

			<h2>Error Proofing</h2>
QMS PQ17	Rev A	Date 09-26-17	Procedure Authority: Production Manager

Purpose: The purpose of this procedure is to describe and direct activities associated with error proofing.

Scope: This procedure applies to part/process specific error proofing provisions, regarding methods, testing, reaction plans, and related documentation.

Responsibility: The Production Manager is responsible for administering this procedure.

Definitions:

Error Proofing = Product and manufacturing process design provisions, meant to prevent manufacture of nonconforming products.

Reference Documents: NA

Procedure:

1. As part of process design, error proofing will be considered and incorporated as appropriate.
2. The degree, to which error proofing is incorporated and decision criteria will be consistent with risk assessment concepts and take into account customer and internal requirements.
3. Once a need for error proofing has been determined, we'll develop part specific applications that:
 - a) Determines and incorporates an appropriate error proofing method;
 - b) Determines testing of error proofing functions for failures or simulated failures¹;
 - c) Determines test frequencies of error proofing methods;
 - d) Determines a reaction to discovered failures in error proofing methods;
 - e) Ensures proper documentation of associated error proofing records;

¹*Note: Challenge parts, when used, shall be identified, controlled, verified, and calibrated where feasible.*

AMENDMENT RECORD

Revision	Date	Details	Authority
A	09-26-17	Originated	Ed Ide