing, installation, operation or maintenance of the system under assessment;
34. “barrier” means a technical, operational or organisational risk control measure outside the system under assessment that either reduces the frequency of occurrence of a hazard or mitigates the severity of the potential consequence of that hazard;
35. “critical accident” means an accident typically affecting a very small number of people and resulting in at least one fatality;
36. “highly improbable” means an occurrence of failure at a frequency less than or equal to 10^{-9} per operating hour;
37. “improbable” means an occurrence of failure at a frequency less than or equal to 10^{-7} per operating hour;
38. “competent authority” means a national authority competent for technical admission as referred to in Article 5 of the ATMF UR.

4. SIGNIFICANT CHANGES

- 4.1 If there is no national requirement for defining whether a change is significant or not in a Contracting State, the proposer shall consider the potential impact of the change in question on the safety of any products and activities which fall within the scope of this UTP as defined in point 2.1. the railway system.
- If the proposed change has no impact on safety within this scope

 OTIF	GENERAL PROVISIONS Risk evaluation and assessment		UTP GEN-G Page 9 of 30
	Status: ADOPTED		Original: EN

, the risk management process described in section 5 need not be applied.

4.2 If the proposed change has an impact on safety, the proposer shall decide, by expert judgement, on the significance of the change based on the following criteria:

- a) failure consequence: credible worst-case scenario in the event of failure of the system under assessment, taking into account the existence of safety barriers outside the system under assessment;
- b) 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;
- c) complexity of the change;
- d) monitoring: the inability to monitor the implemented change throughout the system life-cycle and intervene appropriately;
- e) reversibility: the inability to revert to the system before the change;
- f) additionality: assessment of the significance of the change taking into account all recent safety-related changes to the system under assessment and which were not judged to be significant.

4.3 The proposer shall keep adequate documentation to justify its decision.

5. RISK MANAGEMENT PROCESS

5.1 The proposer shall be responsible for applying this UTP, including the assessment of the significance of the change based on the criteria in section 4, and for conducting the risk management process set out in Annex I.

5.2 The proposer shall ensure that risks introduced by its suppliers and its service providers, including their subcontractors, are also managed in compliance with this UTP. To this end, the proposer may require through contractual arrangements that its suppliers and its service providers, including their subcontractors, participate in the risk management process set out in Annex I.

6. INDEPENDENT ASSESSMENT


6.1 An assessment body shall carry out an independent assessment of the suitability of both the application of the risk management process as set out in Annex I and of its results

(including adequate identification of hazards and the estimation of the risk arising from them).

This assessment body shall meet the criteria listed in Annex II. Where the assessment body is not already designated by existing

| Union or

national legislation, the proposer shall appoint its own assessment body at the earliest appropriate stage of the risk assessment process.

 OTIF	GENERAL PROVISIONS Risk evaluation and assessment		UTP GEN-G Page 10 of 30
Status: ADOPTED			Original: EN Date: 14.6.2023

6.2 To perform the independent assessment, the assessment body shall:

- a) ensure it has a thorough understanding of the significant change based on the documentation provided by the proposer;
- b) conduct an assessment of the processes used for managing safety and quality during the design and implementation of the significant change, if those processes are not already certified by a relevant conformity assessment body;
- c) conduct an assessment of the application of those safety and quality processes during the design and implementation of the significant change.

Having completed its assessment in accordance with points (a), (b) and (c), the assessment body shall deliver the safety assessment report provided for in section 15 and Annex III.

6.3 Duplication of work between the following assessments shall be avoided:


- a) the assessment of conformity of the safety management system in accordance with the EST UR and of the system of maintenance of entities in charge of maintenance as required by Annex A to the ATMF UR (Rules for the certification and auditing of entities in charge of maintenance), and; Directive 2004/49/EC, and;
- b) the conformity assessment carried out in accordance with UTP GEN-D by an assessing entity in the meaning of Article 5 of the ATMF UR, and; by a notified body as defined by Article 2(j) of Directive 2008/57/EC or a body designated in accordance with Article 17 of that Directive, and;
- c) any independent assessment carried out by the assessment body in accordance with this UTP.

6.4 The proposer

Without prejudice to Union legislation, the proposer

may choose the competent authority as the assessment body where that competent authority offers this service and where the significant changes concern the following cases:

- a) a vehicle needs a first admission to operation as referred to in the ATMF UR; an authorisation for placing in service, as referred to in Articles 22(2) and 24(2) of Directive 2008/57/EC;
- b) a vehicle needs a complementary admission to operation in accordance with Article 6 § 4(b) of the ATMF UR; an additional authorisation for placing in service, as referred to in Articles 23(5) and 25(4) of Directive 2008/57/EC;
- c) the safety certificate in accordance with the EST UR of a railway undertaking is updated due to alteration of the type or extent of operation; the safety certificate has to be updated due to alteration of the type or extent of the operation, as referred to in Article 10(5) of Directive 2004/49/EC;

 OTIF	GENERAL PROVISIONS Risk evaluation and assessment		UTP GEN-G Page 11 of 30
Status: ADOPTED			Original: EN Date: 14.6.2023

- | | |
|---|---|
| <ul style="list-style-type: none"> d) the safety certificate in accordance with the EST UR of a railway undertaking is revised due to substantial changes to the applicable safety regulatory framework. e) [reserved] f) [reserved] | <ul style="list-style-type: none"> the safety certificate has to be revised due to substantial changes to the safety regulatory framework, as referred to in Article 10(5) of Directive 2004/49/EC; the safety authorisation has to be updated due to substantial changes to the infrastructure, signalling or energy supply, or to the principles of their operation and maintenance, as referred to in Article 11(2) of Directive 2004/49/EC; the safety authorisation has to be revised due to substantial changes to the safety regulatory framework, as referred to in Article 11(2) of Directive 2004/49/EC. |
|---|---|

Where a significant change concerns a structural subsystem that needs

technical admission in accordance with the ATMF UR, the proposer may choose the national authority competent for technical admission	an authorisation for placing in service as referred to in Article 15(1) or Article 20 of Directive 2008/57/EC, the proposer may choose the national safety authority
--	--

as assessment body, where that competent authority offers this service, unless the proposer has already given that task to

another assessing entity which meets the provisions in UTP GEN-D.	a notified body in accordance with Article 18(2) of that Directive.
---	---


7. ACCREDITATION/RECOGNITION OF THE ASSESSMENT BODY

The assessment body provided for in section 6 shall be either:

- a) accredited by the national accreditation body referred to in section 13.1 using the criteria defined in Annex II, or;
- b) recognised by the recognition body referred to in section 13.1 using the criteria defined in Annex II, or;
- c) the competent authority under the requirement of section 9.2.

8. ACCEPTANCE OF ACCREDITATION/RECOGNITION

- | | |
|--|---|
| <p>8.1 The accreditation or recognition of a railway undertaking or infrastructure manager in accordance with section 7 shall be proof of its ability to act as an assessment body.</p> <p>Safety Certification Authorities shall accept this proof when issuing Safety Certificates in accordance with the EST UR.</p> <p>This is without prejudice to the provisions of Annex A to the EST UR (Common Safety Method on Safety Management System Requirements).</p> | <p>When granting the safety certificate or the safety authorisation in accordance with Regulation (EU) No 1158/2010 or Regulation (EU) No 1169/2010, a national safety authority shall accept accreditation or recognition by a Member State in accordance with Article 7, as proof of the ability of the railway undertaking or infrastructure manager to act as an assessment body.</p> |
|--|---|

 OTIF	GENERAL PROVISIONS Risk evaluation and assessment		UTP GEN-G Page 12 of 30
Status: ADOPTED		Original: EN	Date: 14.6.2023


- 8.2 When granting the certificate to an entity in charge of maintenance in accordance with Annex A to the ATMF UR (Rules for the certification and auditing of entities in charge of maintenance) Regulation (EU) No 445/2011, the certification body shall accept such accreditation or recognition by a Contracting State, as proof of the ability of the entity in charge of maintenance to act as assessment body.
- This is without prejudice to the provisions of Annex A to the ATMF UR.

9. TYPES OF RECOGNITION OF THE ASSESSMENT BODY

- 9.1 The following types of recognition of the assessment body may be used:
- a) recognition by the Contracting State of an entity in charge of maintenance, an organisation or a part of it or an individual;
 - b) recognition by the competent authority of the ability of an organisation or a part of it or an individual to conduct independent assessment through the assessment and supervision of the safety management system of a railway undertaking or an infrastructure manager;
 - c) when the competent authority is acting as ECM certification body in conformity with Article 6 of Annex A to the ATMF UR (Rules for the certification and auditing of entities in charge of maintenance), Article 10 of Regulation (EU) No 445/2011, recognition by the competent authority of the ability of an organisation or a part of it or an individual to conduct independent assessment through assessment and surveillance of the system of maintenance of an entity in charge of maintenance;
 - d) recognition by a recognition body designated by the Contracting State of the ability of an entity in charge of maintenance, an organisation or a part of it or an individual to conduct independent assessment.
- 9.2 When the Contracting State recognises the competent authority as an assessment body, it is the responsibility of that Contracting State to ensure that the competent authority fulfils the requirements set out in Annex II; In this case, the assessment body functions of the competent authority shall be demonstrably independent of the other functions of the competent authority.

10. VALIDITY OF RECOGNITION

- 10.1 In the cases referred in section 9.1(a) and (d) and section 9.2, the period of validity of recognition shall not exceed 5 years from the date it is granted.
- 10.2 In the case referred in section 9.1 (b):
- a) the statement of recognition for a railway undertaking or an infrastructure manager shall be displayed on the relevant safety certificate; safety certificate in field 5 'Additional Information' of the harmonised format of safety certificates provided in Annex I to Regulation

 OTIF	GENERAL PROVISIONS Risk evaluation and assessment		UTP GEN-G Page 13 of 30
	Status: ADOPTED		Original: EN

653/2007/EC and in an appropriate part of the safety authorisations;

- b) the period of validity of recognition shall be limited to the validity of the safety certificate or authorisation under which it is granted. In this case, the request of recognition shall be made at the next application for renewal or update of the safety certificate or authorisation.

10.3 In the cases referred in section 9.1 (c):

- a) the statement of recognition for an entity in charge of maintenance shall be displayed on the relevant certificate

according to Annex A to the ATMF UR (Rules for the certification and auditing of entities in charge of maintenance);

in field 5 'Additional Information' of the harmonised format of certificates for entities in charge of maintenance provided in Annex V, or in Annex VI where relevant, of Regulation (EU) No 445/2011;

- b) the period of validity of recognition shall be limited to the validity of the certificate issued by the certification body under which it is granted. In this case, the request of recognition shall be made at the next application for renewal or update of that certificate.

11. SURVEILLANCE BY RECOGNITION BODY

11.1 National accreditation bodies shall monitor the conformity assessment bodies to which they have issued an accreditation certificate, and by analogy

By analogy to the requirements in Article 5(3) and 5(4) of Regulation (EC) No 765/2008 for accreditation,

the recognition body shall conduct periodic surveillance in order to verify that the assessment body it recognised continues to satisfy the criteria set out in Annex II during the validity of the recognition.

11.2 If the assessment body no longer satisfies the criteria set out in Annex II, the recognition body shall limit the scope of application of the recognition, suspend or withdraw the recognition, depending on the degree of non-compliance.

12. RELAXED CRITERIA WHERE A SIGNIFICANT CHANGE IS NOT TO BE MUTUALLY RECOGNISED

Where the risk assessment for a significant change is not to be mutually recognised, the proposer shall appoint an assessment body meeting at least the competency, independency and impartiality requirements of Annex II. The other requirements of paragraph 1 in Annex II may be relaxed in agreement with the competent authority in a non-discriminatory way.


13. PROVISION OF INFORMATION TO THE

SECRETARY GENERAL

AGENCY

13.1 Where applicable, Contracting States

Where applicable, by no later than 21 May 2015
Member States

 OTIF	GENERAL PROVISIONS Risk evaluation and assessment		UTP GEN-G Page 14 of 30
Status: ADOPTED			Original: EN Date: 14.6.2023

shall inform the

Secretary General without delay of | Agency which is

their national accreditation body and/or recognition body or recognition bodies for the purposes of this UTP, as well as of the assessment bodies they recognised in conformity with section 9.1 (a). They shall also notify any change to that situation within one month of the change.

The Secretary General | The Agency

shall make this information publicly available.

- 13.2 The national accreditation body shall inform the Secretary General without delay | By no later than 21 May 2015 the national accreditation body shall inform the Agency of the assessment bodies accredited, as well as of the area of competence for which those assessment bodies are accredited as provided for in points 2 and 3 of Annex II. They shall also notify any change to that situation within 1 month of the change.

The Secretary General | The Agency

shall make this information publicly available.

- 13.3 The recognition body shall inform the Secretary General without delay | By no later than 21 May 2015 the recognition body shall inform the Agency of the assessment bodies recognised, as well as of the area of competence for which those assessment bodies are recognised as provided for in points 2 and 3 of Annex II. They shall also notify any change to that situation within 1 month of the change.

The Secretary General | The Agency


shall make this information publicly available.

14. SUPPORT

FROM THE AGENCY

TO ACCREDITATION OR RECOGNITION OF THE ASSESSMENT BODY

- 14.1 Accreditation bodies and recognition bodies shall actively pursue coordination and exchange of good practices at international level. | The Agency shall organise peer evaluations between the recognition bodies based on the same principles as set out in Article 10 of Regulation 765/2008/EC.
- 14.2 Accreditation bodies that are members of the European cooperation for Accreditation (EA) shall participate in the relevant activities, such as training and exchange of practices, if they have access to these activities. | The Agency shall organise, in collaboration with the European cooperation for Accreditation (EA), training on this Regulation for the national accreditation bodies and for the recognition bodies at least at each new revision of this Regulation.

 OTIF	GENERAL PROVISIONS Risk evaluation and assessment		UTP GEN-G Page 15 of 30
Status: ADOPTED			Original: EN Date: 14.6.2023

15. SAFETY ASSESSMENT REPORT

- 15.1 The assessment body shall provide the proposer with a safety assessment report in accordance with the requirements set out in Annex III. The proposer shall be responsible for determining if and how to take into account the conclusions of the safety assessment report for the safety acceptance of the assessed change. The proposer shall justify and document the part of the safety assessment report for which the proposer eventually disagrees.
- 15.2 In the case referred to in point b) of section 2.3, in accordance with point 5 of this section (section 15.5), the declaration referred to in section 16 shall be accepted by the competent authority in its decision for the admission to operation of structural sub-systems and vehicles.
- 15.3 The competent authority

Without prejudice to Article 16 of Directive 2008/57/EC, the national safety authority

may not request additional checks or risk analyses unless it is able to demonstrate the existence of a substantial safety risk.
- 15.4 In the case referred to in point (a) of section 2.3, in accordance with point 5 of this section (section 15.5), the declaration referred to in section 16 shall be accepted by the
assessing entity in the meaning of Article 5 of the ATMF UR, which performs the assessment of conformity with the structural UTP

the notified body

in charge of delivering the conformity certificate, unless it justifies and documents its doubts concerning the assumptions made or the appropriateness of the results.
- 15.5 When a system or part of a system has already been accepted following the risk management process specified in this UTP, the resulting safety assessment report shall not be called into question by any other assessment body in charge of performing a new assessment for the same system. Mutual recognition shall be conditional upon demonstration that the system will be used under the same functional, operational and environmental conditions as the already accepted system, and that equivalent risk acceptance criteria have been applied.


16. DECLARATION BY THE PROPOSER

Based on the results of the application of this UTP and on the safety assessment report provided by the assessment body, the proposer shall produce a written declaration that all identified hazards and associated risks are controlled to an acceptable level.

17. RISK CONTROL MANAGEMENT AND AUDITS

- 17.1 Any proposer which has had a CSM on risk evaluation and assessment carried out shall continue to monitor the application and audit the effects of the application, in particular the hazard identification, risk estimation and risk evaluation on which the conclusions were based.

The railway undertakings and infrastructure managers shall include audits of the application of this Regulation in their recurrent auditing scheme for the safety management system as referred to in Article 9 of Directive 2004/49/EC.

 OTIF	GENERAL PROVISIONS Risk evaluation and assessment		UTP GEN-G Page 16 of 30
Status: ADOPTED		Original: EN	Date: 14.6.2023

17.2 The entities in charge of maintenance shall include audits of the application of this UTP in their recurrent auditing scheme for the system of maintenance as referred to in

Annex A to the ATMF UR (Rules for the certification and auditing of entities in charge of maintenance).

Article 14a(3) of Directive 2004/49/EC.

17.3 [reserved]

As part of the tasks defined in Article 16(2)(e) of Directive 2004/49/EC, the national safety authority shall monitor the application of this Regulation by railway undertakings, infrastructure managers and the entities in charge of maintenance that do not fall within the scope of Regulation (EU) No 445/2011 but are identified in its National Vehicle Register.

17.4 As part of the tasks defined in

Annex A to the ATMF UR (Rules for the certification and auditing of entities in charge of maintenance),

Article 7(1) of Regulation (EU) No 445/2011,

the certification body of an entity in charge of maintenance of freight wagons shall perform surveillance of the application of this UTP by the entity in charge of maintenance.

18. FEEDBACK AND TECHNICAL PROGRESS

18.1 [reserved]

Each infrastructure manager and each railway undertaking shall, in its annual safety report referred to in Article 9(4) of Directive 2004/49/EC, report briefly on its experience with the application of this Regulation. The report shall also include a synthesis of the decisions taken related to the level of significance of the changes.

18.2 Contracting States that become aware of problems with the application of this UTP encountered by actors active on their territory shall, where relevant, report these problems to the Committee of Technical Experts.


Each national safety authority shall, in its annual safety report referred to in Article 18 of Directive 2004/49/EC, report on the experience of the proposers with the application of this Regulation, and, where appropriate, its own experience.

18.3 The annual maintenance report of entities in charge of maintenance

referred to in Annex A to the ATMF UR (Rules for the certification and auditing of entities in charge of maintenance),

of freight wagons referred to in point I (7)(4)(k) in Annex II to Regulation (EU) No 445/2011,

shall include information about the experience of entities in charge of maintenance in applying this UTP.

 OTIF	GENERAL PROVISIONS Risk evaluation and assessment		UTP GEN-G Page 17 of 30
Status: ADOPTED			Original: EN Date: 14.6.2023

18.4 [reserved]

The Agency shall gather this information in coordination with the respective certification bodies.

The other entities in charge of maintenance that do not fall within the scope of Regulation (EU) No 445/2011, shall also share their experience with the Agency on the application of this Regulation. The Agency shall coordinate the sharing of experience with these entities in charge of maintenance and with the NSAs.

18.5 [reserved]

The Agency shall collect all information on the experience of application of this Regulation and shall, when necessary, make recommendations to the Commission with a view to improving this Regulation.

18.6 [reserved]

Before 21 May 2015 the Agency shall submit to the Commission a report containing:

- a) an analysis of the experience with the application of this Regulation, including cases where the CSM has been applied by proposers on a voluntary basis before the relevant date of application provided for in Article 20;
- b) an analysis of the experience of proposers concerning decisions on the level of significance of changes;
- c) an analysis of the cases where codes of practice have been used as set out in point 2.3.8 of Annex I;
- d) an analysis of the experience with the accreditation and recognition of assessment bodies;
- e) an analysis of the overall effectiveness of this Regulation.


The national safety authorities shall support the Agency in collecting such information.

19. REPEAL

The previous version of this UTP, dated 1 January 2014, as last amended on 1 December 2016, is repealed with effect from the entry into force of this UTP.

Regulation (EC) No 352/2009 is repealed with effect from 21 May 2015.

References to the repealed Regulation shall be construed as references to this Regulation.

 OTIF	GENERAL PROVISIONS Risk evaluation and assessment		UTP GEN-G Page 18 of 30
Status: ADOPTED			Original: EN Date: 14.6.2023

References to the repealed UTP shall be construed as references to this UTP.

20. APPLICATION

For the purpose of the APTU and ATMF UR, this UTP shall apply from its entry into force.


For the purpose of the EST UR, this UTP shall apply from the moment of entry into force of the EST UR.

ENTRY INTO FORCE AND APPLICATION

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

It shall apply from 21 May 2015.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

 OTIF	GENERAL PROVISIONS Risk evaluation and assessment		UTP GEN-G Page 19 of 30
	Status: ADOPTED		Original: EN

ANNEX I

1. GENERAL PRINCIPLES APPLICABLE TO THE RISK MANAGEMENT PROCESS

1.1 General principles and obligations

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

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

This risk management process is iterative and is depicted in the diagram of the Appendix. The process ends when compliance of the system with all the safety requirements necessary to accept the risks linked to the identified hazards is demonstrated.

1.1.2 The risk management process shall include appropriate quality assurance activities and be carried out by competent staff. It shall be independently assessed by one or more assessment bodies.

1.1.3 The proposer in charge of the risk management process shall maintain a hazard record in accordance with point 4.³

1.1.4 The actors who already have in place methods or tools for risk assessment may continue to apply them if such methods or tool are compatible with the provisions of this UTP and subject to the following conditions:


- a) the risk assessment methods or tools are described in a safety management system limited by the scope of the APTU, ATMF and EST UR.

accepted by a national safety authority in accordance with Article 10(2)(a) or Article 11(1)(a) of Directive 2004/49/EC; or

- b) the risk assessment methods or tools are required by a UTP or comply with publicly available recognised standards specified in national requirements.

1.1.5 Without prejudice to civil liability in accordance with the legal requirements of the Contracting States, the risk assessment process shall fall within the responsibility of the proposer. In particular the proposer shall decide, with agreement of the actors concerned, who will be in charge of fulfilling the safety requirements resulting from the risk assessment. The safety requirements assigned by the proposer to those actors shall not go beyond the scope of their responsibility and domain of control. This decision shall depend on the type of safety measures selected to control the risks to an acceptable level. The demonstration of compliance with the safety requirements shall be conducted in accordance to point 3.

³ When the word "point" or "section" is used in this Annex I, it means a section of this Annex.

 OTIF	GENERAL PROVISIONS Risk evaluation and assessment		UTP GEN-G Page 20 of 30
Status: ADOPTED			Original: EN Date: 14.6.2023

1.1.6 The first step of the risk management process shall be to identify in a document, to be drawn up by the proposer, the different actors' tasks, as well as their risk management activities. The proposer shall coordinate close collaboration between the different actors involved, according to their respective tasks, in order to manage the hazards and their associated safety measures.

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

1.2 Interfaces management

1.2.1 For each interface relevant to the system under assessment and without prejudice to specifications of interfaces defined in relevant UTPs, the rail-sector actors 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.

1.2.2 If, in order to fulfil a safety requirement, an actor identifies the need for a safety measure that it cannot implement itself, it shall, after agreement with another actor, transfer the management of the related hazard to the latter in accordance with the process set out in point 4.

1.2.3 For the system under assessment, any actor who discovers that a safety measure is non-compliant or inadequate is responsible for notifying it to the proposer, who shall in turn inform the actor implementing the safety measure.

1.2.4 The actor implementing the safety measure shall then inform all the actors affected by the problem either within the system under assessment or, as far as known by the actor, within other existing systems using the same safety measure.

1.2.5 When agreement cannot be reached between two or more actors it is the responsibility of the proposer to find a solution.

1.2.6 When a requirement in a national requirement cannot be fulfilled by an actor, the proposer shall seek advice from the relevant competent authority.

1.2.7 Independently from the definition of the system under assessment, the proposer is responsible for ensuring that the risk management covers the system itself and its integration into the railway system as a whole.


2. DESCRIPTION OF THE RISK ASSESSMENT PROCESS

2.1 General description


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

- a) the system definition;
- b) the risk analysis including the hazard identification;
- c) the risk evaluation.

The risk assessment process shall interact with hazard management in accordance with point 4.1.

 OTIF	GENERAL PROVISIONS Risk evaluation and assessment		UTP GEN-G Page 21 of 30
Status: ADOPTED			Original: EN Date: 14.6.2023

- 2.1.2 The system definition shall address at least the following issues:
- a) system objective (intended purpose);
 - b) system functions and elements, where relevant (including human, technical and operational elements);
 - c) system boundary including other interacting systems;
 - d) physical (interacting systems) and functional (functional input and output) interfaces;
 - e) system environment (for example energy and thermal flow, shocks, vibrations, electromagnetic interference, operational use);
 - f) existing safety measures and, after the necessary relevant iterations, definition of the safety requirements identified by the risk assessment process;
 - g) assumptions that determine the limits for the risk assessment.
- 2.1.3 A hazard identification shall be carried out on the defined system, in accordance with point 2.2.
- 2.1.4 The risk acceptability of the system under assessment shall be evaluated by using one or more of the following risk acceptance principles:
- a) the application of codes of practice (point 2.3);
 - b) a comparison with similar systems (point 2.4);
 - c) an explicit risk estimation (point 2.5).
- In accordance with the principle referred to in point 1.1.5, the assessment body shall refrain from imposing the risk acceptance principle to be used by the proposer.
- 2.1.5 The proposer shall demonstrate in the risk evaluation that the selected risk acceptance principle is adequately applied. The proposer shall also check that the selected risk acceptance principles are used consistently.
- 2.1.6 The application of these risk acceptance principles shall identify possible safety measures that make the risk(s) of the system under assessment acceptable. Among these safety measures, those selected to control the risk(s) shall become the safety requirements to be fulfilled by the system. Compliance with these safety requirements shall be demonstrated in accordance with point 3.
- 2.1.7 The iterative risk assessment process can be considered as completed when it is demonstrated that all safety requirements are fulfilled and no additional reasonably foreseeable hazards have to be considered.
- 2.2 Hazard identification**
- 2.2.1 The proposer shall systematically identify, using wide-ranging expertise from a competent team, all reasonably foreseeable hazards for the whole system under assessment, its functions where appropriate and its interfaces.
- All identified hazards shall be registered in the hazard record in accordance with point 4.

 OTIF	GENERAL PROVISIONS Risk evaluation and assessment		UTP GEN-G Page 22 of 30
Status: ADOPTED			Original: EN Date: 14.6.2023

2.2.2 To focus the risk assessment efforts upon the most important risks, the hazards shall be classified according to the estimated risk arising from them. Based on expert judgement, hazards associated with a broadly acceptable risk need not be analysed further but shall be registered in the hazard record. Their classification shall be justified in order to allow independent assessment by an assessment body.

2.2.3 As a criterion, risks resulting from hazards may be classified as broadly acceptable when the risk is so small that it is not reasonable to implement any additional safety measure. The expert judgement shall take into account that the contribution of all the broadly acceptable risks does not exceed a defined proportion of the overall risk.

2.2.4 During the hazard identification, safety measures may be identified. They shall be registered in the hazard record in accordance with point 4.

2.2.5 The hazard identification only needs to be carried out at a level of detail necessary to identify where safety measures are expected to control the risks in accordance with one of the risk acceptance principles referred to in point 2.1.4. Iteration may be necessary between the risk analysis and the risk evaluation phases until a sufficient level of detail is reached for the identification of hazards.

2.2.6 Whenever a code of practices or a reference system is used to control the risk, hazard identification may be limited to:

- a) verification of the relevance of the code of practice or reference system;
- b) identification of the deviations from the code of practice or from the reference system.

2.3 Use of codes of practice and risk evaluation

2.3.1 The proposer, with the support of other involved actors shall analyse whether one, several or all hazards are appropriately covered by the application of relevant codes of practice.


2.3.2 The codes of practice shall satisfy at least the following requirements:

- a) They must be widely recognised in the railway domain. If this is not the case, the codes of practice will have to be justified and be acceptable to the assessment body;
- b) They must be relevant for the control of the considered hazards in the system under assessment. Successful application of a code of practice for similar cases to manage changes and control effectively the identified hazards of a system in the sense of this UTP is sufficient for it to be considered as relevant;
- c) Upon request, they must be available to assessment bodies for them to either assess or, where relevant, mutually recognise, in accordance with section 15.5 of this UTP, the suitability of both the application of the risk management process and of its results.


2.3.3 Where compliance with UTPs is required

| by Directive 2008/57/EC

and the relevant UTP does not impose the risk management process established by this UTP, the UTPs may be considered as codes of practice for controlling hazards, provided requirement b) of point 2.3.2 is fulfilled.

 OTIF	GENERAL PROVISIONS Risk evaluation and assessment		UTP GEN-G Page 23 of 30
Status: ADOPTED			Original: EN Date: 14.6.2023

- 2.3.4 National rules notified in accordance with Article 12 of the APTU UR | Article 8 of Directive 2004/49/EC and Article 17(3) of Directive 2008/57/EC may be considered as codes of practice provided the requirements of point 2.3.2 are fulfilled.
- 2.3.5 If one or more hazards are controlled by codes of practice fulfilling the requirements of point 2.3.2, then the risks associated with these hazards shall be considered acceptable. This means that:
- a) these risks need not be analysed further;
 - b) the use of the codes of practice shall be registered in the hazard record as safety requirements for the relevant hazards.
- 2.3.6 Where an alternative approach is not fully compliant with a code of practice, the proposer shall demonstrate that the alternative approach pursued leads to at least the same level of safety.
- 2.3.7 If the risk for a particular hazard cannot be made acceptable by the application of codes of practice, additional safety measures shall be identified by applying one of the two other risk acceptance principles.
- 2.3.8 When all hazards are controlled by codes of practice, the risk management process may be limited to:
- a) hazard identification in accordance with point 2.2.6;
 - b) registration of the use of the codes of practice in the hazard record in accordance with point 2.3.5;
 - c) documentation of the application of the risk management process in accordance with section 5;
 - d) an independent assessment in accordance with section 6.
- 2.4 Use of reference system and risk evaluation**
- 2.4.1 The proposer, with the support of other involved actors, shall analyse whether one, several or all hazards are appropriately covered by a similar system that could be taken as a reference system.
- 2.4.2 A reference system shall satisfy at least the following requirements:
- a) it has already been proven in-use to have an acceptable safety level and would therefore still qualify for approval in the Contracting State where the change is to be introduced;
 - b) it has similar functions and interfaces as the system under assessment;
 - c) it is used under similar operational conditions as the system under assessment;
 - d) it is used under similar environmental conditions as the system under assessment.
- 2.4.3 If a reference system fulfils the requirements listed in section 2.4.2, then for the system under assessment:
- a) the risks associated with the hazards covered by the reference system shall be considered as acceptable;

 OTIF	GENERAL PROVISIONS Risk evaluation and assessment		UTP GEN-G Page 24 of 30
Status: ADOPTED		Original: EN	Date: 14.6.2023

- b) the safety requirements for the hazards covered by the reference system may be derived from the safety analyses or from an evaluation of safety records of the reference system;
- c) these safety requirements shall be registered in the hazard record as safety requirements for the relevant hazards.

2.4.4 If the system under assessment deviates from the reference system, the risk evaluation shall demonstrate that the system under assessment reaches at least the same safety level as the reference system, applying another reference system or one of the two other risk acceptance principles. The risks associated with the hazards covered by the reference system shall, in that case, be considered as acceptable.

2.4.5 If at least the same safety level as the reference system cannot be demonstrated, additional safety measures shall be identified for the deviations, applying one of the two other risk acceptance principles.

2.5 Explicit risk assessment and evaluation

2.5.1 If the hazards are not covered by one of the two risk acceptance principles laid down in points 2.3 and 2.4, the demonstration of risk acceptability shall be performed by explicit risk estimation and evaluation. Risks resulting from these hazards shall be estimated either quantitatively or qualitatively, or when necessary both quantitatively and qualitatively, taking existing safety measures into account.

2.5.2 The acceptability of the estimated risks shall be evaluated using risk acceptance criteria either derived from or based on legal requirements contained in

COTIF | Union regulations

or in national requirements. Depending on the risk acceptance criteria, the acceptability of the risk may be evaluated either individually for each associated hazard or the combination of all hazards as a whole considered in the explicit risk estimation.

If the estimated risk is not acceptable, additional safety measures shall be identified and implemented in order to reduce the risk to an acceptable level.


2.5.3 If the risk associated with one hazard or a combination of several hazards is considered acceptable, the identified safety measures shall be registered in the hazard record.

2.5.4 The proposer shall not be obliged to perform additional explicit risk estimation for risks that are already considered acceptable by the use of codes of practice or reference systems.

2.5.5 Where hazards arise as a result of failures of functions of a technical system, without prejudice to points 2.5.1 and 2.5.4, the following harmonised design targets shall apply to those failures:

- a) where a failure has a credible potential to lead directly to a catastrophic accident, the associated risk does not have to be reduced further if the frequency of the failure of the function has been demonstrated to be highly improbable.
- b) where a failure has a credible potential to lead directly to a critical accident, the associated risk does not have to be reduced further if the frequency of the failure of the function has been demonstrated to be improbable.

The choice between definition (23) and definition (35) shall result from the most credible unsafe consequence of the failure.

 OTIF	GENERAL PROVISIONS Risk evaluation and assessment		UTP GEN-G Page 25 of 30
Status: ADOPTED		Original: EN	Date: 14.6.2023

2.5.6 Without prejudice to points 2.5.1 and 2.5.4, the harmonised design targets set out in point 2.5.5 shall be used for the design of electrical, electronic and programmable electronic technical systems. They shall be the most demanding design targets that can be required for mutual recognition.

They shall neither be used as overall quantitative targets for the whole railway system of a Contracting State, nor for the design of purely mechanical technical systems.

For mixed technical systems composed of both a purely mechanical part and an electrical, electronic and programmable electronic part, hazard identification shall be carried out in accordance with point 2.2.5. The hazards arising from the purely mechanical part shall not be controlled using the harmonised design targets set out in point 2.5.5.

2.5.7 The risk associated with the failures of functions of technical systems referred to in point 2.5.5 shall be considered as acceptable if the following requirements are also fulfilled:

- a) Compliance with the applicable harmonised design targets has been demonstrated;
- b) The associated systematic failures and systematic faults are controlled in accordance with safety and quality processes commensurate with the harmonised design target applicable to the technical system under assessment and defined in commonly acknowledged relevant standards;
- c) The application conditions for the safe integration of the technical system under assessment into the railway system shall be identified and registered in the hazard record in accordance with point 4. In accordance with point 1.2.2, these application conditions shall be transferred to the actor responsible for the demonstration of the safe integration.

2.5.8. The following specific definitions shall apply in reference to the harmonised quantitative design targets of technical systems:

- a) The term “directly” means that the failure of the function has the potential to lead to the type of accident referred to in point 2.5.5 without the need for additional failures to occur;
- b) The term “potential” means that the failure of the function may lead to the type of accident referred to in point 2.5.5;

2.5.9 Where the failure of a function of the technical system under assessment does not lead directly to the risk under consideration, the application of less demanding design targets shall be permitted if the proposer can demonstrate that the use of barriers as defined in section 3(34) allows the same level of safety to be achieved.

2.5.10 Without prejudice to


Article 12 of the APTU UR,

either the procedure specified in Article 8 of Directive 2004/49/EC, or Article 17(3) of Directive 2008/57/EC of the European Parliament and of the Council,⁴

a more demanding design target than the harmonised design targets laid down in point 2.5.5. may be requested for the technical system under assessment, through a national requirement, in order to maintain the existing level of safety in the Contracting State.

In the case of additional

⁴ Directive 2008/57/EC of the European Parliament and of the Council of 17 June 2008 on the interoperability of the rail system within the Community (OJ L 191, 18.7.2008, p. 1).

 OTIF	GENERAL PROVISIONS Risk evaluation and assessment		UTP GEN-G Page 26 of 30
Status: ADOPTED			Original: EN Date: 14.6.2023

technical admissions of vehicles, Article 6 of the ATMF UR shall apply.

authorisations for placing in service of vehicles, the procedures of Articles 23 and 25 of Directive 2008/57/EC shall apply.

2.5.11 Where a technical system is developed on the basis of the requirements set out in point 2.5.5, the principle of mutual recognition is applicable in accordance with section 15.5 of this UTP.

Nevertheless, if for a specific hazard the proposer can demonstrate that the existing level of safety in the Contracting State where the system is being used can be maintained with a design target that is less demanding than the harmonised design target, then this less demanding design target may be used instead of the harmonised one.

2.5.12 The explicit risk estimation and evaluation shall satisfy at least the following requirements:

- a) the methods used for explicit risk estimation shall reflect correctly the system under assessment and its parameters (including all operational modes);
- b) the results shall be sufficiently accurate to provide a robust basis for decision-making. Minor changes in input assumptions or prerequisites shall not result in significantly different requirements.

3. DEMONSTRATION OF COMPLIANCE WITH SAFETY REQUIREMENTS

3.1 Prior to the safety acceptance of the change, fulfilment of the safety requirements resulting from the risk assessment phase shall be demonstrated under the supervision of the proposer.

3.2 This demonstration shall be carried out by each of the actors responsible for fulfilling the safety requirements, as decided in accordance with point 1.1.5.

3.3 The approach chosen for demonstrating compliance with the safety requirements as well as the demonstration itself shall be independently assessed by an assessment body.


3.4 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 in accordance with point 2. The new hazards shall be registered in the hazard record in accordance with point 4.

4. HAZARD MANAGEMENT

4.1 Hazard management process

4.1.1 Hazard record(s) shall be created or updated (where they already exist) by the proposer during design and implementation until acceptance of the change or delivery of the safety assessment report. A hazard record shall track the progress in monitoring risks associated with the identified hazards. Once the system has been accepted and is in operation, the hazard record shall be further maintained by the infrastructure manager or the railway undertaking in charge of the operation of the system under assessment as an integrated part of its safety management system.

4.1.2 The hazard record shall include all hazards, together with all related safety measures and system assumptions identified during the risk assessment process. It shall contain a clear reference to the origin of the hazards and to the selected risk acceptance principles and clearly identify the actor(s) in charge of controlling each hazard.

 OTIF	GENERAL PROVISIONS Risk evaluation and assessment		UTP GEN-G Page 27 of 30
Status: ADOPTED			Original: EN Date: 14.6.2023

4.2 Exchange of information

All hazards and related safety requirements that cannot be controlled by one actor alone shall be communicated to another relevant actor in order to find jointly an adequate solution. 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 solution is agreed by all concerned.

5. EVIDENCE FROM THE APPLICATION OF THE RISK MANAGEMENT PROCESS

5.1 The risk management process used to assess the safety levels and compliance with safety requirements shall be documented by the proposer in such a way that all the necessary evidence showing the suitability of both the application of the risk management process and of its results are accessible to an assessment body.

5.2 The documentation produced by the proposer under point 5.1. shall at least include:

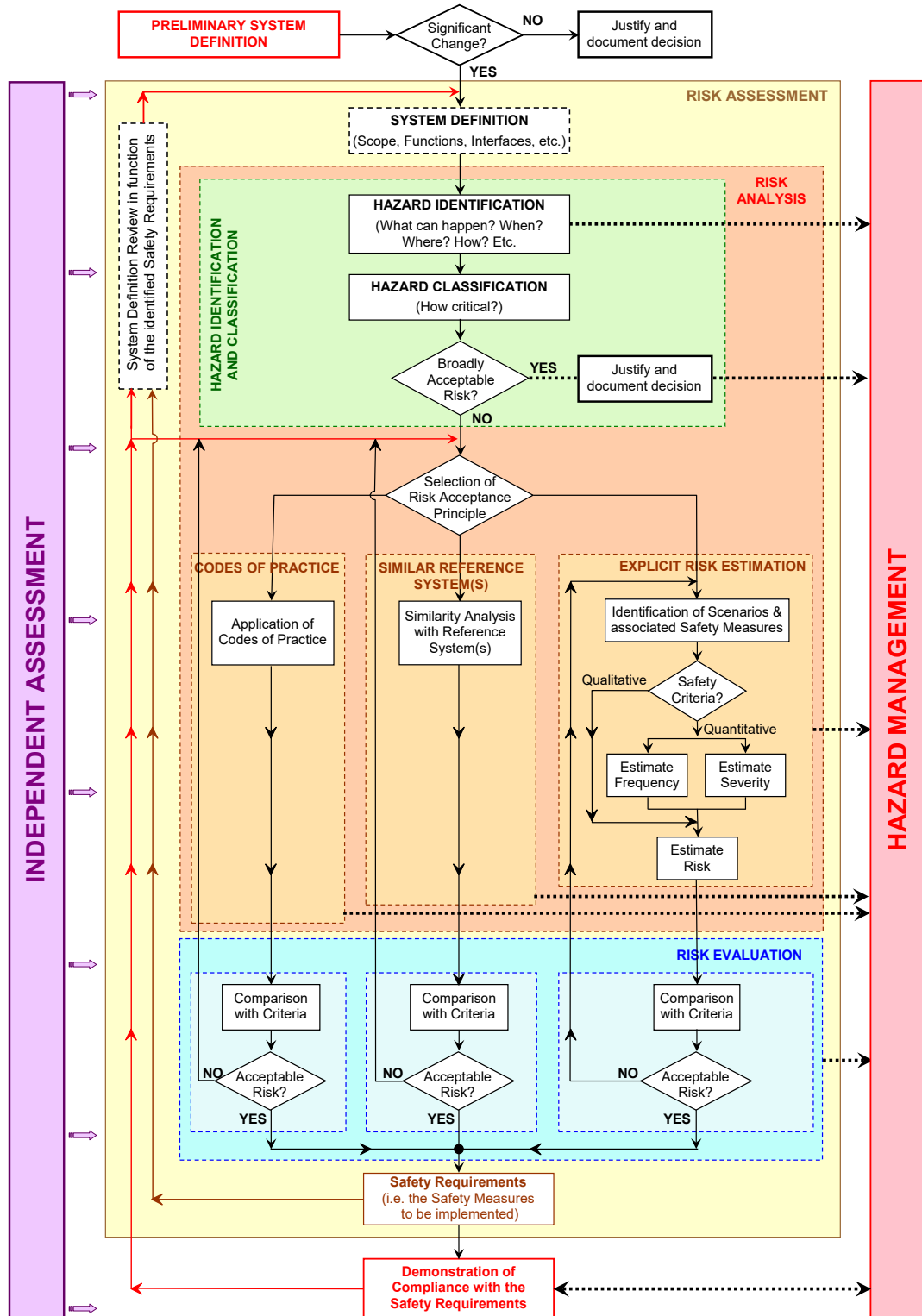
- a) a description of the organisation and the experts appointed to carry out the risk assessment process;
- b) results of the different phases of the risk assessment and a list of all the necessary safety requirements to be fulfilled in order to control the risk to an acceptable level;
- c) evidence of compliance with all the necessary safety requirements;
- d) all assumptions relevant for system integration, operation or maintenance, which were made during system definition, design and risk assessment.


5.3 The assessment body shall establish its conclusion in a safety assessment report as defined in Annex III.



Appendix

Risk management process and independent assessment



 OTIF	GENERAL PROVISIONS Risk evaluation and assessment		UTP GEN-G Page 29 of 30
	Status: ADOPTED		Original: EN

ANNEX II


CRITERIA FOR ACCREDITATION OR RECOGNITION OF THE ASSESSMENT BODY

1. The assessment body shall fulfil all requirements of the ISO/IEC 17020:2012 standard and of its subsequent amendments. The assessment body shall exercise professional judgement in performing the inspection work defined in that standard. The assessment body shall fulfil both the general criteria concerning competence and independence in that standard and the following specific competence criteria:
 - a) competence in risk management : knowledge and experience of the standard safety analysis techniques and of the relevant standards;
 - b) all relevant competences for assessing the parts of the railway system affected by the change;
 - c) competence in the correct application of safety and quality management systems may not become involved either directly or in auditing management systems.

2. By analogy to
UTP GEN-D and UTP GEN-E, Article 28 of Directive 2008/57/EC concerning the notification of notified bodies,
the assessment body shall be accredited or recognised for the different areas of competence within the railway system, or parts of it for which an essential safety requirement exists, including the area of competence involving the operation and maintenance of the railway system.

3. The assessment body shall be accredited or recognised for assessing the overall consistency of the risk management and the safe integration of the system under assessment into the railway system as a whole. This shall include competence of the assessment body in checking the following:
 - a) organisation, that is the arrangements necessary to ensure a coordinated approach to achieving system safety through a uniform understanding and application of risk control measures for subsystems;
 - b) methodology, that is evaluation of the methods and resources deployed by various stakeholders to support safety at subsystem and system level; and
 - c) the technical aspects necessary for assessing the relevance and completeness of risk assessments and the level of safety for the system as a whole.

4. The assessment body may be accredited or recognised for one, several or all of the area of competences listed in points 2 and 3.

 OTIF	GENERAL PROVISIONS Risk evaluation and assessment		UTP GEN-G Page 30 of 30
Status: ADOPTED			Original: EN Date: 14.6.2023

ANNEX III

SAFETY ASSESSMENT REPORT OF THE ASSESSMENT BODY

The safety assessment report of the assessment body shall contain at least the following information:

- a) identification of the assessment body;
- b) the independent assessment plan;
- c) the definition of the scope of the independent assessment as well as its limitations;
- d) the results of the independent assessment including in particular:
 1. detailed information on the independent assessment activities for checking the compliance with the provisions of this UTP;
 2. any identified cases of non-compliances with the provisions of this UTP and the assessment body's recommendations;
- e) the conclusions of the independent assessment.