



AS9100 Rev B (2004) Comparison with AS9100 Rev C (2009)

The differences between AS9100 Rev B (2004) and AS9100 Rev C (2009) are shown in the comparison matrix below.

In order to provide a more visual overview, different text attributes are used in this document. All ISO 9001 text is shown in plain black, and AS9100-specific text is in *blue italics*. Deleted text (both AS9100 Rev B and ISO 9001:2000) is indicated by ~~strikethrough~~, and new text (both AS9100 Rev C and ISO 9001:2008) is in underlined red.

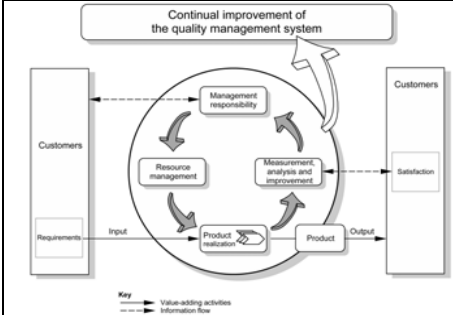
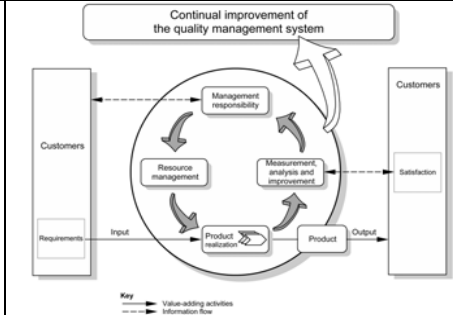
The *italics*, ~~strikethrough~~ and underlining will allow readers to see the changes, even if printed without color.

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AS9100 Rev B (2004)	AS9100 Rev C (2009)	Comments
Quality Management Systems - Aerospace— Requirements	Quality Management Systems – Requirements for Aviation, Space and Defense Organizations	
Foreword	Foreword	
<i>To assure customer satisfaction, aerospace industry organizations must produce, and continually improve, safe, reliable products that meet or exceed customer and regulatory authority requirements. The globalization of the aerospace industry, and the resulting diversity of regional/ national requirements and expectations, has complicated this objective. End-product organizations face the challenge of assuring the quality of, and integrating, product purchased from suppliers throughout the world and at all levels within the supply chain. Aerospace suppliers and processors face the challenge of delivering product to multiple customers having varying quality expectations and requirements.</i>	<i>To assure customer satisfaction, aviation, space and defense organizations must produce, and continually improve, safe, reliable products that meet or exceed customer and applicable statutory and regulatory requirements. The globalization of the industry and the resulting diversity of regional and national requirements and expectations have complicated this objective. Organizations have the challenge of purchasing products from suppliers throughout the world and at all levels of the supply chain. Suppliers have the challenge of delivering products to multiple customers having varying quality requirements and expectations.</i>	AS9100 adds space and defense organizations to the scope. The new scope also allows use in other industries where beneficial. Other minor clarifications have been added throughout.
<i>The aerospace industry established the International Aerospace Quality Group (IAQG) for the purpose of achieving significant improvements in quality and safety, and reductions in cost, throughout the value stream. This organization includes representation from aerospace companies in the Americas, Asia/Pacific, and Europe. This international standard has been prepared by the IAQG.</i>	<i>Industry has established the International Aerospace Quality Group (IAQG), with representatives from companies in the Americas, Asia/Pacific and Europe, to implement initiatives that make significant improvements in quality and reductions in cost throughout the value stream. This standard has been prepared by the IAQG.</i>	
<i>This document standardizes, to the greatest extent possible, quality management system requirements for the aerospace industry. The establishment of common requirements, for use at all levels of the supply-chain, by organizations around the world, should result in improved quality and safety, and decreased costs, due to the elimination or reduction of organization-unique requirements and the resultant variation inherent in these multiple expectations.</i>	<i>This document standardizes quality management system requirements to the greatest extent possible and can be used at all levels of the supply chain by organizations around the world. Its use should result in improved quality, schedule and cost performance by the reduction or elimination of organization-unique requirements and wider application of good practice. While primarily developed for the aviation, space and defense industry, this standard can also be used in other industry sectors where a quality management system with additional requirements over an ISO 9001 system is needed.</i>	
Revision summary	Revision summary/Rationale	AS9100 adds rationale to header.
<i>The portion of the standard that was based on ISO 9001:1994 has been deleted and the Bibliography has been updated. This revision has not changed the technical content of the standard and is considered administrative in nature.</i>	<i>This standard has been revised to incorporate the requirements of ISO 9001:2008. In addition, industry requirements, definitions and notes have been revised and additional requirements have been included in response to stakeholder needs.</i>	AS9100 includes changes to ISO 9001:2008 and other changes to meet stakeholder needs.
Introduction	Introduction	
General	0.1 General	AS9100 restores numbering.
The adoption of a quality management system should be a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by varying needs, particular objectives, the products provided, the processes employed and the size and structure of the organization. It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.	The adoption of a quality management system should be a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by a) its organizational environment, changes in that environment, and the risks associated with that environment, b) its varying needs, c) its particular objectives, d) the products it provides, e) the processes it employs, f) its size and organizational structure. It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.	ISO 9001:2008 adds clarification that "business environment," including risk, is an aspect that influences quality management system design and implementation.
The quality management system requirements specified in this International Standard are complementary to requirements for products. Information marked "NOTE" is for guidance in understanding or clarifying the associated requirement.	The quality management system requirements specified in this International Standard are complementary to requirements for products. Information marked "NOTE" is for guidance in understanding or clarifying the associated requirement.	
This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, regulatory and the organization's own requirements.	This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, statutory and regulatory requirements applicable to the product, and the organization's own requirements.	ISO 9001:2008 adds statutory requirements throughout the standard.
The quality management principles stated in ISO 9000 and ISO 9004 have been taken into consideration during the development of this International Standard.	The quality management principles stated in ISO 9000 and ISO 9004 have been taken into consideration during the development of this International Standard.	

AS9100 Rev B (2004)	AS9100 Rev C (2009)	Comments
<p>Process Approach</p> <p>This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements.</p> <p>For an organization to function effectively, it has to identify and manage numerous linked activities. An activity using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one process directly forms the input to the next.</p> <p>The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management, can be referred to as the “process approach”.</p> <p>An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.</p> <p>When used within a quality management system, such an approach emphasizes the importance of</p> <ol style="list-style-type: none"> understanding and meeting 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. <p>The model of a process-based quality management system shown in Figure 1 illustrates the process linkages presented in clauses 4 to 8. This illustration shows that customers play a significant role in defining requirements as inputs. Monitoring of customer satisfaction requires the evaluation of information relating to customer perception as to whether the organization has met the customer requirements. The model shown in Figure 1 covers all the requirements of this International Standard, but does not show processes at a detailed level.</p> <p>NOTE: In addition, the methodology known as “Plan-Do-Check-Act” (PDCA) can be applied to all processes. PDCA can be briefly described as follows. Plan: establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization’s policies. Do: implement the processes. Check: monitor and measure processes and product against policies, objectives and requirements for the product and report the results. Act: take actions to continually improve process performance.</p>  <p>FIGURE 1 - Model of a Process-Based Quality Management System</p>	<p>0.2 Process Approach</p> <p>This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements.</p> <p>For an organization to function effectively, it has to determine and manage numerous linked activities. An activity or set of activities using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one process directly forms the input to the next.</p> <p>The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management to produce the desired outcome, can be referred to as the “process approach”.</p> <p>An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.</p> <p>When used within a quality management system, such an approach emphasizes the importance of</p> <ol style="list-style-type: none"> understanding and meeting 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. <p>The model of a process-based quality management system shown in Figure 1 illustrates the process linkages presented in clauses 4 to 8. This illustration shows that customers play a significant role in defining requirements as inputs. Monitoring of customer satisfaction requires the evaluation of information relating to customer perception as to whether the organization has met the customer requirements. The model shown in Figure 1 covers all the requirements of this International Standard, but does not show processes at a detailed level.</p> <p>NOTE In addition, the methodology known as “Plan-Do-Check-Act” (PDCA) can be applied to all processes. PDCA can be briefly described as follows. Plan: establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization’s policies. Do: implement the processes. Check: monitor and measure processes and product against policies, objectives and requirements for the product and report the results. Act: take actions to continually improve process performance.</p>  <p>FIGURE 1 - Model of a Process-Based Quality Management System</p>	<p>AS9100 restores numbering.</p> <p>ISO 9001:2008 adds minor clarifications. “Identify” is replaced by “determine,” a more proactive word implying analysis and decision, rather than just discovery.</p> <p>ISO 9001:2008 emphasizes that processes and their interactions should “produce the desired outcome.” In other words, the system and processes must be effective.</p>

AS9100 Rev B (2004)	AS9100 Rev C (2009)	Comments
1. Scope	1. Scope	
1.1 General	1.1 General	
<p><i>This standard includes ISO 9001:2000¹ quality management system requirements and specifies additional requirements for a quality management system for the aerospace industry. The additional aerospace requirements are shown in bold, italic text.</i></p>	<p><i>This standard includes ISO 9001:2008¹ quality management system requirements and specifies additional aviation, space and defense industry requirements, definitions and notes as shown in bold, italic text.</i></p>	<p>The AS9100 revision includes all requirements of ISO 9001:2008 as well as additional industry requirements for aviation, space and defense consistent with the revised scope of the document.</p>
<p><i>It is emphasized that the quality management system requirements specified in this standard are complementary (not alternative) to contractual and applicable law and regulatory requirements.</i></p>	<p><i>It is emphasized that the requirements specified in this standard are complementary (not alternative) to contractual and applicable statutory and regulatory requirements. Should there be a conflict between the requirements of this standard and applicable statutory or regulatory requirements, the latter shall take precedence.</i></p>	<p>If a conflict exists between AS9100 and legal requirements, the legal requirements take precedence.</p>
<p>This International Standard specifies requirements for a quality management system where an organization</p> <p>a) needs to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements, and</p> <p>b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements.</p>	<p>This International Standard specifies requirements for a quality management system where an organization</p> <p>a) needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements, and</p> <p>b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.</p>	<p>ISO 9001:2008 clarifies that the term “product” applies not only to product for a customer, but also to product needed for realization processes. Also, “statutory and regulatory” means legal.</p>
<p>NOTE: In this International Standard, the term “product” applies only to the product intended for, or required by, a customer.</p>	<p>NOTE 1 In this International Standard, the term “product” only applies to</p> <p>a) product intended for, or required by, a customer.</p> <p>b) any intended output resulting from the product realization processes.</p>	
	<p>NOTE 2 Statutory and regulatory requirements may be expressed as legal requirements.</p>	
1.2 Application	1.2 Application	
<p>All requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product provided.</p>	<p>All requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product provided.</p>	
<p>Where any requirement(s) of this International Standard cannot be applied due to the nature of an organization and its product, this can be considered for exclusion.</p>	<p>Where any requirement(s) of this International Standard cannot be applied due to the nature of an organization and its product, this can be considered for exclusion.</p>	
<p>Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within clause 7, and such exclusions do not affect the organization’s ability, or responsibility, to provide product that meets customer and applicable regulatory requirements.</p>	<p>Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within clause 7, and such exclusions do not affect the organizations ability, or responsibility, to provide product that meets customer and applicable statutory and regulatory requirements.</p>	<p>ISO 9001:2008 adds statutory requirements throughout the standard.</p>
	<p><i>This standard is intended for use by organizations that design, develop and/or produce aviation, space and defense products; and by organizations providing post-delivery support, including the provision of maintenance, spare parts or materials for their own products.</i></p>	<p>AS9100 now provides clarification on the scopes of three aviation, space and defense standards:</p>
	<p><i>Organizations whose primary business is providing maintenance, repair and overhaul services for aviation commercial and military products; and original equipment manufacturers with maintenance, repair and overhaul operations that operate autonomously, or that are substantially different from their manufacturing/production operations; should use the IAQG-developed 9110 standard (see Bibliography).</i></p>	<p>AS9100 is for organizations that design, develop and produce products.</p> <p>AS9110 is for organizations that provide maintenance, repair and overhaul services.</p>
	<p><i>Organizations that procure parts, materials and assemblies and resell these products to a customer in the aviation, space and defense industries, including organizations that procure products and split them into smaller quantities for resale, should use the IAQG-developed 9120 standard (see Bibliography).</i></p>	<p>AS9120 is for organizations that buy products and resell them</p>
<p>¹ With the permission of the International Organization for Standardization (ISO). The complete standard may be obtained from any ISO member or from the ISO Central Secretariat, Case Postale 56, 1211 Geneva 20, Switzerland. Copyright remains with ISO.</p>	<p>¹ With the permission of the International Organization for Standardization (ISO). The complete standard can be obtained from any ISO member or from the ISO Central Secretariat: 1, ch. de la Voie-Creuse, Case postale 56, CH-1211 Geneva 20, SWITZERLAND, or visit www.iso.org. Copyright remains with ISO.</p>	<p>AS9100 adds contact information for ISO.</p>

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<p>2. Normative reference</p> <p>The following normative document contains provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO (<i>International Organization for Standardization</i>) and IEC (<i>International Electrotechnical Commission</i>) maintain registers of currently valid International Standards.</p> <p>ISO 9000:2000, Quality management systems - Fundamentals and vocabulary.</p>	<p>2. Normative references</p> <p>The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.</p> <p>ISO 9000:2005, Quality management systems — Fundamentals and vocabulary.</p>	<p>ISO 9001:2008 updates the normative reference from ISO 9000:2000 to ISO 9000:2005</p>
<p>3. Terms and definitions</p> <p>For the purposes of this International Standard, the terms and definitions given in ISO 9000 apply.</p> <p>The following terms, used in this edition of ISO 9001 to describe the supply chain, have been changed to reflect the vocabulary currently used:</p> <p style="text-align: center;">supplier → organization → customer</p> <p>The term “organization” replaces the term “supplier” used in ISO 9001:1994, and refers to the unit to which this International Standard applies. Also, the term “supplier” now replaces the term “subcontractor”. Throughout the text of this International Standard, wherever the term “product” occurs, it can also mean “service”.</p>	<p>3. Terms and definitions</p> <p>For the purposes of this document, the terms and definitions given in ISO 9000 apply.</p> <p>Throughout the text of this International Standard, wherever the term “product” occurs, it can also mean “service”.</p>	<p>ISO 9001:2008 removes text describing changes from the old ISO 9001:1994 version.</p>
<p>Key Characteristics: <i>The features of a material, process, or part whose variation has a significant influence on product fit, performance, service life, or manufacturability.</i></p>	<p>3.1 Risk <i>An undesirable situation or circumstance that has both a likelihood of occurring and a potentially negative consequence.</i></p> <p>3.2 Special requirements <i>Those requirements identified by the customer, or determined by the organization, which have high risks to being achieved, thus requiring their inclusion in the risk management process. Factors used in the determination of special requirements include product or process complexity, past experience and product or process maturity. Examples of special requirements include performance requirements imposed by the customer that are at the limit of the industry’s capability, or requirements determined by the organization to be at the limit of its technical or process capabilities.</i></p> <p>3.3 Critical items <i>Those items (e.g., functions, parts, software, characteristics, processes) having significant effect on the product realization and use of the product: including safety, performance, form, fit, function, producibility, service life, etc.; that require specific actions to ensure they are adequately managed. Examples of critical items include safety critical items, fracture critical items, mission critical items, key characteristics, etc.</i></p> <p>3.4 Key Characteristic <i>An attribute or feature whose variation has a significant effect on product fit, form, function, performance, service life or producibility, that requires specific actions for the purpose of controlling variation. NOTE Special requirements and critical items are new terms and, along with key characteristics, are interrelated. Special requirements are identified when determining and reviewing requirements related to the product (see 7.2.1 and 7.2.2). Special requirements can require the identification of critical items. Design output (see 7.3.3) can include identification of critical items that require specific actions to ensure they are adequately managed. Some critical items will be further classified as key characteristics because their variation needs to be controlled.</i></p>	<p>AS9100 adds definitions for Risk, Special Requirements, and Critical Items. These terms are used as appropriate throughout the new version.</p> <p>AS9100 clarifies the definition for Key Characteristic.</p>

AS9100 Rev B (2004)	AS9100 Rev C (2009)	Comments
4 Quality management system	4 Quality management system	
4.1 General requirements	4.1 General requirements	
The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.	The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard. <i>The organization's quality management system shall also address customer and applicable statutory and regulatory quality management system requirements.</i>	AS9100 adds clarification that the quality management system must address customer and legal requirements.
The organization shall a) identify the processes needed for the quality management system and their application throughout the organization (see 1.2), b) determine the sequence and interaction of these processes, c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective, d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes, e) monitor, measure and analyse these processes, and f) implement actions necessary to achieve planned results and continual improvement of these processes.	The organization shall a) identify <i>determine</i> the processes needed for the quality management system and their application throughout the organization (see 1.2), b) determine the sequence and interaction of these processes, c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective, d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes, e) monitor, measure <i>where applicable</i> , and analyse these processes, and f) implement actions necessary to achieve planned results and continual improvement of these processes.	ISO 9001:2008 adds minor clarifications in this clause. "Determine the processes" replaces "identify the processes." Determine is a more proactive word implying analysis and decision, rather than just discovery. ISO 9001:2008 recognizes that although all processes must be monitored, not all may need to be measured. ISO 9001:2008 Note 1 removes the word "should." This emphasizes the fact the quality management system processes defined and controlled by the organization must include more than just "product realization" processes. It also adds "analysis" and "improvement" processes.
These processes shall be managed by the organization in accordance with the requirements of this International Standard.	These processes shall be managed by the organization in accordance with the requirements of this International Standard.	
Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes.	Where an organization chooses to outsource any process that affects product conformity <i>to</i> requirements, the organization shall ensure control over such processes.	
Control of such outsourced processes shall be identified within the quality management system.	<i>The type and extent of control to be applied to these</i> outsourced processes shall be <i>defined</i> within the quality management system.	ISO 9001:2008 provides extensive clarification about outsourced processes. This includes: • Emphasis that outsourced process controls are not just identified, but are defined and applied. • Clarification of what an outsourced process is. • Considerations for controls of outsourced processes. • An inferred linkage between outsourced processes and the purchasing clause 7.4. • Responsibility for all requirements remains with the organization even when processes are outsourced.
NOTE Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement.	NOTE <u>1</u> Processes needed for the quality management system referred to above include processes for management activities, provision of resources, product realization, measurement, <i>analysis and improvement.</i>	
	<i>NOTE 2 An "outsourced process" is a process that the organization needs for its quality management system and which the organization chooses to have performed by an external party.</i>	
	<i>NOTE 3 Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory and regulatory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such as a) the potential impact of the outsourced process on the organization's capability to provide product that conforms to requirements, b) the degree to which the control for the process is shared, c) the capability of achieving the necessary control through the application of 7.4.</i>	

AS9100 Rev B (2004)	AS9100 Rev C (2009)	Comments
4.2 Documentation requirements	4.2 Documentation requirements	
4.2.1 General	4.2.1 General	
<p>The quality management system documentation shall include</p> <ul style="list-style-type: none"> a) documented statements of a quality policy and quality objectives, b) a quality manual, c) documented procedures required by this International Standard, d) documents needed by the organization to ensure the effective planning, operation and control of its processes, e) records required by this International Standard (see 4.2.4), and f) quality system requirements imposed by the applicable regulatory authorities. <p>The organization shall ensure that personnel have access to quality management system documentation and are aware of relevant procedures.</p> <p>Customer and/or regulatory authorities representatives shall have access to quality management system documentation.</p>	<p>The quality management system documentation shall include</p> <ul style="list-style-type: none"> a) documented statements of a quality policy and quality objectives, b) a quality manual, c) documented procedures and records required by this International Standard, and d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes. <p><i>The organization shall ensure that personnel have access to, and are aware of, relevant quality management system documentation and changes.</i></p>	<p>ISO 9001:2008 shuffles the records requirement from e) to c). Also provides clarification for organization documents.</p> <p>AS9100 removes the regulatory reference now implied in 4.1.</p> <p>AS9100 adds the requirement for access and awareness of relevant documentation changes.</p>
<p>NOTE 1 Where the term “documented procedure” appears within this International Standard, this means that the procedure is established, documented, implemented and maintained.</p>	<p>(Deleted)</p>	<p>AS9100 removes regulatory authority access requirement now included in 4.1.</p>
<p>NOTE 2 The extent of the quality management system documentation can differ from one organization to another due to</p> <ul style="list-style-type: none"> a) the size of organization and type of activities, b) the complexity of processes and their interactions, and c) the competence of personnel. 	<p>NOTE 2 The extent of the quality management system documentation can differ from one organization to another due to</p> <ul style="list-style-type: none"> a) the size of organization and type of activities, b) the complexity of processes and their interactions, and c) the competence of personnel. <p><i>A single document may address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.</i></p>	<p>ISO 9001:2008 Note 1 provides clarification that a “documented procedure” does not imply a single document. Also multiple procedures may be included in a single document according to the organization’s needs.</p>
<p>NOTE 3 The documentation can be in any form or type of medium.</p>	<p>NOTE 3 The documentation can be in any form or type of medium.</p>	
4.2.2 Quality manual	4.2.2 Quality manual	
<p>The organization shall establish and maintain a quality manual that includes</p> <ul style="list-style-type: none"> a) the scope of the quality management system, including details of and justification for any exclusions (see 1.2), b) the documented procedures established for the quality management system, or reference to them, and — when referencing the documented procedures, the relationship between the requirements of this International Standard and the documented procedures shall be clearly shown. c) a description of the interaction between the processes of the quality management system. 	<p>The organization shall establish and maintain a quality manual that includes</p> <ul style="list-style-type: none"> a) the scope of the quality management system, including details of and justification for any exclusions (see 1.2), b) the documented procedures established for the quality management system, or reference to them, and c) a description of the interaction between the processes of the quality management system. 	<p>AS9100 removes the requirement that quality manual references to procedures include linkage to AS9100 requirements.</p>
4.2.3 Control of documents	4.2.3 Control of documents	
<p>Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.</p>	<p>Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.</p>	
<p>A documented procedure shall be established to define the controls needed</p> <ul style="list-style-type: none"> a) to approve documents for adequacy prior to issue, b) to review and update as necessary and re-approve documents, c) to ensure that changes and the current revision status of documents are identified, d) to ensure that relevant versions of applicable documents are available at points of use, e) to ensure that documents remain legible and readily identifiable, f) to ensure that documents of external origin are identified and their distribution controlled, and g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose. 	<p>A documented procedure shall be established to define the controls needed</p> <ul style="list-style-type: none"> a) to approve documents for adequacy prior to issue, b) to review and update as necessary and re-approve documents, c) to ensure that changes and the current revision status of documents are identified, d) to ensure that relevant versions of applicable documents are available at points of use, e) to ensure that documents remain legible and readily identifiable, f) to ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose. 	<p>ISO 9001:2008 provides clarity that only external documents needed by the organization must be identified and distribution controlled.</p>
<p>The organization shall coordinate document changes with customers and/or regulatory authorities in accordance with contract or regulatory requirements.</p>	<p>(Deleted)</p>	<p>AS9100 deletes a requirement now addressed in 4.1.</p>

AS9100 Rev B (2004)	AS9100 Rev C (2009)	Comments
4.2.4 Control of records	4.2.4 Control of records	
Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system.	Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled.	ISO 9001:2008 clarifies that the "maintenance" of required records is actually "control" as specified below.
Records shall remain legible, readily identifiable and retrievable.	(Moved to below)	
A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.	The organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.	ISO 9001:2008 minor rewording.
<i>The documented procedure shall define the method for controlling records that are created by and/or retained by suppliers.</i>	<i>The documented procedure shall define the method for controlling records that are created by and/or retained by suppliers.</i>	
Records shall be available for review by customers and regulatory authorities in accordance with contract or regulatory requirements.	(Deleted)	AS9100 deletes a requirement now addressed in 4.1.
(Moved from above)	Records shall remain legible, readily identifiable and retrievable.	
4.3 Configuration Management	(Moved to 7.1.3)	AS9100 moved configuration management clause to 7.1.3 as it applies throughout product realization.
<i>The organization shall establish, document and maintain a configuration management process appropriate to the product.</i>		
<i>NOTE: Guidance on configuration management is given in ISO 10007.</i>		
5 Management responsibility	5 Management responsibility	
5.1 Management commitment	5.1 Management commitment	
Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements, b) establishing the quality policy, c) ensuring that quality objectives are established, d) conducting management reviews, and e) ensuring the availability of resources.	Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements, b) establishing the quality policy, c) ensuring that quality objectives are established, d) conducting management reviews, and e) ensuring the availability of resources.	No changes.
5.2 Customer focus	5.2 Customer focus	
Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1).	Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1).	AS9100 adds requirements for measurements of product conformity and on-time delivery performance. Also actions if results are not achieved
	<i>Top management shall ensure that product conformity and on-time delivery performance are measured and that appropriate action is taken if planned results are not, or will not be, achieved.</i>	
5.3 Quality policy	5.3 Quality policy	
Top management shall ensure that the quality policy a) is appropriate to the purpose of the organization, b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system, c) provides a framework for establishing and reviewing quality objectives, d) is communicated and understood within the organization, and e) is reviewed for continuing suitability.	Top management shall ensure that the quality policy a) is appropriate to the purpose of the organization, b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system, c) provides a framework for establishing and reviewing quality objectives, d) is communicated and understood within the organization, and e) is reviewed for continuing suitability.	No changes.
5.4 Planning	5.4 Planning	
5.4.1 Quality objectives	5.4.1 Quality objectives	
Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within the organization.	Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within the organization.	No changes.
The quality objectives shall be measurable and consistent with the quality policy.	The quality objectives shall be measurable and consistent with the quality policy.	

AS9100 Rev B (2004)	AS9100 Rev C (2009)	Comments
5.4.2 Quality management system planning Top management shall ensure that a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.	5.4.2 Quality management system planning Top management shall ensure that a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.	No changes.
5.5 Responsibility, authority and communication	5.5 Responsibility, authority and communication	
5.5.1 Responsibility and authority	5.5.1 Responsibility and authority	
Top management shall ensure that responsibilities and authorities are defined and communicated within the organization.	Top management shall ensure that the responsibilities and authorities are defined and communicated within the organization.	No changes.
5.5.2 Management representative	5.5.2 Management representative	
Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes a) ensuring that processes needed for the quality management system are established, implemented and maintained, b) reporting to top management on the performance of the quality management system and any need for improvement, c) ensuring the promotion of awareness of customer requirements throughout the organization, <i>and</i> d) <i>the organizational freedom to resolve matters pertaining to quality.</i>	Top management shall appoint a member of <i>the organization's</i> management who, irrespective of other responsibilities, shall have responsibility and authority that includes a) ensuring that processes needed for the quality management system are established, implemented and maintained, b) reporting to top management on the performance of the quality management system and any need for improvement, c) ensuring the promotion of awareness of customer requirements throughout the organization, <i>and</i> d) <i>the organizational freedom and unrestricted access to top management to resolve quality management issues.</i>	ISO 9001:2008 clarifies that the management representative is a member of the organization's management. AS9100 adds to the management representative's authority the unrestricted access to top management to resolve quality management issues.
NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.	NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.	
5.5.3 Internal communication	5.5.3 Internal communication	
Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.	Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.	No changes.
5.6 Management review	5.6 Management review	
5.6.1 General	5.6.1 General	
Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Records from management reviews shall be maintained (see 4.2.4).	Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Records from management reviews shall be maintained (see 4.2.4).	No changes.
5.6.2 Review input	5.6.2 Review input	
The input to management review shall include information on a) results of audits, b) customer feedback, c) process performance and product conformity, d) status of preventive and corrective actions, e) follow-up actions from previous management reviews, f) changes that could affect the quality management system, and g) recommendations for improvement.	The input to management review shall include information on a) results of audits, b) customer feedback, c) process performance and product conformity, d) status of preventive and corrective actions, e) follow-up actions from previous management reviews, f) changes that could affect the quality management system, and g) recommendations for improvement.	No changes.
5.6.3 Review output	5.6.3 Review output	
The output from the management review shall include any decisions and actions related to a) improvement of the effectiveness of the quality management system and its processes, b) improvement of product related to customer requirements, and c) resource needs.	The output from the management review shall include any decisions and actions related to a) improvement of the effectiveness of the quality management system and its processes, b) improvement of product related to customer requirements, and c) resource needs.	No changes.

AS9100 Rev B (2004)	AS9100 Rev C (2009)	Comments
6 Resource management	6 Resource management	
6.1 Provision of resources	6.1 Provision of resources	
The organization shall determine and provide the resources needed a) to implement and maintain the quality management system and continually improve its effectiveness, and b) to enhance customer satisfaction by meeting customer requirements.	The organization shall determine and provide the resources needed a) to implement and maintain the quality management system and continually improve its effectiveness, and b) to enhance customer satisfaction by meeting customer requirements.	No changes.
6.2 Human resources	6.2 Human resources	
6.2.1 General	6.2.1 General	
Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.	Personnel performing work affecting <u>conformity to product requirements</u> shall be competent on the basis of appropriate education, training, skills and experience. <u>NOTE Conformity to product requirements can be affected directly or indirectly by personnel performing any task within the quality management system.</u>	ISO 9001:2008 clarifies that the intent of "product quality" is conformity to product requirements. Personnel may affect conformity directly (e.g. production personnel) or indirectly (e.g. management or design personnel).
6.2.2 Competence, awareness and training	6.2.2 Competence, <u>training</u> and <u>awareness</u>	ISO 9001:2008 reorders the words in the section title.
The organization shall a) determine the necessary competence for personnel performing work affecting product quality , b) provide training or take other actions to satisfy these needs , c) evaluate the effectiveness of the actions taken, d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and e) maintain appropriate records of education, training, skills and experience (see 4.2.4).	The organization shall a) determine the necessary competence for personnel performing work affecting <u>conformity to product requirements</u> , b) <u>where applicable</u> , provide training or take other actions to <u>achieve the necessary competence</u> , c) evaluate the effectiveness of the actions taken, d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and e) maintain appropriate records of education, training, skills and experience (see 4.2.4).	ISO 9001:2008 again clarifies that the intent of "product quality" is conformity to product requirements. The words "where applicable" were added, as there may be no need to provide training or take actions if the person is already competent. Item c) was rewritten to ensure understanding that the end result of actions taken must be the necessary competence.
6.3 Infrastructure	6.3 Infrastructure	
The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable a) buildings, workspace and associated utilities, b) process equipment (both hardware and software), and c) supporting services (such as transport or communication).	The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable a) buildings, workspace and associated utilities, b) process equipment (both hardware and software), and c) supporting services (such as transport, communication <u>or information systems</u>).	ISO 9001:2008 adds information systems as another example of a supporting service.
6.4 Work environment	6.4 Work environment	
The organization shall determine and manage the work environment needed to achieve conformity to product requirements. <u>NOTE: Factors that may affect the conformity of the product include temperature, humidity, lighting, cleanliness, protection from electrostatic discharge, etc.</u>	The organization shall determine and manage the work environment needed to achieve conformity to product requirements. <u>NOTE The term "work environment" relates to those conditions under which work is performed including physical, environmental and other factors (such as noise, temperature, humidity, lighting, or weather).</u>	ISO 9001:2008 adds a note similar to the note in AS9100:2004. This made the AS9100 note redundant.

AS9100 Rev B (2004)	AS9100 Rev C (2009)	Comments
7 Product realization	7 Product realization	
7.1 Planning of product realization	7.1 Planning of product realization	
The organization shall plan and develop the processes needed for product realization.	The organization shall plan and develop the processes needed for product realization.	
Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1).	Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1).	
In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product;	In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; <i>NOTE Quality objectives and requirements for the product include consideration of aspects such as</i> <i>- product and personal safety,</i> <i>- reliability, availability and maintainability,</i> <i>- producibility and inspectability,</i> <i>- suitability of parts and materials used in the product,</i> <i>- selection and development of embedded software, and</i> <i>- recycling or final disposal of the product at the end of its life.</i>	AS9100 adds guidance on aspects to consider when determining product quality objectives and requirements.
b) the need to establish processes, documents, and provide resources specific to the product;	b) the need to establish processes <u>and</u> documents, and <u>to</u> provide resources specific to the product;	ISO 9001:2008 adds appropriate product "measurement" activities.
c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;	c) required verification, validation, monitoring, <u>measurement</u> , inspection and test activities specific to the product and the criteria for product acceptance;	AS9100 adds configuration management to product realization planning (see 7.1.3). Also a minor wording change in identification of resources.
d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4);	d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4);	
e) the identification of resources to support operation and maintenance of the product.	e) <u>configuration management appropriate to the product;</u> f) <u>resources to support the use and maintenance of the product.</u>	
The output of this planning shall be in a form suitable for the organization's method of operations.	The output of this planning shall be in a form suitable for the organization's method of operations.	
NOTE 1 A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan.	NOTE 1 A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract can be referred to as a quality plan.	
NOTE 2 The organization may also apply the requirements given in 7.3 to the development of product realization processes.	NOTE 2 The organization may also apply the requirements given in 7.3 to the development of product realization processes.	
	7.1.1 Project Management	New AS9100 header.
	<i>As appropriate to the organization and the product, the organization shall plan and manage product realization in a structured and controlled manner to meet requirements at acceptable risk, within resource and schedule constraints.</i>	AS9100 adds new project management requirements to mitigate risks and meet resource and schedule restraints.
	7.1.2 Risk Management	New AS9100 header.
	<i>The organization shall establish, implement and maintain a process for managing risk to the achievement of applicable requirements, that includes as appropriate to the organization and the product</i> <i>a) assignment of responsibilities for risk management,</i> <i>b) definition of risk criteria (e.g., likelihood, consequences, risk acceptance),</i> <i>c) identification, assessment and communication of risks throughout product realization,</i> <i>d) identification, implementation and management of actions to mitigate risks that exceed the defined risk acceptance criteria, and</i> <i>e) acceptance of risks remaining after implementation of mitigating actions.</i>	AS9100 adds risk management requirements including: • responsibilities • risk criteria • identification, assessment and communication of risks • actions to mitigate risks • acceptance of unmitigated risks
(Moved from 4.3)	7.1.3 Configuration Management	AS9100 header moved from 4.3.
(Moved from 4.3)	<i>The organization shall establish, <u>implement</u> and maintain a configuration management process that includes, as appropriate to the product</i> <i>a) <u>configuration management planning,</u></i> <i>b) <u>configuration identification,</u></i> <i>c) <u>change control,</u></i> <i>d) <u>configuration status accounting, and</u></i> <i>e) <u>configuration audit.</u></i> <i>NOTE See ISO 10007 for guidance.</i>	The AS9100 configuration management clause was moved from 4 to 7, as it should be applied throughout product realization. More detail is provided as to what must be included.

AS9100 Rev B (2004)	AS9100 Rev C (2009)	Comments
<i>(Moved from 7.5.1.4)</i>	7.1.4 Control of work transfers	AS9100 header moved from 7.5.1.4.
<i>(Moved from 7.5.1.4)</i>	<i>The organization shall establish, implement and maintain a process to plan and control the temporary or permanent transfer of work (e.g., from one organization facility to another, from the organization to a supplier, from one supplier to another supplier) and to verify the conformity of the work to requirements.</i>	The AS9100 work transfer clause moved from 7.5, as it also includes planning. It now also addresses permanent transfers. More detail is provided for clarification.
7.2 Customer-related processes	7.2 Customer-related processes	
7.2.1 Determination of requirements related to the product	7.2.1 Determination of requirements related to the product	
The organization shall determine a) requirements specified by the customer, including the requirements for delivery and post-delivery activities, b) requirements not stated by the customer but necessary for specified or intended use, where known, c) statutory and regulatory requirements related to the product, and d) any additional requirements determined by the organization.	The organization shall determine a) requirements specified by the customer, including the requirements for delivery and post-delivery activities, b) requirements not stated by the customer but necessary for specified or intended use, where known, c) statutory and regulatory requirements applicable to the product, and d) any additional requirements considered necessary by the organization.	ISO 9001:2008 provides only minor clarifications in this clause.
	<i>NOTE Requirements related to the product can include special requirements.</i>	AS9100 adds a note regarding special requirements (see 3.2).
	<i>NOTE Post-delivery activities include, for example, actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.</i>	ISO 9001:2008 adds a note to clarify what is meant by post-delivery activities.
7.2.2 Review of requirements related to the product	7.2.2 Review of requirements related to the product	
The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that a) product requirements are defined, b) contract or order requirements differing from those previously expressed are resolved, c) the organization has the ability to meet the defined requirements, and d) risks (e.g., new technology, short delivery time scale) have been evaluated.	The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that a) product requirements are defined, b) contract or order requirements differing from those previously expressed are resolved, c) the organization has the ability to meet the defined requirements, d) special requirements of the product are determined, and e) risks (e.g., new technology, short delivery time frame) have been identified (see 7.1.2).	AS9100 adds clarification that requirements reviews include review to determine special product requirements.
Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).	Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).	Also minor text changes to clarify risk review.
Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.	Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.	
Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.	Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.	
NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.	NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.	
7.2.3 Customer communication	7.2.3 Customer communication	
The organization shall determine and implement effective arrangements for communicating with customers in relation to a) product information, b) enquiries, contracts or order handling, including amendments, and c) customer feedback, including customer complaints.	The organization shall determine and implement effective arrangements for communicating with customers in relation to a) product information, b) enquiries, contracts or order handling, including amendments, and c) customer feedback, including customer complaints.	No changes.

AS9100 Rev B (2004)	AS9100 Rev C (2009)	Comments
7.3 Design and development	7.3 Design and development	
7.3.1 Design and development planning	7.3.1 Design and development planning	
The organization shall plan and control the design and development of product.	The organization shall plan and control the design and development of product.	
During the design and development planning, the organization shall determine a) the design and development stages, – in respect of organization, task sequence, mandatory steps, significant stages and method of configuration control, b) the review, verification and validation that are appropriate to each design and development stage, and c) the responsibilities and authorities for design and development.	During the design and development planning, the organization shall determine a) the design and development stages, b) the review, verification and validation that are appropriate to each design and development stage, and c) the responsibilities and authorities for design and development.	AS9100 removes the text below a) that was somewhat redundant with other text below.
Where appropriate, due to complexity, the organization shall give consideration to the following activities: – structuring the design effort into significant elements; – for each element, analyzing the tasks and the necessary resources for its design and development. This analysis shall consider an identified responsible person, design content, input data, planning constraints, and performance conditions. The input data specific to each element shall be reviewed to ensure consistency with requirements.	<u>Where appropriate, the organization shall divide the design and development effort into distinct activities and, for each activity, define the tasks, necessary resources, responsibilities, design content, input and output data and planning constraints.</u>	This AS9100 requirement has been reworded to provide clarity. Previously it was only required to “give consideration to” these activities. It is now more strongly worded that these activities shall be done – where appropriate.
(Moved from below)	<u>The different design and development tasks to be carried out shall be based on the safety and functional objectives of the product in accordance with customer, statutory and regulatory requirements.</u>	AS9100 adds “statutory” to be consistent with ISO 9001:2008. This requirement has also been moved and slightly reworded.
	<u>Design and development planning shall consider the ability to produce, inspect, test and maintain the product.</u>	AS9100 adds the requirement for planning to consider downstream processes and customers
The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.	The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.	
Planning output shall be updated, as appropriate, as the design and development progresses.	Planning output shall be updated, as appropriate, as the design and development progresses.	
The different design and development tasks to be carried out shall be defined according to specified safety or functional objectives of the product in accordance with customer and/or regulatory authority requirements.	(moved to above)	ISO 9001:2008 adds a note clarifying that reviews, verification and validation can be conducted and recorded separately or combined according to the organization’s needs.
	<u>NOTE Design and development review, verification and validation have distinct purposes. They can be conducted and recorded separately or in any combination as suitable for the product and the organization.</u>	
7.3.2 Design and development inputs	7.3.2 Design and development inputs	
Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include a) functional and performance requirements, b) applicable statutory and regulatory requirements, c) where applicable, information derived from previous similar designs, and d) other requirements essential for design and development.	Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include a) functional and performance requirements, b) applicable statutory and regulatory requirements, c) where applicable, information derived from previous similar designs, and d) other requirements essential for design and development.	
These inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.	The inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.	ISO 9001:2008 changes “these inputs” to “the inputs.”

AS9100 Rev B (2004)	AS9100 Rev C (2009)	Comments
<p>7.3.3 Design and development outputs</p> <p>The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.</p> <p>Design and development outputs shall</p> <p>a) meet the input requirements for design and development, b) provide appropriate information for purchasing, production and for service provision, c) contain or reference product acceptance criteria, d) specify the characteristics of the product that are essential for its safe and proper use, <i>and</i> e) identify key characteristics, when applicable, in accordance with design or contract requirements.</p> <p>All pertinent data required to allow the product to be identified, manufactured, inspected, used and maintained shall be defined by the organization; for example:</p> <ul style="list-style-type: none"> - drawings, part lists, specifications; - a listing of those drawings, part lists, and specifications necessary to define the configuration 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. 	<p>7.3.3 Design and development outputs</p> <p>The outputs of design and development shall be in a form <u>suitable for</u> verification against the design and development input and shall be approved prior to release.</p> <p>Design and development outputs shall</p> <p>a) meet the input requirements for design and development, b) provide appropriate information for purchasing, production and service provision, c) contain or reference product acceptance criteria, d) specify the characteristics of the product that are essential for its safe and proper use, <i>and</i> e) <u>specify, as applicable, any critical items, including any key characteristics, and specific actions to be taken for these items.</u></p> <p><u>The organization shall define the data required to allow the product to be identified, manufactured, inspected, used and maintained; including for example</u></p> <ul style="list-style-type: none"> - the drawings, part lists, and specifications necessary to define the configuration and the design features of the product, and - the material, process, manufacturing and assembly data needed to ensure conformity of the product. <p><u>NOTE Information for production and service provision can include details for the preservation of product.</u></p>	<p>ISO 9001:2008 removes the unnecessary word “provided.” It also changes “enables verification to “suitable for verification,” which emphasizes that outputs should be readily usable for verification.</p> <p>AS9100 adds text consistent with the new term “critical items” defined in clause 3. It also adds the requirement to specify actions to be taken.</p> <p>AS9100 provides minor changes to more clearly describe the data requirements.</p> <p>ISO 9001:2008 adds a reminder to consider product preservation requirements as outputs of D&D.</p>
<p>7.3.4 Design and development review</p>	<p>7.3.4 Design and development review</p>	<p>No changes.</p>
<p>At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1)</p> <p>a) to evaluate the ability of the results of design and development to meet requirements, and b) to identify any problems and propose necessary actions, <i>and</i> c) <i>to authorize progression to the next stage.</i></p> <p>Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).</p>	<p>At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1)</p> <p>a) to evaluate the ability of the results of design and development to meet requirements, and b) to identify any problems and propose necessary actions, <i>and</i> c) <i>to authorize progression to the next stage.</i></p> <p>Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).</p>	
<p>7.3.5 Design and development verification</p>	<p>7.3.5 Design and development verification</p>	
<p>Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).</p> <p>NOTE: Design and/or development verification may include activities such as:</p> <ul style="list-style-type: none"> - performing alternative calculations; - comparing the new design with a similar proven design, if available; - undertaking tests and demonstrations, and - reviewing the design stage documents before release. 	<p>Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).</p> <p>(Deleted)</p>	<p>AS9100 removes the note providing examples of verification activities.</p>

AS9100 Rev B (2004)	AS9100 Rev C (2009)	Comments
7.3.6 Design and development validation Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).	7.3.6 Design and development validation Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).	
NOTES: – 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.	(Deleted)	AS9100 removes the notes providing examples of validation activities.
(Moved from below)	7.3.6.1 Design and development verification and validation testing	AS9100 moves the header from 7.3.6.2.
(Moved from below)	Where tests are necessary for verification and validation, these tests shall 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.	AS9100 switches the order of D&D V&V testing with D&D V&V documentation. AS9100 removes the word “standard” from c) for clarity.
7.3.6.1 Documentation of design and/or development verification and validation	7.3.6.2 Design and development verification and validation documentation	AS9100 moves the header from 7.3.6.1 and reorders the wording.
At the completion of design and/or development, the organization shall ensure that reports, calculations, test results, etc., demonstrate that the product definition meets the specification requirements for all identified operational conditions.	At the completion of design and/or development, the organization shall ensure that reports, calculations, test results, etc., demonstrate that the product definition meets the specification requirements for all identified operational conditions.	No changes.
7.3.6.2 Design and/or development verification and validation testing:	(Moved to above)	See above.
Where tests are necessary for verification and validation, these tests shall 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 standard of the product is submitted for the test; d) the requirements of the test plan and the test procedures are observed; e) the acceptance criteria are met.	(Moved to above)	See above.

AS9100 Rev B (2004)	AS9100 Rev C (2009)	Comments
<p>7.3.7 Control of design and development changes</p> <p>Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered.</p> <p>The organization's change control process shall provide for customer and/or regulatory authority approval of changes, when required by contract or regulatory requirement.</p> <p>Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).</p>	<p>7.3.7 Control of design and development changes</p> <p>Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered.</p> <p><u>Design and development changes shall be controlled in accordance with the configuration management process (see 7.1.3).</u></p> <p>Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).</p>	<p>AS9100 removes the regulatory reference now implied in 4.1. It also links the D&D change process to the configuration management process.</p>
<p>7.4 Purchasing</p> <p>7.4.1 Purchasing process</p> <p>The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.</p> <p>The organization shall be responsible for the quality of all products purchased from suppliers, including customer-designated sources.</p> <p>The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).</p> <p>The organization shall:</p> <p>a) maintain a register of approved suppliers that includes the scope of the approval;</p> <p>b) periodically review supplier performance; records of these reviews shall be used as a basis for establishing the level of controls to be implemented;</p> <p>c) define the necessary actions to take when dealing with suppliers that do not meet requirements;</p> <p>d) ensure where required that both the organization and all suppliers use customer-approved special process sources;</p> <p>e) ensure that the function having responsibility for approving supplier quality systems has the authority to disapprove the use of sources.</p>	<p>7.4 Purchasing</p> <p>7.4.1 Purchasing process</p> <p>The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.</p> <p><u>The organization shall be responsible for the conformity of all products purchased from suppliers, including product from sources defined by the customer.</u></p> <p>The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).</p> <p><u>NOTE 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 (e.g., information from accredited quality management system or process certification bodies, organization approvals from government authorities). 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.</u></p> <p>The organization shall:</p> <p><u>a) maintain a register of its suppliers that includes approval status (e.g., approved, conditional, disapproved) and the scope of the approval (e.g., product type, process family).</u></p> <p><u>b) periodically review supplier performance; the results of these reviews shall be used as a basis for establishing the level of controls to be implemented,</u></p> <p><u>c) define the necessary actions to take when dealing with suppliers that do not meet requirements,</u></p> <p><u>d) ensure where required that both the organization and all suppliers use customer-approved special process sources,</u></p> <p><u>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 their approval status, and</u></p> <p><u>f) determine and manage the risk when selecting and using suppliers (see 7.1.2).</u></p>	<p>AS9100 rewords this clause for clarity. There is no real change in requirements.</p> <p>AS9100 adds a note for guidance on using external data for supplier selection and evaluation.</p> <p>AS9100 changes the requirement for the supplier register to allow inclusion of all suppliers with their approval status indicated. It also provides clarification for scope of approval.</p> <p>AS9100 clarifies that <u>results</u> (instead of <u>records</u>) of supplier performance reviews are used to establish supplier controls.</p> <p>AS9100 more clearly defines responsibility and authority for those with approval status decision authority.</p> <p>AS9100 adds requirements for supplier risk management.</p>

AS9100 Rev B (2004)	AS9100 Rev C (2009)	Comments
<p>7.4.2 Purchasing information</p> <p>Purchasing information shall describe the product to be purchased, including where appropriate</p> <p>a) requirements for approval of product, procedures, processes and equipment,</p> <p>b) requirements for qualification of personnel,</p> <p>c) quality management system requirements,</p> <p>d) the name or other positive identification, and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data,</p> <p>e) requirements for design, test, examination, inspection and related instructions for acceptance by the organization,</p> <p>f) requirements for test specimens (e.g., production method, number, storage conditions) for design approval, inspection, investigation or auditing,</p> <p>g) requirements relative to —supplier notification to organization of nonconforming product and - arrangements for organization approval of supplier nonconforming material,</p> <p>h) requirements for the supplier to notify the organization of changes in product and/or process definition and, where required, obtain organization approval,</p> <p>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</p> <p>j) requirements for the supplier to flow down to sub-tier suppliers the applicable requirements in the purchasing documents, including key characteristics where required.</p>	<p>7.4.2 Purchasing information</p> <p>Purchasing information shall describe the product to be purchased, including where appropriate</p> <p>a) requirements for approval of product, procedures, processes and equipment,</p> <p>b) requirements for qualification of personnel,</p> <p>c) quality management system requirements,</p> <p>d) <u>the identification and revision status of specifications, drawings, process requirements, inspection/verification instructions and other relevant technical data,</u></p> <p>e) <u>requirements for design, test, inspection, verification (including production process verification), use of statistical techniques for product acceptance, and related instructions for acceptance by the organization, and as applicable critical items including key characteristics,</u></p> <p>f) <u>requirements for test specimens (e.g., production method, number, storage conditions) for design approval, inspection/verification,</u></p> <p>g) <u>requirements regarding the need for the supplier to</u> <u>- notify the organization of nonconforming product,</u> <u>- obtain organization approval for nonconforming product disposition,</u> <u>- notify the organization of changes in product and/or process, changes of suppliers, change of manufacturing facility location and, where required, obtain organization approval, and</u> <u>- flow down to the supply chain the applicable requirements including customer requirements,</u></p> <p>h) <u>records retention requirements, and,</u></p> <p>i) <u>right of access by the organization, their customer and regulatory authorities to the applicable areas of all facilities, at any level of the supply chain, involved in the order and to all applicable records.</u></p>	<p>AS9100 adds clarification for tech data requirements in purchasing.</p> <p>AS9100 adds clarification for test and acceptance requirements, including critical items and key characteristics.</p> <p>AS9100 adds appropriate test specimens for <u>verification</u>.</p> <p>AS9100 clarifies and adds to the requirements for suppliers to notify the organization of nonconforming product and changes, and for suppliers to flow down requirements.</p> <p>AS9100 adds the requirement to communicate supplier record retention requirements consistent with clause 4.2.4.</p> <p>AS9100 clarifies right of access requirements to be communicated to suppliers.</p>
<p>The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.</p>	<p>The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.</p>	
<p>7.4.3 Verification of purchased product</p>	<p>7.4.3 Verification of purchased product</p>	
<p>The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.</p>	<p>The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.</p>	
<p>(Moved from below)</p>	<p><u>NOTE 1 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.</u></p>	<p>AS9100 changes this from a requirement to a guidance note.</p>
<p>Verification activities may include</p> <p>a) obtaining objective evidence of the quality of the product from suppliers (e.g., accompanying documentation, certificate of conformity, test reports, statistical records, process control),</p> <p>b) inspection and audit at supplier's premises,</p> <p>e) review of the required documentation,</p> <p>e) inspection of products upon receipt, and</p> <p>e) delegation of verification to the supplier, or supplier certification.</p>	<p><u>NOTE 2 Verification activities can include</u></p> <ul style="list-style-type: none"> - obtaining objective evidence of the <u>conformity</u> of the product from <u>the supplier</u> (e.g., accompanying documentation, certificate of conformity, test <u>records</u>, statistical records, process control <u>records</u>), - inspection and audit at <u>the supplier's premises</u>, - review of the required documentation, - inspection of products upon receipt, and - delegation of verification to the supplier or supplier certification. 	<p>AS9100 adds minor clarifications.</p>
<p>Purchased product shall 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><u>Where purchased product is released for production 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 the product does not meet requirements.</u></p>	<p>AS9100 adds requirements to "identify and record" product issued pending completion of verification to allow recall and replacement. This is in place of "positive recall."</p>
<p>Where the organization utilizes test reports to verify purchased product, the data in those reports shall be acceptable per applicable specifications. The organization shall periodically validate test reports for raw material.</p>	<p>(Deleted)</p>	<p>AS9100 deletes the requirement to validate supplier test reports.</p>

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<i>Where the organization delegates verification activities to the supplier, the requirements for delegation shall be defined and a register of delegations maintained.</i>	<i>Where the organization delegates verification activities to the supplier, the requirements for delegation shall be defined and a register of delegations maintained.</i>	
Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.	Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.	
Where specified in the contract, the customer or the customer's representative shall be afforded the right to verify at the supplier's premises and the organization's premises that subcontracted product conforms to specified requirements.	(Deleted)	AS9100 removes the contract reference now implied in 4.1.
Verification by the customer shall 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.	(Moved to Note above)	Moved – see above.
7.5 Production and service provision	7.5 Production and service provision	
7.5.1 Control of production and service provision	7.5.1 Control of production and service provision	
<i>Planning shall consider, as applicable,</i> <ul style="list-style-type: none"> - the establishment of process controls and development of control plans where key characteristics have been identified, - the identification of in-process verification points when adequate verification of conformance cannot be performed at a later stage of realization, - the design, manufacture, and use of tooling so that variable measurements can be taken, particularly for key characteristics, and - special processes (see 7.5.2). 	(Moved to below)	Moved – see below.
<p>The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable</p> <ol style="list-style-type: none"> a) the availability of information that describes the characteristics of the product, b) the availability of work instructions, as necessary, c) the use of suitable equipment, d) the availability and use of monitoring and measuring devices, e) the implementation of monitoring and measurement, f) the implementation of release, delivery and post-delivery activities, g) accountability for all product during manufacture (e.g., parts quantities, split orders, nonconforming product), h) evidence that all manufacturing and inspection operations have been completed as planned, or as otherwise documented and authorized, i) provision for the prevention, detection, and removal of foreign objects, j) monitoring and control of utilities and supplies such as water, compressed air, electricity and chemical products to the extent they affect product quality, and k) criteria for workmanship, which shall be stipulated in the clearest practical manner (e.g., written standards, representative samples or illustrations). 	<p>The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable</p> <ol style="list-style-type: none"> a) the availability of information that describes the characteristics of the product, <i><u>NOTE This information can include drawings, parts lists, materials and process specifications.</u></i> b) the availability of work instructions, as necessary, <i><u>NOTE Work instructions can include process flow charts, production documents (e.g., manufacturing plans, travelers, routers, work orders, process cards) and inspection documents.</u></i> c) the use of suitable equipment, <i><u>NOTE Suitable equipment can include product specific tools (e.g., jigs, fixtures, molds) and software programs.</u></i> d) the availability and use of monitoring and measuring <u>equipment</u>, e) the implementation of monitoring and measurement, f) the implementation of <u>product</u> release, delivery and post-delivery activities, g) <u>accountability for all product during production</u> (e.g., parts quantities, split orders, nonconforming product), h) <u>evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized,</u> i) <u>provision for the prevention, detection and removal of foreign objects,</u> j) <u>monitoring and control of utilities and supplies (e.g., water, compressed air, electricity, chemical products) to the extent they affect conformity to product requirements, and</u> k) <u>criteria for workmanship, specified in the clearest practical way</u> (e.g., written standards, representative samples, illustrations). 	<p>AS9100 adds notes with examples of product information, work instructions, and suitable equipment. Some of these were taken from the deleted 7.5.1.1 Production Documentation clause.</p> <p>ISO 9001:2008 changes measuring “devices” to “equipment” wherever it appears.</p> <p>ISO 9001:2008 clarifies that “release” means product release.</p> <p>AS9100 makes several minor text changes for clarification and to be consistent with ISO 9001:2008 text.</p>

AS9100 Rev B (2004)	AS9100 Rev C (2009)	Comments
<i>(Moved from above)</i>	<i>Planning shall consider, as applicable,</i> <ul style="list-style-type: none"> - <u>establishing, implementing and maintaining appropriate processes to manage critical items, including process controls where key characteristics have been identified,</u> - <u>designing, manufacturing and using tooling to measure variable data,</u> - <u>identifying in-process inspection/verification points when adequate verification of conformance cannot be performed at later stages of realization, and</u> - <u>special processes (see 7.5.2).</u> 	AS9100 moves this requirement from above and changes some text to be consistent with the new AS9100 term “critical items.” The reference to control plans is also deleted.
<i>(Was in 8.2.4.2 – First article)</i>	7.5.1.1 <u>Production process verification</u>	AS9100 moves the header from 8.2.4.2 and changes text from “First Article” to “Production Process Verification.”
<i>(Was in 8.2.4.2)</i>	<i>The organization shall use a representative item from the first production run of a new part or assembly to verify that the production processes, production documentation and tooling are capable of producing parts and assemblies that meet requirements. This process shall be repeated when changes occur that invalidate the original results (e.g., engineering changes, manufacturing process changes, tooling changes).</i>	AS9100 moves the former “first article” clause from 8.2 monitoring and measurement to 7.5 production and service provision. The clause has been reworded, but the intent remains the same. It is now more specific and contains examples of when it should be applied.
	<i><u>NOTE This activity is often referred to as first article inspection.</u></i>	AS9100 removes the note referring to AS9102 and adds the first article note here since the header is now changed.
7.5.1.1 <u>Production Documentation</u> <i>Production operations shall be carried out in accordance with approved data. This data shall contain as necessary</i> <i>a) drawings, parts lists, process flow charts including inspection operations, production documents (e.g., manufacturing plans, traveler, router, work order, process cards); and inspection documents (see 8.2.4.1), and</i> <i>b) a list of specific or non-specific tools and numerical control (NC) machine programs required and any specific instructions associated with their use.</i>	(Deleted) <i>(a Moved to notes under 7.5.1 a & b above)</i>	AS9100 deletes this header. AS9100 deletes this clause and moves much of the text to notes in 7.5.1a) and b).
7.5.1.2 <u>Control of production process changes</u>	7.5.1.2 <u>Control of production process changes</u>	
<i>Persons authorized to approve changes to production processes shall be identified.</i>	<i>Personnel authorized to approve changes to production processes shall be identified.</i>	AS9100 makes a minor change from “persons” to “personnel.”
<i>The organization shall identify and obtain acceptance of changes that require customer and/or regulatory authority approval in accordance with contract or regulatory requirements.</i>	(Deleted)	AS9100 adds the explicit requirement to control changes and removes the requirement for “procedures to control their implementation.” Also “programs” is clarified as “software.”
<i>Changes affecting processes, production equipment, tools and programs shall be documented. Procedures shall be available to control their implementation.</i>	<i><u>The organization shall control and document changes affecting processes, production equipment, tools, or software programs.</u></i>	
<i>The results of changes to production processes shall be assessed to confirm that the desired effect has been achieved without adverse effects to product quality.</i>	<i>The results of changes to production processes shall be assessed to confirm that the desired effect has been achieved without adverse effects to product conformity.</i>	AS9100 changes “quality” to “conformity” to be consistent with the new ISO 9001:2008 text.

AS9100 Rev B (2004)	AS9100 Rev C (2009)	Comments
<p>7.5.1.3 Control of production equipment, tools and numerical control (NC) machine programs</p>	<p>7.5.1.3 Control of production equipment, tools and software programs</p>	<p>AS9100 changes the header to include all software, not just NC programs.</p>
<p><i>Production equipment, tools and programs shall be validated prior to use and maintained and inspected periodically according to documented procedures. Validation prior to production use shall include verification of the first article produced to the design data/specification.</i></p>	<p><i>Production equipment, tools and <u>software programs used to automate and control/monitor product realization processes</u>, shall be validated prior to <u>release for production</u> and <u>shall be maintained</u>.</i></p>	<p>AS9100 removes the requirement for documented procedures for maintenance and inspection of process equipment. Other minor changes were made for clarity.</p>
<p><i>Storage requirements, including periodic preservation/condition checks, shall be established for production equipment or tooling in storage.</i></p>	<p><i>Storage requirements, including periodic preservation/condition checks, shall be <u>defined</u> for production equipment or tooling in storage.</i></p>	<p>AS9100 changes the word “established” to “defined.”</p>
<p>7.5.1.4 Control of work transferred, on a temporary basis, outside the organization’s facilities</p>	<p>(Moved to 7.1.4)</p>	<p>Moved – see 7.1.4 above.</p>
<p><i>When planning to temporarily transfer work to a location outside the organization’s facilities, the organization shall define the process to control and validate the quality of the work.</i></p>	<p>(Moved to 7.1.4)</p>	<p>Moved – see 7.1.4 above.</p>
<p>7.5.1.5 Control of Service Operations</p>	<p>7.5.1.4 Post-delivery support</p>	<p>AS9100 clarifies the title.</p>
<p><i>Where servicing is a specified requirement, service operation processes shall provide for</i></p> <ul style="list-style-type: none"> <i>a) a method of collecting and analyzing in-service data,</i> <i>b) actions to be taken where problems are identified after delivery, including investigation, reporting activities, and actions on service information consistent with contractual and/or regulatory requirements,</i> <i>c) the control and updating of technical documentation,</i> <i>d) the approval, control, and use of repair schemes, and</i> <i>e) the controls required for off-site work (e.g., organization’s work undertaken at the customer’s facilities).</i> 	<p><i><u>Post-delivery support shall provide as applicable for the</u></i></p> <ul style="list-style-type: none"> <i>a) <u>collection and analysis of in-service data,</u></i> <i>b) <u>actions to be taken, including investigation and reporting, when problems are detected after delivery,</u></i> <i>c) <u>control and updating of technical documentation,</u></i> <i>d) <u>approval, control and use of repair schemes, and</u></i> <i>e) <u>controls required for off-site work (e.g., organization’s work undertaken at the customer’s facilities).</u></i> 	<p>AS9100 makes minor changes for clarity. Requirements for problem investigation and reporting are added. The overall intent remains the same.</p>
<p>7.5.2 Validation of processes for production and service provision</p>	<p>7.5.2 Validation of processes for production and service provision</p>	
<p>The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.</p>	<p>The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement <u>and as a consequence,</u> deficiencies become apparent only after the product is in use or the service has been delivered</p>	<p>ISO 9001:2008 clarifies that special processes that don’t achieve expected results may result in product deficiencies in the field.</p>
<p><i>NOTE: These processes are frequently referred to as special processes.</i></p>	<p><i>NOTE These processes are often referred to as special processes.</i></p>	
<p>Validation shall demonstrate the ability of these processes to achieve planned results.</p>	<p>Validation shall demonstrate the ability of these processes to achieve planned results.</p>	
<p>The organization shall establish arrangements for these processes including, as applicable</p> <ul style="list-style-type: none"> a) defined criteria for review and approval of the processes, – qualification and approval of special processes prior to use, b) approval of equipment and qualification of personnel, c) use of specific methods and procedures – control of the significant operations and parameters of special processes in accordance with documented process specifications and changes thereto, d) requirements for records (see 4.2.4), and e) revalidation. 	<p>The organization shall establish arrangements for these processes including, as applicable</p> <ul style="list-style-type: none"> a) defined criteria for review and approval of the processes, b) approval of equipment and qualification of personnel, c) use of specific methods and procedures, d) requirements for records (see 4.2.4), and e) revalidation. 	<p>AS9100 removes text determined to be unnecessary.</p>

AS9100 Rev B (2004)	AS9100 Rev C (2009)	Comments
7.5.3 Identification and traceability	7.5.3 Identification and traceability	
Where appropriate, the organization shall identify the product by suitable means throughout product realization.	Where appropriate, the organization shall identify the product by suitable means throughout product realization.	
<i>The organization shall maintain the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration.</i>	<i>The organization shall maintain the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration.</i>	
The organization shall identify the product status with respect to monitoring and measurement requirements.	The organization shall identify the product status with respect to monitoring and measurement requirements throughout product realization.	ISO 9001:2008 clarifies that product must be identified throughout product realization.
<i>When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), the organization shall establish and document controls for the media.</i>	<i>When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), the organization shall establish appropriate controls for the media.</i>	AS9100 removes the requirement for documented controls for stamps, passwords, etc. and instead requires "appropriate" controls.
Where traceability is a requirement, the organization shall control and record the unique identification of the product (see 4.2.4).	Where traceability is a requirement, the organization shall control the unique identification of the product and maintain records (see 4.2.4).	ISO 9001:2008 clarifies the requirement for traceability records.
<i>According to the level of traceability required by contract, regulatory, or other established requirement, the organization's system shall provide for:</i> a) identification to be maintained throughout the product life; b) all the products manufactured from the same batch of raw material or from the same manufacturing batch to be traced, as well as the destination (delivery, scrap) of all products of the same batch; c) for an assembly, the identity of its components and those of the next higher assembly to be traced; d) for a given product, a sequential record of its production (manufacture, assembly, inspection) to be retrieved.	NOTE Traceability requirements may include - identification to be maintained throughout the product life. - the ability to trace all products manufactured from the same batch of raw material, or from the same manufacturing batch, to the destination (e.g., delivery, scrap). - for an assembly, the ability to trace its components to the assembly and then to the next higher assembly, and - for a product, a sequential record of its production (manufacture, assembly, inspection/verification) to be retrievable.	AS9100 changes the conditional requirements for traceability (based on customer or legal requirements) to a note. The requirement is now implied in clause 4.1.
NOTE In some industry sectors, configuration management is a means by which identification and traceability are maintained (see 4.3).	NOTE In some industry sectors, configuration management is a means by which identification and traceability are maintained (see 7.1.3).	AS9100 changes the reference to configuration management from 4.3 to the new clause number 7.1.3.
7.5.4 Customer property	7.5.4 Customer property	
The organization shall exercise care with customer property while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained (see 4.2.4).	The organization shall exercise care with customer property while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records (see 4.2.4).	ISO 9001:2008 modifies the text from passive to active to clarify that the organization must report this to the customer and maintain records.
NOTE: Customer property can include intellectual property including customer furnished data used for design, production and/or inspection.	NOTE Customer property can include intellectual property and personal data.	AS9100 removes text clarifying intellectual property, and ISO 9001:2008 adds personal data.
7.5.5 Preservation of product	7.5.5 Preservation of product	
The organization shall preserve the conformity of product during internal processing and delivery to the intended destination. This preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.	The organization shall preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.	ISO 9001:2008 makes minor changes to the text and clarifies that preservation includes the items listed only as applicable.
<i>Preservation of product shall also include, where applicable in accordance with product specifications and/or applicable regulations, provisions for:</i> a) cleaning; b) prevention, detection and removal of foreign objects; c) special handling for sensitive products; d) marking and labeling including safety warnings; e) shelf life control and stock rotation; f) special handling for hazardous materials.	<i>Preservation of product shall also include, where applicable in accordance with product specifications and applicable statutory and regulatory requirements, provisions for</i> a) cleaning. b) prevention, detection and removal of foreign objects. c) special handling for sensitive products. d) marking and labeling including safety warnings. e) shelf life control and stock rotation, and f) special handling for hazardous materials.	AS9100 rewords the text and adds "statutory" to be consistent with ISO 9001:2008.
<i>The organization shall ensure that documents required by the contract/order to accompany the product are present at delivery and are protected against loss and deterioration.</i>	(Moved to 8.2.4)	This AS9100 requirement has been moved to 8.2.4

AS9100 Rev B (2004)	AS9100 Rev C (2009)	Comments
<p>7.6 Control of monitoring and measuring devices</p> <p>The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1).</p> <p><i>The organization shall maintain a register of these monitoring and measuring devices, and define the process employed for their calibration including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria.</i></p> <p><i>NOTE: Monitoring and measuring devices include, but are not limited to: test hardware, test software, automated test equipment (ATE) and plotters used to produce inspection data. It also includes personally owned and customer supplied equipment used to provide evidence of product conformity.</i></p> <p>The organization shall establish processes 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.</p> <p><i>The organization shall ensure that environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out.</i></p> <p>Where necessary ensure valid results, measuring equipment shall</p> <ol style="list-style-type: none"> be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded; be adjusted or re-adjusted as necessary; be identified to enable the calibration status to be determined; be safeguarded from adjustments that would invalidate the measurement result; be protected from damage and deterioration during handling, maintenance and storage; be recalled to a defined method when requiring calibration. <p>In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained (see 4.2.4).</p> <p>When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.</p> <p>NOTE See ISO 10012-1 and ISO 10012-2 for guidance.</p>	<p>7.6 Control of monitoring and measuring <u>equipment</u></p> <p>The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring <u>equipment</u> needed to provide evidence of conformity of product to determined requirements.</p> <p><i>The organization shall maintain a register of the monitoring and measuring <u>equipment</u> and define the process employed for their calibration/<u>verification</u> including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria.</i></p> <p><i>NOTE Monitoring and measuring <u>equipment</u> includes, but <u>is</u> not limited to: test hardware, test software, automated test equipment (ATE) and plotters used to produce inspection data. It also includes personally owned and customer supplied equipment used to provide evidence of product conformity.</i></p> <p>The organization shall establish processes 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.</p> <p><i>The organization shall ensure that environmental conditions are suitable for the calibration, inspection, measurement and <u>testing being carried out</u>.</i></p> <p>Where necessary to ensure valid results, measuring equipment shall</p> <ol style="list-style-type: none"> be calibrated or verified, <u>or both</u>, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded (<u>see 4.2.4</u>); be adjusted or re-adjusted as necessary; <u>have identification in order to determine its</u> calibration status; be safeguarded from adjustments that would invalidate the measurement result; be protected from damage and deterioration during handling, maintenance and storage. <p><i><u>The organization shall establish, implement and maintain a process for the recall of monitoring and measuring equipment requiring calibration or verification.</u></i></p> <p>In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained (see 4.2.4).</p> <p>When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.</p> <p><u>NOTE Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.</u></p>	<p>ISO 9001:2008 changes measuring “devices” to “equipment” wherever it appears.</p> <p>AS9100 changes “devices” to “equipment” and adds the word “verification” to be consistent with ISO 9001:2008.</p> <p>AS9100 changes “devices” to “equipment” and adjusts the grammar to be consistent with ISO 9001:2008.</p> <p>AS9100 makes minor text adjustments without affecting the meaning.</p> <p>ISO 9001:2008 makes minor text adjustments for clarification that equipment may be calibrated or verified or both.</p> <p>ISO 9001:2008 makes a minor text change that does not affect the intent of the requirement.</p> <p>AS9100 strengthens the requirement for the organization to establish a process for recall of equipment due for calibration. It also now includes equipment due for <u>verification</u>.</p> <p>ISO 9001:2008 deletes the note referencing the ISO 10012 standards. The updated version of ISO 10012 is now only referenced in the bibliography.</p> <p>ISO 9001:2008 also adds a note with guidance for software confirmation.</p>

AS9100 Rev B (2004)	AS9100 Rev C (2009)	Comments
8 Measurement, analysis and improvement	8 Measurement, analysis and improvement	
8.1 General	8.1 General	
The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed a) to demonstrate conformity of the product, b) to ensure conformity of the quality management system, and c) to continually improve the effectiveness of the quality management system.	The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed a) to demonstrate conformity <u>to</u> product <u>requirements</u> , b) to ensure conformity of the quality management system, and c) to continually improve the effectiveness of the quality management system.	ISO 9001:2008 clarifies that the intent is conformity to product requirements.
This shall include determination of applicable methods, including statistical techniques, and the extent of their use.	This shall include determination of applicable methods, including statistical techniques, and the extent of their use.	
<i>NOTE: According to the nature of the product and depending on the specified requirements, statistical techniques may be used to support:</i> - design verification (e.g., reliability, maintainability, safety); - process control: - selection and inspection of key characteristics; - process capability measurements; - statistical process control; - design of experiment; - inspection - matching sampling rate to the criticality of the product and to the process capability; - failure mode and effect analysis.	<i>NOTE According to the nature of the product and depending on the specified requirements, statistical techniques <u>can</u> be used to support</i> - design verification (e.g., reliability, maintainability, safety). - process control. - selection and inspection of key characteristics. - process capability measurements. - statistical process control. - design of experiment. - inspection, <u>and</u> - failure mode, <u>effect and criticality</u> analysis.	AS9100 removes text in this note regarding inspection that was confusing and seemed prescriptive. Also, text was modified to refer to failure mode, effect and criticality analysis (FMECA) instead of failure mode and effect analysis (FMEA).
8.2 Monitoring and measurement	8.2 Monitoring and measurement	
8.2.1 Customer satisfaction	8.2.1 Customer satisfaction	
As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.	As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.	
	<u>Information to be monitored and used for the evaluation of customer satisfaction shall include, but is not limited to, product conformity, on-time delivery performance, customer complaints and corrective action requests. Organizations shall develop and implement plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results.</u>	AS9100 adds requirements for some specific information to be monitored for evaluation of customer satisfaction. Also a requirement is added to develop customer satisfaction improvement plans for deficiencies identified.
	<u>NOTE Monitoring customer perception can include obtaining input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims and dealer reports.</u>	ISO 9001:2008 adds a note for guidance on input sources for customer satisfaction

AS9100 Rev B (2004)	AS9100 Rev C (2009)	Comments
<p>8.2.2 Internal audit</p> <p>The organization shall conduct internal audits at planned intervals to determine whether the quality management system</p> <p>a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and</p> <p>b) is effectively implemented and maintained.</p>	<p>8.2.2 Internal audit</p> <p>The organization shall conduct internal audits at planned intervals to determine whether the quality management system</p> <p>a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and</p> <p><i>NOTE Planned arrangements include customer contractual requirements.</i></p> <p>b) is effectively implemented and maintained.</p>	<p>AS9100 adds a note to remind that audits must include contractual requirements</p>
<p>An audit program shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.</p>	<p>An audit program <u>me</u> shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. <u>The</u> selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.</p>	<p>AS9100 reverts to the original spelling of “programme” in ISO 9001.</p> <p>ISO 9001:2008 slightly rewords the documented procedure requirement and clarifies and strengthens the audit record requirements.</p>
<p>The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure.</p>	<p><u>A documented procedure shall be established to define</u> the responsibilities and requirements for planning and conducting audits, <u>establishing records</u> and reporting results.</p> <p>Records <u>of the audits and their results shall be maintained</u> (see 4.2.4).</p>	<p>ISO 9001:2008 uses the proper terms “correction” and “corrective action” as defined in ISO 9000.</p>
<p>The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).</p>	<p>The management responsible for the area being audited shall ensure that <u>any necessary corrections and corrective</u> actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).</p>	<p>AS9100 removes the requirement for detailed tools and techniques and the requirement to measure their effectiveness.</p>
<p>Detailed tools and techniques shall be developed such as checksheets, process flowcharts, or any similar method to support audit of the quality management system requirements. The acceptability of the selected tools will be measured against the effectiveness of the internal audit process and overall organization performance.</p>	<p>(Deleted)</p>	<p>AS9100 removes reference to contract & regulatory requirements now included in the new note under 8.2.2a and implied in 4.1.</p>
<p>Internal audits shall also meet contract and/or regulatory requirements.</p> <p>NOTE: See ISO 10011-1, ISO 10011-2 and ISO 10011-3 for guidance.</p>	<p>(Deleted)</p> <p>NOTE See ISO <u>19011</u> for guidance.</p>	<p>ISO 9001:2008 updates the audit guidance document from ISO 10011 (cancelled) to ISO 19011.</p>
<p>8.2.3 Monitoring and measurement of processes</p>	<p>8.2.3 Monitoring and measurement of processes</p>	
<p>The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.</p>	<p>The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate.</p>	<p>ISO 9001:2008 removes the reference to product conformity. Some processes may only indirectly affect product conformity but may have significant impact on the organization’s planned results.</p>
	<p><u>NOTE When determining suitable methods, it is advisable that the organization consider the type and extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to product requirements and on the effectiveness of the quality management system.</u></p>	<p>ISO 9001:2008 adds guidance on determining appropriate process monitoring and measurement methods.</p>
<p><i>In the event of process nonconformity, the organization shall</i></p> <p>a) take appropriate action to correct the nonconforming process,</p> <p>b) evaluate whether the process nonconformity has resulted in product nonconformity, and</p> <p>c) identify and control the nonconforming product in accordance with clause 8.3.</p>	<p><i>In the event of process nonconformity, the organization shall</i></p> <p>a) take appropriate action to correct the nonconforming process,</p> <p>b) evaluate whether the process nonconformity has resulted in product nonconformity,</p> <p>c) <u>determine if the process nonconformity is limited to a specific case or whether it could have affected other processes or products,</u> and</p> <p>d) identify and control <u>any nonconforming product (see 8.3).</u></p>	<p>AS9100 adds the requirement to widen the scope of evaluations to include other processes and products when process nonconformities occur. It also makes a minor clarification for nonconforming product control.</p>

AS9100 Rev B (2004)	AS9100 Rev C (2009)	Comments
8.2.4 Monitoring and measurement of product	8.2.4 Monitoring and measurement of product	
The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). (Moved from below)	The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained.	AS9100 moves the requirements for product acceptance from the deleted clause 8.2.4.1. It clarifies minimum records for measurement results, and clarifies requirements for specific measurement equipment, recognizing that there may be none.
(Moved from 8.2.4.1)	<i>Measurement requirements for product acceptance shall be documented and shall include</i> a) <i>criteria for acceptance and/or rejection,</i> b) <i>where in the sequence measurement and testing operations are performed,</i> c) <i>required records of the measurement results (at a minimum, indication of acceptance or rejection), and</i> d) <i>any specific measurement instruments required and any specific instructions associated with their use.</i>	AS9100 includes “critical items” consistent with the new terms in clause 3. It adds requirements for established processes to control and monitor them.
<i>When key characteristics have been identified, they shall be monitored and controlled.</i>	<i>When critical items, including key characteristics, have been identified the organization shall ensure they are controlled and monitored in accordance with the established processes.</i>	AS9100 clarifies that sampling plans must be justified based on recognized statistical principles.
<i>When the organization uses sampling inspection as a means of product acceptance, the plan shall be statistically valid and appropriate for use. The plan shall preclude the acceptance of lots whose samples have known nonconformities. When required, the plan shall be submitted for customer approval.</i>	<i>When the organization uses sampling inspection as a means of product acceptance, the sampling plan shall be justified on the basis of recognized statistical principles and appropriate for use (i.e., matching the sampling plan to the criticality of the product and to the process capability).</i>	Justification examples are provided.
<i>Product shall not be used until it has been inspected or otherwise verified as conforming to specified requirements, except when product is released under positive recall procedures pending completion of all required measurement and monitoring activities.</i>	<i>Where product is released for production use pending completion of all required measurement and monitoring activities, it shall be identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.</i>	AS9100 adds requirements to “identify and record” product issued pending completion of verification to allow recall and replacement. This is in place of “positive recall.”
Evidence of conformity with the acceptance criteria shall be maintained.	(Moved to above)	ISO 9001:2008 clarifies that the identity of those releasing product only to customers must be recorded.
Records shall indicate the person(s) authorizing release of product (see 4.2.4). (Moved from 8.2.4.1)	Records shall indicate the person(s) authorizing release of product for delivery to the customer (see 4.2.4). <i>Where required to demonstrate product qualification, the organization shall ensure that records provide evidence that the product meets the defined requirements.</i>	AS9100 moves the requirement for records of product qualification from the deleted clause 8.2.4.1.
Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer. (Moved from 7.5.5)	<i>The release of product and delivery of service to the customer shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.</i>	ISO 9001:2008 clarifies again that planned arrangements must be met prior to delivery to the customer.
8.2.4.1 Inspection Documentation	<i>The organization shall ensure that all documents required to accompany the product are present at delivery.</i>	AS9100 moves the requirement for required documentation to be present at delivery from 7.5.5.
<i>Measurement requirements for product or service acceptance shall be documented. This documentation may be part of the production documentation, but shall include</i> a) <i>criteria for acceptance and/or rejection,</i> b) <i>where in the sequence measurement and testing operations are performed,</i> c) <i>a record of the measurement results, and</i> d) <i>type of measurement instruments required and any specific instructions associated with their use.</i>	(Moved to 8.2.4 above)	AS9100 deletes this header.
<i>Test records shall show actual test results data when required by specification or acceptance test plan.</i>	(Deleted)	AS9100 deletes this requirement.
<i>Where required to demonstrate product qualification the organization shall ensure that records provide evidence that the product meets the defined requirements.</i>	(Moved to 8.2.4 above)	AS9100 moves these requirements to clause 8.2.4 above.
8.2.4.2 First Article Inspection		AS9100 deletes this header.
<i>The organization's system shall 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 subsequent change that invalidates the previous first article inspection result.</i> <i>NOTE: See (AS) (EN) (SJAC) 9102 for guidance.</i>	(Moved to 7.5.1.1 above)	AS9100 moves these requirements to clause 7.5.1.1.

AS9100 Rev B (2004)	AS9100 Rev C (2009)	Comments
8.3 Control of nonconforming product	8.3 Control of nonconforming product	
The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.	The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. <u>A documented procedure shall be established to define</u> the controls and related responsibilities and authorities for dealing with nonconforming product.	ISO 9001:2008 rewords the requirement for a documented procedure for clarity.
NOTE: The term "nonconforming product" includes nonconforming product returned from a customer.	NOTE The term "nonconforming product" includes nonconforming product returned <u>by</u> a customer.	AS9100 makes minor text changes for clarity.
The organization's documented procedure shall define the responsibility for review and authority for the disposition of nonconforming product and the process for approving personnel making these decisions.	The organization's documented procedure shall define the responsibility and authority for the <u>review and</u> disposition of nonconforming product, and the process for approving personnel making these decisions.	
The organization shall deal with nonconforming product by one or more of the following ways: a) by taking action to eliminate the detected nonconformity; b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer; c) by taking action to preclude its original intended use or application. (d is moved from below)	<u>Where applicable,</u> the organization shall deal with nonconforming product by one or more of the following ways: a) by taking action to eliminate the detected nonconformity; b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer; c) by taking action to preclude its original intended use or application; d) by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started; – The organization's nonconforming product control process shall provide for timely reporting of delivered nonconforming product; NOTE Parties requiring notification of nonconforming product can include suppliers, internal organizations, customers, distributors and regulatory authorities. e) by taking actions necessary to contain the effect of the nonconformity on other processes or products.	ISO 9001:2008 adds "where applicable" to the ways that organizations deal with nonconforming product. ISO 9001:2008 moves text from the end of the clause to add to the list of ways to deal with nonconforming product. AS9100 moves text and a note from below to the ways of dealing with nonconforming product.
(Moved from below)	<u>Dispositions of use-as-is or repair shall only be used after approval by an authorized representative of the organization responsible for design.</u>	AS9100 adds containment of effects of nonconforming product to the list of ways to deal with nonconforming product.
	NOTE Authorized representative includes personnel having delegated authority from the design organization.	
The organization shall not 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.	The organization shall not use dispositions of use-as-is or repair, unless specifically authorized by the customer, if the nonconformity results in a departure from the contract requirements.	AS9100 rewords and clarifies the conditions under which dispositions of use-as-is may be made. This includes use of the new term "authorized representative."
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 from customer specified requirements.	(Moved to above)	
Product dispositioned for scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable.	<u>Product dispositioned for scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable.</u>	
(Moved from below)	When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.	ISO 9001:2008 reorders the sequence of two sentences, placing requirements for records at the end of the clause.
Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).	Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).	
When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.	(Moved to above)	
When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.	(Moved to 8.3d above)	
In addition to any contract or regulatory authority reporting requirements, the organization's system shall provide for timely reporting of delivered nonconforming product that may affect reliability or safety. Notification shall include a clear description of the nonconformity, which includes as necessary parts affected, customer and/or organization part numbers, quantity, and date(s) delivered.	(Moved to 8.3d above)	
NOTE: Parties requiring notification of nonconforming product may include suppliers, internal organizations, customers, distributors, and regulatory authorities.	(Moved to note below 8.3d above)	

AS9100 Rev B (2004)	AS9100 Rev C (2009)	Comments
8.4 Analysis of data	8.4 Analysis of data	
<p>The organization shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.</p>	<p>The organization shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.</p>	<p>ISO 9001:2008 changes the reference of product requirement from the clause where they are determined to the clause where they are measured. It also adds linkages to other appropriate clauses.</p>
<p>The analysis of data shall provide information relating to</p> <ul style="list-style-type: none"> a) customer satisfaction (see 8.2.1), b) conformity to product requirements (see 7.2.4), c) characteristics and trends of processes and products including opportunities for preventive action, and d) suppliers. 	<p>The analysis of data shall provide information relating to</p> <ul style="list-style-type: none"> a) customer satisfaction (see 8.2.1), b) conformity to product requirements (see 8.2.4), c) characteristics and trends of processes and products, including opportunities for preventive action (see 8.2.3 and 8.2.4), and d) suppliers (see 7.4). 	
8.5 Improvement	8.5 Improvement	
8.5.1 Continual improvement	8.5.1 Continual improvement	
<p>The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.</p>	<p>The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.</p>	<p>AS9100 adds the requirement to monitor implementation of improvement activities and to evaluate the effectiveness of the results. A new note gives guidance on improvement opportunities.</p>
	<p><i>The organization shall monitor the implementation of improvement activities and evaluate the effectiveness of the results.</i></p> <p><i>NOTE Continual improvement opportunities can result from lessons learned, problem resolutions and the benchmarking of best practices.</i></p>	
8.5.2 Corrective action	8.5.2 Corrective action	
<p>The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.</p>	<p>The organization shall take action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.</p>	<p>ISO 9001:2008 makes "cause" plural, recognizing that there may be multiple causes for each nonconformity.</p>
<p>A documented procedure shall be established to define requirements for</p> <ul style="list-style-type: none"> a) reviewing nonconformities (including customer complaints), b) determining the causes of nonconformities, c) evaluating the need for action to ensure that nonconformities do not recur, d) determining and implementing action needed, e) records of the results of action taken (see 4.2.4), f) reviewing corrective action taken, g) <i>flow down of the corrective action requirement to a supplier, when it is determined that the supplier is responsible for the root cause, and</i> h) <i>specific actions where timely and/or effective corrective actions are not achieved.</i> 	<p>A documented procedure shall be established to define requirements for</p> <ul style="list-style-type: none"> a) reviewing nonconformities (including customer complaints), b) determining the causes of nonconformities, c) evaluating the need for action to ensure that nonconformities do not recur, d) determining and implementing action needed, e) records of the results of action taken (see 4.2.4), f) reviewing <i>the effectiveness of the</i> corrective action taken, g) <i>flowing down corrective action requirements to a supplier when it is determined that the supplier is responsible for the nonconformity,</i> h) <i>specific actions where timely and/or effective corrective actions are not achieved, and</i> i) <i>determining if additional nonconforming product exists based on the causes of the nonconformities and taking further action when required.</i> 	
8.5.3 Preventive action	8.5.3 Preventive action	
<p>The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.</p>	<p>The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.</p>	<p>ISO 9001:2008 clarifies that the <u>effectiveness</u> of the action should be reviewed, not just the action.</p>
<p>A documented procedure shall be established to define requirements for</p> <ul style="list-style-type: none"> a) determining potential nonconformities and their causes, b) evaluating the need for action to prevent occurrence of nonconformities, c) determining and implementing action needed, d) records of results of action taken (see 4.2.4), and e) reviewing preventive action taken. 	<p>A documented procedure shall be established to define requirements for</p> <ul style="list-style-type: none"> a) determining potential nonconformities and their causes, b) evaluating the need for action to prevent occurrence of nonconformities, c) determining and implementing action needed, d) records of results of action taken (see 4.2.4), and e) reviewing <i>the effectiveness of the</i> preventive action taken. 	
	<p><i>NOTE 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.</i></p>	

AS9100 Rev B (2004)	AS9100 Rev C (2009)	Comments
<p><u>Bibliography</u></p> <p>AS/EN/SJAC 9102 Aerospace First Article Inspection Requirement</p> <p>ISO 9000:2000 Quality management systems – Fundamentals and vocabulary</p> <p>ISO 9001:2000 Quality management systems – Requirements</p> <p>ISO 9004:2000 Quality management systems—Guidelines for performance improvements</p> <p>ISO 10007:1995 Quality management – Guidelines for configuration management</p> <p>ISO 10011-1:1990 Guidelines for auditing quality systems—Part 1: Auditing²</p> <p>ISO 10011-2:1991 Guidelines for auditing quality systems—Part 2: Qualification criteria for quality systems auditors²</p> <p>ISO 10011-3:1991 Guidelines for auditing quality systems—Part 3: Management of audit programmes²</p> <p>ISO 10012:2003 Measurement management systems—Requirements for measurement processes and measuring equipment</p> <p>ISO 10012-1:1992 Quality assurance requirements for measuring equipment—Part 1: Metrological confirmation system for measuring equipment³</p> <p>ISO 10012-2:1997 Quality assurance for measuring equipment—Part 2: Guidelines for control of measurement processes³</p> <p>ISO 19011:2002 Guidelines for quality and/or environmental management systems auditing</p> <p>² Superseded by ISO 19011, Guidelines for quality and/or environmental management systems auditing</p> <p>³ Superseded by ISO 10012, Measurement management systems—Requirements for measurement processes and measuring equipment</p>	<p><u>Bibliography</u></p> <p>AS/EN 9110 Quality Management Systems – Requirements for Aviation Maintenance Organizations</p> <p>AS/EN 9120 Quality Management Systems – Requirements for Aviation, Space and Defense Distributors</p> <p>ISO 9000 Quality management systems – Fundamentals and vocabulary</p> <p>ISO 9001 Quality management systems – Requirements</p> <p>ISO 9004² Managing for the sustained success of an organization – A quality management approach</p> <p>ISO 10007 Quality management systems – Guidelines for configuration management</p> <p>ISO 19011 Guidelines for quality and/or environmental management systems auditing</p> <p>² To be published. (Revision of ISO 9004:2000)</p>	<p>AS9100 adds AS9110 and AS9120 to the list of standards. It removes all version dates from standards listed. It deletes reference to first article and measurement system guidance documents. It also deletes reference to obsolete standards.</p>

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