S9.2 Part 2: Quality Management Report

for the development of an STM ATB

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Contents

1 Preface

Text, STMA-72925 - This report is part of the Generic Product Safety Case for STM ATB and provides documented evidences of quality management throughout the STM ATB system development phase.

1.1 References

Text, STMA-33933 - Reference documents

All the documents references used in this document can be found in the document P6.1 Bibliography available in the Polarion folder Processes

Abbreviations, definitions and terminology

An overview of the abbreviations, definitions and terminology used in this document can be found in document P6.2 List of abbreviations, definitions and terms available in the Polarion folder Processes

Requirement identification

The STM ATB project makes use of an automated requirement management system. In this system each requirement has been identified as a work item. Each work item has been automatically assigned with a unique ID, with the format "STMA-<number>". As a result requirement ID's are not in logical order. An overview of all the used STMA-numbers is given in document P6.3 Requirement Overview available in the Polarion folder Processes

2 Project organisation

2.1 Organisational structure

2.1.1 STM ATB project organisation

Text, STMA-40755 - The STM ATB project is managed by a program manager, supported by a project manager. The project manager is responsible for project quality management. The STM ATB project is divided in separate teams, in compliance with the normative independence requirements for SIL3/4 product development:

- System Development Team
- Verification and Test Team
- Safety Management and Validation Team

Each team is supervised by a team leader, who is reporting to the project manager. The Safety Manager is independent from the project management and reports to the upper next project management level (program manager).

The detailed STM ATB project organisation chart is defined and maintained in SharePoint - ERTMS@NS. The organisation chart is managed and updated by the STM ATB project manager, who is also responsible for recruitment and team competence (see below).

2.1.2 STM ATB staff competences

Text, STMA-40760 - The STM ATB project staff competences are maintained in a competence workbook (P7.2.1) in SharePoint - ERTMS@NS in compliance with privacy regulations (AVG). Staff competences is checked during staff recruitment and based on basic job duties and responsibilities. The appraisal is based on CV and a job interview by project manager and a team leader.
Staff introduction in the project specific QMS, RAMS management, the product development and test environment used, is through 'training on the job'.

2.1.3 STM ATB responsibilities and authorisation scheme

Text, STMA-40761 - The key responsibilities and authorities for the STM ATB project are defined in a RACI-VS table (Q1.3.3 RACI VS table).
For all relevant processes in the STM ATB project, the RACI-VS table defines which project role is:
- Responsible
- Accountable
- Consulted
- Informed
- Verifier
- Signatory

2.1.4 Team recruitment

Text, STMA-40769 - Based on the organisational requirements specialists teams are recruited. Recruitment is on basis of a job profile. The recruitment process is managed along the formal project recruitment procedures of the NS recruitment desk. The recruitment of new staff includes a job interview with the STM ATB project leader and an STM ATB team leader involved. The team members and competences are documented in the competence workbook (with has access restrictions due to AVG privacy rules).

2.1.5 Stakeholders and organisational interfaces

2.1.5.1 Stakeholders

Text, STMA-40757 - The key stakeholders for the STM ATB generic product (ToCs, Freight Operators, Inframanagers) are represented in the ERTMS NL programme through their liaisons.
NS internal stakeholders for STM ATB are the ETCS retrofit projects, purchase department, HQSE department, System Engineering department and maintenance services.
The main point of contact is through the STM ATB project manager.

2.1.5.2 Inspectie Leefomgeving en Transport (NL Railway Inspectorate)

Text, STMA-79816 - In the Netherlands there are no legit rules for product development and admission of an STM ATB, however new and modified Rolling Stock requires a permit to operate, therefore the Railway Inspectorate (ILT) has been involved on an ad-hoc basis. Main point of contact is through the safety manager for the STM ATB project. Since the rules for admission of an STM ATB are not defined, the proposed admission process is also shared with ILT.
Another topic is the update of standards and norms, in a late stage of the project. According to the current regulations, the permit to operate will only be given if compliance with the latest standards and norms is demonstrated. In case of a derogation to this rule, agreement should be sought with ILT in an early stage.

2.1.5.3 Assessment body

Text, STMA-79817 - The assessment body (NoBo, DeBo, ISA) involved is TUV SUD. The main point of contact is through the STM ATB project manager and the TUV SUD project manager (contractual) and the STM ATB safety manager and the TUV SUD assessors (functional).

2.1.5.4 External suppliers

Text, STMA-79814 - The main point of contact is through the STM ATB project manager and the supplier project manager (contractual) and the STM ATB team leader/specialists and the supplier specialists (functional).
For STM ATB V1.0 following products and services have been outsourced to external suppliers:

- Hardware design, PCB design of SAP Board.
- FPGA filtering and diagnostics module.
- ATB EG/Vv decoder software module.

- Lab testing of EMC/EMI test.

- Lab testing of environmental tests (temperature, shock- and vibration, salt water spray tests, power supply etc.
- Lab testing (SS-058, SS-056, SS-057, SS-058 and SS-059, SS-074-2) of the interface STM - ETCS onboard system.

For STM ATB V1.1 the hardware redesign of the PSU/DIO board is outsourced, as well as the EMC/EMI lab tests and the functional safety tests.

2.1.5.5 Purchase department

Text, STMA-79815 - The main point of contact with the purchase department is through the STM ATB project manager, the STM project manager support and the NS purchasers assigned to the ERTMS@NS programme. Subjects:

- Procurement and purchase orders (external suppliers, test laboratories, assessment body).
- Contract extensions/prolongations.
- Procurement of STM ATB series production.
- Purchase of test equipment, PCB's and electronic components for the STM ATB test interface.

2.1.5.6 Legal department

Text, STMA-79812 - The main point of contact with the legal department is through the STM ATB project manager.
Subjects:

- STM ATB procurement strategy.
- STM ATB IPR of the ATB decoder software module.
- STM ATB handover and service organisation.
- STM ATB licensing and contractual issues.

2.1.5.7 Recruitment desk

Text, STMA-40770 - Recruitment of new staff is through the formal recruitment procedures of NS. The main contact with the recruitment desk is through the STM ATB project manager.

3 Planning phase

3.1 Quality and safety policy, quality objectives

Text, STMA-40767 - A quality and safety policy for the STM ATB project is defined in Q1.1 STM ATB Safety and Quality Policy which was defined for STM ATB V1.0 and remains unchanged for STM ATB V1.1.
Quality objectives for the STM ATB project are defined in Q1.2 STM ATB Quality Objectives and targets. The key-performance indicators are being revised to better match the NS line-organisation.
The quality and safety policy, as well as the quality objectives for the project are reviewed and updated on a regular basis. The quality management is the responsibility of the STM ATB project manager.
Project issues progress and actions are being discussed between STM ATB project manager and STM ATB program manager on a regular basis.

3.2 Top level plans

Text, STMA-40764 - The following top level plans describe the managerial planning aspects of the STM ATB V1.0 project:

P1.0 Project Management Plan
D0.4.1 Development + RAMS plan
S1.0 Safety Management Plan
Q1.0 Quality Management Plan
R1.0 Verification Plan
T1.0 Master Test Plan
V1.0 Validation Plan

The top level plans are being reviewed (and updated) periodically, to ensure that the plans reflect the current state of affairs within the STM ATB project.

3.3 QMS documentation

Text, STMA-79813 - The STM ATB project team has implemented a quality management system (QMS) in line with EN50126-1, Ch. 6.5.1.
The QMS is set up according ISO9001:2015 and contains the following procedures:

- Q2.1.1 STM ATB Requirement Management Procedure
- Q2.2.1 Issue Management Procedure
- Q2.2.2 Change Management Procedure
- Q2.3 Document Control Procedure
- Q2.4 Control of Records Procedure
- Q2.5.1 Internal Audit Procedure
- Q2.6 Control of non-conformance Procedure
- Q2.7 Corrective Action Procedure
- Q2.8 Preventive Action Procedure
- Q2.9 Configuration Management Procedure
- Q2.10 Product development procedure
- Q2.10.1 Workinstruction for software design and development
- Q2.10.2 Software Testing Procedure
- Q2.10.3 EN50128:2011 compliance checklist
- Q2.11 Review, Approval and Distribution of QMS documentation
- Q2.12 Gate Review Procedure
- Q2.13 Requirement and Product Handover Procedure
- Q2.14 Test Results Verification Checklist
- Q2.15 Supplier Control Procedure

The above quality procedures have been subject to external assessment and in the cause of the STM ATB project, their implementation has been audited during internal and external audits.
The NS specific quality procedures have been transferred to SharePoint - ERTMS@NS and the quality procedures in Polarion are continued for licensing purposes.

4 Specification phase

4.1 Legal and normative framework

Text, STMA-79782 - The legal and normative framework for the product development of an STM ATB comprises of European and National legislation and associated (railway) standards and norms. In inventory of relevant legislation is made.
The legal and normative framework is defined in D3.0. This framework has been discussed with ILT. Since there is no official licensing process for the authorization of STM ATB, a preliminary authorization and acceptance process has been proposed with the consent of ILT.

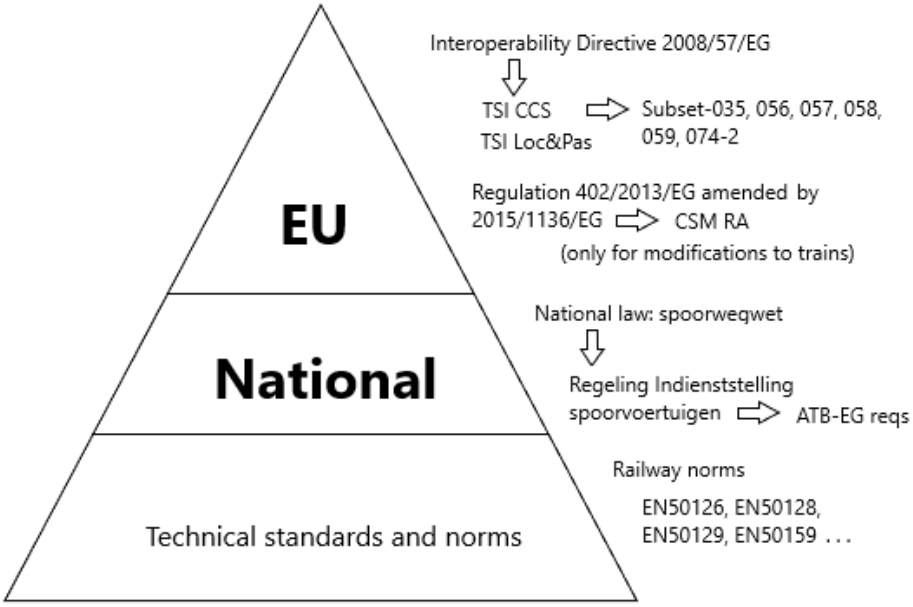

Figure 1 Hierarchy of legislative and reglementary requirements

4.1.1 TSI CCS

Text, STMA-79783 - The Technical Specification for Interoperability of the subsystem Control Command and Signalling (TSI CCS, reference: 2016/919/EU) is applicable. As per decision of ERTMS NL, ETCS Baseline 3 Release 2 is applicable for the STM ATB. For communication between STM ATB and the ETCS onboard system, a (closed) Profibus network interface is used, based on the open specification (see below).
The mandatory technical requirements for the STM ATB - ETCS interface are specified in TSI CCS chapter 4.2.6.1, which refers to Annex 4.2.6.a. This annex contains index numbers to the applicable subsets. TSI CCS (2016/919/EU) table A 2.3 provides a full list of mandatory specifications for ETCS Baseline 3 Release 2 and GSM-R Baseline 1 (set #3). Based on the index

numbers in annex 4.2.6.a the following subsets are applicable for an STM, when the standard communications interface is used:

Index nr.	Subset	Version
8	SUBSET-035 Specific Transmission Module FFFIS	3.2.0
25	SUBSET-056 STM FFFIS Safe time layer	3.0.0
26	SUBSET-057 STM FFFIS Safe link layer	3.1.0
36c	SUBSET-074-2 FFFIS STM Test cases document	3.1.0
49	SUBSET-059 Performance requirements for STM	3.1.0
52	SUBSET-058 FFFIS STM Application layer	3.2.0

Subset-035, subset-056, subset-057 and subset-058 contain the detailed functional and technical requirements for the STM - ETCS standard communications interface. These subsets are used to define the STM ATB interface requirements of the closed Profibus network interface with ETCS. Subset-074-2 and Subset-059 contain performance and test requirements. These subsets are used to define the interface and performance tests.

4.1.2 RIS

Text, STMA-79778 - The Regeling Indienststelling Spoorvoertuigen is applicable (See D3.0). The RIS requirements are defined for the purpose of Rolling Stock admission. The RIS contains a mixture of functional and technical requirements for ATB-EG wayside and onboard equipment and is updated periodically. Interpretation of these requirements by ATB experts is necessary to derive technical and functional requirements for an STM ATB. The relevant requirements for STM ATB are captured in D3.1 Requirements from Regeling Indienststelling Spoorvoertuigen.

The product development of STM ATB V1.0 is based on RIS 2016. The differences between the RIS 2016 and RIS 2022 have been analysed and the system requirement specifications for STM ATB V1.1 have been amended according to the RIS 2022 requirements for ATB-EG / STM ATB.

4.1.3 Requirements mapping

Text, STMA-79779 - The figure below depicts the requirements mapping of TSI CCS and RIS on the STM ATB system functional architecture.

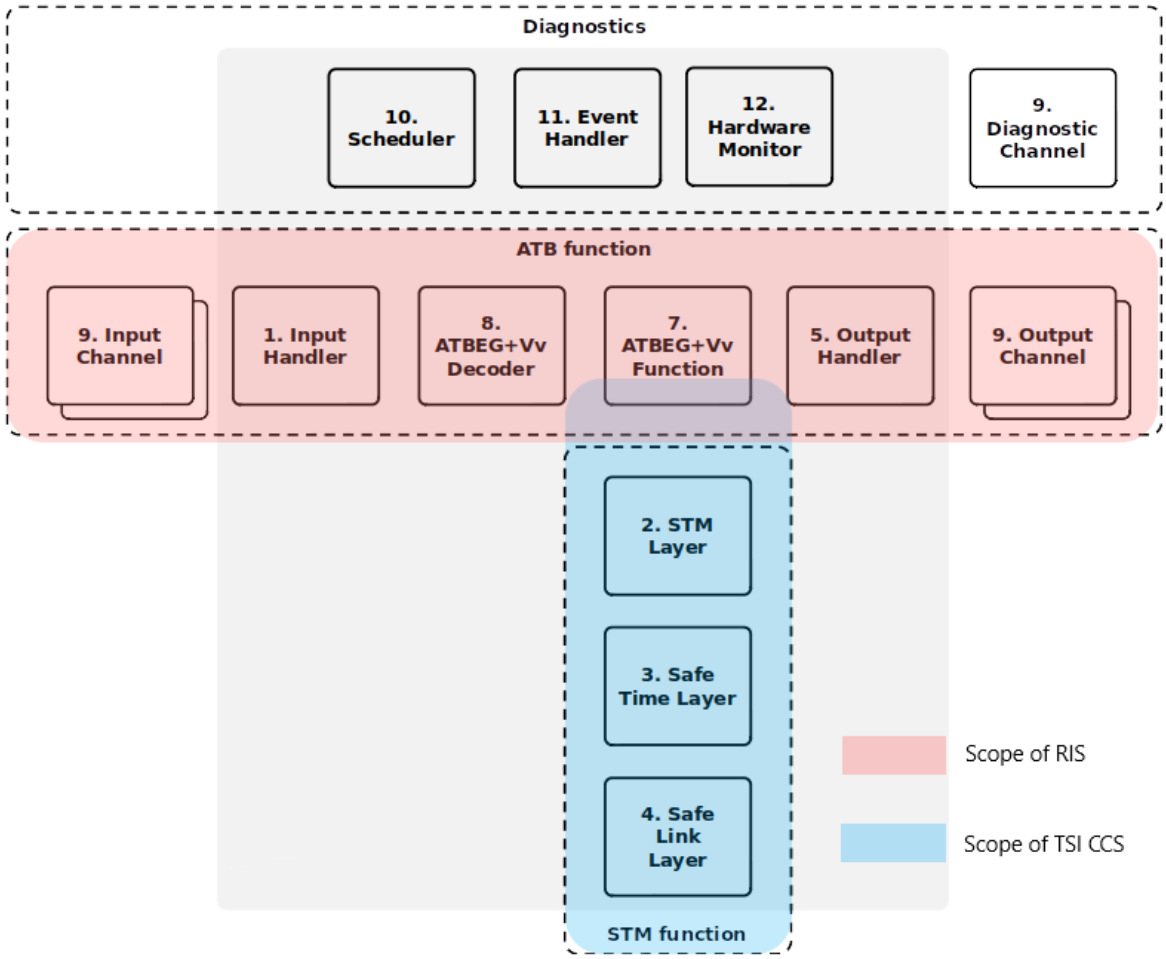

Figure 2 Requirements mapping on STM ATB system architecture

4.2 Stakeholder involvement

Text, STMA-79776 - The STM ATB V1.0 development project has started as a part of the "Programma ERTMS", which was funded by the Dutch Ministry of Infrastructure. The Programme involves all relevant stakeholders such as passenger train operators, freight operators, yellow fleet operators, railway musea and the Infrastructure manager and their key suppliers such as the signalling industry, engineering companies and contractors. For the STM ATB V1.0 development stakeholders representatives have been involved in the specification process, by means of consultation on technical issues and by means of review of specifications.
STM ATB V1.1 has been developed by the Nederlandse Spoorwegen on basis of STM ATB V1.0 in consultation with NS internal stakeholders. Modifications to STM ATB V1.0 have been

authorised by the chairman of the NS change control board.

4.3 Customer requirements

Text, STMA-79777 - Customer requirements are part of Phase 3 of the life cycle. The customer requirements concern properties of the system that have to be specified on top of the legal requirements from RIS, to meet the project goals and to realise a product that is suitable for its intended purpose, within the operational context and that is suitable for fitting in existing and future rolling stock.
The resulting products are a number of documents that are stored in Polarion, the requirement management system used in the STM ATB product development project. This includes also the specifications for the ATB Vv functionality (*ATB Verbeterde Versie*).

- D3.0 Legal framework standards and norms
- D3.1 Requirements from Regeling Indienststelling Spoorvoertuigen
- D3.2 ATBvv requirements
- D3.3 Tolerable Functional Fault Rates
- D3.4 Additional User Requirements

4.4 System requirements

Text, STMA-79780 - System requirements for STM ATB V1.0 are part of Phase 4 of the life cycle, based on the input from phase 3. In this phase the relevant ERTMS subsets and non-functional requirements such as RAMS, environment and performance are elaborated. The resulting products are a number of documents that are stored in Polarion.

- D4.1 Interface Requirements Specification (IRS)
- D4.2 Safety requirements
- D4.3 System Requirements Specification (SRS)
- D4.5 Environmental Requirement Specification (ERS)
- D4.6 Exported constraints
- D4.7.1 STM FFFIS Safe Link Layer (SS057 v3.1.0)
- D4.7.2 STM FFFIS Safe Time Layer (SS056 v3.0.0)
- D4.7.3 STM FFFIS Application Layer (SS058 v3.2.0)
- D4.7.4 Specific Transmission Module (SS035 v3.2.0)
- D4.7.5 Performance requirements (SS059 v3.1.0)

STM ATB V1.1 has been developed to:

- resolve known issues in STM ATB V1.0

- resolve functional bugs in STM ATB V1.0
- resolve integration issues found during integration testing with ETCS onboard systems
- implement modifications requested by internal stakeholders

The modifications introduced in STM ATB V1.1 are described in:

- D4_9_V1_1_Updates

4.5 Requirement verification

Text, STMA-79781 - The requirement verification is performed by the verification team and supported by Polarion. Traceability to previous phases is linked in Polarion. For each phase a final verification report has been made, which is stored in Polarion.

- R4.99 Final verification report for phase 4
- R5.99 Final verification report for phase 5
- R6.99 Final verification report for phase 6
- R7.99 Final verification report for phase 7
- R8.99 Final verification report for phase 8

4.6 Stakeholder acceptance

Text, STMA-78213 - Specifications for STM ATB V1.0 have been submitted to relevant stakeholder by the Programma ERTMS. Stakeholders have performed reviews on the phase 4 requirement specifications.
The impact of modifications in STM ATB V1.1 has been investigated (D4.9). The modifications have been approved by the NS change control board.

5 Design and implementation phase

5.1 Design Control

Text, STMA-78212 - The design activities are elaborated in D0.4.1 Development + RAMS plan .

Design control is managed by means of:

- Polarion for system requirement specifications, system architecture, module requirement specifications, HW/SW descriptions, design documents and V&V plans and reports;
- SharePoint for supporting technical documentation;
- Cloud based repository for software code and test scripts.

The tools mentioned above include version control and baseline management for HW and SW.
The design control is checked using a design review process (Polarion) and code reviews (GIT).

5.2 Design Verification and Reviews

Text, STMA-78191 - Design Reviews on modified design items are stored in Polarion.
For each document the status and history can be checked.
The design reviews results and requirement verification reports are checked as part of the Validation Process.

6 Procurement and manufacturing prototype phase

6.1 Overview of outsourced products and services

Text, STMA-78210 - The detailed design and implementation of the FPGA has been outsourced to: Topic Embedded Systems.
Hardware design and testing of the SAP board has been outsourced to: Neways Electronics.
The ATB decoder software module has been outsourced to Ricardo Rail.
On basis of the TPD's for STM ATB V1.1 and the manufacturing manual a small batch of STM ATB units has been manufactured by Cimar Electronics.

6.2 Supplier control process

Text, STMA-78211 - As parts of the design and manufacturing has been outsourced a supplier control process is part of the Quality Management System. The relevant part is Q2.15.
For each supplier, the input requirements have been defined and a supplier audit has been held.
The deliverables of the suppliers are subject to review/tests from the STM ATB team.

6.3 Supplier control records

Text, STMA-78201 - The following supplier audits have been held for STM ATB V1.0:

- Q4.3.1 Topic
- Q4.3.2 Neways
- Q4.3.3 Ricardo

The manufacturing process of a small batch of STM ATB V1.1 units has been audited at Cimar Electronics.
There were no major findings or blocking issues, however during acceptance testing some (minor) anomalies with the positioning of parts have been found.
The anomalies have been corrected by the supplier and have been checked OK.

6.4 Acceptance Records

Text, STMA-78202 - STM ATB 'system acceptance' is based on compliance evidence of STM ATB V1.0.

In addition the following tests have been performed:

- STM ATB operational tests in an ICM train, using STM ATB in parallel with the existing ATB-EG system (shadow operation)
- STM ATB V1.1 system integration tests with ETCS onboard suppliers
- Reliability tests in a climate chamber
- Tests with full length of ATB antenna cables

The issues found during these tests have been investigated and resolved in STM ATB V1.1

7 Manufacturing of the Series product

Text, STMA-78199 - The scope of the project is the development of an STM that is ready for manufacturing. Selected parties will, by means of a license, be allowed to produce the STM ATB. Requirements to the manufacturing process are included in M9.2 Manufacturing Manual.
The manufacturing Manual describes in more detail

- HQSE guidelines
- Manufacturing guidelines
- Hardware production
- Software installation and Testing
- Assembling
- System testing
- Cabling manufacturing and testing
- Factory tests for assembled series product

7.1 Packaging and delivery

Text, STMA-78200 - Guidelines for packaging, transport and storage are given in M9.2 Manufacturing Manual.

7.2 Installation and commissioning

Text, STMA-78206 - Constraints to Installation and Commissioning are included in M9.3 Installation Manual.

7.3 Testing and certification of specific STM implementations

Text, STMA-78208 - Testing and certification of specific implementations of the STM are not in the scope of the development project. Trains that are fitted with the STM, either retrofit or new build projects, are subjected to rolling stock assessment and certification according to the EU Directives and National legislation for the countries in which the train is foreseen to operate.

8 Integration and testing

8.1 Master Test Plan

Text, STMA-78203 - In the early phases of the project, the test strategy has been defined in the document T1.0 Master Test Plan.

• Input and output documentation
• Testing Approach
• Test levels

The following test have defined and elaborated:

• Hardware Unit Test
• Software Unit Test
• Software Module Test
• Module Integration Test
• Profibus interface Tests
• EMC test
• System Test
• Environmental Test

The Master test plan furthermore elaborates on:
Test organisation, structure of meetings, structure of reporting, completion, test environments, automated test environment, office setup, test process management, defects procedure, change procedure, test process criticalities and mitigations, test effort estimation and test schedule.

The V1.0 Validation Plan (incl. V1.1 update) elaborates on functional safety tests of ATBEG and ATBVv functions, test of the diagnostic functions, interface tests, operational scenario tests, including STM control functions.

9 Assessments, audits and test witnessing

9.1 NoBo, DeBo, ISA assessment

Text, STMA-78196 - TÜV SÜD has been contracted as the Assessor to perform the NoBo, DeBo and ISA assessment of the STM ATB V1.0 product development.
The certification process for STM ATB V1.0 was concluded successfully in 2020.

The development of STM ATB V1.1 is based on STM ATB V1.0. For this purpose TÜV SÜD has been contracted again as the Assessor to perform the NoBo, DeBo and ISA assessment
The assignment comprised of:

- Assessment of the corrected STM ATB V1.0' license dossier *);
- Assessment of STM ATB V1.1.

The assessors questions, remarks and findings are recorded in a List of Open Points (LOP). Separate LOPs are used for the ISA, NoBo and DeBo assessment.

*) Prior to the publication and handover of the STM ATB V1.0 license dossier, the entire dossier has been anonymised and (references to) norm texts have been removed, making the STM ATB V1.0 dossier unsuitable for future certification purposes. The STM ATB V1.0 license dossier has been corrected to enable the use for STM ATB V1.1 certification.

9.2 Plan assessment

Text, STMA-78438 - the STM ATB V1.0 Top Level project plans, as described in Ch 3.2 of this report, have been assessed. The remarks have been documented in the LOPs.
The plans have been updated for the modifications in STM ATB V1.1.

9.3 Internal audits

Text, STMA-78194 - During each life cycle phase of the STM ATB project internal audits have been held. The results of these audits are documented audit reports, which are stored in SVN. All audits have been held on basis of ISO9001 and EN50126, EN50128 and EN50129 standards.
The early life cycle phases (1, 2, 3 and 4) have been audited by the ERTMS-NL safety manager. The system requirement specification has been assessed by representatives from the main stakeholders (ERTMS-NL, NS and ProRail).
For the architecture, the design, implementation and the test phases (5,6,7,8 and 9) an external auditor team with qualified auditors from the electronics industry and from the railway industry have been contracted to perform audits on the project management, quality assurance, safety assurance, design, the implementation and testing processes.
For the modifications in STM ATB V1.1 an internal audit was held on project management, change

control and quality assurance.
The findings from the audits have been resolved and where necessary, corrective actions have been implemented.
No blocking issues remain.

9.4 External audits

Text, STMA-78195 - The Assessor has held a number of audits covering the quality and safety processes, requirement specifications, requirement management, configuration management, system architecture, system design, module design, software development ane software testing within the STM ATB project.
Findings have been followed up by means of the LOP. The results of the Assessor audits have been summarised in the Assessor reports. For the modifications in STM ATB V1.1 no external audits have been held.

9.5 Test witnessing

Text, STMA-78192 - During the product development of STM ATB V1.0 ISA has held software test witnessing sessions at the test team of the STM ATB project.
The hardware fault injection tests at Neways Electronics have been witnessed.
Also the T9.0.2 system level tests at Ricardo Rail and the T9.0.3 system level tests at Multitel have been witnessed.
The result of the test witnessing are summarised in the assessor reports.
For the modifications in STM ATB V1.1 no additional testwitnessing was deemed necessary.

10 Acceptance and handover

10.1 Acceptance and handover process

Text, STMA-78193 - On the request of Nederlandse Spoorwegen, the STM ATB project development team will continue to deliver product support while STM ATB V1.1 is being rolled out over the NS fleet in ERTMS retrofit projects.
Dependent on operational experience, future modification may be required. The hand-back of the STM ATB V1.1 product development dossier to the ERTMS-NL program is under discussion.

10.2 Acceptance and handover deliverables

Text, STMA-78207 - Deliverables will be made available to suppliers under a license agreement, as mentioned in the previous paragraph. Further practical arrangements will be elaborated when necessary. Some technical support will be available.

10.3 Product Safety Approval

Text, STMA-78209 - Product safety approval is limited to the delivery of an ISA report that enables the product to be used in revenue service, taking all SRAC's stated in this safety case an (if applicable) any imposed conditions from the ISA into account.

10.4 EC type certificate

Text, STMA-78204 - Compliance to European directives has been demonstrated in the technical documentation and will be assessed according to EC/2010/713, module CB. Evidence will be included in the technical file for STM ATB V1.1.

10.5 RIS compliance

Text, STMA-78205 - The compliance of STM ATB to the ATBEG requirements will be stated in a DeBo statement, that can be used during the DeBo assessment of Rolling Stock equipped with STM ATB.

10.6 EC declaration of conformity

Text, STMA-78198 - The EC type certificate will enable Nederlandse Spoorwegen to issue an EC declaration of conformity for STM ATB V1.1.