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Železniške naprave - Specifikacija in prikaz zanesljivosti, razpoložljivosti, vzdrževalnosti in varnosti (RAMS) - 2. del: Sistemski pristop k varnosti

Railway Applications - The Specification and Demonstration of Reliability, Availability, Maintainability and Safety (RAMS) - Part 2: Systems Approach to Safety

Bahnanwendungen - Spezifikation und Nachweis von Zuverlässigkeit, Verfügbarkeit, Instandhaltbarkeit und Sicherheit (RAMS) - Teil 2: Systembezogene Sicherheitsmethodik

Applications ferroviaires - Spécification et démonstration de la fiabilité, de la disponibilité, de la maintenabilité et de la sécurité (FDMS) - Partie 2: Approche systématique pour la sécurité

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Railway Applications - The Specification and Demonstration of Reliability, Availability, Maintainability and Safety (RAMS) - Part 2: Systems Approach to Safety

Applications ferroviaires - Spécification et démonstration de
la fiabilité, de la disponibilité, de la maintenabilité et de la
sécurité (FDMS) - Partie 2: Approche systématique pour la
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Bahnanwendungen - Spezifikation und Nachweis von
Zuverlässigkeit, Verfügbarkeit, Instandhaltbarkeit und
Sicherheit (RAMS) - Teil 2: Systembezogene
Sicherheitsmethodik

This draft European Standard is submitted to CENELEC members for enquiry.
Deadline for CENELEC: 2015-12-04.

It has been drawn up by CLC/TC 9X.

If this draft becomes a European Standard, CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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<https://standards.iteh.ai/catalog/standards/sist/f9147e51-1237-4aaf-9414-542f5a9ee782/sist-en-50126-2-2018>

112 European foreword

113 This document (prEN 50126-2:2015) has been prepared by CLC/TC 9X "Electrical and electronic
114 applications for railways".

115
116 This document is currently submitted to the Enquiry.
117

118 The following dates are proposed:
119

- latest date by which the existence of (doa) dor + 6 months
this document has to be announced
at national level
- latest date by which this document has to be (dop) dor + 12 months
implemented at national level by publication
of an identical national standard or by
endorsement
- latest date by which the national standards (dow) dor + 36 months
conflicting with this document have to (to be confirmed or
be withdrawn modified when voting)

120
121 This document will supersede CLC/TR 50126-2:2007.
122

123 EN 50126 "*Railway applications – The specification and demonstration of Reliability, Availability,*
124 *Maintainability and Safety (RAMS)*" consists of the following parts:

- 125 – Part 1: Generic RAMS process;
- 126 – Part 2: Systems approach to safety;

127
SIST EN 50126-2:2018
<https://standards.iteh.ai/catalog/standards/sist/f9147e51-1237-4aaf-9414-542f5a9ee782/sist-en-50126-2-2018>

128 Introduction

129 EN 50126-1:1999 was aimed at introduce the application of a systematic RAMS management
130 process in the railway sector. Through the application of these standards and the experiences
131 gained over the last years, the need for revision and restructuring became apparent with a need
132 to deliver a systematic and coherent approach to RAMS applicable to all the railway application
133 fields Signalling, Rolling Stock and Electric power supply for Railways (Fixed Installations).

134 The revision work improved the coherency and consistency of the standards, the concept of
135 safety management and the practical usage of EN 50126 and took into consideration the existing
136 and related Technical Reports as well.

137 This European Standard provides railway duty holders and the railway suppliers, throughout the
138 European Union, with a process which will enable the implementation of a consistent approach to
139 the management of reliability, availability, maintainability and safety, denoted by the acronym
140 RAMS.

141 Processes for the specification and demonstration of RAMS requirements are cornerstones of
142 this standard. This European Standard promotes a common understanding and approach to the
143 management of RAMS.

144 EN 50126 is the railway sector specific application of IEC 61508. Meeting the requirements in
145 this European Standard is sufficient to ensure that additional compliance to IEC 61508 does not
146 need to be demonstrated.

147 With regard to safety EN 50126-1 provides a Safety Management Process which is supported by
148 guidance and methods described in EN 50126-2.

149 EN 50126-1 and EN 50126-2 are independent from the technology used. As far as safety is
150 concerned, EN 50126 takes the perspective of functional safety. This does not exclude other
151 aspects of safety. However, these are not the focus.

152 The application of this standard should be adapted to the specific requirements of the system
153 under consideration.

154 This European Standard can be applied systematically by the railway duty holders and railway
155 suppliers, throughout all phases of the life-cycle of a railway application, to develop railway
156 specific RAMS requirements and to achieve compliance with these requirements. The systems-
157 level approach developed by this European Standard facilitates assessment of the RAMS
158 interactions between elements of railway applications even if they are of complex nature.

159 This European Standard promotes co-operation between the stakeholders of Railways in the
160 achievement of an optimal combination of RAMS and cost for railway applications. Adoption of
161 this European Standard will support the principles of the European Single Market and facilitate
162 European railway inter-operability.

163 The process defined by this European Standard assumes that railway duty holders and railway
164 suppliers have business-level policies addressing Quality, Performance and Safety. The
165 approach defined in this standard is consistent with the application of quality management
166 requirements contained within the ISO 9001.

167 In accordance with CENELEC editing rules ¹⁾, mandatory requirements in this standard are
168 indicated with the modal verb "shall". Where justifiable, the standard permits process tailoring.

169 Specific guidance on the application of this standard for Safety aspects is provided in
170 EN 50126-2. EN 50126-2 provides various methods for use in the safety management process.
171 Where a particular method is selected for the system under consideration, the mandatory
172 requirements of this method are by consequence mandatory for the safety management of the
173 system under consideration.

1) CENELEC "Internal Regulations Part 3: Rules for the structure and drafting of CEN/CENELEC Publications (2009-08), Annex H

174 **1 Scope**

175 This part 2 of EN 50126

- 176 • considers RAMS, understood as reliability, availability, maintainability and safety and their
177 interaction;
- 178 • considers the generic aspects of the RAMS life-cycle. The guidance in this part is still
179 applicable in the application of specific standards;
- 180 • defines:
 - 181 – a process, based on the system life-cycle and tasks within it, for managing RAMS;
 - 182 – a systematic process, tailorable to the type and size of system under consideration, for
183 specifying requirements for RAMS and demonstrating that these requirements are
184 achieved;
- 185 • addresses railway specifics;
- 186 • enables conflicts between RAMS elements to be controlled and managed effectively;
- 187 • does not define:
 - 188 – RAMS targets, quantities, requirements or solutions for specific railway applications;
 - 189 – rules or processes pertaining to the certification of railway products against the
190 requirements of this standard;
 - 191 – an approval process by the safety authority;
- 192 • does not specify requirements for ensuring system security.

193

194 This part 2 of EN 50126 is applicable

- 195 • to the specification and demonstration of RAMS for all railway applications and at all levels
196 of such an application, as appropriate, from complete railway systems to major systems and
197 to individual and combined sub-systems and components within these major systems,
198 including those containing software; in particular:
 - 199 – to new systems;
 - 200 – to new systems integrated into existing systems accepted prior to the creation of this
201 standard, but only to the extent and insofar as the new system with the new
202 functionality is being integrated. It is otherwise not applicable to any unmodified
203 aspects of the existing system;
 - 204 – as far as reasonably practicable, to modifications and extensions of existing systems
205 accepted prior to the creation of this standard, but only to the extent and insofar as
206 existing systems are being modified. It is otherwise not applicable to any unmodified
207 aspect of the existing system;
- 208 • at all relevant phases of the life-cycle of an application;
- 209 • for use by railway duty holders and the railway suppliers.

210 It is not required to apply this standard to existing systems including those systems already
211 compliant with any version of former EN 50126, which remain unmodified. Railway applications
212 means Command, Control & Signalling, Rolling Stock and Fixed Installations.

213 Processes for the specification and demonstration of RAMS requirements are cornerstones of
214 this standard. This European Standard promotes a common understanding and approach to the
215 management of RAMS.

216 The process defined by this European Standard assumes that railway duty holders and railway
217 suppliers have business-level policies addressing Quality, Performance and Safety. The
218 approach defined in this standard is consistent with the application of quality management
219 requirements contained within the EN ISO 9001.

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220 **2 Normative references**

221 The following documents, in whole or in part, are normatively referenced in this document and
 222 are indispensable for its application. For dated references, only the edition cited applies. For
 223 undated references, the latest edition of the referenced document (including any amendments)
 224 applies.

225 prEN 50126-1:2015, *Railway applications – The Specification and Demonstration of Reliability,*
 226 *Availability, Maintainability and Safety (RAMS) – Part 1: Generic RAMS process*

227 **3 Terms and definitions**

228 For the purposes of this document, the terms and definitions given in prEN 50126-1:2015 apply.

229 **4 Abbreviations**

| | | |
|-----|----------|--|
| 230 | ALARP | As Low As Reasonable Practicable |
| 231 | CBA | Cost Benefit Analysis |
| 232 | CCF | Common Cause Failure (Analysis) |
| 233 | CoP | Code of Practice |
| 234 | DRA | Differential Risk Aversion |
| 235 | ERE | Explicit Risk Estimation |
| 236 | EMC | Electromagnetic compatibility |
| 237 | ETA | Event Tree Analysis |
| 238 | FMECA | Failure Mode Effect & Criticality Analysis |
| 239 | FTA | Fault Tree Analysis |
| 240 | GA, GASC | Generic Application, Generic Application Safety Case |
| 241 | GP, GPSC | Generic Product, Generic Product Safety Case |
| 242 | GAME | Globalement Au Moins Equivalent |
| 243 | HAZOP | Hazard and Operability study |
| 244 | ISA | Independent Safety Assessment |
| 245 | MEM | Minimum Endogenous Mortality |
| 246 | RAC | Risk Acceptance Criterion |
| 247 | RAMS | Reliability, Availability, Maintainability, Safety |
| 248 | RBD | Reliability Block Diagram |
| 249 | RRA | Rapid Ranking Analysis |
| 250 | SA, SASC | Specific Application, Specific Application Safety Case |
| 251 | SDR | Safe Down Rate |
| 252 | SDT | Safe Down Time |
| 253 | SIL | Safety Integrity Level |
| 254 | SRAC | Safety-related Application Conditions |
| 255 | TFFR | Tolerable Functional unsafe Failure Rate |
| 256 | THR | Tolerable Hazard Rate |
| 257 | VPF | Value of Preventing a Fatality |

258 **5 Guidance on Safety process**

259 **5.1 Risk Assessment and Hazard Control**

260 In this subclause, the so-called Hourglass Model is introduced: it offers a simplified approach
 261 that although not containing all aspects implied in the life-cycle model helps to clarify some
 262 issues.

263 The Hourglass Model provides an overview of the major safety-related activities that are needed
 264 to ensure an acceptable safety level for a technical system, including the corresponding
 265 responsibility areas.

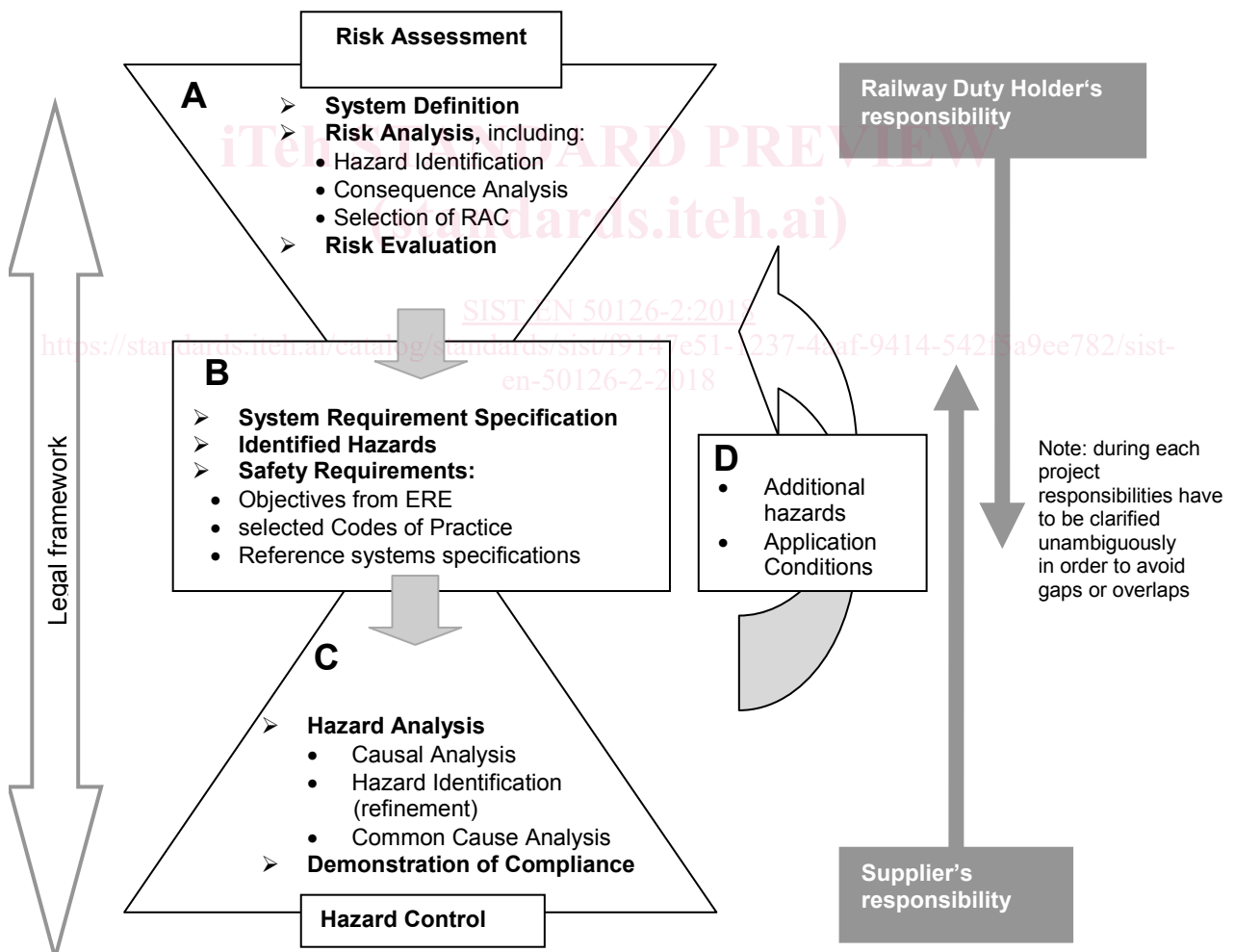
266 Technical system means a product or an assembly of products including the design,
 267 implementation and support documentation. The development of a technical system starts with
 268 its requirements specification and ends with its acceptance. The design of relevant interfaces
 269 with human behaviour is considered, while human operators and their actions are not included in
 270 a technical system. Both the maintenance process (described in the maintenance manuals) and
 271 the operation are specified but are not considered parts of the technical system itself. They can
 272 be restricted in “application conditions”.

273 The purpose of this model is to highlight the separation between risk analysis (at the railway
 274 system level) from hazard analysis (at the level of the system under consideration).

275 This enhances co-operation between the relevant stakeholders, clarifying responsibilities and
 276 interfaces and has the advantages of reducing complexity and facilitating modularization.

277 The Hourglass Model describes two main aspects:

- 278 • “risk assessment”, i.e. deriving high-level safety requirements for operational and technical
 279 issues (including maintenance), and
- 280 • “hazard control”, i.e. design and implementation of the safety-related system under
 281 consideration by determining and analysing causes internal to the system and implementing
 282 control measures on the basis of the given safety requirements.



283
 284

285

Figure 1 – The Hourglass Model

286 5.2 A. Risk Assessment

287 5.2.1 General

288 Risk assessment is performed at the railway system level.

289 It relies on System Definition and includes Risk analysis and Risk evaluation.

290 It defines the high level system safety requirements, in particular safety requirements for the
291 system under consideration from the perspective of operator. It takes into account safety-related
292 operational aspects, previous experience and the regulatory requirements of the railway
293 application.

294 The main task for this activity is the risk analysis, which is derived from the system definition.
295 The risk analysis includes hazard identification, consequence analysis, and selection of Risk
296 Acceptance Criterion (RAC).

297 The specification of safety requirements is the final result of risk assessment; in Figure 1 it is
298 allocated to box B, because it has an interface purpose (together with system requirement
299 specifications and the list of identified hazards) between different responsibilities.

300 **5.2.2 Gaining and sharing system knowledge**

301 All the knowledge gained during the process and the documented analyses, resulting from the
302 risk assessment, should be considered as relevant information together with the specification of
303 safety requirements.

304 This knowledge should be shared and distributed among the relevant stakeholders involved in
305 the lifecycle of the system. It will provide significant potential benefits in terms of improved
306 awareness of hazards and risk of accidents in the given operational and maintenance context,
307 and will also help to understand the scope and limits of the risk reduction measures.

308 **5.2.3 Conducting risk assessment**

309 The level of detail in a risk assessment should be adequate to the risk. The purpose is not to
310 catalogue every trivial hazard, nor is it expected that hazards beyond the limits of current
311 knowledge will always be identified. A suitable and sufficient risk assessment should reflect a
312 reasonable analysis of hazards and their associated risks within the railway operation and within
313 the applied technology itself. Where reasonably practicable, risk assessments should be
314 correlated with historical records of accidents and the records of causes.

315 When possible, consideration of technical implementation/architecture should be avoided in this
316 first stage i.e. the system to be developed should be considered as a black box, of which
317 functions and hazards are evaluated only at the boundaries. These boundaries are well defined
318 interfaces between the operational environment and the system under consideration.

319 As an example, an “unintentional train motion” is a hazard for a train. It can be observed as an
320 abstraction at the boundary of the “system train” and it could lead to different accidents
321 depending on the operational context (e.g. collision in context with over-speeding while running
322 or fall of persons in connection with a train moving in a station while expected to stand still, etc.).

323 Assumptions defined during the risk assessment have to be checked and updated throughout the
324 life-cycle phases.

325 **5.3 B. Outcome of the risk assessment**

326 The results of the risk assessment are a set of safety requirements associated to clearly-
327 identified functions, systems or operating rules. They are part of the System Requirement
328 Specification that establishes the technical interface between the stakeholders.

329 NOTE The project organisational structure and responsibilities are another factor to consider in understanding
330 and controlling risk. For organisational aspects and requirements refer to 7.2 .

331 On the basis of the selected risk acceptance principles, safety requirements can refer to Codes
332 of Practice, to Similar Systems, or give explicit targets derived from an Explicit Risk Estimation
333 (ERE).

334 Safety requirements include required efficiency of safety functions, that could be assessed
335 quantitatively (e.g. maximum rates of hazards), semi-quantitatively or qualitatively (e.g. use of
336 trained drivers for controlling human factor errors).

337 Safety requirements should be assessed with a holistic approach, i.e. the residual risk should be
338 evaluated as acceptable taking into consideration the identified hazards.

339 **5.4 C. Hazard control**

340 The hazard control stage in the hourglass model is dedicated to ensuring that the system under
341 consideration is compliant with the safety requirements. Hazard control is performed for a
342 specific system architecture.

343 NOTE Hazard control as here defined has a narrow meaning and is limited to the design and implementation
344 phase.

345 The major impacts of human factors, operational and general maintenance rules as well as
346 procedures are part of the preceding risk analysis and should have already been taken into
347 account in the safety requirements. Therefore, during hazard control, the designer of the system
348 under consideration can focus on the internal causes of the identified hazards.

349 The main task for this activity is the “hazard analysis” comprising:

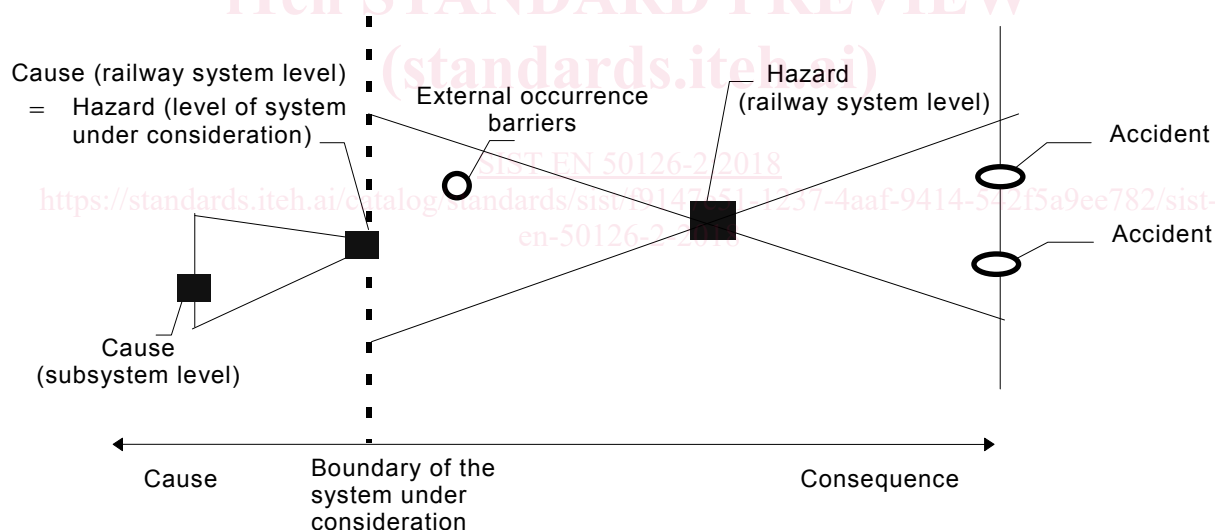
- 350 – causal analysis;
- 351 – a dedicated hazard identification focusing on the system under consideration;
- 352 – a Common Cause Analysis.

353 Hazard identification is a recurring task that can appear on several iteration levels for subsets of
354 the system under consideration. In order to distinguish these different tasks (and related
355 documents) the hazard identification has been quoted twice in Figure 1:

- 356 1. during risk assessment, hazard identification focuses on high level hazards derived from the
357 system functions (black box) and related operation of the system as well as its environment;
- 358 2. within the hazard control, a refined/iterated hazard identification focuses on hazards and
359 their causes derived from the technical solutions, i.e. from defined architecture and internal
360 interfaces of the system under consideration, and potential new hazards introduced by the
361 system itself.

362 Figure 2 shows the general case where the cause of a hazard at the railway system level
363 consists in a hazard on the level of the system under consideration, with respect to its boundary.
364 The boundary for a hazard identification is always given in the system definition that limits the
365 scope of the task. This implies that the hazards are structured hierarchically. Hence a
366 hierarchical approach to hazard analysis and hazard logging should be used.

367



368

369

370 **Figure 2 – Definition of hazards with respect to the system boundary**

371

372 The picture is hazard-oriented and shows a “bow-tie” shape, suggesting that several causes may
373 lead to the same hazard and one hazard may lead to several different accidents.

374 The demonstration of compliance with the safety requirements of the system under consideration
375 can be performed in various forms. These forms depend on the nature of the underlying
376 requirements set at the beginning of the hazard control.

377 5.5 D. Revision of Risk Assessment

378 During the hazard control stage, fulfilment of safety targets could not be reached at the first
379 iteration:

- 380 – additional hazards may be identified at the level of the system under consideration;
- 381 – a need of new operational rules may arise;

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382 – additional external safety measures may be required to fulfil the safety objectives.
 383 In all these cases, a revision of the risk assessment is necessary.
 384 This revision should also take account of the application conditions that could arise at the level
 385 of the system under consideration.

386 **5.6 Responsibilities**

387 Risk assessment is mainly within the responsibility of the railway duty holders and operators.
 388 The roles and responsibilities may however be contracted to other parties in relation to their
 389 accountabilities, provided that they have a documented and suitable range of competencies to
 390 consider the whole operational context in detail. They need to take into account safety-related
 391 operational aspects, previous experience and regulatory requirements. In any case the railway
 392 duty holders should approve the results of the risk assessment.
 393 The hazard control, for hazards associated purely with the technical system, is the responsibility
 394 of the supplier of the technical system.
 395 Railway duty holder and supplier need to comply with the prevailing legal requirements.
 396

397 **6 Guidance on Safety Demonstration and Acceptance**

398 **6.1 Introduction**

399 This clause defines the safety acceptance and approval process for the system under
 400 consideration. Except where considered appropriate, it does not specify who should carry out the
 401 work at each stage, since this may vary in different circumstances.

402 In terms of safety processes, the development of a system can be classified in three types:

- 403 • **Generic Product:** The system is considered from a generic point of view, applicable to
 404 different classes of applications;
 405 Analyses are carried out within an operational context which is application-independent. The
 406 safety process is typically completed with Phase 6 (Design & Implementation).
- 407 • **Generic Application:** The system is considered suitable for multiple applications of the same
 408 class;
 409 Analyses are carried out within an operational context which is application-dependent. The
 410 safety process is typically completed within Phase 6 (Design & Implementation) and includes
 411 the definition of the application design process.
- 412 • **Specific application:** The system is considered for a specific application (including its
 413 physical implementation).
 414

415 Three conditions shall be satisfied before the system under consideration can be accepted as
 416 adequately safe for its intended application:

- 417 • evidence of quality management;
- 418 • evidence of safety management;
- 419 • evidence of functional and technical safety.

420 The evidence of quality management, safety management and functional/technical safety are
 421 included in the safety case.

422 Three different categories of Safety Case can be defined according to the involved type of
 423 development as previously defined.

424

425 **6.2 Safety acceptance process**

426 Before system acceptance can be considered, an Independent Safety Assessment (ISA) of the
 427 system under consideration with related safety case should be carried out, to provide assurance
 428 that the necessary level of safety has been achieved.

429 Its results should be presented in an ISA Report. The report should explain the activities carried
 430 out by the Safety Assessor to determine whether the system under consideration has been
 431 designed to meet its specified requirements, and if necessary specify some additional conditions
 432 for its operation.

433 The overall documentary evidence should consist in:

- 434 • the system (or sub-system/component) requirements specification;
- 435 • the safety requirements specification (and related Risk Analysis whenever applicable);
- 436 • the safety case, including
 - 437 – Part 1: Definition of system/sub-system/component;
 - 438 – Part 2: Quality Management report (evidence of quality management);
 - 439 – Part 3: Safety Management Report (evidence of safety management);
 - 440 – Part 4: Technical Safety Report (evidence of functional/technical safety);
 - 441 – Part 5: Related Safety Cases (if applicable);
 - 442 – Part 6: Conclusion.
- 443 • the Independent Safety Assessment (ISA) Report, if appropriate.

444 Provided all the conditions for safety acceptance have been satisfied, as demonstrated by the
 445 Safety Case, and subject to the results of the independent safety assessment where necessary,
 446 the system under consideration may be granted safety acceptance by the stakeholders
 447 responsible for its incorporation or final use. Acceptance may be subject to the fulfilment of
 448 additional conditions imposed by the legal framework.

449 When using a Generic Product (i.e. independent of application), or a Generic Application (i.e.
 450 class of application) in the context of a Specific Application, it should be possible for safety
 451 acceptance to be based on existing related independent safety assessment (i.e. cross-
 452 acceptance). This is not considered possible for Specific Applications.

453 The safety acceptance process, for all three categories of Safety Case, is illustrated in Figure 3,
 454 where for the Specific Application cases of reference to either Generic Products or to Generic
 455 Application are provided.

456 According to tailoring requirements defined in Part 1, the stakeholder responsible for a given
 457 safety process shall provide evidence and justification of the coverage and limits of the covered
 458 life-cycle phases.

459 NOTE The shaded area in Figure 3 relates to life-cycle phases 1-3, meaning that this life-cycle phases are
 460 generally covered with different level of extent in Generic Product and Generic / Specific Application. Assumptions
 461 shall be justified in the associated Safety Cases.

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