

<b>KAIZEN ENGINEERS</b>	<b>QUALITY MANUAL</b>	<b>Doc. No.: Annexure-B</b>
		<b>Rev. No.: 00</b>
	Title: Product Safety	<b>Eff. Dt.: 01.04.2018</b>
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#### **4.4.1.2 Rules for ensuring control of Product Safety**

- All product safety related statutory & regulatory requirements shall be indicated in the relevant areas and product profiles for appropriate identification
- Any customer notified safety requirements shall be integrated into the above.
- Where the Design FMEA requires special approval from the customer for validation arrangements for control of to product-safety related parameters, such approvals will be obtained and evidences maintained.
- Such product safety related characteristics will be identified as appropriate in the product drawings or other Quality Planning documents.
- Where controls are to be exercised on product-safety related parameters during manufacturing, these control methods will be appropriately marked in the relevant quality planning documents eg., PFMEA, Control Plan, Work Instructions, etc.
- As applicable, approval from the customer will be obtained for these PFMEA & Control plans.
- Reaction plans to be defined where these product-related controls have shown deficiency in operation.
- Responsibilities for the effective operation of these controls related to product-safety related parameters have been defined (refer the organization chart & description of responsibilities and authorities). Also, an escalation procedure has been displayed in the appropriate areas where this responsibility fails to function satisfactorily. System of conveying the information to the applicable authority has been defined up to Top Management level. Customer will be also notified where applicable and required.
- Requisite training for all personnel concerned with control of product-safety related product & process characteristics has been included as a permanent part of the training planning.
- Any changes to product-safety related product & process related characteristics to be routed through the engineering change management procedure with approval by customer as applicable or required.
- All product-safety related characteristics shall be identified in all applicable procedures and documents issued to the supply chain including the external service providers, whether customer approved or not.
- For products with safety characteristics, traceability shall be maintained as defined by customer or determined by the organization whoever is severe. This shall be ensured throughout the supply chain including the external service providers.
- Lessons learnt related to product-safety related characteristics & parameters shall be incorporated into all the quality planning documents including those with the external supply chain.

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