

			<b>Inspection Procedure During Production</b>
QMS GI-Q2	Rev C	Date 05-14-12	<b>Procedure Authority: Quality Assurance Manager</b>

**Purpose:** The purpose of this procedure is to describe inspection activities and decisions associated with production. The Quality Department's involvement is meant to validate customer and internal requirements.

**Scope:** The scope includes the circumstances that lead to sample submission, the inspection processes and response when good or defective parts are detected, and communication between the Production and Quality Departments.

**Responsibility:** The Quality Manager is responsible for the adherence to this procedure and the Production Supervisor is responsible for material handling logistics.

**Reference Documents:** FM1 Production Control Sheet  
 FQ6 In-process Inspection Sheet  
 FQ7 Inspection Report – Part Specific  
 Inspection Plan – Part Specific  
 PQ4 Control of Nonconforming Product  
 FQ9 Tool Repair Work Order

**Procedure:**

1. When the Production Department has a need to run a particular job, they'll initiate the Set-up process. When the Set-up is complete they must submit two sample parts per lane (pre-inspected by set-up personnel), along with form FM1 (Production Control Sheet), to the Quality Department for validation.
2. An inspector must perform a "first part inspection" in accordance with the prescribed FQ7 (Inspection Report – part specific). A decision will be made based on the following.
  - If the samples are to specifications, the "Production Control Sheet" will be initialed or stamped by the inspector to signify acceptance. An "In-Process Inspection Sheet" (FQ6) will be attached to the back of the "Production Control Sheet" and one of the two parts per lane will be marked "SAMPLE", to be used as a visual reference during production. The paperwork (FM1 & FQ6) and the "SAMPLE" will be given to the production department to start the run.
  - If the samples are found "nonconforming", the inspector will notify the production department of the discrepancies. When corrective measures have been taken, a new part must be submitted for re-inspection per step1.

**Procedure Continued:**

3. During the course of production, Inspectors and Operators<sup>1</sup> will perform “In-Process inspections” per the prescribed inspection plan and record their results on FQ6 “In-Process Inspection Sheet.” In-Process Inspection will be performed at a minimum of once every 2 hours.

***Note #1 - Operators are trained and encouraged to perform the same checks as inspectors, provided their attention to equipment and safety is not compromised. At the Production and Quality Manager’s discretion, operator checks may deviate from the inspection plan.***

4. If at any time during production a discrepancy is detected, production will be stopped, the production supervisor will be notified of the problem and all questionable parts will be tagged (in accordance with PQ4). When corrective measures have been taken, new parts must be submitted to the Quality department for validation.
5. If production is interrupted for Die or Press adjustments or repair, the containers at the press must be validated as uncontaminated and moved away during the maintenance activity. Samples produced after the adjustments must be submitted to the inspection department for validation and approval. The former containers can then be returned to the press and production continued.
6. At the end of the production run, last part samples must be submitted to the inspection department, and an inspector will initial or stamp the “Production Control Sheet” indicating the receipt of last parts.
7. A “last part inspection” will be performed in accordance with the inspection plan. If discrepancies are detected, all questionable parts will be tagged (in accordance with PQ4).
8. In addition to the last part inspection, the inspector will look for conditions that may require Die maintenance, to prepare for future production. If these conditions exist, form FQ9 (Tool Repair Work Order) will be completed to initiate further Die review and repair as appropriate.