

Organisation and management systems		Quality
Fundamentals of quality assurance		120.0381V17
List of products subject to quality inspection –		Page 1
Telecommunications for rail operations		

Products subject to quality inspection

Telecommunications for rail operations

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Organisation and management systems	Quality
Fundamentals of quality assurance	120.0381V17
List of products subject to quality inspection – Telecommunications for rail operations	Page 2

Table of contents

Part 1: General provisions

1	Purpose, general information	3
2	Products subject to inspection	4
3	Quality capability of the contractor	5
4	Inspection levels	6
5	Product manufacturing processes, measuring equipment, special processes/manufacturing methods	7
6	Manufacturer-related product qualification (HPQ)	8
7	Regular inspections	9
8	Failure mode and effects analysis (FMEA)	10
9	8D report	12
10	Documentation and certificate of conformity	13
11	Marking	13
12	Contractor's management of subcontractors	14
13	Specific regulations for the technical disciplines Telecommunications product area	15
14	List of abbreviations	16

Part 2: Definition of the minimum scope of quality assurance measures for products (parts, components and systems)

Organisation and management systems	Quality
Fundamentals of quality assurance	120.0381V17
List of products subject to quality inspection – Telecommunications for rail operations	Page 3

Part 1: General provisions

1 Purpose, general information

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| <p>(1) The list of products subject to quality inspection (LgP) is part of the "Quality Assurance in Procurement" policy, 120.0381, issued by Deutsche Bahn AG (DB AG). It lists all infrastructure products to be procured within the respective technical discipline that are subject to mandatory quality assurance by DB AG, and sets out the quality assurance measures and their scope.</p> <p>(2) The provisions set out herein apply both to the procurement of these products by DB AG and its affiliated companies, and to the procurement of these products by contractors and subcontractors in connection with contracts awarded by DB AG and its affiliated companies.</p> | Basis |
| <p>(3) The list of products subject to quality inspection (LgP) consists of</p> <ul style="list-style-type: none"> - Part 1: General provisions - Part 2: Definition of the minimum scope of quality assurance measures for products (parts, components and systems) | Components |
| <p>(4) This LgP applies to the procurement of products for new construction and maintenance work on control-command and signalling equipment, i.e. it also applies to contractors carrying out re-conditioning or repair work.</p> | Scope |
| <p>(5) The work shall be performed in accordance with the contractually agreed documents and standards (e.g. EVB, DIN, EN, UIC, DBS, drawings, checklists and specifications).</p> | Applicable documents |

Organisation and management systems	Quality
Fundamentals of quality assurance	120.0381V17
List of products subject to quality inspection – Telecommunications for rail operations	Page 4

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2 Products subject to inspection

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| <p>(1) The LgP is drawn up by a team of subject matter experts together with representatives of the relevant product line support function of the internal customer and DB AG's Quality Assurance department.</p> | Creation |
| <p>(2) The products subject to inspection are assessed according to the following criteria and the risks resulting from these, and the results are documented internally in an evaluation matrix.</p> <ol style="list-style-type: none"> 1. Safety 2. Reliability 3. Reliability of supply 4. Special processes/manufacturing methods 5. Costs for unplanned maintenance work 6. Customer relevance | Evaluation criteria |
| <p>(3) In accordance with this risk assessment, the products subject to inspection are assigned to inspection levels (PS) I or II. The inspection levels form the basis for the quality assurance measures to be carried out by the contractor. Products of</p> <ol style="list-style-type: none"> 1. IL I: are subject to a product-specific inspection in all cases 2. IL II: do not require continuous product-specific inspection. | Meaning of the inspection levels |
| <p>(4) New products that are not listed in Part 2 but are comparable with the listed products shall be allocated appropriate quality assurance measures.</p> | New products |
| <p>(5) So-called COTS products (<i>commercial off-the-shelf</i> or <i>components-off-the-shelf products</i>), which are manufactured in large quantities but not specifically for Deutsche Bahn or the railway market (non-railway-specific requirements) and which can be used as they are, are generally not subject to inspection and are therefore not usually subject to quality assurance measures.</p> | COTS products |

Organisation and management systems	Quality
Fundamentals of quality assurance	120.0381V17
List of products subject to quality inspection – Telecommunications for rail operations	Page 5

3 Quality capability of the contractor

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| (1) DB AG's Quality Assurance department assesses the contractor's quality capability and classifies the contractor into category Q1, Q2 or Q3 ("quality capability assessment"). | Quality capability of the contractor |
| (2) Quality capability is evaluated through (system, process and product) audits carried out on-site at the contractor's premises, both at central production sites and at those relevant to the products in question. The questionnaires used for this purpose are available on the Deutsche Bahn AG Supplier Portal. | Audits, audit locations |
| (3) This quality capability classification is normally valid for one year and can be updated regularly as required. The update is carried out on the basis of an evaluation of quality data (e.g. complaints, product performance, quality data) and/or the results of audits conducted during the year (see routine monitoring). | Update |
| (4) The quality capability classification can be changed at any time if there are changes to the quality capabilities of the contractor or its subcontractors, to the product quality, or in ownership. | Change |
| (5) If a contractor does not achieve Q1 status in the quality capability classification, or if a contractor has been downgraded to Q2, measures shall be taken in consultation with the internal customer and the Procurement department to stabilise or develop the contractor. If procurement from this contractor is to continue, acceptance inspections, which are subject to a fee, must be carried out by DB AG's Quality Assurance department. | Failure to meet Q1 status, downgrade |
| (6) Unclassified contractors at DB AG are treated in the same way as contractors in category Q3. | Unclassified contractor |
| (7) The quality capability classification by DB AG's Quality Assurance department applies to all contractors who introduce products subject to inspection into the infrastructure; this includes contractors who do not themselves manufacture or recondition such products, but merely procure them from subcontractors, such as dealers or distributors. | Reconditioners, dealers and distributors |
| (8) For special processes or manufacturing methods, separate quality assurance measures may be required in accordance with ISO TS 22163:2018-01, Clause 8.5.1.2, e.g. a "manufacturer-related product qualification". | Special processes |
| (9) In individual cases or under certain conditions, remote audits may also be carried out instead of on-site visits | Remote audits |

Organisation and management systems	Quality
Fundamentals of quality assurance	120.0381V17
List of products subject to quality inspection – Telecommunications for rail operations	Page 6

4 Inspection levels

- (1) Allocation of the products to IL I/IL II and Contractor's quality capability classification - Q1, Q2 or Q3 - determine the type and scope of the quality assurance measures to be carried out by DB AG's quality assurance department and by the Contractor.
- (2) The scope of the quality assurance measures is fundamentally based on the tables below.

Scope

Table 1: Quality assurance measures for products of inspection level I

Products with inspection level	Contractor classification	Quality assurance measure
I	Q1	As part of its product inspection procedures, DB AG carries out spot checks on deliveries. Delivery with an inspection certificate 3.1 and a delivery approval/inspection record issued by DB AG.
	Q2	DB AG inspects every delivery. Delivery with an inspection certificate 3.1 and a delivery approval/inspection record issued by DB AG.
	Q3	Contractor suspended

Table 2: Quality assurance measures for products of inspection level II

Products with inspection level	Contractor classification	Quality assurance measure
II	Q1	DB AG accepts full inspection performed by the contractor. Routine monitoring of the contractor by DB AG. Delivery with a certificate of conformity in accordance with DIN EN ISO/IEC 17050-1*
	Q2	As part of its product inspection procedures, DB AG carries out spot checks on deliveries. Delivery with an inspection certificate 3.1 and a delivery approval/inspection record issued by DB AG.
	Q3	Contractor suspended

*These are usually retained by the manufacturer and must be made available on request. The statutory retention periods must be observed.)

Organisation and management systems	Quality
Fundamentals of quality assurance	120.0381V17
List of products subject to quality inspection – Telecommunications for rail operations	Page 7

5 Product manufacturing processes, measuring equipment, special processes/manufacturing methods

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| (1) | During audits carried out for the purpose of quality capability classification or routine assessment of the contractor's quality capability (see routine monitoring), the entire product manufacturing process is examined, from the initial enquiry through to production, inspection and delivery of the product. For certain products, audits of the product development process (for new products and, where necessary, modifications) may be carried out or specified by DB AG's Quality Assurance department; this applies in particular to interfaces between different manufacturers. Further details are set out in Section 13, which relates to the specific technical discipline. | Processes,
product
development |
| (2) | One of the key tasks of quality assurance is the monitoring of inspection criteria. Suitable measuring and inspection equipment is required to ensure the comparability of measurement and test results. Calibration is carried out using appropriate procedures and institutions. | Measuring
equipment |
| (3) | For measuring and inspection equipment used in the railway sector, the general requirements for the competence of testing and calibration laboratories in accordance with DIN ISO 17025 shall apply. Part 2 of this document lists, where applicable, the measuring equipment to which this provision applies as products, together with the associated calibration. | Testing
laboratories |
| (4) | If special processes or manufacturing methods are used in production by the contractor/subcontractor, separate quality assurance measures, such as a manufacturer-related product qualification (HPQ), may be required. These are governed by the relevant norms and Deutsche Bahn standards. | Special
processes |

Organisation and management systems	Quality
Fundamentals of quality assurance	120.0381V17
List of products subject to quality inspection – Telecommunications for rail operations	Page 8

- (5) Special processes or manufacturing methods are generally regarded as those in which the conformity of the manufactured product cannot be verified readily (e.g. only by destructive testing) or cannot be verified cost-effectively. In the context of DB AG's quality assurance, this includes processes and procedures such as:

- Casting
- Forging
- Welding
- Rolling
- Heat treatment
- Concrete processing
- Soldering
- Crimping
- Wire-wrap connections

6 Manufacturer-related product qualification (HPQ)

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| <p>(1) Manufacturer-related product qualification is a tool for quality assurance used by DB AG and is generally based on requirements set out in national and international railway-specific standards and regulations.</p> | Basis |
| <p>(2) The objective of HPQ is to ensure that products manufactured using special processes or manufacturing methods are supplied only by manufacturers who have demonstrated that they can meet the requirements for safety, reliability and process capability. The HPQ is normally required by manufacturers involved in special processes or manufacturing methods who supply DB AG either directly or indirectly. The products in question are identified in Part 2 of this document.</p> | Objective |
| <p>(3) The HPQ is subject to a fee and must be applied for by the manufacturer of the relevant products in accordance with Part 2 of this document.</p> | |
| <p>(4) If, during an HPQ, manufacturing methods or production lines are inspected that are used in exactly the same way for different products subject to HPQ, the inspection applies to all products subject to HPQ that are manufactured using this manufacturing method or production line, even if the specific product is not being manufactured at the time of the HPQ.</p> | |

Organisation and management systems	Quality
Fundamentals of quality assurance	120.0381V17
List of products subject to quality inspection – Telecommunications for rail operations	Page 9

- (5) The HPQ is normally valid for three years. An HPQ must be repeated **Validity**
- In the event of production being relocated
 - In the event of changes to production methods or process flows
 - In the case of subcontractors with no direct supply relationships with DB AG, once the three-year validity period has expired
 - After 6 years at the latest for direct suppliers to DB AG (a one-off extension may be granted after 3 years, provided that the conditions on the basis of which the HPQ was granted have not changed).

7 Regular inspections

- (1) Regular inspections are used to regularly assess the quality capability of the respective contractors. **Regular inspection by the contractor**
- (2) Regular inspections are carried out regularly by DB AG's Quality Assurance department for all contractors handling products subject to inspection of IL II and classified as Q1. The number of regular inspections to be carried out for each product subject to inspection is set out in the table in Part 2.
- (3) As part of regular inspections, product and/or process audits (including the inspection process and product inspection) are carried out. The audits may also take the form of unannounced inspections. The questionnaires used for this purpose are available on the Deutsche Bahn AG Supplier Portal.
- (4) If quality risks or quality defects are identified during regular inspections, this may result in a change to the quality capability classification and/or the withdrawal of the HPQ. The immediate impact on existing supply and service contracts will be assessed by the Purchasing department once the results are available, and appropriate measures will be taken to stabilise or develop the contractor.
- (5) If, during a regular inspection, manufacturing methods or production lines are inspected which are used in exactly the same way for different products subject to inspection, the inspection shall apply to all products subject to inspection that are manufactured using that manufacturing method or production line, even if the product in question is not being manufactured at the time of the review.

Organisation and management systems	Quality
Fundamentals of quality assurance	120.0381V17
List of products subject to quality inspection – Telecommunications for rail operations	Page 10

8 Failure mode and effects analysis (FMEA)

- (1) The selection of appropriate measures by the contractor to prevent risks must be based on a risk-based approach. An FMEA must be carried out to assess the risks associated with processes. In the context of DB AG's quality assurance, this refers to the manufacturing and inspection processes for products subject to inspection. When it comes to risk assessment, product development processes are generally considered only in terms of their impact on manufacturing. For certain products, however, it may be stipulated that the product development processes are subject to scrutiny with regard to risk assessment. This shall not affect any approval, authorisation or certification processes for the products that may be carried out by the contractor.

Processes

- (2) A risk assessment of the (manufacturing) processes is a mandatory result of the contractor's product and process development. This document must record the progress made in minimising risk.

Objective

- (3) When carrying out a risk assessment in the form of a process FMEA, the following standards shall be applied:
 - DIN EN 60812
 - AIAG & VDA FMEA Handbook

The contractor must provide evidence that FMEA/risk assessments based on standards other than those specified, such as ISO 31000, are equivalent.

Organisation and management systems	Quality
Fundamentals of quality assurance	120.0381V17
List of products subject to quality inspection – Telecommunications for rail operations	Page 11

- (4) In addition to the aforementioned standards, the following list must be used to assess the failure severity:

Table 1: Failure severity

1	Very low , very minor functional impairment, detectable only by qualified personnel
2-3	Low , minor impairment of the component's function; to be rectified during the next maintenance period; functional limitation of operating and comfort systems
4-6	Moderate , component functionality is limited; immediate rectification is not essential; functional limitations affecting key operating and comfort systems; an alternative is available
7-8	High , component functionality is severely limited, immediate fault rectification is essential, functional limitation affecting key subsystems, slow running, train comes to a halt
9-10	Very high , security risk, non-compliance with legal requirements; disproportionately high costs associated with replacement in the event of failure, in the event of damage, and during maintenance work

- (5) The existing process FMEA documents must be kept up to date at all times; in particular, field data, test results and internal and external complaints must be taken into account. Furthermore, a revision of the process FMEA is required in the following cases:

Update

- Relocation of production
- Changes to manufacturing methods or process sequences

- (6) The effectiveness of the measures resulting from the process FMEA must be verified by the contractor through annual reviews.

- (7) The process FMEA reports must be submitted to DB AG for inspection upon request. Product or design FMEAs are considered solely in terms of measures that affect production. However, for certain products, the analyses may still need to be inspected.

Access to documents

- (8) As part of an HPQ, the process FMEA is reviewed prior to the start of initial "series production".

Initial inspection

Organisation and management systems	Quality
Fundamentals of quality assurance	120.0381V17
List of products subject to quality inspection – Telecommunications for rail operations	Page 12

9 8D report

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| <p>(1) In the event of a complaint, DB AG may require the contractor to submit an 8D report. The process must include the following elements:</p> <p style="margin-left: 20px;">D1: Team selection</p> <p style="margin-left: 20px;">D2: Failure description</p> <p style="margin-left: 20px;">D3a: Immediate measures by DB AG</p> <p style="margin-left: 20px;">D3b: Immediate measures by supplier</p> <p style="margin-left: 20px;">D4: Failure causes</p> <p style="margin-left: 20px;">D5: Possible remedial measures</p> <p style="margin-left: 20px;">D6: Remedial measures implemented</p> <p style="margin-left: 20px;">D7: Preventive measures</p> <p style="margin-left: 20px;">D8: Documentation, lessons learned</p> | Basics |
| <p>(2) The 8D reports must be carried out in accordance with the usual rules and standards.</p> | Implementation |
| <p>(3) Form 120.0381V30, "Guideline & Form 8D Report", which is included in the annex to the policy, is to be used internally for the preparation of the 8D report. A separate external guideline is also available on the Supplier Portal.</p> | Guideline on the Supplier Portal |

Organisation and management systems	Quality
Fundamentals of quality assurance	120.0381V17
List of products subject to quality inspection – Telecommunications for rail operations	Page 13

10 Documentation and certificate of conformity

- (9) For products on Part 2 of this list, the contractor must, as a general rule, provide documentation/a certificate of conformity in accordance with Table 1 and Table 2, depending on the product's inspection level (PS I or PS II) and the quality capability classification (Q1 or Q2) for each delivery or partial delivery. The contractor must retain the certificates of conformity for at least 10 years.
- (10) A certificate of conformity documents that the product supplied by the contractor
 - Meets the requirements set out in the order and/or
 - Complies with the approved/authorised condition as specified by DB AG.
- (11) For raw materials that may be further processed by the contract/subcontractor using special processes or manufacturing methods, separate documents such as material certificates may be required. Further details, where applicable, are set out in section 13, which relates to specific technical disciplines.
- (12) For certain products, a TSI certificate of conformity may be required. These certificates of conformity serve as evidence to DB AG, the German Federal Railway Authority (EBA) and the supplier that the agreed quality assurance measures have been carried out and that the products meet the quality requirements. Furthermore, the aim is to ensure that products can be identified and clearly allocated in the event of reports of defects. Further details, where applicable, are set out in section 13, which relates to specific technical disciplines.

Inspection certificate

11 Marking

- (1) For certain products, specific markings may be required, such as the U-EBA mark, the CE mark or special machine-readable markings. The products in question are marked accordingly in Part 2 of this document. Further details, where applicable, are set out in section 13, which relates to specific technical disciplines.

Possible markings

Organisation and management systems	Quality
Fundamentals of quality assurance	120.0381V17
List of products subject to quality inspection – Telecommunications for rail operations	Page 14

12 Contractor's management of subcontractors

- (1) The contractor is obliged to assess its subcontractors on the basis of risk-based criteria, irrespective of the products or services to be supplied.
- (2) If a contractor who supplies products subject to inspection to DB AG and its affiliated companies is not the manufacturer of those products but instead procures them from a subcontractor, the following regulations apply:
 - If the subcontractor, which supplies products subject to inspection to the contractor, has no direct business relations with DB AG or its affiliated companies, the relevant contractor must carry out the quality capability classification and the specified number of regular inspections itself at the subcontractor or have them carried out by the subcontractor (see "Guideline on routine monitoring" in the Purchasing Supplier Portal). The contractor must provide evidence of the planning of the quality capability classification/ regular inspections and its results (including findings and measures) as part of the quality capability assessment or the contractor's routine monitoring by DB AG.
 - A quality capability classification and the corresponding regular inspections by the contractor at the subcontractor are not required if the subcontractor holds a valid HPQ or if the subcontractor maintains direct business relations with DB AG or its affiliated companies.
- (3) Where risks and/or defects have been identified at the subcontractor, the implications for the quality capability classification of one or more contractors, as well as the further measures to be taken at the subcontractor, shall be determined in consultation with the contractor's Purchasing and Quality Assurance departments. Any additional costs incurred by DB AG as a result shall be borne by the contractor.

Organisation and management systems	Quality
Fundamentals of quality assurance	120.0381V17
List of products subject to quality inspection – Telecommunications for rail operations	Page 15

13 Specific regulations for the technical disciplines/ product area Telecommunications for rail operations

- (1) If, in accordance with Part 2 of this LgP, the software contained in products is subject to inspection, the following distinction is made (in very simplified terms) to define the relevant processes:
 - System/application software
 - Project planning data
- (2) System and application software may be subject to approval and authorisation processes, which are the responsibility of the contractor/subcontractor in conjunction with the relevant departments. Therefore, only process audits (not expert opinions or similar) are conducted on these software components as part of the audits carried out by DB AG's Quality Assurance department for the purpose of quality capability classification and routine monitoring of the contractor. These could include, for example
 - European Committee for Electrotechnical Standardization process in accordance with DIN EN 5012x
 - Compliance with interface specifications and verification thereof (e.g. in test centres/fields, laboratories)
 - Handling software in general within production (e.g. implementation, testing, configuration management) and, where applicable, in the field (e.g. for updates)
- (3) With regard to project planning data, the process of compiling this data during the project planning phase, as well as its handling during production and, where applicable, in the field as part of routine monitoring, is reviewed from a process perspective by DB AG's Quality Assurance department on the basis of project examples. Inspection processes based on the VV BAU STE or EIGV remain unaffected.

Organisation and management systems	Quality
Fundamentals of quality assurance	120.0381V17
List of products subject to quality inspection – Telecommunications for rail operations	Page 16

14 List of abbreviations

AIAG	Automotive Industry Action Group
Contractor	Contractor
DB AG	Deutsche Bahn AG
DB PB	DB AG inspection record
DBS	Deutsche Bahn standard
DIN	German Institute for Standardisation
GFRA	German Federal Railway Authority
EN	European standard
SCT	Supplementary Contractual Terms
FMEA	(English) Failure mode and effects analysis
HPQ	Manufacturer-related product qualification
LgP	List of products subject to quality inspection
LF	Delivery approval
P I	Inspection level 1
P II	Inspection level 2
QE	Quality engineering
Regular monitoring	Regular monitoring
TSI	Technical specifications for interoperability
Subcontractor	Subcontractors
UIC	(French) Union internationale des chemins de fer (International Union of Railways)
VDA	Verband der Automobilindustrie e.V (German Association of the Automotive Industry)

Organisation and management systems	Quality
Fundamentals of quality assurance	120.0381V17
List of products subject to quality inspection – Telecommunications for rail operations	Page 17

Part 2: Definition of the minimum scope of quality assurance measures for products (parts, components and systems)

	Product groups/ products	Other applicable documents	HPQ	Inspection level	Routine monitoring p.a.	Documentation	Manufacturer's marking	Commodity group	Comments
1	BOS Radio (digital)								
2	Emergency call systems								
3	Operational CCTV for level crossings, end-of-train detection								
4	GSM-R infrastructure and platform (ART)								
4.5	Base station subsystem (BSS)								

Organisation and management systems	Quality
Fundamentals of quality assurance	120.0381V17
List of products subject to quality inspection – Telecommunications for rail operations	Page 18

	Product groups/ products	Other applicable documents	HPQ	Inspection level	Routine monitoring p.a.	Documentation	Manufacturer's marking	Commodity group	Comments
5	Operational telecommu- nications systems (BFMA)								
5.1	Trackside end user de- vices for BFMA (tele- phones)	-	-	II	1	DIN EN ISO/IEC 17050- 1	-	10803100	
5.2	Exchange/switching system for BFMA	-	-	II	1	DIN EN ISO/IEC 17050- 1	-	10803100	
6	Basic infrastructure (telecommunications)								
6.1	Telecommunications cables								
6.1.1	Outdoor telecommuni- cations cables (copper and fibre-optic)	Specifications	-	II	1	DIN EN ISO/IEC 17050- 1	-	10570020	
6.2	Cable guide systems								

Organisation and management systems	Quality
Fundamentals of quality assurance	120.0381V17
List of products subject to quality inspection – Telecommunications for rail operations	Page 19

	Product groups/ products	Other applicable documents	HPQ	Inspection level	Routine monitoring p.a.	Documentation	Manufacturer's marking	Commodity group	Comments
7	FRMCS								
7.1	FRMCS hardware								
7.1.1	Steel mast	Ril 859.0611 Specifications Drawings	-	II	1	DIN EN ISO/IEC 17050- 1	-	10311600	
7.1.2	Track site gateway	Specifications Drawings	-	II	1	DIN EN ISO/IEC 17050- 1	-	10311600	
7.2	FRMCS software								
7.2.1	BBU software	Specifications	-	II	1*	DIN EN ISO/IEC 17050- 1	-	10311600	*In the following context: software development
7.2.2	Software radio unit	Specifications	-	II	1*	DIN EN ISO/IEC 17050- 1	-	10311600	*In the following context: software development
7.2.3	5G core software	Specifications	-	II	1*	DIN EN ISO/IEC 17050- 1	-	10311600	*In the following context: software development
7.2.4	IMS software	Specifications	-	II	1*	DIN EN ISO/IEC 17050- 1	-	10311600	*In the following context: software development

* Explanation in Part 1 of the LgP (Section 13: Specific regulations for the technical discipline/product area telecommunications)

Organisation and management systems	Quality
Fundamentals of quality assurance	120.0381V17
List of products subject to quality inspection – Telecommunications for rail operations	Page 20

	Product groups/ products	Other applicable documents	HPQ	Inspection level	Routine monitoring p.a.	Documentation	Manufacturer's marking	Commodity group	Comments
7.2.5	MCx software (server and end user devices)	Specifications	-	II	1*	DIN EN ISO/IEC 17050- 1	-	10311600	*In the following context: software development

* Explanation in Part 1 of the LgP (Section 13: Specific regulations for the technical discipline/product area telecommunications)