Qualification Plan

for

CR-IBM-

1. **Scope:**

|  |  |
| --- | --- |
| **Change Request (CR)** |  |
| **Customer** |  |
| **Color** |  |
| **Part Description** |  |
| **Berry (JDE) Part Number** |  |
| **Drawing Number & Ver.** |  |
| **Mold** |  |
| **Material** |  |
| **`Press Location** |  |
| **Press Process Data Sheet** |  |
| **Control Plan** |  |
| **Cavities** |  |
| ***\*\*\*\*Lot Number to be added to the table below by Operators \*\*\*\**** | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Qualification Plan Authorization Table** | | | | |
|  | **Printed Name** | **Title** | **Signature** | **Date** |
| **Author** |  |  |  |  |
| **Approval** | Derik Bailey | Quality Manager: |  |  |
|  |  |  |  |  |
| **Requirement** | **Required Input** | **Title** | **Signature** | **Date** |
| **Lot #:** |  | Press Operator: |  |  |
|  |  | Quality Technician: |  |  |
| Qualification Comments: | | | | |

***Note: Quality manager or designee signature above is approval to run qualification.***

1. **Qualification Type:**

* .

1. **Run Conditions:**

* Ppk will be calculated using data pooled across all cavities and stations. Refer to the chart below for sample size.

1. **Sampling Plan and Acceptance Criteria**

All process settings recorded on the press process data sheet must be within their listed ranges.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Required**  **(X)** | **Quality Characteristic** | **Responsibility** | **Sample Size** | **Acceptance Criteria** |
|  |  | Metrology |  |  |
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\*Ppk calculated using data pooled across all cavities.

1. **Qualification Procedure** 
   1. Conduct a minimum 4 - hour capability study running within the process parameters identified on the press process data sheet per the following steps:
   2. Allow a warm up period of no less than ½ hour and review bottle attributes before beginning sampling. Raise any concerns to Management.
   3. Obtain samples from all cavities, all stations (Full shot = 8 cavities per station x 3 stations = 24 pieces total per full shot):
      1. One full shot after warm up - all stations (A, B and C)
      2. Four additional full shots, spaced 1 hour apart. Each group of shots to include all stations.
      3. Total of 120 parts.
   4. Put one station per zipped bag and mark each bag with the CR#, shot number (#1-5) and station (A, B, or C).
   5. Provide a copy of the completed Press Data Sheet to Joseph Neeson.or Jennifer Dillehay.
   6. Perform all attribute inspections in accordance with Control Plan TBD. Document the attribute inspections in Infinity. **Attributes MUST pass review. Any concerns need to be brought to Quality Manager for review**.
   7. If attribute review passes, turn in the parts to Metrology using the Metrology Ticket. Metrology will perform all variable inspections on the samples collected and record the data in Infinity.
2. **Qualification Run Table:**

*(Add additional cavities or runs to the table below as required for the specific qualification)*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Cavity Number** | **Run #1 A, B, C** | **Run #2 A, B, C** | **Run #3 A, B, C** | **Run #4 A, B, C** | **Run #5 A, B, C** |
| 1 |  |  |  |  |  |
| 2 |  |  |  |  |  |
| 3 |  |  |  |  |  |
| 4 |  |  |  |  |  |
| 5 |  |  |  |  |  |
| 6 |  |  |  |  |  |
| 7 |  |  |  |  |  |
| 8 |  |  |  |  |  |
| Total Samples | 24 | 24 | 24 | 24 | 24 |
|  |  |  |  | **120** |

1. **If the Qualification is to be part of a production work order (build at risk):**
2. The production work order must be available before the start of the run.
3. Work with Quality to initiate an Event Based Investigation (EBI) form prior to starting the run. Identify the discrepancy as “Qualify new manifold.”
4. Keep the EBI form in the work order packet.
5. Notify a Quality Tech when the qualification portion of the run is complete.
6. Both during the qualification portion of the run, and after commencing normal build, all inspections required by the Control Plan or additional instructions in the work order packet must be completed and recorded in Infinity, the same as for a normal production run.  If the attribute inspections required by the Qualification Plan also meet the requirements of the work order, they do not need to be repeated.
7. **If all parts run are solely for qualification:**
   1. Stop producing parts after the required qualification period is complete and the required number of samples has been collected.
   2. Scrap all ware produced.

***\*\*\*\*DO NOT SAVE PARTS WHEN QUALIFICATION RUNS ARE COMPLETED\*\*\*\****