

			<b>Product Safety</b>
<b>QMS</b> PQ7	<b>Rev</b> A	<b>Date</b> 08-03-17	<b>Procedure Authority: Quality Assurance Manager</b>

**Purpose:** The purpose of this procedure is to describe our provisions for product-safety related requirements.

**Scope:** This procedure applies to requirements initially identified by our customers as well as subsequent discoveries based on new knowledge and experience.

**Responsibility:** The Quality Manager is responsible for administering this procedure.

**Definitions:**

**Reference Documents:**

PQ4 Control of Non-conforming Product

**Procedure:**

1. The relevant department Manager and Quality Manager collectively, will review all product-safety related products, as defined by our customer, and their associated manufacturing processes, and insure appropriate control measures are applied. Areas of focus will include but not be limited to the following, where applicable:
  - a) identification of statutory and regulatory product-safety requirements
  - b) customer notification of requirements in item a;
  - c) special approvals for design FMEA;
  - d) identification of product-safety related characteristics;
  - e) identification and controls of safety related characteristic of product and at the point of manufacture;
  - f) special approval of control plans and process FMEA's;
  - g) reaction plans;
  - h) defined responsibilities, definition of escalation process and flow of information, including top management, and customer notification;
  - i) training for personnel involved in product-safety related products and associated manufacturing processes;
  - j) changes of product or process shall be approved prior to implementation,
  - k) including evaluation of potential effects on product safety from process and product changes;

**Procedure contd:**

- l) transfer of requirements with regard to product safety throughout the supply chain;
  - m) lessons learned for new product introduction.
2. Regarding new projects, product-safety related items will be obtained during APQP activities and properly addressed in associated documents, consistent with customer requirements. Control Plan and PFMEA provisions will then be carried forward to production and control activities to adequately control risk.
  3. Regarding existing projects, product-safety related items brought to our attention in the way of revisions, new information provided by our customer, and other discoveries will be addressed and provided for with revised APQP documents. Again, these provisions will then be carried forward to production and control activities to adequately control risk.
  4. If at any time, a breach in product-safety requirements has been identified, immediate actions will be taken in accordance with procedure PQ4 “Control of Non-conforming Product”.

***AMENDMENT RECORD***

<b>Revision</b>	<b>Date</b>	<b>Details</b>	<b>Authority</b>
A	08-03-17	Originated	E. Ide