Tooling Validation Protocol

1.0 Purpose

To provide guidance in generating protocols for validating plastic injection mold tooling.

2.0 Scope

This specification applies to both transferred and new plastic injection mold tooling. It is intended to provide guidelines for the validation protocol; discussions with the customer may lead to the protocol being modified to suit their specific requirements. Similarly, when customers have their own validation requirements, these may be followed. Where alternative protocols are followed, the rational for following the alternative should clearly recorded.

This protocol does not include mould tool design or manufacture, nor does not cover automated inspection or component assembly.

3.0 Definitions

CTQ – Critical to Quality. Dimensions, features, or functionality deemed by the Customer to be critical.

EOAT – End Of Arm Tooling. Specialized Equipment built to assist the ejection of the components from the mold and control their placement for the next operation.

FAIR – First Article Inspection Report. The verification of all dimensional, functional, and visual features of the product, as defined by the customer. Also known as ISIR.

IQ – Installation Qualification. Establishes through documented evidence that the equipment has been properly installed, meets safety requirements, meets the manufacturer’s specifications and requirements, and is capable of operating in the range required for the process being validated.

ISIR – Initial Sample Inspection Report. The verification of all dimensional, functional, and visual features of the product, as defined by the customer. Also known as FAIR.

OQ – Operational Qualification. Establishes through documented evidence that specific process settings, process control limits, and action levels, result in product that meets all predefined requirements.
Title: Tooling Validation Protocol

**PQ** – Performance Qualification. Establishing by objective evidence that the process, under anticipated conditions, consistently produces a product, which meets all predetermined requirements.

**SOP** – Standard Operating Procedure

**WI** – Work Instruction

4.0 Associated Materials

4.1 Customer Requirements Checklist, CF-010-REQUIREMENTS
4.2 Proposal
4.3 Tooling Specification, CF-020-TOOLSPEC

5.0 Process Flow

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<table>
<thead>
<tr>
<th>Validation (050)</th>
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<tr>
<td>Validation Plan Developed</td>
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<td>Validation Plan submitted to the Customer</td>
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<tr>
<td>Customer Approves the Validation Plan</td>
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<td>OQ</td>
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<tr>
<td>PQ</td>
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</tbody>
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Responsibility

- Project Engineer
- Project Engineer
- Customer
- Project Engineer
- Project Engineer
- Customer
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6.0 Inputs and Outputs

Key Inputs | Process | Key Output
---|---|---
Identification of Personnel | IQ | Customer IQ Approval
Equipment Description | | 
WIs / SOPs | | 
Gages Required | | 
Mold Steel Type and Dimensional Cert. | | 

Key Inputs | Process | Key Output
---|---|---
Process Determination | OQ | Customer OQ Approval
Shrinkage Study | | 
FAIR (or ISIR) | | 
Preliminary Capability Study | | 
Process Sensitivity Analysis | | 

Key Inputs | Process | Key Output
---|---|---
Capability Study | PQ | Customer PQ Approval

7.0 Installation Qualification

The IQ for the injection mold tooling will verify that all necessary equipment, documentation, instruments/tools, and utilities are available and installed as specified in relevant design and production documentation and drawings; and, when properly installed and in the appropriate environment, the system will operate safely and correctly over the specified range of operating conditions.

7.1 Procedurally, the IQ is a checklist-style process of verifying and documenting that all required items are available and installed correctly.
7.1.1. Identification of Personnel

Document full names and signatures for all individuals who participate in the execution of the IQ. Verify that appropriately trained/skilled/qualified individuals participate in the qualification activities, including any training required to perform the qualification. Utilize Appendix IQ.1 – Identification of Personnel for this purpose.

7.1.2. Equipment Description

List all equipment required to validate the injection mold tooling. Include description, manufacturer, location, model number, and serial number. Appendix IQ.2 – Equipment Description is provided to collect this information.

7.1.3. Work Instructions / Standard Operating Procedures

List all relevant in-house WIs and SOPs associated with the equipment listed in Appendix IQ.2 – Equipment Description. Document this list in Appendix IQ.3 – Equipment Work Instructions / Standard Operating Procedures.

7.1.4. Gages Required

Verify the calibration status of all gages used to validate the injection mold tooling. Specify the gages to be used during the installation qualification and document the status of each. Identify the gage to be used for each measurement. Capture the calibration information in Appendix IQ.4 - Gages.

7.1.5. Mold Steel Type and Dimensional Certification

For each cavity (including spares), verify that all mold steel dimensions corresponding to the CTQ features on the component drawing are in conformance with the appropriate design documentation/drawings. For each CTQ, the mold steel dimensional specification, actual measurement, and measurement device used shall be documented.

Verify that the mold steel materials are the type, grade and hardness specified in the mold design.

Record the results in Appendix IQ.5 - Mold Steel Type and Dimensional Certification. This Appendix may be completed by the injection mold tooling supplier.

7.2 IQ Approval

All acceptance criteria listed in Appendix IQ.1 – Appendix IQ.5 must be met. Any deviations have been noted and addressed. All deviations must be approved by the customer prior to completion of the protocol execution. Acceptance status and deviations are noted in Appendix IQ.6 – IQ Approval.

Upon completion of the executed protocol, all results and documentation will be forwarded to the Project Engineer for generation of a summary report, which will be submitted to the Customer for review and approval.

Signatures in Appendix IQ.6 – IQ Approval signify the approval of the IQ.

8.0 Operational Qualification
This protocol applies to injection mold tooling and any auxiliary equipment required to support the molded product. The equipment includes, but is not limited to; the mold, molding machine, hopper loader, mold water temperature controller(s), hot runner temperature controller, robot/EOAT, and any part handling equipment (not including specialized equipment).

All OQ activities shall be performed at the location and with the equipment specified in the Installation Qualification (IQ) Protocol.

8.1 Process Determination

Initial sample runs are conducted on the finished injection molding tools. These sample runs are used to establish baseline molding-parameters and identify any issues with the production of parts and/or running of the molds. Studies such as Gate Freeze, Mold Balance, Fill Time, and Coefficient of Variation are utilized to determine process parameters. Process parameters are established after initial issues are satisfactorily addressed during the initial sample. Metrology typically verifies the critical dimensions at this point in the validation. The process setup sheets and Critical Dimension Measurements are attached as Appendix OQ.1 – Process Setup and Appendix OQ.2 – Critical Measurements respectively.

8.2 Shrinkage Study

The initial samples are submitted to metrology to perform the shrinkage study to determine the optimum wait period before First Article Inspection. One or two overall dimensions are selected for this study.

Three components (this number may be adjusted to an entire shot) will be taken from the mold tool in order to conduct the shrinkage study. The control dimensions of each component shall be measured approximately at the following intervals after molding:

- 15 minutes
- 30 minutes
- 60 minutes
- 2 hours
- 4-24 hours
- 48 hours
- 7 days
- 28 days

Metrology will record the exact time of measurement. The shots will be retained at laboratory temperature (20-24°C) for this time.

These shots will be measured and the results reported. It is accepted that 95% stability is usually achieved within 2 days and the ISIR measurements may be started after 2 days, i.e. before the shrinkage study has been completed.

The shrinkage data and corresponding shrinkage curves will be attached to Appendix OQ.3 – Shrinkage Study.

8.3 First Article Inspection Report

Sampling is conducted immediately after the initial sample without interruption if no mold or part issues exist. Once the process is established and running in a stable manner, shots are pulled and submitted to metrology for first article inspection.

Typically a minimum of 45 shots are collected after the process has stabilized. The wait time is typically 2 hours or more. These 45 shots will be use as follows:

- 7 shots sent to customer
• 7 shots used to determine component weight
• 1 shot used for ISIR measurement
• 30 shots retained for record purposes.

Metrology inspects the parts after 95% of the shrinkage has occurred. A First Article Inspection Report (FAIR) is compiled and consists of recorded measurements of all drawing dimensions and drawing note stipulations, except ’reference’ dimensions, from a sample(s) from each mold cavity. Any dimensions outside of agreed tolerance should be identified. If appropriate, the tool may undergo correction at this time. If this is the case, a First Article Inspection should be repeated for those affected areas.

A copy of the FAIR is provided to the customer for their approval along with sample parts from the sample run. The FAIR will be attached to Appendix OQ.4 – FAIR when complete.

8.4 Preliminary Capability Study

A preliminary capability study on critical measurements is performed on 15 randomly selected shots from the First Article Inspection sample to assess whether the tool is capable and ready for the final capability study. Dimensional discrepancies will be addressed when the molds require modifications to meet part print specifications or a process capability. The target $C_{pk}$ for the final capability study in the PQ is 1.33 or better. Results from the preliminary capability study will be attached to Appendix OQ.5 – Preliminary Capability Study.

8.5 Process Sensitivity Analysis

From a 'Cold Start-up', with process parameters established and recorded, select the parameters which most affect the dimensional stability of the components being moulded, and will vary these parameters to establish upper, and lower processing limits at which acceptable components can still be produced. This may be done through a “Design of Experiment” (DOE) evaluation.

Typically, a Taguchi ’L8’ is used varying the following parameters between a low and a high setting:

• Mould Temperature
• Hold Pressure
• Hold Time (Cooling)
• Change Over distance
• Melt Temperature
• Injection Speed
• Injection Pressure

In each experiment, the control dimensions are measured on a sample size that is large enough for 95% confidence in the mean. From these experiments, the molding parameters, which have a great effect on dimensional tolerances, can be identified, and optimal process settings along with alarms can be determined.

If required, additional DOE studies may be performed to define these parameters with greater accuracy.

The sensitive parameters and corresponding alarm limits along with any DOE results are documented in Appendix OQ.6 – Process Sensitivity Analysis.

8.6 OQ Approval

All acceptance criteria listed in Appendix OQ.3 and Appendix OQ.5 must be met. Any deviations have been noted and addressed. All deviations must be approved by the customer prior to completion of the protocol execution. Acceptance status and deviations are noted in Appendix OQ.7 – OQ Approval
Upon completion of the executed protocol, all results and documentation will be forwarded to the Project Engineer for generation of a summary report, which will be submitted to the Customer for review and approval. Signatures in Appendix OQ.7 – OQ Approval signify the approval of the OQ.

9.0 Performance Qualification

Following identification of the optimal process settings, the capability of the tool, machine and process to produce dimensionally acceptable moldings is investigated.

Following machine set-up, 3 production batches, each of 3 hours minimum duration, will be molded. Between batches, the tool and molding machine will be allowed to cool for a minimum of 30 minutes. A total of 10 shots from each batch spaced evenly through the run will be collected (approximately every 20 minutes for a minimum of 30 shots throughout the 3 runs).

Critical dimensions will be measured from each shot. On the basis of these measurements, \( C_p \) (all batches) and \( C_{pk} \) (individual batches) values will be calculated. It is anticipated that both \( C_p \) and \( C_{pk} \) should be greater than 1.33 for the trial to be acceptable.

Components produced during the capability study are manufactured, inspected and measured by normal production staff. They shall be handled throughout as though they were normal production batches. It is anticipated that product manufactured during these studies will be suitable for sale to the customer. The batches shall remain in quarantine until the customer releases the mould for production. Quality Department may then release these batches for supply to the customer.

Capability Study results will be attached to Appendix PQ.1 – Capability Study.

All acceptance criteria listed in Appendix PQ.1 must be met. Any deviations have been noted and addressed. The customer prior to completion of the protocol execution must approve all deviations. Acceptance status and deviations are noted in Appendix PQ.2 – PQ Approval

Signatures in Appendix PQ.2 – PQ Approval signify the approval of the PQ.

10.0 Records