



Function of ISV in the certification process

Experiences from our work as notified body



Content

- Legal background
- ISV – when to be used (and when not)
- Combination of different module types
- Summary



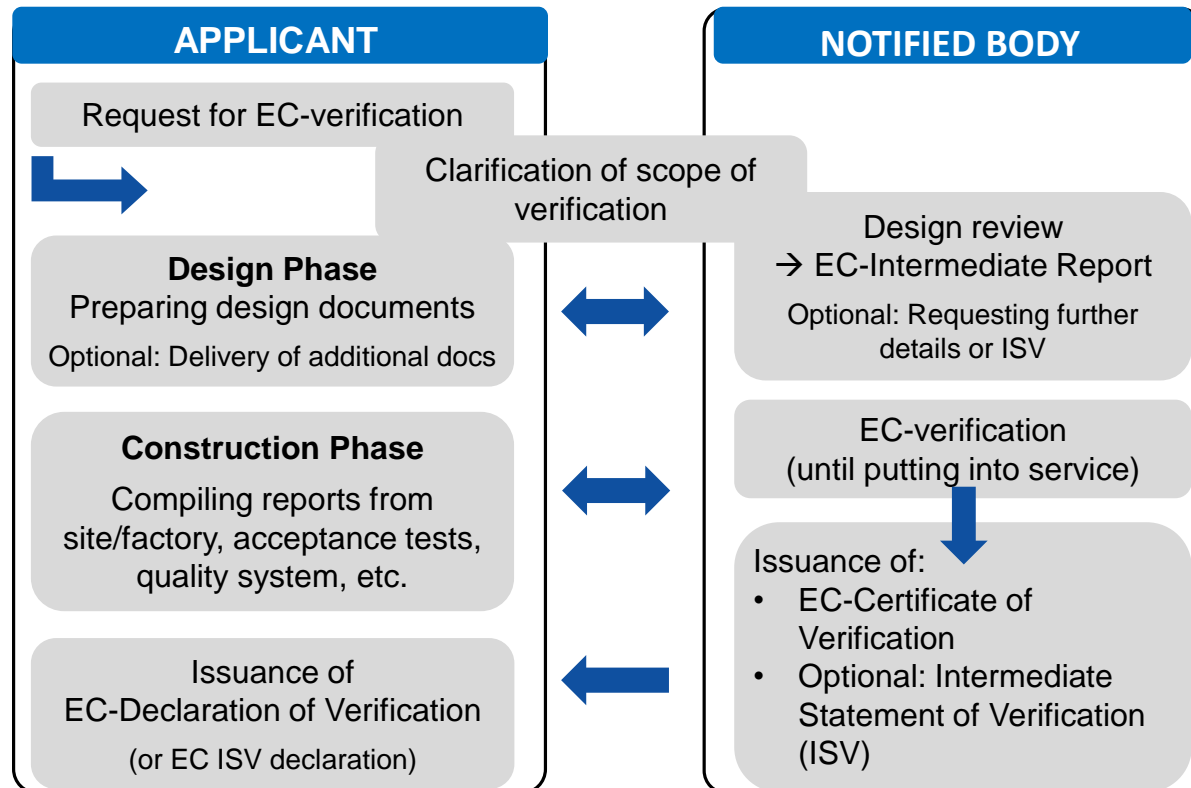
Legal background

- Notified body performs the EC Verification procedure
- Result: EC Certificate of Verification + NoBo-File

- Applicant prepares the EC Declaration of Verification + Technical File accompanying the EC Decl. of Ver.
- This Technical File includes:
 - NoBo-File
 - DeBo-File
 - AsBo report
 - Information for registers (RINF, ERATV, ...)
 - Other information required from IOD 08/57 resp. 2016/797
 - Certificates related to other legislation derived from the Treaty
 - ...



EC verification process simplified for module SG





ISV explanation

- ISV = Intermediate Statement of Verification
 - Issued by the notified body
- Directive (EU) 2016/797
 - Article 15 (6): „*The notified body may issue intermediate statement verifications to cover **certain stages** of the verification procedure or **certain parts** of the subsystem.*”
 - Annex IV: chapter 2.2 gives detailed explanations
 - The applicant may apply for an ISV for any part into which he decides to split the subsystem.

➔ This allows for a great flexibility during the process
Many different kinds of ISV are possible

- Same definitions are given in Directive 2008/57/EC
 - Article 18 (4) and Annex VI are (nearly) identical to new IOD



Legal background

- RFU-STR-001 Content of EC Certificates
 - Definition of certificate types
 - Type numbers for ISV 8.x
 - Clear labelling which kind of ISV

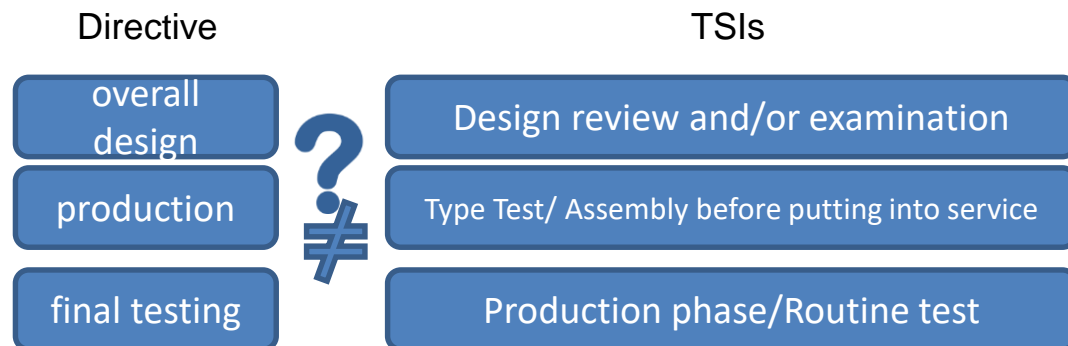
No.	Exact English title
8.1	Intermediate Statement of Verification – EC Type Examination
8.2	Intermediate Statement of Verification – EC Design Examination
8.4	Intermediate Statement of Verification – Quality Management System Approval
8.6	Intermediate Statement of Verification

- **Type 8.6 requires the corresponding NoBo-file**



ISV explanation

- Applicant may:
 - The applicant may request an ISV for design stage (including type assessments) and production stage for the whole or certain parts of the subsystem.
 - Stages of the verification procedure:





Legal background

- Responsibility of the notified body
- Subsystem assessment includes:
 - verifies that the ISV correctly covers the relevant TSI(s) requirements,
 - checks all aspects that are not covered by the ISV,
 - Particularly interfaces to the subsystem
 - checks the completeness of the subsystem as a whole.
- ISVs of other notified bodies **shall** be recognized
- Finally all parts and stages shall be assessed



Legal background

- When will an ISV be issued?
 - ISVs are only allowed for subsystems
 - If only parts of a subsystem were (positively) assessed
 - Single phases of a subsystem were assessed
 - If only parts were assessed for single phases
- Exemption: TSI CCS (EU) 2016/919:
 - Chapter 6.4.1 defines certain parts of the subsystem for which EC-verifications can be issued
 - Train protection, voice/data radio communication, train detection
 - Chapter 6.4.3.2 Subsystems: allows not to implement all functions, performance and interfaces (e.g. due to an IC) and issue an EC certificate of verification => but subsystem shall still be interoperable – see RFU-CCS-077
- In these cases an EC Certificate of Verification is issued



Legal background

- When will no ISV be issued?
 - in case of a derogation acc. to art. 9 of 2008/57 or Non-application of TSI acc. to art. 7 of 2016/797
 - in case of partial application of TSI due to renewal or upgrade acc. to art. 20 of 2008/57/EC or art. 16 of 2016/797 or based on basic design characteristics as defined in new TSIs (vehicles)
 - in case of partial application due to transitional periods in a TSI (e.g. existing parts)
 - in case a specific case applies
 - For Interoperability Constituents (ICs) ISVs are not allowed!



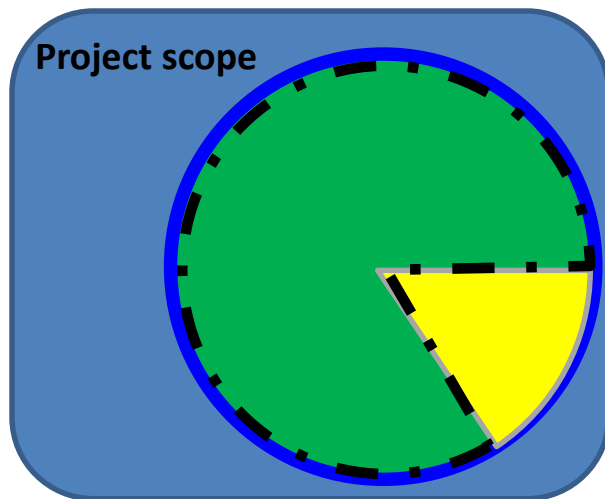
In these cases: EC certificate of verification can be issued

- Reminder: EC certificate of verifications are issued for a subsystem, not for a TSI



EC Certificate of Verification

Assessment scope = scope of the EC
Certificate of Verification = **work of NoBo**



Technical scope of the EC verification

Areas where TSI does not apply

- NNTR
- Open points in TSI
- Specific cases, without spec. in TSI
- Derogations/Non-applications of TSI granted according to article 9/7

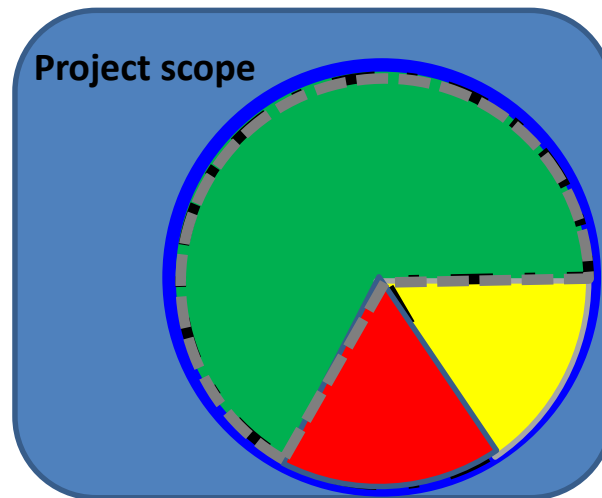
= **work of DeBo, AsBo, ...**

Requirements that are not applicable for this project

e.g. TSI PRM for Infrastructure project without stations or cross wind for vehicle with speed lower 140 km/h

There are no restrictions for a positive EC certificate of verification

Intermediate Statement of Verification ISV



Assessment scope

Technical scope of the EC verification

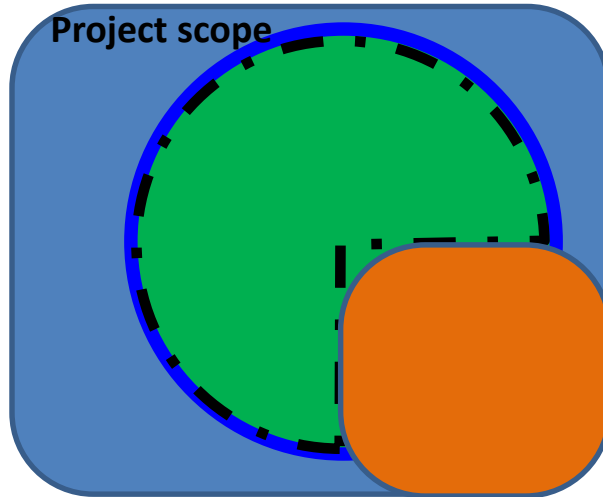
Areas where TSI does not apply
= work of DeBo, AsBo,...

Requirements that are not applicable for this project

Not fulfilled clauses:
Negatively assessed or not yet assessed parts/function or stages/phases

Upgrading or renewal project

Scope of the EC certificate of verification = **work of NoBo**



Technical scope of the EC verification in general

Areas where TSI does not apply

- NNTR
- Open points in TSI
- Specific cases, without spec. in TSI
- Derogations/Non-applications of TSI granted according to article 9/7

= **work of DeBo, AsBo, ...**

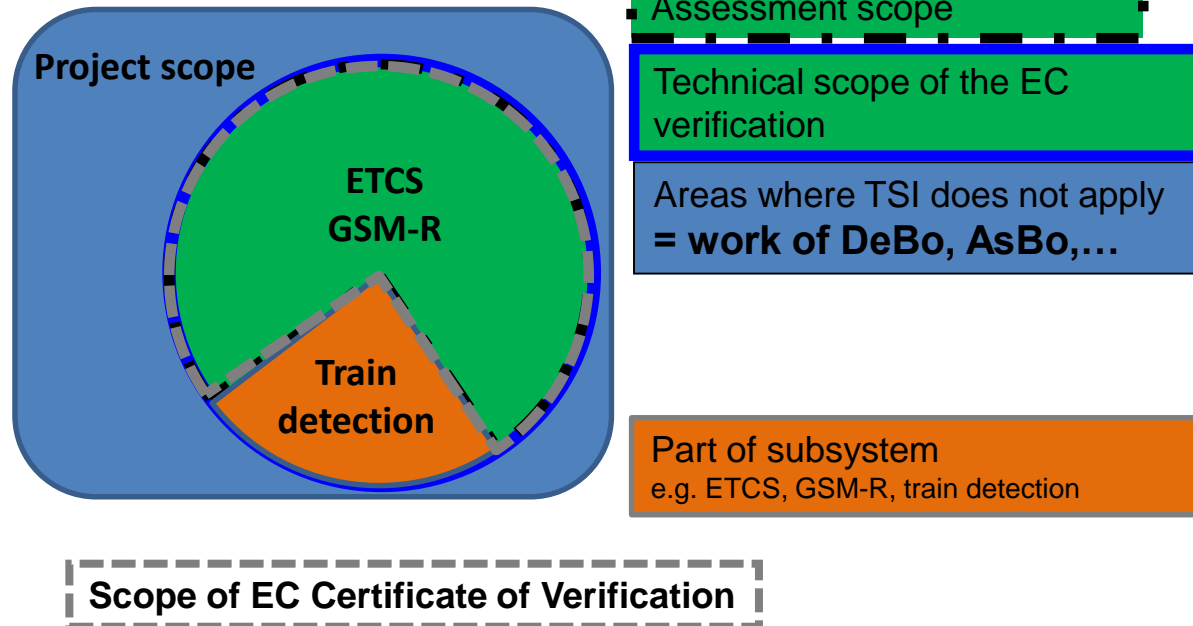
Parts that are not changed =
Not part of assessment by NoBo

- Those parts that remain without modifications and are not affected by modifications
- Fixed installations – Art. 20 MS (08/57), Art. 16 NSA (2016/797)
- Rolling stock – basic design characteristics (in TSI defined)

For upgrading and renewal projects an EC certificate of verification can be issued! (no ISV)

TSI CCS: 6.4.1 parts of subsystem

- Train protection (ETCS)
- Voice/data radio communication (GSM-R)
- Train detection



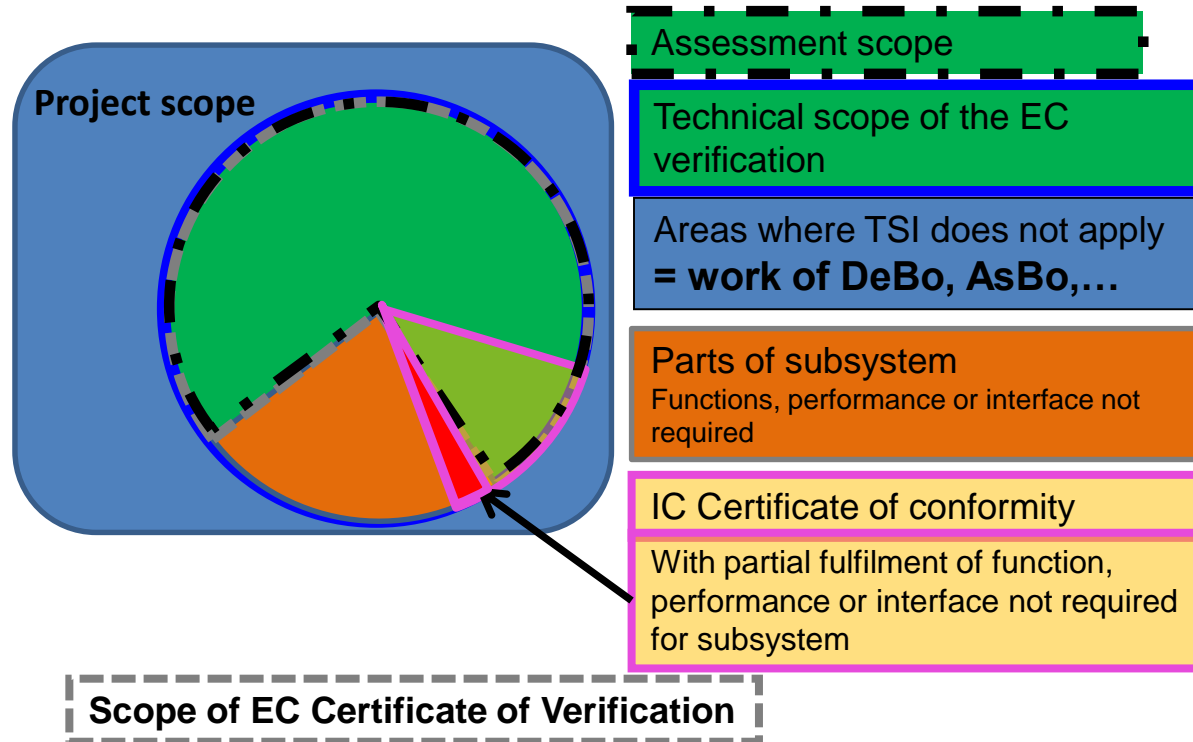


TSI CCS: Partial fulfilment of the requirements

- Chapter 6.4.3.1: Interoperability constituents
- If an IC does not implement all functions and interfaces still an **EC certificate of conformity** may be issued
 - if the unimplemented functions and interfaces are not required to integrate the interoperability constituent into a subsystem
 - e.g. on-board ETCS interface to STM
 - e.g. RBC-RBC interface
- Chapter 6.4.3.2: Subsystem
- If a CCS subsystem does not implement all functions and interfaces of TSI CCS (e.g. because of an IC integrated into it), the **certificate of verification** shall clearly indicate which requirements have been assessed and the conditions of use

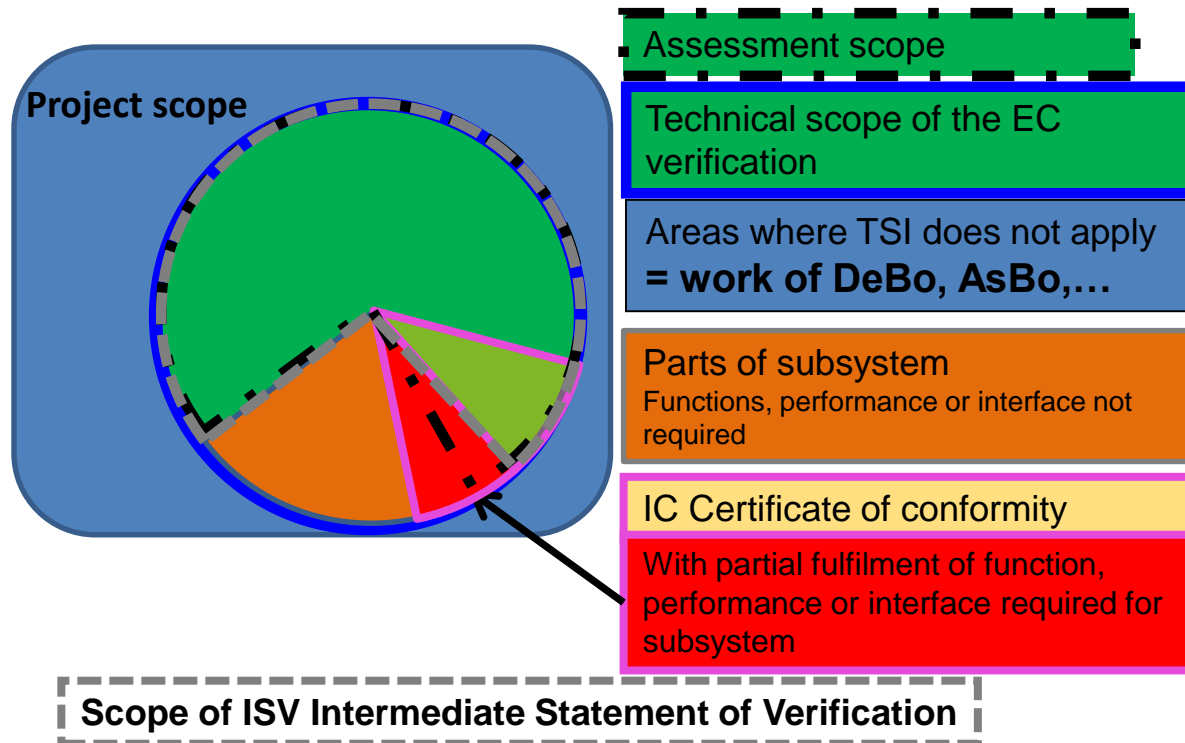
TSI CCS: 6.4.3 Partial fulfilment

- IC with partial fulfilment



TSI CCS: 6.4.3 Partial fulfilment

- IC with partial fulfilment





Important information

- ISVs shall clearly indicate:
 - Which TSIs (version) are used
 - Which stages/phases are positively checked
 - Which parts of the subsystem are positively checked
 - or vice versa:
 - Which parts or stages of the subsystem or TSI do not comply
 - Which clauses of the TSI are positively assessed
 - Which clauses of the TSI do not comply
 - **The interfaces of the ISV to the whole subsystem**
 - Those interfaces that have to be assessed on subsystem level when integrating an ISV into a subsystem
 - The conditions and limits of use



Practical implementation

- ISVs are useful:
 - for extensive projects to subdivide
 - for long-term projects to outline intermediate status
 - to divide to several TSIs and/or different notified bodies
 - to outline single negative assessed items
 - if components are not defined as interoperability constituents but it would be preferred
 - when using different modules for a subsystem with appropriate division
 - for platform certification (vehicles)
- Practical challenges
 - with regards to different defined stages/phases in TSIs
 - With regards to the combination of ISVs for modules with different certificate types (eg. SB, SD, SH1)



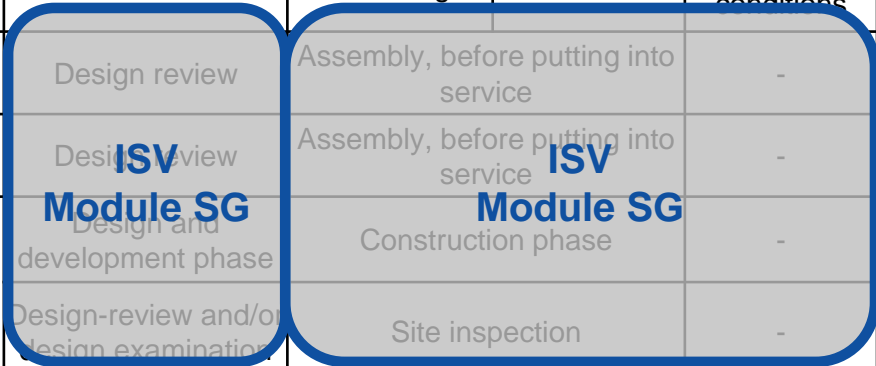
Vehicle: Module SB+SD

	Sub-system	Overall concept	Manufacturing: construction, production and assembly	
TSI PRM 1300/2014	RST	Design and development phase		Production phase
		Design-review and design examination	Type examination	Routine test
TSI Loc&Pas 1302/2014	RST	Design and development phase		Production phase
		Design review	Type examination	Routine test
TSI Noise 1304/2014	RST	Design review	Type examination	Routine test
TSI WAG 321/2013	RST	Design and development phase		Production phase
		Design review	Type examination	Routine test
TSI CCS 2016/919	CCO/CC T	Design and development phase		Production phase



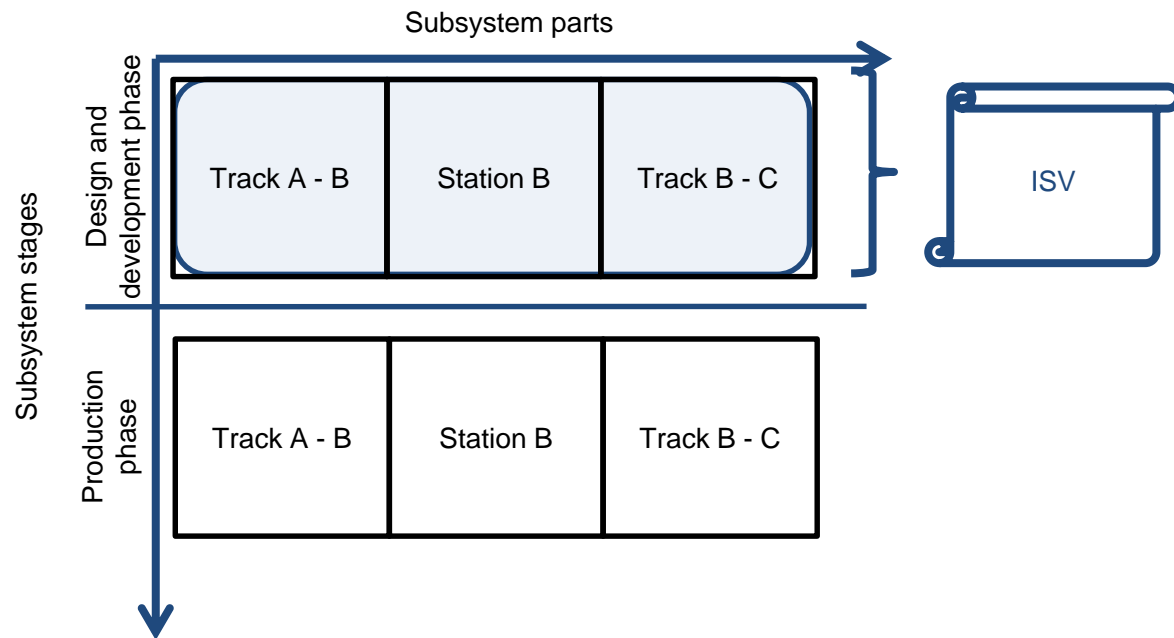
Infrastructure project: module SG

	Sub-system	Overall concept	Manufacturing: construction, production and assembly		Final testing
TSI ENE 1301/2014	ENE	Design development phase	Production phase		
		Design review	Construction, assembly, mounting	Assembly, before putting into service	Validation under full operating conditions
TSI SRT 1303/2014	INF/ENE	Design review	Assembly, before putting into service		-
TSI INF 1299/2014	INF	Design review	Assembly, before putting into service		-
TSI PRM 1300/2014	INF	Design and development phase	Construction phase		-
		Design-review and/or design examination	Site inspection		-



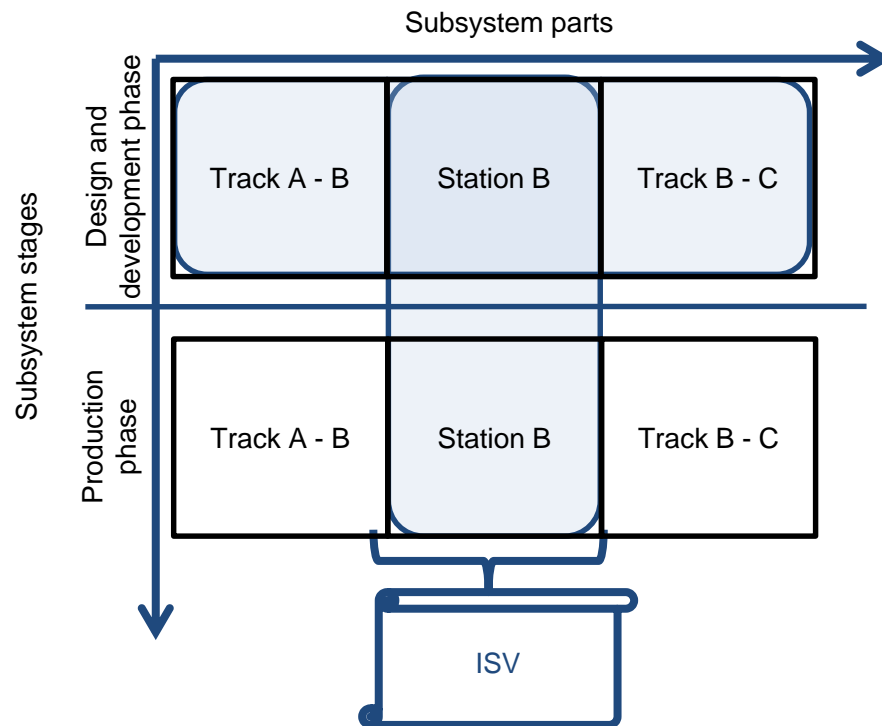
Breakdown in phases/stages

- Assessment module SG, Subsystem infrastructure



Breakdown in parts

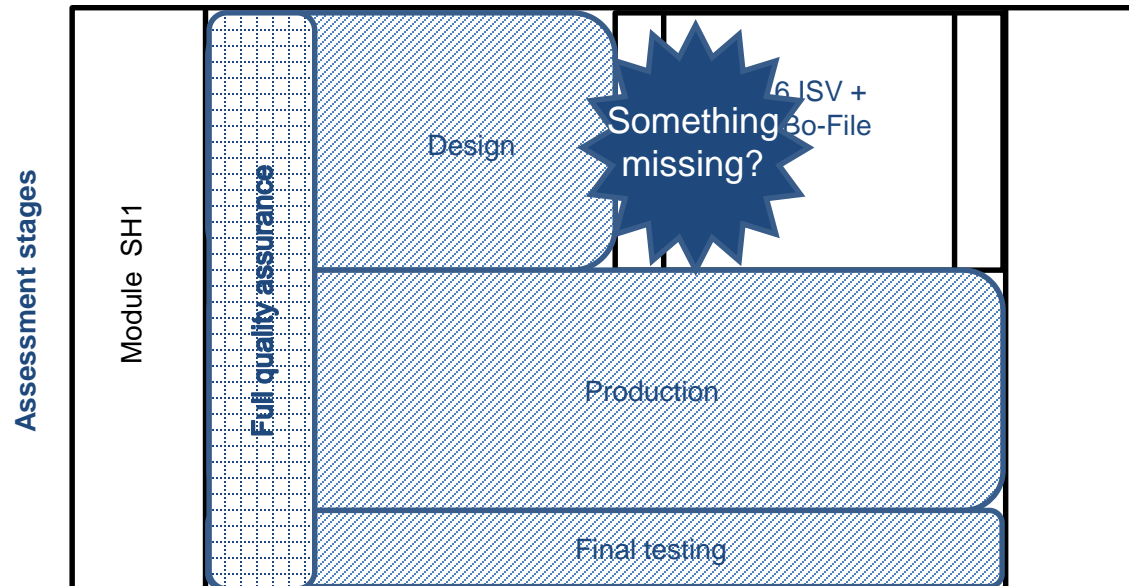
- Assessment module SG, Subsystem infrastructure



Combination of different modules

- Module SH1 and SG
 - When using different modules, then single parts shall be assessed in complete form (=all phases/stages), otherwise „gaps“ may arise

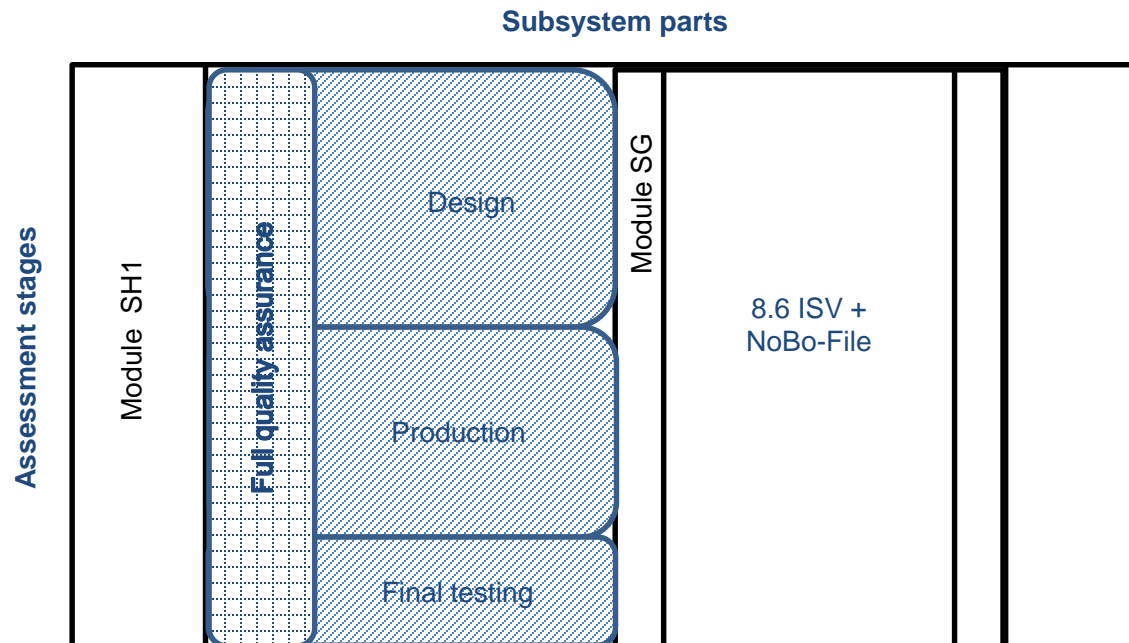
Subsystem parts





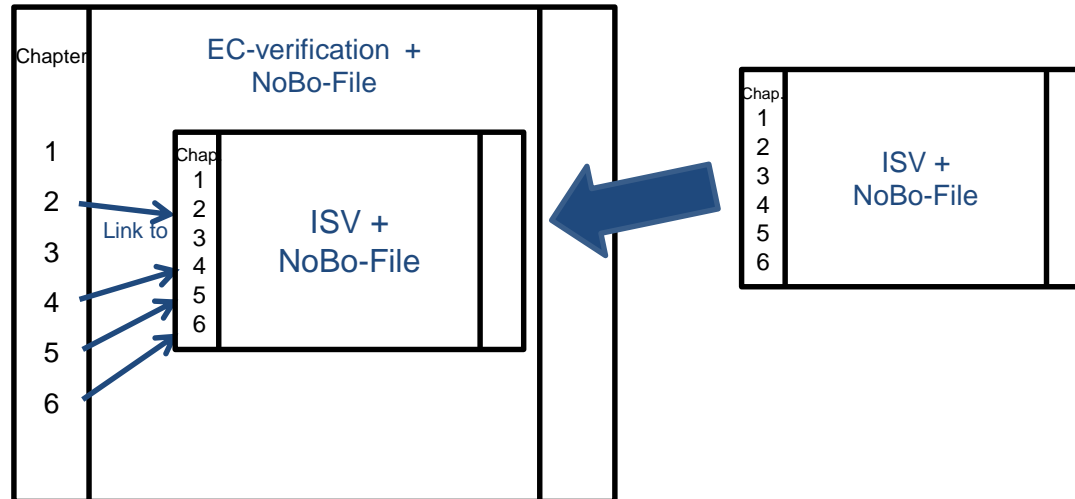
Combination of different modules

- Module SH1 and SG
 - Attention for type 8.6 at module SG: all phases shall be covered



Practical implementation

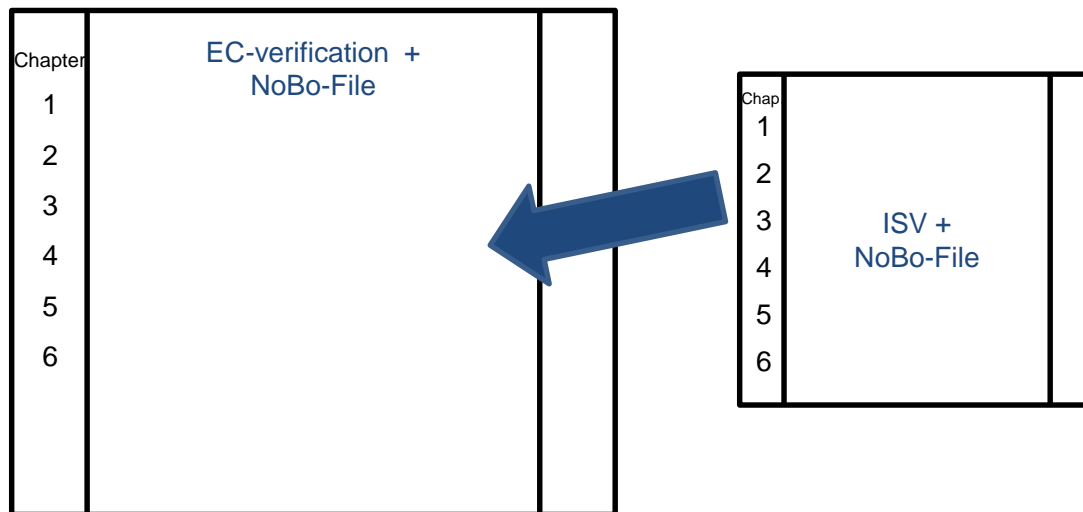
- Merging ISVs + NoBo-Files
 - full transfer of NoBo-File into overall NoBo-File
 - Mostly done when an ISV of an other NoBo is integrated





Practical implementation

- Merging ISVs + NoBo-Files
 - Integration into overall NoBo-File
 - Can be done when ISV is from the same NoBo





ISVs for components

- ISVs are often used for components that are not defined as interoperability constituents
 - Example: steel sleeper or other new types in TSI INF
 - Attention: to be used according to subsystem modules
=> Module SG or SH1
 - Compare: for concrete or wooden sleepers
=> Module CA or CH
 - Use of module SG:
 - No assessment of quality management system in production phase
 - Use of module SH1
 - Assessment of quality management system
- Other examples: energy measurement system in RST or components of the brake system
- Important: conditions for integration into the subsystem shall be clearly defined!



Summary

- ISVs are being used more and more
 - more flexibility for the applicant
 - huge versatility in use
 - They provide certainty and clear statements of project status
 - They enable independent „component certification“ if not defined as interoperability constituent
 - They enable a kind of „platform certification“
- ISVs shall be used correctly
 - They require correct and proper execution and merger
 - Clear definition and declaration of interface conditions necessary
 - Special attention when combining different modules
- Standardized phase titles in all TSIs as well as clear assignment to the phases as defined in the different modules would be very helpful.



THANK YOU for your attention!

Do you have QUESTIONS?

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