

Quality and Riskmanagement System (QRM) Annex 3 to the GTC for the Procurement of Rolling Stock Components (GTC-RKomp)

- 1 Scope of application, purpose and content**
- 1.1 This Annex shall apply to interoperability components (IO), safety-relevant components (SK) and operations-relevant components (BK) and all goods and services connected therewith (hereinafter referred to as “products”). It shall describe the minimum requirements of the company’s QRM and set out rights and obligations in relation to the long-term safeguarding of product quality, safety and availability. It shall supplement the provisions of the relevant legislation, in particular with respect to rail interoperability and railway and product safety at locations where rolling stock is operated, and also regarding ISO 9001, IRIS Standard Version 2, RAMS standards (EN 50126, EN 50128 and EN 50129) and requirements specific to the customer and operating site.
- 1.2 This Annex shall specify and govern the company’s principal technical and organisational quality-assurance measures and processes in all contract fulfilment phases that are required in order to achieve “zero fault” quality targets and to meet the requirements set out in sections 3.6 and 8.1 of the GTC-RComp. The QRM must pervade all areas of the company’s operations as well as its collaboration with SBB. It must focus on the SBB incoming goods inspection (see *the Logistics Annex*).
- 2 Existence and demonstration of the company’s QRM system / the company’s reporting obligation**
- 2.1 The company shall maintain in existence and consistently apply a state-of-the-art company-related rail-technology QRM system, appropriate in terms of its nature and scope, together with any project-specific QRM system required of the company for product development, design, creation, manufacture, testing, approval, delivery and maintenance, until the products are no longer sold. The company shall introduce effective processes and procedures for the QRM system’s implementation. It shall invite SBB in good time to the agreed design reviews and tests.
- 2.2 SBB shall expressly reserve the right to demand from the company to apply special quality methods, such as handling SBB’s complaints in accordance with the 8D reporting methodology. If required to prove that it has done so, the company must submit the respective evidence to SBB within 14 days.
- 2.3 The company shall notify SBB of significant changes to its QRM system at any time during the term of the contract. It shall submit relevant documentation and evidence to SBB without being called upon to do so as part of a documented derogation procedure. It shall report the renewal or withdrawal of the relevant certificates directly to SBB in writing. Section 7.2 shall apply to changes.
- 2.4 The company shall notify SBB of all facts that are notifiable to examining agencies, and of any instructions issued by such agencies to the company or its subcontractors. If necessary the company shall release these agencies from their confidentiality obligation.
- 3 The company’s quality representatives**
- The company shall appoint responsible contacts to monitor compliance with the requirements set out in this Annex (quality representatives, obsolescence management representatives, etc.).
- 4 Consultation of third parties by the company**
- 4.1 If the company employs third parties to deliver its services, it must fully integrate those services into its QRM system and show SBB on request that it has done so. The company shall maintain an appropriate system for the assessment, selection and regular evaluation of third parties employed by it.
- 4.2 The company must be able to prove that it has placed third parties employed by it under an obligation to comply with the obligations assumed by the company pursuant to this Annex, or must itself take steps to safeguard the quality of their pre-supplies and supplies. SBB may request from the company documented evidence that it is convinced of the effectiveness of the QM systems of the third parties employed by it. Furthermore, SBB may request from the company written evidence of its subcontractors’ testing and other quality assurance procedures. This shall apply even when third parties are introduced to the company by SBB.
- 5 SBB’s inspection and auditing rights**
- 5.1 SBB shall be entitled at any time to monitor contract performance, conduct progress checks and quality inspections, request information and inspect any documents. To this end, within the company’s house rules and subject to the protection of its manufacturing and business secrets, SBB shall have free access to the premises of the company and its subcontractors, in particular laboratories, workshops, etc., where work under the contract is performed. In addition, SBB may at any time request a copy of the company’s current QM manual and that of the third parties employed by it. SBB may request from the company further evidence of the existence and effectiveness of its QRM systems, and also – in pursuit of continuous improvement – conduct process, product and requalification tests on the company’s premises based on its own experiences from other contracts with the company. SBB representatives shall enjoy the same inspection and auditing rights.
- 5.2 The company shall be notified of audit results. If any shortcomings are identified, the company shall undertake to draw up a timetabled action plan in consultation with SBB, to implement it on schedule, and to notify SBB accordingly without being called upon to do so.
- 6 Safeguarding product and process quality / product approval / FAI**
- 6.1 The company’s planning, organisation and implementation of its quality assurance processes must ensure that quality is comprehensively monitored and controlled. It shall formulate its QRM to ensure that contractual requirements are understood, recorded, met, monitored and documented.
- 6.2 In the development, production and testing phases the company shall apply suitable preventive quality planning methods such as manufacturing feasibility analysis, reliability studies and FMEA, and also undertake process planning. It shall draw on its experience of similar projects. The company shall coordinate its manufacturing and testing conditions for prototypes and pre-production parts with SBB. The company shall at the request of SBB coordinate its testing equipment and methods at the series production stage with those of SBB. If testing is conducted by third parties, they must be proven to be accredited for the purpose.
- 6.3 Production processes, product testing and product approval shall be conducted on the basis of technical regulations (laws, TSI), standards issued by recognised organisations, SBB or UIC technical rules, quality standards (IRIS standard), or by procedures recommended as conforming to the state of the art. SBB may participate in the respective tests.
- 6.4 Before commencing series production, the company shall submit on schedule the agreed quantity of product prototypes manufactured under series production conditions, including an initial sample test report and documents on safety data collection, together with a safety data sheet. Series production deliveries may not begin until product

approval has been obtained from SBB (*FAI report and SBB approval certificate or FSII initial installation test report*). Prototypes must be unambiguously labelled as such. SBB may request initial sample tests / initial installation tests after a suspension or interruption of deliveries or after production facilities have been shut down for more than one year.

- 6.5 The company shall prepare acceptance inspection certificates 3.1 or higher level according to DIN EN 10204 standard as evidence of material properties. Such certificates shall be made available to SBB within 24 hours on request.
- 6.6 Should test results indicate defective products before or after delivery to SBB, the process must be immediately interrupted and corrected and the products concerned discarded. All inventory stocks still available, together with subsequent batches, must undergo a screening inspection for the defect concerned until the cause of defect has been eliminated. Corrective measures must be initiated without delay and documented. SBB must be notified immediately in writing. Products already in possession of or on their way to SBB must be screened and inspected by the company on site, or alternatively sent back to the company at its expense according to prior scheduling.
- 6.7 Rejected products shall be returned to the company. It shall undertake to analyse every shortcoming and to notify SBB as soon as possible of its causes, the immediate corrective measures it has planned and initiated, their effectiveness, and their consequences in terms of deadlines and quality. Furthermore, the company shall undertake to notify SBB of any effects on new evaluations, operating / commissioning permits, costs, LCC, reliability, availability, maintainability, safety (RAMS according to EN 50126, EN 50128 and EN 50129) or other contractual items.

7 Document control / traceability

- 7.1 The company shall transparently document all quality assurance measures (manuals, regulations and directives, tests, internal audits, etc.) taken between the signing of the contract and the discontinuation of the products, together with their results (records, evidence, test documents and certificates, certificates of conformity, complaint analyses, etc.), providing SBB on request with the so-called product life cycle according to EN 62402.
- 7.2 Traceability must be such (*professional configuration management (CM) according to ISO 10007*) that the time of delivery, delivery data, production stage, production location, production company, production period and the competent conformity testing agency may be unambiguously identified. There must be a functional tracking system covering the entire chain (including subcontractors and component suppliers). The company shall supply SBB with all the configuration data and configuration audit reports in machine-readable form.
- 7.3 The company shall be responsible for ensuring that a procedure for the control of records, including guaranteed access rights to all information and measures, particularly for the control of safety-relevant information, is described and observed. The company must ensure that documents are properly prepared, labelled, version-identified, checked, approved, circulated and made available at the place of performance, and that following invalidation they are withdrawn and archived in a controlled procedure.
- 7.4 The company shall prepare full, intelligible documentation for all processes necessary for comparison, receipt, processing and management, as well as guaranteed access rights to all information on contract fulfilment and on the operating integrity of rolling stock, its subsystems and components. This shall in particular include processes ensuring that SBB is provided with reliable information conforming with the relevant regulations.

8 Overall responsibility of the company

Overall responsibility for product conformity shall lie solely with the company, even if individual stages of the conformity assessment process are conducted under the responsibility of conformity assessment agencies or national safety authorities at locations where rolling stock is to be used.

9 Costs

SBB may invoice the company for the audit costs that it incurs (see section 5). The company shall bear its own internal costs.