ORGANISATION INTERGOUVERNEMENTALE POUR LES TRANSPORTS INTERNATIONAUX FERROVIAIRES

ZWISCHENSTAATLICHE ORGANISATION FÜR DEN INTERNATIONALEN EISENBAHNVERKEHR

INTERGOVERNMENTAL ORGANISATION FOR INTERNATIONAL CARRIAGE BY RAIL

OTIF

Uniform Technical Prescription

COMMON SAFETY METHOD ON RISK EVALUATION AND ASSESSMENT

UTP GEN-G

Applicable from xxxxx

APTU Uniform Rules (Appendix F to COTIF 1999)

Uniform Technical Prescriptions (UTP)

General provisions –

COMMON SAFETY METHOD (CSM) ON RISK EVALUATION AND ASSESSMENT (RA)

Explanatory note:

The texts of this UTP which appear across two columns are identical to corresponding texts of the European Union regulations. Texts which appear in two columns differ; the left-hand column contains the UTP regulations, the right-hand column shows the text in the corresponding EU regulations. The text in the right-hand column is for information only and is not part of the OTIF regulations.

OTIF UTP	*Corresponding text in EU regulations* [1]	*EU ref.*

0. EQUIVALENCE

Following their adoption by the Committee of Technical Experts, the OTIF regulations included in this document have been declared equivalent to the corresponding EU regulations within the meaning of Article 13 of APTU and Article 3a of ATMF.

1. SUBJECT MATTER Article 1

1.1 This

UTP	Regulation

establishes a revised common safety method (CSM) for risk evaluation and assessment

of safety risks of subsystems and integration into their environment.	as referred to in Article 6(3)(a) of Directive 2004/49/EC.

1.2 This

UTP	Regulation

shall facilitate

cross-border	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

[1] Commission Implementing Regulation (EU)402/2013 of 30 April 2013, ~~published in the Official Journal of the European Union on 3.5.2013 L 121/8~~as amended by Commission Implementing Regulation (EU) 2015/1136 of 13 July 2015.

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

Article 2

2.1 This

UTP	Regulation

shall apply to any change of the proposer as defined

in section 3(11)	in Article 3(11)

when making any change to the

railway system of the Contracting States which has an impact on international traffic.	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.	Article 4.

2.2 When, on the basis of an assessment under the criteria set out in:

points a) to f) of section 4.2:	Article 4(2) (a) to (f):

a) the change is considered significant, the risk management process set out in

section 5	Article 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	Regulation

shall apply also to structural subsystems to which

COTIF 1999	Directive 2008/57/EC

applies:

a) if a risk assessment is required by the relevant

uniform technical prescriptions (UTP);	technical specification for interoperability (TSI);

in this case the

UTP	TSI

shall, where appropriate, specify which parts of this

	UTP	Regulation
	apply;	
b)	if the change is significant as set out in	
	section 4.2,	Article 4(2),
	the risk management process set out in	
	section 5	Article 5
	shall be applied within the placing in service of structural sub-systems 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	Regulation
	in the case referred to in	
	point b) of section 2.3	paragraph (b) of Article 2(3)
	shall not lead to requirements contradictory to those laid down in the relevant	
	UTPs.	TSIs.
	If such contradictions occur, the proposer shall inform the	
	Contracting State	Member State
	concerned which may then decide to ask for a revision of the	
	UTP	TSI
	in accordance with	
	Article 8a of APTU	Article 6(2) or Article 7 of Directive 2008/57/EC
	or a derogation in accordance with	
	ATMF Annex B.	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 APTU.	within the meaning of Article 2(t) of Directive 2008/57/EC.

at the date of application of this

UTP.	Regulation.

3. DEFINITIONS

Article 3

For the purpose of this	
UTP	Regulation

the definitions

in ATMF Article 2 and APTU Article 2	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;
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;	Regulation;

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 ~~and its operation (including operational rules) and maintenance necessary~~ 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

ATMF Article 15 and Annex A to ATMF (ECM Uniform rules);	Article 14a(3) of Directive 2004/49/EC;

    c) a contracting entity or a manufacturers which invites

an assessing entity to assess a 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;
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~~consequence~~" means ~~fatalities and/or multiple severe injuries and/or major damages to the environment resulting from an accident;~~ 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. "notified national rule" means any national rule notified by

    a Contracting State in accordance with APTU Article 12. | 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 Section 3 of Annex A to ATMF (ECM Uniform rules); | as defined in Article 3 of Regulation (EU) No 445/2011;
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 ATMF. ~~an attestation by a national accreditation body that a conformity assessment body meets the applicable requirements~~. | ~~accreditation as defined in~~ 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	Regulation

to carry out the independent assessment activity specified in

sections 6.1 and 6.2.	Article 6(1) and (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.

4. SIGNIFICANT CHANGES

Article 4

4.1 If there is no notified national rule for defining whether a change is significant or not in a

Contracting State,	Member State,

the proposer shall consider the potential impact of the change in question on the safety of the railway system.

If the proposed change has no impact on safety, the risk management process described in

section 5	Article 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

Article 5

5.1 The proposer shall be responsible for applying this

UTP, | Regulation,

including the assessment of the significance of the change based on the criteria in

section 4, | Article 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. | Regulation.

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 ou in Annex I.

6. INDEPENDENT ASSESSMENT

Article 6

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.

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 | Article 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 and of

the system of maintenance of entities in charge of maintenance as required by

Annex A to ATMF (ECM Uniform rules), and;	Directive 2004/49/EC, and;

b) the conformity assessment carried out by

an assessing entity in accordance with UTP GEN-D ; and;	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. | Regulation.

6.4 Without prejudice to

regional or international regulations, | Union legislation,

the proposer may choose the

Competent authority in the meaning of ATMF Article 5 | national safety authority

as assessment body where that

Competent authority | national safety 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 ATMF;	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 ATMF Article 6 §4(b);	an additional authorisation for placing in service, as referred to in Articles 23(5) and 25(4) of Directive 2008/57/EC;
(reserved)	(c) 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;

(reserved)	(d) 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;
(reserved)	(e) 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;
(reserved)	(f) 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 ATMF, 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

national authority competent for technical admission	national safety 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

Article 7

7.1 The assessment body provided for in

section 6	Article 6

shall be either:

a) accredited by the national accreditation body referred to in

section 13.1	Article 13(1)

using the criteria defined in Annex II, or;

b) recognised by the recognition body referred to in

section 13.1	Article 13(1)

using the criteria defined in Annex II, or;

c) the

National authority competent for technical admission under the requirement of section 9.2.	national safety authority under the requirement of Article 9(2).

8. ACCEPTANCE OF ACCREDITATION/RECOGNITION

Article 8

8.1 (Reserved)[2]

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.

8.2 When granting the certificate to an entity in charge of maintenance in accordance with

Annex A to ATMF (ECM Uniform rules) | Regulation (EU) No 445/2011,

the certification body shall accept such accreditation or recognition by a

Contracting State | Member State,

as proof of the ability of the entity in charge of maintenance to act as assessment body

9. TYPES OF RECOGNITION OF THE ASSESSMENT BODY

Article 9

9.1 The following types of recognition of the assessment body may be used:

a) recognition by the

Contracting State | Member State,

of an entity in charge of maintenance, an organisation or a part of it[3] or an individual;

b) (reserved)

recognition by the national safety 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

national authority competent for technical admission | national safety authority

is acting as certification body in conformity with

section 10 of Annex A to ATMF (ECM Uniform rules) | Article 10 of Regulation (EU) No 445/2011,

recognition by the

[2] In OTIF a railway undertaking or infrastructure manager cannot be recognised as assessment body through the assessment and supervision of their SMS. For acting as an assessment body, a railway undertaking or infrastructure manager need to be accredited according to clause 7.1 indent a) or recognised according to indent 9.1 a) or d).

national authority competent for technical admission	national safety 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	Member 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	Member State

recognises the

national authority competent for technical admission	national safety authority

as an assessment body, it is the responsibility of that

Contracting State	Member State

to ensure that the

national authority competent for technical admission	national safety authority

fulfils the requirements set out in Annex II; In this case, the assessment body functions of the

national authority competent for technical admission	national safety authority

shall be demonstrably independent of the other functions of the

national authority competent for technical admission.	national safety authority.

10. VALIDITY OF RECOGNITION

Article 10

10.1 In the cases referred in

points a) and d) of section 9.1. and in section 9.2	Article 9(1)(a) and (d) and Article 9(2),

the period of validity of recognition shall not exceed 5 years from the date it is granted.

10.2 (reserved)

	In the case referred in Article 9(1)(b): (a) the statement of recognition for a railway undertaking or an infrastructure manager shall be displayed on the relevant safety certificate in field 5 ‘Additional Information’ of the

harmonised format of safety certificates provided in Annex I to Regulation 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

point c) of section 9.1: | Article 9(1)(c):

a) the statement of recognition for an entity in charge of maintenance shall be displayed on the relevant certificate in field 5 'Additional Information' of the harmonised format of certificates for entities in charge of maintenance provided in Annex V

of Annex A to ATMF (ECM Uniform rules); | , 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

Article 11

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

Article 12

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

national authority competent for technical admission | the national safety authority.

in a non-discriminatory way.

			Article 13
13.	**PROVISION OF INFORMATION TO THE**		
	SECRETARY GENERAL	**AGENCY**	
13.1	Where applicable, by no later than 21 May 2015		
	Contracting States	Member States	
	shall inform the		
	Secretary General	Agency	
	which is their national accreditation body and/or recognition body or recognition bodies for the purposes of this		
	UTP,	Regulation,	
	as well as of the assessment bodies they recognised in conformity with		
	point a) of section 9.1.	Article 9(1)(a).	
	They shall also notify any change to that situation within one month of the change.		
	Secretary General	The Agency	
	shall make this information publicly available.		
13.2	By no later than 21 May 2015 the national accreditation body shall inform the		
	Secretary General	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.		
	Secretary General	The Agency	
	shall make this information publicly available.		
13.3	By no later than 21 May 2015 the recognition body shall inform the		
	Secretary General	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.		
	Secretary General	The Agency	
	shall make this information publicly available.		
14.	**SUPPORT FROM THE**		Article 14
	SECRETARY GENERAL	**AGENCY**	
	TO ACCREDITATION OR RECOGNITION OF THE ASSESSMENT BODY		
14.1	National accreditation bodies shall subject themselves to peer evaluation organised at international level, with the assistance of the	The Agency shall organise peer evaluations between the recognition bodies based on the same principles as set out in Article 10 of	

	Secretary General. Contracting States shall ensure that their national accreditation bodies regularly undergo peer evaluation.	Regulation 765/2008/EC.
14.2	(reserved)	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.

15. SAFETY ASSESSMENT REPORT Article 15

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 paragraph 5 of this section,	point b) of Article 2(3), in accordance with paragraph 5 of this Article,
the declaration referred to in	
section 16	Article 16
shall be accepted by the	
national authority competent for technical admission	national safety authority
in its decision	
for the admission to operation of	to authorise the placing in service of
structural sub-systems and vehicles.	

15.3	The national authority competent for technical admission	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 paragraph 5 of this section,	point (a) of Article 2(3), in accordance with paragraph 5 of this Article,
the declaration referred to in	
section 16	Article 16
shall be accepted by the	

assessing entity 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,	Regulation,

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

Article 16

16.1 Based on the results of the application of this

UTP	Regulation

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

Article 17

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.

17.2 The entities in charge of maintenance shall include audits of the application of this

UTP	Regulation

in their recurrent auditing scheme for the system of maintenance as referred to in

Annex A to ATMF (ECM Uniform rules).	Article 14a(3) of Directive 2004/49/EC.
17.3	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

section 7.1 of Annex A to ATMF (ECM Uniform rules),

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

Regulation

by the entity in charge of maintenance.

18. FEEDBACK AND TECHNICAL PROGRESS

Article 18

18.1 The observations made in the monitoring and audits according to chapter 17 shall, in the case of significant deviation from one or more of the presumptions on which the CSM conclusions are based, be reported to the competent authority of the Contracting State which has issued the technical admission.

1. 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 A Contracting State which has issued one or more technical admissions where CSM on risk evaluation and assessment has/have been applied shall, on an annual basis – or immediately in the case of serious consequences being observed - report[4] to the Committee of Technical Experts (through the OTIF Secretary General) on their experiences and feedback.

In the case of problems with the applications or the efficiency of the CSM system, the Contracting State shall, where applicable, make recommendations to the Committee of Technical Experts with a view to improving them/it.

2. 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 of freight wagons referred to in point I(7)(4)(k) in Annex III to

Annex A to ATMF (ECM Uniform rules),

Regulation (EU) No 445/2011,

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

UTP. The Competent Authorities of the Contracting States in which the entity has its place of business,

Regulation. The Agency

shall gather this information in coordination with the respective certification bodies

[4] The report to the Committee of Technical Experts may be made by the EU for those Contracting States which are also Member States of the EU.

and make it available to the Secretary General upon request.

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18.4 The other entities in charge of maintenance that do not fall within the scope of Annex A to ATMF (ECM Uniform rules), may also be requested by the Competent authority of the country where they have their place of business to report on their activities. This information should also be made available to the Secretary General upon request.

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. 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. 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

Article 19

The previous version ~~01~~ of this UTP, dated ~~01.05.2012~~01.01.2014 is repealed with effect from ~~21 May 2015~~xx.xx.201x.

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

20. APPLICATION

This UTP shall apply from ~~21 May 2015~~xx.xx.201x.

ENTRY INTO FORCE AND APPLICATION Article 20

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*. [5]

~~It shall apply from 21 May 2015.~~

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

[5] The latest amendments to with which this UTP is equivalent were published in the Official Journal of the European Union L 185 on 14.7.2015

ANNEX I [6]

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. [76]

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	Regulation

and subject to the following conditions:

a) (Reserved) [8]	the risk assessment methods or tools are described in a safety management system 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	TSI

or comply with publicly available recognised standards specified in notified national rules.

1.1.5 Without prejudice to civil liability in accordance with the legal requirements of the

Contracting States,	Member 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

[6] When the word “point" or "section” is used in this Annex I, it means a section of this Annex.
[7] When the word “point" or "section” is used in this Annex I, it means a section of this Annex.
[8] COTIF does not prescribe the use of safety management systems (SMS)

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.

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, | TSIs,

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 notified national rule 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.

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.

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) The 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	Regulation

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,	Article 15(5),

the suitability of both the application of the risk management process and of its results.

2.3.3 Where compliance with

UTPs	TSIs
is required	
	by Directive 2008/57/EC
and the relevant	
UTP	TSI

does not impose the risk management process established by this

UTP, the UTPs	Regulation, the TSIs

may be considered as codes of practice for controlling hazards, provided requirement b) of point 2.3.2 is fulfilled.

2.3.4 National rules notified in accordance with

Article 12 of APTU	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.	Article 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 ro 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 Member 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;

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 regulations | Union regulations

or in notified national rules. 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 ~~If hazards arise from failures of technical systems not covered by codes of practice or the use of a reference system, the following risk acceptance criterion shall apply for the design of the technical system:~~

~~For technical systems where a functional failure has a credible direct potential for a catastrophic consequence, the associated risk does not have to be reduced further if the rate of that failure is less than or equal to 10^{-9} per operating hour.~~

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 A~~ ~~Without prejudice to the procedure specified in Article 8 of Directive 2004/49/EC, a~~

~~more demanding criterion then the one laid down in point 2.5.4 may be requested, through a notified national safety rule, in order to maintain a national safety level.~~

~~In the case of additional~~

~~technical admissions of vehicles, Article 6 of ATMF shall apply.~~ | ~~authorisations for placing in service of vehicles, the procedures of Articles 23 and 25 of Directive 2008/57/EC shall apply.~~

2.5.5 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.

~~2.5.6 If a technical system is developed by applying the 10^{-9} criterion laid down in point 2.5.4 the principle of mutual recognition is applicable in accordance with~~

~~section 15.5 of this UTP.~~ | ~~Article 15(5) of this Regulation.~~

~~Nevertheless, if the proposer can demonstrate that the national safety level in the~~

~~Contracting State~~ | ~~Member State~~

~~of application can be maintained with a rate of failure higher than 10^{-9} per operating hour, this criterion may be used by the proposer in that~~

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~~.~~ | Member 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 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 serve as robust decision support. Minor changes in input assumptions or prerequisites shall not result in significantly different requirements.~~

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 Article 3(34) allows the same level of safety to be achieved.

2.5.10 Without prejudice to

Article 12 of APTU,	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,[9]

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 notified national rule, in order to maintain the existing level of safety in the

Contracting State.	Member State.

In the case of additional

technical admissions of vehicles, Article 6 of ATMF 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.	Article 15(5).

Nevertheless, if for a specific hazard the proposer can demonstrate that the existing level of safety in the Member 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

[9] 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).

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.

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;

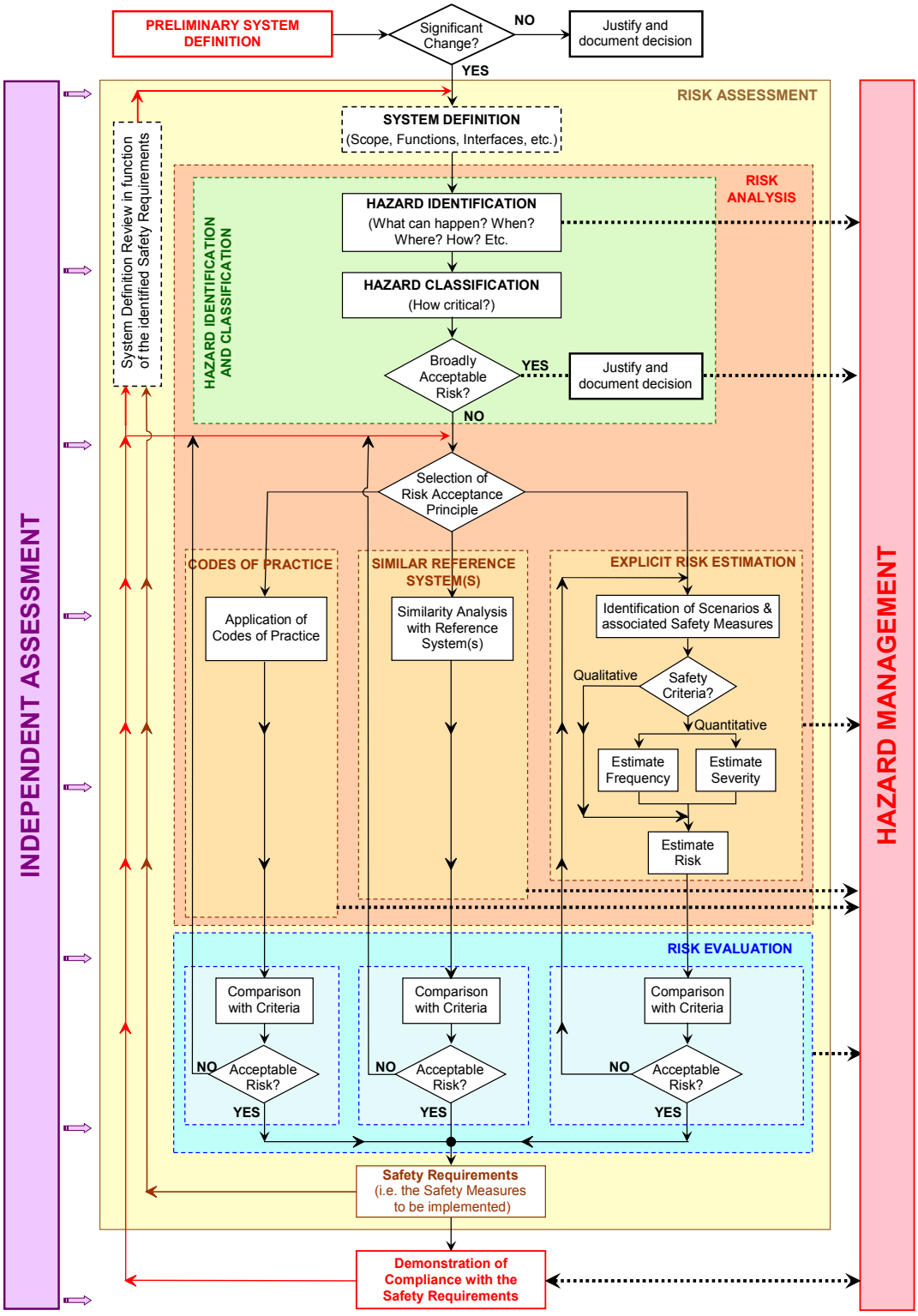
c) evidence of compliance with all the necessary safety requirements;

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



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	
assessing entities,	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.

ANNEX III

SAFETY ASSESSMENT REPORT OF THE ASSESSMENT BODY

1. 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; | Regulation;

      2) any identified cases of non-compliances with the provisions of this

         UTP | Regulation

         and the assessment body's recommendations;

   e) the conclusions of the independent assessment.