PLASTICS Molding Company			Planning & Control of Changes
QMS PQ15	Rev A	Date 09-22-17	Procedure Authority: Quality Manager

Purpose: The purpose of this procedure is to describe and direct activities associated with planning and controlling changes that impact production processes and potential impacts on customer requirements.

Scope: This procedure applies to changes considered internally, customer requested changes and supplier changes as appropriate. The procedure is also applicable to temporary changes to process controls.

Responsibility: The Quality Manager is responsible administering this procedure.

Definitions: NA

Reference Documents: NA

Procedure:

1. The Quality Manager and a multidisciplinary team as appropriate, will plan and control changes that impact production processes and the potential impact on customer requirements.

2. The team will evaluate associated risks and determine the necessary verification and validation activities to ensure compliance with customer requirements and change objectives.

3. Appropriate validation will be made before there is permanent implementation of a change.

4. Associated verification and validation results will be documented and maintained in accordance with procedure PQ2, “Records Control”.

5. When required by the customer, we will notify, obtain documented approval prior to the change, identify product as required and complete additional verification as required.

6. Regarding temporary change of process controls; the Quality Manger will facilitate to ensure process controls are identified and documented, including inspection, measuring, test, and error-proofing devices (including both the primary process control and the approved alternate method).

7. Execution of alternate methods will be determined collectively by the department manager and Quality Manager, and proper notification will be consistent with customer requirements.

8. During such times that alternate control methods are used, the process and associated product will be reviewed and verified a minimum of once per day. With an ultimate goal of returning to the normal process controls as soon as possible.

Procedure Continued:

9. Traceability records of the affected product from the alternate control method, will be maintained in accordance with procedure PQ2, “Records Control”.

10. Periodic reviews will be conducted of any such alternate process control methods.

AMENDMENT RECORD

Revision	Date	Details	Authority
A	09-22-17	Originated	Ed Ide