

Guide to initial sampling supplier

1. Purpose of initial sampling

Initial sampling prior to the beginning of serial production is intended to demonstrate that the agreed quality requirements are being satisfied.

The aim is to ensure that the contractor has correctly understood the requirements on the product. The production department is expected to be in a position to manufacture the product consistently in accordance with the requirements and in the requisite quantity.

2. Definitions

Initial samples

Initial samples are products that are manufactured entirely using serial production facilities under serial production conditions, and inspected with serial test equipment and found to be in order. The process of sampling using initial samples is called initial sample inspection. The sampling for the production process - and product approval - must be carried out with initial samples. The consequence of a positive or negative evaluation of the initial samples by Hydreco, including the associated documentation, is either their approval or rejection.

Other samples

Other samples are products and materials that have not been produced under serial production conditions. These samples must meet the specifications. Other samples are not subject to any special approval procedure.

Guide

A guide is a set of instructions for the implementation of a task and in this case offers support for the procedure of initial sampling. At this point it is explicitly pointed out that a guide is not a substitute for applicable standards and guidelines, but should only be regarded as a tool to assist in the smooth processing of an initial sampling of components.

RoHS

Restriction of certain Hazardous Substances

EU Directive 2011/65/EU of 03.01.2013 (RoHS 2)

EU Directive 2015/863/EU of 22.07.2019 (RoHS 3) on the restriction of the use of certain hazardous substances in electrical and electronic equipment

REACH

Registration, Evaluation and Authorization of Chemicals

(EU) No. 1907/2006 OF THE EUROPEAN PARLIAMENT AND THE COUNCIL of 18 December 2006 on the

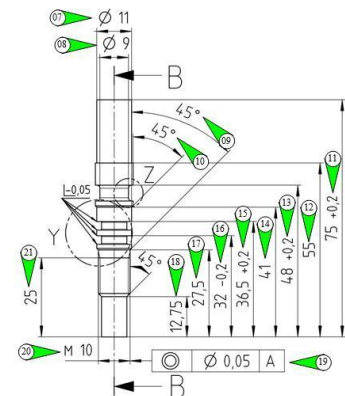
registration, evaluation, authorisation and restriction of chemical substances (REACH), establishing a European Chemicals Agency

3. Requirements

- Unless otherwise agreed, 3 units of each product are sampled.
- Material certification (Test acceptance certificate - Material certificate / Test certificate 3.1 in accordance with EN10204 of the batch from which the initial sample was produced)
- The measurement report must be created on the basis of the Hydreco drawing. For this purpose all the features on the drawing must be labelled ("stamped") with an identification number (see example below). In addition to dimensions the relevant specifications also include characteristics that are listed on the drawing in the form of text. Bracketed dimensions, on the other hand, are not part of the initial sampling. If the drawing does not contain any measurable characteristics, these must be verified using appropriate measures (test gauges, indirect measurement methods, etc.).
- The following information must be clearly visible in a legible form in the measurement report for each characteristic:
 - Reference to the initial sample part (Sample 1, Sample 2, Sample 3)
 - Nominal dimension
 - Upper and lower limits (tolerances)
 - Measured actual dimension
 - A list of the measuring and test equipment used, including identification number and current calibration status. When several measuring instruments are used it must be identifiable from the measurement report which measurement has been inspected with which measuring instrument.
 - Assessment (OK or deviation) by the supplier
 - Placeholders for validation measurements and observations by Hydreco
 - The measurement report must contain the date and the name of the inspector

Example:

Nr.	Merkmale / Nennwerte / Toleranz / Einheit / Prüfmethode	Istwerte Lieferant	Spezifikation erfüllt		Istwerte Abnehmer
			Ja	Nein	
7	Ø / 11 / ± 0,2 / mm / Digit. Messschieber	11,01	x		
8	Ø / 9 / ± 0,2 / mm / Digit. Messschieber	9,01	x		
9	Winkel / 45° / ± 1° / Profil-Projektor	44°09'	x		
10	Winkel / 45° / ± 1° / Profil-Projektor	44°41'	x		
11	LM / 75 / + 0,2 / Digit. Messschieber	75,05	x		
12	LM / 55 / ± 0,3 / Digit. Tiefenmessschieber	55,06	x		
13	LM / 48 / + 0,2 / Digit. Tiefenmessschieber	48,12	x		
14	LM / 41 / ± 0,3 / Digit. Tiefenmessschieber	41,05	x		



- Confirmation of the RoHS and REACH compliance is required for each initial sample inspection report. The confirmation must include compliance with the provisions of Directive 2011/65/EU RoHS / Directive 2015/863/EU RoHS 3 and the fulfilment of the REACH Regulation (No. 1907/2006). If a general RoHS/REACH confirmation from the supplier is available at Hydreco, this may be referenced
- Definition and documentation of the process flow
- Create instructions for the operator (document instructions and train operators)
- Create and document a control plan
- Arrangement of the measurement procedures

4. Carrying out sampling procedures

The supplier is responsible for the performance and accuracy of the test and measurement results of the sample testing and generates the relevant documentation. Hydreco reserves the right to perform counter-checking. The supplier can access the basic requirements on the initial samples from item 3.

The supplier carries out all activities necessary for the sampling on the basis of the specified requirements, criteria and characteristics, and generates the documentation.

The supplier checks the completeness and the fulfilment of the requirements, prepares and signs the initial sample test report. The supplier sends the initial samples including the required documentation by the deadline, specifying the order number. If in the course of the initial sampling deviations occur with regard to completeness and fulfilment of the specifications, then the causes must be determined and appropriate corrective measures introduced. The remedial measures must be appropriately documented and communicated to Hydreco.

Hydreco then assesses the submitted documents and the sampled parts. The approval status is added to the cover sheet of the initial sample report. The approval status is forwarded to the supplier with the cover sheet.

5. When must initial samples be sent?

Initial samples are generally requested by Hydreco with an initial sample order in the following circumstances:

- New parts and new modules
- Product changes (e.g.: design, specification, material change)
- Production outsourcing
- New supplier
- Modification of production process
- If the last delivery of the product by the supplier is more than 2 years ago

The supplier is always responsible for notifying changes/discrepancies to Hydreco Purchasing department prior to delivery/implementation in the following circumstances:

- Production outsourcing
- Change in the production process
- Changes of suppliers of products or services
- The use of new, modified or replacement tools
- After conversion and/or extensive maintenance of tools
- Changes of purchased parts
- Rectification of a fault in the case of already approved parts
- Changes of any kind (geometrical, material-related, chemical, physical, functional)

The written notification will contain an accurate description of the discrepancies and the assessment of the possible effects on function, service life, appearance, etc... Hydreco will assess the matter and inform the supplier in writing of how they intend to proceed.

6. Archiving

All test and measurement data from sampled parts must be archived by the supplier so that these may be requested by Hydreco if necessary. The evaluation of measurement data must be based on product characteristics and take into account basic statistical calculations, such as maximum, mean and minimum value and standard deviation.

7. Initial sample documentation

Unless otherwise agreed, the provisions of VDA 2 series or QS 9000 guidelines shall apply, including the pre-defined forms.

The initial sample documents must be clearly legible and therefore digitally generated. This means the avoidance of hand-written entries where possible - especially in the case of measuring results.

All initial samples are submitted in accordance with the following structure/sequence in a documentation set (paper and digital):

1. Cover sheet
2. Measurement report with stamped drawing
3. Material certificate
4. Test equipment used
5. RoHS / REACH confirmation
6. documentation of the process flow
7. instructions for the operator
8. control plan

The documentation of the first sample inspection report must always be provided in both paper and digital form.

- The hard copy of the initial sample inspection report is attached to the initial samples
- The digital version (PDF documents) is sent by e-mail to qualitaet@hydreco.de.

8. Test equipment

The test equipment capability is subject to the requirements of the respective current edition of QS 9000 - Measurement System Analysis - MSA and to VDA 5.

Notes on testing and measuring accuracy for the test equipment used.

The required level of accuracy is dependent on the individual application and/or the specification of the parts. All measuring and test characteristics must be capable of being measured with an acceptable accuracy, taking into account all influences (non-device-specific/device-specific), where the following criteria apply:

- The measuring and test equipment uncertainty should not exceed 10% of the smallest permissible tolerance of the measurement and test criteria.
- The monitoring of the measuring device in the development and production process is a prerequisite for ensuring the necessary confidence in the accuracy and precision of the measurement results and in the decision based on them.

9. Initial sample approval by Hydreco

The approval of the samples by Hydreco does not relieve the supplier from the responsibility for the quality of its products. Neither does it constitute an order for supply.

Incompletely supplied sampling documents or non-fulfilment of additional requirements (specific customer - supplier agreements) automatically lead to "Approval with conditions". The results of the initial sampling enter into the supplier assessment.

Approval stages at Hydreco

Approval level	Details
approved	The approval means that the part or material satisfies all the contractor's specifications and requirements. The supplier is entitled to deliver production quantities of the part in accordance with the approval of the scheduling department of Hydreco.
approved with conditions, resampling is required	This allows the delivery of production material for a limited period or in limited quantities. The batch is accepted with the proviso that further processing will be problem-free. A temporary approval is only granted if the supplier: 1.) Has clearly defined the underlying causes of the discrepancy that are preventing approval, and 2.) has agreed an action plan with Hydreco. Material which is subject to a temporary approval but does not comply with the action plan, either with regard to the due date or the number of parts, is rejected. Further deliveries are not permitted unless an extension of the temporary approval is granted.
rejected, resampling is required	Rejected means that the initial samples do not satisfy the customer's requirements, the discrepancies cannot be accepted. The contractor shall immediately introduce corrective measures, the deadline for the resampling specified by Hydreco must be observed.

10. Initial sample packaging and labelling

The delivery of the initial samples must take place on the agreed delivery date and must be clearly identifiable using the "Identification of initial samples" document.

The initial samples must be numbered and identified as initial samples. In applying the identification, it is important to ensure that the identification must not be allowed to affect the application of the initial samples. This means that a completely removable or detachable form of identification is required.

Initial samples may only be packed separately, this excludes delivery in a container with serially produced parts. The delivery receipt and the sheet 6 "Identification of initial samples" must be attached to the outside of the package.

In addition to the usual details the delivery receipt must indicate that it is an initial sample. The initial sample test report must be included with the parts in the delivery packaging. A unique assignment between initial sample and the initial sample documentation, including the measurement logs, is a mandatory requirement.



Kennzeichnung für Erstmuster *Identification of Initial Samples*

Adresse Lieferant / <i>Adress Supplier:</i>	Bestellnummer / <i>Order number:</i>
	Lieferscheinnummer / <i>delivery receipt number:</i>

ERSTMUSTER // *INITIAL SAMPLE*

Achtung Bitte umgehend an die Abteilung Qualitätssicherung weiterleiten Attention Please forward immediately to Quality Assurance department	Bezeichnung / <i>Description:</i>	
	Zeichnungs-Nummer / <i>Drawing number:</i>	
	Index / <i>Revision:</i>	
	Versanddatum / <i>Delivery date:</i>	
Original-Erstmusterunterlagen der Lieferung beigefügt?		☐
Original first article inspection reports attached to delivery?		
Kopie an qualitaet@hydreco.de gesendet?		☐
Copy sent to qualitaet@hydreco.de?		

Jede Verpackungseinheit ist mit diesem Formular zu kennzeichnen
Every packaging unit has to be labeled with this form

**KONFORMITÄTSERKLÄRUNG
DECLARATION OF CONFORMITY**

Name und Anschrift :

Name and address:

Wir erklären hiermit, dass die von uns an die Hydreco Hydraulics GmbH gelieferten Produkte den folgenden einschlägigen Bestimmungen entsprechen:

We hereby declare that the products delivered to Hydreco Hydraulics GmbH comply with the following relevant provisions of:

RICHTLINIE 2011/65/EU (RoHS 2)
DIRECTIVE 2011/65 / EU (ROHS 2)

RICHTLINIE 2015/863/EU (RoHS 3)
DIRECTIVE 2015/863 / EU (ROHS 3)

UND/ AND

VERORDNUNG (EG) NR. 1907/2006 (REACH)
REGULATION (EC) NO. 1907/2006 (REACH)

Wir bestätigen ebenfalls, dass wir unsere Unterlieferanten zur Einhaltung dieser Bestimmungen verpflichten. Sollten sich Änderungen diesbezüglich ergeben, werden wir die Hydreco Hydraulics GmbH umgehend und unaufgefordert informieren.

We also confirm our commitment to our subcontractors to comply with these provisions.

Should any changes occur, we will inform Hydreco Hydraulics GmbH immediately and without special request.

Bemerkung Lieferant:

Comment Supplier:

Name / name:

Position / position

Datum / date

Unterschrift / signature