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etreff / Subject: nhalt und For EMENA und A	mat von E	rstmuster Insp	ektions- Beric	hten (ISIR)		gültig ab: valid from: 01.01.2022 Ersetzt: replaces: Nr. TQ-058/2
Contents and EMENA and A		Initial Sample	Inspection Re	ports (ISIR)		No. 10 050/2 vom: from: 01.05.2011
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	TDA TDB TDC TDD	- M. Engelha - Dr. W. Gaio - T. Scholz - D. Mainka		<u>z. K.:</u>	TIE HOR GDP	- B. Bartels - M. Pingel - M. Fromme
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<u>English</u>						
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<u>Klaeng:</u>	TQ/KL TQI/KL TE/KL	- S. Waijai - K. Songsrii - S. Boonsita		<u>Jiangmen:</u>	TQ/JG TQI/JG TI/JG	- L. Li - J. Zhang - F. Guo

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# 1. General

#### 1.1 Subject

This guideline is intended to support the smooth handling of the initial sample process of components between GROHE AG (EMENA and APAC) and its suppliers. It describes the requirements that Grohe places on the samples (maturity requirement) and the associated documentation. Furthermore, the procedural instruction describes the content and format of written initial sample inspection reports (in short: ISIR). This PI applies to all purchased materials, i.e. both production materials (incl. lacquers, surface coatings, label and packaging as well as any external processing) and purchased complete products (so-called "boxed products").

#### 1.2 Scope

The requirements of this guideline are part of the Grohe AG Quality Management System. This PI applies to all plants and divisions of Grohe AG (EMENA and APAC) worldwide.

#### 1.3 Definitions

# 1.3.1 Initial sample inspection report (ISIR)

The initial sample inspection is intended to prove that the components or complete products manufactured by the supplier meet the requirements according to the current drawing or GSO (Grohe Standard Organization), as well as the legal regulations and applicable national and international DIN/EN/ISO standards.

For this purpose, the supplier must present the test reports in accordance with the requirements together with the initial samples before series delivery. The contents and requirements are explicitly discussed with the supplier and the central quality department (TQ) in a sample coordination meeting (BAG) after the contract has been awarded.

The production of the samples for the initial sample inspection, must be produced under series conditions. Based on the maturity requirement, there must be at least one classification with D or S (see 1.3.2 Maturity requirement). The test reports are summarized in the ISIR.

Any deviations identified by the supplier that cannot be corrected shall be discussed and clarified with R&D in advance.

These samples are not to be presented without prior clarification.

The ISIR contains the decision for release for material with or without conditions or non-release.



# 1.3.2 *Maturity requirement*

	Definition	Requirement	Restriction	Supplement	Usage
A	<b>Conditionally</b> functional with limited range of functions	conditionally functional sample	Not suitable for long-term testing		Prototype test
В	functional with (planned) complete range of functions	functional sample Auxiliary tools	possibly not yet a complete range of functions	Long-term tests possible	
С	Not yet fully qualified, but with complete range of functions	Series material Series tools <b>near-series</b> conditions	Deviations from the specification can occur	Complete range of functions should be ensured	Prototype test Acceptance test
D	Requirements for a series component are fulfilled	Series material Series tools Series conditions	Long-term capability not yet proven	Deviations from the specification are corrected	
S	all requirements for a series component are fulfilled	Series material Series tools Series conditions	No restriction	Long-term capability proven	Acceptance test Series production

# 1.3.3 On-site Check

The **On-site Sample Check** is intended as a preliminary check of sample parts (initial samples and the associated sampling documents) that are to be sent to the sampling plant.

The scope of the check must be coordinated in advance with the respective Grohe Quality of the responsible sampling plant (TQ).

The **On-site sample check** can also be carried out by the SQE (Service Quality Engineers) from the purchasing team in China.

# 1.3.4 On-site Pre-Release

On-site pre-release is a positively completed preliminary sampling of sample parts at the supplier.

TQO - Corporate Quality On-site Release in China is responsible for the preparation of on-site release reports.

# 1.3.5 Test centers

For the purposes of this PI, the following are considered test centers: the TQ/..departments, suppliers of all plants, logistics centers, central laboratories of Grohe AG, the laboratories of the suppliers, approved laboratories of the suppliers, as well as the commissioned external (accredited) testing institutes.

# 1.3.6 Special characteristics

Product features or production process parameters that affect the safety or compliance with regulatory requirements, the fit, function, performance or further processing of the product. As part of the product development process, it should be ensured that no products with

As part of the product development process, it should be ensured that no products with defective special characteristics are created.

These are to be marked and evaluated accordingly in the ISIR.



\* Boxed Products Central TQ

# 1.3.7 Submission stage

The requirements for sampling are derived from GSO 0.80.1002 (ECN:252355) "Guidelines for sampling according to submission stages". Basically, the requirement for all sampling is **submission stage 2**. Deviations can be made in the project in the BAG with the central quality.

The submission stage for change sampling of series components is in each case taken from the submission stage, see appendix page 14.

#### 1.4 Responsibilities

#### 1.4.1 ISIR

Sampling of the components is carried out via the responsible plants.

Some Grohe plants do not have their own TQ/... department, the sampling required there is carried out at the Grohe plants shown below:

Plant without TQ / TQ without plant	Performance ISIR in the plant
000/	
0201	0202
0203	7301*
0204	7301*
0205	7301*
0253	5201
3401	5102
4001	7301

LSP (Logistics Service Provider) Plant without ISIR deliveries and sampling	
0299 5299	

#### 1.4.2 ISIR Boxed products Asia

For ISIR for Boxed Products Asia, it is possible to obtain approvals directly from the respective plant in Asia.

# 1.5 Abbreviations

- LP Supplier portal of GROHE AG
- ISIR Initial Sample Inspection Report
- P/O Purchase Order
- BAG Sampling coordination meeting
- TQ Quality
- TQL\_Plant / TQS Supplier Quality
- CI Cost Improvement
- AIRO Approval of initial ramp-up order



# 2. 6 ISIR phases at Grohe AG for components process description and responsibilities

Phase	Description	Responsible	Comment
1	Create material specification	Grohe development	Operation Excellence for end products, Grohe development documentation for components
2	Send material specification to supplier and trigger purchase order (PO)	Grohe procurement	Standard sampling scope according to template (see GSO 080.0.1002) In case of series change, coordination of procurement with TQ of the responsible sampling plant about the scope and BAG
3	Review of requirements and determination of required evidence (tests/examinations).	Grohe quality <b>Project</b> TQP (LITQ/R&D) <b>Series</b> TQ of the responsible sampling plant	in close coordination with the project team and the supplier "Sampling coordination meeting"
4	Provision of the initial samples and test certificates/test results	Supplier	
5	Inspection of the initial samples	Grohe Quality	In coordination with TQ, internal testing or testing at an external accredited approved laboratory is also possible.
6	Preparation and distribution of the initial sample inspection report (ISIR) and usage decision	Grohe Quality if applicable R&D	Decision on the use of the initial samples supplied and determination of any subsequent sampling that may be required.

# The Grohe initial sampling is divided into 6 ISIR phases:

#### 2.1 Create material specification

In phase 1, all requirements for the part to be supplied are defined and specified in the form of drawings, works standards (GSO = Grohe Standard Organization) and/or special delivery standards.

For boxed products, i.e. complete products, the requirements are additionally defined in test specifications for end products.

This also applies to products that are not fully specified via GSO's or drawings.

#### **2.2** Send material specification to supplier and trigger purchase order (PO) The supplier receives an inquiry from Grohe Procurement regarding costs and feasibility on new / modified components and products.

Furthermore, the required specification (drawings, GSOs, delivery standards), in the case of boxed products also additionally (the test specifications) or the description of the overall requirements incl. packaging for the complete product are communicated to the supplier. This also includes the requirements for the tests to be performed and their documentation to prove that the requirements have been met. The number of



test samples per test as well as the type, execution and documentation of the tests to be performed are included with the request to submit the offer (prices)

In the case of a purchase order (PO) of initial samples, a distinction is made between 2 cases:

• Normal (ISIR-) PO: usually 30 sample parts

(AIRO required for more than 30 parts)

 AIRO (ISIR-) PO: max. sample parts according to the planned released launch quantity (approval of Initial Ramp-up Orders, Limited quantity or schedule must be defined)

# 2.3 Verification of the requirements and determination of the required evidence (tests/examinations)

The Grohe requirements for components and boxed products are divided into the following main aspects. The fulfillment of these requirements are decisive for a positive ISIR evaluation by Grohe AG:

- 1. dimension
- 2. function
- 3. surface
- 4. material
- 5. packaging
- 6. endurance (service life requirements)
- 7. compliance with all applicable specifications and standards

In addition, the CE (Europe) markings (UL for USA) must be observed for all electrical components or boxed products. This point is also documented in the ISIR.

The supplier is responsible for providing evidence of the required tests in the laboratory. Deviations must always be agreed upon in advance at BAG:

• Supplier, requirement: the laboratory is approved by Grohe AG and the test equipment is capable according to requirement

Possible criteria for the deviating case are:

- Grohe plant responsible for the ISIR
- Grohe plant commissioned by the responsible plant
- Development (MFE)
- External laboratory (certified according to ISO 9001 and accredited according to ISO 17025), commissioned by the supplier and/or Grohe AG

# The 30 ISIR samples are always sent to the plant TQ/.. responsible for sampling. The further distribution of the samples to the various laboratories is carried out by TQ/...

When sampling components from a mold with several cavities, at least 1 part per cavity must be completely measured, which can increase the number of required initial samples (specification by the project team or TQ/.. of the responsible plant within the scope of the BAG).

For the identification of the ISIR samples, a marking of the delivery with at least the following information on the part of the supplier is necessary:



Supplier No.	Drawing No.	GSO / Rev.		
Product description	Status / Date	Material No.		
Purchase order No.	ÄM Number / ECN	CDX		
ISIR SAMPLE				

See applicable document ISIR Labeling:

#### 2.4 Submitting of the initial samples and test certificates/test results

The time schedule of the project is binding for the supplier to perform the sampling. The sampling date is also confirmed by the supplier in the course of the BAG.

In the normal ISIR, the 30 samples for the initial sampling, together with the documentation of the tests already performed, are sent by the supplier to the TQ/.. of the Grohe plant responsible for the ISIR (ISIR at least 5 working days before the ETA, in advance to the e-mail group mailbox of the respective plant). The supplier has received the corresponding PO from Purchasing for this purpose (see clause 2.2).

- Werk HEMER: qm-supplier.Hemer@grohe.com
- Werk LAHR: qm-supplier.Lahr@grohe.com
- Werk PORTA: tq.pw@grohe.com
- Werk ALBEGERIA: PT-SQA@central-it.grohe
- Werk KLAENG: tq.kl@grohe.com

#### **E-Mail Correspondence:**

- Betreffend: Erstmusterberichte ( ISIR )
- Regarding: Initial Samples ( ISIR )

Description: ISIR		Material 4120230		ECN: 244154	Vendor No. 41059
	Example				
	-	An			
	Senden	Cc			
	Senden	Betreff	ISIR - 41	2023038 - 244154 -	41059
	-				

Example: Regarding E-Mail Correspondence

If the schedule is tight, it is possible to carry out an **on-site check** of the samples (to be used exclusively for the Asian continent) at the supplier's premises. If necessary, these **on-site checks** must be coordinated and released by the supplier with the TQ/... of the Grohe plant responsible for the ISIR.

The following variants are possible:

On-site Sample Check; Goal: Reduction of the sampling time, as the risk of a new sampling loop is reduced by the pre-sample check. On-site Sample Checks can also be performed by a TQS (Supplier Quality Engineer), e.g.: from the Asia Quality Team. No batches are released for use, only the ISIR samples provided are checked in advance at the supplier's site and sent to the responsible Grohe plant if suitable (Ceramics are fully sampled and approved on site);

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and the

- **On-site Pre-release**; Goal: Review and pre-release of a production lot for an urgent launch date. For this purpose, the ISIR samples provided from a production lot are checked by TQS at the supplier's site. If suitable, the pre-release can release a limited quantity of components or boxed products for production, subject to the following conditions:
- Approval and test performance only by TQ (Central TQ/..) or authorized representative
- Approval of initial ramp-up order" must be available => limited number of pieces
- Minimum fulfillment of requirements Dimensions and performance / life cycle tests
- All Special Characteristics must be positively verified (failure to do so may result in a product liability case = water damage or even personal injury)
- From the released lot, the 30 required ISIR samples will be sent to the responsible Grohe plant within one week
- A complete ISIR at the responsible Grohe plant must be carried out
- The test equipment at the supplier must have the general test equipment capability and the laboratory must be approved (see 2.3)

# 2.5 Testing of initial samples for the ISIR

The initial samples for the ISIR are checked by the supplier with regard to all required features and requirements and documented in the ISIR. All necessary proofs (in German or English) are attached to the ISIR and sent to Grohe AG.

In the following cases, the test documentation (report) must be prepared in English:

- Supplier is not located in Germany and/or
- ISIR responsible plant is not located in Germany and/or
- the component or boxed product is also used in a non-German plant (Exceptions are to be coordinated with the respective TQ/..)

# 2.6 Creation of the usage decision and distribution of the initial sample inspection report (ISIR)

In this sixth and final phase of the ISIR process, the report is reviewed and a decision is made on the use of the initial samples supplied, as well as on any subsequent sampling that may be required. The ISIR's usage decision is then communicated to the supplier.

The usage decisions in the ISIR are classified below:

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

- Requirements (fully) met (i.O.) no restrictions, the process carried out to create these samples is approved, produced parts that correspond to these samples can be used
- Requirements not met, new samples to be presented (n.i.O.) the process carried out to create these samples is not approved, produced parts that correspond to these samples cannot be used (correction) re-sampling required



#### • Requirements not fully met (b.i.O.)

the process carried out to create these samples is not approved and must be optimized, parts already produced that correspond to these samples can be used per limited special release. Re-sampling required or ECN with resampling.

Customer's decision Approval																	
				Product/Process													
	Overall	Overall	Overall	1	1	-	1	1	1	2	4	ъ	6	- 1	8	6	_
		Process	Product	<u>`</u> _	N	ω	4	Ċī	6		4	0	0,	7	6	<i>w</i>	0
ОК																	
Conditionally ok - follow-on submission required																	
submission required NOK - Reapproval of PPA Process required																	
Deviation Approval N	lo.:			Qua	antity	/:											

# 2.7 General information about initial sampling

# 2.7.1 ISIR Requirements

An ISIR is requested in the course of the new presentation of initial samples for new projects. Furthermore, an ISIR must be provided by the supplier for:

- Product changes (specification changes)
- production relocation
- Changes in production processes
- Suspension of production for longer than 12 months
- Tool changes/corrections (dimension relevant)
- Material changes
- Change of purchased parts
- Change of suppliers
- Changes of quality influencing factors

**Further regulation**: If the changes are so minor/insignificant that no qualification is required (editorial change), the TQ- of the responsible plant may decide that only a cover sheet sampling and thus no sample parts are required.

# 2.7.2 Archiving of initial samples

The supplier shall keep at least one initial sample per cavity (reserve sample) fully labeled in a room not generally accessible under suitable conditions for the duration of the product/contract plus 5 additional years.

#### 2.7.3 Initial Sample inspection report cover sheet

The ISIR cover sheet is to be used as the only valid template. Form 96.073 can also be downloaded from the GROHE website under the following designation:

96.073 ISIR Cover Sheet

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Initial sample inspection report and cover sheet

# 2.7.4 Process and product verification / capability

The performance of a PPCS (Preliminary Process Capability Study) depends on the process requirements, it is not generally required and is coordinated with the supplier. Exceptions are special characteristics with direct/indirect influence on the product, if not coordinated, Ppk (preliminary process capability) >1.67 must be considered.

Basic procedure for the removal of parts for PPCS:

- 1. Removal of at least 30 components from a production lot (in case of several cavities: 30 per cavity)
- 2. capability analysis on the basis of the extracted components
- 3. in the course of the process behavior (not capable due to extreme process variations, one-sided position behavior, etc.), an analysis must be carried out according to individual nests, pallets, etc., in order to be able to recognize where the unstable process behavior comes from.
- 4. according to the nature of the problems, the process is to be optimized until the overall process is capable. The necessary measures are to be included in an action plan.
- 5. sampling again at least 60 workpieces and verifying the optimization loop(s), (repeat(s) again if necessary until a capable result is obtained.

An evaluation based on the PPCS shall be attached in a summarized and clearly arranged form. The measured parts are to be numbered and marked as "measured parts" and delivered with the sampling lot.

Recommendations for the statistical evaluation of the measured values: On the part of GROHE, the evaluation with a suitable statistical evaluation program is required (e.g. QS Stat, MINITAB, Statistica...). When performing the statistical analysis, the first step is to select the optimum distribution type suggested by the software and to check it for plausibility. For reasons of unverifiable process stability (long-term capability of the process), the mixed distribution is not permissible.



# 2.7.5 General

The delivery of initial samples and other samples must be made with **complete documentation according to the order. If this is not the case, the supplier may be invoiced for additional expenses**. Grohe will inform the supplier of any additional documentation requirements. The forms for initial sampling can be downloaded from the Grohe website www.grohe.com.

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

# 3. Process description - reporting / filling in the form

#### 3.1 Cover Sheet

		Cover Sheet					
Sender	Recipient	Supplier I	ISIR Report No.:				
		Production p	process and product approval report	english 💌			
		Report coveri	ing other samples				
		Sample s	submission				
• • • • • • • • • • • • • • • •		New parts	Product modification	Modification supply chain			
• • • • • • • • • • • • • • • •		Process mod	dification Reapproval of PPA Process	Colour approval			
		Attachment inspection					
		Product / Process					
	3 Compliance with legal requirements	10 List of measurment de		site pre-release			
	4 Compliance with Grohe GSO	11 Confirmation of proces					
	5 Process FMEA 6 Design FMEA	12 Design, development i 13 Achivement of special		iers			
	7 Software test report		ystems acc. customer requirements				
	8 Process flow chart	15 Capability study of tes					
	9 Control plan	16 On-site sample-check					
			per submission level GSO 080.0.1002 current	t Index)			
Supplier No.:	Drawing No.:		GSO / Rev.:				
Part description:	Issue/Date:		Batch No.:				
Order Schedule No.:	AM-Nr. / ECN	~	CDX:				
		œ					
Name:	Department:		Signature / Date:				
ISIR Report No.:	Custon	her					
Customer's decision	Approval						
	Product/Proc	ess					
Overall Overall Overa		6 7 8 9 10 11 13 14	5 6 7 8 6				
Process Produ			5 6 7 8 9				
<u>&gt;</u> K □ □ □							
Conditionally ok - follow-on United States of the states o							
Process required							
Deviation Approval No.:	Quantity:	Tool release	se: Yes No				
Date: Signature Ir	spector Inbound:	Date:	Signature Grohe TQL:				
Comments:							
Distribution: Purchasing, Project Management, Inc.	lustrial Engineering, Central Quality	0					

#### 3.2 Cover Sheet Header

When preparing the report, the form/template according in the valid version is to be used.

The contact address details in the "Sender - Recipient" field are to be adapted according to the responsible test center.

	Cover	Sheet				
Sender	Recipient	Supplier ISIR Report No.:				
		Production process and product appro				
		Report covering other samples				
		Sample submission				
		New parts				
		Process modification R				
		t inspection				
	Product	/ Process				
1.1 Geometry, dimension check	3 Compliance with legal requirements	10 List of measurment devices				
1.2 Function check	4 Compliance with Grohe GSO	11 Confirmation of process capability				
1.3 Surface check 5 Process FMEA		12 Design, development release of the supplier				
1.4 Packaging	6 Design FMEA	13 Achivement of special characteristics				
1.5 Material test certificate	7 Software test report	14 Approval of coating systems acc. customer re-				

The contents of the first page should clearly indicate the basis on which the report was prepared. Furthermore, a clear assignment of the ISIR reason must be recognizable.

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Supplier ISIR Report N	lo.:					
Production process and product approval report english						
Report covering other samples						
Sample submission						
New parts	Product modification	Modification supply chain				
Process modification	Reapproval of PPA Process	Colour approval				

# 3.3 Cover sheet Medium block

All fields in the middle block must be considered mandatory fields. It is essential that the specifications from the sample approval meeting are also taken into account.

Attachment inspection Product / Process							
1.1 Geometry, dimension check	3 Compliance with legal requirements	10 List of measurment devices	17 On-site pre-release				
1.2 Function check	4 Compliance with Grohe GSO	11 Confirmation of process capability	18 Sample				
1.3 Surface check	5 Process FMEA	12 Design, development release of the supplier	19 Others				
1.4 Packaging	6 Design FMEA	13 Achivement of special characteristics					
1.5 Material test certificate	7 Software test report	14 Approval of coating systems acc. customer requirements	_				
1.6 Drinking water conformity	8 Process flow chart	15 Capability study of testing equipments					
2 Material check	9 Control plan	16 On-site sample-check					

Supplier details (Confirmation of us	ing sample submission in accordance of requirements per	submission level GSO 080.0.1002 current Index)
Supplier No.:	Drawing No.:	GSO / Rev.:
Part description:	Issue/Date:	Batch No.:
Order Schedule No.:	ÄM-Nr. / ECN	CDX:
Name:	Department:	Signature / Date:

Important: The change notice no. refers to the drawing and not to the material

# 3.4 Cover sheet Lower block

These fields are filled in by the report reviewer (customer).

A report number (initial sample inspection report) is also to be entered, which includes a sequential number.

	S	upp	lie	r de	etai	ls (	Col	nfiri	mat	ior
Supplier No.:										
Part description:										
Order Schedule	lo.:									
Name:										
ISIR Report No.:										

Customer's decision									P	Аррг	OVa	al																											-
										uct/																													
	Overall	Overall Process	Overall Product	1.1	1.2	1.3	1.4	1.5	× •	24	. <mark>0</mark>	יס	7	<b>1</b> 00	9	10	11	12	i 🕹	14	: 7	16	5	1 0	b a	5												Τ	
ОК									][		][										1		1		][	]									Τ		Т	Т	
Conditionally ok - follow-on submission required									]														][		][	ו											Τ	T	
NOK - Reapproval of PPA Process required									][		][										][		][	][	][	ו											Γ	Т	
Deviation Approval N	lo.:			Qu	antit	y:												T	ool	rele	eas	e:			Ye	es [			No							 	 		
Date:		Sig	nature Insp	pecto	or In	ibou	ind:									D	ate:								Si	igna	ature	e G	roh	e T	QL	:							

If the samples are functionally approved, i.e. usually dimension (1.) and function test (5.), tool approval can be checked with yes and issued.

# 3.5 Cover sheet comments

In this field, comments or additional information can be entered in written form as text.



# 4. Applicable documents

Relevant DIN ISO standards, e.g.: Test certificates according to EN 10204; ISO 9001; ISO 17025

Grohe documents: OG 73 (GIP) Grohe Innovation Process PI-TB 020 and 021 Supplier Quality PI -TQ 039 Method and process qualification PI -TQ 062 Internal guideline for initial sample inspections of the GROHE AG (EMENA and APAC) GSO 080.0.1002 Guideline for sampling according to submission stages 96.073 ISIR Cover Sheet 96.081 ISIR Sample Labeling

Note: The respective valid revisions of the documents apply to the request for quotation and quotation submission phase.

# 5. Appendix

Bemusterungsgründe	ISIR Vorlagestufe
reasons for sampling	ISIR Submission level
Neuteil - <i>new part</i>	Level 2
Nachbemusterung - <i>resampling</i>	Level 2
Änderung am Produkt - changes of the specification	Level 2
Änderung am Prozess - changes in processes	Level 2
Änderung in der Lieferkette - changes in the supply chain	Level 2
Neuer Prozess - new production process	Level 2
Produktionspause > 12 Monate suspension of production > 12 month	Level 1
Farbbemusterung - color sampling	Level 1
Neue Technologien - new technologies	Level 3
Redaktionelle Änderung - editorial change	Level 0

Submission stage according initial sampling reason