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Contents

Change log

SINTEF SJS will undertake to maintain this memo. It is our goal that the information provided is both timely and accurate. If errors are brought to our attention, we will correct them.

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0.1	2011-06-14	For review
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1 Summary

ISO and CENELEC have already issued standards presenting requirements for safety plans (EN 50126-1, ch.6.2.3.4), quality plans (ISO 10005) and project plans (ISO 10006). The guidance provided in this Certification Plan is complementary to these plans.

The first parts include abbreviations and definitions relevant for certification. In addition the changes in the regulations since 1996, when the first railway interoperability directive was issued, are presented.

The Certification Plan constitutes the plan to be used by the Applicant to carry out its specific certification work.

The main part of this Guide includes a description of relevant content for a Certification Plan, this includes a description of:

- Scope
- Objectives
- Inputs and basis for the Certification Plan
- Requirements to be met
- Contract(s)
- The methods for using Conformity Verification Specification and Conformity Verification Report are briefly described
- Necessary resources
- Design and development
- Purchasing
- Audits
- Flow chart showing the certification process (e.g. including assessment, certification and authorisation)

In the Annex, several internet references are listed where most of the requirement sources can be found.

1 Introduction

ISO and CENELEC have already issued standards presenting requirements for safety plans (EN 50126-1, ch.6.2.3.4 [25]), quality plans (ISO 10005 [35]) and project plans (ISO 10006 [36]).

The guidance for a certification plan provided in the present memo is intended to be complementary to these plans, which often don't include sufficient plans for certification topics such as e.g.:

- how to ensure that the constituent or subsystem is certified
- regulation to be used and changes in regulation during the project
    - standards to be used as e.g. the CENELEC 5012x standards
    - commission decisions
- parties involved e.g. Applicant/Contracting entity, manufacturer(s) ISA (internal and/or external), NoBo and DeBo
- cross-acceptance
- split of responsibility between Contracting entity (applicant) and supplier (manufacturer)
- which procedure for assessment of conformity shall be used

The Certification Plan(s) constitutes the plan(s) to be used by the Applicant (and the manufacturer) to achieve certification.

Experience has shown that most of the development projects are delayed, often due to a lack of planning related to certification. The existence of a proper certification plan is therefore of great importance and the first edition of the plan should be issued at the very beginning of the project.

The first approval of a new railway system, such as a trackside assembly or an on-board assembly, includes mainly the safety issues thus ensuring safe operation. This is ensured by issuing e.g. an interim statement of conformity. Later all the ERTMS requirements, most of them functional requirements, are satisfied.

In this report the main emphasis is on CCS constituents and subsystems but also non-ERTMS products as e.g. IXL are included.

1.1 Abbreviations, terms and definitions

The terms *CVS* and *CVR* are SINTEF's own terms, not described in directives, TSI's, RFU's or standards.

Abbreviation/term	Definition
ACP	Applicant Certification Plan
CCS	Control, command and signalling
Contracting Entity	Article 2 (r) of Directive 2008/57/EC [13]: Contractin entity "*means any entity, whether public or private, which orders the design and/or construction or the renewal or upgrading of a subsystem. This entity may be a railway undertaking, an infrastructure manager or a keeper, or the concession holder responsible for carrying out a project*.
Cross-acceptance	According to EN 50129 [28]: *The status achieved by a product that has been accepted by one authority to the relevant European Standards and is acceptable to other authorities without the necessity for further assessment.*
CVR	Conformity Verification Specification
CVS	Conformity Verification Report
DeBo	Designated Body
DoC	Declaration of Conformity
ERA	European Railway Agency
ERTMS	European Rail Traffic Management System
European specification	Copy from 2008/57/EC [13]: Article 2 Definitions *(h) 'European specification' means a common technical specification, a European technical approval or a national standard transposing a European standard, as defined in Annex XXI to Directive 2004/17/EC;*
GA	Generic Application
GoICs	Group of Interoperability Constituents
GP	Generic Product
Harmonised standards	Copied from directive 2008/57/EC Article 2, definitions (u) *'harmonised standard' means any European standard adopted by one of the European standardisation bodies listed in Annex I to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services (1) in connection with a mandate by the Commission drawn up in accordance with the procedure referred to in Article 6(3) of that Directive, which, by itself or together with other standards, provides a solution as regards compliance with a legal provision;* Copied from http://ec.europa.eu/enterprise/glossary/index_en.htm 6th of January 2011: *A standard adopted by one of the European standardization bodies listed in Annex I to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on information society services on the basis of a request made by the Commission in accordance with Article 6 of that Directive.*
HS	High Speed
IC	Interoperability Constituent

Abbreviation/term	Definition
ICAR	Interim Conformity Assessment Report
IXL	Interlocking
ISA	Independent Safety Assessor
ISV	Intermediate statement of verification
LVD	Low Voltage Directive
Mandatory standards	Copy from EU directive 2008/57/EC [13]: *"(14) TSIs may in certain cases make an explicit reference to European standards or specifications where this is strictly necessary in order to achieve the objectives of this Directive. Such explicit reference has consequences which must be made clear; in particular, these European standards or specifications become mandatory from the moment the TSI is applicable".* The latest editions of the mandatory standards are presented in the TSIs, CR [9] and HS [3].
NoBo	Notified Body
OJ	Official Journal
QMSA	Quality Management System Approval
NSA	National Safety Authority
Pre-existing software	EN 50128: draft 2011 [27] section 3.1.16 pre-existing software *All software developed prior to the application currently in question is classed as pre-existing software including* *- COTS (commercial off-the-shelf) and open-source software,* *- software previously developed*
Project at an advanced stage of development	Copy from EU directive 2008/57/EC [13]: *"Any project whose planning/construction stage has reached a point where a change in the technical specifications would be unacceptable to the Member State concerned. Such an impediment may be legal, contractual, economic, financial, social or environmental in nature and must be duly substantiated."*
SA	Specific Application
Safety Case	EN 50126-1 [25], 3.36: *safety case: The documented demonstration that the product complies with the specified safety requirements.*
SAR	Safety Assessment Report
SRS	System Requirement Specification
TSI	Technical Specification of Interoperability

1.2 Change in regulations

ERTMS is still not in a mature stage and regulations in all technical fields are changing due to development. As a result the requirements are changed often compared to the time it takes to develop a new subsystem. To develop a new subsystem, as e.g. a CCS, may take up to 5 years or more.

The table below shows the changes in the regulations and the main railway standards since 1996. In addition to the changes mentioned in the table below, other standards have been issued and updated, and national regulations have been changed.

Year	Directives, commission regulations and commission decision issued or updated	Main CENELEC safety standards
1996	Directive 96/48/EC (HS Interoperability) [1]	
1997		
1998		
1999		EN 50126-1 [25]
2000		
2001	Directive 2001/16/EC (CR Interoperability) [2]	EN 50128 [26] EN 50159-1 [29] EN 50159-2 [30]
2002	Commission decision 2002/731/EC TSI for HS system [3]	
2003		EN 50129 [28]
2004	• Directive 2004/49/EC (safety) [4] • Directive 2004/108/EC (EMC) [5] • Directive 2004/50/EC (amendments of 96/48/EC and 2001/16/EC) [7]	
2005		
2006	• Directive 2006/95/EC (LVD) [8] • Commission decision 2006/679/EC TSI for CR system [9] • Commission decision 2006/860/EC modifying Annex A to decision 2006/679/EC [10]	
2007	• Directive 2007/32/EC amending Annex VI to 96/48/EC and 2001/16/EC [11] • Commission decision 2007/153/EC [12] Modifying Annex A to Decision 2006/679/EC concerning the technical specification for interoperability relating to the control-command and signalling subsystem of the trans-European conventional rail system and Annex A to Decision 2006/860/EC concerning the technical specification for interoperability relating to the control-command and signalling subsystem of the trans-European high speed rail system	

Year	Directives, commission regulations and commission decision issued or updated	Main CENELEC safety standards
2008	• Directive 2008/57/EC (Interoperability) [13] • Directive 2008/110/EC [14] OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 amending Directive 2004/49/EC on safety on the Community's railways (Railway Safety Directive) • Commission decision 2008/386/EC [15] modifying Annex A to decision 2006/679/EC and Annex A to Decision 2006/860/EC • Decision 768/2008 [16] on a common framework for the marketing of products	
2009	• Directive 2009/131/EC [17] of 16 October 2009 amending Annex VII to Directive 2008/57/EC of the European Parliament and of the Council on the interoperability of the rail system within the Community • Commission regulation 352/2009 [18] on the adoption of ac common safety method on risk evaluation and assessment as referred to in Article 6(3) of Directive 2004/49/EC of the European Parliament and of the Council	
2010	• Commission decision 2010/79/EC [19] amending Decisions 2006/679/EC and 2006/860EC as regards TSI for CR and HS • Commission decision 2010/713/EU [20] on modules. The decision will be implemented when the respective TSIs are updated	EN 50159
2011	• Commission Directive 2011/18/EU [21] of 1 March 2011 amending Annexes II, V and VI to Directive 2008/57/EC of the European Parliament and of the Council on the interoperability of the rail system within the Community • Commission decision 2011/155/EU [22] on the publication and management of the reference document referred to in Article 27(4) of Directive 2008/57/EC	The following important changes are expected: Edition 2 of EN 50128 [27] will be issued as EN 50126-5
2012	The following important changes are expected: • Merging of HS and CR TSIs	

2 Certification plan content

2.1 Scope

The scope should be clearly stated in the certification plan. The scope should include:

- A statement of the purpose and expected deliverables
- Constituents
  - Constituents to be used
  - Whether the constituents are already certified or not
  - Cross-acceptance of constituents [59]
  - HW development (an EMC compliance plan should then be referenced to or included in this plan)
- Description of or reference to a description of Subsystems to be certified
  - Already certified or not
  - Cross-acceptance [23] and [59]
- Non-ERTMS products
  - ISA to be used for the different products. And shall internal or external ISA be used. This also depends on whether the ISA is accepted by the NSA (and the NoBo).
  - GP, GA, SA (see also [50])
  - Cross-acceptance [23]
- Documents to be issued by the relevant parties (e.g. ICAR, ISV etc)
  - Templates for Constituents and subsystems are presented in "RFU, Content of issued certificates" [52]
  - Conformities declared in accordance to other directives may be declared according to ISO/IEC 17050 [38] and [39]
  - For declarations according to the EMC Directive, see "Guide for the EMC directive" [6]
- Limitations
- Conditions
- Inclusions
- Exclusions
- Upgrade of the system if necessary (see e.g. the ERA ERTMS newsletter. Issue 21, Nov 2010 [40])

2.2 Objectives

The objectives should be clearly stated in the certification plan.

The objective is to identify and describe the activities and the documentation to be produced by the Applicant as required by the TSI and national requirements as a part of the certification process. The plan forces the Applicant to be specific about the certification process, enabling the NoBo (and ISA and DeBo) to be proactive and to plan the certification work according to the Applicant's schedule.

Depending on the type of certification (i.e. the module(s) to be applied and the constituent/subsystem to be certified) the activities and documentation to produce will vary, but must be in accordance with the applicable TSIs. The main basis for writing an Applicant Certification Plan (ACP, both the Contracting entity and the manufacturer should have a plan) should be the TSI module description (see TSI Annex E [3] and [9]), and in that context the description of the Application(s) that shall be lodged by the Applicant [49].

The ACP constitutes the plan to be used by the Applicant to carry out its specific certification work. The NoBo shall, at an early stage in the project, review the plan in order to determine eventual shortcomings and to plan its own NoBo certification work.

2.3 Inputs and basis for the certification plan

It is necessary to list and describe the inputs and basis for the certification plan.

The certification plan is based on several documents related to the system to be certified. All the relevant documents should be listed and their content and relation to the system be described. The list may contain documents such as technical and functional system descriptions and specifications as well as safety related system and certification documents.

2.4 Requirements to be met

An overview of the requirements shall be included or referred to. An overview of typical requirements and recommendations is presented below:

- Directives
  - Interoperability directive [13]
  - RFU [53] and WKD [55] lists all relevant directives
  - ISO/IEC 17050 [38] and [39] presents requirements and guidelines for Declarations of Conformity (DoC)
- Commission decisions:
  - TSIs
  - Separate issues of Annex A of the TSIs
- Relevant regulations, e.g. "Commission regulation 352/2009 [18] on the adoption of a common safety method"
- Mandatory standards (Annex A [9] and [10])
- Harmonised standards (not required to use harmonised standards, but should be evaluated as part of the contract between e.g. the manufacturer and the Contracting entity). The Contracting entity should evaluate whether it shall require the use of harmonised standards
- National standards

Within Europe, national standards are increasingly being replaced by European standards, but several standards may still apply in a given project. That is why an important part of defining requirements at the beginning of a project is to define and agree which standards shall and shall not be applied.

Advanced stage of development:

The Interoperability Directive [13] states that member states need not apply new or revised TSIs for projects at an advanced stage of development. From Article 8: *A Member State need not apply the new or revised TSIs adopted in accordance with paragraph 2 in the case of projects at an advanced stage of development or subject to a contract in the course of performance when the relevant group of TSIs is published.*

However; each member state must, within one year of entry into force of each TSI, communicate to the Commission a list of projects that are at an advanced stage of development in its territory. From Article 9: *In the case referred to in paragraph 1(a), within one year of entry into force of each TSI each Member State shall communicate to the Commission a list of projects that are taking place within its territory and are at an advanced stage of development.*

Requirement freeze:

At some time in the project it is necessary to ensure that no further requirements are introduced or changed.

The ERA report [42] states that:

"*Requirements freeze: All the requirements conform to agreed approach and are settled. From this point it is agreed that no additional requirements may be subsequently imposed. The applicant is given protection from any deviation from the agreed requirements (e.g. new rules being imposed)*"

and

"*Some Member States include a "requirements freeze" in their procedure whereby at a point the applicant, the manufacturer and the NSA agree which specifications and rules will apply. In other MSs applicants are exposed to the risk of rule changes until the day of authorisation. This legal uncertainty often adds costs and delay in the form of last minute modification and the associated verification. At such a late stage any modifications will be extremely costly*."

2.5 Contract(s)

Relevant contracts are:

- Between the Contracting entity/applicant and the manufacturer (one or more)
- Contracting entity/manufacturer and ISA (one or more)
- Contracting entity/manufacturer and NoBo (one or more)
- Contracting entity/manufacturer and DeBo
- Contracting entity and subcontractors (one or more)
- Manufacturer and subcontractors (one or more)

The split of responsibility between the relevant parties involved is important.

2.6 CVS and CVR

The method using CVS and CVR is described in [48]. A short introduction is presented below:

Certification of constituents or subsystems according to Technical Specification for Interoperability (TSI) implies a certification process that involves a Notified Body (NoBo) and other parties (i.e. Contracting Entity or Manufacturer). The roles and responsibilities of the involved parties are defined in the Guide to the implementation of directives based on the New Approach and the Global Approach (for more information, see www.newapproach.org).

Experience has shown that to have an efficient and cost-effective certification process, it is very important that the author(s) of the conformity verification documentation (i.e. the Applicants) and the NoBo agree about some basic principles concerning the contents, traceability and quality of the documentation to be used by the NoBo as conformity verification evidence in the certification process.

As an aid to achieve this we present SINTEF's approach, including our expectations to the Applicant. The method applies to both constituents and subsystems, and to all the different modules presented in the TSIs. The method is based on the production of three documents (or document collections, but herein referred to as separately defined documents), i.e. the:

- Applicant Certification Plan (in accordance with this report),
- Conformity Verification Specification (CVS), and
- Conformity Verification Report (CVR),

all normally produced by the Applicant and used by both the Applicant and NoBo in the certification work to be performed.

In addition to this the Applicant has to lodge the Application(s) for the disposal of the NoBo. The required content of the Application is defined by the applied module(s).

Conformity Verification Specification (CVS). The CVS shall show in detail how compliance of the constituent/assembly to the TSIs (high-speed and conventional rail) is to be demonstrated and identifying all applicable requirements. This applies to all essential requirements including all relevant technical specifications as given by the TSI and the referenced specifications.

Conformity Verification Report (CVR). The CVR shall contain evidence showing that all the requirements as identified by the Conformity Verification Specification have been met. There will therefore be a one-to-one correspondence between the CVS and the CVR. These reports are to be presented to SINTEF for scrutiny. The CVR will be SINTEF's main basis for certification of the constituent/assembly.

2.7 Resources

The certification plan should define the type and amount of resources needed for e.g.

- Materials
- Human resources for e.g. the
  - Different phases
  - Locations
  - Tasks
- Tools
- Work environment
- Test locomotives
- etc.

2.8 Design and development

This should be complementary to the "quality plan" [35] and e.g. the "design and development plan" according to chapter 7.3 in ISO 9001 [34].

For developing the SRS, see IEEE Std. 1233-1998 [32].

If using SCRUM, the paper [51] should be adhered to.

2.9 Purchasing/acquisition

The certification plan may include topics as:

- Already certified ICs or GoICs
- Relevant certification aspects
- Limits in certificates
- Limits in certificate reports
- Limits in Safety cases and SAR
- Limits in Type examination certificates etc.
- How to verify the limits
- How to verify conformity to specified requirements
- COTS HW, SW (part of pre-existing software) and products
- Pre-existing software including open source software

For further information related to acquirers and software, see "Process for acquirers" [37].

2.10 Audits

The audit plan should be planned together with quality (e.g. ISO 9001 and IRIS, see www.iris-rail.org/), safety and Certification audits. In addition the audits performed by other involved parties as e.g. the ISA and NoBo should be planned together with the involved parties.

Note:

Current CENELEC EN 5012X standards:
No audits have to be performed by the assessor if it is not included in the Safety Plan or similar document issued by Applicant/manufacturer. It can be decided as part of the project whether the required audits are performed internally or by an ISA.

EN 50128: draft 2011:
Audits as appropriate shall be performed by the assessor. Additional audits may be required by the Safety Plan issued by Applicant/manufacturer.

2.11 Documents to be delivered by the manufacturer, ISA, NoBo and NSA

In the figure 1 below the main documents to be delivered by the manufacturer (the SC's), ISA (the SAR's), NoBo (the QMSA and Certificate of Conformity (depending on the module used)) and NSA are shown for a typical trackside ERTMS L2 system.

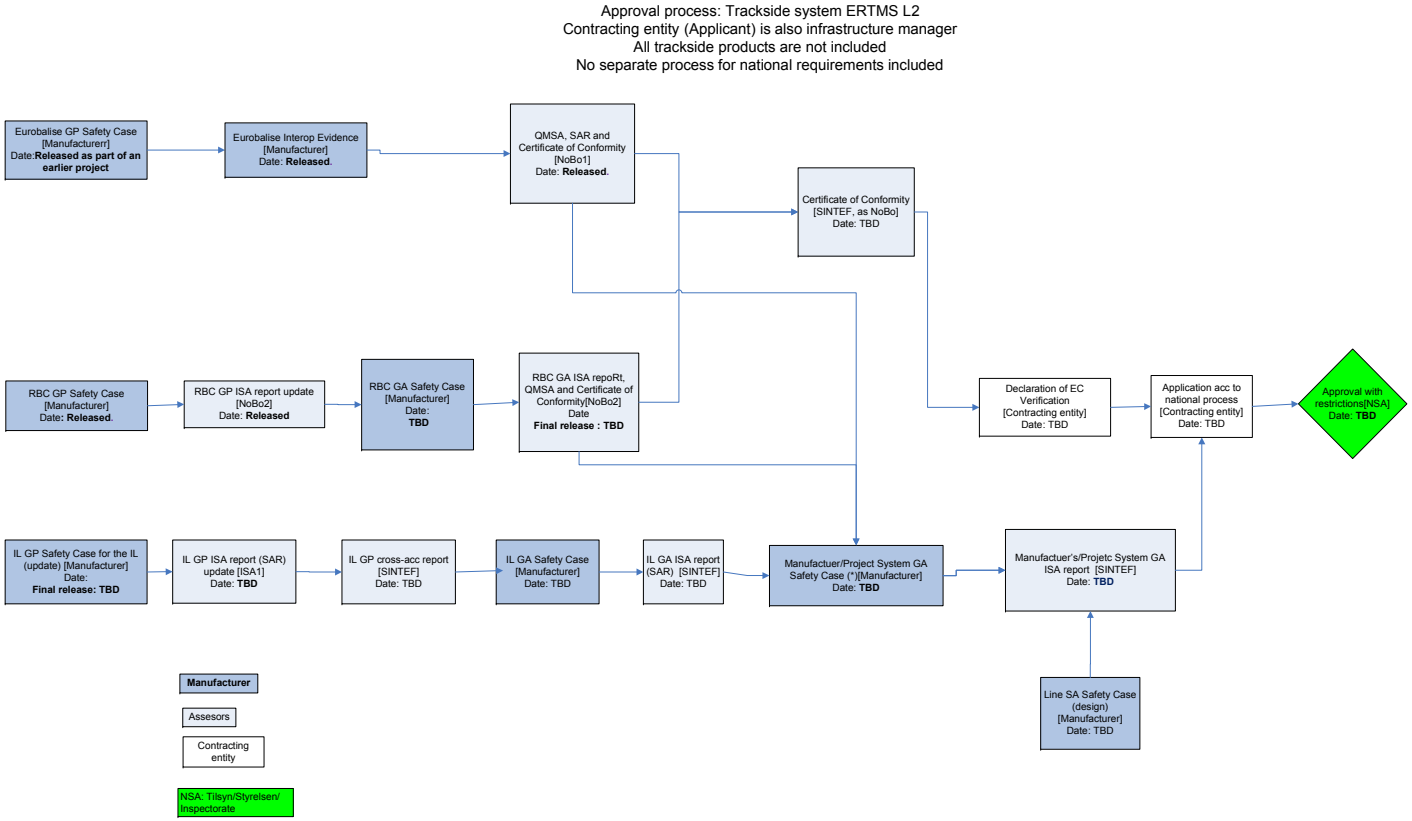

Figure 1: Flow chart

3 Review and acceptance of the certification plan

The certification plan should be reviewed for completeness, correctness and effectiveness.

The plan should formally be approved by the Contracting Entity/manufacturer and the NoBo (system level). If the NoBo is different from the ISA also the ISA should approve the plan.

It is important that in total the persons involved in the review and acceptance process represent relevant functions, knowledge and experience.

In contractual situations a certification plan may need to be submitted to the customer by the manufacturer for review and acceptance.

The plan should be reviewed at well defined stages during the project.

4 Implementation of the certification plan

In the implementation of the certification plan the involved organisations should give consideration to the following issues:

- Distribution
- Training
- Monitoring conformity

5 Revision of the certification plan

The certification plan should be revised at appropriate times to reflect changes to the plans.

- Input
- Agreed improvements
- Changed schedule

6 References

6.1 Directives, regulations, commission decisions, standards and Guidelines

1. Directive 96/48/EC (HS Interoperability)
2. Directive 2001/16/EC (CR Interoperability)
3. Commission decision 2002/731/EC TSI for HS system
4. Directive 2004/49/EC (safety)
5. Directive 2004/108/EC (EMC)
6. Guide for the EMC Directive 2004/108/EC. 8th February 2010. The Guide can be downloaded at www.ec.europa.eu/.../files/emc_guide__updated_20100208_v3_en.pdf
7. Directive 2004/50/EC (amendments of 96/48/EC and 2001/16/EC)
8. Directive 2006/95/EC (LVD)
9. Commission decision 2006/679/EC TSI for CR system
10. Commission decision 2006/860/EC modifying Annex A to decision 2006/679/EC
11. Directive 2007/32/EC amending Annex VI to 96/48/EC and 2001/16/EC
12. Commission decision 2007/153/EC Modifying Annex A to Decision 2006/679/EC concerning the technical specification for interoperability relating to the control-command and signalling subsystem of the trans-European conventional rail system and Annex A to Decision 2006/860/EC concerning the technical specification for interoperability relating to the control-command and signalling subsystem of the trans-European high speed rail system
13. Directive 2008/57/EC Interoperability
14. Directive 2008/110EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 amending Directive 2004/49/EC on safety on the Community's railways (Railway Safety Directive)
15. Commission decision 2008/386/EC modifying Annex A to decision 2006/679/EC and Annex A to Decision 2006/860/EC
16. Decision 768/2008 on a common framework for the marketing of products
17. Directive 2009/131/EC of 16 October 2009 amending Annex VII to Directive 2008/57/EC of the European Parliament and of the Council on the interoperability of the rail system within the Community
18. Commission regulation 352/2009 on the adoption of ac common safety method on risk evaluation and assessment as referred to in Article 6(3) of Directive 2004/49/EC of the European Parliament and of the Council
19. Commission decision 2010/79/EC amending Decisions 2006/679/EC and 2006/860EC as regards TSI for CR and HS
20. Commission decision 2010/713/EU of 9 November 2010 on modules for the procedures for assessment of conformity, suitability for use and EC verification to be used in the technical specifications for interoperability adopted under Directive 2008/57/EC of the European Parliament and of the Council
21. Commission Directive 2011/18/EU of 1 March 2011 amending Annexes II, V and VI to Directive 2008/57/EC of the European Parliament and of the Council on the interoperability of the rail system within the Community
22. Commission decision 2011/155/EU on the publication and management of the reference document referred to in Article 27(4) of Directive 2008/57/EC

23. CLC TR 50506-1: 2007 Railway applications - Communication, signalling and processing systems - Application Guide for EN 50129 - Part 1: Cross-acceptance
24. CLC TR 50506-2:2009 Railway applications - Communication, signalling and processing systems - Application Guide for EN 50129 - Part 2: Safety assurance
25. EN 50126-1: 1999 Railway applications – The specification and demonstration of Reliability, Availability, Maintainability and Safety (RAMS)
26. EN 50128:2001 Railway applications – Software for railway control and protections systems
27. EN 50128: draft 2011 Railway applications – Software for railway control and protections systems
28. EN 50129:2003 Railway applications – Hardware for railway control and protection systems
29. EN 50159-1:2001Railway applications – Communication, signalling and processing systems – Part 1: Safety-related communication in closed transmission systems (IEC 62280-1 is based on this standard)
30. EN 50159-2:2001 Railway applications – Communication, signalling and processing systems – Part 2: Safety Related Communication in Open Transmission Systems (IEC 62280-2 is based on this standard)
31. EN 50159: 2010: Railway applications - Communication, signalling and processing systems - Safety-related communication in transmission systems
32. IEEE Std 1233-1998 Guide for developing system requirements specifications
33. ISO 9000:2005 Quality management systems - Fundamentals and vocabulary
34. ISO 9001: 2008 Quality management systems - Requirements
35. ISO 10005:2005 Quality management systems – Guidelines for quality plans. Second edition.
36. ISO 10006: 2003 Quality management systems – Guidelines for quality management in projects
37. ISO/IEC 14598-4: 1999 Software engineering – Product evaluation – Part 4: Process for acquirers
38. ISO/IEC 17050-1 ed1.0 (2004-09) Conformity assessment -- Supplier's declaration of conformity - Part 1: General requirements
39. ISO/IEC 17050-2 ed1.0 (2004-09) Conformity assessment -- Supplier's declaration of conformity - Part 2: Supporting documentation
40. ERA Newsletter Issue 21, Nov 2010
41. ERTMS deployment outside Europe. The fact sheet can be downloaded at www.ertms.com
42. ERA: Report on railway vehicle authorisation. Part 1 – The current situation. ERA/REP/2011-01/XAC. Version 1.9.5. 14th April 2011
43. ERA: Guide for the application of Technical Specifications for Interoperability (TSIs). According to Framework Mandate C(2007)3371 final of 13/07/2007. ER/GUI//07-2011/INT. Version 1.0. 19 April 2011.
44. ERA: Guide for the application of Technical Specifications for Interoperability (TSIs). Annex 1 To be published
45. ERA: Guide for the application of Technical Specifications for Interoperability (TSIs). Annex 2 – Conformity assessment and EC verification. Version 1.0, 18 April 2011
46. ERA: Guide for the application of Technical Specifications for Interoperability (TSIs). Annex 3 – The European framework. Version 1.0, 18 April 2011
47. ERA: Guide for the application of Technical Specifications for Interoperability (TSIs). Annex 4 – Examples of application of TSIs at different stages, version 1.0, 18 April 2011
48. SINTEF Memo 90513021-NOT-2009-02: Guideline for: Applicant Certification Plan (ACP), Conformity Verification Specification (CVS), Conformity Verification Report (CVR). Edition 2.0, 2010-05-31

49. SINTEF Memo 90513021-NOT-2010-02: Guideline for applications for the modules H2 and SH2. 2010-09-27
50. SINTEF Memo 90513021-NOT-2011-05: Guidelines for safety documentation. 2011-02-03
51. T. Stålhane, T. Myklebust and Geir K. Hanssen. The application of Scrum to IEC 61508 certifiable software. To be presented at ETFA 2011

6.2 NB-Rail documents related to CCS

NB-Rail RFU (with an effect on CCS) documents (published on the NB-Rail web 19th of May 2011)
52. RFU 0-000-01 Content of issued certificates
53. RFU 0-000-04 Certify compliance with other Directives
54. RFU-PLG-013 Conformity to other regulations
55. WKD-STR-004 Directive listing – Annex to RFU-PLG-013
56. RFU 0-000-10 Certificate expiry dates
57. RFU-STR-011 Content of Technical File
58. RFU 0-000-14 Verification evidence from others
59. RFU 2-000-16, Cross Acceptance of Safety Case Assessments
60. RFU 5-000-19 Maintenance file
61. RFU 2-400-23 Use of SH2 modules for CCS subsystem
62. RFU-STR-024 Common certificates
63. RFU-STR-022 Use of Test Results from testing bodies other than Notified Bodies Issue 03, date 10/02/2010
64. RFU-CCS-030 The Use of Computer Tools for Conformity Verification
65. RFU-CCS-040 IC RBC Certification
66. RFU-STR-036 QM System of Manufacturer or Applicant
67. RFU-STR-041 Use of IC certified using an earlier version of the TSI
68. RFU-STR-044 Derogations, open points, reserved points and specific cases
69. RFU-STR-045 Applicable European Specifications
70. RFU-STR-046 IC HW-SW modifications

Annex A: Internet references

Relevant sources for references are listed in the table below:

Source/internet address	Documents	Comments
European commission www.ec.europe.eu	Harmonised standards http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/index_en.htm	These lists for the different directives are not always up to date.
European Union legislation http://eur-lex.europa.eu/	Official Journal	
New Approach Standardisation in the Internal Market www.newapproach.org/	Directives and standards The site includes links for directives to standard activities and harmonised standards	Copy from the website 4th of September 2010: "*This Web site has been realised to increase the visibility of New Approach Standardisation in Europe and to provide information on the standardisation process. This site provides access to information on standards and routes into the standardisation process, irrespective of which of the three European Standards Organisations is responsible for the standards applicable to the products*".

Source/internet address	Documents	Comments
Official Journal of the European Union http://eur-lex.europa.eu/JOIndex.do	The L series contains EU legislation, including • regulations • directives • decisions • recommendations • opinions In addition, the *Directory of Community legislation in force* is published as part of the OJ L series. This directory lists references to the initial texts and to any subsequent amendments. It also includes references to agreements made and conventions signed by the European Union in the framework of external relations, binding acts under the EU Treaties, complementary acts, such as those of the Council of Ministers and Heads of State or Government, and other non-binding acts which are relevant for the institutions.	Copy from the website 4th of September 2010: *The authoritative source of EU law* *The Official Journal of the European Union (OJ) is the only periodical published every working day in all official languages of the European Union (EU).* *It consists of two related series (L for legislation and C for information and notices) and a supplement (S for public procurement). There is also an electronic section to the C series, known as the OJ C E. Documents published in the OJ C E are only published electronically.*
European Railway Agency www.era.europe.eu	Link and comments to TSIs Subsets that are listed in Annex A, including future subsets. Guidelines	

Source/internet address	Documents	Comments
NB-Rail http://circa.europa.eu/irc/nbg/nbrail/info/data/en/information/nbrail/00nb%20rail%20homepage.htm	RFU Q&C	NB-RAIL provides a forum for: • *Sharing experiences and exchanging views on the conformity assessment procedures* • *Drafting and issuing technical recommendations* • *Ensuring consistency with European standardisation work;* • *Drawing up reports on technical aspects of the assessment procedures;* • *Discussing Commission documents and other information relevant to Railway Interoperability;* • *Discussing questions and problems that arise from the practical application of the Interoperability Directives.*
Committee for Electrotechnical Standardization www.cenelec.org	EN standards	
The European Telecommunications Standards Institute www.etsi.org	ETSI standards	
International Organization for Standardization www.iso.org	ISO standards	