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Inhalt und Format von Erstmuster Inspektions- Berichten (ISIR) **Contents and format of Initial Sample Inspection Reports (ISIR)**	Ersetzt Replaces Nr.: No.: TQ-062/0 vom: of: 01.02.2009
	VA-TQ-062/1

Englisch Version

Ausgabe für Lieferanten der Grohe AG

Handout for Grohe AG suppliers

Contents

1. General

1.1 Purpose

This internal guideline serves the purpose of a smooth processing of the initial sampling process of parts between GROHE AG and its suppliers.
The guideline describes the requirements of Grohe regarding the samples and the associated documentation. Furthermore, the responsibilities for the different process steps are defined (see QS-Plan Z-71-10-03/2).

1.2 Scope of application

This guideline applies for all suppliers of production materials (incl. grease), series and spare parts and components, electronic parts, heat treatment, varnishing, surface coatings and purchase finished products (commodities). The requirements of this internal guideline are part of the GROHE Quality Management System. GROHE specific requirements are valid which are explained in detail in the following parts of this guideline.

1.3 Definitions

1.3.1 Initial samples

Initial samples are products which are produced completely with series resources/equipment and under series conditions. Sampling with initial samples is called an initial sample inspection. The sampling for the production process and product release must be carried out with initial samples. Positive evaluation from the customer regarding the initial samples (incl. documentation)will lead to the release by the supplier - series process. In the case of complex or difficult to control processes with potentially high scrap parts, an additional process release (PI TQ-039) will be necessary: this will be determined from case to case. Initial samples are not other samples (see definition below).

1.3.2 Other samples

Other samples (DIN 55350, part 15) are products and materials which are not produced completely under series conditions. Other samples must not be used for the production process and product release. These samples can be used for delivery of products to the customer if they fulfil the specifications. The release of other samples does not mean it is a special release.

Prototype samples serve the purpose of verifying a specific development status of a component in the prototype phase. The parts are produced by means of special (not series processes), or produced by hand and can normally not be produced under a safe process. The use of auxiliary tools does not guarantee a process reliable production. The parts have a prototype character and are not used in products for the customer.

Pre-series samples originate from small series tools or series similar equipment which guarantee a process-safe production. The use of production procedures corresponds to the future series production but the tool is not the series tool at this stage. As a safeguard for the series running phase, the parts are not only from the qualitative aspect, but also due to the produced quantity, suitable for the use in customer products: therefore they are suitable for sampling. Whether the criterion of the small series tools is fulfilled is decided from case to case.

1.3.3 Internal guideline

This internal guideline is an instruction for the implementation of the Grohe initial sampling and in this case offers support for the procedure of this process. At this point it should be made perfectly clear that this guideline does not substitute applicable laws, standards and other guidelines: it is solely an aid in the sense of a process description for the smooth processing of a GROHE initial sampling of components.

1.3.4 Critical components

Critical components are parts that will induce hazard to life or physical condition in case of function failure. They have to be tested completely within the scope of the sampling, i.e. the following main features must be inspected:

1. Measurements
2. Surface according to GSO 409.1.001 ff (visual check)
3. Material
4. Long-term use suitability (requirements of life cycle)
5. Function
6. GSO (bom, packaging, etc.)

Critical components are marked with „F-Parts" in the SAP master data (MM03) in the field „classification". These details are determined with the core data of the material.
The determination of a material as „critical component" is ensured by Development based on the definition and selection, which are defined by the departments MF, TQ and TI.

1.3.5 Responsibility for ISIR of each Plant

As there is not a TQ/... department in every plant, the sampling required by individual plants will be carried out in the plants as follows:

Plant without TQ	Implementation ISIR in Plant
0201 0203 0253 3402	0202 7301 5201 5102

The LSP (Logistic Service Provider) – Plants 0299 and 5299 are not designated for ISIR deliveries/sampling. This LSP only represents series products/components.

1.3.6 Abbreviations

LP – Supplier portal of GROHE AG
ISIR – Initial Sample Inspection Report
PO – Purchase Order

2. The 6 ISIR phases: Procedural description and responsibility

The Grohe initial sampling is subdivided into 6 ISIR phases:

1. Material Specification - preparation (responsible (res.): Grohe Development) and define responsible sampling plant (res.: Operation Excellence for end products, Grohe development documentation for components).

2. Material Specification – send to supplier and release order (PO) (res.: Grohe Procurement).

3. Review of requirements and determination of required proof (test/inspections) (res.: Grohe Quality Control of the respective sampling Plant (TQ/..) in close agreement with the project team and the supplier).

4. Provision of initial samples and test reports/test results documentation (res.: supplier).

5. Inspection of initial samples (res.: supplier – an internal inspection can take place at the supplier location or in an approved external laboratory if agreed with TQ/....). Provision of the inspection results (res.: supplier as the case may be if agreed (see above), also at a Grohe laboratory or an approved external laboratory.

6. Preparation and distribution of an initial sampling inspection report (ISIR) and utility assessment - decision regarding the use of the delivered initial samples and determination of the (as the case may be) required re-sampling (res.: TQ/..).

2.1 Material Specification - preparation

The technical condition of a component/part/product is principally determined by means of the following 3 core details:

- Material number
- Revision status with Change Notification number and validity date.
- Supplier (supplier no.)

Should one of these 3 core details change, then a new sampling must be carried out!

Further rule: If there are minimal/insignificant changes so that no qualification is necessary, the Q-Management of the respective Plant can make a decision regarding non-sampling and therefore no sample parts are required.

Therefore initial samples are usually requested or assigned in the following cases:

- new parts
- product changes (i.e. construction, specification, material changes)
- process changes which influence the product features
- change of supplier (i.e. relocation of tools)

The requirements of the part to be delivered are defined in the form of drawings, Plant standards (GSO = Grohe Standard Organisation) and/or specific delivery standards.

The requirements regarding the procurement of commodities (boxed products) are additionally defined in the test specifications.

The production site of end products into which the components are integrated is determined by the central department Operation Excellence (TI).

The respective responsible Grohe Plant is defined by the development documentation (MFD) and can be identified/ is documented in the SAP part master (transaction MM03).

A new supplier must in principal be inspected by means of an audit with regards to the quality capability and released, as the case may be further qualification steps will be necessary (refer to PI TB 020 and 021).

2.2 Material Specification – send to supplier and release order (PO)

The delivery of new/changed components is dependent on an enquiry regarding costs and feasibility of the supplier.

The supplier will receive the required specification from the Grohe Procurement (drawings, GSOs, delivery standards): in the case of commodities, the supplier will also receive additional test specifications or the description of the complete requirements (including packaging) regarding the complete product.

The request for a quotation (RFQ) sent to the supplier is one of the requirements of the tests to be carried out and the respective documentation for the proof of the fulfilment of the requirements. The quantity of test samples per test as well as the type, version and documentation of tests to be carried out must be submitted to the supplier together with the request for quotation (prices). This information can be obtained from the specification – additional details specifically enquired through TQ/... of the respective Plant or Development and Central Quality Management. The measuring device capability must be considered with all tests/inspections. Grohe Procurement is responsible for enquiries or requests for quotations. .

If the offer of the supplier is to be accepted, the supplier will receive a purchase order for the required initial samples: a PO number is created in SAP for tracking purposes.

A precondition for the creation of the PO in SAP is a corresponding QINFO data clause with the required quantity (transaction Q103) which is based on the 3 above mentioned core details (material no., rev. status, supplier no.) – the Quality Management of the respective Plant is responsible for the creation of the QINFO clause. The PO can not be created in SAP without this QINFO clause.

When a first purchase order (PO) for initial samples is placed, one of 3 different cases must be considered:

- Normal (ISIR-) PO: normally 30 sample parts
- Advanced (ISIR) PO: max number of samples in accordance of the Approval of authorized initial ramp-up orders = AIRO (the 30 sample parts must be ordered separately in order by the project purchase, according to the quantities in excess. AIRO be appointed by the responsible disposition of the work)
- Risky order (ISIR-) PO: max. sample parts corresponding to the planned released launch quantity (Approval of Initial Ramp-up Orders)

Overview PO (Purchase Order): regarding orders within the scope of initial sampling, the following cases are distinguished:

PO	Start of production	Requirement(s)	Identification in P/O -Text ("text block")
Normal P/O (dispatcher)	Must only take place after the receipt of a positive ISIR: incl. the decision: ISIR – YES ISIR–YES-IMP ISIR-YES-Con	Positive ISIR	none
ISIR P/O (Procurement)	May take place immediately after receipt of order normally limited to 30 pieces	Procurement info clause and Q-info clause created. Status 22	**ISIR order -** The suppliers are responsible for the quality of the delivery according to the most current status of documentation. Samples are presented in accordance with Grohe ISIR guidelines (+Link to Homepage).
Extended ISIR P/O (Procurement + Dispo plant)	As ISIR P/O - limited by AIRO	Procurement info clause and Q-info clause created. Status 22 Supplier audit pos.	**Extended ISIR order -** The suppliers are responsible for the quality of the delivery according to the most current status of documentation. Samples are presented in accordance with Grohe ISIR guidelines (+Link to Homepage). Deviations (due process) in dimensional tolerance and surface finish must be accepted by Grohe!
Risky Order (Procurement + Dispo plant)	After receipt of positive on-site release	ISIR PO done previously by the Procurement (30 pieces) After pos. on-site inspection of ISIR samples (pre-release)	**Risky order -** The suppliers are responsible for the quality of the delivery according to the most current status of documentation and the samples of the pre-release.

The respective Plant Quality Management will be informed in writing about the required preparation of the QINFO clause, by the Procurement or project team (via email). A quantity of 30 will be entered in the QINFO clause for a normal (ISIR-) PO. In the case of an extended or risky order ISIR-PO, an „Approval of initial ramp-up order" must be available – the Procurement or project team must send to Quality Management of the respective Plant via email with the request for the preparation of the QINFO clause.

Remarks:

1. A special ISIR order is not available in SAP, but the abbreviation „ISIR" must be used in the order text so that this ID is read electronically and can be evaluated. The extended ISIR order must always be divided so that an order for more than 30 pieces plus a further order for the remaining quantity of required parts is created.

2. A release of the so-called „Approval of initial ramp-up order" for all components or commodities which are procured within the Grohe Innovation Process (GIP) are strictly issued with the signature of the Gate Keeper (Gate Meeting). The release of the „Approval of initial ramp-up order" for all components or commodities which take place within the scope of Cost Improvement (CI) Projects, must be approved by means of the signature of the department head or representative (see respective form for route). An „Approval of initial ramp-up order" must include a cost centre to which costs can be allocated to in the case of non-usability of the ordered components or commodities, or costs for rework. These costs must not be booked under failure costs of the Plants! This procedure is described on form 96.509. It makes sense to capture these costs as Q-costs in the run-up.

2.3 Review of requirements and determination of required proof (tests/inspections)

The Grohe requirements for components and commodities are divided into the following criterion:

1. Measurements
2. Surface according to GSO 409.1.001 ff
3. Material
4. Long-term use suitability (requirements of life cycle)
5. Function
6. GSO (BOM, packaging, etc.)

In addition attention must be paid to the CE (Europe) marking and UL (USA) of all electrical components or commodities. This point is also documented in the ISIR.

The necessary inspections for the fulfilment of the requirements are carried out according to this division and documented in the ISIR (form 96.067, see PI-TQ 058).

As some inspections/tests are not always possible at the supplier's location or in the laboratory of the respective Plant, outstanding tests/inspections must be carried out at MFE and/or an accredited external laboratory (accreditation of the laboratory in accordance with DIN EN ISO 17025).

The inspections/tests to be carried out will be coordinated by the Grohe Project Team (from GIP-Projects) or the Quality Management of the respective Grohe Plant responsible for the ISIR, that means:

- Determination of the inspections in accordance with requirements (drawings, GSOs).
- Review of Plant internal testing possibilities and capacity for these tests.
- Review of the requirement for additional testing capacities in a different Grohe Plant or at external testing laboratories under consideration of the time schedule.
- Determination of the test schedule: which test will be carried out when and where (by whom).
- Determination of required on-site tests for the acceleration of the procedure.
- Dependent on: to whom (location), quantity (amount), when (deadline) and what for (tests), the required samples must be dispatched.
- Information to the supplier regarding required tests and quantity of samples which must be available at the defined location and when.

The coordination of the activities for sampling supports:

- Standard (ISIR-) PO: 30 samples of the respective Plant Quality Management and for
- Advanced (ISIR) PO: max. Number of parts acc. AIRO (30 ISIR test parts on separate order ISIR and max. More parts, a total acc. AIRO) or
- Risky Order (ISIR) PO: max. Samples according to the production site of the planned launch of the shared volume (AIRO).

The Project Team (from GIP-Projects).

The 30 ISIR samples are always dispatched to the Plant Quality Management responsible for the sampling. The further distribution of the samples to the various laboratories is carried out by TQ/....

In the case of sampling of components from a tool with various cavities, at least 1 part of the cavity must be measured: this could mean an increase of the quantity of the required samples (details to be provided by the project team or TQ/.... of the respective plant).

2.4 Provision of initial samples and test reports/test results

The time schedule of the project team determines the implementation of the sampling.

In the case of a **normal-ISIR**, 30 samples for initial sampling are dispatched together with the documentation of the tests already carried out by the supplier to the Quality Management of the respective Plant responsible for the ISIR. For this purpose the supplier will receive the corresponding PO from Procurement (see point 2.2.).

In the case of a tight time schedule, a pre-inspection of the samples at the supplier location is possible: this is a so-called "**on-site check**".

The following variants are possible:

- **On-site Sample Check** Aim: reduction of sampling duration as the pre-inspection reduces the risk of a new sampling loop. On-site sample checks can also be carried out by a SQE (Supplier Quality Engineer), i.e. from the China sales team. No batches are released for usage, but only the provided ISIR samples inspected beforehand at the supplier location and after agreement dispatched to the respective Grohe plant:
  and the
- **On-site pre-release** Aim: Check and pre-release of a production batch for an urgent launch date. For this purpose the ISIR samples provided from one production batch by TQ (Central Quality Management) is inspected at the supplier location. After suitability is established, a limited quantity of components or commodities are released for production – in which case the following requirements must be adhered to:

  - Release and implementation of inspection only via TQ (Central Quality Management) or representative.
  - „Approval of initial ramp-up order" must be available => limited quantity of pieces.

  - Minimum fulfilment of the required measurements and SO2 Test (corrosion).

- **Not for critical parts** (in the case of failure, this could lead to a product liability case = water, or even personal injury).
- The 30 required ISIR samples from the released batch are dispatched to the respective Grohe Plant within one week.
- A complete ISIR must be carried out in the respective Grohe Plant.
- The testing equipment at the supplier's must meet the general requirements and the laboratory must be approved (DIN EN ISO 17025).
- The pre-release report is sent to the Grohe project team including Procurement and saved on the server (also under the QINFO clause at a later date).

2.5 Inspection of initial samples for the ISIR

The initial samples are inspected according to the respective test schedule: which means that the requirements regarding the main features in accordance with 2.2 (see above) are inspected. The inspections can be carried out in the following laboratories:

- Supplier; requirement: the laboratory is released by Grohe and the testing equipment meets the specified requirements.
- Grohe Plant; which is responsible for the ISIR.
- Grohe Plant; which is appointed by the responsible Plant.
- Development (MFE)
- External laboratory (certified in accordance with ISO 9001 and ISO 17025), appointed by the supplier and/or Grohe.

The inspection report/test results must be prepared in English in the following cases:

- Supplier is not located in Germany and/or
- ISIR responsible Plant is not located in Germany and/or
- The component or commodity is also used in a non-German plant.

2.6 Preparation of utility assessment and distribution of the initial sample inspection report (ISIR)

In the sixth and last phase of the ISIR process, the report is prepared and the decision made regarding the use of the delivered initial samples as well as a decision as to whether re-sampling is required is made. The ISIR is then distributed to the supplier and internally. Distribution list: Procurement; Project Leader; KAP; TQP; TQ/...; TI/...; TF/...

All results of the qualification inspections are summarized in a report for which Grohe form 96.067 must be used. The respective Plant (TQ/..) in accordance with SAP (transaction MM03) is responsible for the preparation, completeness, distribution and saving/filing of the ISIR.

The correct use of the ISIR form is defined in PI-TQ 058.

Depending on the inspection results, the following decisions can be made:

- **Requirements (completely) fulfilled**: no corrections, the process carried out for these samples is released; produced parts which correspond to these samples can be used.

- **Requirements not fulfilled: new samples to be presented,** the process carried out for these samples is not released, produced parts which correspond to these samples can not be used (correction).

- **Requirement not completely fulfilled**: the process carried out for the production of these samples is not released and must be optimized, produced parts which correspond to these samples can be used under a limited special release.

  During the special release a decision is made whether this is a case of **customer relevant and not customer relevant.**

  Customer relevant means that, as the case may be, complaints/claims could arise: in this case a **Special Release** with the approval of Category Management (MC) and Corporate Quality Management (TQ) is required..

  Should the deviation be **non customer relevant** (i.e. non-visual shape or measurement deviation without influence on durability or functionality), the plant can **(per Special Release Plant)** approve a limited deviation approval (without the involvement of Category Management (MC) and Corporate Quality Management (TQ)).

The procedure for **Special Release** and **Special Release Plant** are defined in PI-TQ 012.

2.7 General questions regarding the subject of initials sampling

2.7.1 Storage of initial samples

At least one initial sample (retained sample) from the supplier and the respective Grohe Plant Quality Management (completely marked), must be stored in a non-accessible room under suitable conditions for the duration of the product/contract, plus 5 additional years. .

2.7.2 What does the complete initial sample documentation contain?

If not agreed otherwise, the guidelines of the respective valid version of the GROHE procedural instruction comes into effect (PI TQ-058) – see attachment.

2.7.3 General

The delivery of initial samples and other samples must take place with the complete documentation according to the purchase order. If this is not the case, the supplier could be presented an invoice for the costs of the additional work. The documentation requirements are principally to be taken from the PI TQ-058. The supplier will be informed of additional documentation requirements by Grohe. The forms for the initial sampling can be called-up on the Grohe website www.grohe.com.

Further points listed below must be noted for the completeness of the initial sample documentation.

2.7.4 Initial sample inspection report – cover page

The only valid template to be used is the ISIR cover page (according to GROHE PI TQ-058).

The form Initial Sample Inspection Report 96.067 can also be called-up on the GROHE webpage under the following datafile:

The form 96.067 can also be called-up on the GROHE webpage under the following datafile:

VA TQ 058 Initial sample inspection report and cover page.

2.7.5 The supplier always has the evaluation of the prime values of the preliminary process feasibility tests (VPFU)

The implementation of a VPFU is dependent on the requirements of the process: it is not always requested and agreed with the supplier. The general procedure for the selection of parts for the VPFU is as follows:

1. Selection of a minimum of 20 parts from a production batch (where there are several cavities: 20 per cavity)
2. Feasibility analysis on the basis of the selected parts/components.
3. As part of the process restraints (not feasible due to extreme process variations, one-sided status etc), an analysis of individual nests, pallets etc. must be carried out in order to identify what the unstable process restraint is caused by.
4. Depending on the type of problem, the process must therefore be optimized until the overall process is feasible. The required measures must be recorded in an action list.
5. Repeated selection of a minimum of 60 work pieces and verification of the optimization loop(s), as the case may be, must be continuously be repeated until a feasible result is achieved.

An evaluation which underlies the VPFU must be attached to the summarized and clear form. The measured parts must be numbered and marked „**measured parts**“ and delivered with the sample batch.

Recommendations for the statistical evaluation of the established measured data:

On the part of GROHE, an evaluation with a suitable statistical evaluation programme is required (i.e. QS Stat, MINITAB, Statistics ....).

During the implementation of the statistical analysis, in the first step the optimal distribution type recommended by the software should be selected and tested for plausibility. For reasons regarding the non-verifiable process stability (long-term feasibility of the process), a mixed distribution is not acceptable.

3 Other applicable norms and standards

Relevant DIN ISO standards, i.e. inspection reports according to EN 10204; ISO 9001; ISO 17025

Grohe documents:

OR 73/3 (GIP) Grohe Innovation Process

VA-TB 020 and 021 supplier qualification

VA-TQ 039 Procedural and process qualification

VA-TQ058 Content and form of GROHE initial inspections reports (ISIR)

QS-Plan Z-71-10-03/2 „The 6 phases of the Grohe ISIR process“