SINTEF

SINTEF ICT

Address: NO-7465 Trondheim
Norway
Location: S.P. Andersens v 15B
Telephone: +47 - 73 59 30 00
Telefax: +47 - 73 59 43 02

Enterprise number: NO 948 007 029 MVA

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MEMO CONCERNS

Guide for the CoVeR method that ensures that all regulatory requirements are met

FOR YOUR ATTENTION	COMMENTS ARE INVITED	FOR YOUR INFORMATION	AS AGREED

DISTRIBUTION

Customers of SINTEF that are going to work out CVS and CVR in rail certification processes related to conformity verification according to the EU Technical Specifications of Interoperability	x			

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1 Introduction

1.1 Background, Objective and Scope

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 the Manufacturer, commonly denoted in this document as Applicant [1]). The roles and responsibilities of the involved parties are described in the ERA Guide [14] and in the New Approach and the Global Approach [2].

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. issued by the Applicant) and the NoBo agree about some basic principles concerning the contents, detailing level, traceability and quality of the documentation to be used by the NoBo in the certification process.

As an aid to achieve this we present SINTEF's method to this including our expectations to the Applicant. The method applies to constituents and subsystems, and to all the different modules presented in the relevant TSIs and the modules presented in the Commission decision [15]. TSIs adopted before 2010 include a description of conformity assessment modules in each TSI. TSIs adopted in 2010 refer to this Commission decision [15] on conformity assessment modules.

The CoVeR method (Conformity Verification Report) is based on the production of three documents (or document collections, but herein referred to as separately defined documents), i.e.:

- Applicant Certification Plan (ACP), this is described in *Guideline for a Certification plan* [12],
- Conformity Verification Specification (CVS), see chapter 2.1 below and
- Conformity Verification Report (CVR), see chapter 2.2 below

all to be produced by the Applicant (and the manufacturer if different from the Applicant) and used by both the Applicant and NoBo in the certification work.

In addition to this the Applicant has to lodge the Application for Certification by the NoBo. The required content of the Application is defined by the applied module(s) in e.g. Annex E for CCS in the TSIs [5] and [6]. See also the SINTEF application Guideline for the H2 and SH2 modules [11] and the Commission decision [15].

1.2 Version description

Issue	Date	Description
4.0	2012-	• General improvements • Deleted ACP information as reference to the to the Memo for Certification Plan is sufficient • New chapter: Reuse included • Included more information related to Commission decisions, Commission Regulation and Commission directives

1.3 Terms

Terms	Description
ACP	Applicant Certification Plan
Applicant	Common term for Manufacturer, Contracting Entity, Authorised representative used in this document, in the directives and the TSIs. For definition see [1] and [14]
CR	Conventional Rail
CCS	Control-Command Subsystem
CoVeR	Conformity Verification Specification
CVS	Conformity Verification Specification
CVR	Conformity Verification Report
HS	High Speed
IC	Interoperability Constituent
NoBo	Notified Body
TSI	Technical Specification for Interoperability
WKD	Working Document (as used by NB-Rail)

2 The content and use of ACP, CVS and CVR

The Applicant Certification Plan (ACP), the Conformity Verification Specification (CVS) and the Conformity Verification Report (CVR) are related in the way that CVS and CVR become deliverables in the ACP describing the Applicant and NoBo certification process.

As seen from a NoBo point of view only the CVR is mandatory documentation to be provided by the Applicant. It is however strongly recommended to develop both an ACP and a CVS as this will improve the possibility for the NoBo to work proactively with respect to obtaining an effective certification process with high quality results, and to reduce the project risk that the NoBo in a later phase of the project will identify not or unsatisfactorily covered requirements as a result of the conformity verification.

The CVS and CVR can be developed using tools as e.g. excel, word and DOORS.

A more detailed description concerning the objective, content and use of ACP, CVS and CVR is included in the following subsections.

The following table identifies some issues to be considered when planning a certification:

Issue	*Comments*
Applied Directives, Commission decisions, Commission directives and Commission regulations	The directive of relevance for the type of certification that are concerned by this document are: - 2008/57/EC [1] (replaced the directives [3] and [4]) including amendment [13], [16], [17], [18], [19] and [20]: Mostly requirements in the directives will be covered by the corresponding directive implementation defined in the TSIs, however there may be situations where the TSIs refer to the directives for supplementary or complementary information. Note: Also other relevant directives have to be fulfilled, see e.g. RFU-PLG-013 [9] and WKD [8]. The most relevant directive is the EMC (ElectroMagnetic Compatibility) directive [21]. The EU commission has issued a helpful Guide for the EMC directive [22].
Applied TSIs for CCS (as an example) and Commission decisions	The TSIs, including amendments, of relevance for the type of certification that are addressed by this document are: - 2006/679/EC of 28 March 2006 concerning the technical specification for interoperability relating to the **control-command and signalling subsystem** of the trans-European **conventional rail** system [6]; - 2006/860/EC of November 2006 concerning a technical specification for interoperability relating to the **control-command and signalling** subsystem of the trans-European **high speed rail** system and 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 [5]; - 2010/79/EC [10] Commission decision 2010/79/EC amending Decisions 2006/679/EC and 2006/860EC as regards TSI for CR and HS These define the technical interoperability requirements to be satisfied for conventional and high speed rail systems. It is planned to issue a revised version of the CCS TSI in 2012.
Applied Modules (Annex E) or 2010/713/EC [15]	TSI modules specified in Annex E in the current TSIs define activities and documentation relevant for the certification process. Depending on type of application (e.g. constituent or subsystem) and type of certification (e.g. type examination, production quality management system) the Applicant has to decide about which module(s) to apply. The description of the selected module(s) and chapter 6 in the TSI should serve as a main basis for the definition of the Applicant Certification Plan to be produced. See also SINTEF Guideline for application [11].

Issue	*Comments*
Lodge of application(s) and the corresponding Application	Most of the modules require the application to be issued from the Applicant to the NoBo, where the Application(s) will describe the scope of certification process and provide the documentation needed by the NoBo to carry out the certification work. The TSI defines, depending on which module(s) shall be applied what at least shall be covered in the Application documentation. This documentation should be applied by the Applicant and the NoBo to specifically identify which parts of the TSIs (i.e. TSI requirements) are relevant for the certification [11].
NB-Rail relevant issues	NB Rail (http://circa.europa.eu/irc/nbg/nbrail/info/data/en/information/nbrail/00nb%20rail%20homepage.htm) supports the rail related directives and TSIs by providing recommendation for interpretation, clarification and use, but without representing absolute requirements. The NB-Rail main and most formal means are the Recommendations for Use (RFUs), and in addition the Questions & Clarification (QoC) and the Frequently asked Questions (FAQ).

2.1 Conformity Verification Specification (CVS)

The objective is to describe in detail how compliance to the applicable Directive(s) and corresponding TSI(s) shall be demonstrated, identifying all applicable requirements and which evidence for compliance that will be presented. This applies to the essential requirements in the railway directives as well as all relevant technical specifications for interoperability as given by the TSIs including the referenced specifications/subsets. The applied module(s) require constituents to satisfy the requirements of the HS/CR TSI, while subsystems shall comply with the HS/CR TSI and "comply with the other regulations deriving from the Treaty" as specified in the TSI. NB-rail issues a Working Document (WKD) [8] three times a year that present an overview of relevant regulations.

The CVS should be used by the Applicant as a basis for producing the CVR. There should be a one to one mapping between the two where the CVS specifies **how** compliance for all relevant TSI requirements shall be demonstrated and the CVR which gives **the references to the corresponding evidence**. The NoBo can then at an early phase in the project review and comment on the CVS to ensure that all relevant requirements are covered and that the planned evidence for requirement fulfilment is deemed satisfactory. This is a prerequisite for proactive NoBo work.

The following table identifies some issues to be considered when writing a CVS for CCS:

Issue	***Comments***
Lodge of application(s) and the corresponding Application	The lodge of application(s) and the corresponding Application define the scope of certification as a prerequisite for writing a CVS. This because it will identify which (parts of) directives and TSIs that has relevance in the certification work, implicitly identifying interoperability requirements that should be satisfied. A separate SINTEF "guide for lodging application(s)" exists [11]
Applied directives and TSIs	These form the main basis for the identification of each and every individual requirement whose fulfilment shall be verified during the certification work. TSIs represent the main basis for the requirements. Directives are addressed from the TSIs where that is of relevance and where they may represent additional or supplementary requirements. Unless implicitly or explicitly excluded (e.g. not applied modules and constituents/subsystems according to the definition of the Application) all parts of a TSI should be considered to contain relevant requirements. Where both the High speed and the Conventional rail TSIs are applicable it has been said that High speed TSI is the last issued TSI. Both TSIs refer to the same specifications, i.e. Annex A, currently defined in[10], implying that the differences between CR and HS rail are defined through the TSIs – not the technical specifications. ERA has issued a Guide related to the application of the TSIs [14]. Note: Also other relevant directives, than the railway directives, have to be fulfilled, see e.g. WKD [8]
TSI chapter 1	No requirements
TSI chapter 2	Concern: Class A/B; Application Level; Infrastructure Network Borders
TSI chapter 3	Concern: Essential requirements (Safety, R&A, Health, Environmental protection, Technical Compatibility)
TSI chapter 4	Identifies the technical requirements covering the CCS subsystem as a whole

Issue	*Comments*
TSI chapter 5	Identifies the set of constituents and subsystems, maps constituents to subsystem, apportions the requirements in chapter 4 to each constituent/subsystem and relates constituents to relevant modules for certification.
TSI chapter 6	Requirements to the assessment process
TSI chapter 7	Strategy and associated technical solutions for the implementation of the TSI
TSI Annex A	List of mandatory and informative specifications (Subset-xxx), which are common to both the HS and the CR TSIs, and the list of mandatory standards. The list of applicable subsets must be specified, and for each subset the identification of each applicable requirement. The set of applicable subsets includes all subsets specified to be mandatory for the constituent to be certified, and in addition the set of optional subsets that are applied. Applicable requirements include mandatory requirements in applied subsets and in addition applied optional requirements. For subsystems the subsets are considered as implicit through the included set of constituents the subsystem consists of.
TSI Annex nn. This is only correct for the current TSIs [5] and [6]	Annex B: Relevant if Class B Signalling Systems are applied Annex C: Line specific characteristics Annex D and E: Definition of modules for certification of constituents and subsystems. Annex F: Conformity assessment procedure Annex G: Open points Annex H: Synthesis of ETCS-net corridors
Related TSIs	This is relevant for the subsystems, where relevant TSIs are identified in tables 6.1 and 6.2 in the TSIs.

2.2 Conformity Verification Report (CVR)

The objective is to provide evidence showing fulfilment of all requirements as identified by the CVS. There should therefore be a one-to-one correspondence between the CVS and the CVR, where the CVS shows how compliance to the requirements will be demonstrated while CVR contains the actual evidence.

CVR will be the main and mandatory document to be used in the conformity assessment as a basis for the certification. The document constitutes the final and complete evidence with respect to which requirements have/have not been verified. Evidence for every applicable requirement in the TSI and other relevant requirements as stated in CVS have to be presented in the CVR.

A CVR may be a CVS with an additional column presenting the evidence and/or referring to the evidence.

The NoBo will check the CVR and all the referenced documents.

2.3 Reuse

All the documents mentioned (Certification Plan, Application, CVS and CVR) can be reused for similar projects.

When reusing the documents the change in regulation has to be evaluated.

3 References

Ref.	*Title, version, date*	*Comments*
[1].	Directive 2008/57/EC, 2008-06-17	This is a recast of the directives 96/48/EC, 2001/16/EC and 2004/50/EC.
[2].	Guide to the implementation of directives based on the New Approach and the Global Approach, NA, 2000	ISBN 92-828-7500-8 (http://ec.europa.eu/enterprise/newapproach/legislation/guide/document/1999_1282_en.pdf)
[3].	96/48/EC of 23 July 1996 on the Interoperability of the trans-European high-speed rail system, NA, 1996-07-23	The High Speed Rail interoperability directive that has been replaced by 2008/57/EC
[4].	2001/16/EC of 19 March 2001 on the interoperability of the trans-European conventional rail system, NA, 2001-03-19	The Conventional Rail interoperability directive that has been replaced by 2008/57/EC
[5].	2006/860/EC of 7 November 2006 concerning a technical specification for interoperability relating to the control-command and signalling subsystem of the trans-European high speed rail system and 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, NA, 2006-11-07	The High Speed Rail interoperability TSI for CCS
[6].	2006/679/EC of 28 March 2006 concerning the technical specification for interoperability relating to the control-command and signalling subsystem of the trans-European conventional rail system, NA, 2006-03-28	The Conventional Rail interoperability TSI for CCS

Ref.	*Title, version, date*	*Comments*
[7].	2008/386/EC of 23 April 2008 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, NA, 2008-04-23	The identification of Subsets, the specifications for CCS, replaced by [10]
[8].	NB-Rail: WKD-STR-004, Listing of directives	The document can be downloaded at http://circa.europa.eu/irc/nbg/nbrail/info/data/en/information/nbrail/RFU.htm
[9].	RFU-PLG-013, Issue 05, 20/07/2010: Obligation to "Check conformity" to "other regulations arising from the Treaty"	The document can be downloaded at http://circa.europa.eu/irc/nbg/nbrail/info/data/en/information/nbrail/RFU.htm
[10].	Commission decision 2010/79/EC amending Decisions 2006/679/EC and 2006/860EC as regards TSI for CR and HS	
[11].	SINTEF 90513021-NOT-2010-02: Guideline for Lodging of application(s), edition 1.0	
[12].	SINTEF 90513021-NOT-2011-09: Guideline for a Certification plan, edition 1.0	
[13].	Commission 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	
[14].	ERA/GUI/07-2011/INT. Guide for the application of Technical Specifications for Interoperability (TSIs), version 1.01	The Guide can be downloaded at www.era.europa.eu/Core-Activities/Interoperability/Pages/TSI-Application-Guide.aspx
[15].	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	TSIs adopted before 2010 include a description of conformity assessment modules in each TSI. TSIs adopted in 2010 refer to this Commission decision on conformity assessment modules, and thus do not contain the description of modules themselves.

Ref.	*Title, version, date*	*Comments*
[16].	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	
[17].	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	
[18].	Commission regulation 201/2011 of 1 March 2011 on the model of declaration of conformity to an authorised type of railway vehicle	
[19].	Commission recommendation 2011/217/EU of 29 March 2011 on the authorisation for the placing in service of structural subsystems and vehicles under Directive 2008/57/EC of the European Parliament and of the Council	
[20].	Commission implementing decision 2011/633/EU on the common specifications of the register of railway infrastructure	
[21].	Directive 2004/108/EC (EMC)	
[22].	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