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Products subject to quality inspection

Telecommunications for rail operations

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

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Part 1: General rules

1 Purpose, general information

- (1) The list of products subject to quality inspection (LgP) is part of Deutsche Bahn AG's (DB AG) Policy 120.0381 "Quality assurance in procurement". It includes all infrastructure products to be procured in the subsystem concerned that are subject to mandatory quality assurance by DB AG and specifies the quality assurance measures and their scope.
- (2) The rules in place apply to the procurement of these products both by DB AG and its affiliated companies, and by Contractor or its subcontractors for the purposes of orders placed by DB AG and its affiliated companies.
- (3) The list of products subject to quality inspection (LgP) consists of
 - Part 1: General rules
 - Part 2: Defining the minimum scope of the quality assurance measures for products (elements, components and systems)
- (4) This LgP applies to the procurement of products for the construction of new equipment as well as for maintenance measures performed on existing telecommunications equipment for rail operations, i.e. it also applies to contractors engaged in overhaul work.
- (5) The contractually agreed provisions (e.g. supplementary contractual terms, DIN, EN, UIC, DBS, drawings, checklists, specifications) constitute the basis for action.

Basis

Constituent parts

Scope

Basis for action

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2 Products subject to inspection

(1) The LgP is drawn up jointly by a team of subject matter experts and representatives of the relevant product line support team from the end user and the quality assurance department at DB AG.

Creation

Evaluation criteria

- (2) The products subject to inspection are evaluated according to the following criteria and the resulting risks, with the results being documented internally in an evaluation matrix:
 - 1. Safety

- 2. Reliability
- 3. Supply reliability
- 4. Special processes/production methods
- 5. Expenses for unscheduled maintenance work
- 6. Customer relevance
- (3) According to this risk assessment, the products subject to inspection are assigned to inspection levels (IL) I or II. The quality assurance measures to be carried out by Contractor result from the inspection level. Products assigned to

Meaning of the inspection levels

- 1. IL I: products are always subject to product-specific inspection
- 2. IL II: products do not require continuous product-specific inspection.
- (4) Corresponding appropriate quality assurance measures shall be allocated to new products that are not listed in Part 2 but are comparable with the products listed.

New products

(5) COTS (commercial off-the-shelf or components-off-the-shelf) products that are not manufactured in large quantities specifically for DB or the railway market (non-railway-specific requirements) and which can be used unchanged are generally not subject to inspection and are therefore generally not subject to quality assurance measures.

COTS products

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3 Quality capability of Contractor

(1) DB AG's quality assurance department assesses Contractor's quality capability and categorises the contractor as Q1, Q2 or Q3 (quality capability classification)

Quality capability of Contractor

(2) Quality capability is assessed by (system, process and product) audits on Contractor's premises, both at central production sites and at production sites relevant to the products concerned. The questionnaires used in the audits are available on the Supplier Portal of Deutsche Bahn AG.

Audits, audit locations

(3) This quality capability classification is usually valid for one year and can be updated on a regular basis if necessary. The rating is updated based on an evaluation of the quality data (e.g. complaints, product proving, quality data) and/or with reference to the result of unscheduled audits (see "Regular inspections").

Updating

(4) The quality capability classification can be changed at any time in the event of changes in the quality capability of Contractor or its subcontractors, in the quality of the products or in company ownership.

Change

(5) If a contractor does not achieve the Q1 category in the quality capability classification or if a contractor has been downgraded to Q2, measures will be taken to stabilise or develop Contractor in consultation with the end user and the procurement department. Failure to achieve Q1, downgrading

(6) Contractors of DB AG with no Q-rating shall be treated as Q3 contractors.

Contractors with no Q-rating

(7) DB AG's quality assurance department performs a quality capability classification on all contractors who introduce products subject to inspection into the infrastructure, i.e. this also includes contractors who do not manufacture or overhaul products subject to inspection themselves but merely procure them from subcontractors, e.g. dealers/distributors.

Overhaul contractors, dealers/ distributors

(8) Separate quality assurance measures may be required for special processes/production methods in accordance with ISO TS 22163:2018-01 Section 8.5.1.2, e.g. manufacturer-related product qualification.

Special processes

(9) In individual cases or under certain conditions, remote audits can be performed instead visiting Contractor's premises.

Remote audits

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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.

Scope

(2) The basic scope of the quality assurance measures is shown in the following tables.

Table 1: Quality assurance measures for products allocated to inspection level I

Products with inspection level	Contrac- tor's Q- rating	Quality assurance measures
	Q 1	DB AG carries out sample testing of the deliveries for product inspection purposes.
	,	Delivery with inspection certificate 3.1 and DB AG delivery approval/inspection certificate.
1	Q2	DB AG checks every delivery. Delivery with inspection certificate 3.1 and DB AG delivery approval/inspection certificate.
	Q3	Contractor is barred

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Table 2: Quality assurance measures for products allocated to inspection level II

Products with inspection level	Contrac- tor's Q- rating	Quality assurance measures
	Q1	DB AG accepts full inspection by Contractor. Regular inspections of Contractor by DB AG. Delivery with certificate of conformity according to DIN EN ISO/IEC 17050-1*
II	Q2	DB AG carries out sample testing of the deliveries for product inspection purposes. Delivery with inspection certificate 3.1 and DB AG delivery approval/inspection certificate.
	Q3	Contractor is barred

(*As a rule, these remain with the manufacturer and must be made available on request. Legal retention periods must be observed)

Processes for product creation, measuring equipment, special processes/production methods

(1) The complete product creation process - from enquiry to production and inspection to product shipment - is considered during the quality capability classification audits or regular review of Contractor's quality capability (see Regular inspection). As a rule, product development processes are not analysed by DB AG's OA department.

Processes, product development

(2) If special processes/manufacturing methods are used in production at Contractor's or subcontractor's company, special quality assurance measures such as a manufacturer-related product qualification (HPQ) are required. These are regulated in the relevant norms and DB standards.

Special processes

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- (3) Special processes/production methods are generally considered to be those manufacturing methods in which the conformity of the manufactured product cannot be easily (e.g. only destructively) verified or cannot be verified cost-effectively.

 Regarding quality assurance for DB AG, this includes processes and methods such as:
 - Casting
 - Forging
 - Welding
 - Rolling
 - Heat treatment
 - Concrete production
 - Soldering
 - Crimping
 - Wire wrap connections
- (4) Monitoring inspection criteria is a key task of quality assurance. Suitable measuring and inspection equipment is required to ensure the reproducibility of measurement and inspection results. Calibration is carried out by appropriate methods and institutions.

Measuring equipment

(5) The general requirements for the competence of testing and calibration laboratories in accordance with DIN ISO 17025 apply to measuring and inspection equipment used in the railway environment.

Testing laboratories

Part 2 of this document lists, where applicable, the measuring equipment as a product (together with the associated calibration) to which this regulation applies.

6 Manufacturer-related product qualification (HPQ)

(1) The manufacturer-related product qualification is a quality assurance tool used by DB AG and normally based on requirements from German and international railway-specific standards, regulations, and guidelines.

Basis

(2) The aim of the HPQ is to ensure that products manufactured using special processes/production methods are only supplied by manufacturers who have proven that they can fulfil requirements in terms of safety, reliability and process capability. The HPQ is usually required from manufacturers for special processes/production methods that supply directly or indirectly to DB AG. The products concerned are identified in Part 2 of this document.

Objective

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- (3) The HPQ is subject to a fee and must be applied for by the manufacturer of the products concerned in accordance with Part 2 of this document.
- (4) The HPQ is normally valid for three years. An HPQ must be reacquired:

Validity

- If production is relocated
- If production methods or process cycles are changed
- In the case of subcontractors with no direct supply relationships with DB AG after expiry of the 3-year validity period
- After 6 years at the latest (a one-off extension can be granted after 3 years if the assumptions based on which the HPQ was issued have not changed).

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7 Quality engineering (QE) methods

(1) To support Contractor's quality planning during the entire product development process, DB AG's requirements re quality engineering methods are described below. QE methods should accompany quality assurance measures involving scrutiny, such as HPQ and regular inspections, and must supplement these through its preventive approach.

Basis

(2) The objective of the QE measures is to ensure the translation of requirements into product features and to appropriately manage the delivery quality of products subject to quality inspection through preventive quality assurance and the evaluation of design and manufacturing processes.

Objective

(3) Contractors with responsibility for development are obliged to document planned measures for the safeguarding of product and process quality during development in a QE plan. Suitable processes and components should be selected using a risk-based approach.

Quality planning (QE plan)

(4) Contractor's product and process development must result in design and process FMEAs according to DIN EN 60812 in which the progress of risk minimisation must be documented. The requirements of the current AIAG & VDA FMEA manual must be applied as a minimum. The equivalence of FMEAs based on standards other than those specified must be substantiated by Contractor. In addition to the above-mentioned standards, the following scale should be used to assess the importance of an error:

FMEA

Table 1: Importance of errors

1	Very minor, very minor functional impairment, only detectable by skilled personnel
2-3	Minor, minor functional impairment of the components, elimination during the next maintenance session, functional limitation of operating and comfort systems
4-6	Moderate, functionality of components limited, immediate error-elimination not absolutely necessary, functional limitation of important operating and comfort systems, alternatives possible
7-8	Severe , severe functional limitation of components, immediate elimination mandatory, functional limitation of important subsystems, trains forced to run slowly or unable to run
9-10	Very severe, safety risk, statutory requirements not met, disproportionately high cost of replacement in the event of breakdown, damage, or maintenance work, danger to life and limb

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(5) Consideration must be given in the design FMEA to maintainability and availability in operation, in accordance with DIN EN 50126.

Maintainability & availability

(6) Contractor is obliged to implement an FMEA process prior to the commencement of series production and to document this as one of the conditions of internal production release.

Internal production release

(7) The documentation of the QE measures must be kept constantly up to date, with account taken of field data, test results and internal and external complaints in particular. In addition, design and process FMEAs must be revised in the following cases:

Updating

- Design changes
- Relocation of production
- Change in production methods or process cycles
- (8) The effectiveness of the QE methods and the resulting QE measures must be reviewed on an annual basis by Contractor's internal audit.

Effectiveness checks

(9) The QE plan and design and process FMEAs must be submitted to Deutsche Bahn AG for inspection, upon request.

Inspection

(10) The QE plan and the design and process FMEAs shall be checked by Deutsche Bahn AG. An initial check of the process FMEA shall take place prior to series production at the latest, for example regarding the HPQ or initial sample inspection.

Initial inspection

(11) Contractor is obliged to assess its subcontractors using risk-based criteria. Points (1) - (10) apply analogously to subcontractors making a substantial contribution to the success of the final product. The application of points (1) to (10) by the responsible subcontractors must be checked by Contractor.

Subcontractors

(12) Any of points 7 (1) to 7 (3) or a new call for tender will result in the immediate application of the requirements of this guideline. A process FMEA must be prepared by 31 December 2018 for all of the products subject to quality inspection to be delivered to DB AG. A design FMEA is only required for newly developed products that are approved by DB InfraGO AG after 31 December 2018.

Transition period

8 Special production methods

(1) Special production methods are regulated in the respective standards and DB Standards.

DB standards

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9 Regular inspections

(1) To secure the quality interests of Deutsche Bahn AG, all contractors with IL II products and a Q1 status as well as an existing supply agreement shall be monitored by DB AG's quality assurance unit. Product and/or process audits shall be carried out as part of these regular inspections. Audits can also take place in the form of unannounced inspections.

Regular inspections at Contractors' premises

(2) If quality risks or quality shortcomings are identified during regular inspections, this can result in a change in the Q-rating and/or retraction of the HPQ.

Shortcomings & validity

Purchasing will review the direct impact on existing delivery and performance contracts once the results are available and initiate appropriate action.

Regular inspections at subcontractors' premises

(3) For subcontractors who supply DB AG's contractors with products subject to quality inspection as per this list, the respective contractor must carry out the defined number of regular inspections or arrange for these to be carried out (see "FAQs on regular inspections by DB contractors" in Purchasing's Supplier Portal). Deutsche Bahn AG must be provided with evidence of the planning and results of the regular inspections (including findings and measures) as part of the assessment of quality capability or regular inspections of Contractor.

Shortcomings

(4) If risks and/or shortcomings are identified regarding subcontractors, the impact on the Q-rating of one or more contractor(s) and further measures to be taken re the subcontractor(s) shall be determined by Purchasing in coordination with Contractor's quality assurance team.

Contractor shall bear any additional expenses incurred by Deutsche Bahn AG as a result of this.

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10 8D report

(1) Within the framework of complaints, an 8D report will be exchanged between Contractor and DB AG. The process covers the following elements:

Basics

- D1: Team definition
- D2: Error description
- D3a: Immediate measures by DB AG
- D3b: Immediate measures by supplier
- D4: Error causes
- D5: Possible remedial measures
- D6: Remedial measures implemented
- D7: Preventive measures
- D8: Documentation, lessons learned
- (2) (D1) Depending on the character of the problem, an interdisciplinary team must be appointed with sufficient product and process knowledge.

Implementation

- (D2) The description of the error should be based on facts.
- (D3) In order to directly avert additional damage, immediate action (e.g. blocking the material or 100% testing) should be taken if necessary, both by Contractor (and/or its subcontractor) and by DB AG.
- (D4) The probable causes of the error should be analysed by Contractor (subcontractor) on the basis of data and facts.
- (D5) Contractor is responsible for selecting remedial measures to remove the cause of the error. Based on the root cause analysis, measures should be identified, which permanently fix the error in the interests of DB AG and do not give rise to any undesired side effects. Before any measure is implemented, its effectiveness must be checked, with a particular focus on error avoidance and error detection.
- (D6) According to their verified effectiveness under D5, remedial measures should be determined which will reliably prevent the error from re-occurring. The effectiveness of the measures implemented should be monitored over a reasonable period. Once their effectiveness has been substantiated, immediate measures (e.g. additional inspections) that are still ongoing can be retracted.

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- (D7) To preclude the reoccurrence of the error(s) that occurred/similar errors, preventive measures must be taken by Contractor (and/or its subcontractor(s)), such as recording the error in the design and/or process FMEA, adapting guidelines, work instructions, and internal processes, and checking additional production lines or related processes for robustness.
- (D8) The most important findings from the 8D are documented as lessons learned. An 8D report can only be concluded by appropriately authorised personnel and with the agreement of Client (DB AG).
- (3) In order to provide the departments affected with the opportunity to coordinate with each other, the introduction of the 8D report within the framework of complaints provides for a transition period of one year beginning on 1 January 2016.

Transition period

(4) The "Supplier guidelines for completing the 8D report" in the Supplier Portal can be used to create an 8D report.

Form

11 Documentation and proofs of conformity

(1) Regarding products and components according to DB's list of products subject to quality inspection: telecommunications for rail operations" Part 2, the supplier must always provide documentation/a certificate of conformity relating to the inspection level of the product (IL I or IL 2) and its classification (Q1 or Q2) for each delivery or partial delivery. The supplier must retain the certificates of conformity for at least 10 years.

Inspection certificate

Proof for inspection level I products:

- as a Q1 supplier: inspection certificate 3.1 in accordance with DIN EN 10204 and DB AG delivery release/inspection certificate
- as a Q2 supplier: inspection certificate 3.1 in accordance with DIN EN 10204 and DB AG delivery release/inspection certificate

Proof for inspection level II products:

- as a Q1 supplier: certificate of conformity in accordance with DIN EN 17050
- as a Q2 supplier: inspection certificate 3.1 in accordance with DIN EN 10204 and DB AG delivery release/inspection certificate

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12 Special cases (see Part 2)

Not applicable

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13 List of abbreviations

AIAG Automotive Industry Action Group DB AG Deutsche Bahn AG **DBS** Deutsche Bahn standard DIN German Institute for Standardisation **EBA** German Federal Railway Authority ΕN European norm **FMEA** Failure mode and effects analysis Manufacturer-related product qualification **HPQ** LgP List of products subject to quality inspection IL I Inspection level 1 IL II Inspection level 2 QΕ Quality engineering RΙ Regular inspections TSI Technical specifications for interoperability UIC (French) Union International des Chemins de Fer (International Union of Railways) **VDA** German Association of the Automotive Industry

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

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level	products	documents	HPQ	tion level	Regular Insp./year	for Q1	for Q2	er's mark	number	Comments
Α	General materials									
A1a	Bolts: from grade 8.8 from M 16; from grade 10.9 all (also expansion and fitting bolts) from grade 5 from 5/8 inch; from grade 8 all (also expansion and fitting bolts) Nuts: from grade 8 from M16; from grade 10 all	Various DIN	-	_	_	Insp. Cert. 3.1	-	*	11311100	Product is in the list of rail vehicle products subject to quality inspection

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Structure	Product groups/	Applicable	пРО	PQ In- spec tion level	spec tion Regular	Documentation		Manufactur-	Material group	
level	products	documents				for Q1	for Q2	er's mark	number	Comments
1	BOS (emergency servi	ices) radio (digital)								
1.1	Tunnel radio control station	-	-	H	1	DIN EN 17050	Insp. cert. 3.1+delivery approval/DB insp. cert.	-	10311500	-
1.2	Tunnel radio communication station	-	-	#	1	DIN EN 17050	Insp. cert. 3.1+delivery approval/DB insp. cert.	-	10311500	-
1.3	Radiating cables (antenna)	-	-	#	1	DIN EN 17050	Insp. cert. 3.1+delivery approval/DB insp. cert.	-	10311500	-
1.4	Power supply	-	-	H	1	DIN EN 17050	Insp. cert. 3.1+delivery approval/DB insp. cert.	-	10920160	as for CCS
2	Emergency call syster	ns								
2.1	Tunnel emergency call centre	-	_	#	1	DIN EN 17050	Insp. cert. 3.1+delivery approval/DB insp. cert.	-	10803200	-

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Structure	Product groups/	Applicable	LIDO	In- spec	Number of	Docur	Documentation		Material group	Comments
level	products	documents	HPQ	tion level	Regular Insp./year	for Q1	for Q2	er's mark	number	Comments
2.2	Tunnel emergency call stations	-	-	H	1	DIN EN 17050	Insp. cert. 3.1+delivery approval/DB insp. cert.	-	10803200	-
2.3	Power supply	-	-	#	1	DIN EN 17050	Insp. cert. 3.1+delivery approval/DB insp. cert.	-	10920160	as for CCS
3	Operational CCTV for	evel crossings, end	d-of-tra	in dete	ction					
3.1	Camera	-	-	#	1	DIN EN 17050	Insp. cert. 3.1+delivery approval/DB insp. cert.	-	10314200	-
3.2	Monitor	-	-	H	1	DIN EN 17050	Insp. cert. 3.1+delivery approval/DB insp. cert.	-	10314200	-
3.3	Data storage	-	-	#	1	DIN EN 17050	Insp. cert. 3.1+delivery approval/DB insp. cert.	-	10314200	-

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level	products	aucts aocuments	HPQ	tion level	Regular Insp./year	for Q1	for Q2	er's mark	number	
4	GSM-R infrastructure a	and platform (ART)								
4.1	GSM-R end user device lineside telephone (fixed terminal system)	-	-	H	1	DIN EN 17050	Insp. cert. 3.1+delivery approval/DB insp. cert.	-	10311400	-
4.2	Operation & maintenance centre (fixed terminal system OMC)	-	-	#	1	DIN EN 17050	Insp. cert. 3.1+delivery approval/DB insp. cert.	-	10311100	-
4.3	GSM R voice recording	-	-	H	1	DIN EN 17050	Insp. cert. 3.1+delivery approval/DB insp. cert.	-	10311200	the software is included
4.4	Regional switching centre	-	-	#	1	DIN EN 17050	Insp. cert. 3.1+delivery approval/DB insp. cert.	-	10311200	-
4.5	Base station subsystem	(BSS)								
4.5.1	Base station controller (BSC)	_	_	#	1	DIN EN 17050	Insp. cert. 3.1+delivery approval/DB insp. cert.	-	10311200	-

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level	products	documents	HPQ	tion level	Regular Insp./year	for Q1	for Q2	er's mark	number	Comments
4.5.2	Transcoder	-	_	H	1	DIN EN 17050	Insp. cert. 3.1+delivery approval/DB insp. cert.	-	10311200	-
4.5.3	Base station (BS)	-	-	H	1	DIN EN 17050	Insp. cert. 3.1+delivery approval/DB insp. cert.	-	10311200	-
4.5.4	Antenna	-	_	H	1	DIN EN 17050	Insp. cert. 3.1+delivery approval/DB insp. cert.	-	10311200	-
4.5.5	Mobile phone repeaters	-	-	#	1	DIN EN 17050	Insp. cert. 3.1+delivery approval/DB insp. cert.	-	10311200	-

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Structure	Product groups/	Applicable ,		In- spec	Number of	Documentation		Manufactur-	Material group	C
level	products	documents	HPQ	tion level	Regular Insp./year	for Q1	for Q2	er's mark	number	Comments
5	Operational telecommi	unications installat	ions							
5.1	Trackside operational telecommunications devices (telephones)	-	-	II	1	DIN EN 17050	Insp. cert. 3.1+delivery approval/DB insp. cert.	-	10803100	-
5.2	Exchange/switchboard for telecommunications installations	-	-	II	1	DIN EN 17050	Insp. cert. 3.1+delivery approval/DB insp. cert.	-	10803100	-
6	Basic infrastructure (te	elecommunications)							
6.1	TC (telecommunications	s) cables								
6.1.1	TC cables (copper and fibre optic)	-	-	#	1	DIN EN 17050	Insp. cert. 3.1+delivery approval/DB insp. cert.	-	10570020	-

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level	products	documents	HPQ	tion level	Regular Insp./year	for Q1	for Q2	er's mark	number	Comments
6.1.2	TC cable accessories (copper and fibre optic)	-	-	#	1	DIN EN 17050	Insp. cert. 3.1+delivery approval/DB insp. cert.	-	10570020	Applies solely to products for which there is cur rently only one supplier
6.2	Cable guide systems									
6.2.1	Concrete cable guide systems	-	-	-	-	-	-	-	21190100	The product has been transferred to the list of civil engineering products (TB) and specified in TB1.1 and TB1.2 products.

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level	products	documents		tion level	Regular Insp./year	for Q1	for Q2	er's mark	number	Comments
6.2.2	Plastic cable guide systems standing/in ground	-	_	H	1	DIN EN 17050	Insp. cert. 3.1+delivery approval/DB insp. cert.	-	21190100	-
6.2.3	Cable and closure tray kits and feeder distribution interfaces made of plastic	-	-	#	1	DIN EN 17050	Insp. cert. 3.1+delivery approval/ DB insp. cert.	-	21190100	-
6.2.4	Wooden telecom py- lons	DBS 918.463	_	#	1	DIN EN 17050	Insp. cert. 3.1+delivery approval/DB insp. cert.	-	10850100	-