Appendix A

Ref no.	Clause in ISO 13485:2016	Clause in AS9100D	Comments on Comparison
1	1 Scope 4.1.1 (no title)	1 Scope 4.3 Determining the Scope of the Quality Management System	• Establish the boundaries and context of the organization • Adjust the description as required
	4 Quality Management System	4 Context of the Organization 4.1 Understanding the Organization and its Context 4.2 Understanding the Needs and Expectation of Interested Parties 4.4 Quality Management System and its Processes	
2	4.1 General Requirements	4.4 Quality Management System and its Processes 8.4 Control of Externally Provided Processes, Products and Services	• ISO 13485 4.1 General Requirements has many subsections which are numbered but not titled. • ISO 13485 4.1.2 covers the roles undertaken by the organization • ISO 13485 4.1.3 discusses QMS processes, their interactions and risk assessment required • ISO 13485 4.1.4 discusses requirement for necessary resources, planning, operation, controls, monitoring and measurement together with records for QMS processes • ISO 13485 4.1.5 discusses change control for QMS processes • ISO 13485 4.1.6 discusses the need for control, validation and risk assessment for software used in QMS processes
3	4.2 Documentation Requirements	7.5 Documented Information	• ISO 13485:2016 has as its base, ISO 9001:2008. AS9100D has at its base ISO 9001:2015. Numbering, title headings and to some degree documentation requirements correlate better with previous version, AS9100C.
4	4.2.1 General	7.5.1 General	• Since documentation requirement changed from ISO 9001:2008 to ISO 9001:2015, careful review must be made to determine the extent to which the current AS9100D QMS documentation (based on ISO 9001:2015) lines up with the ISO 13485 (based on ISO 9001:2008) • Additional ISO 13485 requirements must also be covered

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5	4.2.2 Quality Manual	4.3 Determining the Scope of the Quality Management System 4.4 Quality Management System and its Processes 7.5.1 General	• ISO 13485 4.2.2 requires that a Quality Manual be documented; AS9100D states documented information *"can"* be compiled in a Quality Manual. • Mandatory Quality Manual must contain interaction of QMS processes
6	4.2.3 Medical Device File	*No equivalent clause*	• No equivalent AS9100D clause exists. ISO 13485 4.2.3 Requirement outlines the elements of the medical device file • At least 1 file for each medical device or medical device family must be kept
7	4.2.4 Control of Documents	7.5.2 Creating and Updating 7.5.3 Control of Documented Information	• Individual organizations must compare existing QMS documentation (i.e. procedures, work instructions, forms etc.) and their control to determine the extent of compliance with ISO 13485 4.2.4 documentation requirements.
8	4.2.5 Control of Records	7.5.2 Creating and Updating 7.5.3 Control of Documented Information	• ISO 13486 4.2.5 deals with requirement of record control, including record retention. Extent of compliance must be reviewed.
	5 Management Responsibility	5 Leadership	
9	5.1 Management Commitment	5.1 Leadership and Commitment 5.1.1 General	• ISO 13485 5.1 stipulations regarding management commitment are compatible with those listed in AS9100D 5.1 • Further discussion regarding management reviews in item 17 below
10	5.2 Customer Focus	5.1.2 Customer Focus	• ISO 13485 requirements are addressed in AS9100D 5.1.2
11	5.3 Quality Policy	5.2 Policy 5.2.1 Establishing the Quality Policy 5.2.2 Communicating the Quality Policy	• General alignment between standards • ISO 13485 5.3 requirement that the Quality Policy is reviewed for continuing suitability should be verified
	5.4 Planning	6 Planning	
12	5.4.1 Quality Objectives	6.2 Quality Objectives and Planning to Achieve Them	• ISO 13485 5.4.1requirements are covered in AS9100D 6.2 and subsections thereof
13	5.4.2 Quality Management System Planning	6 Planning 6.1 Actions to Address Risks and Opportunities 6.3 Planning of Changes	• ISO 13485 5.4.2 requirements are covered in AS9100D 6.1 and 6.3
	5.5 Responsibility, Authority and	5 Leadership	

	Communication		
Ref no.	**Clause in ISO 13485:2016**	**Clause in AS9100D**	**Comments on Comparison**
14	5.5.1 Responsibility and Authority	5.3 Organizational Roles, Responsibilities and Authorities	• AS9100D 5.3 tasks top management with assigning responsibility and authority for ensuring that the processes are effective, delivering intended outputs, are improved and customer focused • Documentation required outlining interrelation of all personnel who manage, perform and verify work affecting quality – thereby demonstrating independence
15	5.5.2 Management Representative	5.3 Organizational Roles, Responsibilities and Authorities	• AS9100D 5.3 covers the management representative requirement in ISO 13485 5.5.2
16	5.5.3 Internal Communication	7.4 Communication	• AS9100D 7.4 does not assign responsibility for communication of the QMS to top management; however, 5.1.1 identifies top management as being responsible for effectiveness and communicating the importance of the QMS
	5.6 Management Review	9.3 Management review	
17	5.6.1 General	9.3.1 General	• ISO 13485 5.6.1 requires that there be a documented procedure for management reviews with a specified interval; AS9100D 9.3.1 does not have these requirements • Recommend that the list of items to be covered is as specified in ISO 13485 5.6.1
18	5.6.2 Review Input	9.3.2 Management Review Inputs	• AS9100D 9.3.2 does not have “preventive action” as being a mandatory input; this needs to be added
19	5.6.3 Review Output	9.3.3 Management Review Outputs	• AS9100D 9.3.3 needs to include reviews of improvement requirements for products and review of new or revised regulatory requirements
	6 Resource Management	7.1 Resources	
20	6.1 Provision of Resources	7.1.1 General 7.1.2 People	• ISO 13485 6.1 b) meet applicable regulatory and customer requirements is covered in AS9100D 5.1.1 and 5.1.2 which cover top management responsibilities to ensure customer and regulatory requirements are determined, understood and met

Ref no.	Clause in ISO 13485:2016	Clause in AS9100D	Comments on Comparison
21	6.2 Human Resources	7.2 Competence 7.3 Awareness	• Documented process for establishing competence and establishing training needs to be added to AS9100D 7.2 • Check records of competence for evidence of compliance with ISO 13485 6.2 requirements
22	6.3 Infrastructure	7.1.3 Infrastructure	• Check for evidence of regular and/or preventative maintenance on production equipment
	6.4 Work Environment and Contamination Control	7.1.4 Environment for the Operation of Processes	
23	6.4.1 Work Environment	7.1.4 Environment for the Operation of Processes	• AS9100D 7.1.4 needs to accommodate the special environmental and operational conditions, such as cleanliness which apply when manufacturing medical devices
24	6.4.2 Contamination Control	7.1.4 Environment for the Operation of Processes	• Special requirements for control of contamination and cleanliness requirements during assembly and packaging should be incorporated into AS9100D 7.1.4.
	7 Product Realization	8 Operation	
25	7.1 Planning of Product Realization	8.1 Operational Planning and Control	• Elements are covered in AS9100D 8.1, however there is a need to document the procedure for planning of product realization
	7.2 Customer-Related Processes	8.2 Requirements for Products and Services	
26	7.2.1 Determination of Requirements Related to Product	8.2.2 Determining the Requirements for Products and Services	• AS9100D 8.2.2 should accommodate the ISO 13485 7.2.1 requirement to provide any user training required
27	7.2.2 Review of Requirements Related to Product	8.2.3 Review of the Requirements for Products and Services 8.2.4 Changes to Requirements for Products and Services	• AS9100D 8.2.3 and 8.2.4 address the ISO 13485 7.2.3 requirements with the exception of providing user training as required
28	7.2.3 Communication	8.2.1 Customer Communication	• AS9100D 8.2.1 addresses the communication requirements, however arrangements and processes should be documented
	7.3 Design and Development	8.3 Design and Development of Products and Services	
29	7.3.1 General	8.3.1 General	• Procedure for Design and Development per ISO 13485 7.3.1 must be documented

Ref no.	Clause in ISO 13485:2016	Clause in AS9100D	Comments on Comparison
30	7.3.2 Design and Development Planning	8.3.2 Design and Development Planning	• Processes for Design and Development Planning per ISO 13485 7.3.2 must be documented. AS9100D 8.3.2 states the need for documented information. Review for compliance
31	7.3.3 Design and Development Inputs	8.3.3 Design and Development Inputs	• Supplement AS9100D 8.3.3 with additional inputs of safety requirements, usability, output(s) of risk management, that it is verifiable and evidence of review and approval
32	7.3.4 Design and Development Outputs	8.3.5 Design and Development Outputs	• AS9100D 8.3.5 should be supplemented with additional outputs: to provide appropriate information for purchasing, production and service provision • Verify outputs against design and development inputs
33	7.3.5 Design and Development Review	8.3.4 Design and Development Controls	• Ensure review date is recorded
34	7.3.6 Design and Development Verification	8.3.4 Design and Development Controls	• Ensure design outputs meet the design input when the medical device is connected or interfaced, if applicable.
35	7.3.7 Design and Development Validation	8.3.4 Design and Development Controls	• Ensure first production unit is used to validated the production process • Add requirement to AS9100D 8.3.4 that medical devices used in performance/clinical evaluations cannot be released to the customer
36	7.3.8 Design and Development Transfer	8.3.4 Design and Development Controls	• Verify outputs as being suitable for manufacturing prior to finalizing production specifications • Verify production capabilities can meet product requirements • Documented procedure required
37	7.3.9 Control of Design and Development Changes	8.3.6 Design and Development Changes 8.5.6 Control of Changes	• A documented procedure is required for control of design and development changes according to ISO 13485 7.3.9
38	7.3.10 Design and Development Files	7.5.3 Control of Documented Information	• ISO 13485 requires that a design and development file for each medical device or medical device family. This should be added to AS9100D 7.5.3
	7.4 Purchasing	8.4 Control of Externally Provided Processes, Products and Services	
39	7.4.1 Purchasing Process	8.4 Control of Externally Provided Processes, Products and Services 8.4.1 General 8.4.2 Type and Extent of Control	• Ensure that documented procedures exist and specify that purchased products conform to purchasing requirements. • Ensure that suppliers are evaluated on basis of product risk

Ref no.	Clause in ISO 13485:2016	Clause in AS9100D	Comments on Comparison
40	7.4.2 Purchasing Information	8.4.3 Information for External Providers	• ISO 13485 7.2.4 requirements are covered in AS9100D 8.4.3 • Ensure records are maintained
41	7.4.3 Verification of Purchased Product	8.4.2 Type and Extent of Control 8.4.3 Information for External Providers 8.6 Release of Products and Services	• ISO 13485 7.4.3 requirements are covered in AS9100D 8.4.2, 8.4.3 and 8.6 • Ensure records are maintained
	7.5 Production and Service Provision	8.5 Production and Service Provision	
42	7.5.1 Control of Production and Service Provision	8.5.1 Control of Production and Service Provision	• Ensure that ISO 13485 7.5.1 medical device/batch records have required level of traceability and include delivery and post-delivery activities listed
43	7.5.2 Cleanliness of Product	*No equivalent clause*	• New clause required for ISO 13485 7.5.2 Cleanliness of Product; possible insertion into AS9100D 8.5
44	7.5.3 Installation Activities	*No equivalent clause*	• New clause required for ISO 13485 7.5.3 installation Activities; possible insertion into AS9100D 8.5 if required
45	7.5.4 Servicing Activities	*No equivalent clause*	• New clause/procedure required for ISO 13485 7.5.4 Servicing activities; possible insertion into AS9100D 8.5.5 if required
46	7.5.5 Particular Requirements for Sterile Medical Devices	*No equivalent clause*	• New clause required for ISO 13485 7.5.5 Particular requirements for sterile medical devices; possible insertion into AS9100D 8.5
47	7.5.6 Validation of Process for Production and Service Provision	8.5.1 Control of Production and Service Provision	• Document procedures for controlling “special processes” – i.e. those whose output cannot be verified by monitoring or measuring the product
48	7.5.7 Particular Requirements for Validation of Processes for Sterilization and Sterile Barrier System	*No equivalent clause*	• New clause/procedure required for ISO 13485 7.5.7 Particular requirements for validation of processes for sterilization and sterile barrier systems; possible insertion into AS9100D 8.5.1
49	7.5.8 Identification	8.5.2 Identification and Traceability	• Ensure a documented procedure exists for Identification and traceability AS9100D 8.5.2
50	7.5.9 Traceability	8.5.2 Identification and Traceability	• Ensure a documented procedure exists for Identification and traceability AS9100D 8.5.2 • New clause required if ISO 13485 7.5.9.2 covering requirements for implantable medical devices applies

51	7.5.10 Customer Property	8.5.3 Property Belonging to Customers or External Providers	• ISO 13485 7.5.10 Customer Property - requirements covered in AS9100D 8.5.3
Ref no.	**Clause in ISO 13485:2016**	**Clause in AS9100D**	**Comments on Comparison**
52	7.5.11 Preservation of Product	8.5.4 Preservation	• Documented procedure is required for preserving the product throughout production, storage, handling, distribution, including special environmental conditions
53	7.6 Control of Monitoring and Measuring Equipment	7.1.5 Monitoring and Measuring Resources	• Document procedure for calibration and verification of monitoring and measuring equipment, including validation of any software used for such an application
	8 Measurement, Analysis and Improvement	9 Performance Evaluation 9.1 Monitoring, Measurement, Analysis and Evaluation	
54	8.1 General	9.1.1 General	• Requirement covered in AS9100D 9.1.1
	8.2 Monitoring and Measurement	9.1 Monitoring, Measurement, Analysis and Evaluation	
55	8.2.1 Feedback	8.5.5 Post-delivery Activities 9.1.2 Customer Satisfaction	• Documented procedure is required for the feedback process • Post-delivery information is to be used in conjunction with risk management. Possible insertion into AS9100D 8.5.5
56	8.2.2 Complaint Handling	9.1.2 Customer Satisfaction	• Documented procedure required for timely complaint handling • Ensure procedure includes justification for complaints which were not investigated
57	8.2.3 Reporting to Regulatory Authorities	8.5.5 Post-delivery Activities	• Documented procedures are required for providing notification to regulatory authorities, should they meet specified reporting criteria
58	8.2.4 Internal Audit	9.2 Internal Audits	• Documented procedure required which describes the responsibilities and requirements for planning, conducting, recording and reporting internal audits/results
59	8.2.5 Monitoring and Measurement of Processes	9.1.1 General	• Review AS9100D 9 Performance Evaluation (9.1.1 General) to ensure all elements listed in ISO 13485 8.2.5 are covered
60	8.2.6 Monitoring and Measurement of Product	8.6 Release of Products and Services	• Product realization processes must identify the product verification steps and the equipment used for the measurement activities

	8.3 Control of Nonconforming Product	8.7 Control of Nonconforming Outputs	
Ref no.	**Clause in ISO 13485:2016**	**Clause in AS9100D**	**Comments on Comparison**
61	8.3.1 General	10.2 Nonconformity and Corrective Action	• Documented procedure required which defines the entire process covering nonconforming product.
62	8.3.2 Actions in Response to Nonconforming Product Detected Before Delivery	8.7 Control of Nonconforming Outputs	• Actions taken in response to nonconforming product detection before delivery, as outlined in ISO 13485 8.3.2, are covered in AS9100D 8.7
63	8.3.3 Actions in Response to Nonconforming Product Detected After Delivery	8.7 Control of Nonconforming Outputs	• Documented procedure is required for issuing advisory notices in accordance with regulatory requirements
64	8.3.4 Rework	8.7 Control of Nonconforming Outputs	• Documented procedure is required for conducting rework
65	8.4 Analysis of Data	9.1.3 Analysis and Evaluation	• Documented procedure is required for data collection and analysis demonstrating the effectiveness of the QMS
	8.5 Improvement	10 Improvement	
66	8.5.1 General	10.1 General 10.3 Continual Improvement	• ISO 13485 8.5.1 has detailed requirements for determining and implementing opportunities for improvement. Section needs to be carefully reviewed and AS9100D 10.1 and 10.3 need to be expanded to include additional stipulations
67	8.5.2 Corrective Action	10.2 Nonconformity and Corrective Action	• Ensure that AS9100D 10.2 requirement for documented information is fulfilled with a documented procedure • Ensure that the procedure stipulates that the corrective action taken does not adversely affect product requirements or safety performance
68	8.5.3 Preventive Action	0.3.3 Risk-based Thinking 6.1 Actions to Address Risks and Opportunities 10.1 General 10.3 Continual Improvement	• Documented procedure is required for preventive action