Veridiam

QM-1 Supplement

QUALITY MANAGEMENT SYSTEMS MANUAL SUPPLEMENT

Revision 7

APPROVED BY:	TITLE	DATE
B. Olevson	Quality Director / Management Representative	07 NOV 2017

DOCUMENT REVISION HISTORY

Paragraph or Section:	Revisions:	Rev:	Date:
All	Initial Release	0	12/14/09
	Table 1, Section 7, Product Realization. Removed IP 7.1.2, Production Job Planning—requirements covered in IP 7.1.1 and IP 7.5.1	1	7/10/10
4	Replaced IP 4.2.1 with CQP 4.2.1	2	8/13/10
Table 1	Replaced IP 5.6.1 with CQP 5.6.1	3	10/18/10
Table 1	Replaced CQP 4.2.1 with IP 4.2.1 Replaced CQP 5.6.1 with IP 5.6.1	4	12/7/13
Table 1	Replaced IP 4.3.2 with IP 7.1.3	5	3/18/14
2.1	Deleted reference to Quality Manager	6	10/3/15
All	Complete rewrite to match the new numbering of clauses of the Quality Manual and revisions of ISO9001:2015, AS9100D & ISO 13485:2016	7	11/7/17

1. PURPOSE

1.1 The purpose of this document is to provide supplemental information to QM-1 Quality Management System Manual.

1.2 This Supplement depicts by section, the second tier procedures that address how the Quality Manual requirements are met and the correlation between different standards applicable to Veridiam.

2 SCOPE

2.2 This supplemental procedure is applicable for El Cajon

2.3 This document requires only the approval of the Quality Management Representative.

2.4 In the event that a second tier procedure changes, this document is revised to reflect those changes.

2.5 Newly developed procedures may also be added.

2.6 Training of applicable personnel is required.

3 REFERENCES

3.1 Table 1 lists, by section, QM-1 Quality Management Systems Manual, a correlation between the different standards, procedures and documents applicable to each section

Veridiam

TABLE 1

QM Section (ISO9001/AS9100)	Element Description	Cross reference to ISO13485	QM section or Procedures #	Applicable Forms/Work Instructions, etc.
4.0	**Context of the Organization**			
4.1	Understanding the Organization and Its Context		IP 4.1.1 Context of the Organization	• QS1227, COTO log and Risk assessment
4.2	Understanding the needs and expectations of interested parties			
4.3	Determining the scope of quality management system	4.1 General Requirements 4.2.1 General 4.2.2 Quality Manual	QM-1 Quality Management Systems Manual	• QM-1 Supplement
4.4	Quality Management System and Its processes			
4.4.1	General Requirements			
4.4.2	Quality Manual			
5.0	**Leadership**			
5.1	Management commitment	5.1 Management Commitment	QM-1 (p 5.1)	
5.1.2	Customer focus	5.2 Customer focus	IP 7.2.1 Customer-Related process Administration	• PROD0092, Contract Review • PURCH0004, Receiving Inspection/Purchase Req (RIPR)
5.2	Quality Policy and communication	5.3 Quality Policy	QM-1 (p 5.2)	
5.3	Organizational Roles, Responsibilities and Authorities	5.5 Responsibility, Authority and communication	QM-1 (5.3)	
5.3.1	Responsibility and Authority			
5.3.2	Management Representative		QM-1 (p 5.3)	• M0001 – Appointment of Management Representative
6.0	**Planning**			
6.1	Actions to address Risks and Opportunities	5.4.2 QMS Planning 8.5.3 Preventive Action	QM-1 (p 6.1)	

QM Section (ISO9001/AS9100)	Element Description	Cross reference to ISO13485	QM section or Procedures #	Applicable Forms/Work Instructions, etc.
6.2	Quality Objectives and Planning to Achieve them	5.4.1 Quality Objectives	OP 8.2.2 Monitoring and Measurement of KPI's	• QS1230 – KPI & PEAR Form
6.3	Quality Management System Planning of Changes	5.4.2 QMS Planning	QM-1 (p 6.2, 6.3)	
7.0	**Support**			
7.1.1	Provision of Resources	6.1 Provision of resources	QM-1 (p 7.1.1)	
7.1.2	Assignment of Personnel	6.2 Human Resources	QM-1 (p 7.1.2) IP 6.2.2 Personnel Competence	
7.1.3	Infrastructure	6.3 Infrastructure	IP 6.3.1 Maintenance Procedures	• QS1030, Corrective - Breakdown - Process Improvement Maintenance Review
7.1.4	Work Environment	6.4 Work Environment	QM-1 (p 7.1.4)	•
7.1.5	Monitoring and Measuring of Resources	7.6 Control of monitoring and measuring equipment	IP 7.6.1 Control & Calibration of Measurement and Test Equipment	• QS0084, Gage Evaluation Form • QS1190, Calibration Extension Request Form • QS1195, Calibration Certificate Review Checklist • QS1207, Calibration Certificate Review – Heat Treat Furnace • WA-297, Guide for SAT and TUS report review
7.2	Competence	6.2 Human Resources	IP 6.2.1 Training and Qualification Records IP 6.2.2 Personnel Competence	• TRAINING0001 – Training Record • HR0020, Training waiver form • QS0385, Training waiver form
7.3	Awareness	6.2 Human Resources		

QM Section (ISO9001/AS9100)	Element Description	Cross reference to ISO13485	QM section or Procedures #	Applicable Forms/Work Instructions, etc.
				• QS1027, QMS Training Matrix • QS0854 - Production Department Orientation Checklist • QS1202, New Hire Orientation Checklist
7.4	Communication	5.5.3 Internal Communication	QM-1 (p 7.4)	•
7.5	Documented Information	Documentation requirements	IP 4.2.1 Document Control IP 4.2.2 Quality Record Control IP 4.3.1 Software QA Controls OP 7.23.1 Creating a DHR for ISI	• QS0055, Document Release Authorization (DRA) form • QS1109, PPI Review and Comment Form • QS1106, Document Approval Matrix • QS1210, Document Review Record
7.5.1	General	4.2.1 General		
7.5.2	Creating and updating	4.2.3 Medical device file		
7.5.3	Control of documented information	4.2.4 Control of Documents 4.2.5 Control of records		
8.0	**Operation**			
8.1	Operation Planning and Control	7.1 Planning of product realization	IP 4.1.1 Context of the Organization IP 7.1.1 Product Development	• QS1227, COTO log and Risk assessment
8.1.1	Operation Risk management	7.1 Planning of product realization		
8.1.2	Configuration Management		IP 7.1.1 Product Development IP 7.1.3 Configuration Management	• QS1177 Engineering Change Request (ECR) Form • QS1178 Engineering Change Order (ECO) Form • QS1179 Engineering Change Notification (ECN) Form • QS1180 Configuration Definition Form • QS1181 Standard Cost Definition Form

QM Section (ISO9001/AS9100)	Element Description	Cross reference to ISO13485	QM section or Procedures #	Applicable Forms/Work Instructions, etc.
				• QS1182 Effectivity Assessment and Disposition Form
8.1.3	Product safety		IP 7.4.1 Purchase Order Administration	• PU0001 Standard Purchase Order Quality Clauses • PU0002 ASL – Approved Supplier List • QS1003 Purchase Requisition (PR)
8.1.4	Prevention of Counterfeit Parts			
8.2	Requirements for product and services	7.2 Customer related processes	IP 7.2.1 Customer-Related process Administration	• Customer satisfaction survey • PROD0092, Contract Review
8.2.1	Customer communication	7.2.3 Communication		
8.2.2	Determine requirements of products and services	7.2.1 Determination of requirements related to product		
8.2.3	Review requirements of products and services	7.2.2 Review of requirements related to product		
8.2.4	Changes to requirements of products and services	7.2.2 Review of requirements related to product		
8.4	Control of externally provided process, products and services	7.4 Purchasing	IP 7.4.1 Purchase Order Administration	• PU0001 Standard Purchase Order Quality Clauses • PU0002 ASL – Approved Supplier List • QS1003 Purchase Requisition (PR) • QS1117 Quality Clause Flow Down Guidelines • QS1234 Traveling Requisitions
8.4.1	General	7.4.1 Purchasing process		

QM Section (ISO9001/AS9100)	Element Description	Cross reference to ISO13485	QM section or Procedures #	Applicable Forms/Work Instructions, etc.
				(Green Card)
8.4.2	Type and extent of control	7.4.1 Purchasing process 7.4.3 Verification of purchased products	IP 7.4.2 Verification of Purchased Product IP 7.4.3 Supplier Selection & Evaluation	• QS1003 Purchase Requisition (PR) • NCM0035 – Non Conformance Report • QS0018 Approved Supplier List (ASL) Action Form • QS0060 Supplier Corrective Action Report (SCAR) • QS0207 Supplier Evaluation • PU0002 Approved Supplier List (ASL)
8.4.3	Information for external providers	7.4.2 Purchasing information 7.4.3 Verification of purchased products		
8.5	Production and Service Provision	7.5 Production and service provision	IP 7.5.1 Traveler Requirements	PROD0007 - TRAVELER CHANGE NOTICE
8.5.1	Control of production and service provision	7.5.1 Control of production and service provision 7.5.2 7.5.6 Validation of processes for production and service provision	IP 7.5.2 Process Validation	
8.5.2	Identification and Traceability	7.5.8 Identification 7.5.9 Traceability	IP 7.5.3 Identification & Traceability of Products	• PROD0051 Accept Status – Green Tag • PROD0052 Hold Status – Yellow TAG • PROD0053 Reject Status – Red Tag • PROD0054 Conditional Release – Blue Tag

QM Section (ISO9001/AS9100)	Element Description	Cross reference to ISO13485	QM section or Procedures #	Applicable Forms/Work Instructions, etc.
8.5.3	Property belonging to customers or external providers	7.5.10 Customer property	IP 7.5.4 Handling Customer Property	• Customer/Supplier Specific
8.5.4	Preservation	7.5.11 Preservation of product	IP 7.5.5 Preservation of Product	
8.5.6	Control of changes	7.3.9 Control of design and development changes	IP 7.1.3 Configuration Management	• QS1177 Engineering Change Request (ECR) Form • QS1178 Engineering Change Order (ECO) Form • QS1179 Engineering Change Notification (ECN) Form • QS1180 Configuration Definition Form • QS1181 Standard Cost Definition Form QS1182 Effectivity Assessment and Disposition Form
8.6	Release of Product and services	7.4.3 Verification of purchased products 8.2.6 Monitoring and measurement of product	IP 7.4.2 Verification of Purchased Product IP 8.2.4 Monitoring and Measurement of Product IP 8.2.5 Product Certification	• Customer Specific (MQCP, Fixed Process, etc) • Customer specific
8.7	Control of Nonconforming Outputs	8.3 Control of nonconforming product	IP 8.3.1 Control of Nonconforming Product	• NCM0035 – Non Conformance Report
9.0	**Performance Evaluation**			
9.1.1	General	8.1 General 8.2.5 Monitoring and measurement of processes	IP 8.4.1 Analysis of Data OP 8.2.2 Monitoring and Measurement of KPI's	QS1230 – KPI & PEAR Form

QM Section (ISO9001/AS9100)	Element Description	Cross reference to ISO13485	QM section or Procedures #	Applicable Forms/Work Instructions, etc.
9.1.2	Customer Satisfaction	8.2.1 Feedback	IP 7.2.1 Customer-Related process Administration	• Customer satisfaction survey • PROD0092, Contract Review
9.1.3	Analysis and evaluation	8.4 Analysis of data	IP 8.4.1 Analysis of Data	
9.2	Internal Audit	8.2.4 Internal Audit	IP 8.2.2 Internal Audit Program	• QS0259 Audit Plan and Summary Report • QS0208 On-Site Audit Checklist • QS1196 QMS Checklist • QS1211 Internal Audit Agenda • QS1226 Auditor Skill Matrix
9.3	Management Review	5.6 Management review	IP 5.6.1 Management Review	• QS1228, Management Review Presentation • QS1229, Management Review Meeting minutes
9.3.1	General	5.6.1 General		
9.3.2	Management Review Inputs	5.6.2 Review input		
9.3.3	Management Review Outputs	5.6.3 Review output		
10.0	**Improvement**			
10.1	General	8.5.1 General	IP 4.1.1 Context of the Organization IP 8.3.1 Preventive Action	• QS1227, COTO log and Risk assessment
10.2	Nonconformity and Corrective Action	8.3 Control of nonconforming products 8.5.2 Corrective Action	IP 8.3.1 Control of Nonconforming Product IP 8.5.2 Corrective Action	• NCM0035 – Non Conformance Report • QS0060, Supplier Corrective Action Report (SCAR) • Problem Improvement Request (PIR) Form (Rolls Royce SABRE requirement – 8D

QM Section (ISO9001/AS9100)	Element Description	Cross reference to ISO13485	QM section or Procedures #	Applicable Forms/Work Instructions, etc.
				• root cause analysis tool) • QS1192, 8D Report • QS1193, CAR Status Tracker
10.3	Continual Improvement	8.5.3 Preventive Action	QM-1 (p 10.3) IP 8.5.2 Preventive Action	