

			<h2>Identification & Traceability</h2>
QMS PQ16	Rev A	Date 09-22-17	Procedure Authority: Production Manager

Purpose: The purpose of this procedure is to describe and direct activities associated with identification and traceability of product.

Scope: This procedure applies to part specific arrangements in concert with customer requirements.

Responsibility: The Production Manager is responsible administering this procedure.

Definitions: Traceability purpose = is to support identification of clear start and stop points for product received by the customer, that may contain quality and/or safety related nonconformities.

Reference Documents: NA

Procedure:

1. As part of process design, provisions for identification and traceability will be considered and incorporated as appropriate.
2. The degree to which product is identified, is customer driven and can range from container labels with traceability information, to permanent markings on individual parts, i.e. date codes with traceable information to production records.
3. Once the customer has decided the method of identification, we will develop a system that:
 - a) Enables us to identify nonconforming and/or suspect product;
 - b) Enables us to segregate nonconforming and/or suspect product;
 - c) Ensures the ability to meet the customer and/or regulatory response time requirements;
 - d) Ensures documented information is retained in the format that enables us to meet the response time requirements;
 - e) Ensures serialized identification of individual products, if specified by the customer or regulatory standards;
 - f) Ensures the identification and traceability requirements are extended to externally provided products with safety/regulatory characteristics.
4. Again, identification and traceability is part specific and dependant on customer requirements.

AMENDMENT RECORD

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