

**Intertek**

# Comparison of Requirements

## ISO/TS 16949 vs. AS9100 and ISO 13485





## Introduction

If your business is starting to diversify into the Medical or Aerospace industries, your existing ISO/TS 16949 certified quality management system (QMS) can help you meet the QMS requirements that those industries mandate.

To help you assess the differences and transition your QMS, Intertek has prepared the following “matrix” documents comparing the requirements of ISO/TS 16949 to AS9100 and ISO 13485.

By recognizing the similarities and differences between ISO/TS 16949, ISO 13485, and AS9100, you will be able to more effectively:

- Perform a gap analysis and develop a "road map to compliance" to a new standard
- Integrate multiple management systems, while avoiding waste and minimizing the impact on your organization
- Attract new business in the Aerospace and Medical sectors
- Get your management team on board

## For more information

If you review these documents and have any further questions, please feel free to send an email to [intertek-sc@intertek.com](mailto:intertek-sc@intertek.com). Our website also contains up-to-date information:

ISO/TS 16949 / Automotive:	<a href="http://www.intertek.com/auditing/automotive/">http://www.intertek.com/auditing/automotive/</a>
AS9100 / Aerospace:	<a href="http://www.intertek.com/auditing/aerospace/">http://www.intertek.com/auditing/aerospace/</a>
ISO 13485 / Medical:	<a href="http://www.intertek.com/auditing/medical/">http://www.intertek.com/auditing/medical/</a>

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# Comparison of Requirements ISO/TS 16949:2009 vs. AS9100B & AS9100C



Requirement	ISO/TS 16949:2009 Reference	AS9100B:2004 Reference	AS9100C:2009 Reference	Impact Vs. AS9100
Foreword	Technical Specification QMS requirements for Automotive	Standardizes QMS requirements for Aerospace	Revised to ISO 9001:2008 and Industry requirements	<b>None</b> – TS 16949 was updated to ISO 9001:2008. (June 15, 2009). Revisions do not change technical content.
Introduction	0.1	General	0.1	<b>None</b> - TS & AS9100B are exact. AS9100C same information – layout is changed
Process Approach	0.2	Defined in the introduction	0.2	<b>None</b> – All 3 documents are exactly the same – including Figure 1
Relationship with ISO 9004	0.3	Introduction - consideration	Introduction - consideration given	<b>TS16949</b> - More detailed on this and the 8 QMS Principles are noted
Compatibility with other QMS	0.4	None	None	<b>TS16949</b> - Refers to Annex A – shows the correspondence between ISO 9001:2008 and ISO 14001:2004
Goal of Document	0.5	None	None	<b>None</b> –TS16949 Includes Customer Specific Requirements – Common approach for automotive
Scope	1	1	1	All 3 are the same except; <b>TS16949</b> - Specifies it is for automotive, states applicability requirements and specifies Support Sites can not obtain stand alone certification
Application	1.2	1.2	1.2	<b>TS16949 &amp; AS9100B</b> are the same. <b>AS9100C</b> - Specifies it is for Aviation, Space and defense products. Refers to IAQG-developed 9110 for Maintenance, Repair and overhaul. Both AS9100B & C indicate exclusions are <b>limited to Clause 7. TS indicates clause 7.3 only</b> - where the organization is not design responsible
Normative Reference	2	2	2	<b>AS9100C</b> - Has been updated to reference the current version of <b>Fundamentals and Vocabulary</b> : TS16949 & AS9100B reference – ISO9000:2000 AS9100C- ISO9000:2005
Terms and Definitions	3	3	3	<b>None</b> - TS16949 & AS9100B reference <b>Supplier – Organization – Customer</b> TS has automotive related definitions / AS9100C has expanded definitions from B rev.
QMS– General Requirements	4 4.1	4 4.1	4 4.1	<b>None</b> - All 3 are the same
General Requirements Supplemental	4.1.1		Note 1 Note 2 Note 3	<b>TS16949 - Includes additional requirements:</b> For outsourced processes and the responsibility for conformity to customer requirements. <b>AS9100C</b> - Also includes the TS16949 requirement and additional Notes on Outsourced processes. <b>Note 1</b> –Include mgt. activities, resources, product realization, measurement, analysis and Improvement <b>Note 2</b> –“Outsourced”; performed by external party <b>Note 3</b> – Ensure control over outsourced processes
Documentation Requirements	4.2	4.2	4.2	<b>TS16949</b> – All requirements included. <b>AS9100B</b> – <b>Has Additional requirements:</b> (f) Quality System requirements imposed by the applicable regulatory authorities and requirement related to personnel having access to documentation <b>including customers &amp; regulatory authority representatives.</b> <b>AS9100C</b> – Removed requirements (e) and (f). Also removed - <b>including customers and regulatory authority representatives.</b>

Requirement	ISO/TS 16949:2009 Reference	AS9100:2004 Reference	AS9100C:2009 Reference	Impact Vs. AS9100
Quality Manual	4.2.2	4.2.2	4.2.2	<b>TS16949 &amp; AS9100C</b> are the same. <b>AS9100B</b> – Included additional requirements related to a clear relationship between the requirements of the standard and the procedures.
Control of Documents	4.2.3	4.2.3	4.2.3	<b>TS16949</b> – All requirements included. <b>AS9100B</b> – Includes additional requirements related to coordinating changes with the customer and/or regulatory authorities. <b>AS9100C</b> - Removes the above requirement.
Engineering Specifications	4.2.3.1	None	None	<b>TS16949</b> – Includes an additional requirement for timely review of Engineering Specifications, and maintaining records - not included in the <b>AS9100B or C</b>
Control of Records Record Retention	4.2.4 4.2.4.1	4.2.4	4.2.4	<b>TS16949</b> - Includes 2 additional Notes. <b>Note 1:</b> “Disposition” includes disposal. <b>Note 2:</b> “Records” also includes customer specified records. Retention shall satisfy statutory, regulatory and customer requirements. <b>AS9100B</b> – Includes requirements for a documented procedure for controlling records and the availability for customers and regulatory authorities in accordance with contract or regulatory requirements. <b>AS9100C</b> – Removes the requirement related to <b>availability for customers and regulatory authorities in accordance with contract or regulatory requirements.</b>
Configuration Management	None	4.3	None	<b>AS9100B</b> - Includes requirement to establish, document and maintain a configuration management appropriate to the product (Reference ISO 10007)
Management Responsibility	5.	5.	5.	<b>None</b> - All 3 are the same
Process efficiency	5.1.1	None	None	<b>TS16949</b> – Includes requirements for top management to review the product realization process.
Customer Focus	5.2	5.2	5.2	<b>AS9100C</b> – Includes an additional requirement to ensure product conformity and on-time delivery are measured and that action is take if planned results are not or will not be achieved.
Quality Policy	5.3	5.3	5.3	<b>None</b> - All 3 are the same
Planning Quality Objectives	5.4 5.4.1 5.4.1.1	5.4 5.4.1	5.4 5.4.1	<b>TS16949</b> – Has additional requirement of top Mgt to define objectives & measurements / include in business plan – used to deploy Q. Policy. <b>NOTE:</b> Should address customer expectations & be achievable within a defined time period.
Quality Management System Planning	5.4.2	5.4.2	5.4.2	<b>None</b> - All 3 are the same
Responsibility and Authority	5.5 5.5.1 5.5.1.1	5.5 5.5.1	5.5 5.5.1	<b>TS 16949</b> – Includes additional requirements for <b>Responsibility for Quality.</b> 1) Mgrs with responsibility for quality informed or products / processes not meeting requirements. 2) Personnel with responsibility for quality having authority to stop production 3) All production shifts having personnel assigned the responsibility for quality.

Requirement	ISO/TS 16949:2009 Reference	AS9100:2004 Reference	AS9100C:2009 Reference	Impact Vs. AS9100
Management Representative	5.5.2	5.5.2	5.5.2	<b>AS9100B</b> - Includes additional requirement d) The organizational freedom to resolve matters pertaining to quality. <b>AS9100C</b> – Includes additional requirement d) The organizational freedom and unrestricted access to top Management to resolve Quality Management issues and a <b>TS16949 and AS9100C includes the Note:</b> Responsibility can include Liaison with external parties on matters relating to the QMS
Customer Representative	5.5.2.1	None	None	<b>TS16949</b> – Includes additional requirement of top mgt. to designate personnel with responsibility and authority to ensure customer requirements are addressed – Special char., Quality Objectives, Training, C/A & P/A, Product Design & Development.
Internal Communication	5.5.3	5.5.3	5.5.3	<b>None</b> - All 3 are the same
Management Review	5.6 5.6.1	5.6 5.6.1	5.6 5.6.1	<b>None</b> - All 3 are the same
Quality Management System Performance	5.6.1.1	None	None	<b>TS16949</b> – Includes additional requirements Quality Management System Performance – Review of Performance Trends as part of Continuous Improvement, Monitoring of Cost of Poor Quality. Recorded results including evidence of achievement of Quality Objectives and Customer Satisfaction
Review Input	5.6.2 5.6.2.1	5.6.2	5.6.2	<b>TS16949</b> – Includes additional requirement to include actual and potential field failures and their impact on quality, safety and the environment.
Review Output	5.6.3	5.6.3	5.6.3	<b>None</b> - All 3 are the same
Resource Management	6 6.1	6 6.1	6 6.1	<b>None</b> - All 3 are the same
Human Resources	6.2	6.2 6.2.1	6.2 6.2.1	<b>AS9100C</b> – Includes an additional Note: Conformity to product requirements can be affected directly or indirectly by personnel performing any QMS task.
Competence, Awareness and Training	6.2.2	6.2.2	6.2.2	<b>None</b> - All 3 are the same
Product Design Skills	6.2.2.1	None	None	<b>TS 16949</b> – Has additional requirement: Regarding Product Design Skills. Personnel with Product Design Responsibilities are competent in Design Requirements and Skilled in Applicable Tools & Techniques.
Training	6.2.2.2	None	None	<b>TS 16949</b> – Has additional requirement: Regarding a documented procedure for identifying training needs and achieving competence for personnel performing activities affecting product quality. Personnel performing specifically assigned tasks are qualified with attention to customer requirements. Also 2 notes are included; <b>Note 1</b> - Applies to all employees at all levels. <b>Note 2</b> - An example of customer requirements is Digitized Math Data.
Training on the Job	6.2.2.3	None	None	<b>TS 16949</b> – Has additional requirement: To provide on the job training in any new or modified job affecting product quality including agency personnel and inform personnel about the consequences to the customer for nonconformity to quality requirements.

Requirement	ISO/TS 16949:2009 Reference	AS9100:2004 Reference	AS9100C:2009 Reference	Impact Vs. AS9100
Employee Motivation and Empowerment	6.2.2.4	None	None	<b>TS 16949 – Has additional requirement:</b> To motivate and empower personnel to achieve quality objectives, Continuous Improvement, to promote quality and technical awareness throughout the organization. Requirement to a Process to measure the extent to which personnel are aware of the quality objectives and how they contribute to the achievement of them.
Infrastructure	6.3	6.3	6.3	<b>AS9100C– C)</b> Supporting Services includes – Information Systems.
Plant, Facility and Equipment Planning	6.3.1	None	None	<b>TS 16949 – Has additional requirement:</b> To use a multi-disciplinary team to develop plant, facility and equipment planning. Optimize material travel, handling and synchronous material flow. Methods to evaluate & monitor effectiveness of existing operations.
Contingency Plans	6.3.2	None	None	<b>TS 16949 – Has additional requirement:</b> To prepare contingency plans to satisfy customer requirements in event of emergency.
Work Environment	6.4	6.4	6.4	<b>AS9100B – Has additional Note:</b> Factors that may affect conformity of the product include temperature, humidity, lighting, cleanliness, protection from electrostatic discharge, etc. <b>AS9100C – Has additional Note;</b> The term ‘work environment’ relates to those conditions under which work is performed including physical, environmental and other factors (noise, temp., humidity, lighting or weather).
Personal Safety to Achieve Product Quality	6.4.1	None	None	<b>TS 16949 – Has additional requirement:</b> To address product safety and means to minimize potential risk to employees, especially in design & development and manufacturing activities.
Cleanliness of Premises	6.4.2	None	None	<b>TS 16949 – Has additional requirement:</b> To maintain premises in a state or order, cleanliness and repair
Product Realization	7 7.1	7. 7,1	7 7.1	<b>TS 16949 – Has additional Note;</b> Project management or APQP as a means to achieve product realization. APQP concepts of error prevention & Continuous Improvement, is based on a multi-disciplinary approach. <b>AS9100B – Has additional requirement:</b> e) The identification of resources to support operation and maintenance of the product. <b>AS9100C - Has additional requirement:</b> - e) Configuration management appropriate to the product and f) Resources to support the use and maintenance of the product.
Project Management	7.1.1	None	7.1.1	<b>TS16949 - Has additional requirement:</b> To include customer requirements and reference to Technical Specification in planning of product realization as a component of the quality plan. <b>AS9100C - Has an additional requirement:</b> As appropriate to the organization and the product, to plan and manage product realization in a structured controlled manner to meet requirements at acceptable risk, within resources and scheduled constraints.
Acceptance Criteria	7.1.2	None	None	<b>TS16949 - Has additional requirement:</b> To define acceptance criteria & where appropriate have customer approval. Attribute data sampling acceptance as zero defects.

Requirement	ISO/TS 16949:2009 Reference	AS9100:2004 Reference	AS9100C:2009 Reference	Impact Vs. AS9100
Risk Management	None	None	7.1.2	<b>AS9100C - Has an additional requirement:</b> To implement a risk management process including: a) Assignment of responsibilities b) Definition of risk criteria c) Identification, assessment and communication of risk throughout product realization d) Identification, implementation and management of action to mitigate risk that exceed the defined risk acceptance criteria e) Acceptance of risk remaining after implementation of mitigation actions
Confidentiality	7.1.3	None	None	<b>TS16949 - Has additional requirement:</b> To ensure confidentiality of customer contracted products under development and related product information.
Configuration Management	None	None	7.1.3	<b>AS9100C - Has an additional requirement:</b> To establish, implement and maintain a configuration management process that includes, as appropriate to the product a) configuration management planning b) configuration identification c) change control.
Change Control	7.1.4	None		<b>TS16949 - Has additional requirement:</b> For a process to control & react to Changes that impact product realization. Defined changes addressed, verification and validation defined to ensure customer requirements. Validation to be performed before implementation. Proprietary changes to be reviewed with the customer. When defined by the customer, additional requirements shall be met. 2 additional Notes included; <b>Note 1:</b> Product realization changes affecting customer requirements requires notification to and agreement from the customer. <b>Note 2:</b> the note above applies to both product and manufacturing process changes.
Control of Work Transfers			7.1.4	<b>AS9100C – Has requirements for:</b> Establishing, implementing and maintaining a process to plan and control the temporary or permanent transfer of work and to verify the conformity of the work to requirements.
Customer Related Processes	7.2 7.2.1	7.2 7.2.1	7.2 7.2.1	<b>TS16949 - Has 3 additional Notes;</b> <b>Note 1:</b> Post delivery includes after sale service as part of the contract or PO. <b>Note 2:</b> Includes recycling, environmental impact and characteristics identified as a result of knowledge of the product and manufacturing processes. <b>Note 3:</b> Compliance to c) includes government, safety and environment regulations related to acquisition, storage, handling, recycling, elimination or disposal of materials. <b>AS9100C – Has additional Note;</b> <b>Note:</b> Post delivery activities include; actions under warranty provisions, contractual obligation such as maintenance service, and supplementary services such as recycling or final disposal.
Customer Designated Special Characteristics	7.2.1.1	None	Note under 7.2.1	<b>TS16949 – Has requirement:</b> To demonstrate conformity to customer requirements for designation, documentation and control of special characteristics. <b>AS9100C – Has additional Note;</b> <b>Note:</b> Requirements related to the product can include special characteristics.

Requirement	ISO/TS 16949:2009 Reference	AS9100:2004 Reference	AS9100C:2009 Reference	Impact Vs. AS9100
Review of Requirements Related to Product	7.2.2 7.2.2.1	7.2.2	7.2.2	<p><b>AS9100B – Has additional requirement:</b> d) Risks (e.g. new technology, short delivery time scale) have been evaluated.</p> <p><b>AS9100C – Has additional requirements:</b> d) Special requirements of the product are determined and e) Risks (e.g. new technology, short delivery time scale) have been evaluated.</p> <p><b>TS 16949 – Has additional requirement:</b> Indicating Waiving a formal review (7.2.2) requires customer authorization.</p>
Organization Manufacturing Feasibility	7.2.2.2	None	None	<p><b>TS 16949 – Has additional requirement:</b> To investigate, confirm and document the manufacturing feasibility proposed products in the contract review process, including risk analysis</p>
Customer Communication	7.2.3 7.2.3.1	7.2.3	7.2.3	<p><b>TS 16949 – Has additional requirement:</b> To have the ability to communicate information including data in a customer specified language and format</p>
Design and Development	7.3 7.3.1	7.3 7.3.1	7.3 7.3.1	<p><b>TS 16949 – Has additional Note:</b> Requires that 7.3 include product and manufacturing process design and development and focus on error prevention rather than detection.</p> <p><b>AS9100B – Has additional requirements: Under a)</b> In respect of organization, task sequence, mandatory steps, significant stages and method of configuration control. <b>And c)</b> Where appropriate, due to complexity, consideration to; Structuring the design effort to significant elements; For each element, analyzing the tasks and resources for design &amp; development. Analysis to consider identified person responsible, design content, input data, planning constraints and performance conditions. The input data to be reviewed to ensure consistency with requirements. And; The design &amp; development tasks shall be defined according to specified safety or functional objectives of the product in accordance with customer and/or regulatory authority requirements. Manage the interfaces between groups involved in design &amp; development to ensure effective communication and clear responsibility. Planning output to be updated as the design &amp; development progresses.</p> <p><b>AS9100C- Has additional requirements: Under c)</b> Where appropriate; divide the design and development effort into distinct activities, for each activity define the tasks, resources, responsibilities, design content, input &amp; output data and planning constraints. The design &amp; development tasks carried out based on safety &amp; functional objectives of the product with customer statutory and regulatory requirements. Design &amp; development planning to consider the ability to produce, inspect, test and maintain the product. Manage the interfaces between groups involved in design &amp; development to ensure effective communication and clear responsibility. Planning output to be updated as the design &amp; development progresses.</p>

Requirement	ISO/TS 16949:2009 Reference	AS9100:2004 Reference	AS9100C:2009 Reference	Impact Vs. AS9100
Multidisciplinary Approach	7.3.1.1	None	None	<b>TS 16949 – Has additional requirement:</b> To use a multidisciplinary approach; Development/finalization and monitoring of special characteristics. Development and review of FMEAs including risks. Development and review of control plans. And a Note: Multidisciplinary approach typically includes Design, Manufacturing, Engineering, Quality, Production and other appropriate personnel.
Design and Development Input	7.3.2	7.3.2	7.3.2	<b>TS 16949 – Has additional Note:</b> indicating special characteristics are included in this requirement.
Product Design Input	7.3.2.1	None	None	<b>TS 16949 – Has additional requirement:</b> To identify, document and review product design inputs including; Customer requirements, (sp. Characteristics, identification traceability and packaging). Use of information, (process to deploy information gained from previous designs, competitor analysis, supplier feedback, internal input, field data). Targets for product quality, life, reliability, durability, maintainability, timing & cost.
Manufacturing Process Design Input	7.3.2.2	None	None	<b>TS 16949 – Has additional requirement:</b> To Identify, document and review process design inputs including; Product design output data. Targets for productivity, process capability and cost. Customer requirements and experience from previous developments. And additional <b>Note:</b> Process design includes the use of error proofing to the degree appropriate to magnitude of problems commensurate with the risk encountered.
Special Characteristics	7.3.2.3	None	None	<b>TS 16949 – Has additional requirement:</b> To Identify special characteristics; include them in control plans, comply with customer specified definitions and symbols, identify process control documents (control plans, FMEAs, WI, etc) with customers symbol or organizations equivalent symbol to include process steps that affect sp. Characteristics. And additional <b>Note:</b> Sp. Characteristics can include product characteristics and process parameters.
Design and Development Output	7.3.3	7.3.3	7.3.3	<b>AS9100B – Has additional requirements: under e)</b> Identify key characteristics, when applicable, in accordance with design or contract requirements. All pertinent data required to allow the product to be identified, manufactured, inspected, used and maintained shall be defined by the organization; for example:  -Drawings, part lists, specifications -a listing of those drawings, part lists, and specifications and the design features of the product. -information on material, processes, type of manufacturing and assembly of the product necessary to ensure the conformity of the product.

Requirement	ISO/TS 16949:2009 Reference	AS9100:2004 Reference	AS9100C:2009 Reference	Impact Vs. AS9100
Design and Development Output (Con't)	7.3.3	7.3.3	7.3.3	<p><b>AS9100B – Has additional requirements under e)</b> specify as applicable, any critical items. Including any key characteristics, and specify actions to be taken for these items.</p> <p>The organization shall define the data required to allow the product to be identified, manufactured, inspected, used and maintained; including for example:</p> <ul style="list-style-type: none"> <li>-the drawings, part lists, and specifications necessary to define the configuration and the design features of the product, and</li> <li>-material, process, manufacturing and assembly data needed to ensure conformity of the product.</li> </ul> <p><b>NOTE:</b> Information for production and service provision can include details for the preservation of product.</p>
Product Design Outputs-Supplemental	7.3.3.1	None	None	<p><b>TS 16949 – Has additional requirements:</b> Indicate the design output is to be expressed in terms that can be verified and validated against product design input requirements. Design Output requirements include:</p> <ul style="list-style-type: none"> <li>-design FMEA, reliability results</li> <li>-product special characteristics and specifications</li> <li>-product error-proofing, as appropriate</li> <li>-product definition including drawings or mathematically based data.</li> <li>-product design review results, and</li> <li>-diagnostic guidelines when applicable</li> </ul>
Manufacturing process design output	7.3.3.2	None	None	<p><b>TS 16949 – Has additional requirements:</b> Indicating the manufacturing process design output is to be expressed in terms that can be verified against manufacturing process design input requirements and validated. Manufacturing Process design output include:</p> <ul style="list-style-type: none"> <li>-specifications and drawings,</li> <li>-manufacturing process flow chart/layout</li> <li>-manufacturing process FMEAs</li> <li>-control plan</li> <li>-work instructions</li> <li>-process approval acceptance criteria</li> <li>-data for quality, reliability, maintainability and measurability</li> <li>-results of error--proofing activities, as appropriate, and</li> <li>-methods of rapid detections and feedback of product/manufacturing process nonconformities</li> </ul>
Design and Development Review	7.3.4	7.3.4	7.3.4	<p><b>AS9100B and AS9100C – Have and additional requirement: Under c)</b> to authorize progression to the next stage.</p>
Monitoring	7.3.4.1	None	None	<p><b>TS 16949 – Has additional requirements:</b> That indicate Measurements at specified stages of design and developments shall be defined, analyzed and reported with summary results as and input into management review.</p> <p><b>NOTE</b> These measurements include quality risks, costs, lead-times, critical paths and others, as appropriate.</p>
Design and Development Verification	7.3.5	7.3.5	7.3.5	<p><b>AS9100B has an additional NOTE:</b> Design and Development verification may include activities such as:</p> <ul style="list-style-type: none"> <li>-performing alternative calculations</li> <li>-comparing the new design with a similar proven design, if available</li> <li>-undertaking tests and demonstrations, and</li> <li>-reviewing the design stage documents before release</li> </ul>

Requirement	ISO/TS 16949:2009 Reference	AS9100:2004 Reference	AS9100C:2009 Reference	Impact Vs. AS9100
Design & Development Validation	7.3.6	7.3.6	7.3.6	<p><b>TS 16949 – Has additional NOTES:</b>  <b>NOTE 1</b> The validation process normally includes an analysis of field reports for similar products.  <b>NOTE 2</b> The requirements of 7.3.5 and 7.3.6 apply to both product and manufacturing processes.  <b>AS9100B has an additional NOTES:</b>                      -Design and/or development validation follows successful design and/or development verification.                      -Validation is normally performed under defined operating conditions.                      -Validation is normally performed on the final product, but may be necessary in earlier stages prior to product completion.                      -Multiple validations may be performed if there are different intended uses.</p>
Design and Development Validation - <b>supplemental</b>	7.3.6.1	7.3.6.1  <b>Documentation of Design and/or Development Verification and Validation:</b>	7.3.6.1  <b>Design and Development Verification and Validation Testing</b>	<p><b>TS 16949 – Has additional statement;</b> Design and development validation to be performed in accordance with customer requirements including program timing.  <b>AS9100B has an additional statement;</b> Documentation of Design and/or Development Verification and Validation: At the completion of design and/or development, the organization must insure that reports, calculations, tests results, etc., demonstrate that the product definition meets the specification requirements for all identified operational conditions.  <b>AS9100C has additional requirements;</b> Design and Development Verification and Validation Testing. Where test are necessary for verification and validation, these tests are to be planned, controlled, reviewed and documented to ensure and prove the following                      a) Test plans or specifications identify the product being tested and the resources being used, define test objectives and conditions, parameters to be recorded and relevant acceptance criteria.                      b) test procedures describe the method of operation, the performance of the test and the recording of the results,                      c) the correct configuration of the product is submitted for the test                      d) the requirements of the test plan and the test procedures are observed, and                      e) The acceptance criteria are met.</p>
Prototype Program	7.3.6.2	7.3.6.2	7.3.6.2	<p><b>TS 16949 – Has additional Prototype Program requirements;</b> When required by the customer, the organization must have a prototype program and control plan. The organization must use, whenever possible, the same suppliers, tooling and manufacturing processes as will be used in production. All performance testing activities must be monitored for timely completions and conformity to requirements. While services may be outsourced, the organization is responsible for the outsourced services, including technical leadership.</p>

Requirement	ISO/TS 16949:2009 Reference	AS9100:2004 Reference	AS9100C:2009 Reference	Impact Vs. AS9100
Prototype Program (Con't)		Design and/or Development Verification and Validation Testing	for Design and Development Verification and Validation Documentation	<b>AS9100B has an additional requirement for Design and/or Development Verification and Validation Testing: The same requirement at stated above under AS9100C 7.3.6.1 (a-e).</b> <b>AS9100C has additional requirements for Design and Development Verification and Validation Documentation:</b> At the completion of design and/or development, the organization must ensure that reports, calculations, test results, etc., demonstrate that the product definition meets the specification requirements for all identified operational conditions.
Product Approval Process	7.3.6.3	None	None	<b>TS 16949 – Has additional product approval process requirements:</b> The organization must conform to a product and manufacturing process approval procedure recognized by the customer. NOTE Product approval should be subsequent to the verification of the manufacturing process. This Product and manufacturing process approval procedure shall also be applied to suppliers.
Control of Design and Development Changes	7.3.7	7.3.7	7.3.7	<b>TS 16949 – Has additional NOTE:</b> Design and development changes include all changes during the product program life. <b>AS9100B has an additional requirement:</b> The organizations change control process shall provide for customer and/or regulatory authority approval of changes, when required by contract or regulatory requirement. <b>AS9100C has an additional requirement:</b> Design and development changes must be controlled in accordance with the configuration management process.
Purchasing	7.4 7.4.1	7.4 7.4.1	7.4 7.4.1	<b>TS 16949 – Has 2 additional NOTES:</b> <b>NOTE 1</b> Purchased products above include all products and services that affect customer requirements such as sub-assembly, sequencing, sorting, rework and calibration services. <b>NOTE 2</b> When there are mergers, acquisitions or affiliations associated with suppliers, the organization should verify the continuity of the supplier's QMS and its effectiveness. <b>AS9100B has additional requirements:</b> The organization is responsible for quality of all products purchased from suppliers, including customer designated sources. The organization must: a) maintain a register of approved suppliers that includes the scope of the approval b) periodically review supplier performance; records of these reviews shall be used as a basis for establishing the level of control to be implemented c) define the necessary actions to take when dealing with suppliers that do not meet requirements d) ensure where required that both the organization and all suppliers use customer approved special process sources e) Ensure that the function having responsibility for approving supplier quality systems has the authority to disapprove the use of sources.

Requirement	ISO/TS 16949:2009 Reference	AS9100:2004 Reference	AS9100C:2009 Reference	Impact Vs. AS9100
Purchasing (Con't)	7.4 7.4.1	7.4 7.4.1	7.4 7.4.1	<p><b>AS9100C has an additional requirements including:</b> The organization is responsible for the conformity of all products purchased from suppliers, including product from sources defined by the customer. And an additional <b>NOTE:</b> One factor that can be used during supplier selection and evaluation is supplier quality data from objective and reliable external sources, as evaluated by the organization. Use of such data would be only one component of an organization's supplier control process and the organization remains responsible for verifying that purchased product meets specified purchase requirements.</p> <p><b>AS9100C also includes: The Organization Shall:</b> a) Maintain a register of its suppliers that includes approval status. b) Periodically review supplier performance; the results of these reviews shall be used as a basis for establishing the level of control to be implemented c) Define the necessary actions to take when dealing with suppliers that do not meet requirements d) Ensure where required that both the organization and all suppliers use customer approved special process sources e) Define the process, responsibilities and authority for the approval status decision, changes of the approval status and conditions for a controlled use of suppliers depending on the supplier's approval status, and f) Determine and manage risk when selecting and using suppliers.</p>
Regulatory Conformity	7.4.1.1	None	None	<p><b>TS 16949 – Has additional requirement:</b> All purchased products or materials used in product must conform to regulatory requirements</p>
Supplier Quality Management System Development	7.4.1.2	None	None	<p><b>TS 16949 – Has additional requirement:</b> The organization shall perform supplier quality management system development with the goal of supplier conformity with TS. Conformity to ISO 9001:2000 is the first step in achieving this goal.</p> <p><b>NOTE:</b> The prioritization of suppliers for development depends upon, for example, the supplier's quality performance and the importance of the product supplied.</p> <p>Unless otherwise specified by the customer, suppliers to the organization must be third party registered to ISO 9001:2000 by an accredited third-party CB.</p>
Customer Approved Sources	7.4.1.3	None	None	<p><b>TS 16949 – Has additional requirement:</b> Where specified by he contract, the organization is to purchase products, material or services from approved sources.</p>

Requirement	ISO/TS 16949:2009 Reference	AS9100:2004 Reference	AS9100C:2009 Reference	Impact Vs. AS9100
Purchasing Information	7.4.2	7.4.2	7.4.2	<p><b>AS9100B Has additional requirements under Purchasing Information:</b></p> <ul style="list-style-type: none"> <li>d) The name or other positive identification, and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data,</li> <li>e) Requirements for design, test, examination, inspection and related instructions for acceptance by the organization.</li> <li>f) Requirements for test specimens, for design approval, inspection, investigation r auditing,</li> <li>g) Requirements relative to               <ul style="list-style-type: none"> <li>- Supplier notification to organization of nonconforming product and</li> <li>- Arrangements for organization approval of supplier nonconforming material</li> </ul> </li> <li>h) Requirements for the supplier to notify the organization of changes in product and/or process definition and, where required obtain organizations approval.</li> <li>i) Right of access by the organization, their customer, and regulatory authorities to all facilities involved in the order and to all applicable records, and</li> <li>j) Requirements for the supplier to flow down to sub-tier suppliers applicable requirements from purchasing documents, including key characteristics (when required)</li> </ul>
Purchasing Information	7.4.2	7.4.2	7.4.2	<p><b>AS9100C Has additional/ Changed requirements under Purchasing Information:</b></p> <ul style="list-style-type: none"> <li>d) The identification and revision status of specifications, drawings, process requirements, inspection/verification instructions and other relevant technical data,</li> <li>e) Requirements for design, test, inspection, verification, use of statistical techniques for product acceptance, and related instructions for acceptance by the organization, and as applicable critical items including key characteristics.</li> <li>f) Requirements for test specimens, for design approval, inspection/verification, investigation or auditing.</li> <li>g) Requirements regarding the need for the supplier to               <ul style="list-style-type: none"> <li>- notify the organization of nonconforming product</li> <li>- obtain organization approval for nonconforming product disposition</li> </ul> </li> <li>h) Notify the organization of changes in product and/or process, changes of suppliers, changes of manufacturing facility location and, where required obtain organizations approval, and</li> <li>i) Flow down to the supply chain the applicable requirements, record retention requirements, and right of access by the organization, their customer, and regulatory authorities to all facilities at any level of the supply chain, involved in the order and to all applicable records.</li> </ul>

Requirement	ISO/TS 16949:2009 Reference	AS9100:2004 Reference	AS9100C:2009 Reference	Impact Vs. AS9100
Verification of Purchased Product	7.4.3	7.4.3	7.4.3	<p><b>AS9100B Has additional requirements: Verification activities may include:</b></p> <ul style="list-style-type: none"> <li>a) Obtaining objective evidence of the quality of the product from suppliers</li> <li>b) Inspections and audit at supplier's premises</li> <li>c) Review of required documentation</li> <li>d) Inspection of products upon receipt, and</li> <li>e) Delegation of verification to the supplier, or supplier certification.</li> </ul> <p>Purchased product is not be used or processed until it has been verified as conforming to specified requirements unless it is released under positive recall procedure.</p> <p>Where the organization utilizes test reports or verify purchased product, the data in those reports shall be acceptable per applicable specifications. The organization must periodically validate test reports for raw material.</p> <p>Where specified in the contract, the customer or the customer's representative must be afforded the right to verify at the supplier's premises and the organization's premises that subcontracted product conforms to specified requirements.</p> <p>Verification by the customer must not be used by the organization as evidence of effective control of quality by the supplier and shall not absolve the organization of the responsibility to provide acceptable product, nor shall it preclude subsequent rejection by the customer.</p>
Verification of Purchased Product	7.4.3	7.4.3	7.4.3	<p><b>AS 9100C Has 2 additional NOTES:</b></p> <p><b>NOTE 1</b> Customer verification activities performed at any level of the supply chain should not be used by the organization or the supplier as evidence of effective control of quality and does not absolve the organization of its responsibility to provide acceptable product and comply with all requirements.</p> <p><b>NOTE 2:</b> Verification Activities can include:</p> <ul style="list-style-type: none"> <li>- Obtaining objective evidence of the conformity of the product from the supplier</li> <li>- Inspection and audit at the suppliers premises</li> <li>- Review of required documentation</li> <li>- Inspection of products upon receipt, and</li> <li>- Delegation of verification activities to the supplier or supplier certification.</li> </ul> <p>Where purchased product is released of production and use pending completion of all required verification activities, it shall be identified and recorded to allow recall and replacement if it is subsequently found that there product does not meet requirements.</p> <p>Where the organization delegate's verification activities to the supplier, the requirements for delegation shall be defined and a register of delegation maintained.</p>

Requirement	ISO/TS 16949:2009 Reference	AS9100:2004 Reference	AS9100C:2009 Reference	Impact Vs. AS9100
Incoming Product Quality	7.4.3.1	None	None	<b>TS 16949 – Has additional requirement:</b> The organization shall have a process to assure the quality of purchased product Using one of the following: <ul style="list-style-type: none"> <li>- Receipt of, and evaluation of, statistical data by the organization</li> <li>- Receiving inspection and/or testing such as sampling based on performance</li> <li>- Second or third party assessments or audits of supplier sites, when coupled with records of acceptable delivered product quality</li> <li>-Part evaluation by a designated laboratory</li> <li>- Another method agreed with the customer</li> </ul>
Supplier Monitoring	7.4.3.2	None	None	<b>TS 16949 – Has additional requirement:</b> Supplier performance shall be monitored through the following: <ul style="list-style-type: none"> <li>- Delivered product quality</li> <li>- Customer disruptions including field returns</li> <li>- Delivery scheduled performances (including premium freight)</li> <li>- Special status customer notification related to quality or delivery issues</li> </ul> <p>The organization shall promote supplier monitoring of the performance of their manufacturing processes.</p>
Production and Service Provision	7.5 7.5.1	7.5 7.5.1	7.5 7.5.1	<b>AS9100B Additional requirements:</b> Planning shall consider, as applicable, <ul style="list-style-type: none"> <li>- The establishment of process controls and development of control plans where key characteristics have been identified.</li> <li>- The identification on in-process verification points when adequate verification of conformance cannot be performed at a later stage of realization,</li> <li>- The design, manufacture and use of tooling so that variable measurements can be taken, particularly for key characteristics, and</li> <li>- Special processes</li> </ul>
Production and Service Provision	7.5 7.5.1	7.5 7.5.1	7.5 7.5.1	<b>AS9100B Has additional requirements added g-k):</b> <ul style="list-style-type: none"> <li>g) Accountability for all product during manufacture</li> <li>h) Evidence that all manufacturing and inspection operation have been completed as planned, or as otherwise documented and authorized,</li> <li>i) Provision for the prevention, detection, and removal of foreign objects,</li> <li>j) Monitoring and control of utilities and suppliers such as water, compressed air, electricity, and chemical products to the extent they affect product quality, and</li> <li>k) Criteria for workmanship, which shall be stipulated in the clearest practical manner.</li> </ul> <p><b>AS 9100C Has additional NOTE under a)</b>  <b>NOTE:</b> This information can include drawings, part lists, materials and process specifications.  <b>And additional NOTE under b) NOTE:</b> Work instructions can include process flow charts, production documents and inspection documents.  <b>And additional NOTE under c) NOTE:</b> Suitable equipment can include product specific tools and software programs.  <b>AS9100C Has additional requirements added g-k) – Same as in AS9100B above except the word ‘manufacturing’ is replaced with “Production”.</b></p>

Requirement	ISO/TS 16949:2009 Reference	AS9100:2004 Reference	AS9100C:2009 Reference	Impact Vs. AS9100
Control Plan	7.5.1.1	7.5.1.1  Production Documentation	7.5.1.1  Production Process Verification	<p><b>TS 16949 – Has additional requirements for Control Plans:</b> To be developed at the system, subsystem, component and/or material level for the product including bulk material and parts, and to have pre-launch and production control plans that take into account DFMEA and FMEA outputs. Control plans must list the controls for process control, include special characteristics, customer required information and reaction plans. Control plans are to be updated when changes occur – Customer approval may be required.</p> <p><b>AS9100B – Has requirements for Production Documentation: Approved data shall contain as necessary;</b> Drawings, part lists, process flow charts including inspection operations, production documents and inspection documents and a list of specific or non-specific tools and numerical control machine programs required and any instructions.</p> <p><b>AS9100C – Has additional requirements for Production Process Verification:</b> For use of a representative item from the first production run of a new part or assembly to verify production processes, documentation and tooling are capable of producing parts and assemblies that meet requirements. The process is to be repeated when changes occur that invalidate the original results (eng. changes, mfg. process changes, tooling changes) Note: referred to as first article inspection.</p>
Work Instructions	7.5.1.2	7.5.1.2  Control of Production Process Changes	7.5.1.2  Control of Production Process Changes	<p><b>TS 16949 – Has additional requirement:</b> To prepare documented work instructions for all employees having responsibilities for processes that impact product quality. These instructions are to be accessible at the work station and derived from sources such as the quality plan, control plan and product realization process</p> <p><b>AS9100B – Has requirements for Control of Production Process Changes;</b> Persons authorized to approve changes to production processes are to be identified. Must identify and obtain acceptance of changes that require customer and/or regulator authority approval in accordance with contract or regulatory requirements. Changes affecting processes, production equipment, tools and programs must be documented and procedures must be available to control their implementation. The results of changes are to be assessed to confirm the desired effect has been achieved without affecting product quality.</p> <p><b>AS9100C – Has requirements for Control of Production Process Changes;</b> Persons authorized to approve changes to production processes are to be identified. Must control and <b>document</b> changes affecting processes, production equipment, tools or <b>software</b> programs. The results of changes are to be assessed to confirm the desired effect has been achieved without affecting product <b>conformity</b>.</p>

Requirement	ISO/TS 16949:2009 Reference	AS9100:2004 Reference	AS9100C:2009 Reference	Impact Vs. AS9100
Verification of Job Set-ups	7.5.1.3	7.5.1.3  Control of Production Equipment	7.5.1.3  Control of Production Equipment, Tools and Software Programs	<p><b>TS 16949 – Has additional requirement:</b> To verify job set-up's whenever performed; initial run of job, material changeover or job change. Work instructions are to be available for set-up personnel. Statistical methods of verification are to be used where applicable. Note: Last off part comparisons are recommended</p> <p><b>AS9100B – Has requirements for Control of Production Equipment, Tools and Numerical Control Machine Programs;</b> Must be validated prior to use and maintained and inspected periodically according to documented procedures. Validation prior to production use including first article produced to design data/specification. Storage requirements, periodic preservation/condition checks are to be established for production equipment or tooling in storage.</p> <p><b>AS9100C – Has requirements for Control of Production Equipment, Tools and Software Programs;</b> Used to automate and control/monitor product realization processes are to be validated prior to release for production and must be maintained. Storage requirements, periodic preservation/condition checks are to be <b>defined</b> for production equipment or tooling in storage.</p>
Preventive and Predictive Maintenance	7.5.1.4	7.5.1.4  Control of work transferred on a temporary basis, outside the organization's facilities	7.5.1.4  Post Delivery Support	<p><b>TS 16949 – Has additional requirement:</b> To identify key process equipment and provide resources for machine/equipment maintenance and develop and effective planned total preventive maintenance system. Minimum requirements include:</p> <ul style="list-style-type: none"> <li>-Planned maintenance activities</li> <li>- Packaging &amp; Preservation of equip., tooling &amp; gauging</li> <li>- Availability of replacement parts for key equipment</li> <li>- Document, evaluate &amp; improve maintenance objectives. Must utilize predictive maintenance methods to continually improve the effectiveness and efficiency of production equipment.</li> </ul> <p><b>AS9100B – Has requirements for Control of work transferred on a temporary basis, outside the organization's facilities;</b> The organization must define the process to control and validate to quality of the work.</p> <p><b>AS9100C – Has requirements for Post Delivery Support;</b> Must provide as applicable for the;</p> <ul style="list-style-type: none"> <li>- Collection &amp; Analysis of in-service data</li> <li>- Actions to be taken, investigation &amp; reporting, when problems are detected after delivery</li> <li>- Control and updating of technical documentation</li> <li>- Approval, control &amp; use of repair schemes, and</li> <li>- Controls required for off-site work</li> </ul>

Requirement	ISO/TS 16949:2009 Reference	AS9100:2004 Reference	AS9100C:2009 Reference	Impact Vs. AS9100
Management of Production Tooling	7.5.1.5	7.5.1.5  Control of Service Operations	None	<p><b>TS 16949 – Has additional requirement:</b> To provide resources for tool and gauge design, fabrication and verification activities and establish a system for production tool management including;</p> <ul style="list-style-type: none"> <li>- Maintenance &amp; repair facilities &amp; personnel</li> <li>- Storage &amp; recovery</li> <li>- Set-up</li> <li>- Tool change programs for perishable tools</li> <li>- Tool design modification documentation (Chg level)</li> <li>- Tool modification &amp; revision to documentation</li> <li>- Tool identification, defining status (i.e. production, repair, disposal)</li> </ul> <p>Implementing a system to monitor outsourced activities</p> <p><b>AS9100B – Has requirements for Control of Service Operations where servicing is a specified requirement must provide for;</b></p> <ul style="list-style-type: none"> <li>- Collection &amp; Analysis of in-service data</li> <li>- Actions to be taken where problems are detected after delivery, investigation &amp; reporting, actions on service information consistent with contractual or regulatory requirements</li> <li>- Control and updating of technical documentation</li> <li>- Controls required for off-site work</li> </ul>
Production Scheduling	7.5.1.6	None	None	<p><b>TS 16949 – Has additional requirement:</b> To schedule to meet customer requirements (just-in-time) supported by an information system that permits key information at key stages and is order driven</p>
Feedback of Information from Service	7.5.1.7	None	None	<p><b>TS 16949 – Has additional requirement:</b> To have a process (established &amp; maintained) for communication of information on service concerns to Mfg., Eng., and Design activities. <b>Note:</b> Intent is to ensure awareness of external nonconformities.</p>
Service Agreement with Customer	7.5.1.8	None	None	<p><b>TS 16949 – Has additional requirement when there is a service agreement;</b> To verify the effectiveness of:</p> <ul style="list-style-type: none"> <li>- Any organization service centers</li> <li>- Any special-purpose tools / measuring equipment</li> <li>- Training of service personnel</li> </ul>
Validation of Processes for Production and Service	7.5.2	7.5.2	7.5.2	<p><b>AS9100B – Has additional Note:</b> These processes are frequently referred to as special processes. And <b>additional NOTE under a)</b> Qualification and approval of special processes prior to use and <b>additional NOTE under c)</b> Control of the significant operations and parameters of special processes in accordance with documented process specifications and changes.</p> <p><b>AS9100C – Has additional Note:</b> These processes are frequently referred to as special processes.</p>
Validation of processes for production and service provision - supplemental	7.5.2.1	None	None	<p><b>TS 16949 – Has additional requirement:</b> 7.5.2 applies to all processes for production and service provision.</p>
Identification & Traceability	7.5.3	7.5.3	7.5.3	<p><b>TS 16949 – Has additional NOTE:</b> Inspection and test status is not indicated by the location of product in the production flow unless inherently obvious, such as in an automated production transfer process. Alternatives are permitted, if the status is clearly identified, documented and achieves the designated purpose.</p>

Requirement	ISO/TS 16949:2009 Reference	AS9100:2004 Reference	AS9100C:2009 Reference	Impact Vs. AS9100
Identification & Traceability (Con't)	7.5.3	7.5.3	7.5.3	<p><b>AS9100B – Has additional requirements:</b> To maintain the identification of the configuration of product to identify differences between the actual configuration and the agreed configuration. Also; when acceptance authority media are used (stamps, electronic signatures, passwords) controls for the media must be established and documented. And based on the level of traceability required by the contract, regulatory, or other established requirement, the system must provide for:</p> <ul style="list-style-type: none"> <li>- Identification to be maintained though out product life</li> <li>- All products manufactured from same batch of raw material or mfg batch be traced, as well as the destination for all products of the same batch</li> <li>- For assemblies, the identification of its components and the next higher assembly to be traced</li> <li>- For a given product, sequential record of its production (mfg., assy., inspection) to be retrieved</li> </ul> <p><b>AS9100C – Has the same requirements as B (placed under a NOTE: Traceability requirements)</b></p>
Identification & Traceability – Supplemental	7.5.3.1			<p><b>TS 16949 – Has additional requirement:</b> Indicating the words “where appropriate” in 7.5.3 do not apply.</p>
Customer Property	7.5.4	7.5.4	7.5.4	<p><b>AS9100B – Has additions to the Note:</b> Including customer furnished data used for design, production, and/or inspection.</p> <p><b>AS9100C – Has added to the Note:</b> And personal data.</p>
Customer Owned Production Tooling	7.5.4.1	None	None	<p><b>TS 16949 – Has additional requirement:</b> Customer owned tools, manufacturing, test, inspection tooling and equipment is to be permanently marked so that ownership is visible and can be determined</p>
Preservation of Product	7.5.5	7.5.5	7.5.5	<p><b>AS9100B &amp; AS9100C– Have additional requirements:</b> To include, where applicable based on product specification and/or applicable regulations, provision for:</p> <ul style="list-style-type: none"> <li>- Cleaning</li> <li>- Prevention, detection and removal of foreign objects</li> <li>- Special handling for sensitive products</li> <li>- Marking and labeling including safety warnings</li> <li>- Shelf life control and stock rotation</li> <li>- Special handling for hazardous materials</li> </ul> <p>The organization is to ensure documents required by the contract/order to accompany the product are present at delivery and are protected against loss and deterioration.</p>
Storage and Inventory	7.5.5.1	None	None	<p><b>TS 16949 – Has additional requirement:</b> To detect deterioration, the condition of the stock is to be assessed at appropriate planned intervals. Use of an inventory management system to optimize inventory turns over time (FIFO). Obsolete material to be controlled similar to nonconforming product.</p>

Requirement	ISO/TS 16949:2009 Reference	AS9100:2004 Reference	AS9100C:2009 Reference	Impact Vs. AS9100
Control of Monitoring and Measuring Devices	7.6	7.6	7.6	<p><b>AS9100B – Has additional requirements:</b> To maintain a register of devices, and define the process for calibration, including details of equipment type, unique identification, location, frequency of checks. Check method and acceptance criteria and a <b>NOTE:</b> Includes, but not limited to: test hardware, test software, automated test equipment and plotters used to produce inspection data and personally owned and or customer supplied equipment used to provide evidence of product conformity. Must also ensure environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out. <b>Has an additional requirement f):</b> be recalled to a defined method when requiring calibration.</p> <p><b>AS9100C – Has additional requirements the same as rev B except:</b> The additional requirement identified as f) is only an additional line under e) which indicates the same as above except the words “or verification” have been added to the end. <b>And an additional Note:</b> Confirmation of the ability of computer software to satisfy the intended application would typically include verification and configuration management to maintain its suitability for use.</p>
Measurement System Analysis	7.6.1	None	None	<p><b>TS 16949 – Has additional requirement:</b> To conduct statistical studies to analyze variation in each type of measuring and test equipment system (as listed on control plans). Methods &amp; acceptance criteria used is to conform to Customer Ref. Manuals (MSA), other methods &amp; acceptance criteria may be used if approved by customer.</p>
Calibration / Verification Records	7.6.2	None	None	<p><b>TS 16949 – Has additional requirement:</b> To maintain records for all gauges &amp; test equipment including:</p> <ul style="list-style-type: none"> <li>- equipment identification, including standard used</li> <li>- revisions following engineering changes</li> <li>- out of spec readings as received for calibration</li> <li>- assessment of impact- for out of spec conditions</li> <li>- statement of conformity – after calibration</li> <li>- Notification to customer – If suspect product is shipped.</li> </ul>
Laboratory Requirements	7.6.3  7.6.3.1 Internal Lab	None	None	<p><b>TS 16949 – Has additional requirements for Internal and External Laboratories:</b></p> <p><b>Internal Labs</b> Must have a defined scope including: capabilities included in the QMS documentation. Must specify technical requirements for:</p> <ul style="list-style-type: none"> <li>- Adequacy of lab procedures</li> <li>- Competency of lab personnel</li> <li>- Testing of the product</li> <li>- Capability to perform services correctly, traceable to relevant process standard</li> <li>- Review of related records</li> </ul> <p><b>NOTE:</b> Accreditation to ISO/IEC 17025 may be used to demonstrate conformity but is not mandatory.</p>

Requirement	ISO/TS 16949:2009 Reference	AS9100:2004 Reference	AS9100C:2009 Reference	Impact Vs. AS9100
Laboratory Requirements	7.3.6.2 External Lab	None	None	<p><b>External Labs</b> used for inspection, test or calibration services must have a defined scope that included the capability to perform the required inspection, test or calibration and either</p> <ul style="list-style-type: none"> <li>- Have evidence that the lab is acceptable to the customer or</li> <li>- The lab is accredited to ISO/IEC 17025 or equivalent</li> </ul> <p><b>Note1:</b> Evidence may be by customer assessment or customer approved 2<sup>nd</sup> party  <b>Note2:</b> when a qualified lab is not available for a given piece of equipment the service may be performed by the equipment manufacturer (7.6.3.1 must be met).</p>
Measurement Analysis and Improvement	8 8.1	8 8.1	8 8.1	<p><b>AS9100B – Has additional Note:</b> Based on the nature of the product and specified requirements, statistical techniques may be used to support;</p> <ul style="list-style-type: none"> <li>- Design verification (reliability, maintainability, safety)</li> <li>- Process control</li> <li>- Selection and inspection of key characteristics</li> <li>- Process capability measurements</li> <li>- SPC</li> <li>- DOE</li> <li>- Inspection matching sampling rate to criticality of product and to process capability</li> <li>- Failure Mode Effect Analysis</li> </ul> <p><b>AS9100C – Has the same additional NOTE:</b> Except “Criticality” is added to Failure Mode Effect and Criticality Analysis</p>
Identification of Statistical Tools	8.1.1	None	None	<p><b>TS 16949 – Has additional requirement:</b> To determine during advance quality planning appropriate statistical tools to be used and include them in control plans.</p>
Knowledge of Basic Statistical Concepts	8.1.2	None	None	<p><b>TS 16949 – Has additional requirement:</b> To ensure knowledge of Basic Statistical Concepts are understood and utilized through the organization.</p>
Monitoring and Measurement	8.2 8.2.1	8.2 8.2.1	8.2 8.2.1	<p><b>AS9100C – Has additional requirement:</b> Information to be monitored includes, but is not limited to, product conformity, OTD performance, customer complaints and corrective action requests. Must develop and implement plans for customer satisfaction improvement that addresses deficiencies identified and assess the effectiveness of the results. And an additional <b>NOTE:</b> Can include obtaining input from surveys, delivered part quality, lost business analysis, complaints, warranty claims and dealer reports.</p>
Customer Satisfaction - Supplemental	8.2.1.1	None	None	<p><b>TS 16949 – Has additional requirement:</b> Satisfaction is to be monitored through continual evaluation of the realization process. Performance indicators based on objective data and include but not limited to:</p> <ul style="list-style-type: none"> <li>- Delivered part quality performance</li> <li>- Customer disruptions including field returns</li> <li>- Delivery schedule performance (and premium freight)</li> <li>- Customer notification related to quality or delivery</li> </ul> <p>Must monitor the performance of the manufacturing process to demonstrate compliance with customer requirements for product quality &amp; efficiency of process</p>

Requirement	ISO/TS 16949:2009 Reference	AS9100:2004 Reference	AS9100C:2009 Reference	Impact Vs. AS9100
Internal Audit	8.2.2	8.2.2	8.2.2	<p><b>AS9100B – Has additional requirements:</b> To develop detailed tools such as check sheets, process flowcharts, to support audit of QMS requirements. The acceptability of selected tools will be measured against the effectiveness of the internal audit process and overall organizations performance. Internal audits shall also meet contract and/or regulatory requirements.</p> <p><b>AS9100C – Has additional Note: Under a)</b> Planned arrangements include customer contractual requirements and only lists ISO 19011 for guidance.</p>
Quality Management System Audit	8.2.2.1	None	None	<p><b>TS 16949 – Has additional requirement:</b> To audit the QMS to verify compliance with TS and any additional QMS requirements (customer specific requirements)</p>
Manufacturing Process Audit	8.2.2.2	None	None	<p><b>TS 16949 – Has additional requirement:</b> To audit each manufacturing process to determine effectiveness</p>
Product Audit	8.2.2.3	None	None	<p><b>TS 16949 – Has additional requirement:</b> To audit products at appropriate stages of production and delivery for conformity to all specified requirements, dimensions, functionality, packaging, labeling, at a defined frequency.</p>
Internal Audit Plans	8.2.2.4	None	None	<p><b>TS 16949 – Has additional requirement:</b> To cover all quality management related processes, activities and shifts; scheduled according to an annual plan. When internal/external nonconformities or customer complaints occur, the audit frequency must be appropriately increased.</p> <p><b>NOTE:</b> Specific checklists should be used for each audit.</p>
Internal Auditor Qualifications	8.2.2.5	None	None	<p><b>TS 16949 – Has additional requirement:</b> To have internal auditors who are qualified to audit the requirements of the Technical Specification (TS)</p>
Monitoring and Measurement of Processes	8.2.3	8.2.3	8.2.3	<p><b>AS9100B – Has additional requirements:</b> In the event of process nonconformity to:</p> <ul style="list-style-type: none"> <li>- take appropriate action to correct the process</li> <li>- evaluate the process nonconformity as to whether there is resulting product nonconformity</li> <li>- identify and control nonconforming product (8.3)</li> </ul> <p><b>AS9100C – Has additional NOTE and requirement:</b></p> <p><b>NOTE:</b> When determining suitable methods, consider the type and extent of monitoring and measurement appropriate to each of the processes in relation to their impact on the conformity to product requirements and the effectiveness of the QMS.</p> <p><b>Additional requirement:</b> (In addition to rev B above) Determine if the process nonconformity is limited to a specific case or whether it could have affected other processed or products</p>

Requirement	ISO/TS 16949:2009 Reference	AS9100:2004 Reference	AS9100C:2009 Reference	Impact Vs. AS9100
Monitoring and Measurement of Manufacturing Processes	8.2.3.1	None	None	<p><b>TS 16949 – Has additional requirements:</b> To perform process studies on all new mfg. processes to verify process capability and provide input for process control. Results must be documented and include objectives for process capability, reliability, maintainability and availability as well as acceptance criteria. Must maintain process capability or performance as specified by the customer part approval process requirements. The control plan and process flow are implemented including adherence to:</p> <ul style="list-style-type: none"> <li>- measurement technique</li> <li>- sampling plans</li> <li>-reaction plans when acceptance criteria is not met</li> </ul> <p>Recording of significant events (tool change, machine repairs). Initiate the reaction plan from the control plan for characteristics that are either not statistically capable or unstable –including containment and 100 % inspection as appropriate, completion of corrective action plans with specific timing and responsibilities. Plans are to be reviewed / approved by customer when required. Must maintain records of effective dates of process changes.</p>
Monitoring and Measurement of Product	8.2.4	8.2.4	8.2.4	<p><b>TS 16949 – Has additional NOTE:</b> When selecting product parameters to monitor compliance to specified internal and external requirements the organization determines the types of product characteristics, leading to;</p> <ul style="list-style-type: none"> <li>- the types of measurements</li> <li>- suitable measurement means</li> <li>- the capability and skills required</li> </ul> <p><b>AS9100B – Has additional requirements:</b> To monitor and control Key Characteristics. Sampling plans used as a means of product acceptance must be statistically valid and appropriate for use. The plan must preclude the acceptance of lots with known nonconformities. When required the plan must be submitted for customer approval. Product must not be used until inspected or otherwise verified as conforming to specified requirements, except under positive-recall procedures pending completion of all required measurement and monitoring activities.</p> <p><b>AS9100C – Has revised wording from rev B:</b> Sampling plans used as a means of product acceptance must be justified on the basis of recognized statistical principles and appropriate for use. Sentence regarding know nonconformities has been removed. Where product is released for production pending completion of all required measurement and monitoring activities, it shall be identified and recorded to allow recall and replacement if it is found that the product does not meet defined requirements.</p> <p><b>And additional requirements:</b> Where required to demonstrate product qualification, must ensure records provide evidence product meets defined requirements. And Must ensure all documents required to accompany the product are present at the delivery.</p>

Requirement	ISO/TS 16949:2009 Reference	AS9100:2004 Reference	AS9100C:2009 Reference	Impact Vs. AS9100
Layout Inspection and Functional Testing	8.2.4.1	8.2.4.1  Inspection documentation	None	<p><b>TS 16949 – Has additional requirements:</b> Requiring a layout and functional verification to applicable customer engineering, material and performance standards must be performed for each product as specified in control plans, results must be available for customer review. NOTE: layout is the complete measurement of all product dimensions shown on design records.</p> <p><b>AS9100B – Has Inspection Documentation:</b> Measurement requirements for product or service acceptance must be documented – Including:  <ul style="list-style-type: none"> <li>- Criteria for acceptance and/or rejection</li> <li>- Where in sequence measurements &amp; testing operations are performed</li> <li>- A record of the measurement result, and</li> <li>- Type of measurement instruments required and any specific instructions associated with their use.</li> </ul>                     Test records showing actual results when required by the specification or acceptance test plan. Where required to demonstrate product qualification must ensure records provide evidence product meets defined requirements.</p>
Appearance Items	8.2.4.2	8.2.4.2 First Article Inspection	None	<p><b>TS 16949 – Has additional requirements:</b> For parts designated as “appearance items” must provide:  <ul style="list-style-type: none"> <li>- Appropriate resources including lighting</li> <li>- Masters for color, grain, gloss, metallic brilliance, texture, DOI as appropriate.</li> <li>- Maintenance and control of appearance masters and evaluation equipment</li> <li>- Verification of personnel making acceptance evaluations are competent and qualified to do so</li> </ul> </p> <p><b>AS9100B – Has First Article Inspection:</b> To provide a process for the inspection, verification, and documentation of a representative item from the first production run of a new part, or following any changes that invalidate the previous first article inspection result.  <b>NOTE:</b> See (AS) (EN) (SJAC) 9102 for guidance.</p>
Control of Nonconforming Product	8.3	8.3	8.3	<p><b>AS9100B – Has additional Requirements and NOTE:</b> The term “nonconforming product” includes nonconforming product returned from the customer.  <b>Additional requirements for:</b> Documented procedure to define responsibility for review and authority for the disposition on nonconforming product and the process for approving personnel making these decisions. <b>And:</b> <b>Not</b> to use dispositions of “use as is” or “repair” unless specifically authorized by the customer, if the product is produced to customer design, or the nonconformity results in a departure from the contract requirements.  <b>And:</b> Unless otherwise restricted in the contract, organization-designed product which is controlled via a customer specification may be dispositioned by the organization as “use as is” or “repair”, provided the nonconformity does not result in a departure for customer specified requirements. “Use as is” or “repair”</p>

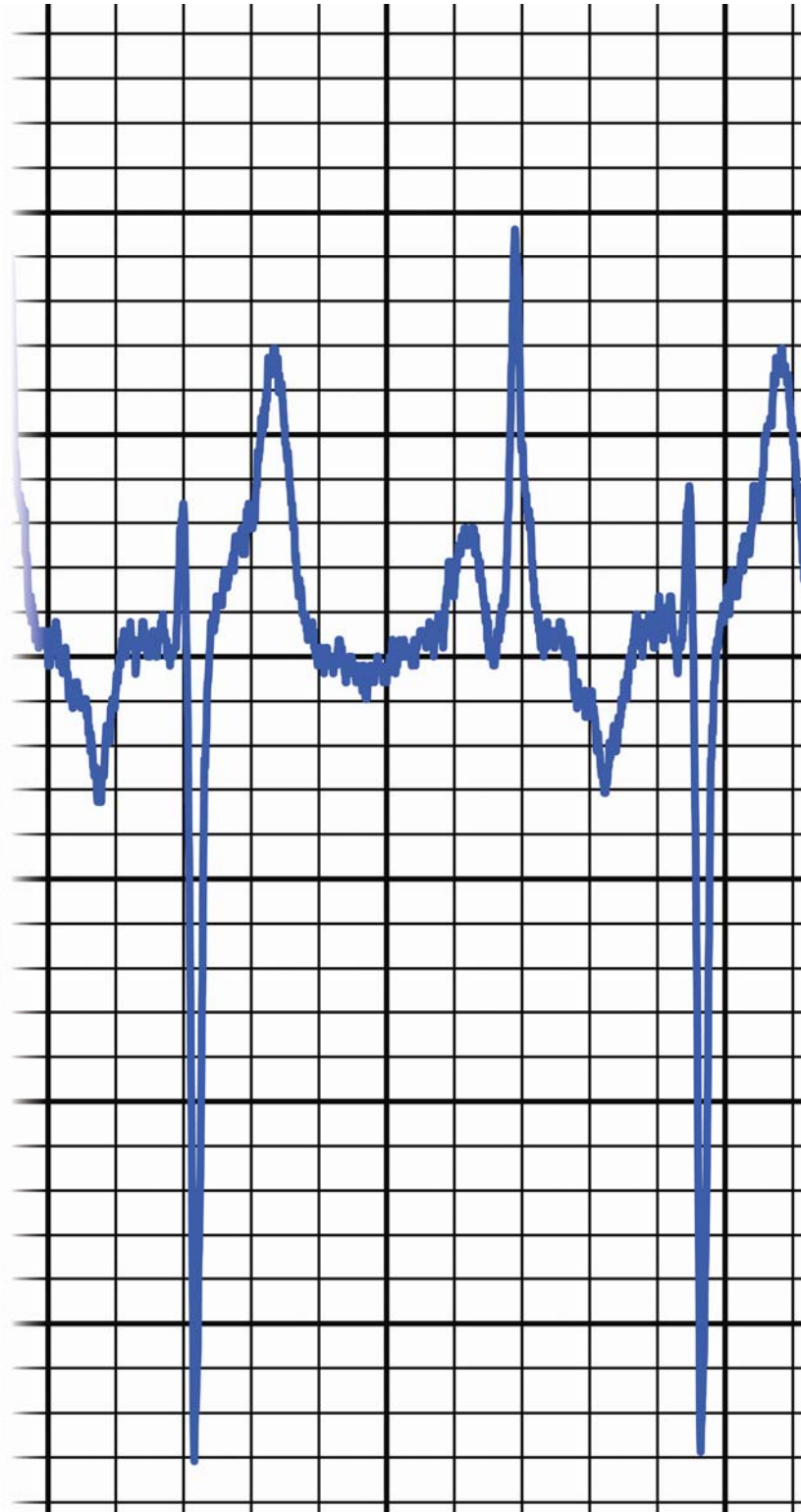
Requirement	ISO/TS 16949:2009 Reference	AS9100:2004 Reference	AS9100C:2009 Reference	Impact Vs. AS9100
Control of Nonconforming Product (Con't)	8.3	8.3	8.3	<p><b>AS9100B – Additional requirements and NOTE:</b> Product dispositioned for scrap must be conspicuously and permanently marked, or positively controlled, until physically rendered unusable. <b>And:</b> In addition to any contract or regulatory authority reporting requirements, the system must provide for timely reporting of delivered nonconforming product that may affect reliability or safety. Notification including a clear description of the nonconformity, as necessary parts affected, customer and/or organization part numbers, quantity and dates delivered. <b>NOTE:</b> Parties requiring notification of nonconforming product may include suppliers, internal organizations, customers, distributors, and regulatory authorities.</p> <p><b>AS9100C – Has additional NOTE:</b> The term “nonconforming product” includes nonconforming product returned from the customer. <b>Additional requirement: d)</b> by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.</p> <p>- The organization’s nonconforming product control process must provide for timely reporting of delivered nonconforming product. <b>NOTE:</b> Parties requiring notification of nonconforming product may include suppliers, internal organizations, customers, distributors, and regulatory authorities. <b>Additional requirement: e)</b> by taking action necessary to contain the effect of the nonconformity on other processes or products. Dispositions of “use as is” or “repair” can only be used after approval by an authorized representative of the organization responsible for design. <b>NOTE:</b> Authorized representative included personnel having delegated authority from the design organization.</p>
Control of nonconforming product - supplemental	8.3.1	None	None	<b>TS 16949 – Has additional requirement:</b> To classify suspect product as nonconforming product. (7.5.3)
Control of Reworked Product	8.3.2	None	None	<b>TS 16949 – Has additional requirement:</b> Instructions for rework, including re-inspections requirements, are to be accessible and utilized by appropriate personnel.
Customer Information	8.3.3	None	None	<b>TS 16949 – Has additional requirement:</b> To inform customers promptly when nonconforming product has been shipped.
Customer Waiver	8.3.4	None	None	<b>TS 16949 – Has additional requirement:</b> Must obtain customer concession or deviation permit prior to further processing whenever the product or manufacturing process is different from that which is currently approved. Must maintain a record of the expiration date or quantity authorized – ensure compliance with original or superseding specification and requirements when the authorization expires. Material shipped on an authorization is to be properly identified on the shipping container. Applies equally to purchased product, the organization shall approve suppliers requests before submission to the customer.

Requirement	ISO/TS 16949:2009 Reference	AS9100:2004 Reference	AS9100C:2009 Reference	Impact Vs. AS9100
Analysis of Data	8.4	8.4	8.4	<b>None</b> - All 3 are the same
Analysis and Use of Data	8.4.1	None	None	<b>TS 16949 – Has additional requirement:</b> Trends in quality and performance must be compared toward objectives and lead to action to support: - Development of priorities for prompt solution of customer related problems. - Determination of key customer related trends and correlation for status review, decision making and longer term planning. - An information system for the timely reporting of product information arising from usage. <b>NOTE:</b> Data should be compared to competitors and/or appropriate benchmarks.
Improvement Continual Improvement	8.5 8.5.1	8.5 8.5.1	8.5 8.5.1	<b>AS9100C – Has additional requirement and NOTE:</b> Must monitor the implementation of improvement activities and evaluate the effectiveness of the results. <b>NOTE:</b> Continual improvement opportunities can result from lessons learned, problem resolutions and the benchmarking of best practices
Continual Improvement of the organization	8.5.1.1	None	None	<b>TS 16949 – Has additional requirement:</b> To define a process for continual improvement.
Manufacturing Process Improvement	8.5.1.2	None	None	<b>TS 16949 – Has additional requirement and 2 NOTES:</b> To continually focus upon control and reduction of variation in product characteristics and manufacturing process parameters. <b>NOTE 1:</b> Controlled characteristics are documented in the control plan. <b>NOTE 2:</b> Continual improvement is implemented once manufacturing processes are capable and stable, or product characteristics are predictable and meet customer requirements.
Corrective Action	8.5.2	8.5.3	8.5.2	<b>AS9100B – Has additional requirements: Under g)</b> Flow down the corrective action requirement to a supplier, when it is determined that the supplier is responsible for root cause and <b>Under h)</b> Specific actions where timely and/or effective corrective actions are not achieved. <b>AS9100C – Has additional requirements g) and h) as in rev B and additional requirement i)</b> Determining if any additional nonconforming product exists based on the causes of the nonconformities and taking further action when required.
Problem Solving	8.5.2.1	None	None	<b>TS 16949 – Has additional requirement:</b> To define a process for problem solving leading to root cause identification and elimination.
Error Proofing	8.5.2.2	None	None	<b>TS 16949 – Has additional requirement:</b> To use error-proofing methods in their corrective action process.
Corrective Action Impact	8.5.2.3	None	None	<b>TS 16949 – Has additional requirement:</b> To apply to other similar processes and products the corrective action, and to controls implemented, to eliminate the cause of nonconformity.

Requirement	ISO/TS 16949:2009 Reference	AS9100:2004 Reference	AS9100C:2009 Reference	Impact Vs. AS9100
Rejected Product Test/Analysis	8.5.2.4	None	None	<b>TS 16949 – Has additional requirements and NOTE:</b> To analyze parts rejected by the customer's manufacturing plants, engineering facilities and dealerships. To minimize cycle time for this process. Records are to be kept and made available upon request. To perform analysis and initiate corrective action to prevent recurrence. <b>NOTE:</b> Cycle time related to rejected product analysis should be consistent with the determination or root cause, corrective action and monitoring the effectiveness of implementation.
Preventive Action	8.5.3	8.5.3	8.5.3	<b>AS9100C – Has additional NOTE:</b> Examples of preventive action opportunities include risk management, error proofing, failure mode and effect analysis (FMEA), and information on product problems reported by external sources.
Annex A	Control Plan	None	None	<b>TS 16949 – Has additional Annex: (Normative) Control Plan:</b> This page describes the Control Plan: A.1 Phases of the control plan A.2 Elements of the control plan a) General data b) Product control c) Process control d) Methods e) Reaction plan and corrective actions

# Comparison of Requirements

## ISO/TS 16949:2009 vs. ISO 13485:2003



Requirement	ISO/TS 16949:2009 Reference	ISO 13485	Impact vs. TS
Foreword	Technical Specification QMS requirements for Automotive	Medical Devices – -Requirements for Regulatory purposes	<b>None</b> – TS 16949 Updated to include ISO 2001:2008 (2009-06-15)
Introduction	0.1	01.	<b>TS 16949</b> – ISO 9000 and ISO 9004 have been taken into consideration in development. <b>ISO 13485</b> – There is a wide variety of medical devices and some of the particular requirements only apply to named groups of medical devices (defined in Clause 3)
Process Approach	0.2	0.2	<b>TS 16949</b> - Also describes the advantages of the process approach including the importance of; - Understanding the requirements - The need to consider processes in terms of added value - Obtaining results of process performance and effectiveness, and - Continual Improvement of processes based on objective measurement. Also included the Model of a process-based QMS (figure 1) and describes PDCA.
Relationship with ISO 9004	0.3	0.3	<b>TS 16949</b> – defines relationship with ISO 9004 and 9001. <b>Note Added:</b> The knowledge and use of the eight quality Management principles referred to in ISO 9000:2005 and ISO 9004 – Should be demonstrated and cascaded through the organization by top Management
Relationship with ISO 9001	None	0.3.1	<b>ISO 13485</b> – Stand-alone Standard, based on ISO 9001. Also indicates that ISO 9001 quoted clauses are in normal format and text that is not identical to the text in ISO 9001 is in italics – The nature and reasons for the text changes are noted in Annex B.
Relationship with ISO/TR 14969	None	0.3.2	<b>ISO 13485</b> – ISO/TR 14969 Technical Report intended to provide guidance for the application of ISO 13485
Compatibility with other QMS	0.4	0.4	<b>TS 16949</b> – Refers to Annex A – shows the correspondence between ISO 9001:2008 and ISO 14001:2004
Goal of Document	0.5	None	<b>TS16949</b> - Includes Customer Specific Requirements – Common approach for automotive.
Scope	1 1.1	1 1.1	<b>TS16949</b> – Specifies it is for automotive, states applicability requirements and specifies Support Sites can not obtain stand alone certification <b>ISO 13485</b> – Specifies requirements needed to demonstrate ability to provide medical devices and related services. Objective to harmonize medical device regulatory requirements for quality management systems – Excludes some ISO 9001 requirements that are not appropriate as regulatory requirements.

Requirement	ISO/TS 16949:2009 Reference	ISO 13485	Impact vs. TS
Application	1.2	1.2	<p><b>TS 16949</b> – Defines the only permitted exclusions relate to 7.3 where the organization is not responsible for product design &amp; development – Does not include process design</p> <p><b>ISO 13485</b> – Specifies requirements are specific to organizations providing medical devices regardless of the type or size of the organization And indicates; If regulatory requirements permit exclusions of design &amp; development controls (7.3) they can be excluded from the QMS. IF any requirements in clause 7 are not applicable due to the nature of the device the requirement do not need to be included. Processes required applicable to the device, but not performed by the organization are the responsibility of the organization. Terms “if appropriate” and “where appropriate” are applicable unless the organization can document a justification – A requirement is considered “appropriate” if it is necessary in order for the product to meet specified requirements and/or the organization to carry out corrective action.</p>
Normative Reference	2	2	<p><b>None</b> – Both specify ISO 9000 QMS - Fundamentals and Vocabulary</p>
Terms and Definitions	<p>3</p> <p>3.1</p> <p>3.1.1</p> <p>3.1.2</p> <p>3.1.3</p> <p>3.1.4</p> <p>3.1.5</p> <p>3.1.6</p> <p>3.1.7</p> <p>3.1.8</p> <p>3.1.9</p> <p>3.1.10</p> <p>3.1.11</p> <p>3.1.12</p>	<p>3</p> <p>3.1</p> <p>3.2</p> <p>3.3</p> <p>3.4</p> <p>3.5</p> <p>3.6</p> <p>3.7</p> <p>3.8</p>	<p><b>TS 16949</b> – Indicates terms and definitions for the automotive industry;</p> <p><i>Control Plan</i></p> <p><i>Design Responsible Organization</i></p> <p><i>Error Proofing</i></p> <p><i>Laboratory</i></p> <p><i>Laboratory Scope</i></p> <p><i>Manufacturing</i></p> <p><i>Predictive Maintenance</i></p> <p><i>Preventive Maintenance</i></p> <p><i>Premium Freight</i></p> <p><i>Remote Location</i></p> <p><i>Site</i></p> <p><i>Special Characteristic</i></p> <p><b>ISO 13485</b> – Indicates terms and definitions for the medical devices;</p> <p><i>Active Implantable Device</i></p> <p><i>Active Medical Device</i></p> <p><i>Advisory Notice</i></p> <p><i>Customer Complaint</i></p> <p><i>Implantable Medical Device</i></p> <p><i>Labeling</i></p> <p><i>Medical Device</i></p> <p><i>Sterile Medical Device</i></p> <p><b>Note:</b> The requirements for sterility of a medical device might be subject to national or regional regulations or standards.</p>

Requirement	ISO/TS 16949:2009 Reference	ISO 13485	Impact vs. TS
QMS– General Requirements	4 4.1	4 4.1	<b>TS 16949 – f)</b> Indicates <i>continual improvement</i> of these processes. (follows ISO) <b>Note 1;</b> also includes <i>analysis and improvement</i> . <b>Also includes 2 additional notes regarding outsourced processes</b> <b>Note 2:</b> –“Outsourced”; performed by external party <b>Note 3 –</b> Ensure control over outsourced processes. <b>ISO 13485 - f)</b> Indicates <i>maintain</i> the effectiveness of these processes.
General Requirements Supplemental	4.1.1	None	<b>TS16949 - Includes additional requirements:</b> For outsourced processes and the responsibility for conformity to customer requirements.
Documentation Requirements	4.2	4.2 4.2.1	<b>TS 16949 –</b> (Follows ISO) <b>ISO 13485 - Has additional requirements e)</b> Records required by this internal standard and <b>f)</b> Any other documentation specified by national or regional regulations. <b>And Specifies: (replaces ISO Note 1):</b> Where a requirement, procedures, activity or special arrangement must be “documented”, it must also be “implemented” and “maintained”. <b>And Specifies:</b> Each type of model or medical device has a file either containing or identifying documents defining product specifications and QMS requirements, shall also define the complete manufacturing process, and if applicable, installation and servicing.
Quality Manual	4.2.2	4.2.2	<b>TS 16949 –</b> (Follows ISO) <b>ISO 13485 – a) Added –</b> and/or non-application. <b>Also indicates:</b> shall outline the structure of the documentation used in the QMS.
Control of Documents	4.2.3	4.2.3	<b>TS 16949 –</b> (Follows ISO) <b>ISO 13485 –a) Added: Review</b> <b>And Specifies:</b> Ensuring changes are reviewed and approved either by the original approving function or another designated function with access to background information to base decisions. Includes a requirement to define the period for which at least one copy of obsolete controlled documents shall be retained, ensuring availability for at least the lifetime of the medical device – not less than the retention period of any resulting record or as specified by relevant regulatory requirements.
Engineering Specifications	4.2.3.1	None	<b>TS 16949 –</b> Includes an additional requirement for timely review of Engineering Specifications, and maintaining records. <b>And a Note:</b> Change in these standards/specifications requires an updated record of customer production part approval when referenced on the design record or if they affect documents of production part approval process such as control plans / FMEAs

Requirement	ISO/TS 16949:2009 Reference	ISO 13485	Impact vs. TS
Control of Records	4.2.4	4.2.4	<b>TS 16949</b> - (Follows ISO) Also includes 2 additional Notes. <b>Note 1:</b> "Disposition" includes disposal. <b>Note 2:</b> "Records" also includes customer specified records. <b>ISO 13485</b> – Retention of records for a period of time at least equivalent to the lifetime of the medical device as defined by the organization, but not less than 2 years from the date of product release or as specified by relevant regulatory requirements.
Record Retention	4.2.4.1	See 4.2.4 above	Retention shall satisfy statutory, regulatory and customer requirements.
Management Responsibility Commitment	5 5.1	5 5.1	<b>TS 16949</b> - (Follows ISO) <b>ISO 13485</b> – Has added <b>NOTE:</b> For the purposes of this standard, statutory requirements are limited to the safety and performance of the medical device only.
Process efficiency	5.1.1	None	<b>TS16949</b> – Includes requirements for top management to review the product realization process.
Customer Focus	5.2	5.2	<b>TS16949</b> – Has added "with the aim of enhancing customer satisfaction."
Quality Policy	5.3	5.3	<b>TS 16949</b> - (Follows ISO) <b>ISO 13485</b> – b) Changed wording from "continually Improve" to "maintain" the effectiveness.
Planning Quality Objectives	5.4 5.4.1	5.4 5.4.1	<b>Both follow ISO</b>
Quality Objectives-Supplemental	5.4.1.1	None	<b>TS 16949</b> - Has additional requirement of top Mgt to define objectives & measurements / include in business plan – used to deploy Q. Policy. <b>NOTE:</b> Should address customer expectations & be achievable within a defined time period.
Quality Management System Planning	5.4.2	5.4.2	<b>Both follow ISO</b>
Responsibility and Authority	5.5 5.5.1	5.5 5.5.1	<b>ISO 13485</b> – Has added the word "documented" and additional requirement for top mgt. to establish the interrelation of all personnel who manage, perform, and verify work affecting quality, and ensure the independence and authority necessary to perform these tasks. <b>NOTE:</b> National or regional regulations may require the nomination of specific persons as responsible for activities related to monitoring experience from the post-production stage and reporting adverse events.
Responsibility for quality	5.5.1.1	See above 5.5.1	<b>TS 16949</b> - Includes additional requirements for <b>Responsibility for Quality</b> . 1) Mgrs with responsibility for quality informed or products / processes not meeting requirements. 2) Personnel with responsibility for quality having authority to stop production 3) All production shifts having personnel assigned the responsibility for quality.

Requirement	ISO/TS 16949:2009 Reference	ISO 13485	Impact vs. TS
Management Representative	5.5.2	5.5.2	<b>TS 16949</b> - (Follows ISO) <b>ISO 13485</b> – c) Changed wording – Added “Regulatory” and customer requirements.
Customer Representative	5.5.2.1	None	<b>TS16949</b> – Includes additional requirement of top mgt. to designate personnel with responsibility and authority to ensure customer requirements are addressed – Special char., Quality Objectives, Training, C/A & P/A, Product Design & Development.
Internal Communication	5.5.3	5.5.3	<b>Both follow ISO</b>
Management Review	5.6 5.6.1	5.6 5.6.1	<b>Both follow ISO</b>
Quality Management System Performance	5.6.1.1	None	<b>TS16949</b> – Includes additional requirements Quality Management System Performance – Review of Performance Trends as part of Continuous Improvement, Monitoring of Cost of Poor Quality. Recorded results including evidence of achievement of Quality Objectives and Customer Satisfaction
Review Input	5.6.2	5.6.2	<b>TS 16949</b> - (Follows ISO) <b>ISO 13485</b> – Added requirement - h) New or revised regulatory requirements.
Review input - Supplemental	5.6.2.1	None	<b>TS16949</b> – Includes additional requirement to include actual and potential field failures and their impact on quality, safety and the environment.
Review Output	5.6.3	5.6.3	<b>TS 16949</b> - (Follows ISO) <b>ISO 13485</b> – a) Changed wording – “Improvements needed <i>to maintain</i> the effectiveness”
Resource Management	6 6.1	6 6.1	<b>TS 16949</b> - (Follows ISO) <b>ISO 13485</b> – a) Changed wording – “To implement the QMS and <i>maintain</i> its effectiveness, and b) adds “ <b>regulatory</b> ”.
Human Resources	6.2 6.2.1	6.2 6.2.1	<b>TS 16949</b> - (Follows ISO) <b>ISO 13485</b> – Does <b>not</b> include the NOTE.
Competence, Awareness and Training	6.2.2	6.2.2	<b>TS 16949</b> - (Follows ISO) <b>ISO 13485</b> – b) Removes “ <b>where applicable</b> ” and adds <b>NOTE</b> : National or Regional regulations may require the organization to establish documented procedures for identifying training needs
Product Design Skills	6.2.2.1	None	<b>TS 16949</b> - <b>Has additional requirement:</b> Regarding Product Design Skills. Personnel with Product Design Responsibilities are competent in Design Requirements and Skilled in Applicable Tools & Techniques
Training	6.2.2.2	None	<b>TS 16949</b> – <b>Has additional requirement:</b> To document a procedure for identifying training needs and achieving competence for personnel performing activities affecting product quality. Personnel performing specifically assigned tasks are qualified with attention to customer requirements. Also 2 notes are included; <b>Note 1</b> - Applies to all employees at all levels. <b>Note 2</b> - An example of customer requirements is Digitized Math Data.

Requirement	ISO/TS 16949:2009 Reference	ISO 13485	Impact vs. TS
Training on the Job	6.2.2.3	None	<b>TS 16949 – Has additional requirement:</b> To provide on the job training in any new or modified job affecting product quality including agency personnel and inform personnel about the consequences to the customer for nonconformity to quality requirements
Employee Motivation and Empowerment	6.2.2.4	None	<b>TS 16949 – Has additional requirement:</b> To motivate and empower personnel to achieve quality objectives, Continuous Improvement, to promote quality and technical awareness throughout the organization. Requirement to a Process to measure the extent to which personnel are aware of quality objectives and how they contribute to the achievement of them.
Infrastructure	6.3	6.3	<b>TS 16949 - (Follows ISO)</b> <b>ISO 13485 – Has added requirement –</b> The organization shall establish documented requirements for maintenance activities, including their frequency, when such activities or lack thereof can affect product quality. Records of such maintenance activities shall be maintained.
Plant, Facility and Equipment Planning	6.3.1	None	<b>TS 16949 – Has additional requirement:</b> To use a multi-disciplinary team to develop plant, facility and equipment planning. Optimize material travel, handling and synchronous material flow. Methods to evaluate & monitor effectiveness of existing operations.
Contingency Plans	6.3.2	None	<b>TS 16949 – Has additional requirement:</b> To prepare contingency plans to satisfy customer requirements in event of emergency.
Work Environment	6.4	6.4	<b>TS 16949 - (Follows ISO)</b> <b>ISO 13485-</b> Does <i>not</i> include the NOTE. And has changed wording: The following requirements shall apply. a) The organization shall establish documented requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could adversely affect the quality of the product. b) If work environment conditions can have an adverse effect on product quality, the organization shall establish documented requirements for the work environment conditions and documented procedures or work instructions to monitor and control these work environment conditions. c) The organization shall ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are appropriately trained or supervised by a trained person d) If appropriate, special arrangements shall be established and documented for the control of contaminated or potentially contaminated product in order to prevent contamination of other product, the work environment or personnel.

Requirement	ISO/TS 16949:2009 Reference	ISO 13485	Impact vs. TS
Personal Safety to Achieve Product Quality	6.4.1	None	<b>TS 16949 – Has additional requirement:</b> To address product safety and means to minimize potential risk to employees, especially in design & development and manufacturing activities.
Cleanliness of Premises	6.4.2	None	<b>TS 16949 – Has additional requirement:</b> To maintain premises in a state or order, cleanliness and repair
Product Realization	7 7.1	7 7.1	<b>TS 16949 -</b> (Follows ISO) with additional <b>NOTE:</b> Project management or APQP as a means to achieve product realization. APQP concepts of error prevention & Continuous Improvement, is based on a multi-disciplinary approach. <b>ISO 13485-</b> Has additional requirement – To establish documented requirements for risk management throughout product realization. Records arising from risk management shall be maintained. Added <b>Note 3:</b> See ISO 14971 for guidance related to risk management.
Project Management	7.1.1	None	<b>TS16949 - Has additional requirement:</b> To include customer requirements and reference to Technical Specification in planning of product realization as a component of the quality plan
Acceptance Criteria	7.1.2	None	<b>TS16949 - Has additional requirement:</b> To define acceptance criteria & where appropriate have customer approval. Attribute data sampling acceptance as zero defects.
Confidentiality	7.1.3	None	<b>TS16949 - Has additional requirement:</b> To ensure confidentiality of customer contracted products under development and related product information
Change Control	7.1.4	None	<b>TS16949 - Has additional requirement:</b> For a process to control & react to Changes that impact product realization. Defined changes addressed, verification and validation defined to ensure customer requirements. Validation to be performed before implementation. Proprietary changes to be reviewed with the customer. When defined by the customer, additional requirements shall be met. 2 additional Notes included; <b>Note 1:</b> Product realization changes affecting customer requirements requires notification to and agreement from the customer. <b>Note 2:</b> the note above applies to both product and manufacturing process changes.
Customer Related Processes	7.2 7.2.1	7.2 7.2.1	<b>TS 16949 -</b> (Follows ISO) <b>with 3 additional Notes;</b> <b>Note 1:</b> Post delivery includes after sale service as part of the contract or PO. <b>Note 2:</b> Includes recycling, environmental impact and characteristics identified as a result of knowledge of the product and manufacturing processes. <b>Note 3:</b> Compliance to c) includes government, safety and environment regulations related to acquisition, storage, handling, recycling, elimination or disposal of materials. <b>ISO 13485-</b> Removes post delivery Note.

Requirement	ISO/TS 16949:2009 Reference	ISO 13485	Impact vs. TS
Customer Designated Special Characteristics	7.2.1.1	None	<b>TS16949 – Has requirement:</b> To demonstrate conformity to customer requirements for designation, documentation and control of special characteristics.
Review of Requirements Related to Product	7.2.2	7.2.2	<b>TS 16949 -</b> (Follows ISO) <b>ISO 13485-</b> Has added to – a) <b>“and documented”</b>
Review of Requirements Related to Product - Supplemental	7.2.2.1	None	<b>TS 16949 – Has additional requirement:</b> Indicating Waiving a formal review (7.2.2) requires customer authorization.
Organization Manufacturing Feasibility	7.2.2.2	None	<b>TS 16949 – Has additional requirement:</b> To investigate, confirm and document the manufacturing feasibility proposed products in the contract review process, including risk analysis.
Customer Communication	7.2.3	7.2.3	<b>TS 16949 -</b> (Follows ISO) <b>ISO 13485-</b> Has added requirement – d) <b>“Advisory notices”</b>
Customer Communication - Supplemental	7.2.3.1	None	<b>TS 16949 – Has additional requirement:</b> To have the ability to communicate information including data in a customer specified language and format.
Design and Development	7.3 7.3.1	7.3 7.3.1	<b>TS 16949 – Has additional Note:</b> Requires that 7.3 include product and manufacturing process design and development and focus on error prevention rather than detection. <b>ISO 13485-</b> Has added requirement – To establish documented procedures for Design & Development and changes to; b) Added <b>“Design Transfer Activities”</b> <b>And</b> - planning output shall be documented, and updated as appropriate, as the design and development progresses. <b>And NOTE:</b> Design transfer activities during the design and development process ensure that design and development outputs are verified as suitable for manufacturing before becoming final production specifications.
Multidisciplinary Approach	7.3.1.1	None	<b>TS 16949 – Has additional requirement:</b> To use a multidisciplinary approach; Development/finalization and monitoring of special characteristics. Development and review of FMEAs including risks. Development and review of control plans. And a <b>NOTE:</b> Multidisciplinary approach typically includes Design, Manufacturing, Engineering, Quality, Production and other appropriate personnel.
Design and Development Input	7.3.2	7.3.2	<b>TS 16949 -</b> (Follows ISO) With added <b>NOTE:</b> Special Characteristics are included in this requirement. <b>ISO 13485-</b> Has added requirement – To a) <b>“Safety”</b> requirements. Also <b>added e) Outputs of Risk Management.</b> Added to requirement: These Inputs shall be reviewed for adequacy and <b>“approved”</b> .

Requirement	ISO/TS 16949:2009 Reference	ISO 13485	Impact vs. TS
Product Design Input	7.3.2.1	None	<b>TS 16949 – Has additional requirement:</b> To identify, document and review product design inputs including; Customer requirements, (sp. Characteristics, identification traceability and packaging). Use of information, (process to deploy information gained from previous designs, competitor analysis, supplier feedback, internal input, field data). Targets for product quality, life, reliability, durability, maintainability, timing & cost.
Manufacturing Process Design Input	7.3.2.2	None	<b>TS 16949 – Has additional requirement:</b> To identify, document and review process design inputs including; Product design output data. Targets for productivity, process capability and cost. Customer requirements and experience from previous developments. And additional <b>Note:</b> Process design includes the use of error proofing to the degree appropriate to magnitude of problems commensurate with the risk encountered.
Special Characteristics	7.3.2.3	None	<b>TS 16949 – Has additional requirement:</b> To Identify special characteristics; include them in control plans, comply with customer specified definitions and symbols, identify process control documents (control plans, FMEAs, WI, etc) with customers symbol or organizations equivalent symbol to include process steps that affect sp. Characteristics. And additional <b>Note:</b> Sp. Characteristics can include product characteristics and process parameters.
Design and Development Output	7.3.3	7.3.3	<b>TS 16949 - (Follows ISO)</b> <b>ISO 13485-</b> Has additional requirement: To maintain records of design and development outputs. And a changed <b>NOTE:</b> Records of design and development outputs can include specifications, manufacturing procedures, engineering drawings, and engineering or research logbooks.
Product Design Outputs- Supplemental	7.3.3.1	None	<b>TS 16949 – Has additional requirements:</b> Indicate the design output is to be expressed in terms that can be verified and validated against product design input requirements. Design Output requirements include:  -design FMEA, reliability results -product special characteristics and specifications -product error-proofing, as appropriate -product definition including drawings or mathematically based data. -product design review results, and -diagnostic guidelines when applicable

Requirement	ISO/TS 16949:2009 Reference	ISO 13485	Impact vs. TS
Manufacturing process design output	7.3.3.2	None	<b>TS 16949 – Has additional requirements:</b> Indicating the manufacturing process design output is to be expressed in terms that can be verified against manufacturing process design input requirements and validated. Manufacturing Process design output include: -specifications and drawings, -manufacturing process flow chart/layout -manufacturing process FMEAs -control plan -work instructions -process approval acceptance criteria -data for quality, reliability, maintainability and measurability -results of error--proofing activities, as appropriate, and -methods of rapid detections and feedback of product/manufacturing process nonconformities
Design and Development Review	7.3.4	7.3.4	<b>TS 16949 - (Follows ISO) With an added NOTE:</b> These reviews are normally coordinated with the design phases and include manufacturing process design and development. <b>ISO 13485-</b> Has added requirement – To include representatives of functions concerned with the design and development stage(s) being reviewed, as well as <b>other specialist personnel.</b>
Monitoring	7.3.4.1	None	<b>TS 16949 – Has additional requirements:</b> That indicate Measurements at specified stages of design and developments shall be defined, analyzed and reported with summary results as and input into management review. <b>NOTE</b> These measurements include quality risks, costs, lead-times, critical paths and others, as appropriate.
Design and Development Verification	7.3.5	7.3.5	<b>Both Follow ISO</b>
Design & Development Validation	7.3.6	7.3.6	<b>TS 16949 – Has 2 additional NOTES:</b> <b>NOTE 1:</b> The validation process normally includes an analysis of field reports for similar products. <b>NOTE 2</b> The requirements of 7.3.5 and 7.3.6 apply to both product and manufacturing processes. <b>ISO 13485-</b> Removes the wording “ <b>where known</b> ” and “ <b>wherever practicable</b> ”. Also added the following additional <b>Requirements and NOTES:</b> As part of the design and development validation, the organization shall perform clinical evaluations and/or evaluation of performance of the medical device, as required by national or regional regulations. <b>NOTE 1:</b> If a medical device can only be validated following assembly and installation at point of use, delivery is not considered to be complete until the product has been formally transferred to the customer. <b>NOTE 2:</b> Provision of the medical device for clinical evaluation and/or evaluation of performance is not considered to be delivery.

Requirement	ISO/TS 16949:2009 Reference	ISO 13485	Impact vs. TS
Design and Development Validation - <b>supplemental</b>	7.3.6.1	None	<b>TS 16949 – Has additional statement;</b> Design and development validation to be performed in accordance with customer requirements including program timing.
Prototype Program	7.3.6.2	None	<b>TS 16949 – Has additional Prototype Program requirements;</b> When required by the customer, the organization must have a prototype program and control plan. The organization must use, whenever possible, the same suppliers, tooling and manufacturing processes as will be used in production. All performance testing activities must be monitored for timely completions and conformity to requirements. Services may be outsourced; organization is responsible for the outsourced services, including technical leadership.
Product Approval Process	7.3.6.3	None	<b>TS 16949 – Has additional product approval process requirements:</b> The organization must conform to a product and manufacturing process approval procedure recognized by the customer. <b>NOTE</b> Product approval should be subsequent to the verification of the manufacturing process. Shall also be applied to suppliers.
Control of Design and Development Changes	7.3.7	7.3.7	<b>TS 16949 – Has additional NOTE:</b> Design and development changes include all changes during the product program life. <b>ISO 13485-</b> (Follows ISO)
Purchasing	7.4 7.4.1	7.4 7.4.1	<b>TS 16949 – Has 2 additional NOTES:</b> <b>NOTE 1</b> Purchased products above include all products and services that affect customer requirements such as sub-assembly, sequencing, sorting, rework and calibration services. <b>NOTE 2</b> When there are mergers, acquisitions or affiliations associated with suppliers, the organization should verify the continuity of the supplier's QMS and its effectiveness. <b>ISO 13485-</b> Has an additional requirement – To establish documented procedures to ensure that purchased product conforms to specified purchase requirements.
Regulatory Conformity	7.4.1.1	None	<b>TS 16949 – Has additional requirement:</b> All purchased products or materials used in product must conform to regulatory requirements
Supplier Quality Management System Development	7.4.1.2	None	<b>TS 16949 – Has additional requirement:</b> The organization shall perform supplier quality management system development with the goal of supplier conformity with TS. Conformity to ISO 9001:2000 is the first step in achieving this goal. <b>NOTE:</b> The prioritization of suppliers for development depends upon, for example, the supplier's quality performance and the importance of the product supplied. Unless otherwise specified by the customer, suppliers to the organization must be third party registered to ISO 9001:2000 by an accredited third-party CB.

Requirement	ISO/TS 16949:2009 Reference	ISO 13485	Impact vs. TS
Customer Approved Sources	7.4.1.3	None	<b>TS 16949 – Has additional requirement:</b> Where specified by the contract, the organization is to purchase products, material or services from approved sources.
Purchasing Information	7.4.2	7.4.2	<b>TS 16949 - (Follows ISO)</b> <b>ISO 13485-</b> Has additional requirement – To the extent required for traceability given in 7.5.3.2, the organization shall maintain relevant purchasing information (documents & records).
Verification of Purchased Product	7.4.3	7.4.3	<b>TS 16949 - (Follows ISO)</b> <b>ISO 13485-</b> Has additional requirement – To maintain records of the verification.
Incoming Product Quality	7.4.3.1	None	<b>TS 16949 – Has additional requirement:</b> The organization shall have a process to assure that the quality of purchased product utilizing one or more of the following methods: <ul style="list-style-type: none"> <li>- Receipt of, and evaluation of, statistical data by the organization</li> <li>- receiving inspection and/or testing such as sampling based on performance</li> <li>- second or third party assessments or audits of supplier sites, when coupled with records of acceptable delivered product quality</li> <li>- part evaluation by a designated laboratory</li> <li>- another method agreed with the customer</li> </ul>
Supplier Monitoring	7.4.3.2	None	<b>TS 16949 – Has additional requirement:</b> Supplier performance shall be monitored through the following indicators; <ul style="list-style-type: none"> <li>- Delivered product quality</li> <li>- Customer disruptions including field returns</li> <li>- Delivery scheduled performances (including premium freight)</li> <li>- Special status customer notification related to quality or delivery issues</li> </ul> The organization shall promote supplier monitoring of the performance of their manufacturing processes.
Production and Service Provision	7.5 7.5.1	7.5 7.5.1	<b>TS 16949 - (Follows ISO)</b> <b>ISO 13485-</b> Has additional requirement –g) The implementation of defined operations for labeling and packaging. And – The requirement to establish and maintain a record for each batch of medical devices that provides traceability to the extent specified in 7.5.3 and identifies the amount manufactured and amount approved for distribution. The batch record shall be verified and approved. <b>NOTE:</b> A batch can be a single medical device.
Control Plan	7.5.1.1	None	<b>TS 16949 – Has additional requirements for Control Plans:</b> To be developed at the system, subsystem, component and/or material level for the product including bulk material and parts, and to have pre-launch and production control plans that take into account DFMEA and FMEA outputs. Control plans must list the controls for process control, include special characteristics, customer required information and reaction plans. Control plans are to be updated when changes occur – Customer approval may be required.

Requirement	ISO/TS 16949:2009 Reference	ISO 13485	Impact vs. TS
Work Instructions	7.5.1.2	See below	<b>TS 16949 – Has additional requirement:</b> To prepare documented work instructions for all employees having responsibilities for processes that impact product quality. These instructions are to be accessible at the work station and derived from sources such as the quality plan, control plan and product realization process
Control of Production and Service provision – Specific Requirements		7.5.1.2 7.5.1.2.1	<b>ISO 13485-</b> Has additional requirements – The organization shall establish documented requirements for cleanliness of product if a) Product is cleaned by the organization prior to sterilization an/or its use, or b) Product is supplied non-sterile to be subjected to a cleaning process prior to sterilization and/or its use, or c) Product is supplied to be used non-sterile and its cleanliness is of significance in use, or d) Process agents are to be removed from product during manufacture. If product is cleaned in accordance with a) or b) above, the requirements contained in 6.4 a) and 6.4 b) do not apply prior to the cleaning process.
Installation activities		7.5.1.2.2	<b>ISO 13485-</b> Has additional requirements – if appropriate, shall establish documented requirements which contain acceptance criteria for installing and verifying the installation of the medical device. If agreed customer requirements allow installation to be performed other than by the organization or its authorized agent, the organization shall provide documented requirements for installation and verification. Records of installation and verification performed by the organization or its authorized agent shall be maintained.
Servicing activities		7.5.1.2.3	<b>ISO 13485-</b> Has additional requirements – If servicing is a specified requirement, to establish documented procedures, work instructions and reference materials and reference measurement procedures, as necessary, for performing servicing activities and verifying that they meet the specified requirements. Records of servicing activities carried out by the organization shall be maintained. <b>NOTE:</b> Servicing can include, for example, repair and maintenance.
Verification of Job Set-ups	7.5.1.3	See below	<b>TS 16949 – Has additional requirement:</b> To verify job set-up's whenever performed; initial run of job, material changeover or job change. Work instructions are to be available for set-up personnel. Statistical methods of verification are to be used where applicable. Note: Last off part comparisons are recommended.
Particular requirements for sterile medical devices		7.5.1.3	<b>ISO 13485-</b> Requires – The organization shall maintain records of the process parameters for the sterilization process which was used for each sterilization batch. Sterilization records shall be traceable to each production batch or medical devices

Requirement	ISO/TS 16949:2009 Reference	ISO 13485	Impact vs. TS
Preventive and Predictive Maintenance	7.5.1.4	None	<b>TS 16949 – Has additional requirement:</b> To identify key process equipment and provide resources for machine/equipment maintenance and develop and effective planned total preventive maintenance system. Minimum requirements include: <ul style="list-style-type: none"> <li>-Planned maintenance activities</li> <li>- Packaging &amp; Preservation of equip., tooling &amp; gauging</li> <li>- Availability of replacement parts for key equipment</li> <li>- Document, evaluate &amp; improve maintenance objectives. Must utilize predictive maintenance methods to continually improve the effectiveness and efficiency of production equipment.</li> </ul>
Management of Production Tooling	7.5.1.5	None	<b>TS 16949 – Has additional requirement:</b> To provide resources for tool and gauge design, fabrication and verification activities and establish a system for production tool management including; <ul style="list-style-type: none"> <li>- Maintenance &amp; repair facilities &amp; personnel</li> <li>- Storage &amp; recovery</li> <li>- Set-up</li> <li>- Tool change programs for perishable tools</li> <li>- Tool design modification documentation (Chg level)</li> <li>- Tool modification &amp; revision to documentation</li> <li>- Tool identification, defining status (i.e. production, repair, disposal)</li> </ul> Implementing a system to monitor outsourced activities
Production Scheduling	7.5.1.6	None	<b>TS 16949 – Has additional requirement:</b> To schedule to meet customer requirements (just-in-time) supported by an information system that permits key information at key stages and is order driven
Feedback of Information from Service	7.5.1.7	None	<b>TS 16949 – Has additional requirement:</b> To have a process (established & maintained) for communication of information on service concerns to Mfg., Eng., and Design activities. <b>Note:</b> Intent is to ensure awareness of external nonconformities.
Service Agreement with Customer	7.5.1.8	None	<b>TS 16949 – Has additional requirement when there is a service agreement;</b> To verify the effectiveness of: <ul style="list-style-type: none"> <li>- any organization service centers</li> <li>- any special-purpose tools / measuring equipment</li> <li>- training of service personnel</li> </ul>
Validation of Processes for Production and Service	7.5.2	7.5.2 7.5.2.1	<b>TS 16949 - (Follows ISO)</b> <b>ISO 13485-</b> Has additional requirements – To establish documented procedures for the validation of the application of computer software (and changes to such software and/or its application) for production and service provisions that affect the ability to conform to specified requirements. Shall be validated prior to initial use. Records of validation shall be maintained.

Requirement	ISO/TS 16949:2009 Reference	ISO 13485	Impact vs. TS
Validation of processes for production and service provision - supplemental	7.5.2.1	See above	<b>TS 16949 – Has additional requirement:</b> 7.5.2 applies to all processes for production and service provision.
Particular requirements for Sterile Medical Devices	None	7.5.2.2	<b>ISO 13485-</b> Has additional requirements – To establish documented procedures for the validation of sterilization processes. Sterilization processes shall be validated prior to initial use. Records of each sterilization process shall be maintained.
Identification & Traceability	7.5.3	7.5.3	<b>TS 16949 – Has additional NOTE:</b> Inspection and test status is not indicated by the location of product in the production flow unless inherently obvious, such as in an automated production transfer process. Alternatives are permitted, if the status is clearly identified, documented and achieves the designated purpose.
Identification & Traceability – Supplemental	7.5.3.1		<b>TS 16949 – Has additional requirement:</b> Indicating the words “where appropriate” in 7.5.3 do not apply.
Identification		7.5.3.1	<b>ISO 13485-</b> Has additional requirement – To establish documented procedures for product identification including procedures to ensure medical devices returned to the organization are identified and distinguished from conforming product.
Traceability		7.5.3.2 7.5.3.2.1	<b>ISO 13485-</b> Has additional requirement – To establish documented procedures for traceability and to define the extent of product traceability and the records required. Where traceability is a requirement, the organization shall control and record the unique identification of the product. <b>NOTE:</b> Configuration management is a means by which identification and traceability can be maintained.
Particular requirements for active implantable medical devices and implantable medical devices	None	7.5.3.2.2	<b>ISO 13485-</b> Has additional requirements– In defining the records required for traceability to include records of all components, materials and work environment conditions, if these could cause the medical device not to satisfy its specified requirements. <b>And</b> to require agents or distributors to maintain records of the distribution or medical devices to allow traceability and that such records are available for inspection. Records of the name and address of the shipping package consignee shall be maintained.
Status identification		7.5.3.3	<b>ISO 13485-</b> Has additional requirements– To identify the product status with respect to monitoring and measurement requirements.
Customer Property	7.5.4	7.5.4	<b>TS 16949 -</b> (Follows ISO) with an additional <b>NOTE:</b> Customer owned returnable packaging is included in this sub-clause. <b>ISO 13485 -</b> (Follows ISO)

Requirement	ISO/TS 16949:2009 Reference	ISO 13485	Impact vs. TS
Customer Owned Production Tooling	7.5.4.1	None	<b>TS 16949 – Has additional requirement:</b> Customer owned tools, manufacturing, test, inspection tooling and equipment shall be permanently marked so that the ownership of each item is visible, and can be determined.
Preservation of Product	7.5.5	7.5.5	<b>ISO 13485-</b> Has changed wording – The organization shall establish documented procedures or documented work instructions for preserving conformity of product during internal processing and delivery to the intended destination – Including identification, handling, packaging, storage and protection. Also applies to constituent parts of a product. <b>And</b> to document procedures or work instructions for the control of product with a limited shelf-life or requiring special storage conditions – such special storage conditions shall be controlled and recorded.
Storage and Inventory	7.5.5.1	None	<b>TS 16949 – Has additional requirement:</b> To detect deterioration, the condition of the stock is to be assessed at appropriate planned intervals. Use of an inventory management system to optimize inventory turns over time (FIFO). Obsolete material to be controlled similar to nonconforming product.
Control of Monitoring and Measuring Devices	7.6	7.6	<b>TS 16949 -</b> (Follows ISO) with an additional <b>NOTE:</b> A number or other identifier traceable to the device calibration record meets the intent of requirement c). <b>ISO 13485- Has additional requirement:</b> To establish documented procedures to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements. <b>NOTE:</b> See ISO 10012 for guidance related to measurement management systems.
Measurement System Analysis	7.6.1	None	<b>TS 16949 – Has additional requirement:</b> To conduct statistical studies to analyze variation in each type of measuring and test equipment system (as listed on control plans). Methods & acceptance criteria used is to conform to Customer Ref. Manuals (MSA), other methods & acceptance criteria may be used if approved by customer.
Calibration / Verification Records	7.6.2	None	<b>TS 16949 – Has additional requirement:</b> To maintain records for all gauges & test equipment including: <ul style="list-style-type: none"> <li>- Equipment identification, including standard used</li> <li>- Revisions following engineering changes</li> <li>- Out of spec readings as received for calibration</li> <li>- Assessment of impact- for out of spec conditions</li> <li>- Statement of conformity – after calibration</li> <li>- Notification to customer – If suspect product is shipped</li> </ul>

Requirement	ISO/TS 16949:2009 Reference	ISO 13485	Impact vs. TS
Laboratory Requirements	7.6.3  7.6.3.1 Internal Lab   7.3.6.2 External Lab	None	<p><b>TS 16949 – Has additional requirements for Internal and External Laboratories:</b></p> <p><b>Internal Labs</b> Must have a defined scope including: capabilities included in the QMS documentation. Must specify technical requirements for:</p> <ul style="list-style-type: none"> <li>- Adequacy of lab procedures</li> <li>- Competency of lab personnel</li> <li>- Testing of the product</li> <li>- Capability to perform services correctly, traceable to relevant process standard</li> <li>- Review of related records</li> </ul> <p><b>NOTE:</b> Accreditation to ISO/IEC 17025 may be used to demonstrate conformity but is not mandatory.</p> <p><b>External Labs</b> used for inspection, test or calibration services must have a defined scope that included the capability to perform the required inspection, test or calibration and either</p> <ul style="list-style-type: none"> <li>- Have evidence that the lab is acceptable to the customer or</li> <li>- The lab is accredited to ISO/IEC 17025 or equivalent</li> </ul> <p><b>Note1:</b> Evidence may be by customer assessment or customer approved 2<sup>nd</sup> party</p> <p><b>Note2:</b> when a qualified lab is not available for a given piece of equipment the service may be performed by the equipment manufacturer (7.6.3.1 must be met).</p>
Measurement Analysis and Improvement	8 8.1	8 8.1	<p><b>TS 16949 -</b> (Follows ISO)</p> <p><b>ISO 13485-</b> Has changed wording – c) To maintain the effectiveness of the quality management system. <b>NOTE:</b> National or regional regulations may require documented procedures for implementation and control of the application of statistical techniques.</p>
Identification of Statistical Tools	8.1.1	None	<p><b>TS 16949 – Has additional requirement:</b> To determine during advance quality planning appropriate statistical tools to be used and include them in control plans.</p>
Knowledge of Basic Statistical Concepts	8.1.2	None	<p><b>TS 16949 – Has additional requirement:</b> To ensure knowledge of Basic Statistical Concepts are understood and utilized through the organization.</p>
Monitoring and Measurement	8.2 8.2.1		<p><b>TS 16949 -</b> (Follows ISO) with an additional <b>NOTE:</b> Consideration should be given to both internal and external customers.</p> <p><b>ISO 13485-</b> Has changed wording – As one of the measurements of the QMS, the organization shall monitor information relating to whether the organization <b>has met customer requirements.</b> The organization shall establish a documented procedure for a feedback system to provide early warning of quality problems and for input into the corrective and preventive action processes.</p>

Requirement	ISO/TS 16949:2009 Reference	ISO 13485	Impact vs. TS
Customer Satisfaction - Supplemental	8.2.1.1	None	<b>TS 16949 – Has additional requirement:</b> Satisfaction is to be monitored through continual evaluation of the realization process. Performance indicators based on objective data and include but not limited to: - Delivered part quality performance - Customer disruptions including field returns - Delivery schedule performance (and premium freight) - Customer notification related to quality or delivery Must monitor the performance of the manufacturing process to demonstrate compliance with customer requirements for product quality & efficiency of process
Internal Audit	8.2.2	8.2.2	<b>TS 16949 -</b> (Follows ISO) <b>ISO 13485-</b> (Follows ISO) And has added to the <b>NOTE:</b> See ISO 19011 for guidance <i>related to quality auditing.</i>
Quality Management System Audit	8.2.2.1	None	<b>TS 16949 – Has additional requirement:</b> To audit the QMS to verify compliance with TS and any additional QMS requirements (customer specific requirements)
Manufacturing Process Audit	8.2.2.2	None	<b>TS 16949 – Has additional requirement:</b> To audit each manufacturing process to determine effectiveness
Product Audit	8.2.2.	None	<b>TS 16949 – Has additional requirement:</b> To audit products at appropriate stages of production and delivery for conformity to all specified requirements, dimensions, functionality, packaging, labeling, at a defined frequency.
Internal Audit Plans	8.2.2.4	None	<b>TS 16949 – Has additional requirement:</b> To cover all quality management related processes, activities and shifts; scheduled according to an annual plan. When internal/external nonconformities or customer complaints occur, the audit frequency must be appropriately increased.  <b>NOTE:</b> Specific checklists should be used for each audit.
Internal Auditor Qualifications	8.2.2.5	None	<b>TS 16949 – Has additional requirement:</b> To have internal auditors who are qualified to audit the requirements of the Technical Specification. (TS)
Monitoring and Measurement of Processes	8.2.3	8.2.3	<b>TS 16949 -</b> (Follows ISO) <b>ISO 13485-</b> (Follows ISO) And adds: To ensure conformity of the product.

Requirement	ISO/TS 16949:2009 Reference	ISO 13485	Impact vs. TS
Monitoring and Measurement of Manufacturing Processes	8.2.3.1	None	<p><b>TS 16949 – Has additional requirements:</b> To perform process studies on all new mfg. processes to verify process capability and provide input for process control. Results must be documented and include objectives for process capability, reliability, maintainability and availability as well as acceptance criteria. Must maintain process capability or performance as specified by the customer part approval process requirements. The control plan and process flow are implemented including adherence to:</p> <ul style="list-style-type: none"> <li>- Measurement technique</li> <li>- Sampling plans</li> </ul> <p>-Reaction plans when acceptance criteria is not met</p> <p>Recording of significant events (tool change, machine repairs). Initiate the reaction plan from the control plan for characteristics that are either not statistically capable or unstable –including containment and 100 % inspection as appropriate, completion of corrective action plans with specific timing and responsibilities. Plans are to be reviewed / approved by customer when required. Must maintain records of effective dates of process changes.</p>
Monitoring and Measurement of Product	8.2.4	8.2.4	<p><b>TS 16949 – Has additional NOTE:</b> When selecting product parameters to monitor compliance to specified internal and external requirements the organization determines the types of product characteristics, leading to;</p> <ul style="list-style-type: none"> <li>- The types of measurements</li> <li>- Suitable measurement means</li> <li>- The capability and skills required.</li> </ul> <p><b>ISO 13485- Has Added – And Documented Procedures. And has removed Unless otherwise approved by a relevant authority, and where appropriate , by the customer.</b></p>
General		8.2.4.1	
Layout Inspection and Functional Testing	8.2.4.1	See Above	<p><b>TS 16949 – Has additional requirements:</b> Requiring a layout and functional verification to applicable customer engineering, material and performance standards must be performed for each product as specified in control plans, results must be available for customer review.</p> <p><b>NOTE:</b> layout is the complete measurement of all product dimensions shown on design records.</p>
Appearance Items	8.2.4.2	8.2.4.1	<p><b>TS 16949 – Has additional requirements:</b> For parts designated as “appearance items” must provide:</p> <ul style="list-style-type: none"> <li>- Appropriate resources including lighting</li> <li>- Masters for color, grain, gloss, metallic brilliance, texture, DOI as appropriate.</li> <li>- Maintenance and control of appearance masters and evaluation equipment</li> <li>- Verification of personnel making acceptance evaluations are competent and qualified to do so.</li> </ul>

Requirement	ISO/TS 16949:2009 Reference	ISO 13485	Impact vs. TS
Particular requirement for active implantable medical devices and implantable medical devices	See above	8.2.4.2	<b>ISO 13485- Has additional requirement –</b> To record and identify personnel performing any inspection or testing.
Control of Nonconforming Product	8.3	8.3	<b>TS 16949 -</b> (Follows ISO) <b>ISO 13485- Has changed Wording – b)</b> Removed <b>By a relevant authority and, where applicable, by the customer. And –</b> Removed d). Also Added statements – The organization shall ensure that nonconforming product is accepted by concession only if regulatory requirements are met. Records of the identity of the person(s) authorizing the concession shall be maintained. And; If product needs to be reworked (one or more times), the organization shall document the rework process in a work instruction that has undergone the same authorization and approval procedure as the original work instruction. Prior to authorization and approval of the work instruction, a determination of any adverse effect of the rework upon product shall be made and documented.
Control of nonconforming product - supplemental	8.3.1	None	<b>TS 16949 – Has additional requirement:</b> To classify suspect product as nonconforming product. (7.5.3)
Control of Reworked Product	8.3.2	See 8.3 Above	<b>TS 16949 – Has additional requirement:</b> Instructions for rework, including re-inspections requirements, are to be accessible and utilized by appropriate personnel.
Customer Information	8.3.3	None	<b>TS 16949 – Has additional requirement:</b> To inform customers promptly when nonconforming product has been shipped.
Customer Waiver	8.3.4	None	<b>TS 16949 – Has additional requirement:</b> Must obtain customer concession or deviation permit prior to further processing whenever the product or manufacturing process is different from that which is currently approved. Must maintain a record of the expiration date or quantity authorized – ensure compliance with original or superseding specification and requirements when the authorization expires. Material shipped on an authorization is to be properly identified on the shipping container. Applies equally to purchased product, the organization shall approve suppliers requests before submission to the customer.

Requirement	ISO/TS 16949:2009 Reference	ISO 13485	Impact vs. TS
Analysis of Data	8.4	8.4	<b>TS 16949 -</b> (Follows ISO) <b>ISO 13485- Has changed Wording</b> – To establish documented procedures to determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the QMS and to evaluate <i>if improvement</i> of the effectiveness of the QMS can be made. And replaced a) “Customer Satisfaction” with “ <b>Feedback</b> ”. <b>Also</b> Added requirement for Records of the result of the analysis of data shall be maintained.
Analysis and Use of Data	8.4.1	None	<b>TS 16949 – Has additional requirement:</b> Trends in quality and performance must be compared toward objectives and lead to action to support: - Development of priorities for prompt solution of customer related problems. - Determination of key customer related trends and correlation for status review, decision making and longer term planning. - An information system for the timely reporting of product information arising from usage. <b>NOTE:</b> Data should be compared to competitors and/or appropriate benchmarks.
Improvement Continual Improvement	8.5 8.5.1	8.5 8.5.1	<b>TS 16949 -</b> (Follows ISO) <b>ISO 13485- Has changed Wording – As follows:</b> <b><i>The organization shall identify and implement any changes necessary to ensure and maintain the continued suitability and effectiveness of the QMS through the use of the Quality Policy, Quality Objectives, audit results, analysis of data, corrective and preventive actions and management review.</i></b> <b>And added requirements:</b> The organization shall establish documented procedures for the issue and implementation of advisory notices. These procedures shall be capable of being implemented at any time. Records of all customer complaint investigations shall be maintained . If investigation determines that the activities outside the organization contributed to the customer complaint, relevant information shall be exchanged between the organizations involved. If any customer complaint is not followed by corrective and/pr preventive action, the reason shall be authorized and recorded. If national or regional regulations required notification of adverse events that meet specified reporting criteria, the organization shall establish documented procedures to such notification to regulatory authorities.
Continual Improvement of the organization	8.5.1.1	None	<b>TS 16949 – Has additional requirement:</b> To define a process for continual improvement.

Requirement	ISO/TS 16949:2009 Reference	ISO 13485	Impact vs. TS
Manufacturing Process Improvement	8.5.1.2	None	<b>TS 16949 – Has additional requirement and 2 NOTES:</b> To continually focus upon control and reduction of variation in product characteristics and manufacturing process parameters. <b>NOTE 1:</b> Controlled characteristics are documented in the control plan. <b>NOTE 2:</b> Continual improvement is implemented once manufacturing processes are capable and stable, or product characteristics are predictable and meet customer requirements.
Corrective Action	8.5.2	8.5.2	<b>TS 16949 - (Follows ISO)</b> <b>ISO 13485- Has changed Wording – d)</b> Determining and implementing action needed, including, if appropriate, updating documentation. <b>And – e)</b> Recording of the results of any investigation and of action taken. <b>And – f)</b> Reviewing the corrective action taken and its effectiveness.
Problem Solving	8.5.2.1	None	<b>TS 16949 – Has additional requirement:</b> To define a process for problem solving leading to root cause identification and elimination.
Error Proofing	8.5.2.2	None	<b>TS 16949 – Has additional requirement:</b> To use error-proofing methods in their corrective action process.
Corrective Action Impact	8.5.2.3	None	<b>TS 16949 – Has additional requirement:</b> To apply to other similar processes and products the corrective action, and to controls implemented, to eliminate the cause of nonconformity.
Rejected Product Test/Analysis	8.5.2.4	None	<b>TS 16949 – Has additional requirements and NOTE:</b> To analyze parts rejected by the customer's manufacturing plants, engineering facilities and dealerships. To minimize cycle time for this process. Records are to be kept and made available upon request. To perform analysis and initiate corrective action to prevent recurrence. <b>NOTE:</b> Cycle time related to rejected product analysis should be consistent with the determination or root cause, corrective action and monitoring the effectiveness of implementation.
Preventive Action	8.5.3	8.5.3	<b>TS 16949 - (Follows ISO)</b> <b>ISO 13485- Has changed Wording – d)</b> Recording the results of any investigations and of actions taken. <b>And - e)</b> Reviewing preventive action taken and its effectiveness.