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PYRAMIDS IQ/OQ/PQ FLOW

IQ = Installation Qualification

◎ **Definition :**

The purpose of the IQ is to show that the mold fits in the injection mold machine and can be mounted securely.
It will verify that the components being produced are being ejected successfully without damaging the finished part.
It will also verity that the mold tooling has been properly marked with customer's Part number or mold# .

◎ **Success Criteria :**

1. Mold fits in the injection mold machine selected and can be mounted securely.
2. Mold components are being produced and ejected without damage.
3. Mold tool must be correctly marked.

◎ **Procedure :**

1. Locate the mold to be qualified
2. Obtain correct resin
3. Dry resin / colorant mixture / or compound in material
4. Verify that mold tooling properly marked customer's Part number or mold# .
5. Install mold in injection molding press
6. verify that the mold fits and is able to be securely mounted in the injection mold machine selected
7. verify that parts can be produced and ejected without damage.

◎ **PARAMETER STUDY**

(successfully complete IQ prior to performing parameter study)

Manufacturer's Recommended Parameters			
Mold Temperature	Melt Temperature Range	Drying Time	Drying Temperature
?? °F - ?? °F	?? °F - ?? °F	?? HR MINIMUM	?? °F

1. Set injection molding settings (within manufacturer's recommended parameters above) to produce a complete part.
2. Run mold and verify that acceptable parts are produced and ejected without being damaged.
3. Vary mold temperature a minimum of 10°F both above and below nominal settings（Depends on customer's requirement）
4. Vary holding pressure a minimum of 5% both above and below nominal settings. Depends on customer's requirement）

5. Run mold at all (4) process extremes and verify that acceptable parts are produced and ejected without being damaged.
6. Record nominal, high, and low settings in the table below and in the appropriate sections of the OQ – Qualification Table in the OQ portion of the procedure.

PARAMETER LIMITS		
SETTINGS	MOLD TEMPERATURE (°F)	HOLDING PRESSURE (psi)
NOMINAL		
HIGH		
LOW		

◎ **Results :**

1) Mold fits in injection molding machine and is securely mounted. Yes ☐ No ☐

2) Molded components are produced and ejected without damage. Yes ☐ No ☐

3) Mold is marked correctly. Yes ☐ No ☐

OQ = Operational Qualification

◎ **Definition :**

The purpose of the OQ is to validate the process parameters at the edges of parameter ranges that consistently produce components without "short shots , voids , or excessive flash " . Nominal parameters will then be derived from upper and lower process parameters. Data will be collected on dimensions identified below to show consistency in the molding process. These dimensions were chosen because they are most likely to show process variation

	Specification & Print Location	Inspection Method Record
1		
2	↓	
3		

◎ **Success Criteria :**

1. Part meets the criteria of the part drawing
2. Data collected on dimension(s) listed in table
3. No " short shots , voids , or flash " may be present on any samples (flash standard) ??
4. Measurements meet acceptance criteria listed under sample size rationale.

◎ **Procedure :**

(successfully completed IQ and parameter study prior to performing OQ)

1. Mold (15) parts using settings in "Experiment#1" section of the OQ qualification table below.
2. Number each components with experiment# and its own individual sequential samples number from 1-15.
3. Measure and record feature(s) listed in appropriate section of the data sheet for Experiment#1
4. Inspect parts for voids and short shot and record " accept / reject" in appropriate section of the data sheet for Experiment#1.
5. Repeat steps 1 through 4 for Experiment #'s 2,3,& 4 .

OQ - QUALIFICATION TABLE		
EXPERIMENT #	MOLD TEMPERATURE °F	HOLDING PRESSURE (PH 4) psi
Range		
Experiment #1 Low Temp/Low Pressure Parameter		
Experiment #2 Low Temp /High Pressure Parameter		
Experiment #3 High Temp/Low Pressure Parameter		
Experiment #4 High Temp/High Pressure Parameter		
Nominal		

◎ **Sample size :**

N=15 Samples per parameter combination

2- Sided specifications

Accept = Ppk is equal to or greater than 0.87 and Pp >= 0.91 ;

Reject = Ppk is less than 0.87 and Pp < 0.91

Data Collection

OQ: Unit of measure = inches

Experiment #1 – **Low Temp/Low Pressure Parameters**

Sample #	(List Dim.)	(List Dim.)	(List Dim.)	Flash ≤.003" (P/F)	Void or Short Shot (P/F)
1 … 15					
Avg					
Ppk					

Tested By: _____ **Date:** _____

Approved: _____ **Date:** _____

PQ = Process (Performance) Qualification

◎ **Definition :**

The purpose of the PQ is to prove under anticipated conditions, the process for molding of parts consistently produces parts that meet specified requirement.

◎ **Prerequisites :**

1. IQ/OQ samples must be molded and checked for conformance to requirements prior to execution of this protocol.
2. Nominal settings and range for mold temperature and holding pressure from the IQ/OQ protocol recorded in mold settings table in the procedure section of this document.
3. All receiving inspections for this part shall be released/pre-released.
4. The primary source of variability between lots for this molding process is variations in setup of the machine. For this reason the machine shall be shut off, purged, and allowed to cool between each lot and the equipment settings re-set for each lot.
5. Production personnel shall perform all production activities associated with this protocol.
6. Any deviations to this protocol shall be documented and approved prior to execution

◎ **Sample size / Acceptance Criteria :**

Depends on customer's requirement ??

◎ **Procedure :**

1. Mold 3 lots of parts using nominal mold settings as recorded in the OQ qualification protocol. Settings and range for mold temperature and holding pressure recorded in table below. Attach record of nominal settings to report.

Mold Settings		
	HOLDING PRESSURE (PH 4) PSI	MOLD TEMPERATURE °F
Range		
Nominal		

2. Once each lot run is complete, samples shall be pulled randomly from the lot to meet the above described sampling number.
3. Perform testing and record results.
4. Analyze data to determine if the lot met acceptance criteria.
5. If parts meet the acceptance criteria, ship parts to customer and supply customer with data and analysis. Customer will perform receiving inspection and place all parts in a hold location until the PQ report is complete and approved.

6. If parts do not meet the acceptance criteria, supply data and analysis to customer and place entire lot on hold for further determination.
7. Repeat steps 2-6 for all three lots.
8. Note: intermediate reports can be completed to show approval of individual lots so that parts can be moved forward for verification or validation testing. No clinical parts may move forward prior to completion of the entire PQ study report.