

NSA Acceptance/Approval Process

Guide prepared for Banedanmark's
Signalling Programme (BDK SP)

Preface

This guide contains the overall principles of Trafikstyrelsen's (TS) Acceptance / Approval Process for Banedanmark's Signalling Programme (BDK SP).

TS for Trafikstyrelsen and NSA for National Safety Authority are used as synonyms.

BDK SP is the Programme organisation embedded in the national Infrastructure Manager (IM): Banedanmark (BDK). In this Guide BDK SP is used as an abbreviation for both: The national IM's Signalling Programme with all its activities and the Signalling Programme organisation.

This guide describes Trafikstyrelsen's regulatory frame for acting as National Safety Authority (NSA) for BDK SP. It also explains the roles and responsibilities related to all relevant stakeholders of the Acceptance / Approval Process. BDK SP has chosen Lloyd's Register EMEA as General Independent Safety Assessor (G-ISA) and Notified Body (NoBo) for the life cycle of the BDK SP.

The guide also describes the expectations with regard to BDK SP's Safety Management System and compliance with the CENELEC standards EN 5012x and particularly with the System life cycle of EN 50126 and its 14 phases.

At a generic level, this guide describes the services that NSA offers, the communication level and NSA actions following BDK SP's expressed needs in order to push forward.

As a service this guide is produced in English, even though the formal Trafikstyrelsen-language is Danish. All approved legislative documents may be found on the official TS website: www.trafikstyrelsen.dk.

A first draft of this Guide was introduced and commented by BDK SP and their G-ISA during the overall Tender phase. This initial phase of the BDK SP has been characterised by many meetings and workshops, which can be summarised under one of NSA's services during an early Programme phase: Preliminary dialogue.

The Trafikstyrelsen Signalling Programme (TS SP) team was formed during the overall BDK SP Tender Phase by mirroring BDK SP and its Safety organisation. It is the TS SP team's ambition to continue to match the BDK SP Safety organisation also during the following overall BDK SP phases: Design, Early Deployment, Roll-out and Programme Close in order to safeguard the safety level of the Danish Railway systems, which are to be re-signalled; and to finally issue the necessary NSA approvals for placing the new systems into safe service.

All relevant stakeholders within the BDK SP are responsible for legal compliance with European and national Danish laws plus Quality Assurance in their daily work and safety activities.

Due to continuous alterations to any legislative documentation referred to in this guide, this guide shall be seen as a snapshot of the railway world in this regard and in its current version when published.

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1 Organisation and roles

1.1 Legal Frame of NSA's Role and Responsibility

The regulatory framework for the Danish railway sector is composed of both national regulation and European regulation. The national regulation consists of the Act on Railway (*Lov om jernbane*) and various regulations and decisions, also called: Statutes for Railway (*Bekendtgørelser og Bestemmelser for Jernbane*) while the European regulation consists of directives, regulations, decisions and Technical Specifications for Interoperability (TSIs).

Danish regulation and directives are found on:

- the website for legal information: <https://www.retsinformation.dk/> and
- TS' website: <http://www.trafikstyrelsen.dk/DA/Databases/Lovstof.aspx>

European regulation is found on:

- the website: <http://eur-lex.europa.eu/en/legis/index.htm>

1.2 Hierarchy and communication flow

According to EU legislation the body responsible for railway safety is the Infrastructure Manager (IM) and the body responsible for the final approval, read: Authorisation for Placing In Service (APIS), is the NSA.

The leading role of the Safety Authority, as the top body in a process domain supported by independent trusted bodies, can be displayed as in Figure 1.

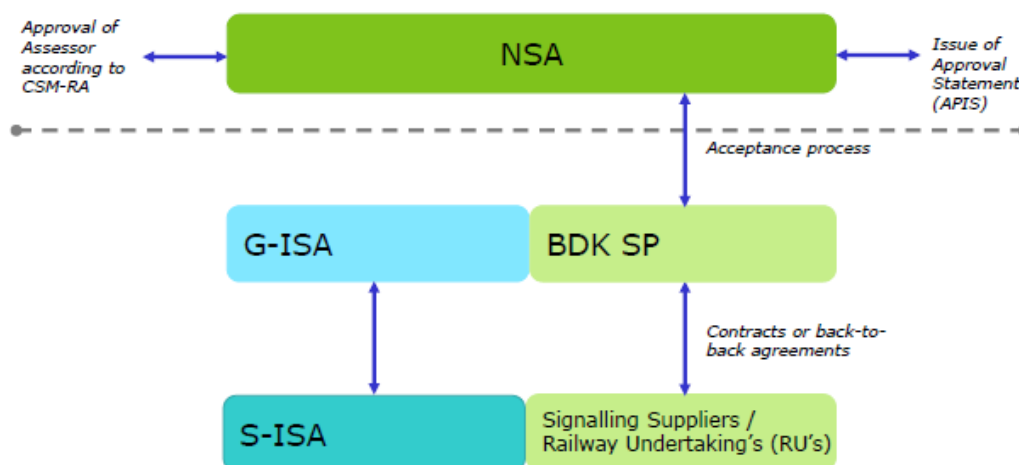


Figure 1: Main stakeholders within BDK SP¹

¹ Figure 1 does not take into account how other Danish IM-organisations on F-bane, e.g.: *Storebælt A/S* (Great Belt Link) and *Øresundsforbindelsen* (Oresund Link) are set up as stakeholders within the complete BDK SP. NSA expects this in a preliminary system definition document from the F-bane Infrastructure project.

As described in Figure 1, BDK shall have an assessor to assess its safety process. In BDK SP, this assessor is called a G-ISA has taken on the role and responsibility of a combined General Independent Safety Assessor and Notified Body, G-ISA / NoBo.

In BDK SP, other relevant actors are Suppliers that supply the different technologies and systems and Railway Undertakings (RU's) that own the vehicles on which e.g. Onboard systems are to be placed. All of these actors shall have a Specific Independent Safety Assessor (S-ISA) that handles both safety assessment and any Notified Body issues.

BDK SP and its G-ISA shall collate all documentation from the other relevant actors and ensure its quality as described in Figure 4 before sending it to NSA.

2 NSA Services

The Signalling Programme is a complex programme composed of individual large projects focusing on specific technologies and systems, i.e. CBTC for Copenhagen's Suburban mass transport railway: S-bane and ERTMS for the entire Danish long distance and regional rail network: F-bane.

As the BDK SP has larger project risks during acceptance / approval processes, NSA acknowledges and accepts that the acceptance / approval process is in continuous progress, running on many parallel routes simultaneously.

BDK SP shall express what is needed for them to push forward and in turn, NSA shall guide and regulate the entire Danish railway safety sector on equal terms for all applicants (*Vejledningsforpligtigelse*) and thus applying its principle of Equality (*Lighedsprincip*).

NSA offers three different services which may lead to final approval, i.e.: Authorisation for Placing In Service (APIS)

- Preliminary dialogue
- Acceptance
- Approval

For an overview of which actions and services are voluntary or mandatory, please see Figure 2.

2.1 Preliminary dialogue

Preliminary dialogue is a service provided by NSA that is voluntary for the Programme / projects to enter into.

Participants: the Programme / projects and NSA and may include the ISA when this is seen as relevant.

Purpose: To clarify any matters concerning the Programme / projects and in this way ensure that the actors, i.e. BDK SP, NSA, G-ISA, and any other relevant stakeholder obtain a common understanding of the Programme / projects. The objective of preliminary dialogue is to prevent any delays that may occur subjective to the Programme / projects not being adequately described to begin with.

The preliminary dialogue shall expose the extent of the Programme / projects and further actions including, as a minimum:

- the precise scope of the Programme / projects
- which systems, subsystems, subject areas (infrastructure, interlocking, train control, traction current, etcetera²) and geography are in play
- how to handle safety within the Programme / projects

² System according to the definition in: CSM-RA and Interoperability Directive

- which rules and regulation, including European shall be followed
- will there be a need for derogations
- a draft Scope of Work (SoW) by G-ISA.

Preliminary dialogue is usually dealt with through a continuous number of meetings; see Chapter 4.3, the extent depending on the scope and complexity of the Programme / projects.

2.2 Acceptance

Acceptance is a service provided by NSA to larger Programme / projects. It is voluntary for the Programme / projects to make use of Acceptance.

Participants: the Programme / project plus their ISA and NSA. The acceptance process cannot move forward without G-ISA's involvement.

Purpose: To make BDK SP secure with regard to following the correct process during Programme / project progress. In other words, acceptance is a methodology that may contribute to reducing BDK SP's uncertainty and thus BDK SP's Programme / project risks. Acceptance statements are rendered in writing and they are NSA's formal declaration that the Programme / projects are on the right track.

Often, the acceptance process is used continuously throughout the life-time of the Programme / projects.

The approach and methodology used during the Acceptance activities, where many ongoing multifaceted safety activities shall be handled simultaneously and this requires the existence of a strong safety management culture.

Amongst other things, this includes:

- Good documentation practice (production, filing, distribution,...)
- Stringent Configuration Management (Consistency across Programme / projects, version control,...)

Above systematic processes, implemented in a sound safety management culture, shall typically be demonstrated by the applicant and ISA-bodies during the early stages of a Programme / project to establish the trust and confidence at NSA for a long lasting, dependable relationship.

When BDK SP, on Programme or project level applies for acceptance, G-ISA shall endorse of all documentation, preferably by closing all of its Safety Notices or by clearly demonstrating how these are managed, when BDK SP proceeds into a next phase, before BDK SP is to forward applications to NSA together with the safety documentation: i.e.: The BDK SP submission shall include all relevant G-ISA safety documentation.

2.3 Approval

Approval is the fundamental service provided by NSA. It is mandatory for the Programme / projects to make use of Approvals; see Figure 2.

Participants: the Programme / project plus their ISA and NSA. The approval process cannot move forward without G-ISA's involvement.

Purpose: Granting the applicant Authorisation for Placing In Service (APIS), based on a positive ISA-endorsement (G-ISA Assessment report) that verifies a clear and assessed result of the applicant's safety activities, as documented in a "package application" composed of BDK SP- and hereto related ISA-documents.

NSA requires that larger Programmes / projects shall have an Assessor that shall independently assess whether or not the applicant is handling its safety properly and in accordance with European rules and regulations.

Furthermore European rules and regulations may require that the applicant meets Interoperability requirements and thus needs to engage a Notified Body (NoBo)-organisation.

NSA approves the Assessor/s that BDK SP wants to use.

The approach and methodology, which already has been introduced and exercised during Acceptance activities requiring the existence of a strong safety management culture, also applies for the Approval process.

NSA is obligated to render guidance towards the processes leading to approval and ultimately an APIS. This may happen through meetings as detailed in Chapter 4.3. This means that preliminary dialogue, acceptance and approval of safety documents often will happen in parallel in the various projects that compose a Programme like BDK SP, and often in different stages.

2.4 Level of voluntariness

Figure 2 sums up the central services and displays the voluntary services and the mandatory approval process.

Actions \ Services	Voluntary	Mandatory
Preliminary dialogue	X	
Acceptance	X	
Approval		X

Figure 2: The 3 essential NSA services and their level of voluntariness

For the voluntary services provided by NSA, it is BDK SP who decides if it is necessary for the Programme / projects to request these services.

Preliminary dialogue may be requested when it is necessary to obtain a common understanding of the Programme / projects. For more information on the scope of preliminary dialogue, see: Chapter 3.1.

Acceptance may be requested when it is necessary to ensure that the correct process is followed and may contribute to reducing Programme / projects uncertainty and risks. For more information on the scope of Acceptance activities; see: Chapter 3.2.

Mandatory services provided by NSA are for approvals. Approval services may be offered for approval for a full safety package in order to obtain an APIS as described in Chapter 2.5. For more information on the scope of Approval activities, see also: Chapter 3.3.

2.5 Authorisation for Placing In Service (APIS)

There are two kinds of NSA Approval-statements:

1. Approval of an Assessor
 - Professional Independency
 - Impartiality
 - Competences
2. Approval, as an Authorisation for Placing Into Service (APIS)

Approvals may only be given for the full case work, i.e. a Safety Case where the safety documentation package including all safety documents substantiate that a specific Programme / project meets the requirements given by Danish

and European law and when relevant the declarations of verification based on TSI requirements.

For BDK SP, the decisive approval statement to be obtained is the APIS for commercial operation of the Danish F-bane rail network and the Copenhagen S-bane. The Danish legal term for APIS is: *Ibrugtagningstilladelse*.

A first "APIS-exercise", however, will be the challenge when S-bane and F-bane are about to enter their phase of Early Deployment.³

As a general guideline, NSA requests that:

- An Applicant has achieved acceptance of safety-related documentation before applying for approval. Therefore, a timeline for an application process will always show acceptance activities in the first part as a pre-condition for the subsequent phases with approval activities. Exceptions are shown in Chapter 5.4.
- The scope of an approval statement is valid for what the applicant is capable of at the time of application and not for what the applicant may be capable of in future.
- Final authorisation may only be rendered when all safety documents have been accepted. This includes the final G-ISA assessment report that covers all final versions of safety documents with closed Safety Notices and also Declarations of Verifications, made by BDK SP based on certificates issued by Notified Body.

The process for issuing certificates by a Notified Body follows the process outlined in the Interoperability Directive and the relevant TSI's.

Normally, an APIS is issued in order to announce that NSA considers a technical system safe for its intended use and may be put into service. It should be noticed that "intended use" and "service" may be both:

- Situations, where system functions could influence railway safety while the railway system is in commercial operation/service
- Situations, where system functions could only influence railway safety during testing scenarios i.e.: No commercial operation/service⁴
- When Interoperability requirements exist

G-ISA shall assess all documentation, close all Safety Notices and thus endorse BDK SP to forward applications for approval to NSA together with the safety documentation. This includes G-ISA safety documentation.

³ Until BDK SP reaches those stages, it will be 2014 for S-bane and 2017 for F-bane East, according to our present knowledge. NSA expects the issue of how BDK SP plans to apply for Early Deployment-APIS to be described in a preliminary system definition document for both S- and F-bane Railway.

⁴ According to the Act on Infrastructure.

2.6 Complaints

The applicant may issue a complaint to the independent party *Jernbanenævnet*, the Danish Rail Regulatory Body, if an approval statement is not granted or if granted with conditions that the applicant finds unacceptable.

The website for *Jernbanenævnet* is: <http://www.jernbanenaevnet.dk/DA.aspx>

3 Activities with regard to NSA services

3.1 Voluntary preliminary dialogue activities

3.1.1 Authority Approval Process Plan (AAPP) and Safety Plan

BDK SP and NSA have agreed that BDK SP at a very early stage of the Programme / projects presents an Authority Approval Process Plans (AAPP) in order to have an overview of the processes and methodologies used by BDK SP and in order to establish the content of the safety management within the Programme / projects.

AAPP is a planning tool to be produced by BDK SP and may be discussed with NSA in view of acceptance during the preliminary dialogue period. AAPP can be produced as a separate Safety document or it can be part of the Safety Plan.

When BDK SP formally submits an AAPP or Safety Plan to NSA for acceptance, it is expected that as a minimum the following contents, as well as those mentioned in Chapter 2.1, are clearly described:

- References to relevant safety documents (e.g. System Definition)
- Acceptance criteria
- Approval criteria, if and when they are already known at that early stage
- Interfaces with other projects
- Acceptance for all safety documentations plus Approval-Milestones, both incl. milestones for relevant G-ISA documents; and for all phases
- Alignment with the EN 50126 Life cycle phases⁵

3.2 Voluntary acceptance activities

This Chapter contains:

- G-ISA safety documents; see Chapters 3.2.1 and 3.2.2
- BDK SP safety documents; see Chapter 3.2.3
- Safety documentation package; See Chapter 3.2.4
- Conditional acceptance statement; see Chapter 3.2.5

When the applicant requests an Acceptance Statement in order to be secure in its activities, the safety documents relating to these activities shall be forwarded by BDK SP to NSA for Acceptance using a formal request for Acceptance-letter or template together with the required G-ISA-documentation, see Chapter 4.2.

⁵ BDK SP has decided to found its Programme / projects on the EN 50126, 128 and 129 CENELEC standards.

Figure 3 illustrates the process where BDK SP forwards a product for acceptance. NSA spot tests the product and when there are no essential comments returns an Acceptance Statement.

When there are comments, NSA returns these to BDK SP in order for BDK SP and their ISA to respond to these comments and then for BDK SP to forward a new revised version of the product for acceptance, once again endorsed by the ISA. NSA will make new spot tests and the process will iterate until there are no essential comments.

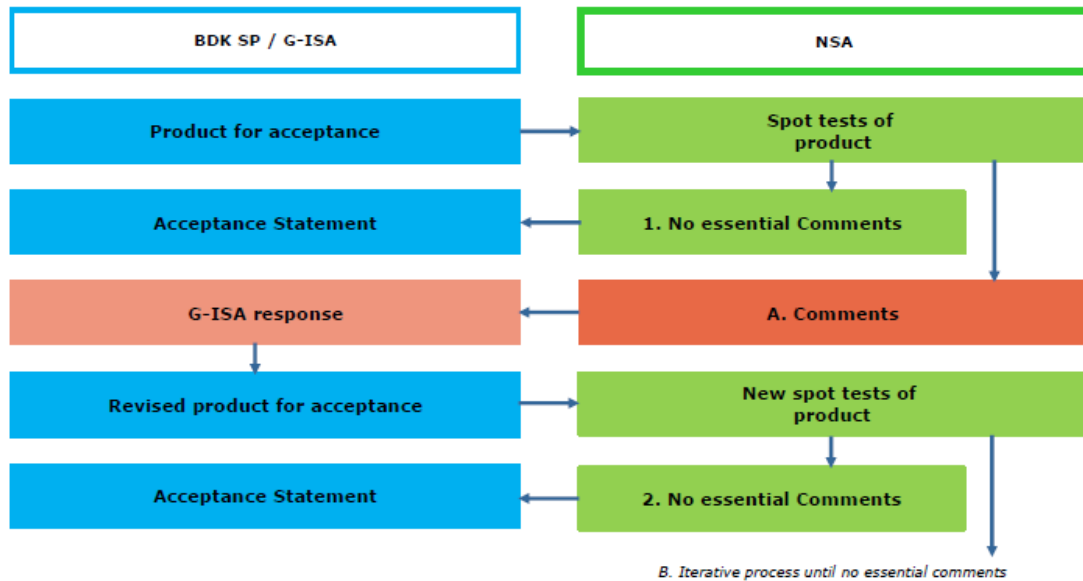


Figure 3: Acceptance process

3.2.1 G-ISA Safety documents

NSA will not necessarily spot test G-ISA Safety documents, however, NSA will use these documents to check that G-ISA is performing as NSA expects and in order to maintain faith in the safety process of the Programme / projects.

3.2.1.1 Acceptance of G-ISA Scope of Work (SoW)

In order to commence a phase, NSA would expect BDK SP to submit a G-ISA SoW document.

When BDK SP formally applies NSA for acceptance of this G-ISA SoW, it is expected that the ISA SoW document references the CSM-RA and other for norms and standards relevant to assessment work. If not, then as a minimum the following contents are to be clearly described in the SoW document:

- Legal basis
- Assessment process and methodology, incl. independence
- Documentation of assessment
- Interface management
- Overall phase activities including Assessment plan for more detailed safety-related

When NSA has no comments, NSA will issue an Acceptance Statement to BDK SP for the G-ISA SoW.

When NSA has comments to the contents, NSA will invite the applicant, BDK SP, and/or G-ISA to a meeting and discuss the issues in order to achieve alignment. When alignment has been achieved, NSA will issue an Acceptance Statement.

NSA will not be able to accept of G-ISA/NoBo SoW valid for e.g. a Design phase before acceptance of a G-ISA Assessment report for the relevant preceding tender phase; see Chapter 3.2.2.

3.2.1.2 G-ISA Assessment plan

Some of the first relevant safety documents, after acceptance of the G-ISA Scope of Work, are G-ISA Assessment plans for the various Programme / projects.

Assessment plans are more detailed than G-ISA SoW and are established for each Programme / project at the start of a phase to describe which deliveries may be expected from G-ISA for each phase and what this may entail. The assessment plan shall describe and form the basis for the content of the subsequent G-ISA assessment report at the end of a phase.

NSA considers it good practice when a G-ISA Assessment plan is submitted to NSA by BDK SP for acceptance, following the acceptance of the G-ISA SoW for the same phase.

When NSA is asked to accept G-ISA Assessment plans, it is expected that as a minimum, the following contents are clearly described in the Assessment plan:

- Specific Assessor team
- Reference to Safety Plan / AAPP
- Scope of assessment, incl.: Conclusion on contemporary phase plus outlook on activities in succeeding phases
- S-ISA, when relevant
- Interfaces with other projects
- Assessment process per EN 50126 lifecycle phases including Overall Time Schedule (OTS)⁶

When there are Programme / project changes during a phase, which have an impact on the accepted Assessment plan, NSA expects that BDK SP will submit a new version to NSA for acceptance.

When NSA has no comments to the contents, NSA will issue a Statement of acceptance for the G-ISA Assessment plan.

If NSA has comments to the contents, NSA will render its comments in writing to BDK SP requesting G-ISA to re-issue his Assessment plan in a new and updated version for another spot test and acceptance. This process will

⁶ BDK SP has decided to found its Programme / projects on the EN 5012x CENELEC standards.

continue as seen in Figure 3 until NSA is able to finally accept the G-ISA Assessment plan.

NSA will not be able to accept of a G-ISA Assessment plan valid for e.g. the Design phase before acceptance of a G-ISA SoW for the same phase; see Chapter 3.2.1.1.

3.2.2 G-ISA Assessment report

The G-ISA Assessment report is the final safety document to conclude and close a Programme / project phase. When NSA shall accept of G-ISA Assessment reports, it is expected that the contents clearly mirror the contents described in the corresponding Assessment plans.

The G-ISA Assessment report is the final safety document to be submitted NSA for acceptance following the final acceptance of a full BDK SP Safety documentation package at the end of each Programme / project phase. A Safety documentation package is described in detail in Chapter 3.2.4.

When NSA has comments to the contents, NSA will render its comments in writing and request G-ISA to re-issue the G-ISA Assessment report in a new and updated version for another spot test and accept. This process will continue as seen in Figure 4 until NSA is able to finally accept the G-ISA Assessment report.

When NSA has no comments to the contents, NSA will issue a Statement of acceptance for the G-ISA Assessment report.

NSA will not be able to accept of G-ISA Assessment reports before all safety documentation related to the same phase has been accepted by NSA and referenced in the Assessment report.

NSA will not be able to accept of G-ISA SoW for a subsequent phase before a G-ISA Assessment report for the previous phase has been accepted, see Chapter 3.2.1.1.

In order to finalise a phase, a G-ISA assessment report shall conclude how the current process has been handled by BDK SP and cover all final versions of safety documents for that phase. Furthermore, the G-ISA assessment report shall close the actions in the G-ISA assessment plan that need closing and describe which of the G-ISA Assessment plan actions that shall continue to the next phase.

NSA considers it good practice that Safety activities of a new phase will only be started after NSA accept of a G-ISA Assessment report for the previous phase.

The NSA Acceptance-statement of a G-ISA Assessment report acknowledges that the Programme / project has entered into a new phase.

3.2.3 BDK SP Safety documentation

Safety documentation must be subjected to an internal quality control prior to forwarding to NSA.

When BDK SP needs clarification from NSA with regard to BDK SP Programme, Railway or Project Level being on the right track towards a later, final approval, NSA requires that BDK SP forwards a formal application letter

for acceptance, see Chapter 4.2, together with the relevant safety documentation package.

Trafikstyrelsen will produce a generic form for all applicants to be used as a template that is to be filled in; in Danish called: "*Ansøgningsforklæde*".

BDK SP may forward application letters for acceptance to NSA for each phase as seen in Figure 4. When on Programme or project level, BDK SP applies for acceptance, G-ISA shall endorse of all documentation, preferably by closing all its Safety Notices or by clearly demonstrating how they are managed, when BDK SP proceeds into a next phase, before BDK SP is to forward applications to NSA together with the safety documentation: i.e.: The BDK SP submission shall include all relevant G-ISA safety documentation.

By spot tests, NSA will assess whether or not the document meets the requirements, e.g. has been through internal review and that G-ISA has closed all SN.

If this is not the case, the process will repeat itself until there are no comments; see below Figure 4 and also Figure 3. When there are no comments, NSA will issue a Statement of acceptance delimiting the parts that are relevant for the NSA to accept. The Acceptance Statement will lapse if the assumption/ preconditions of the issued Acceptance Statement change.

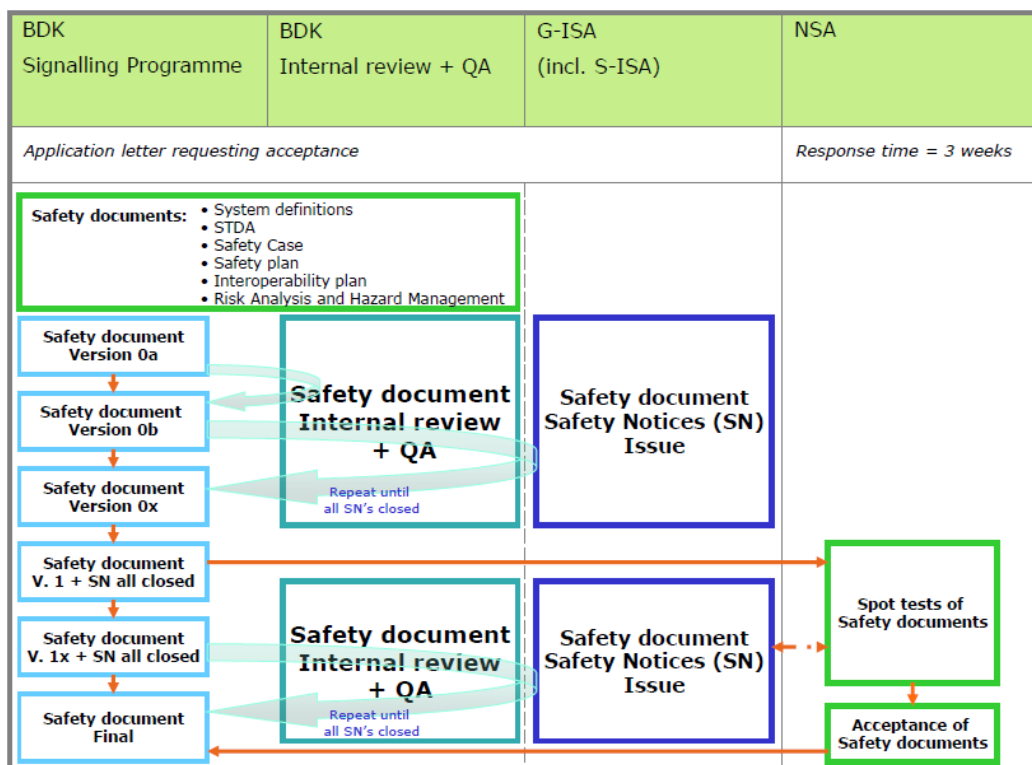


Figure 4: Full Acceptance process

3.2.3.1 System Definition

A System Definition is to be produced by BDK SP following the process described in Figure 4. Depending on which stage BDK SP is in, they may call it a (preliminary) System Definition

When NSA is asked to accept a (preliminary) System Definition, it is expected that as a minimum, the following contents are clearly described:

- System Scope and implementation
- Specifications
- System architecture; incl. external and internal system objects
- Interfaces
- Users
- Training, operation and maintenance

3.2.3.2 Safety targets determination and apportionment (STDA)

NSA sets the national target for railway safety. BDK SP has to comply with this safety target bar.

BDK SP shall determine the safety target of its entire Signalling Programme and equally important apportion the top target figure as a safety budget to all BDK SP projects.

BDK SP submits its Programme / project-STDA document to NSA for acceptance following the process described in Figure 4.

When NSA is asked to accept a STDA document, it is expected that as a minimum the following contents are clearly described:

- Scope incl. system definition
- Methodology and reference models
- General analysis
 - Hazards
 - Expected risk
 - Sensitivity analysis
- Associated Tolerable Hazard Rates (THR)
- Open points, if applicable

NSA shall object to the determination and apportionment when NSA finds that the apportionment has unacceptable safety consequences.

3.2.3.3 Safety plan and AAPP

A Programme / project Safety plan is produced by BDK SP and may be submitted NSA for acceptance for each phase following the process described in Figure 4: Full Acceptance process.

When NSA shall accept the Safety plan, it is expected that e.g. the following contents are clearly described:

- References to relevant legal and safety documents
- Scope
- Safety organisation
- Safety policies and acceptance criteria
- Safety management; incl. Interface management and OTS
- Safety activity plan; incl. Documentation plan
- Verification and validation plan
- Safety audit

3.2.3.4 Risk Analysis and Hazard Management

BDK SP will produce a Risk Analysis and Hazard Management log that shall be assessed by G-ISA before being submitted to NSA for acceptance.

When NSA shall accept of Risk Analysis and Hazard Management, it is expected that e.g. the following contents are clearly described:

- Risk Analysis according to legal requirements
- Safety critical items list
- Interface Hazard Analysis
- Operation and Maintenance Hazard Analysis
- Safety Evidence

The risk analysis and the hazard management log may be integrated into the safety plan, though this is not required.

3.2.3.5 Interoperability plan

An Interoperability plan is to be produced by BDK SP for the relevant projects and following the process in Figure 4.

The interoperability plan describes the NoBo process leading to a declaration of verification for the relevant subsystem⁷ or subsystems according to the chosen modules⁸.

When NSA is asked to accept an Interoperability plan, it is expected that as a minimum the following contents are clearly described:

- Scope and implementation
- Project Quality Plan
- Specifications
- Constituents
- Subsystems
- Cross-Acceptance
- Interfaces
- Other European legislation

3.2.3.6 Preliminary Safety Case (prSC) and Safety Case (SC)

Already, in the contemporary tender phase, a prSC is to be produced by BDK SP and may be submitted NSA for acceptance as described in Figure 4.

When BDK SP has chosen its supplier, the supplier will provide the information to BDK SP in order to start generating a prSC for the design and each subsequent phase following the process described in Figure 4, until a final SC is made, which may be submitted NSA for acceptance.

⁷ Subsystem according to the definition in Interoperability Directive and CSM-RA.

⁸ Modules describe the methodology of verification according to Interoperability Directive and TSI's.

When NSA is asked to accept a prSC, it is expected that as a minimum the following contents are clearly described:

- References to relevant safety documents (e.g. System Definition)
- Quality management report
- Safety management report
- Technical safety report; incl. Interoperability, if applicable
- Related safety cases
- Hazard Log
- Safety requirements

3.2.4 Safety Documentation Package

According to a 3-party agreement between BDK SP, G-ISA/NoBo and NSA, key safety management documentation shall be submitted to NSA as a documentation package.

- Documents that are logically connected shall be collated and submitted as one whole
- Documents shall be presented in the correct sequence. When assessing the validity of a document C, documents: A and B (containing information necessary or natural to know to assess document C) shall be presented first or at least together
- A BDK SP submission of Safety documentation shall always include the relevant G-ISA documents
- BDK SP shall enable NSA to understand all basic assumptions and to produce an acceptance statement based on a comprehensive approach
- At a given milestone for a phase shift, NSA will not grant acceptance statements for isolated safety documents or fragmented pieces of safety management documentation

Only if the documentation package is comprehensive and provides NSA with a holistic view of the safety work performed in the actual phase; NSA will render a Statement of Acceptance.

- G-ISA and S-ISA Safety documents are described in Chapters 3.2.1 and 3.2.2.
- BDK SP Safety documents are described in Chapter 3.2.3.

Figure 4 describes the full process of the key safety documents including the internal review and G-ISA process before NSA is involved in the acceptance process.

The indication of acceptance will not comprise full documents or methodologies, but will comprise e.g. safety target values and other fixed measures in safety management documentation. I.e. the NSA Acceptance statement will have a clear and precise scope chapter, which delimits the parts that are accepted.

Even when acceptance is not indicated, BDK SP may choose to continue working towards an approval. However, BDK SP shall allow that the lack of acceptance implies that NSA is not satisfied with the presented documentation and BDK SP may expect an increased risk of not obtaining final NSA approval i.e. an APIS-statement (Authorisation for Placing In Service.)

3.2.5 Conditional Acceptance statement

NSA recognises that information in an accepted document may be more detailed later on in the process. However, when a significant change is made in the document, the Applicant is advised to enter into dialogue with NSA for a new acceptance statement.

Examples of Acceptance criteria:

- The document contents are adequate (sufficiently detailed) and of sufficient quality when taking into account the programme, railway or project stage at the specific time
- The safety requirements or safety information in the documents are suitable for use as a basis for the subsequent stages in the development process

All statements issued by TS may be conditional. Conditions may be of the following types:

- Permanent conditions
- Time-limited conditions
- Functional conditions, e.g. specific technical features
- Application conditions; specific circumstances of how a system, equipment is applied

Conditions are used when TS wants to highlight that a statement is only valid if the applicant meets certain conditions.

When a condition has been included in the statement, the applicant shall comply with this condition.

Functional provisions are used e.g. when the conditions for using a constituent need to be tightened. The functional provision is important with regard to safety issues that have to be handled in relation to the authorisation for placing in service (APIS). These provisions are permanent.

Time-limited provisions are used e.g. when NSA does not receive enough or adequate documentation from the applicant to be able to issue a permanent APIS or when e.g. the result of an upgrade does not match the description in the safety plan. Here it will be necessary to update plans, drawings, etcetera, in order to have the correct information on the infrastructure in the future when it needs maintaining or upgrading. In these cases, NSA most often issues an APIS-statement with time-limited provisions, e.g. the applicant shall provide the required documentation within a specific time limit.

3.3 Approval activities

This Chapter contains the process for Authorisation for Placing in Service (APIS); see Chapter 2.5.

As such, the documentation provided for Trafikstyrelsen by BDK SP must include the following:

- 1) A complete system definition
- 2) A safety assessment report as defined in the CSM for risk assessment
- 3) Declarations of verification for the relevant TSIs

The approval process is similar to the acceptance process and thus also follows the process described in Figure 4.

However, this time the process is mandatory. BDK SP's request for Approval will be the final stage, where all up-to-now paper based safety documentation shall stand its test in the field, with actual rail operation. In order to be allowed to do that BDK SP needs APIS; see Chapter 2.5.

NSA implements regulation on safety and interoperability and this forms the basis for any final approval. Once again, final approval means that NSA grants the applicant an Authorisation for Placing in Service (APIS).

When an APIS is dependent on TSI requirements being met, the safety case shall include or make reference to all relevant EU declarations of verification and NoBo certificates. It shall be possible to unambiguously identify the version of subsystems and Interoperability Constituents (IC) via the safety case.

In order to place a structural subsystem in service, an APIS is required. However, in addition to the APIS, certain conditions must be met, before a subsystem may actually be placed in service. As an example, the Railway Undertaking (RU) / Infrastructure Manager (IM) must have a valid safety certificate / safety approval, relevant certificates for the staff intended to be used in the new (or altered) subsystem, etc.

Thus, an APIS is a prerequisite for allowing the placing in service of a subsystem, but in itself insufficient to do so.

4 Communication

4.1 Responsibilities

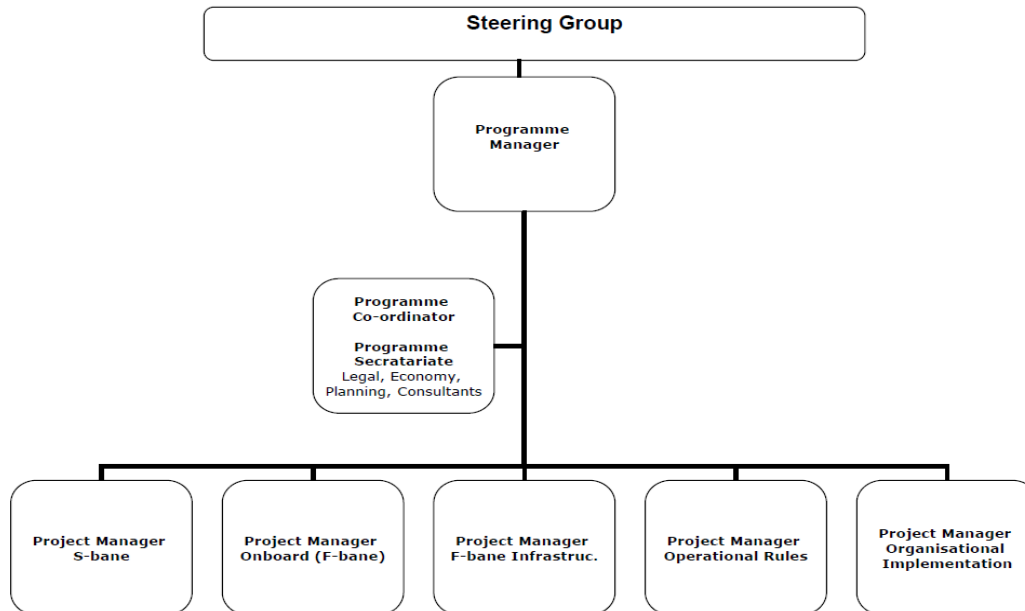


Figure 5: TS SP team organisation

Figure 5 shows NSA's organisation that mirrors that of BDK SP. The Steering Group is serviced by the Secretariat and has the objective of steering and guiding the TS SP team, also in view of TS resources, prioritising activities, keeping time schedules and working in compliance with Trafikstyrelsen's policy; i.e.: Principle of equality for all applicants (*Lighedsprincip*), which also is a foundation of a uniform case management at Trafikstyrelsen.

Each TS project within the TS Programme has a Project Manager that is responsible for all requests from BDK SP.

When BDK SP contacts the relevant Project Manager by mail, the TS Signalling Programme signalprogam@trafikstyrelsen.dk shall receive a copy in order for NSA to meet the requirements of a response time of 3 weeks.

Applicants for e.g. approvals of safety management systems and other generic safety issues are not included in this organisation and shall be directed the proper entity in Trafikstyrelsen.

E.g. it is the national Infrastructure Manager's basis organisation Quality & Safety (BDK Q&S) who is responsible of managing BDK's Safety Certificate. This includes performing all necessary changes in BDK's Safety Management Systems (SMS) during implementation of BDK's Signalling Programme. NSA actions to serve these basis BDK Q&S activities are not within the scope of the diagram shown above and thus not part of the TS SP team's responsibility.

The BDK SP project Organisational Implementation (and thus the corresponding TS SP project OI) has a special status here, since BDK SP OI is an internal supplier to BDK Q&S of all relevant input and documents related to

Education and Training in order to achieve the required level of competences for safety-related work on S-bane and F-bane.

BDK SP OI and TS SP OI have reached an agreement that all safety-related material, which is submitted NSA for Acceptance / Approval, will be in Danish.

4.1.1 Communication NSA – BDK SP

BDK SP is the single applicant and thus responsible for all communications regarding applications for acceptance, see Chapter 3.2 and approval, see Chapter 3.3, with regard to NSA.

BDK SP has contracts with the Suppliers and Back-to-back agreements with the RU's, and will supply NSA with all necessary information and safety documentation with regard to all relevant Suppliers and RU's.

Each and every Supplier and TOC shall acquire their own S-ISA that is to provide S-ISA / NoBo documentation to G-ISA / NoBo.

BDK SP may request NSA for preliminary dialogues in order to clarify any disputes, as described in Chapter 2.1.

The quality of the documentation to be forwarded NSA shall be sufficient and coherent enough for NSA to be able to respond within three weeks. In cases of a more complex nature, the first response may be initiation of a preliminary dialogue.

4.1.2 Communication NSA – G-ISA

Communication between NSA and G-ISA during programme execution will consist of:

- Mandatory approval (Delta approval of changes) of G-ISA competences
- Voluntary meetings / agreements, whenever alignment is required

Some of the most important formal requirements set by NSA, to be met by G-ISA and finally approved by NSA are:

- the relevant competences within the G-ISA organisation
- the independence and integrity of the G-ISA organisation; i.e. the G-ISA shall be independent from the applicant organisation

Competences and independence/integrity issues are dealt with in progress meetings between G-ISA and NSA or when it is deemed necessary.

4.1.3 NSA and S-ISA Organisation

It is expected that the process model used during the S-bane project design phase with regard to S-ISA shall make precedence for the remaining BDK SP projects.

Any communication regarding S-ISA shall go through either BDK SP or G-ISA.

NSA approval will follow the process in Chapters 3.2.1.and 3.2.2.

Also, NSA expects G-ISA to contain S-ISA acceptance planning and acceptance reporting within the G-ISA Assessment plan and G-ISA Assessment report as described in Chapters 3.2.1.and 3.2.2.

4.2 Application forms

When BDK SP needs clarification from NSA with regard to the BDK SP Programme / projects Level being on the right track towards a later, final approval, i.e. an APIS-statement; NSA requires that BDK SP forwards a formal application letter⁹ for acceptance together with the relevant safety documentation package as described in Figure 4.

- Application form for acceptance
- Application form for APIS Infrastructure
- Application form for APIS Onboard equipment
- Application form for APIS Vehicles
- Application form for Operational Rules
- Application form for Competences and Training

If BDK SP wants to employ components or sub-systems, which have previously been approved in either Denmark or another country (reference systems); this must be duly noted in the relevant APIS form.

All application templates are in the progress of being finalised in a generic version and may be retrieved from the NSA project manager for the specific BDK SP project.

4.3 Meetings related to action flow

Preliminary dialogue may be handled through meetings.

The following types of meetings may be held between NSA, BDK SP and G-ISA/NoBo.

- Informal meetings, i.e. Workshop or presentation meeting, where a safety process or Draft-safety documents, may be presented by BDK SP in order to receive guidance from NSA, G-ISA/NoBo respectively and to align expectations.

NSA will not produce any Minutes of such meetings (No MoM);

- Formal Safety-related meetings, e.g. Safety documentation spot-test meetings based on documents submitted to NSA for acceptance, endorsed by G-ISA with an accompanying Safety Notice (SN), after G-ISA's assessment of the said documents.

BDK SP, NSA and G-ISA may rotate the task of producing MoM's in compliance with the MoM agreed process in Chapter 4.4.

- Regular Safety-status and progress meetings, e.g. Executive Meetings on Director level, meetings on Programme level and on project level.

⁹ This request will apply from 01.01.2012 for all APIS approvals in accordance with European legislation.

Executive meetings and Programme level meetings are held according to a fixed schedule. Programme level meetings serve as a platform for agreeing on a common agenda for the subsequent Executive meeting.

G-ISA/NoBo shall attend all regular safety meetings. NSA will produce Exec. Meeting-MoM in compliance with the MoM agreed process.

4.4 Meeting and MoM Process

1. The agenda is forwarded at least 1 week before the meeting
2. Any small (max. 4 pages / slides) documents, e.g. power point presentations to be discussed, shall be forwarded at least 1 week before the meeting and attached to the agenda
3. When the document is a key safety document of more than 4 pages, the document shall be forwarded at least 2 weeks before the meeting
4. MoM owner creates the MoM document
5. The MoM shall be limited to describing decisions made during the meeting and the processes that shall follow ("next steps - action list)
6. The MoM shall be quality controlled internally and afterwards forwarded to the other party of the meeting as a version 01
7. The other party may distribute the MoM within its organisation for comments
8. The other party may not delete any original input from version 01
9. When the other party has comments to the MoM, all proposed changes shall be in another colour font
10. The other party may not include any drawings, figures, tables or other content that has not been presented at the meeting (see point 2 and 3 above)
11. When the other party has any comments, the other party shall forward the MoM back to the MoM owner in a version 02 within 5 workdays of reception
12. When the other party does not have any comments, the MoM owner shall issue the version 01 as the final version within 6 workdays
13. The MoM owner shall decide on which comments are relevant and shall implement these in the MoM
14. The MoM owner is allowed to delete all comments not found relevant
15. The MoM shall be quality controlled internally and afterwards forwarded as a final MoM to the other party of the meeting as a version 03

The benefits of the above structure are:

- The MoM will be a brief, sharp and a useful tool for focusing on the main issues, the processes to reach results and the challenges that need to be solved.

The MoM will be a relevant document that is up-to-date and describes exactly what actions need to be taken as decided at the meeting.

5 NSA duties

5.1 Supervision of Assessors work

The duties of the authority during BDK SP execution consists of:

- Spot tests that the G-ISA tasks are performed according to the agreed Scope of Work (SoW). This test will mainly be done in relation to major milestones e.g. at phase shifts and submitted assessment reports.
- Spot tests of submitted safety documents / evidence and related G-ISA statements. (Testing safety documents and G-ISA statements will usually not be done when the subject in question is broadly known and well specified. However, new concepts, open points in TSI or unique Danish circumstances will require more intensive testing.)
- Monitoring the process at the Applicant's entity in charge of a Safety Management System (SMS) and evaluation of the G-ISA's independence and integrity. The SMS will be monitored / audited from time to time in order to secure safety integrity among and between the stakeholders.

When the NSA is requested to issue official Statements of acceptance / approval, NSA shall:

- test that all relevant documentation has been received and formal requirements are met
- read G-ISA's conclusion, recommendations and judge the overall results

5.1.1 Conclusion: NSA – G-ISA relationship

The above described process forms the basis for respect, confidence and trust amongst the three parties: BDK SP / NSA / G-ISA.

The longer the BDK SP / NSA / G-ISA-relationship evolves without any errors or mistakes, the higher a confidence level is built up and the degree of NSA supervision and the frequency of spot tests will reduce.

5.2 Inspection versus Quality assessment

NSA will randomly spot test safety documents and when there are comments, NSA will inform BDK SP that they need to re-issue the documents in a new updated version and in general improve the contents.

When BDK SP re-issues the document and again forwards it to G-ISA for review and after endorsement re-submits the updated documentation to NSA for acceptance as required, NSA will subsequently make new random spot tests in order to validate that it meets the requirements set by NSA.

NSA will not make any quality assessments.

5.3 EN 5012x actions

In accordance with EN50126- EN50129, NSA shall accept the basis safety documents defined as per phase 4 in the CENELEC standards that according to BDk SP concludes the "tender phase".

These documents are:

- System definition (latest relevant versions)
- Safety Plan (including AAPP)
- Safety target determination and apportionment

Further as a national issue, the System Definition shall include the Operational Concept and the Functional requirements assessment of above.

The phase shift package shall contain a preliminary Safety Case and a G-ISA Assessment report covering all relevant final safety documents for the relevant phase only.

It shall be clearly stated which actions have taken place in which phase of the CENELEC standards.

A phase shift should include the documents that are to be built upon in the next phase.

If a statement is required before phase shift, NSA shall be able to retract the relevant information and issue an acceptance statement with comments based on this.

5.4 Exceptions

NSA will not spot test all documents. NSA will decide which documents shall be spot tested.

6 Need-to-know

Since a fundamental change from the present existing NSA statutes (*Bekendtgørelser, BEK*) to the new NSA statutes on Authority for Placing Into Service (APIS) of infrastructure & rolling stock is scheduled to come into force on 1 January 2012, the following examples shall be introduced highlighted as Need-to-know for BDK SP.

- NSA will execute its "One Applicant"-policy; i.e.: NSA will issue Acceptance / Approval-statements to BDK SP only, provided BDK SP actively applies for such NSA services.
- NSA will no longer approve Safety documentation. NSA is ready and prepared to receive Safety documentation, submitted by BDK SP, in a G-ISA assessed version and issue a Statement of Acceptance, when BDK SP formally applies for this.
- It is important to understand that the entire Acceptance process is a voluntary service, which NSA provides to BDK SP, when this is requested. The Regulation Common Safety Methods – Risk Assessment (CSM-RA) clearly prescribes the role and responsibility of the Assessor being the responsible party to look after and assess the Safety Management culture of the one applicant: BDK SP.
- NSA statements of Approval are the only formal, legal instruments that define the lawful relationship between the NSA, as the top body of railway safety in Denmark and the national Infrastructure Manager BDK and its Signalling Programme organisation BDK SP.
- It is crucial to understand the NSA approach on:
 - a voluntary acceptance service and
 - a final mandatory approval service

However, whenever BDK SP chooses to apply for Acceptance, then their submitted safety documentation must comply with the NSA conditions (*vilkår*) regarding a correct Acceptance process.

7 Terms, abbreviations and references

This guide uses the terms, abbreviations and acronyms of the BDK SP Glossary: "The Signalling Programme Glossary SP-03-008842-117.001".

The following few terms were found useful in addition to above glossary.

- AAPP: Authority Approval Planning Process. A planning tool detailing BDK SP Programme / Project deliveries within a specific phase. AAPP is described in Chapter 3.1.1
- Assessment plan: A planning tool produced by G-ISA in conjunction with BDK SP that details which deliveries exist within a Programme / project for a specific phase. The assessment plan shall found the basis for the G-ISA Assessment report. Assessment plan is described in Chapter 3.2.1.2
- Assessment report: A report collating all information on the assessment process closing all relevant safety documentation for the Programme / project within a specific phase and describing which processes are to be brought forward to a next phase. The report shall be based on the G-ISA assessment plan. Assessment report is described in Chapter 3.2.2
- APIS: Authority for Placing Into Service
- G-ISA: General Independent Safety Assessors
- G-ISA SoW: A collated scope of work describing in detail what the specific phase entails and what may be expected to be taken on by G-ISA with regard to the Programme / projects in the specific phase.
- IC: Interoperability Constituents
- NoBo: Notified Body
- RU: Railway Undertakings, also called: Train Operating Companies (TOC)
- Safety plan: Safety plans shows BDK SP's overall safety management and activity and verification plans, including safety audits.
- S-ISA: Specific Independent Safety Assessors
- SN: Safety Notice

For relevant references to legal sites: see Chapter 1.1.

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**Acceptance / Approval
process**