QAA 2

Production Process and Product Release Procedure

Purpose

By using Scherzinger Pump Technology's *Production Process and Product Release Procedure*, the supplier is meant to prove that all product requirements agreed with the customer are met.

This procedure applies to the processes for manufacturing products (raw materials, semi-finished products and chemical operating materials) and to services such as for example coating or heat treatment. The release includes the assessment of production processes or performance using relevant documents, records and initial production samples to ensure that the preconditions for series production of products conforming with specifications are met.

Assessment of the production process

Before the initial production sampling and therefore before series production release, the supplier must assess the efficiency of his series production processes on his own authority. The suitability of the available series production process to manufacture the product according to the quality requirements of the customer with the agreed production capacity for a prescribed period of time or to provide the services must be determined with a trial production run.

To demonstrate the planned performance, all series production equipment (e.g. installations, machines, tools, inspection equipment) must be in operation

- in situ
- using series production material
- working to full capacity
- using standard personnel
- with all supporting systems

To assess the series production process, a representative batch size (usually a day's requirement from the overall annual quantity) should be manufactured.

At the “developmental product” project level in accordance with QSR-1, the assessment of the series production process is usually performed in the customer's presence or if necessary with their end customer. Dates and scope of the process assessment are agreed as part of the advanced product quality planning between the customer and supplier.

If necessary, this check can also be made at the “standard product” project level.

Types of samples

There are several different types of samples:

Prototypes

Prototypes can come from temporary production processes. If not otherwise requested in the customer’s order, the following minimum requirements apply for sampling of prototypes:

- Inspection report with target / actual comparison of at least one part, e.g. by means of an entry in the drawing
- For prototype tools with several cavities: target/actual comparison of one part per cavity
- Labelling of the checked prototype parts for allocation to inspection report
Information about material composition

Initial production samples

Initial production samples are products or services which have been completely manufactured or rendered using standard operating materials and under standard conditions. They are to be taken from a batch size which is representative of the series production process.

Occasions for initial production sampling

The supplier must in principle on his own initiative present initial production samples for:

- New parts or products (i.e. a specific part, a sub-assembly or material which has not been previously delivered to the customer)
- Modifications to the product through drawing, specification or material
- Modifications to specification with no influence on product or function. Scope of sampling or submission level must be agreed with the recipient site.
- Correction of a defect with an already sampled product, i.e. the approval was conditional or the initial production sample had to be scrapped (new sampling)
- Prolonged suspension of the production (longer than 12 months no production if previously products have been delivered at least four times a year)
- Receipt of the delivery at another or more distant Scherzinger Pump Technology site. Scope of sampling or submission level must be agreed with the recipient site.

After prior notification by the supplier in accordance with QAA 3, Appendix 1 (Modification Approval / Special Release), the customer determines the scope of sampling in the event of the following:

- Modifications in the production process
- Change of subcontractors for raw material or purchased parts or for services, e.g. heat treatment or coating
- Series production with tools, machines or installations, which must be relocated to another production site
- Use of new tools (expect for expendable tools, such as for example replaceable cutting inserts, drills)
- Use of additional or replacement tools, e.g. multi-cavity moulds / cavities
- Series production with available overhauled or modified tools, machines or installations
- Significant modifications to the inspection or testing methods released with the preliminary sampling

The supplier must present initial production samples at the customer's request, e.g.:

- After serious quality problems
- As part of the periodic requalification of products

Documentation

In the initial production sample inspection report the supplier must prove, by giving details about the inspection results, that all features meet the customer requirements, e.g. drawings including related technical delivery conditions and specifications. Deviations must be clearly stated in the inspection report.

The retention period of the initial production sample documentation as well as reference sample parts – in the case of multi-cavity moulds one per cavity – is, unless otherwise agreed in writing, the period of time agreed for the product plus one year.

The documentation is preferably to be sent in advance by electronic means – otherwise attached to the initial production samples or delivery notes – to the competent sampling department of the recipient customer plant. Unless specified otherwise in the order or in the customer’s “Technical Delivery Conditions” which are also pertinent, or agreed with him, the following requirements apply as standard.
Dimension, material and function report

A clear reference to the inspection report (see QAA 2, Appendix 2) must be made (marked characteristics drawing) using a consecutive numeration of the features contained in the drawings including related “Technical Delivery Conditions” and specifications.

Features which cannot be checked by the manufacturer himself are, after prior agreement with the customer, either confirmed with an inspection certificate with specific inspection results (e.g. tool certificate) or proven through inspection certificates by accredited testing institutes.

Components

Unless otherwise required by the customer, five parts taken at random from the process are checked. The actual values must be assigned to the respective numbered sample part in the relevant form sheets of the initial production sample inspection report (see QAA 2, Appendix 2). In the case of multi-cavity moulds (several cavities), five parts per mould cavity must be clearly labelled and delivered. In each case, one part must be measured in full and documented by means of an inspection report.

Raw material and semi-finished products

Unless specified explicitly in a relevant “Technical Delivery Condition” or specification, the scope of inspection and sampling for raw material and semi-finished products (e.g. granules, strip, wire, tubing, rod profiles) must be agreed with the competent sampling department of the customer’s recipient plant.

Chemical operating materials

Unless specified explicitly in a relevant “Technical Delivery Condition” or specification, the scope of inspection and sampling for chemical operating materials (oils and greases) must be agreed with the competent sampling department of the customer.

Evidence of process capability

The preliminary process capability of characteristics identified specifically in the customer drawing or by means of all relevant specifications (according to Schaeffler Standard S 102012) is determined from a minimum of 125 parts (25 random samples of 5 parts). A capable process is deemed to exist if the preliminary process capability generates a capability index Ppk > 1,67.

A minimum of 10 parts must be checked for destructive testing and a minimum of 300 parts for attributive testing.

Appearance report

Where any part is required to have a defined appearance according to a drawing regulation or specification, this feature must be rated accordingly in the inspection report.

Duty to supply information on substances

The inspection report for initial production samples must include confirmation that the materials used and their substances comply with the statutory requirements and the customer’s requirements where environment, recycling and safety are concerned.

The substances of the following products must be specified in the International Material Data System IMDS (www.mdsystem.com):

- Components (e.g. seals, springs, rotating parts)
  - Sub-assemblies
  - Oils / greases for products
  - Coatings (e.g. phosphate coating, chrome plating)
The corresponding IMDS ID no. (ident. number) must be entered in the Part Submission Warrant of the QSR-2, Appendix 1. Following prior agreement with the sampling department at the customer’s recipient plant, the Appendix 4 – Substances to QSR-2 form can also be used as an alternative to an entry in the IMDS database.

Labelling and packaging
Transport containers and delivery notes from consignments of initial production samples must be clearly labelled with “Initial Production Sample”.
If the initial production samples cannot be delivered in the designated series production packaging, then the supplier must ensure by means of suitable packaging that the quality of the sample is not impaired by, for example, damage or corrosion.

Submission levels
The Production Process and Product Release Procedure (PPR) must be completed in full by the supplier and documented. When the customer defines a submission level, the type and scope of the initial production sampling must be transferred to the customer.

<table>
<thead>
<tr>
<th>Level</th>
<th>Requirements</th>
</tr>
</thead>
</table>
| 1     | Only the Part Submission Warrant (form, Appendix 1) is submitted to the customer and, if additionally requested by the customer, an “Appearance Approval Report” (e.g. unmachined cast parts, standard pump parts, no automobile customers)  
  * Supplier known, no problems with sampling and series production deliveries  
  * Products which are easy to make / simple modifications  
  * Product ranges: a part number is sampled according to submission level 2 or 3, the remaining part numbers according to submission level 1 |
| 2     | Part Submission Warrant with sample parts and limited supporting data / documentation are submitted to the customer.  
  (dependent on the production process e.g. die-cast components, injection moulded components)  
  * New supplier  
  * Quality problems with similarly made products (porosity, cavity)  
  * New production processes |
| 3     | Part Submission Warrant with sample parts and complete supporting data / documentation are submitted to the customer.  
  (cost-intensive parts which cannot be tested non-destructively, automobile customers)  
  * No appropriate measuring equipment available at Scherzinger’s premises  
  * New production processes at the suppliers’ premises (assessment of the quality capability)  
  * Complex products which are difficult to manufacture, production processes which are difficult to control  
  * Documents (parts) with specific archiving, (DmbH parts) |

The requirements associated with the relevant submission level can be found in the following table. Unless otherwise determined in the customer’s order, the supplier should in general proceed according to submission level 3.
<table>
<thead>
<tr>
<th>No.</th>
<th>Element / requirement</th>
<th>Explanation / comments</th>
<th>Submission level</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Design records</td>
<td>Customer drawing (marked characteristics drawing)</td>
<td>X X</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Specification, product delivery guidelines, technical delivery conditions (marking of characteristics)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>For components developed by supplier on his own responsibility (Black Box)</td>
<td>X X</td>
</tr>
<tr>
<td></td>
<td></td>
<td>For all other components</td>
<td>X X</td>
</tr>
<tr>
<td>2</td>
<td>Modification documents</td>
<td>Documents on modifications approved by the customer, which are not yet documented in the drawing, if available</td>
<td>X X</td>
</tr>
<tr>
<td>3</td>
<td>Design release from the customer</td>
<td>Design approval from the customer if requested in the customer drawing</td>
<td>X X</td>
</tr>
<tr>
<td>4</td>
<td>Design FMEA</td>
<td>Only applicable to suppliers with design responsibility. Cover sheet to Design FMEA with current modification level, date and group of participants, as a minimum</td>
<td>X X</td>
</tr>
<tr>
<td>5</td>
<td>Process flow diagram(s)</td>
<td>Process flow diagram for the product or product range</td>
<td>X*</td>
</tr>
<tr>
<td>6</td>
<td>Process FMEA</td>
<td>Cover sheet to Process FMEA with current modification level, date and group of participants, as a minimum</td>
<td>X</td>
</tr>
<tr>
<td>7</td>
<td>Control Plan / production control plan</td>
<td>Control Plan / inspection plan, as a minimum for all special characteristics for the product or the product range</td>
<td>V X</td>
</tr>
<tr>
<td>8</td>
<td>Inspection equipment capability study</td>
<td>Inspection equipment capability study of inspection equipment for all special characteristics</td>
<td>X</td>
</tr>
<tr>
<td>9</td>
<td>Dimensional measurement results</td>
<td>Material inspection report on all dimension characteristics in the customer drawing and by means of all relevant specifications (form, Appendix 2), including OK / not OK rating</td>
<td>X X X</td>
</tr>
<tr>
<td>10</td>
<td>Material test results and function test results</td>
<td>Material inspection report on all material data in the customer drawing and by means of all relevant specifications (form, Appendix 3), including OK / not OK rating. Enclose results from raw material suppliers as 3.1 Inspection certificate according to DIN EN 10204</td>
<td>V X</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Substances must be entered in the International Material Data System (IMDS). In exceptional cases, the form Appendix 4 may be used</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Evidence on the use of prohibited substances and substances requiring declaration in accordance with Schaeffler Standard S 132030 Parts 1 to 3</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Inspection report on all function features in the customer drawing and by means of all relevant specifications (form, Appendix 2) including OK / not OK rating</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Process capability study</td>
<td>Process capability evidence for all special characteristics in the customer drawing, and other features specified by the customer, and by means of all relevant specifications (see Schaeffler Standard S 102012); alternatively as Cm/Cmk, Pp/Ppk, or Cp/Cpk values</td>
<td>X X</td>
</tr>
<tr>
<td>12</td>
<td>Documentation from the test laboratory</td>
<td>If an external laboratory has been appointed, the laboratory’s test results and the ISO 17025 certificate must be submitted, with specification of the scope of validity</td>
<td>X</td>
</tr>
<tr>
<td>13</td>
<td>Report for appearance-critical parts</td>
<td>If requested by the customer and specifically agreed within the framework of Advanced Product Quality Planning</td>
<td>V</td>
</tr>
<tr>
<td>14</td>
<td>Sample parts</td>
<td>Check five sample parts, unless specified otherwise. Deliver parts in series production packaging in accordance with packaging data sheet</td>
<td>V X X</td>
</tr>
<tr>
<td>15</td>
<td>Reference sample part</td>
<td>At least one reference sample part per cavity should be stored by the supplier for the life of the product, plus one additional year. The allocation to the initial production sample inspection report should be ensured by means of clear labelling</td>
<td>X X X</td>
</tr>
<tr>
<td>16</td>
<td>Inspection equipment list</td>
<td>Product-specific used inspection and measurement equipment</td>
<td>X</td>
</tr>
<tr>
<td>17</td>
<td>Part Submission Warrant</td>
<td>Part Submission Warrant (form, Appendix 1)</td>
<td>X X</td>
</tr>
<tr>
<td>18</td>
<td>APQP Status Report</td>
<td>For project classification PE 1 or PE 2 in accordance with QAA Part 1 Advanced Product Quality Planning (form, Appendix 2)</td>
<td>X</td>
</tr>
</tbody>
</table>

- X Requirement for the relevant submission level
- X* Requirement for the relevant submission level, for inspection only – documents stay with the supplier
- V In individual cases, the scope must be agreed with the customer
- In addition to AIAG standard – “PPAP 4th Edition”
Customer release

Following submission of the initial production samples and documentation, the customer carries out further inspections at his own discretion, which can also take place at the supplier’s premises in the case of submission level 4 or as part of a trial production run.

One of the following decisions is made by the customer on the basis of the initial production sample report and any inspections carried out by the customer:

- Approved
- Conditional approval (new sampling required)
- Rejected (new sampling required)

The initial production samples must be released by the customer before the mass-produced products can be delivered.

Applicable documents

Applicable appendices for QAA 2
(see www.scherzinger.de)

Appendix 1  Part Submission Warrant
Appendix 2  Inspection Report
Appendix 3  Material Inspection Report
Appendix 4  Substances