

Manufacturer-related product qualification (HPQ) in accordance with TL 889.0007 (Deutsche Bahn standard 918 007)

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Appendix A Application documents *(Documents to be processed and submitted by the applicant, including annexes)*

- 1 Application for HPQ qualification in accordance with DBS 918 007
- 2 QMS matrix in accordance with DBS 918 007 (additional documents on request)

Appendix B HPQ documentation *(For the applicant - for the purposes of information or preparation for the HPQ elements or proof of the HPQ)*

- 1 Checklist for the HPQ in accordance with DBS 918 007, questions for the manufacturer at the on-site inspection
- 2 Report on the HPQ qualification in accordance with DBS 918 007
- 3 Appendix to the report on the HPQ qualification in accordance with DBS 918 007 (if applicable)
- 4 Sample: Certificate for HPQ in accordance with DBS 918 007



1. Purpose and objective

The manufacturer-related product qualification (HPQ) is required as part of Deutsche Bahn AG's quality policy in railway-specific technical regulations such as UIC, RIL and DBS.

The HPQ qualifies the manufacturer to produce and supply aluminium noise barrier elements for use on Deutsche Bahn AG rail lines.

The material properties and the production and testing rules are set out in the relevant delivery standards as well as in DBS 918 007 and GL 804 and their modules, in DB technical guidelines and standards (if applicable) and other regulations indicated by references.

The aim of this manufacturer-related product qualification is to ensure that only manufacturers that are capable of meeting Deutsche Bahn AG's high requirements for safety, reliability and process capability supply the aforementioned products (directly or indirectly) to Deutsche Bahn AG.

2. Application for HPQ

To:

Deutsche Bahn AG
Beschaffung Infrastruktur (*Infrastructure Procurement*)
Qualitätssicherung (*Quality Assurance*)
Caroline-Michaelis-Strasse 5-11
10115 Berlin, Germany

E-mail: qs-postfach@deutschebahn.com

3. Application documents

The applicant must complete, sign and submit the following documents.

Seq. no.	Application documents
1	Application for qualification in accordance with DBS 918 007, see Appendix A in DBS 918 007
2	Completed form "3_HPQ_DBS_918 007_QMS Matrix 2017"

All documents must be submitted with the application in *.pdf format. The documents submitted or the documents to be submitted during the qualification process must be submitted in two languages (local language and German) or in German. The audit language is German*.

(*See requirements pursuant to the German Act to Amend the German Construction Products Act and Other Legal Provisions to Comply with Regulation (EU) No. 305/2011 laying down harmonised conditions for the marketing of construction products (*Gesetz zur Anpassung des Bauproduktengesetzes und weiterer Rechtsvorschriften an die Verordnung (EU) Nr. 305/2011 zur Festlegung harmonisierter Bedingungen für die Vermarktung von Bauprodukten*) of 5 December 2012, Section 6.)

4. Requirements, restrictions, discontinuation, removal of HPQ

4.1 Requirements

- Completeness and legibility of the application documents (see Section 3)
- Qualified processes available on the manufacturer's premises (see application - Section 4.2)
- HR and technical requirements fulfilled by the manufacturer and documented process descriptions and implementation and work instructions
- Completely filled out HPQ 918 007 matrix, column 4
- Completeness of signatures on application documents and binding declaration of cost assumption

4.2 Restrictions, changes

- Deutsche Bahn AG, Infrastructure Procurement, Quality Assurance, must be informed directly and promptly if persons mentioned who are responsible for implementing the HPQ requirements leave the company or if the conditions for obtaining the HPQ have significantly changed. Deutsche Bahn AG, Infrastructure Procurement, Quality Assurance may/will arrange for a new chargeable audit where applicable.
- In the case of a change of ownership.

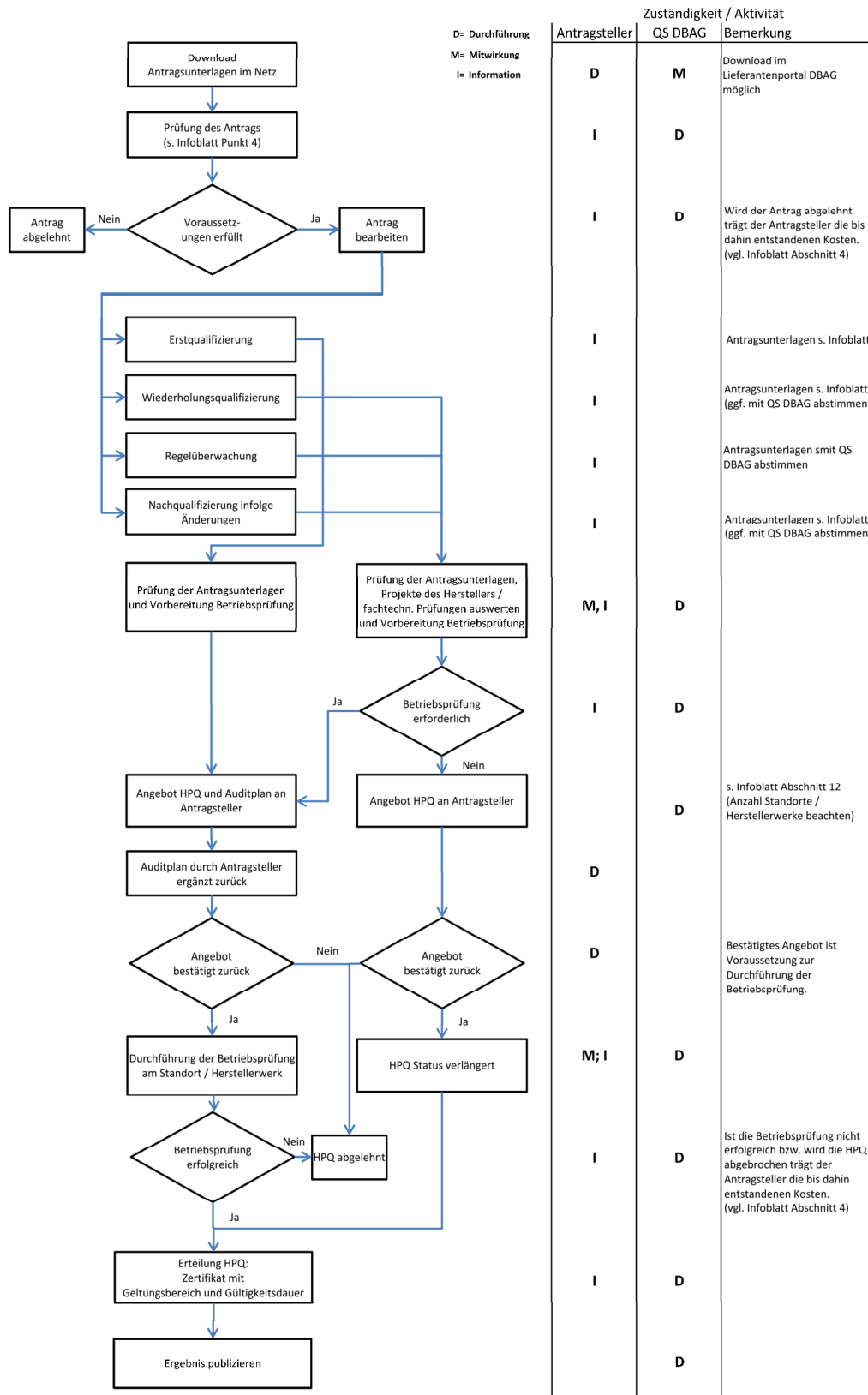
4.3 Discontinuation

- If doubts arise regarding the applicant's quality capability during the HPQ process or the QM documentation is implemented inadequately, the HPQ process may be interrupted/discontinued. The applicant shall reimburse any expenditure incurred up to that point by Deutsche Bahn AG, Infrastructure Procurement, Quality Assurance (see declaration of cost assumption in the application).
- Insufficient preparation of the on-site inspection by the applicant with regard to the process descriptions, documents, records, etc. to be submitted for the on-site inspection (see checklist for HPQ 918 007 - questions for the on-site inspection, column 3).
- Lack of cooperation on the part of the applicant during the preparation and implementation of the HPQ process.

4.4. Removal

- This qualification may be withdrawn at any time with immediate effect and without compensation if the conditions under which it was granted have changed and the provisions of this certificate are no longer met. In case of a withdrawal of the HPQ, the manufacturer is obliged to immediately remove all publicly issued valid HPQ certificates including any references to their ownership.
- Should doubts arise regarding the manufacturer's suitability, and/or the manufacturer (HPQ holder) does not fulfil quality requirements for the products as per the requirements, Deutsche Bahn AG, Infrastructure Procurement, Quality Assurance reserves the right to carry out chargeable on-site inspections at any time or may remove the qualification in the validity period.
- If the manufacturer violates important conditions of this qualification or fails to cooperate with the monitoring bodies/organisational units during the course of the project for the purposes of this qualification, the qualification may be removed in the validity period.

5. Process and deadlines for HPQ



Deadlines

Work step	Activities by	
	Applicant	DB AG QA
Informal application by the applicant, followed by Deutsche Bahn sending the application documents to the applicant	X	X
Processing the application; completing and compiling documents and submitting them for review	X	
Checking the application documents for completeness; admission to the HPQ process; interim information to the applicant		X + 20 WD
Follow-up work/supplementation of application documents after being informed by DB AG QA	X ¹ + 20 WD	
Receipt of complete application documents; notification of applicant; start of document review and preparation of on-site inspection by DB AG QA		X ² + 10 WD
Completion of document review and preparation of on-site inspection by DB AG QA		X ² + 10 WD to 20 WD
On-site inspection for each production site (outward and return journeys or interim periods not included)		1.5 WD
Completion of on-site inspection for each production site, preparation of HPQ certificates and billing; reporting of results		X ³ + 5 WD to 10 WD
Send the HPQ certificates and invoices to applicant; publication on the internet		X ³ + 15 WD to 30 WD
Notification by the applicant that findings from the on-site inspection have been processed	<= 3 months after the date of the on-site inspection	

Notification to Deutsche Bahn AG of changes regarding pre-construction information for the conducted HPQ process	Immediately (within max. 5 working days)	
Notification/confirmation of appointment for the surveillance audit and for HPQ extension or repeat qualification to Deutsche Bahn AG	2 months (before expiry of deadline or validity of HPQ)	
In the case of withdrawal/return or removal, the HPQ certificates and all publicly issued valid certificates and references to their ownership must be removed by the HPQ holder.	1 month (after withdrawal/return or removal of HPQ)	

In the event of deviations from the above deadlines or dates/deadlines not specified here, the applicant must obtain the necessary agreement or consent from Deutsche Bahn AG.

Key: WD = working days
 X = date - receipt of complete application documents by Deutsche Bahn AG, Infrastructure Procurement, Quality Assurance
 X¹ = date - notification by Deutsche Bahn AG, Infrastructure Procurement, Quality Assurance
 X² = date - receipt of complete application documents by DB AG Infrastructure Procurement, QA

X³ = date – after completion of on-site inspection at last production site

6. Elements of the HPQ

6.1. On-site inspection (main element of the qualification)

- Review of **implementation of the requirements of DBS 918 007 in the manufacturer's QMS** in accordance with the desired scope, and the corresponding HR and material resources

- 6.2 Product inspection as part of the HPQ

- See DBS 918 007 (or in consultation with the auditor responsible)

6.3 Product inspection during the validity period of the HPQ/during construction

- Evaluation of the products when used in construction projects (* if applicable or available)

6.4 Component test, operating tests, if required

The type and scope of the HPQ must be agreed with the quality test engineer (auditor) responsible for implementation.

The production process is analysed using checklists and production and test sequence plans.

7. Certificate

Following successful completion of the manufacturer-related product qualification, a certificate in accordance with DBS 918 007 is issued, specifying the scope and period of validity.

- Designation of the products in accordance with the manufacturer's type name
- Designation of associated EBA approval and user declaration (DB Netz AG technical bulletin)

The certificate can be issued in other languages (English or French) subject to a fee.

The HPQ status of a manufacturer is made publicly available and notified to the German Federal Railway Authority.

8. Scope

The scope is based on the range of products tested at the manufacturer's request, the production tests carried out on them and the supplementary documentation (in-house and third-party monitoring, declaration of conformity, etc.).

At the manufacturer's request, the scope of the HPQ can be extended or changed if the requirements for the manufacturer-related product qualification still apply. Necessary measures must be stipulated on a case-by-case basis.

9. Period of validity

The maximum period of validity is three years. In addition, an annual regular inspection is carried out by the testing laboratory, inspection body and certification body after the initial inspection.

After three years, repeat inspections are carried out at the manufacturer's request under the following conditions:

- the qualification requirements have not changed and

- no quality problems have been identified in deliveries made during the validity period of the qualification.

The client must provide evidence of compliance with the above requirements. If the HPQ is to be extended, the manufacturer must coordinate the dates and terms of the extension with Deutsche Bahn AG, Infrastructure Procurement, Supplier Management and Quality Assurance, at least two months prior to the expiry of the validity of the HPQ or before the date of the next inspection.

If no application for repeat qualification is submitted after the expiry of the period of validity of the HPQ, the HPQ shall lose its validity and expire.

In the case of a change of ownership, an existing qualification may be transferred to another company, providing a corresponding application has been submitted. The transfer can only take place if the corresponding content and the conditions that led to the qualification have not changed.

During the period of validity, special audits may be carried out for specific reasons (see Sections 10 and 11).

The HPQ holder must notify the issuing body of any changes without undue delay (see Section 4).

10. Special audits

Regular inspections are carried out in accordance with the following principles:

- a) DBS 918 007
- b) If the requirements for HPQ have changed during the validity period, the validity of the HPQ can be restored by means of a special audit or, if necessary, by a new HPQ process. The HPQ holder shall report any changes in a timely fashion.
- c) Special audits can be carried out at the request of the holder of the HPQ or at the request of Deutsche Bahn AG Quality Assurance (DB AG QA). The costs, as quoted by DB AG QA, shall be borne by the holder of the HPQ.

11. Costs Overview: Effort and costs of HPQ in accordance with DBS 918 007 (for information purposes)

- > Serves as guidance for applicants for manufacturer-related product qualification in accordance with DBS 918 007 when submitting their declaration of cost assumption (see application for qualification in accordance with DBS 918 007)
- > Billing is still based on the project-specific offer for carrying out the HPQ
- > Deviating or additional expenses/costs shall be stated in the specific offer.

Item	Contents	First-time qualification (audit with 2 P)	Repeat qualification (audit with 1 P)	Special audit (audit with 1 P)	Rewriting of documents due to changes (within the term of the HPQ)	Comment
1	2	3	4	5	6	7
<i>Effort [h] per site/manufacturing works</i>						
P 001	Preparation of on-site inspection/HPQ. Produce or arrange for the production of documents, verification documents; coordination with authorities, OUs, etc.	16.0	10.0	10.0	0.0	If there are multiple sites/manufacturing works, the effort may increase.
P 002	On-site inspection - review of implementation of the requirements in accordance with DBS 918 007 in the manufacturer's QMS and the corresponding HR and material resources in accordance with the desired scope.	48.0	50.0	50.0	0.0	Plus expenses for travel time and travel costs
P 003	On-site inspection/HPQ follow-up. Produce or arrange for production of reports, documents, verification documents.	16.0	10.0	10.0	0.0	If there are multiple sites/manufacturing works, the effort may increase.
P 004	Processing of application documents, etc.	0.0	0.0	0.0	8.0	Minimum expenditure.
Total expenditure [h] ¹		80.0	70.0	70.0	8.0	
A 001	Ancillary costs, i.e. costs for travelling to and from the site incl. accommodation etc. >> <u>flat rate/employee</u>	Based on costs and effort required for the project.				All sites/manufacturing works are included in the flat-rate amount.
<i>Cost of certificates [EUR] per site/manufacturing works</i>						
Z 001	Issue of certificate for HPQ EXC3 (German)	360.00	360.00	360.00	360.00	
Z 002	Issue of certificate for HPQ EXC3 (English or French)	280.00	280.00	280.00	280.00	Invoiced when ordered by the applicant.

¹ > **without item A 001**

> **at the hourly cost rate of EUR 116.40/h (valid from 01/2021; if necessary, request current cost rate).**

> **Additional consultations as part of the HPQ process and/or additional expenditure due to on-site document reviews in preparation for the on-site inspection recorded in the offer based on the time and effort involved and the current hourly cost rate and invoiced to the applicant.**



The client (applicant) must agree to bear the costs before the manufacturer-related product qualification process begins. The estimated costs will be communicated to the client in the cover letter.

The costs consist of the implementation costs and travel expenses.

The travel costs include the costs of hotels, flights and train journeys. They also include the costs for the certificate and publication of the HPQ status.

The costs for all audits conducted as part of the HPQ process shall also be borne by the client.

12. Application documents – on-site inspection

(Implementation of the requirements in the manufacturer's QMS, securing the corresponding HR and material resources in accordance with the scope desired by the applicant).

After receipt of the application, the client may be asked in a letter to provide additional documents or further information on HR and technical resources with the following main areas of focus for preliminary review.

1. Information on the company organisation (organisational structure, organisational chart)
2. Information about production, list of production and testing facilities
3. Information about quality assurance
4. Design/development
5. Production and test sequence plans for the relevant products, tests carried out (laboratory)
6. Other specific processes/process instructions, etc.

Should you have any questions, please feel free to contact us.

Yours faithfully,
Deutsche Bahn AG