

DOCUMENT NUMBER <b>91-9003</b>	REVISION <b>B</b>	TITLE <b>Processes and Procedures</b>	REV DATE <b>09/2019</b>	Page <b>1 of 3</b>
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### 1.0 Purpose of Procedure

This document describes Product Resources' breakdown of processes. It provides for a procedure and assigns responsibilities.

### 2.0 Scope of Process

This document describes no active process but rather describes how the QMS transition team, chartered by management, defined the Product Resources' major processes and broke them down further into procedures (Tier 2).

### 3.0 Process Owner(s)

3.1 Quality

### 4.0 Procedure

4.1 The QMS transition team under the direction of the QA Manager was given the responsibility and authority by management to define and create a breakdown of Product Resources' major processes, based both on the scope of operations and a best logical breakdown for both procedure development and internal auditing.

4.2 Procedures, Tier 2 in the documented QMS, have been created to support the defined processes. Where applicable, procedures will be numbered such that their numerical order matches the normal progression of the process; this most applies to the operational major processes 1-5 as opposed to the supporting processes 6-9.

4.3 Each major process has been given a number, and procedures that support them will have document numbers that are in the form 91-[major process number, a single digit]XXX, where XXX is a sequentially-assigned, unique number with respect to the given process.

4.4 The relationships between the process, the procedures, and the Quality Manuals, Tier 1 in the documented QMS, which in turn reflect the related external standards, are given in 43-4769, Process Audit Map. This allows for traceability from, ultimately, the external standards to the procedures that implement the requirements and is a useful reference for audits, both internal and external.

4.5 A breakdown of Product Resources' major processes and associated procedures immediately follows this procedure.

### 5.0 Control of Records

The storage location and retention period for records referenced above are given in 91-6002, Control of Records.

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<u>Major Process #</u>	<u>Major Process</u>	<u>Associated Procedure</u>	<u>Procedure #</u>
1	Customer Processes	New and Repeat Business Inquiries	91-1001
		Quotation and Order Acceptance	91-1002
		Customer Communication, Satisfaction, and Property	91-1003
		Customer Order Shipping	91-1004
2	Design and Development	Design and Development Process	91-2001
		Management of Design and Development Process	91-2002
		Risk Management in the Design and Development Process	91-2003
3	Purchasing Process	Supplier Management	91-3001
		Requirements for Purchased Materials and Order Placement	91-3002
		Verification and Receipt of Purchased Materials	91-3003
4	Manufacturing Processes	Manufacture, Inspection and Test of Material and Product	91-4001
		Control of Nonconforming Material	91-4002
		Preservation and Storage of Material and Product	91-4003
		Production Environment	91-4004
5	Service	Service and Returns	91-5001
6	Control of Information	Control of Documents	91-6001
		Control of Records	91-6002
		Identification and Traceability	91-6003
		Planning for Product Realization and Device Master Records	91-6004
		Device History Records	91-6005
		Product Labeling and Marking	91-6006
7	Risk Management	Internal Audit	91-7001
		Corrective Action	91-7002
		Preventive Action	91-7003
		Control of Measuring Devices	91-7004
		Business Continuity	91-7005
		Product Process Analysis and Validation	91-7006
8	Company Resources	Infrastructure	91-8001

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<u>Major Process #</u>	<u>Major Process</u>	<u>Associated Procedure</u>	<u>Procedure #</u>
		Competence, Awareness, Knowledge, and Training	91-8002
9	Organization and Management	Context of Organization	91-9001
		Quality Policy	91-9002
		Processes and Procedures	91-9003
		Objectives and Analysis of Data	91-9004
		Management Review	91-9005