

# Fragenkatalog

# QS infrastructure

#### Prozesselement: A - management-system

Frage 1:	Does a certified QM system exist?
Beschreibung:	* Does the scope correspond to the product being audited?
	Evidence is e.g. a certificate specific QMS or other certificates - IMS A5

Frage 2:	Are the customers and their requirements known in the company?
Beschreibung:	* Contractual content of individual contracts/framework agreements  * Identification, procurement and communication of information sources
	Evidence is e.g. Contract with publisher (e.g., standards) DB Kommunikation or DB Netz AG (distributor TM)
	* Control of information such as standards, guidelines, DBS, etc.  * Obligation of suppliers to the DB AG Code of conduct or own, adequate rules (Responsibilities and information requirements) Evidences are e.g. Process description, Current Ril 120.0381, Current EVB quality assurance

Frage 3:	Are methods, processes of improvement established / deployed?
Beschreibung:	* KVP, KAIZEN, suggestion schemes, idea management are excisting and effective  * Cause-and-effect analyzes (Ishikawa, 8 D, 5 Why) are used for errors, problems  * FMEA process / product are implemented Evidence is e.g. 8 D template
	/ example, process FMEA (active or planning)  * Tracking of measures from past internal or external audits

Frage 4:	Is the leadership actively involved in the implementation of the management system?
Beschreibung:	* Management evaluation and alignment of the system to meet customer requirements are documented and communicated
	Evidence is e.g. Management review (evaluation/ report), evaluation of effectiveness of measures
	* Appropriate performance indicators for quality data such as Complaint rate, error rate (FPY), delivery times, etc. are fixed and updated continuously

Evidence is e.g. Determination of customer satisfaction (DB), determined
complaint rate/ actions/ effectiveness check

Frage 5:	Are legal requirements such as an occupational safety, environmental protection etc. integrated into the management system and documented?
Beschreibung:	* Identification and control of requirements
	* Is there an integrated management system
	* Additional certifications
	* Integration into the QM documentation
	* Regular inspection Evidences are e.g. Risk assessment with regular
	updating, protocol plant inspection / action plan and effectiveness check,
	proof of disposal
	* Revision control of standards, laws, etc.

Frage 6:	Is a process for the customer satisfaction assessment implemented?
Beschreibung:	* Process description
	* Customer satisfaction assessment categories
	* Assessment criteria
	* Continual improvements/ actions from the customer satisfaction
	assessment

Frage 7:	What elements are anchored in the company's Code of Conduct?
Beschreibung:	Is there a code of conduct or what does the company's Code of Conduct include?
	* Corruption in kind of gifts / invitations?
	* Child labor
	* forced labor
	* Non-discrimination / anti-discrimination
	* Union releases visible
	* Mutual respectful treatment
	* Systems for recording working time and breaks

#### Prozesselement: B - staff/qualification

Frage 1:	Is the suitability and availability of the employees, which are necessary for the realization of internal and external customer requirements, ensured and maintained?
Beschreibung:	* Required qualification  * Qualification matrix, with development potential  * Training: work safety, environmental protection, hazardous materials, quality (methods, objectives, tasks) -> effectiveness check  * Eyesight (e.g., ISO 9712 or DIN EN 13018)  * Driving license for vehicles and means of transport

	* Handling of testing and measuring equipment  * Fire protection, data protection officers, first responders, eviction workers, etc. are named, clear powers are defined
Frage 2:	Is the transfer of responsibilities and powers for the product and process quality as well as for the production facilities regulated?
Beschreibung:	* Signature regulation are existing and effective  * Required designations and assignments are available  * Authorizations for blocking, release and special releases are regulated  * Notification and reporting channels are defined and effective  * Adequate job descriptions, functional descriptions are existing and effective  * Order and tidiness in all areas determinable  * Quality notification / recording is managed
Frage 3:	Are tools for continuous improvement of motivation of the employees effective used?
Beschreibung:	* Effectiveness and conformity of the organization of KVP (continual improvement process, indicator of employee motivation) and suggestion schema  * Information about quality(target / actual values) is available and understood  * Quality islands are effective  * Influence of quality is understood locally, implementation of the 4-eye principle (not an indicator of employee motivation)  * Self-assessment  * Regular appraisal interview  * 360 degree Feedback
Frage 4:	Is a suggestion system / complaints management available to promote employee motivation?
Beschreibung:	* Suggestion System (including suggestion box)  * Idea Management (including suggestion box)
Frage 5:	Is a complaint management available?
Beschreibung:	Complaint management (including complaint box):  * Requirement 3 clicks away from the Main Intranet Page up to message = 10 points
Frage 6:	Are there sufficient personnel with the necessary qualifications to carry out the necessary quality audit?
Beschreibung:	* For example: Quality Officer Certificate, VDA 6.3-Certificate, EOQ-Auditor, Specialist welding engineer, etc.
	Alternative employees with many years of professional experience in

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quality management

# **Prozesselement: C1 - purchasing/procurement**

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Frage 1:	Is it ensured that only released and qualified suppliers/ sub contractors are appointed?
Beschreibung:	* Obligation of suppliers to the Code of Conduct of DB AG or their own, adequate rules  * Supplier selection on the basis of references, prototypes, initial samples, operating trial contracts, etc.  * Conclusion and supervision of quality assurance agreements (QAA)  * Dependencies and substitution options are appropriate  * Supplier audits to assess Q capability are systematically planned and executed  * Supplier talks conducted and documented
Frage 2:	Are there sub contractors which deliver products from the LgP/ HPQ overview?
Beschreibung:	* If NO, the question is not evaluated and rated with nb -> the next question is C2.  * If YES, then the next question is C1.2 on worksheet PE C1.2.
Frage 3:	Is the agreed quality of the procured products ensured and measures taken in the event of nonconformities?
Beschreibung:	* Is the agreed quality of the procured products ensured and measures taken in the event of nonconformities?
Frage 4:	Is it ensured that the test specifications are suitable for verifying product specifications?
Beschreibung:	* Test the right and important adequate and effective  * Test schemas and test criteria are transmitted and known  * Drawings / schemas are available and understood  * Standards / specifications are known and available in the company  * Order specifications and order clarification are documented  * Test / acceptance criteria are accepted  * Good / bad pictures are available, understood
Frage 5:	Is the quality performance of the supplier assessed and are receivables / measures initiated in case of deviations?
Beschreibung:	* Are there records of discussions about quality  * agreement of analysis of cause and action to be taken (8 D, FMEA, etc.)  * evaluation of failure hot spots/challenging suppliers  * evaluation is carried out on a comprehensible and transparent schema/ procedure
Frage 6:	Does the goods receipt (incoming goods department) have a suitable

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	infrastructure and logistics?
Beschreibung:	* Storage and transport areas are appropriate  * Lighting and workplace space are sufficient  * Lock camp (marking) is clearly demarcated and protected  * Requirements for purity, climate, humidity, etc. are known and fulfilled  * suitable means of transport  * access permissions
	* Specifications for delivery with vehicles and load securing are complied

Frage 7:	Is the delivery and storage of the materials appropriate?
Beschreibung:	* Maybe separation delivery and storage?  * Requirements for packaging and storage are known and implemented  * Packaging, delivery takes place acc. the requirements  * Warehouse management system is set up and effective  * Stock principles such as FIFO (first in / first out) are implemented  \-> internal information flow
	* Order and cleanness are implemented sustainably  * Climatic conditions during transport are monitored and maintained  * Protection against damage, pollution ensured  * Labeling of all products as required  * Traceability, test status possible at any time (if required)  * Mixing security given  * Lock camp (furnished, marked and used)  * Localization of materials in the system  * External footprint/ external storage

### **Prozesselement: C1.2 - Purchasing/ Subcontractor**

Frage 1:	Were all required monitoring audits planned and done within the fiscial year?
Beschreibung:	* Usage of the DB AG Questionnaire, naudit schedule/ audit program is available
Frage 2:	Are audit reports and notes of corrective actions/ deviations incl. dead lines and effectiveness checks available?
Beschreibung:	Documentation
	<u>,                                      </u>
Frage 3:	"Were the audit assessments above than 90 % points (Q1 level similar to the DB AG Q1 rating)?
Beschreibung:	* If the answer is "Yes", the question is not assessed -> continue with question 16 from process element C1.  * If the answer is "No", continue with question 24 from process element C1.2.

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Frage 4:	Are product approvals regulated according to EVB?
Beschreibung:	* Q2-Decreases, Sorting out, SFI, etc.
	<pre>  * Otherwise long-standing professional experience in Quality Management</pre>

# Prozesselement: D1 - Product/ process planning

Frage 1:	Are the customer requirements known and how are they conveyed? Also to subcontractors?
Beschreibung:	<ul> <li>* Implementation of the contract contents in the company</li> <li>* Rule Drawings</li> <li>* Standards</li> <li>* Specifications</li> <li>* Specification books</li> <li>* Technical Delivery Conditions (eg. Deutsche Bahn Standards (DBS),</li> <li>TL, Railway Standards (BN))</li> <li>* Techn. Messages (TM)</li> <li>* Access, Storages and steering</li> </ul>

Frage 2:	Are the required qualifications / approvals known and attained?
Beschreibung:	

Frage 3:	If a process FMEA has been created, will it be updated in case of changes and are the measures implemented?
Beschreibung:	* Update on changes  To consider are:  * Customer requirements  * all production stages, even from suppliers (outsourced processes)  * important parameters / characteristics, legal requirements  * material
	* Traceability, environmental aspects

Frage 4:	Are the necessary plans for dimensional, material and functional tests (QM plans) available and are suitable production and test documents prepared?
Beschreibung:	* For significant features labelling and identification is carried out  * Adequate test schema is available  * tests at convenient points of the product realization are planned, implemented, documented  * Test instructions are available, applied

* Clarification of acceptance criteria
* Defined, known, documented, process parameters (e.g., pressures,
temperatures, times, speeds)
* Data on machines / tools / tools known and documented
* Test specifications (important characteristics, test equipment, methods,
test frequencies) available
* Intervention limits defined in process control charts - machine and
process capability certificates, known, documented
* Operating instructions and work instructions available, understood

Frage 5:	Is a short-term reaction ensured in the event of complaints and are measures planned to supply the customer with products?
Beschreibung:	* Contingency plans exist and risks are known and evaluated  * Measures to reduce risks are implemented  * Capacities and response times are known and planned  * Modifications to the systems, special equipment and tools are documented and taken into account in the emergency plan  * Use of external capacity is planned  * Responsibilities and powers are clearly defined in the emergency plan

Frage 6:	How are the requirements for occupational health and safety fulfilled?
Beschreibung:	* DB guidelines
	* Regulation on hazardous substances (operating instructions, subsitution
	checks)
	* Risk assessment (GuB) are available and kept up to date
	* Tests of means of transport, electr. Equipment, shelves, ladders, PPE,
	cranes, gates, load means are currently performed
	* Operating instructions available, understood
	* Evacuation plans (including identification of the current location) are
	defined and escape routes are identified
	* Fire protection measures have been implemented and maintained
	* Evacuation exercises currently performed
	* Occupational safety instructions (for internal and external) and
	workplace inspections
	* Are personal protective equipment available to employees?
	* Are first aid kits available?

### **Prozesselement: D2 - Equipment/ Facilities**

Frage 1:	Are the production facilities / tools suitable to meet the product-specific quality requirements?
Beschreibung:	* Machines and process capability certificates for important characteristics / process-determining parameters are available and maintained * Forced control/ Regulation important parameter is defined and understood * Warnings in case of deviation from target specifications (for example,

lamp, horn, shutdown) are available
* Maintenance, maintenance status of tools / systems / machines
(including preventive, planned maintenance) is monitored
* Requirements for particle freedom, electrostatics, etc. are known,
monitored and adhered to
* Structural condition of the building

Frage 2:	Can the quality requirements during production be effectively monitored with the measuring and testing equipment used?
Beschreibung:	* Required test equipment has been determined and needs are monitored  * Reliability and functional tests are carried out and documented (intervals)  * Measuring accuracy / test equipment capabilities are determined  * Data collection and readability are proven  * Calibration of the test equipment is planned

Frage 3:	Are the work and test stations adequate to the requirements?
Beschreibung:	* Ergonomics
	* Lighting, ventilation, air conditioning
	* Order and Cleanness
	* Environmental Protection
	* Environment/ Handling of components
	* Marking of hazardous areas

Frage 4:	Are the requirements for production and test documents met?
Beschreibung:	* Completeness of the Manufacturing- / test steps  * Tools and test Equipment Used
	* Marking of the Production / test status
	* Documentation of Results

Frage 5:	Are the release of production starts and the recording of setting data as well as the deviations regulated?
Beschreibung:	* Completeness of the manufacturing / test steps  * New/ changed products are monitored separately  * Standstill of the facility/ process interruptions are documented or planned  * Repair, tool change, material change (e.g. batch change) are documented or planned too  * Changed manufacturing parameters are communicated, verified and monitored  * First-time inspection with documentation  * Production parameters are up to date  * Release / change status of tools and test equipment are up to date  * Implementation of correction and improvment action provable, effective and scheduled

Frage 6:	Are the quantities/ production lot sizes production quantities matched to the
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	requirements and is the forwarding between the operations regulated?
Beschreibung:	* Are Sufficiently suitable means of transport available
	* Defined storage bins
	* No or small Intermediate storage
	* KANBAN principle implemented
	* Is "just in time" in time realized
	* First in/ first out implemented
	* Change status communicated, documented
	* Quantity acquisition/ evaluation
	* Communication, Information planned and effective

Frage 7:	Are rejects, rework and good parts as well as internal residual quantities separated, marked and secured against mixing/ confusion?
Beschreibung:	* Blocked storage; Restricted areas established and secured  * Marked containers are set up and secured for scrap or rework  * Defective products are marked  * Error characteristics are recorded, evaluated  * Defined rework stations in production are set up, monitored  * Reworking is planned  * Defined, effective procedures for handling special releases

Frage 8:	Are tools, equipment and test equipment properly used?
Beschreibung:	* Protection against damage
	* Order and cleanness (5 S)
	* Defined repository (computer traceability)
	* Environmental influences
	* Labeling
	* Defined release and change status
	* Check before each use

Frage 9:	Is handling of expiration (date of expiry) controlled in production?
Beschreibung:	* Documented control
	* Labeling/ marking, e.g. no use!
	* Separation/ Disposal

Frage 10:	What are the working conditions?
Beschreibung:	* Hygienic conditions: sanitary, canteen, etc.  * Separate dorms from the goods receipt/ production

### Prozesselement: D3 - Error analysis/ error correction

Frage 1:	Are product and process data recorded completely and evaluable?
Beschreibung:	* Demonstrate how the company controls its processes, which data is collected and evaluated
	* Value cards

* Error collecting cards
* Control charts
* Data collection
* Process parameters (e.g., temperature, time, pressure)
* Plant shutdown
* Parameter change
* Availability, downtime, etc.

Frage 2:	Are quality and process data statistically evaluated and improvement programs derived from it? Does an escalation management exist?
Beschreibung:	* Process capabilities  * Types of errors/ error frequencies  * Error costs (of nonconformity)  * Process parameters  * Rework  * Blocking messages  * Cycle times, throughput times  * Reliability/ failure behavior

Frage 3:	In the case of deviations from product and process requirements, are the causes analyzed and any implemented corrective measures checked for effectiveness?
Beschreibung:	* Supplementary exams  * Cause/ effect diagram  * 5xWhy  * Ishikawa  * Error analysis  * Process capability analysis  * Q compass  * 8D method  * Quality Islands/ Quality information points

Frage 4:	Are processes and products regularly audited internally?
Frage 4: Beschreibung:	Are processes and products regularly audited internally?  Audience events are for example:  * Audit program is implemented  * New projects/ processes/ products  * Non-compliance with quality requirements (internal/ external)  * Proof of compliance with quality requirements  * Identification of potential for improvement   Deviation reports are to be forwarded to the persons responsible and the improvement measures must be followed. An effectiveness check of the
	implemented improvement measures has to be carried out  For instance to consider are:

* Customer requirements
* Important characteristics
* Function
* Process parameters/ capabilities
* Labeling, packaging
* Defined processes and procedures

#### Prozesselement: D4 - Packaging/ Shipping/ Storage

Frage 1:	Is it ensured that products and materials are stored according to requirements?
Beschreibung:	<ul> <li>* Stock quantities and location are defined in relation</li> <li>* Protection against damage</li> <li>* Order, cleanliness, overfilling (storage bins, containers)</li> <li>* Mnitoring the storage time</li> <li>* Environmental influences, air conditioning</li> </ul>
Frage 2:	Is the handling of the minimum shelf life (including expiration dates) regulated?
Beschreibung:	<ul> <li>* Regularly documented, scheduled checks</li> <li>* Spatial separation/ labeling of non-compliant material</li> <li>* Disposal concept</li> </ul>
Frage 3:	Are confusions of packaged products excluded?
Beschreibung:	* Spatial separation  * Identification/ marking
Frage 4:	Are the products protected against external influences during transport/ storage?
Beschreibung:	<ul> <li>* Packaging instructions (pictures)</li> <li>* Suitable material (protection against damage)</li> <li>* Transport packaging</li> <li>* Safety instructions (sticker)</li> </ul>
Frage 5:	Will the legally compliant loading and the safe transport of goods be ensured?
Beschreibung:	<ul> <li>* Loading instructions</li> <li>* Load securing</li> <li>* Dangerous goods marking</li> <li>* Transport damage protection</li> <li>* Distribution logistics (truck, rail)</li> <li>* Fixed logistics companies with contracts</li> </ul>

### Prozesselement: E - Environmental protection

Frage 1:	Do an environmental management system exist?
Beschreibung:	* Environmental Management System in accordance with the internationally recognised standard ISO 14001

Frage 2:	How is the product life-cycle managed?
Beschreibung:	Does a life cycle analysis ( resource procurement> production> transportation> usage> disposal/ recycling) exist?
	Is an eco balance (in accordance with ISO-Standards 14040 and 14044) provided:
	* The eco balance has four requirements: (1) definition of goals and examinitation limits, (2) balance, (3) outcome estimation, (4) evaluation  * Two fundamentals are considered: inter-media consideration (effect of damage to environmental media) and mass flow integrated consideration (where each mass flow - raw material charge and emissions - is included)  * Assessment and criteria are included in management decisions  * Evidence/ documentation e.g. ISO 14001 Certification

Frage 3:	How are emissions determined and reduced? (Reference to anthropogenic and natural emissions)
Beschreibung:	* Accuracy of key data to detect emissions e.g. CO2 balance  * Monitoring of direct emissions  * Proceedings are implemented e.g. positioning balance limitation / identification of the origin of emissions/ emissions calculations/ development of reduction goals / reporting  * Are actions (such as programmes for employees/ technologies for reduction/ renewable energy/ transportation optimization) in place?  * Evidence of EMAS-Certification/ ISO-Certification 14001

Frage 4:	How is unnecessary material usage avoided?
Beschreibung:	* Actions/ methods to optimize material usage and reduction of material
	waste
	* Recycling system for material waste
	* Optimization of production methods e.g. use of correct instruments,
	standardization
	* Communication with responisble person for material selection
	* Evidence / existence of training courses for employees

Frage 5:	How is the waste segregation process managed?
Beschreibung:	Does a transparent waste management system exist? Guidelines for waste separation:
	* Waste separation responsibility  * Waste inspector  * Goals for reduction of waste

* Evidence/ documentation e.g. book for employees/ environmental
balance/ disposal bills

Frage 6:	How are chemicals stored and disposed of?
Beschreibung:	Regulations for chemical usage are documentated and communicated:
Describering.	* Inventory and risk assessment with reference / proof of legally compliant storage; usage and disposal of waste is available:  * Risk assessment in accordance with Regulation (EC) No 1272/2008  * Labelling requirements are satisfied  * Safety data sheets are completed  * Briefing and instruction of employees and proof of expertise (where applicable)  * Employment medical duty examination (in the case of working with dangerous substance) is maintained  * Storage requirements are fulfilled:  * Separate storage for dangerous/ flammable chemicals in accordance with EN 14470-1  * Preventative actions are taken where required  * Disposal of dangerous substances  * Employee responsible for preventative actions determined and known to all  * Evidence and all required documentation in place
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Frage 7:	What is the waste water management process?
Beschreibung:	* Applicable legal regulation/ purpose of water and source of sewage water is documented and known * Data relating to type of water ( drinking water; industrial water) / annual total consumption of water in litres / costs are known and documented * Explanation of industrial water conditioning (where applicable)

Frage 8:	How is hazardous radiation determined, e.g. radioactive radiation?
Beschreibung:	If applicable, ask how to proceed in the event of a fault.

### **Prozesselement: F - Sustainability**

Frage 1:	Does an energy management system exist?
1	Consider the transposition of the Energy Efficiency Directive 2012/27/EU on energy efficiency into national law!

Frage 2:	How is the energy balance/ energy usage monitored?
Beschreibung:	* Is an energy management system (in accordance with ISO 50001/ EN 16247) in place? KPIs are documented and analysed
	* Is there an overview of energy usage and energy inputs (type and

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quantity)?  * Tracking of actions / methods for potential energy savings  * Evidence e.g. energy flow diagram, energy table	
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Frage 3:	How are energy saving goals/actions defined?
Beschreibung:	* Goals and actions are based on an energy balance and are transparent
	for all employees
	* Incentive system to increase employee awareness
	* Evidence e.g. documentation of energy saving goals

Frage 4:	How is it ensured that machinery is not used without a load?
Beschreibung:	Key data for total investment effectiveness ( i.e. the value add of the system) are known and documented:  * Shut off vs. No load  * Availability, power and quality of machinery

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