Comparison of ISO 13485:2016 vs AS9100D Requirements for a Quality Management System

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General Notes

1. In order to tighten the scope of the material to be covered, a certain applicability is assumed, complete with underlying assumptions. Namely you are currently a manufacturer of a tangible good in the aerospace sector, hold an approved AS9100D QMS for Aviation, Space and Defense certification and you wish to fulfill the ISO 13485 Medical Devices QMS requirements as you transition at least a part of your operation into producing PPE / medical devices.

2. Throughout this paper, references are made to various Quality Management System (QMS) specifications and their supplements. Unless otherwise indicated, ISO 13485 is used to denote ISO 13485:2016 (E). Similarly, AS9100D is used synonymously with AS9100:2016 revision D. Generally, to avoid any ambiguity, the full title ISO 9001:2015 is used.

3. This report compares the ISO 13485 QMS requirements with those listed in ISO 9001:2015 together with the supplemental requirements listed in AS9100D. Note that ISO 9001:2015 is the base specification for AS9100D. Clausal numbering and nomenclature cross references were derived from an ISO 13485 to ISO 9001:2015 correlation matrix. For the purposes of this paper ISO 9001:2015 and supplements in AS9100D will be treated as one standard which replaces the previous version, AS9100C, which had, as its basis, ISO 9001:2008.

Foreword Regarding the Evolution of ISO 9001

In order to understand the structure, and to some extent the content and emphasis of the ISO 13485 and the AS9100 standards, it is necessary to review the origin and evolution of the ISO 9001 standard.

When it was first released in the late 1980's the objective of the ISO9001/9002 (no design engineering) /9003 (very simple operation) standards was to harmonize the various quality standards in existence for manufacturing organizations. Over the years, the feedback was that the standard was too narrow in its focus, i.e. predominantly manufacturing. The three categories were merged into one (ISO 9001) and companies could apply exclusions for those areas, such as design engineering which did not apply to their operation. As subsequent revisions were released, the original required "20 elements" (e.g. Statistical Process Control) were replaced by more generally applicable requirements which were more suited to non-production operations such as those in the service sectors.

Furthermore, at the onset the ISO 9001 standard was patterned on the "classic 3 tier" documentation model: Tier 1 – Policy; Tier 2 – Procedures; Tier 3 – Work Instructions, with a 4th tier consisting of records and forms added.

As the standard was adopted by various industry sectors, some elected to use the ISO 9001 as a base standard and apply unique and specific supplemental requirements which their technical committees felt were crucial to their respective sectors.

At the time of this writing, the most current version of ISO 9001 was released in 2015. Sweeping, substantive changes were made to the standard from the 2008 version, not the least of which were revisions to the numbering system and the nomenclature of the section headings. As a result, some of the ISO 9001 based standards adopted the structure of the 2015 version while others did not. ISO 13485:2016 (E) is still based on the 2008 version of the ISO 9001 standard with regards to numbering and clausal titles, while AS9100D has as its base ISO 9001:2015.

As the various ISO 9001 versions were released, they deviated further and further from the classic documentation model described above. ISO 9001:2015 has almost no mandatory procedures and generally refers to requirements as "documented information" or "documented processes". Conversely, because the documentation requirements in ISO 9001:2008 were more prescriptive, ISO 13485:2016 (E) has numerous, specific requirements for various documented procedures. For the purposes of this paper, a documented process or documented information is not taken to be synonymous with a documented procedure, the latter of which requires the inclusion of a scope/applicability/ references / affected organizations / responsibility, etc., in addition to the process.

AS9100D, while based in ISO 9001:2015, and using its nomenclature and numbering system, incorporates a substantive number of aero-specific additional requirements. Not all of these are applicable to the manufacture of medical devices. Conversely, ISO 13485 has requirements for which there are no counterparts in AS9100D. It is up to the individual organization to determine which of the ISO 13485 requirements are covered as a result of their standard operating procedures (e.g. documentation control) and which need additional procedures. It is highly likely that even if a suitable procedure/process exits, it will have to supplemented to include specific reference to the medical devices being manufactured.

INTRODUCTION

Just as having an engineering degree is no guarantee one will obtain a Professional Engineer's license or having a law degree does not equate to passing the bar exam, following the recommendations herein does not automatically ensure successful certification to ISO 13485. What is being highlighted herein are clauses and/or requirements in the ISO 13485 standard which have no direct counterparts in the AS9100D standard, as well as areas which are addressed in both ISO 13485 and AS9100D standards, but which may have differing requirements. It is possible that in fulfilling the AS9100D requirements, some organizations may have already taken an approach that aligns with the ISO 13485 standard (e.g. risk management being *both* business and product risk based). This can only be confirmed through a careful reading of the requirements and context of the standard. Each standard provides a clarification of concepts which refers specifically to the industry sector to which the standard applies. In cases where there are no ISO 13485-equivalent clauses in AS9100D, recommendations are made for possible insertion points.

In essence, the paper points to "what" needs to be addressed. The details of "how" these requirements are satisfied, the ultimate determinant of an organization's ability to obtain certification, is left up to the individual organization.

A Fundamental Choice in Approach

When electing to dual certify the QMS across industry sectors, a fundamental choice must be made at the outset. Does the organization desire to have a separate, stand-alone QMS for each sector or have one, integrated QMS for the entire organization? There are pros and cons to each approach.

Two stand-alone QMS'

Pros: A QMS which is specific to the sector may be easier to create and is much easier to audit from an external regulatory standpoint.

Cons: unless an organization operates a separate, self-contained division which includes, but is not limited to facilities, personnel, equipment etc., having two sets of requirements imposed on the same workforce depending on the target market for the product, is confusing and opens the organization up to possibilities for non-compliance.

Hybrid QMS Manual

Establishing and operating a hybrid QMS manual may not be as straightforward as it first appears. There will always be requirements that are specific to the sector (cleanliness requirements for example). Some areas may benefit from incorporating the most stringent requirement across the board. In other cases, particularly where the sectoral requirements are unique, this can add cost and waste to manufacturing operations.

However an organization approaches the QMS, one significant challenge must be considered. When the latest version of the ISO 9001: 2015 standard was released the entire numbering system was changed, as were the section headings. As many aerospace companies experienced, mapping the changes as well as incorporating the new requirements was a daunting exercise when transitioning from AS9100C which is based on ISO 9001:2008, to AS9100D which has at its root ISO 9001:2015. The latest ISO 13485 standard (third edition – 2016) follows the numbering and title convention of the previous ISO 9001:2008 standard revision.

In the Introduction of the ISO 13485:2016(E) standard, it is stated:

"It is not the intent of this International Standard to imply the need for uniformity in the structure of different quality management systems, uniformity of documentation or alignment of documentation to the clause structure of this International Standard"

As was mentioned previously, however, an implied consideration for any QMS is how external (i.e. regulatory) auditor-friendly it is. This, then, creates a dilemma in that a QMS based on ISO 9001:2015, complete with numbering system and nomenclature is possibly not going to be familiar to the ISO 13485 auditor. Likely the aerospace sector auditors who were practicing prior to the release of AS9100D would

have familiarity with the naming/numbering convention (i.e. ISO 9001:2008) still used by the medical devices ISO 13485 standard. The converse is not probably the case. It will be necessary to prepare and present a very clear and detailed cross-reference matrix in order to demonstrate that the ISO 13485 requirements have been addressed. Consideration must also be given to the impact of a numbering system and nomenclature scheme that is at odds with the appropriate industry standard when working with or being audited by customer quality organizations.

The information in this report is presented in two formats. The first is a report which provides a clause by clause comparison of the standards. Each clausal comparison is numbered. The second format is a table which presents a correlation matrix that compares the contents of the two standards. The number associated with the clausal comparison is referenced in the table for ease of reference. It should be noted that the two standards employ different naming conventions. ISO 13485 capitalizes only the first word in the clause name (e.g. 4.2.4 Control of documents) while AS9100D capitalizes all (e.g. 7.5.3 Control of Documented Information). In order to provide consistency all words in the title have been capitalized.

It is strongly recommended that the ISO 13485 standard be reviewed in its entirety prior to blending the QMS' or creating a new one, as only those elements anticipated to be potential sources of non-compliance were highlighted in this report. The standards are, by necessity, open to interpretation by the organization and to some extent, by an auditor. While following this report is not a guarantee of success, its objective is to be a useful tool in the organization's strategic processes pertaining to entering the medical device manufacturing industry.

As a final note, there are a multitude of additional considerations when endeavoring to cross industry sector boundaries. In Clause 4 of ISO 9001:2015, the context of the organization is explored. Understanding the organization and its context includes identifying internal and external issues that are relevant to the purpose of the organization and which affect the organization's ability to achieve the intended results of the QMS. These contextual matters could arise from legal, technological, competitive, market and national and international regulatory requirements. It is therefore essential that prior to establishing a QMS which fulfills both standards, the organization carefully review the context of the organization, with consideration of this expanded scope. This will need to be addressed in the AS9100D context as well as the ISO 13485 context.

Clausal content comparison between ISO 13485: 2016 and AS9100D

I	ISO 13485:2016 1. Scope	AS9100D 1. Scope & 4.3 Determining the Scope of the Quality Management System

1. To determine the scope of the Quality Management System, the organization must identify and establish the boundaries and context of the organization with respect to incorporating medical devices in its product offerings. The additional information may be added to clause AS9100D 4.3 Determining the Scope of the Quality Management System.

II	ISO 13485:2016 4. Quality Management System	AS9100D 4. Context of the Organization 4.1 Understanding the Organization and its Context 4.2 Understanding the Needs and Expectations of Interested Parties 4.4 Quality Management System and its Processes

2. Ref: ISO 13485 4.1 General Requirements

AS9100D 4.4 Quality Management System and its Processes

8.4 Control of Externally Provided Processes, Products and Services

Note, the sub-sections in ISO 13485 4.1 General Requirements, while numbered, do not have title headings and thus have been grouped under the 4.1 General Requirements heading

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Ref: ISO 13485 4.1.1 (no title)

AS9100D 4.1 Understanding the Organization and its Context

ISO 13485 4.1.1 states the organization shall document the role(s) undertaken by the organization under the applicable regulatory requirements (where roles undertaken by the organization can include manufacturer, authorized representative, importer or distributor.)

The recommendation is to add the requirement to AS9100D clause 4.1 Understanding the Organization and its Context as well as to review and supplement AS9100D clause 4.2 Understanding the Needs and Expectations of Interested Parties.

Ref: ISO 13485 4.1.2

ISO 13485 4.1.2 requires that all processes needed for the QMS be determined, assessed for associated risk and to determine the sequence and interaction of these processes. Any processes specific to medical devises QMS should be included in AS9100D clause 4.4 Quality Management System and its Processes.

Ref: ISO 13485 4.1.3

For each QMS process, ISO 13485 stipulates that the organization determine criteria and methods to ensure effective operation and control; that resources are adequate; that processes achieve planned results; that processes are measured and monitored as appropriate and that records are maintained. (An example of a QMS process is Procurement). AS9100D clause 4.4 should be reviewed for compliance.

Ref: 13485 4.1.4

The organization shall manage these quality management system processes in accordance with the requirements of this International Standard and applicable regulatory requirements. Changes to be made to these processes shall be:

(a) Evaluated for their impact on the quality management system
(b) Evaluated for their impact on the medical devises produced under this QMS

A statement demonstrating compliance could be added to AS9100D 4.4.1 regarding evaluating changes made to the processes.

Ref: ISO 13485 4.1.5

Requirement in this subsection states that if the organization outsources any processes that affect production conformance, it shall monitor and control these processes. The requirement is covered in AS9100D 8.4 Control of externally provided processes, products and services.

Ref: ISO 13485 4.1.6

The organization shall document procedures for the validation of the application of computer software used in the quality management system. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application.

The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software.

Records of such activities shall be maintained. A sub-clause could be added to AS9100D 8.4.2 Type and Extent of Control.

Ref: ISO 13485 4.2 Documentation Requirements **AS9100D 7.5 Documented Information**

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3. General note:

The ISO 13485 general documentation requirements line up to some degree with the requirements outlined in AS9100C as it is based on ISO 9001:2008. As documentation requirements changed significantly in ISO 9001:2015, such as eliminating the mandatory requirement for many documented procedures, a documented QMS created prior to and *maintained after* the issuance of ISO 9001:2015, may be substantially in compliance with the ISO 13485 requirements. Careful review of requirements must be made.

4. Ref: ISO 13485 4.2.1 General

The requirements of the ISO 13485 quality management system documentation must include the following elements. The organization's AS9100D QMS should be reviewed for compliance

a) documented statement of a quality policy and quality objectives
b) a quality manual
c) documented procedures and records required by this International Standard
d) documents including records, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes
e) other documentation specified by applicable regulatory requirements

5. Ref: ISO 13485 4.2.2. Quality Manual

The ISO 13485 4.2.2 clause states that the organization shall document a quality manual that includes:

a) the scope of the quality management system, including details of and justification for any exclusion or non-application
b) the documented procedures for the quality management system or reference to them
c) a description of the interaction between the processes of the QMS

The quality manual shall outline the structure of the documentation used in the quality management system. In AS9100D 4.4 Quality Management System and its Processes, subclause 4.4.2 it states that the required documented information "*can be compiled into a single source of documented information and referred to as a quality manual"*, indicating that it is not a mandatory AS9100D requirement to have a quality manual. ISO 13485 4.2.2 stipulates that an organization document a quality manual. In addition, if interaction between processes is not presently in the AS9100D quality manual, it should be added to clause 7.5.1.

6. Ref: ISO 13485 4.2.3 Medical Device File

Note there is no comparable clause/section in AS9100D covering medical devices.

ISO 13485 clause 4.2.3 Medical Device File, states:

For each medical device type or medical device family, the organization shall establish and maintain one or more files either containing or referencing documents generated to demonstrate conformity to the requirement of this International Standard and compliance with applicable regulatory requirements.

The content of the file(s) shall include, but is not limited to:

a) General description of the medical device, intended use/purpose, and labelling, including any instruction for use;
b) Specification for the product;
c) Specifications or procedures for manufacturing, packaging, storage, handling and distribution
d) Procedures for measuring and monitoring;
e) As appropriate, requirements for installation;
f) As appropriate, procedures for servicing

It is conceivable that product files are kept and that a procedure exists which outlines the type and control of the information therein. The requirement could be added AS9100D section 7.5 Documented Information as needed.

7. Ref: ISO 13485 4.2.4 Control of Documents

The AS9100D revision dropped many of the prescribed requirements for mandatory documented procedures which the ISO 13485 still includes. Review of AS9100D sections 7.5.2 (Creating and Updating) and 7.5.3 (Control of Documented Information) will determine the degree to which documentation must be supplemented and/or controls imposed. AS9100D allows variations in content, at the discretion of the organization based on its size, culture and complexity; ISO 13485 makes no such allowances.

ISO 13485 4.2.4 Control of Documents states:

Documents required by the QMS shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.5

a) Review and approve documents for adequacy prior to issue;
b) Review, update as necessary and re-approve documents;
c) Ensure that the current revision status of and changes to documents are identified;
d) Ensure that relevant versions of applicable documents are available at points of use;
e) Ensure that documents remain legible and readily identifiable;
f) Ensure that documents of external origin, determined by the organization to be necessary for the planning and operation of the quality management system, are identified and their distribution controlled;
g) Prevent deterioration or loss of documents;
h) Prevent the unintended use of obsolete documents and apply suitable identification to them.

The organization shall ensure that changes to documents are reviewed and approved either by the original approving function or another designated function that has access to pertinent background information upon which to base its decisions.

The organization shall define the period for which at least one copy of obsolete documents shall be retained. This period shall ensure that documents to which medical devices have been manufactured and tested are available for at least the lifetime of the medical device as defined by the organization, but not less than the retention period of any resulting record (see 4.2.5) or as specified by applicable regulatory requirements.

8. Ref: ISO 13485 4.2.5 Control of Records

AS9100D sections 7.5.2 (Creating and Updating) and 7.5.3 (Control of Documented Information) should be reviewed for compliance with the following requirements.

ISO 13485 4.2.5 Control of Records states:

Records shall be maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system.

The organization shall document procedures to define the controls needed for the identification, storage, security and integrity, retrieval, retention time and disposition of records.

The organization shall define and implement methods for protecting confidential health information contained in records in accordance with the applicable regulatory requirements.

Records shall remain legible, readily identifiable and retrievable. Changes to a record shall remain identifiable.

The organization shall retain the records for at least the lifetime of the medical device as defined by the organization, or as specified by applicable regulatory requirements, but not less than two years from the medical device release by the organization.

	ISO 13485:2016	AS9100D
	5. Management Responsibility	5. Leadership

9. Ref: ISO 13485 5.1 Management Commitment

Requirements are listed in AS9100D section 5.1 Leadership and Commitment

ISO 13485 5.1 Management Commitment; item d) conducting management reviews, is covered below in the comparison of requirements for management reviews (see item 17 below). Management review requirements are listed in AS9100D 9.3 Management Review.

10. Ref: ISO 13485 5.2 Customer Focus

AS9100D section 5.1.2 Customer Focus addresses the ISO 13485 5.2 requirements.

11. Ref: ISO 13485 5.3 Quality Policy

The requirements in AS9100D 5.2 Policy align with requirements of the ISO 13485 5.3. However, ensure that the following ISO 13485 requirement is explicitly stated and that there is documented evidence of compliance (see ISO 13485 5.3 e) below), as this is implied in the AS9100D standard and not specifically prescribed.

ISO 13485 5.3 e) [Quality policy] is reviewed for continuing suitability

Ref: ISO 13485 5.4 Planning	AS9100D 6. Planning

12. Ref: ISO 13485 5.4.1 Quality Objectives

Requirements listed in AS9100D 6.2 Quality Objectives and Planning to Achieve Them, generally cover those listed in the ISO 13485 5.4 Planning clauses, including the sub-clauses.

13. Ref: ISO 13485 5.4.2 Quality Management System Planning

The requirements listed in ISO 13485 5.4.3 Quality Management System Planning are covered in AS9100D sections 6.1 Actions to Address Risks and Opportunities and 6.3 Planning of Changes. ISO 13485 5.4.2 also makes reference to 4.1 of that specification and thereby includes elements of the context of the organization to be governed by the requirements of quality management system planning.

Ref: ISO 13485 5.5 Responsibility, Authority and Communication — AS9100D 5. Leadership

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14. Ref: ISO 13485 5.5.1 Responsibility and Authority

ISO 13485 5.5.1 emphasizes that the interrelation of all personnel who manage, perform and verify work affecting quality be documented and that top management ensures the independence and authority necessary to perform these tasks.

While AS9100D section 5.3 Organizational Roles, Responsibilities and Authorities does not specify documenting the interrelation of all personnel who manage, perform and verify work affecting quality, it does require that top management assign responsibility and authority for ensuring that the processes are delivering the intended outputs, that the QMS is maintained and effective, that improvements are made and that the customer focus is maintained throughout the organization. Interrelation of the responsible personnel should be documented and added to AS9100D 5.3.

15. Ref: ISO 13485 5.5.2 Management Representative

AS9100D 5.3 covers the management representative requirements outlined in ISO 13485 5.5.2.

16. Ref: ISO 13485 5.5.3 Internal Communication

AS9100D section 7.4 Communication does not specifically identify top management as being responsible for ensuring appropriate communication processes are in place for the quality management system. However, under 5.1.1 Leadership, it states that top management is responsible for communicating the importance of an effective QMS as well as ensuring that the QMS is indeed effective.

Ref: ISO 13485 5.6 Management Review — AS9100D 9.3 Management Review

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17. Ref: ISO 13485 5.6.1 General

ISO 13485 5.6.1 General requires documented procedures for management review while AS9100D 9.3.1 General, does not require this. It specifies that the reviews take place at *planned* intervals (i.e. no specific interval is given).

AS9100D 9.3 Management review section (i.e. 9.3.1 General) should include these requirements.

Note: the mandatory list of items to be covered in the management reviews are substantially the same, however the item headings are phrased differently in ISO 13485 and AS9100D. The external auditors might have difficulty reviewing the record of the review meeting for completeness if the item titles do not line up. As the ISO 13485 has tighter requirements for documenting the results, it is suggested that the item headings from ISO 13485 be used, with embedded reference to the AS9100D requirements.

18. Ref: ISO 13485 5.6.2 Review Input

ISO 13485 lists "preventative action" as a mandatory input. This requirement was in AS9100C but was dropped in revision D and therefore needs to be added back into AS9100D 9.3.2 Management Review Inputs

19. Ref: ISO 13485 5.6.3 Review Output

ISO 13485 5.6.3 specifies that improvement requirements for products and review of new or revised regulatory requirements need to be addressed. Items should be added to AS9100D 9.3.3 Management Review Outputs.

IV ISO 13485:2016 — 6. Resource Management

AS9100D — 7.1 Resources

20. Ref: ISO 13485 6.1 Provision of Resources

It is specified in ISO 13485 6.1 b) [that the organizations] meet applicable regulatory and customer requirements.

AS9100D 7.1 Resources (7.1.1 General) does not specifically mention the requirement to meet applicable regulatory and customer requirements. The section generally deals with plant, facility, equipment and human resources. However, the Leadership clause 5.1.1 requires that top management ensure that the resources needed for the QMS are provided and in section 5.1.2 top management must ensure that all customer, statutory and regulatory requirements are determined, understood and consistently met.

21. Ref: ISO 13485 6.2 Human Resources

ISO 13485 6.2 states: The organization shall document the processes for establishing competence, providing needed training and ensuring awareness of personnel.

While AS9100D 7.2 Competence does stipulate that the competency of personnel is evaluated and documented it does not explicitly require that the processes for establishing competence are documented.

ISO 13485 6.2 states: e) [the organization shall] maintain appropriate records of education, training, skills and experience. AS9100D 7.2 requires that the organization "retain appropriate documented

information as evidence of competence", however which records must be retained are not specified. Records should be checked for compliance to ISO 13485 6.2.

AS9100D 7.3 Awareness stipulates that the organization must ensure that all employees are aware of their contribution to the effectiveness of the QMS and the benefits of improved performance.

22. Ref: ISO 13485 6.3 Infrastructure

ISO 13485 6.3 states: "The organization shall document requirements for the maintenance activities, including the interval of performing the maintenance activities when such maintenance activities, or lack thereof, can affect product quality. As appropriate, the *requirements shall apply to equipment used in production, the control of the work environment and monitoring and measuring."* [italics added]

AS9100D does outline in section 7.1.5 Monitoring and Measuring Resources that the equipment/instruments must be maintained, and records thereof must be kept, however, no mention of the requirement to perform maintenance on production equipment is explicitly stated. It does state in 7.1.3 that "the organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes" where infrastructure may include equipment (hardware and software). This clause should be reviewed to ensure that equipment is identified and evidence of regular and/or preventative maintenance are kept and are available.

Ref: ISO 13485 6.4 Work Environment and Contamination Control **ISO 2001:2015 / IATF 16949 7.1.4 Infrastructure**

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23. Ref: ISO 13485 6.4.1 Work Environment

ISO 13485 6.4.1 states: The organization shall document the requirement for the work environment needed to achieve conformity to product requirements.

If the conditions for the work environment can have an adverse effect of product quality, the organization shall document the requirements for the work environment and the procedures to monitor and control the work environment.

a) Document requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could affect medical devices safety or performance;
b) Ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are competent or supervised by a competent person.

ISO 13485 6.4.1 includes: NOTE: further information can be found in ISO 14644 and ISO 14698

AS9100D 7.1.4 Environment for the Operation of Processes states only that the organization shall determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services [including]

c. physical (e.g. temperature, heat, heat, humidity, light, airflow, hygiene, noise) and that "These factors can differ substantially depending on the products and services provided".

As the products provided in 13485 are described as “medical devices” the requirements are much more specific and AS9100D 7.1.4 should reflect compliance to the ISO 13485 6.4.1 requirements.

24. Ref: ISO 13485 6.4.2 Contamination Control

As per ISO 13485 6.4.2: as appropriate, the organization shall plan and document arrangements for the control of contaminated or potentially contaminated product in order to prevent contamination of the work environment, personnel, or product.

For sterile medical devices, the organization shall document requirements for control of contamination with microorganisms or particulate matter and maintain the requirement cleanliness during the assembly or packing process.

AS9100D has no direct counterpart. Evaluation of current clause 7.1.4 should be made to determine the extent it needs to be supplemented to comply with the ISO 13485 6.4.2 requirement.

V ISO 13485:2016 7 Product Realization AS9100D 8 Operation

25. Ref: ISO 13485 7.1 Planning of Product Realization

AS9100D 8.1 Operational Planning and Control and subsection 8.1.1, 8.1.2, 8.1.3, 8.1.4 cover items listed in ISO 13485 7.1 Planning of Product Realization. However, as is often the case with AS9100D, the explicit requirement to document the procedures is lacking. While documented procedures and records are typically used to demonstrate compliance, it should be verified that they exist. In particular, the risk management process for product realization must be documented and records needed to provide evidence that the realization processes and resulting product meet requirements.

Ref: ISO 13485 7.2 Customer-Related Processes	AS9100D 8.2 Requirements for Products and Services

26. Ref: ISO 13485 7.2.1 Determination of Requirements Related to Product

AS9100D 8.2.2 Determining the Requirements for Products and Services generally aligns with the requirements listed in ISO 13485 7.2.1, however there is no specific mention of being responsible to provide any user training needed to ensure specified performance and safe use of the medical device.

27. Ref: ISO 13485 7.2.2 Review of Requirements Related to Product

ISO 13485 7.2.2 outlines the requirements for contract/order review, contract/order amendment and change management. It stipulates that records of results of the reviews and actions arising thereof be maintained.

AD9100D 8.2.3 Review of the Requirements for Products and Services and 8.2.4 Changes to Requirements for Products and Services address the elements in ISO 13485 7.2.2, with the noted exception of the requirement to identify any user training requirements.

28. Ref: ISO 13485 7.2.3 Communication

ISO 13485 7.2.3 Communication requires that arrangements for communicating with customers are documented. AS9100D 8.2.1 Customer Communication addresses the items, however does not specify that the arrangements/processes be documented.

Ref: ISO 13485 7.3 Design and Development	AS9100D 8.3 Design and Development of Products and Services

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29. Ref: ISO 13485 7.3.1 General

ISO 13485 7.3.1 requires that documented procedures be created for design and development.

AS9100D 8.3.1 Design and Development of Products and Services (General) requires that an organization establishes, implements and maintains a design and development process, however it does not explicitly state that the procedures must be documented.

30. Ref: ISO 13485 7.3.2 Design and Development Planning

ISO 13485 7.3.2 elements are generally covered in AS9100D 8.3.2 Design and Development Planning and both standards require that there be documented information to demonstrate that the design and development requirements have been met. ISO 13485 7.3.2 stipulates that the processes be documented and include design/development states, reviews required at each stage, verification processes required, responsibilities/authorities, traceability of outputs and resources needed, including necessary competence of personnel. AS9100D process should be reviewed for compliance.

31. Ref: ISO 13485 7.3.3 Design and Development Inputs

AS9100D 8.3.3 Design and Development Inputs, should be supplemented with the following elements listed in ISO 13485 7.3.3 Design and Development Inputs: safety requirements, usability, output(s) of risk management and able to be verified, as well as evidence of review and approval.

32. Ref: ISO 13485 7.3.4 Design and Development Outputs

AS9100D 8.3.5 Design and Development Outputs should be supplemented with the following element listed in ISO 13485 7.3.4 Design and Development Outputs: provide appropriate information for purchasing, production and service provision. Furthermore, the outputs of design and development shall be in a form suitable for verification against the design and development inputs.

33. Ref: ISO 13485 7.3.5 Design and Development Review

The requirements of ISO 13485 7.3.5 Design and Development Review are incorporated into AS9100D 8.3.4 Design and Development Controls. Special note should be made that ISO 13485 7.3.5 specifies that the date of the review is to be part of the records.

34. Ref: ISO 13485 7.3.6 Design and Development Verification

The requirements of ISO 13485 7.3.6 Design and Development Verification are incorporated into AS9100D 8.3.4 Design and Development Controls. ISO 13485 7.3.6 states a requirement that if the intended use [of the product] requires that the medical device be connected to, or have an interface with other medical device(s), verification shall include confirmation that the design outputs meet the design inputs when so connected or interfaced. Ensure this is incorporated into AS9100D 8.3.4 if applicable.

35. Ref: ISO 13485 7.3.7 Design and Development Validation

The requirements of ISO 13485 7.3.7 Design and Development Validation are incorporated into AS9100D 8.3.4 Design and Development Controls. The ISO 13485 7.3.7 Design and Development Validation clause stipulates the organization shall document validations plans that include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size. Validation shall be conducted on initial production units and a rationale for the choice of product used for validation shall be recorded. AS9100D 8.3.4 Design and Development Control does not specify that the first production unit be used, in order to validate the production process, although typically it is covered with the First Article Inspection Report (FAIR) which aerospace customers require accompany the first production item/lot.

ISO 13485 7.3.7 states that part of the design and development validation includes the organization performing clinical evaluations or performance evaluations of the medical device in accordance with the regulatory requirements. Any medical device used for clinical evaluation or performance evaluation cannot be released for use to the customer. This requirement needs to be added to AS9100D 8.3.4 Design and Development Control.

36. Ref: ISO 13485 7.3.8 Design and Development Transfer

The requirements of ISO 13485 7.3.8 Design and Development Transfer are incorporated into AS9100D 8.3.4 Design and Development Controls. ISO 13485 7.3.8 stipulates that documented procedures exist for the transfer of design and development outputs to manufacturing. There is no equivalent requirement in AS9100D 8.3.4, which stipulates verifying outputs as being suitable for manufacturing before becoming final production specifications and that production capabilities can meet product requirements.

37. Ref: ISO 13485 7.3.9 Control of Design and Development Changes

ISO 13485 7.3.9 Control of Design and Development Changes requires that the organization document procedures to control design and development changes whereas AS9100D 8.3.6 Design and Development Changes and 8.5.6 Control of Changes, states that a process shall be implemented, and that documented information is to be retained, but does not specifically require a documented procedure which outlines the review, verification, validation and approval processes for the change acceptance, along with accompanying records. A procedure must be established and documented.

38. Ref: ISO 13485 7.3.10 Design and Development Files

ISO 13485 7.3.10 Design and Development Files requires that the organization maintain a design and development file for each medical device type or medical device family. The file shall include, or reference records generated to demonstrate conformity to the requirements for design and development records for design and development changes. AS9100D 7.5.3 Control of Documented Information does not have an equivalent requirement and so this must be added.

Ref: ISO 13485 7.4 Purchasing	AS9100D 8.4 Control of Externally Provided Processes, Products and Services

39. Ref: ISO 13485 7.4.1 Purchasing Process

ISO 13485 7.4.1 Purchasing Process requires that documented procedure(s) exists to ensure that the purchased product conforms to specified purchasing requirements. Suppliers are to be evaluated for their ability to provide product as specified, on their performance, on the quality of their product and based on the risk associated with the medical device. Records shall be kept of the evaluation, selection, monitoring and re-evaluation of supplier capability and/or performance as well as any necessary actions taken for non-compliance.

AS9100D 8.4 Control of Externally Provided Processes, Products and Services (i.e. 8.4.1 General and 8.4.2 Type and Extent of Control) cover both the responsibilities of the organization to control suppliers and to control externally purchased products and services (also see 8.4.3 which stipulates that organizations control and monitor the external provider's performance). Supplier evaluation with regard to product risk must be included and the organization must ensure that the procedures and processes are fully documented and that complete records are kept.

40. Ref: ISO 13485 7.4.2 Purchasing Information

Requirements in ISO 13485 7.4.2 Purchasing Information are covered in AS9100D 8.4.3 Information for External Providers, including flowing down all applicable and customer requirements to the supply chain. Ensure that proper records are maintained.

41. Ref ISO 13485 7.4.3 Verification of Purchased Product

ISO 13485 7.4.3 Verification of Purchased Product requirements are covered in AS9100D 8.4.2 Type and Extent of Control; 8.4.3 Information for External Providers and 8.6 Release of Products and Services, including requirements for record creation and retention.

Ref: ISO 13485 7.5 Production and Service Provision	AS9100D 8.5 Production and Service Provision

42. Ref: ISO 13485 7.5 Control of Production and Service Provision Requirements

ISO 13485 7.5.1 Control of Production and Service Provision Requirements are covered in AS9100D 8.5 Production and Service Provision, together with subsections therein. Ensure that ISO 13485 7.5.1 requirement that the organization establish and maintain a record for each medical device or batch of

medical devices that provides traceability, quantities produced and delivered are covered. Ensure also that product release, delivery and post-delivery activities are listed.

43. Ref: ISO 13485 7.5.2 Cleanliness of Product

While AS9100D 8.5.4 Preservation has stipulations that FOD (foreign object debris) are eliminated and stipulates that the environment be suitable for the product, as the product is not specifically defined and there are no specific guidelines for Cleanliness of Product as in ISO 13485 7.5.2. Therefore, the requirements of 7.5.2 Cleanliness of Product must be documented and incorporated into the AS9100D QMS Manual as applicable. It is suggested that the requirements be given a new subsection in AS9100D 8.5 Production and Service Provision.

44. Ref: ISO 13485 7.5.3 Installation Activities

ISO 13485 7.5.3 Installation Activities stipulates that the organization shall document requirements for medical device installation and acceptance criteria for verification of installation, as appropriate. There is not an equivalent clause in AS9100D, and the ISO 13485 7.5.3 requirements must be reviewed and incorporated into the AS9100D QMS as applicable. It is suggested that the requirements be given a new sub-clause in AS9100D 8.5 Production and Service Provision.

45. Ref: ISO 13485 7.5.4 Servicing Activities

If servicing of the medical device is a specified requirement, the organization must document servicing procedures, reference materials and reference measurements as necessary for performing servicing activities. While there is no direct equivalent clause, the specific requirements in ISO 13485 7.5.4 could be added to AS9100D 8.5.5 Post-Delivery Activities, as it covers maintenance services and supplementary services.

46. Ref: ISO 13485 7.5.5 Particular Requirements for Sterile Medical Devices

There is no equivalent clause in AS9100D, and it is recommended that a new sub-clause be incorporated into AS9100D 8.5 Production and Service Provision to cover the requirements in ISO 13485 7.5.5.

47. Ref: ISO 13485 7.5.6 Validation of Processes for Production and Service Provision

The organization shall validate any processes for production and service provision where the resulting output cannot or is not verified by subsequent monitoring or measurement and as a consequence, deficiencies become apparent only after the product is in use or service has been delivered. AS9100D refers to these processes as “special processes”. ISO 13485 7.5.6 requires that the organization document procedures for validation of these processes. AS9100D 8.5.1.2 Validation and Control of Special Processes addresses the ISO 13485 7.5.6 requirements and specifies that documented procedures are required, and records must be kept.

48. Ref: ISO 13485 7.5.7 Particular Requirements for Validation of Processes for Sterilization and Sterile Barrier Systems

ISO 13485 7.5.7 stipulates that the organization shall document procedures for sterilization and sterile barrier systems. There is no corresponding clause in AS9100D and compliance to the ISO 13485 7.5.7 requirements could be incorporated into AS9100D 8.5.1 Control of Production and Service Provisions under a new sub-clause.

49. Ref: ISO 13485 7.5.8 Identification

ISO 13485 7.5.8 requires that the organization document a procedure for production identification throughout the production process, including product status with respect to monitoring and measurement requirement (i.e. status identifying which inspections/tests the product has undergone and results of thereof). AS9100D 8.5.2 Identification and Traceability likewise requires that the organization identify the status of the output with respect to monitoring and measurement throughout the production process, however there is no specific requirement for a documented procedure.

50. Ref: ISO 13485 7.5.9 Traceability

ISO 13485 7.5.9.1 General requires that a procedure for traceability be documented. AS9100D 8.5.2 Identification and Traceability addresses the general requirements, however does not stipulate that a documented procedure is required.

ISO 13485 7.5.9.2 Particular Requirements for Implantable Medical Devices has no counterpart in AS9100D. Should this apply a new sub-clause would be required in AS9100D 8.5.2 Identification and Traceability.

51. Ref: ISO 13485 7.5.10 Customer Property

Requirements set out in ISO 13485 7.5.3 Customer Property are addressed in AS9100D 8.5.3 Property Belonging to Customers or External Providers.

52. Ref: ISO 13485 7.5.11 Preservation of Product

ISO 13485 7.5.11 Preservation of Product requires a documented procedure for preserving the product throughout production as well as during storage, handling and distribution, including packaging and/or special environmental condition. AS9100D 8.5.4 Preservation addresses the requirements but does not specify the need for documented procedures. Furthermore, if special environmental conditions are required, ISO 13485 7.5.11 required that records be kept of the conditions.

53. Ref: ISO 13485 7.6 Control of Monitoring and Measuring Equipment

ISO 13485 7.6 Control of Monitoring and Measuring Equipment stipulates that the organization document procedures for calibration and verification of monitoring and measuring equipment and that records be kept. Furthermore, the organization shall document procedures for the validation of the application of computer software used for the monitoring and measurement of requirements. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application.

AS9100D 7.1.5.2 Measurement Traceability requires that the organization establish, implement and maintain a process but does not explicitly state that it must be documented. ISO 13485 7.6 requirements should be reviewed to ensure that the AS9100D process meets the requirements and that it is documented and required records are kept.

VI ISO 13485:2016 8 Measurement, Analysis and and Improvement	AS9100D 9. Performance Evaluation 9.1 Monitoring, Measurement, Analysis and Evaluation

54. Ref: ISO 13485 8.1 General

ISO 13485 8.1 General requirements are covered in AS9100D section 9.1.1 General.

Ref: ISO 13485 8.2 Monitoring and Measurement	AS9100 9.1 Monitoring, Measurement, Analysis and Evaluation

55. Ref: ISO 13485 8.2.1 Feedback

ISO 13884 8.2.1 stipulates that the organization shall document procedures for the feedback process.

AS9100D 9.1 Monitoring, Measurement, Analysis and Evaluation, together with 9.1.2 Customer Satisfaction, covers the requirements of ISO 13485 8.2 Monitoring and Measurement, however there is no specific requirement to document the procedure for the processes of acquiring, analyzing and utilizing feedback for improvement purposes. In addition, although mentioned in other areas, AS9100D clause 8.5.5 Post Delivery Activities, does not specifically mention using post-delivery information in conjunction with risk management. This should be explicitly stated in this clause.

56. Ref: ISO 13485 8.2.2 Complaint Handling

Procedures for timely complaint handling shall be documented. AS9100D 9.1.2 Customer Satisfaction covers the topic, however there is no requirement to document the procedures. The processes developed for the purposes of evaluating customer satisfaction, including customer complaints should be reviewed to ensure that all aspects of ISO 13485 8.2.2 Complaint Handling are covered, including, but not limited to, ensuring that documented justification is provided for any complaint not investigated and that complaint handling records are maintained.

57. Ref: ISO 13485 8.2.3 Reporting to Regulatory Authorities

Documented procedures for providing notification to the appropriate regulatory authorities, should the complaints meet specified reporting criteria of adverse events or if advisory notices are issued, are required in ISO 13485 8.2.3. Likewise records of reporting to regulatory authorities are to be maintained.

AS9100D 8.5.5. Post-Delivery Activities includes meeting the statutory and regulatory requirements; however, it does not specify that documented procedures are mandatory nor are any accompanying records.

58. Ref: ISO 13485 8.2.4 Internal Audit

ISO 13485 8.2.4 stipulates that the organization shall document a procedure to describe the responsibilities and requirements for planning and conducting the audits and recording and reporting audit results.

The internal audit plan shall take into consideration the status and importance of the processes and areas to be audited.

While earlier revisions of AS9100 had these requirements, AS9100D 9.2 Internal Audit does not explicitly list them as requirements. The internal process should be reviewed to ensure compliance with ISO 13485 8.2.4 requirements.

59. Ref: ISO 13485 8.2.5 Monitoring and Measurement of Processing

The requirements of ISO 13485 8.2.5 Monitoring and Measurement of Processing are covered in AS9100D 9 Performance Evaluation (9.1.1 General) in non-specific terms, with results and actions being covered in 9.1.3. Analysis and Evaluation. Description should be reviewed in the AS9100D QMS to ensure that all elements are addressed, particularly with regards to measuring processing.

60. Ref: ISO 13485 8.2.6 Monitoring and Measurement of Product

Requirements of ISO 13485 8.2.6 Monitoring and Measurement of Product are covered in AS9100D 8.6 Release of Products and Services. The AS9100D does not specifically require that the product realization processes identify the product verification steps or the measurement equipment used to perform the measurement activities, as prescribed in ISO 13485 8.2.6. Review of product realization processes should be conducted to ensure their inclusion.

Ref: ISO 13485 8.3 Control of Nonconforming Outputs	AS9100D 8.7 Control of Nonconforming Product

61. Ref: ISO 13485 8.3.1 General

ISO 13485 8.3.1 requires a documented procedure to define the controls and related responsibilities and authorities for the identification, documentation, segregation, evaluation and disposition for the nonconforming product. Records must be kept describing the nature of the nonconformance, investigation, actions and justifications for the decisions. AS9100D 8.7 Control of Nonconforming Outputs and 10.2 Nonconformity and Corrective Action require that the organization's nonconformity control process be documented, and records of activities and approvals be kept. There is not specific requirement for a documented procedure, however.

62. Ref: ISO 13485 8.3.2 Actions in Response to Nonconforming Product Detection Before Delivery

ISO 13485 8.3.2 states that prior to delivery, the organization shall deal with nonconforming product by eliminating the detected nonconformity, taking actions to preclude its original use or application or releasing under concession. AS9100D 8.7 Control of Nonconforming Outputs outlines actions which can be taken, including: correction, segregation; containment; notification of interested parties, if applicable; obtaining waiver or concession from an authorized source (e.g. customer); authorized rework; or scrapping the product.

63. Ref: ISO 13485 8.3.3 Actions in Response to Nonconforming Product Detection After Delivery

ISO 13485 8.3.3 has a requirement to document procedures for issuing advisory notices in accordance with regulatory requirements and while AS9100D 8.7 Control of Nonconforming Outputs addresses this action, it is not explicitly stipulated that a documented procedure is required.

64. Ref: ISO 13485 8.3.4 Rework

ISO 13485 8.3.4 requires that a documented procedure exist for conducting rework. As the definitions of "rework" and "repair" are very specific in the aerospace sector, AS9100D 8.7 is more specific regarding these dispositions. While not inherently incompatible, review of the AS9100D QMS section 8.7 Control of Nonconforming Output should be conducted to ensure compliance with ISO 13485 8.3 Control of Nonconforming Product and its documentation requirements.

65. Ref: ISO 13485 8.4 Analysis of Data

ISO 13485 8.4 Analysis of Data states that the organization shall document procedures to cover the determination, collection and analysis of appropriate data to demonstrate the suitability, adequacy and effectiveness of the QMS. The requirement is covered in AS9100D 9.1.3 Analysis and Evaluation, however there is not an explicit requirement for documented procedures.

Ref: ISO 13485 8.5 Improvement AS9100D 10 Improvement

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66. Ref: ISO 13485 8.5.1 General

ISO 13485 8.5.1 is much more prescriptive than AS9100D 10.1 Improvement (General) by itemizing specifically that in addition to ensuring and maintaining the suitability, adequacy and effectiveness of the QMS, it is necessary to demonstrate the same for the medical devices safety and performance through the use of the quality policy, quality objectives, audit results, post-market surveillance, analysis of data, corrective actions, preventative actions and management reviews. AS9100D 10.1 Improvement (General) and 10.3 Continual Improvement verbiage should be amended as required to be in compliance with the ISO 13485 8.5.1 stipulations.

67. Ref: ISO 13485 8.5.2 Corrective Action

ISO 13485 8.5.2 stipulates that a documented procedure exist for corrective action, which is to be taken in order to eliminate the cause of nonconformances in order to prevent recurrence. In addition, there is a requirement for planning and documenting action needed and implementing such action, including, as appropriate, updating documentation.

AS9100D 10.2 Nonconformity and Corrective Action stipulates the organization shall maintain documented information that defines the nonconformity and corrective action management processes. Endure that procedures exist. The procedures should be supplemented with the ISO 13485 8.5.2 e) requirement that the corrective action does not adversely affect the ability to meet applicable regulatory requirements for the safety and performance of the medical device.

Records of the results of any investigation and of action taken must be maintained.

68. Ref: ISO 13485 8.5.3 Preventive Action

ISO 13485 8.5.3 Preventive Action specifies that the organization shall have a documented procedure for determining potential nonconformities and their causes, which evaluates, plans and documents the action needed to prevent occurrence of nonconformities. Verification that the action does not adversely affect the medical device product or violate regulatory requirements. Records shall be kept.

AS9100D 10.2 Nonconformity and Corrective Action clause b. evaluate the need for action to eliminate the cause(s) of the nonconformity in order that it does not recur or occur elsewhere by: [refer to item 3.] Determining if similar nonconformities exist or *could potentially occur* [italics added]. However, there is no requirement for a documented procedure or records for preventive action. The previous revision, AS9100C 8.5.3 Preventive Action had very similar requirements to ISO 13485 8.5.3 Preventive Action. If available, AS9100C QMS requirement could be reintroduced into the AS9100D QMS documentation, i.e. 10.3 Continual Improvement, complete with requirement for procedures and records.

AS9100D sections 0.3.3 Risk-based Thinking; 6.1 Actions to Address Risks and Opportunities; 10.1 General and 10.3 Continual Improvement all contain elements of preventative action.