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Policy: The Company shall ensure the quality of its products and/or services by planning and controlling their design and development.

Purpose: To delineate planning and controls during the design phase to optimize quality, effectiveness, safety, and customer satisfaction prior to manufacturing.

Scope: This procedure applies to all *new* development, as well as to developing significant changes to *existing* products and services.

Responsibilities: All Employees are responsible for ensuring product and process improvement.
The Engineering Manager is responsible for designing, evaluating, testing, and all technical aspects of product and process development.
The Accounting Manager is responsible for evaluating and reporting on the financial aspects of product/process development.
The Marketing Manager is responsible for coordinating product development with the customer base, supervising field trials, finding new markets for the Company's products/processes, and raising awareness of the Company's offerings.
Top Management is responsible for final review and approval of design and development (D&D) projects.
The Product Development Team is responsible for managing the product design-and-development process; may also be known as "the Project Team".

Definitions: Failure Mode and Effects Analysis (FMEA) – Technique for testing design of processes, products or services in which failures can occur. FMEA is useful for evaluating reliability, safety, and general quality in order to design in quality, evaluate and address risks, and improve design results.
The probability of each failure occurring and the result of failure are analyzed. If possible, hazards and faulty performance are designed out of the device; if not, hazards/substandard performance are compensated, reduced, detected, or prevented (by interlocks, warning signs, explicit instructions, alarms, etc.).

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