
Guidance Handbook for the
Transition to AS9100:2009
Including ISO 9001:2008 changes

**Quality Management Systems – Requirements for Aviation, Space
and Defense Organizations**

Instructions

This document has been prepared to provide you guidance to complete the transition of your Quality Management System to the current revision of the AS9100 international industry standard. To support you in this effort the following data has been prepared to provide you with the necessary information for determining where changes in the standard have occurred, what the changes are and why the change was made.

The differences between AS9100B and AS9100:2009 are shown in the following pages as a matrix. The first column provides the text of AS9100B, the second column AS9100:2009 and the third column displays the Changes behind the change. As has always been the case with AS9100 document the basic ISO 9001 requirements will be found as plain text, while the industry specific requirements are shown in ***bold italic type***. In defining the changes which make up the new revision of standard:

- Deleted text (both AS9100 Rev B and ISO 9001:2000) will be displayed as strikethroughs in column 1.
 - New text (both AS9100:2009 and ISO 9001:2008) will be found underlined in column 2.

How to Proceed?

1. Review the material and determine how your system should be modified to address the changes introduced by the AS9100:2009 Quality Management Standard. Take particular note of the revised/added requirements :
 - a. Special Requirements/Critical Items/Key Characteristics
 - b. Project Management
 - c. Risk Management
 - d. Configuration Management
2. Plan, develop, train and implement the appropriate changes to your system.
3. Conduct an internal audit of revised, make necessary changes and report results to management review.
4. Once satisfied notify NQA-USA of your readiness to make the transition.
5. Undergo the transition audit.
 - a. Transition audits conducted during the surveillance cycle will be scheduled for the same period as your reassessment.
 - b. Transition audits programmed during reassessments will be scheduled at the same length as your assessment.
6. Any Nonconformities identified will require corrective action implemented and verified by NQA-USA



AS9100:2009 Transition Guidance Handbook

AS9100B	Changes	AS9100:2009
<p>Quality Management Systems - Aerospace – Requirements</p>		<p>Quality Management Systems –Requirements for Aviation, Space and Defense Organizations</p>
<p>Foreword</p>		<p>Foreword</p>
<p>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.</p> <p>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.</p> <p>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.</p>	<p>AS9100 increases the scope of the standard to include the defense industry along with aviation and space. Traditionally all three industries have shared common interests. During the rewrite exercise all three were represented and as a basic rule for an issue to be included in the standard it must be relevant to all three industry segments.</p>	<p><u>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.</u></p> <p><u>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.</u></p> <p><u>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.</u></p>
<p>Revision summary</p>	<p>Title was expanded for clarity.</p>	<p>Revision summary/Changes</p>
<p>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.</p>	<p>AS9100 identifies the current version of the ISO 9001 standard; as well as introducing the important concept of stakeholders</p>	<p><u>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.</u></p>



AS9100B	Changes	AS9100:2009
<p>Introduction</p>		<p>Introduction</p>
<p>General</p>	<p><i>Renumbered</i></p>	<p>0.1 General</p>
<p>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.</p> <p>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.</p> <p>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.</p> <p>The quality management principles stated in ISO 9000 and ISO 9004 have been taken into consideration during the development of this International Standard.</p>	<p>ISO 9001 adds the explanation that the "business environment," will influence the structure of the quality management system and the method implementation.</p> <p>ISO 9001 includes "statutory" with "regulatory" to better define these types of requirements.</p>	<p>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 <u>a) its organizational environment, changes in that environment, and the risks associated with that environment,</u> <u>b) its varying needs,</u> <u>c) its particular objectives,</u> <u>d) the products it provides,</u> <u>e) the processes it employs,</u> <u>f) its size and organizational structure.</u> It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.</p> <p>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.</p> <p>This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, <u>statutory and regulatory requirements applicable to the product,</u> and the organization's own requirements.</p> <p>The quality management principles stated in ISO 9000 and ISO 9004 have been taken into consideration during the development of this International Standard.</p>
<p>Process Approach</p>	<p><i>Renumbered.</i></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 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>ISO 9001 provided minor clarifications.</p> <p>ISO 9001 emphasizes effectiveness as an essential of a properly implemented quality management system.</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 <u>determine</u> and manage numerous linked activities. An activity or <u>set of activities</u> 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 <u>to produce the desired outcome,</u> can be referred to as the "process approach".</p>

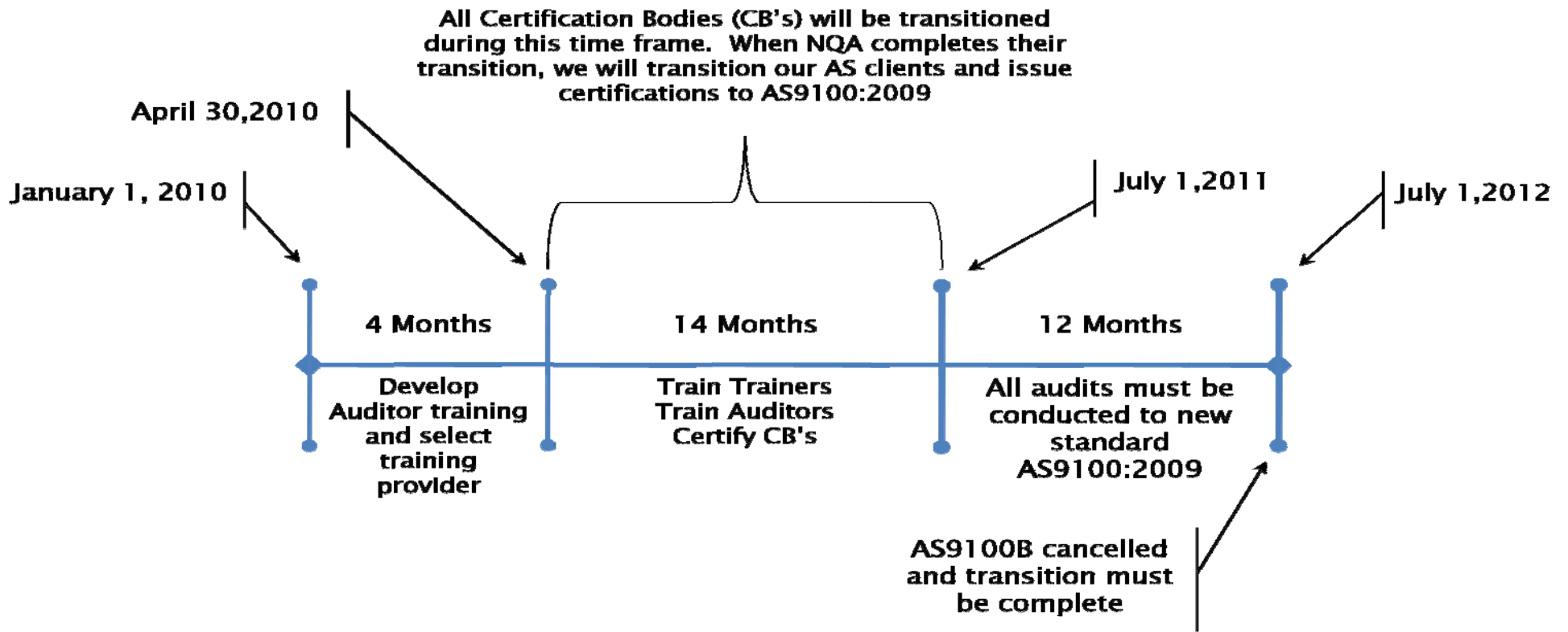
AS9100B	Changes	AS9100:2009
<p>An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.</p> <p>When used within a quality management system, such an approach emphasizes the importance of</p> <ul style="list-style-type: none"> a) understanding and meeting requirements, b) the need to consider processes in terms of added value, c) obtaining results of process performance and effectiveness, and d) 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.</p> <p>Plan: establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization’s policies.</p> <p>Do: implement the processes.</p> <p>Check: monitor and measure processes and product against policies, objectives and requirements for the product and report the results.</p> <p>Act: take actions to continually improve process performance.</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> <ul style="list-style-type: none"> a) understanding and meeting requirements, b) the need to consider processes in terms of added value, c) obtaining results of process performance and effectiveness, and d) 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.</p> <p>Plan: establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization’s policies.</p> <p>Do: implement the processes.</p> <p>Check: monitor and measure processes and product against policies, objectives and requirements for the product and report the results.</p> <p>Act: take actions to continually improve process performance.</p>

AS9100B	Changes	AS9100:2009
<p>1. Scope</p> <p>1.1 General</p> <p><i>This standard includes ISO 9001:2000, 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>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>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>NOTE: In this International Standard, the term “product” applies only to the product intended for, or required by, a customer.</p>	<p>AS9100 adjusts the document scope statement to explain that should a conflict exist between AS9100 and legal requirements, those legal requirements will take precedence.</p> <p>ISO 9001 clarifies the term “product” and again adds “statutory” to “regulatory”, clarifying the discussion of legal requirements</p>	<p>1. Scope</p> <p>1.1 General</p> <p><i>This standard includes ISO 9001:2008, quality management system requirements and specifies additional <u>aviation, space and defense industry</u> requirements, <u>definitions and notes as shown in bold, italic text.</u></i></p> <p><i>It is emphasized that the requirements specified in this standard are complementary (not alternative) to contractual and applicable <u>statutory</u> and regulatory requirements. <u>Should there be a conflict between the requirements of this standard and applicable statutory or regulatory requirements, the latter shall take precedence.</u></i></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 <u>statutory and</u> 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 <u>statutory and</u> regulatory requirements.</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 <u>legal requirements.</u></p>
<p>1.2 Application</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 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>ISO 9001 adds statutory requirements.</p>	<p>1.2 Application</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 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 <u>statutory and</u> regulatory requirements.</p>

AS9100B	Changes	AS9100:2009
<p><i>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.</i></p>	<p>AS9100 provides further clarification for the extension of the scope to aviation, space and defense industries</p> <p>AS9100 provides explanation for the proper application of the appropriate industry standard.</p> <p>AS9100 is to be used by organizations that design, develop and produce products.</p> <p>AS9110 is used by organizations that provide maintenance, repair and overhaul services.</p> <p>AS9120 is used by organizations that buy products and resell them</p> <p>AS9100 adds information for International Organization for Standardization.</p>	<p><u>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.</u></p> <p><u>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).</u></p> <p><u>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).</u></p> <p><i>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.</i></p>
<p>2. Normative reference</p>		<p>2. Normative references</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 (International Organization for Standardization) and IEC (International Electrotechnical Commission) maintain registers of currently valid International Standards.</p> <p>ISO 9000:2000, Quality management systems - Fundamentals and vocabulary.</p>	<p>ISO 9001 deletes unnecessary wording which did not add value or understanding</p> <p>ISO 9001 inserts more effective wording and updates the reference, ISO 9000:2000 to ISO 9000:2005</p>	<p>The following referenced documents are indispensable for the application of this document. For dated references, <u>only the edition cited applies.</u> For undated <u>references</u>, the latest edition of the referenced document (<u>including any amendments</u>) applies.</p> <p>ISO 9000:2005, Quality management systems — Fundamentals and vocabulary.</p>

AS9100B	Changes	AS9100:2009
<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>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>ISO 9001 removes obsolete text.</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>Key Characteristics: The features of a material, process, or part whose variation has a significant influence on product fit, performance, service life, or manufacturability.</p>	<p>Definition of “Risk” The understanding of risk is essential for an organization to develop a proactive quality management system.</p> <p>Definition of “Special Requirements” added to support the introduction of the requirement in section 7. The Change is to improve understanding of the link to “Critical Items” and “Key Characteristics” and to ensure these important requirements are systemically addressed and linked to risk management activities.</p> <p>Definition of “Critical Items” added to support the introduction of the requirement in section 7. and to improve the understanding of “Critical Items” coming from Special Requirements, design output, and/or risk analyses to ensure these items are systemically addressed and adequately managed</p> <p>AS9100 expands the concept for “Key Characteristic”.</p>	<p>3.1 Risk</p> <p><u>An undesirable situation or circumstance that has both a likelihood of occurring and a potentially negative consequence.</u></p> <p>3.2 Special requirements</p> <p><u>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.</u></p> <p>3.3 Critical items</p> <p><u>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.</u></p> <p>3.4 Key Characteristic</p> <p><u>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.</u></p>

AS9100B	Changes	AS9100:2009
	<p>AS9100 includes a Note for insight into the interrelationship between special requirements, critical items and key characteristics and in what type of scenario they might be applied.</p>	<p>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</p>



AS9100B	Changes	AS9100:2009
<p>4 Quality management system</p> <p>4.1 General requirements</p> <p>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.</p> <p>The organization shall</p> <ol style="list-style-type: none"> identify the processes needed for the quality management system and their application throughout the organization (see 1.2), determine the sequence and interaction of these processes, determine criteria and methods needed to ensure that both the operation and control of these processes are effective, ensure the availability of resources and information necessary to support the operation and monitoring of these processes, monitor, measure and analyse these processes, and implement actions necessary to achieve planned results and continual improvement of these processes. <p>These processes shall be managed by the organization in accordance with the requirements of this International Standard.</p> <p>Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes.</p> <p>Control of such outsourced processes shall be identified within the quality management system.</p> <p>NOTE Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement.</p>	<p>AS9100 moved this statement from paragraph 4.2.1 to 4.1 to emphasis is applied at the QMS level, not only at the documentation level. Paragraphs 4.1 is directed to the overall QMS general requirements and are applicable across the entire QMS with the intent that <u>all</u> 9100 requirements shall address customer and applicable statutory and regulatory requirements as applicable.</p> <p>ISO 9001 provides positive wording for the use of analysis to support decisions, rather than just discovery.</p> <p>ISO 9001 explains that all processes must be monitored -however not all need to be measured.</p> <p>ISO 9001 removes a "should" from note 1, but still emphasizes analysis and improvement processes.</p> <p>ISO 9001 adds notes "2" and "3" which supplies extensive clarification about the nature of outsourced processes, to include:</p> <ul style="list-style-type: none"> what an outsourced process is. Considerations for controls of outsourced processes. association between outsourced processes and the purchasing Responsibility for all requirements remains with the organization even when processes are 	<p>4 Quality management system</p> <p>4.1 General requirements</p> <p>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.</p> <p><u>The organization's quality management system shall also address customer and applicable statutory and regulatory quality management system requirements.</u></p> <p>The organization shall</p> <ol style="list-style-type: none"> <u>determine</u> the processes needed for the quality management system and their application throughout the organization (see 1.2), determine the sequence and interaction of these processes, determine criteria and methods needed to ensure that both the operation and control of these processes are effective, ensure the availability of resources and information necessary to support the operation and monitoring of these processes, monitor, measure <u>where applicable</u>, and analyse these processes, and implement actions necessary to achieve planned results and continual improvement of these processes. <p>Where an organization chooses to outsource any process that affects product conformity <u>to</u> requirements, the organization shall ensure control over such processes.</p> <p><u>The type and extent of control to be applied to these</u> outsourced processes shall be <u>defined</u> within the quality management system</p> <p>NOTE 1 Processes needed for the quality management system referred to above include processes for management activities, provision of resources, product realization, measurement, analysis and improvement.</p> <p><u>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.</u></p> <p><u>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</u></p> <ol style="list-style-type: none"> <u>the potential impact of the outsourced process on the organization's capability to provide product that conforms to requirements,</u> <u>the degree to which the control for the process is shared,</u> <u>the capability of achieving the necessary control through the application of 7.4.</u>
AS9100B	Changes	AS9100:2009

<p>4.2 Documentation requirements</p>		<p>4.2 Documentation requirements</p>
<p>4.2.1 General</p>		<p>4.2.1 General</p>
<p>The quality management system documentation shall include</p> <p>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> <p><i>The organization shall ensure that personnel have access to quality management system documentation and are aware of relevant procedures</i></p> <p><i>Customer and/or regulatory authorities representatives shall have access to quality management system documentation.</i></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>NOTE 2 The extent of the quality management system documentation can differ from one organization to another due to</p> <p>a) the size of organization and type of activities, b) the complexity of processes and their interactions, and c) the competence of personnel.</p> <p>NOTE 3 The documentation can be in any form or type of medium.</p>	<p>ISO 9001 moves the “records” requirement from e) to c).</p> <p><i>AS9100 removes the regulatory reference now already made in 4.1.</i></p> <p><i>AS9100 requires staff to have access to and awareness of all relevant parts of management system documentation (and changes), not just awareness of procedures.</i></p> <p><i>AS9100 removes regulatory authority access requirement now included in 4.1.</i></p> <p>ISO 9001 Note 1 provides clarification that a “documented procedure” does not imply individual documents, but rather 1 or many, multiple procedures may be included in a single document according to the organization’s needs.</p>	<p>The quality management system documentation shall include</p> <p>a) documented statements of a quality policy and quality objectives, b) a quality manual, c) documented procedures <u>and records</u> required by this International Standard, <u>and</u> d) documents, <u>including records, determined</u> by the organization <u>to be necessary</u> to ensure the effective planning, operation and control of its processes.</p> <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>NOTE 1 Where the term “documented procedure” appears within this International Standard, this means that the procedure is established, documented, implemented and maintained. <u>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.</u></p> <p>NOTE 2 The extent of the quality management system documentation can differ from one organization to another due to</p> <p>a) the size of organization and type of activities, b) the complexity of processes and their interactions, and c) the competence of personnel.</p> <p>NOTE 3 The documentation can be in any form or type of medium.</p>
<p>4.2.2 Quality manual</p>		<p>4.2.2 Quality manual</p>
<p>The organization shall establish and maintain a quality manual that includes</p> <p>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 <i>—when referencing the documented procedures, the relationship between the requirements of this International Standard and the documented procedures shall be clearly shown.</i></p> <p>c) a description of the interaction between the processes of the quality management system.</p>	<p><i>AS9100 deleted the requirement that quality manual references to procedures include linkage to AS9100 requirements. This requirement added no value to assuring product quality and was viewed as prescriptive in that it specifies a particular method of assuring the requirements of the standard have been met.</i></p>	<p>The organization shall establish and maintain a quality manual that includes</p> <p>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>

AS9100B	Changes	AS9100:2009
<p>4.2.3 Control of documents</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>The organization shall coordinate document changes with customers and/or regulatory authorities in accordance with contract or regulatory requirements.</p>	<p>ISO 9001 provides clarity to why “external documents” needed to be identified and distribution controlled.</p> <p>AS9100 deletes the requirement already addressed in 4.1.</p>	<p>4.2.3 Control of documents</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 <u>determined by the organization to be necessary for the planning and operation of the quality management system</u> 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>4.2.4 Control of records</p> <p>Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system.</p> <p>Records shall remain legible, readily identifiable and retrievable.</p> <p>A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.</p> <p>The documented procedure shall define the method for controlling records that are created by and/or retained by suppliers.</p> <p>Records shall be available for review by customers and regulatory authorities in accordance with contract or regulatory requirements.</p>	<p>ISO 9001 clarifies the expectations of the industry. Maintenance of required records means “control”.</p> <p>ISO 9001 provides minor rewording.</p> <p>AS9100 deletes the requirement already addressed in 4.1.</p>	<p>4.2.4 Control of records</p> <p>Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system <u>shall be controlled.</u></p> <p>The organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.</p> <p>The documented procedure shall define the method for controlling records that are created by and/or retained by suppliers.</p> <p>Records shall remain legible, readily identifiable and retrievable.</p>

AS9100B	Changes	AS9100:2009
<p>4.3 Configuration Management</p> <p><i>The organization shall establish, document and maintain a configuration management process appropriate to the product.</i></p> <p><i>NOTE: Guidance on configuration management is given in ISO 10007.</i></p>	<p>AS9100 moved this subject to section 7.1 Adds focus and addresses interpretation issues arising from it being placed in this section.</p>	

AS9104/1: Requirements for Oversight of Aerospace Quality Management System Registration/Certification Programs

New Requirements

- NQA-USA is required to verify during all surveillance and recertification audits that the organization's **current OASIS administrator is identified in the OASIS database**
- NQA-USA is required to consider **suspending an organization's certificate**, during the surveillance cycle, or delay issuance of recertification should the client **fail to maintain their OASIS administrator**
- The **NQA-USA audit team leader** shall be limited to a maximum of **two consecutive certification cycles** at the client organization before replacement.
- NQA-USA shall ensure that **classified material or export control requirements** are discussed with their aviation, space, and defense clients and **included in the service contract and audit planning activities**.
 - Records of this discussion and the **agreements on auditor access** shall be maintained.
- When auditing **multiple site** organizations, a NQA-USA **AEA will need to be on-site - at each site** during the entire audit.

AS9100B	Changes	AS9100:2009
5 Management responsibility		5 Management responsibility
5.1 Management commitment		5.1 Management commitment
<p>Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by</p> <ul style="list-style-type: none"> 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. 		<p>Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by</p> <ul style="list-style-type: none"> 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.
5.2 Customer focus		5.2 Customer focus
<p>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).</p>	<p><i>AS9100 requirement places the accountability for product conformity and on-time delivery improvement directly with top management (see also clause 8.2.1). Product improvement is a key motivation behind this update.</i></p>	<p>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).</p> <p><u>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.</u></p>
5.3 Quality policy		5.3 Quality policy
<p>Top management shall ensure that the quality policy</p> <ul style="list-style-type: none"> 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. 		<p>Top management shall ensure that the quality policy</p> <ul style="list-style-type: none"> 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.
5.4 Planning		5.4 Planning
5.4.1 Quality objectives		5.4.1 Quality objectives
<p>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.</p> <p>The quality objectives shall be measurable and consistent with the quality policy.</p>		<p>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.</p> <p>The quality objectives shall be measurable and consistent with the quality policy.</p>

AS9100B	Changes	AS9100:2009
<p>5.4.2 Quality management system planning</p> <p>Top management shall ensure that</p> <ul style="list-style-type: none"> 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. 		<p>5.4.2 Quality management system planning</p> <p>Top management shall ensure that</p> <ul style="list-style-type: none"> 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.
<p>5.5 Responsibility, authority and communication</p> <p>5.5.1 Responsibility and authority</p> <p>Top management shall ensure that responsibilities and authorities are defined and communicated within the organization.</p>		<p>5.5 Responsibility, authority and communication</p> <p>5.5.1 Responsibility and authority</p> <p>Top management shall ensure that the responsibilities and authorities are defined and communicated within the organization.</p>
<p>5.5.2 Management representative</p> <p>Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes</p> <ul style="list-style-type: none"> 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, and d) the organizational freedom to resolve matters pertaining to quality. <p>NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.</p>	<p>ISO 9001 clarifies that the management representative be a member of the organization's management.</p> <p>AS9100 included the wording "and unrestrictive access" to avoid the possibility of the Management Representative being unable to directly access top management to ensure are involved in resolving quality management issues.</p>	<p>5.5.2 Management representative</p> <p>Top management shall appoint a member of the <u>organization's</u> management who, irrespective of other responsibilities, shall have responsibility and authority that includes</p> <ul style="list-style-type: none"> 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, and d) the organizational freedom and unrestricted access to top management to resolve quality management issues. <p>NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.</p>
<p>5.5.3 Internal communication</p> <p>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.</p> <p>Records from management reviews shall be maintained (see 4.2.4).</p>		<p>5.5.3 Internal communication</p> <p>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.</p> <p>Records from management reviews shall be maintained (see 4.2.4).</p>
<p>5.6.2 Review input</p> <p>The input to management review shall include information on</p> <ul style="list-style-type: none"> 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. 		<p>5.6.2 Review input</p> <p>The input to management review shall include information on</p> <ul style="list-style-type: none"> 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.

AS9100B	Changes	AS9100:2009
<p>5.6.3 Review output</p> <p>The output from the management review shall include any decisions and actions related to</p> <ul style="list-style-type: none"> 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. 		<p>5.6.3 Review output</p> <p>The output from the management review shall include any decisions and actions related to</p> <ul style="list-style-type: none"> 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.

Significant Deletions from AS9100

- Paragraph 4.2.2.b: Requirement to show the relationship between AS9100 requirements and the organization’s documented procedures
 - Paragraph 7.4.3: Validation of test reports for raw material
- Paragraph 8.2.2: Requirement for “detailed tools and techniques for internal audits

AS9100B	Changes	AS9100:2009
6 Resource management		6 Resource management
6.1 Provision of resources		6.1 Provision of resources
<p>The organization shall determine and provide the resources needed</p> <p>a) to implement and maintain the quality management system and continually improve its effectiveness, and</p> <p>b) to enhance customer satisfaction by meeting customer requirements.</p>		<p>The organization shall determine and provide the resources needed</p> <p>a) to implement and maintain the quality management system and continually improve its effectiveness, and</p> <p>b) to enhance customer satisfaction by meeting customer requirements.</p>
6.2 Human resources		6.2 Human resources
6.2.1 General		6.2.1 General
<p>Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.</p>	<p>ISO 9001 clarifies that the intent of the standard is for “product quality” which is to conform to product requirements.</p> <p>ISO 9001 adds a note to explain that personnel may affect conformity directly (production personnel) or indirectly (design personnel.)</p>	<p>Personnel performing work affecting <u>conformity to product requirements</u> shall be competent on the basis of appropriate education, training, skills and experience.</p> <p><u>NOTE</u> <u>Conformity to product requirements can be affected directly or indirectly by personnel performing any task within the quality management system.</u></p>
6.2.2 Competence, awareness and training	ISO 9001 alters the words in the section title.	6.2.2 Competence, <u>training and awareness</u>
<p>The organization shall</p> <p>a) determine the necessary competence for personnel performing work affecting product quality,</p> <p>b) provide training or take other actions to satisfy these needs,</p> <p>c) evaluate the effectiveness of the actions taken,</p> <p>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</p> <p>e) maintain appropriate records of education, training, skills and experience (see 4.2.4).</p>	<p>ISO 9001 again tells us that “product quality” is conformity to product requirements.</p> <p>ISO 9001 complements the paragraph with “where applicable” to explain that no training may be necessary if the person is already sufficiently competent.</p>	<p>The organization shall</p> <p>a) determine the necessary competence for personnel performing work affecting <u>conformity to product requirements</u>,</p> <p>b) <u>where applicable</u>, provide training or take other actions to <u>achieve the necessary competence</u>,</p> <p>c) evaluate the effectiveness of the actions taken,</p> <p>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</p> <p>e) maintain appropriate records of education, training, skills and experience (see 4.2.4).</p>
6.3 Infrastructure		6.3 Infrastructure
<p>The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable</p> <p>a) buildings, workspace and associated utilities,</p> <p>b) process equipment (both hardware and software), and</p> <p>c) supporting services (such as transport or communication).</p>	<p>ISO 9001 includes Information Systems as another example of a supporting service.</p>	<p>The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable</p> <p>a) buildings, workspace and associated utilities,</p> <p>b) process equipment (both hardware and software), and</p> <p>c) supporting services (such as transport, communication or <u>information systems</u>).</p>
6.4 Work environment		6.4 Work environment
<p>The organization shall determine and manage the work environment needed to achieve conformity to product requirements.</p>		<p>The organization shall determine and manage the work environment needed to achieve conformity to product requirements.</p>

AS9100B	Changes	AS9100:2009
<p>NOTE: Factors that may affect the conformity of the product include temperature, humidity, lighting, cleanliness, protection from electrostatic discharge, etc.</p>	<p>ISO 9001 includes a note comparable AS9100b. This made the industry note unnecessary</p>	<p>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).</p>

Significant Additions and Enhancements:

- Incorporates ISO 9001:2008 changes
 - The scope is extended to include the defense industry with aviation and space
- Introduction of the terms of "special requirements" and "critical items" and bundling it with "key characteristics" to form a new industry concept.
 - Introduction of "Project Management" and "Risk Management" into Section 7
 - Enhancement and re-location of "Configuration Management" from Section 4 to Section 7
- Movement and enhancement of First Article Inspection (FAI) from Section 8 (measurement) to Section 7 (production and service provision)

AS9100B	Changes	AS9100:2009
<p>Product realization</p> <p>7.1 Planning of product realization</p> <p>The organization shall plan and develop the processes needed for product realization.</p> <p>In planning product realization, the organization shall determine the following, as appropriate:</p> <p>a) quality objectives and requirements for the product;</p> <p>b) the need to establish processes, documents, and provide resources specific to the product;</p> <p>c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;</p> <p>d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4);</p> <p>e) the identification of resources to support operation and maintenance of the product</p> <p>The output of this planning shall be in a form suitable for the organization's method of operations.</p> <p>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.</p> <p>NOTE 2 The organization may also apply the requirements given in 7.3 to the development of product realization processes.</p>	<p>AS9100 included a note to emphasize the importance of considering relevant requirements at the earliest point in the product lifecycle</p> <p>ISO 9001 adds direction for appropriate product "measurement" activities</p> <p>AS9100 includes a new subparagraph e) to achieve improved product quality through the use of structured configuration management methods.</p>	<p>7 Product realization</p> <p>7.1 Planning of product realization</p> <p>The organization shall plan and develop the processes needed for product realization.</p> <p>In planning product realization, the organization shall determine the following, as appropriate:</p> <p>a) quality objectives and requirements for the product;</p> <p><u>NOTE Quality objectives and requirements for the product include consideration of aspects such as</u></p> <p><u>- product and personal safety,</u></p> <p><u>- reliability, availability and maintainability,</u></p> <p><u>- producibility and inspectability,</u></p> <p><u>- suitability of parts and materials used in the product,</u></p> <p><u>- selection and development of embedded software, and</u></p> <p><u>- recycling or final disposal of the product at the end of its life.</u></p> <p>b) the need to establish processes <u>and</u> documents, and <u>to</u> provide resources specific to the product;</p> <p>c) required verification, validation, monitoring, <u>measurement</u>, inspection and test activities specific to the product and the criteria for product acceptance;</p> <p>d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4);</p> <p><u>e) configuration management appropriate to the product;</u></p> <p><u>f) resources to support the use and maintenance of the product.</u></p> <p>The output of this planning shall be in a form suitable for the organization's method of operations.</p> <p>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.</p> <p>NOTE 2 The organization may also apply the requirements given in 7.3 to the development of product realization processes.</p>
	<p>AS9100 has incorporated project management to recognize the continued need for the focus on planning and for managing product realization quality, configuration, risks, resources and schedule throughout the product lifecycle. It is included here to show its impact on all aspects of product realization.</p>	<p>7.1.1 Project Management</p> <p><u>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.</u></p>

AS9100B	Changes	AS9100:2009
	<p><i>AS9100 included the stipulation for the use of Risk Management techniques to achieve improved product quality and improved customer satisfaction.</i></p> <p><i>AS9100 includes configuration management in paragraph 7.1 because its requirements apply to all phases of the product lifecycle. The essence of configuration management exact continued knowledge of product configuration from as required to as designed to as built to as delivered to ensure continued product fitness for use.</i></p> <p><i>AS9100 moved and expanded Work Transfer as it can apply at all stages of product realization or possibilities; permanent move or temporary, moves from one supplier to another and moves from one facility to another.</i></p>	<p>7.1.2 Risk Management <u>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</u> <u>a) assignment of responsibilities for risk management,</u> <u>b) definition of risk criteria (e.g., likelihood, consequences, risk acceptance),</u> <u>c) identification, assessment and communication of risks throughout product realization,</u> <u>d) identification, implementation and management of actions to mitigate risks that exceed the defined risk acceptance criteria, and</u> <u>e) acceptance of risks remaining after implementation of mitigating actions.</u></p> <p>7.1.3 Configuration Management <u>The organization shall establish, implement and maintain a configuration management process that includes, as appropriate to the product</u> <u>a) configuration management planning,</u> <u>b) configuration identification,</u> <u>c) change control,</u> <u>d) configuration status accounting, and</u> <u>e) configuration audit.</u> <u>NOTE See ISO 10007 for guidance.</u></p> <p>7.1.4 Control of work transfers <u>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.</u></p>
<p>7.2 Customer-related processes</p>		<p>7.2 Customer-related processes</p>
<p>7.2.1 Determination of requirements related to the product</p>		<p>7.2.1 Determination of requirements related to the product</p>
<p>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</p>	<p>ISO 9001 provides minor clarification in this section.</p>	<p>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,</p>

AS9100B	Changes	AS9100:2009
	<p><i>AS9100 adds a note regarding special requirements (see 3.2). The new Note points out that when defining the overall product requirements the user should always consider any special requirements identified by the customer and the organization.</i></p> <p>ISO 9001 provides a final note defining post-delivery activities.</p>	<p>c) statutory and regulatory requirements <u>applicable</u> to the product, and d) any additional requirements <u>considered necessary</u> by the organization.</p> <p><u>NOTE Requirements related to the product can include special requirements.</u></p> <p>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.</p>
<p>7.2.2 Review of requirements related to the product</p> <p>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</p> <p>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.</p> <p>Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).</p> <p>Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.</p> <p>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.</p> <p>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.</p>	<p><i>AS9100 adds subparagraph d) to incorporate the addition of special requirements into the review of requirements related to the product.</i></p> <p><i>AS9100 updates this section to include instruction to take account of risk in review.</i></p>	<p>7.2.2 Review of requirements related to the product</p> <p>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</p> <p>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).</p> <p>Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).</p> <p>Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.</p> <p>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.</p> <p>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.</p>
<p>7.2.3 Customer communication</p> <p>The organization shall determine and implement effective arrangements for communicating with customers in relation to</p> <p>a) product information, b) enquiries, contracts or order handling, including amendments, and c) customer feedback, including customer complaints.</p>		<p>7.2.3 Customer communication</p> <p>The organization shall determine and implement effective arrangements for communicating with customers in relation to</p> <p>a) product information, b) enquiries, contracts or order handling, including amendments, and c) customer feedback, including customer complaints.</p>

AS9100B	Changes	AS9100:2009
<p>7.3 Design and development</p> <p>7.3.1 Design and development planning</p> <p>The organization shall plan and control the design and development of product.</p> <p>During the design and development planning, the organization shall determine</p> <p>a) the design and development stages, –in respect of organization, task sequence, mandatory steps, significant stages and method of configuration control,</p> <p>b) the review, verification and validation that are appropriate to each design and development stage, and</p> <p>c) the responsibilities and authorities for design and development.</p> <p>Where appropriate, due to complexity, the organization shall give consideration to the following activities: –structuring the design effort into significant elements;</p> <p>- 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.</p> <p>The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.</p> <p>Planning output shall be updated, as appropriate, as the design and development progresses.</p> <p>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.</p>	<p>AS9100 removes the unnecessary explanation below subparagraph a).</p> <p>AS9100 requirement has been rephrased to provide clarity. Previously it was required to “give consideration to” however it is now more strongly worded that these activities shall be done – where appropriate (see risk management).</p> <p>AS9100 has added statutory to be consistent with ISO 9001. This requirement has also been moved and reworded. It is now emphasized that design input be integrated with the products functional and operational requirements as applicable including reliability, safety, maintainability, statutory and regulatory requirements.</p> <p>AS9100 adds the requirement for planning to consider the complete product lifecycle. It is emphasized that design and development planning should account for production preparation, ability to test verify, maintain and repair, etc. and associated risks to be mitigated from the early design stage.</p> <p>ISO 9001 advisory note clarifies that reviews, verification and validation may be accomplished separately or combined.</p>	<p>7.3 Design and development</p> <p>7.3.1 Design and development planning</p> <p>The organization shall plan and control the design and development of product</p> <p>During the design and development planning, the organization shall determine</p> <p>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.</p> <p><i>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.</i></p> <p>Where appropriate, the organization shall <u>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></p> <p>The different design and development tasks to be carried out shall <u>be based on the safety and functional objectives of the product in accordance with customer, statutory and regulatory requirements.</u></p> <p><u>Design and development planning shall consider the ability to produce, inspect, test and maintain the product.</u></p> <p>The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.</p> <p>Planning output shall be updated, as appropriate, as the design and development progresses.</p> <p><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></p>

AS9100B	Changes	AS9100:2009
<p>7.3.2 Design and development inputs</p> <p>Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include</p> <ol style="list-style-type: none"> functional and performance requirements, applicable statutory and regulatory requirements, where applicable, information derived from previous similar designs, and other requirements essential for design and development. <p>These inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.</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>ISO 9001 corrects wording from “these inputs” to “the inputs.”</p>	<p>7.3.2 Design and development inputs</p> <p>Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include</p> <ol style="list-style-type: none"> functional and performance requirements, applicable statutory and regulatory requirements, where applicable, information derived from previous similar designs, and other requirements essential for design and development. <p>The inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.</p>
<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> <ol style="list-style-type: none"> meet the input requirements for design and development, provide appropriate information for purchasing, production and for service provision, contain or reference product acceptance criteria, specify the characteristics of the product that are essential for its safe and proper use, and identify key characteristics, when applicable, in accordance with design or contract requirements. <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 these 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>ISO 9001 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. Critical item along with Special Requirements were developed to be an evolution of the Key Characteristic concept.</p> <p>AS9100 provides minor changes to more clearly describe data requirements.</p> <p>ISO 9001 includes a reminder to consider product preservation requirements as outputs of Design and Development.</p>	<p>7.3.3 Design and development outputs</p> <p>The outputs of design and development shall be in a form <u>suitable for verification</u> against the design and development input and shall be approved prior to release.</p> <p>Design and development outputs shall</p> <ol style="list-style-type: none"> meet the input requirements for design and development, provide appropriate information for purchasing, production and service provision, contain or reference product acceptance criteria, specify the characteristics of the product that are essential for its safe and proper use, and <u>specify, as applicable, any critical items, including any key characteristics, and specific actions to be taken for these items.</u> <p>The organization shall define the data required to allow the product to be identified, manufactured, inspected, used and maintained; including for example</p> <ul style="list-style-type: none"> - <u>the drawings, part lists, and specifications necessary to define the configuration and the design features of the product, and</u> - <u>the material, process, manufacturing and assembly data needed to ensure conformity of the product.</u> <p>NOTE : Information for production and service provision can include details for the preservation of product.</p>

AS9100B	Changes	AS9100:2009
<p>7.3.4 Design and development review</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, and c) to authorize progression to the next stage.</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>7.3.4 Design and development review</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, and c) to authorize progression to the next stage.</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>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>AS9100 deleted Note as unnecessary. The text was determined to be more in line with a "how to" than a requirement.</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>7.3.6 Design and development validation</p> <p>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).</p> <p>NOTES:</p> <ul style="list-style-type: none"> –Design and/or development validation follows successful design and/or development verification. –Validation is normally performed under defined operating conditions. –Validation is normally performed on the final product, but may be necessary in earlier stages prior to product completion. –Multiple validations may be performed if there are different intended uses. 	<p>AS9100 deleted "Notes and text as redundant.."</p>	<p>7.3.6 Design and development validation</p> <p>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).</p>

AS9100B	Changes	AS9100:2009
	<p>AS9100 moves the header and item from 7.3.6.2.</p> <p>AS9100 removes the word "standard" from c) for clarity.</p>	<p>7.3.6.1 Design and development verification and validation testing</p> <p>Where tests are necessary for verification and validation, these tests shall be planned, controlled, reviewed and documented to ensure and prove the following:</p> <p>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,</p> <p>b) test procedures describe the method of operation, the performance of the test and the recording of the results,</p> <p>c) the correct configuration of the product is submitted for the test,</p> <p>d) the requirements of the test plan and the test procedures are observed, <u>and</u></p> <p>e) the acceptance criteria are met.</p>
<p>7.3.6.1 Documentation of design and/or development verification and validation</p>	<p>AS9100 moves the header from 7.3.6.1 and reorders the wording.</p>	<p>7.3.6.2 Design and development verification and validation documentation</p>
<p>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 opeChanges conditions.</p>		<p>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 opeChanges conditions.</p>
<p>7.3.6.2 Design and/or development verification and validation testing:</p> <p>Where tests are necessary for verification and validation, these tests shall be planned, controlled, reviewed, and documented to ensure and prove the following:</p> <p>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;</p> <p>b) test procedures describe the method of operation, the performance of the test, and the recording of the results;</p> <p>c) the correct configuration standard of the product is submitted for the test;</p> <p>d) the requirements of the test plan and the test procedures are observed;</p> <p>e) the acceptance criteria are met.</p>		

AS9100B	Changes	AS9100:2009
<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>AS9100 removes the regulatory reference now found in 4.1.</p> <p>AS9100 also links the Design & Development change process to the configuration management process.</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>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> <ol style="list-style-type: none"> maintain a register of approved suppliers that includes the scope of the approval; periodically review supplier performance; records of these reviews shall be used as a basis for establishing the level of controls to be implemented; define the necessary actions to take when dealing with suppliers that do not meet requirements; ensure where required that both the organization and all suppliers use customer-approved special process sources; 	<p>AS9100 provides a new note emphasizing that the organization should obtain and use as much reliable supplier quality (e.g. audit, OASIS, on time/on quality) data as possible when making a selection decision and provides a number of examples where this data might be found. The last sentence points out that accountability for supplier remains the responsibility of the organization..</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>

AS9100B	Changes	AS9100:2009
<p>e) ensure that the function having responsibility for approving supplier quality systems has</p>	<p>AS9100 changes the requirement for the supplier register to allow inclusion of all suppliers with their approval status indicated and it provides explanation for scope of approval.</p> <p>AS9100 clarifies that the results rather than of records of supplier performance reviews are used to establish the level of control applied to suppliers..</p> <p>AS9100 more clearly defines responsibility and authority for those approving supplier status and specifies supplier risk management.</p>	<p>The organization shall:</p> <p>a) maintain a register of <u>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>b) periodically review supplier performance; <u>the results of these reviews shall be used as a basis for establishing the level of controls to be implemented,</u></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) <u>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>f) <u>determine and manage the risk when selecting and using suppliers (see 7.1.2).</u></p>
<p>7.4.2 Purchasing information</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) 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</p> <p>- supplier notification to organization of nonconforming product and</p> <p>- 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>AS9100 provides clarification for the communication of technical data requirements in purchasing.</p> <p>AS9100 adds clarification for test and acceptance requirements, including critical items and key characteristics</p> <p>AS9100 modifies and clarifies requirements to be communicated to the suppliers including</p> <ul style="list-style-type: none"> - n/c notification: requirements - change notification - supply chain flow down of requirements 	<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) requirements for test specimens (e.g., production method, number, storage conditions) for design approval, inspection/verification, investigation or auditing,</p> <p>g) requirements <u>regarding the need for the supplier to</u></p> <ul style="list-style-type: none"> - <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>

AS9100B	Changes	AS9100:2009
<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>The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.</p>	<p>AS9100 consolidated from 4.2.4 the requirement to communicate records management requirements to the supplier</p> <p>AS9100 modified the right of access requirements to the suppliers.</p>	<p>h) records retention requirements, and, i) 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</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><i>Verification activities may include</i></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>c) review of the required documentation,</p> <p>d) inspection of products upon receipt, and</p> <p>e) delegation of verification to the supplier, or supplier certification.</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>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>Where the organization delegates verification activities to the supplier, the requirements for delegation shall be defined and a register of delegations maintained.</p> <p>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.</p> <p>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.</p>	<p>AS9100 changed "customer verification" to a Note as the need for customer verification would be a contractual requirement and additional to those requirements contained in AS9100.</p> <p>AS9100 Note 2 provides guidance. No shall statement existed, so a note is more appropriate.</p> <p>"Quality" changed to "conformity" in alignment with ISO text (ref. 6.2.1, 6.2.2). Test reports changed to test records to provide flexibility for the stakeholders.</p> <p>AS9100 has significantly reworded this paragraph, adding text that is more specific and proactive. Additional instructions have been added to "identify and record" product issued pending completion of verification to allow recall and replacement. This replaces "positive recall."</p> <p>AS9100 deletes the requirement to validate supplier test reports. Test reports are a tool not applicable to all stakeholders and for all types of products.</p> <p>Deleted contractual language. Covered in clause 4.1.</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><u>NOTE1 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><u>NOTE 2</u>Verification activities can include</p> <ul style="list-style-type: none"> - obtaining objective evidence of the conformity of the product from the supplier (e.g., accompanying documentation, certificate of conformity, test records, statistical records, process control records), - inspection and audit at the supplier's premises, - review of the required documentation, - inspection of products upon receipt, and - delegation of verification to the supplier or supplier certification. <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>Where the organization delegates verification activities to the supplier, the requirements for delegation shall be defined and a register of delegations maintained.</p> <p>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.</p>

AS9100B	Changes	AS9100:2009
<p>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.</p>		
<p>7.5 Production and service provision</p>		<p>7.5 Production and service provision</p>
<p>7.5.1 Control of production and service provision</p>		<p>7.5.1 Control of production and service provision</p>
<p>Planning shall consider, as applicable, - 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).</p> <p>The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable</p> <p>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>	<p>AS9100 deletes the reference to control plans</p> <p>AS9100 adds Notes under subparagraphs a), b), and c) to provide additional guidance and examples to the stakeholders. Some of these were taken from the deleted paragraph 7.5.1.1.</p> <p>ISO 9001 changes terminology from measuring “devices” to “equipment” wherever it appears and clarifies that the term “release” means product release.</p> <p>AS9100 provides minor text changes for clarification and to retain consistent terminology with ISO 9001.</p> <p>AS9100 shifts this requirement from above and changes the text to be consistent with the concept of “critical items.”</p>	<p>The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable</p> <p>a) the availability of information that describes the characteristics of the product, <u>NOTE This information can include drawings, parts lists, materials and process specifications.</u> b) the availability of work instructions, as necessary, <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> c) the use of suitable equipment, <u>NOTE Suitable equipment can include product specific tools (e.g., jigs, fixtures, molds) and software programs.</u> 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) accountability for all product during <u>production</u> (e.g., parts quantities, split orders, nonconforming product), h) evidence that all <u>production and inspection/verification</u> 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 (e.g., water, compressed air, electricity, chemical products) to the extent they affect <u>conformity to product requirements</u>, and k) criteria for workmanship, <u>specified in the clearest practical way</u> (e.g., written standards, representative samples, illustrations).</p> <p>Planning shall consider, as applicable, - establishing, implementing and maintaining appropriate processes to manage critical items, including process controls where key characteristics have been identified,</p>

AS9100B	Changes	AS9100:2009
		<p>- <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></p> <p>7.5.1.1 Production process verification</p> <p><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></p> <p><i>NOTE This activity is often referred to as first article inspection.</i></p>
<p>7.5.1.1 Production Documentation</p> <p>Production operations shall be carried out in accordance with approved data. This data shall contain as necessary 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 b) a list of specific or non-specific tools and numerical control (NC) machine programs required and any specific instructions associated with their use.</p>	<p>AS9100 moved "First Article Inspection" (FAI) was from 8.2 monitoring and measurement, to 7.5.1.1 as a production. The move acknowledges that this requirement is not primarily a measuring and monitoring process, but a process that will be used to assure product realization capability under controlled conditions. Being in clause 7 also allows justifiable exclusion for unique and individual products.</p> <p>AS9100 eliminated this clause, moving much of the text and intent to the notes found in 7.5.1a) and b).</p>	
<p>7.5.1.2 Control of production process changes</p> <p>Persons authorized to approve changes to production processes shall be identified.</p> <p>The organization shall identify and obtain acceptance of changes that require customer and/or regulatory authority approval in accordance with contract or regulatory requirements.</p> <p>Changes affecting processes, production equipment, tools and programs shall be documented. Procedures shall be available to control their implementation.</p>	<p>AS9100 revises "persons" to "personnel."</p> <p>AS9100 provides explicit instructions to control changes" and "Programs" is clarified as "software."</p> <p>AS9100 changes "quality" to "conformity" to be consistent with ISO 9001 language.</p>	<p>7.5.1.2 Control of production process changes</p> <p><u>Personnel</u> authorized to approve changes to production processes shall be identified.</p> <p><u>The organization shall control and document changes affecting processes, production equipment, tools, or software programs.</u></p> <p><u>The results of changes to production processes shall be assessed to confirm that the desired effect has been achieved without adverse effects to product <u>conformity</u>.</u></p>

AS9100B	Changes	AS9100:2009
<p>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.</p>		
<p>7.5.1.3 Control of production equipment, tools and numerical control (NC) machine programs</p>	<p>AS9100 changes the scope of the from NC machine to software.</p>	<p>7.5.1.3 Control of production equipment, tools and software programs</p>
<p>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. Storage requirements, including periodic preservation/condition checks, shall be established for production equipment or tooling in storage.</p>	<p>AS9100 defines the scope as "software programs used to automate and control/monitor product realization processes." AS9100 has removed the requirement for a documented procedure and storage requirements are changed from "established" to "defined."</p>	<p><u>Production equipment, tools and software programs used to automate and control/monitor product realization processes, shall be validated prior to release for production and shall be maintained.</u> Storage requirements, including periodic preservation/condition checks, shall be <u>defined</u> for production equipment or tooling in storage.</p>
<p>7.5.1.4 Control of work transferred, on a temporary basis, outside the organization's facilities</p>	<p>AS9100 moved item to 7.1.4</p>	
<p>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.</p>	<p>AS9100 moved item to 7.1.4</p>	
<p>7.5.1.5 Control of Service Operations</p>	<p>AS9100 Modifies the title.</p>	<p>7.5.1.4 Post-delivery support</p>
<p>Where servicing is a specified requirement, service operation processes shall provide for a) a method of collecting and analyzing in-service data, 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, c) the control and updating of technical documentation, d) the approval, control, and use of repair schemes, and e) the controls required for off-site work (e.g., organization's work undertaken at the customer's facilities).</p>	<p>AS9100 clarified the wording AS9100 provides direction for problem investigation and reporting.</p>	<p><u>Post-delivery support shall provide as applicable for the</u> a) <u>collection and analysis of in-service data,</u> b) <u>actions to be taken, including investigation and reporting, when problems are detected after delivery,</u> c) <u>control and updating of technical documentation,</u> d) <u>approval, control and use of repair schemes, and</u> e) <u>controls required for off-site work (e.g., organization's work undertaken at the customer's facilities).</u></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. NOTE: These processes are frequently referred to as special processes Validation shall demonstrate the ability of these processes to achieve planned results.</p>	<p>ISO 9001:2008 clarifies the explanation of special processes that don't achieve expected results may result in product deficiencies in the field.</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 NOTE These processes are often referred to as special processes. Validation shall demonstrate the ability of these processes to achieve planned results.</p>

AS9100B	Changes	AS9100:2009
<p>The organization shall establish arrangements for these processes including, as applicable</p> <p>a) defined criteria for review and approval of the processes, - qualification and approval of special processes prior to use,</p> <p>b) approval of equipment and qualification of personnel, - control of the significant operations and parameters of special processes in accordance with documented process specifications and changes thereto,</p> <p>c) use of specific methods and procedures</p> <p>d) requirements for records (see 4.2.4), and</p> <p>e) revalidation.</p>	<p>AS9100 has removed excessive and unnecessary text.</p>	<p>The organization shall establish arrangements for these processes including, as applicable</p> <p>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>
<p>7.5.3 Identification and traceability</p>		<p>7.5.3 Identification and traceability</p>
<p>Where appropriate, the organization shall identify the product by suitable means throughout product realization.</p> <p>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.</p> <p>The organization shall identify the product status with respect to monitoring and measurement requirements.</p> <p>When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), the organization shall establish and document controls for the media.</p> <p>Where traceability is a requirement, the organization shall control and record the unique identification of the product (see 4.2.4).</p> <p>According to the level of traceability required by contract, regulatory, or other established requirement, the organization's system shall provide for:</p> <p>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.</p> <p>NOTE In some industry sectors, configuration management is a means by which identification and traceability are maintained (see 4.3).</p>	<p>ISO 9001 highlights the intent that the product must be identified throughout product realization.</p> <p>AS9100 removes the requirement for documented controls for the control of stamps, passwords, etc. and instead directs "appropriate" controls be established</p> <p>ISO 9001 specifies a requirement for traceability records.</p> <p>As the requirement is now implied in section 4.1. AS9100 changed the requirements to a note.</p> <p>AS9100 revised the reference for configuration management from 4.3 to 7.1.3.</p>	<p>Where appropriate, the organization shall identify the product by suitable means throughout product realization.</p> <p>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.</p> <p>The organization shall identify the product status with respect to monitoring and measurement requirements <u>throughout product realization.</u></p> <p>When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), the organization shall establish <u>appropriate</u> controls for the media.</p> <p>Where traceability is a requirement, the organization shall control the unique identification of the product <u>and maintain records</u> (see 4.2.4).</p> <p><u>NOTE</u> Traceability requirements may include</p> <ul style="list-style-type: none"> - <u>identification to be maintained throughout the product life,</u> - <u>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),</u> - <u>for an assembly, the ability to trace its components to the assembly and then to the next higher assembly, and</u> - <u>for a product, a sequential record of its production (manufacture, assembly, inspection/verification) to be retrievable.</u> <p>NOTE In some industry sectors, configuration management is a means by which identification and traceability are maintained (see 7.1.3).</p>

AS9100B	Changes	AS9100:2009
<p>7.5.4 Customer property</p> <p>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).</p> <p>NOTE: Customer property can include intellectual property <i>including customer furnished data used for design, production and/or inspection</i>.</p>	<p>ISO 9001 has modified the text to properly clarify that the organization must report changes and/or adverse conditions affecting customer property to the customer and maintain records.</p> <p>AS9100 has removed text no longer necessary and ISO 9001 has added personal data.</p>	<p>7.5.4 Customer property</p> <p>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, <u>the organization shall report this to the customer and maintain records</u> (see 4.2.4).</p> <p>NOTE Customer property can include intellectual property <u>and personal data</u>.</p>
<p>7.5.5 Preservation of product</p> <p>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.</p> <p>Preservation of product shall also include, where applicable in accordance with product specifications and/or applicable regulations, provisions for:</p> <p>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.</p> <p>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.</p>	<p>ISO 9001 has provided minor changes to the text to explain that preservation includes the following items listed only as applicable</p> <p>AS9100 rewords this sentence and adds "statutory" to be consistent with ISO 9001.</p> <p>AS9100 has moved the last paragraph to 8.2.4</p>	<p>7.5.5 Preservation of product</p> <p>The organization shall preserve the product during internal processing and delivery to the intended destination <u>in order to maintain conformity to requirements</u>. As applicable, preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.</p> <p>Preservation of product shall also include, where applicable in accordance with product specifications and applicable <u>statutory and regulatory requirements</u>, provisions for</p> <p>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, <u>and</u> f) special handling for hazardous materials.</p>
<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>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.</p>	<p>ISO 9001 has changed terminology from "devices" to "equipment"</p> <p>AS9100 changes "devices" to "equipment" and adds the word "verification" to be consistent with ISO 9001.</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>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.</p>

AS9100B	Changes	AS9100:2009
<p>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.</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>The organization shall ensure that environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out.</p> <p>Where necessary ensure valid results, measuring equipment shall</p> <p>a) 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;</p> <p>b) be adjusted or re-adjusted as necessary;</p> <p>c) be identified to enable the calibration status to be determined;</p> <p>d) be safeguarded from adjustments that would invalidate the measurement result;</p> <p>e) be protected from damage and deterioration during handling, maintenance and storage;</p> <p>f) be recalled to a defined method when requiring calibration.</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>NOTE See ISO 10012-1 and ISO 10012-2 for guidance.</p>	<p>AS9100 adjusts its syntax to be consistent with ISO 9001.</p> <p>AS9100 adjusts its text</p> <p>ISO 9001 adjusts the text to clarify that equipment may be calibrated or verified or both.</p> <p>ISO 9001 corrects its text.</p> <p>AS9100 strengthens the requirement to establish a process for the recall of equipment due for calibration. It also now includes equipment due for verification.</p> <p>ISO 9001 deletes the referencing note to the ISO 10012 standards. This reference referenced is now in the bibliography.</p> <p>ISO 9001 includes a note with guidance for software confirmation.</p>	<p>NOTE Monitoring and measuring equipment includes, but is 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.</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>The organization shall ensure that environmental conditions are suitable for the calibration, inspection, measurement and testing being carried out.</p> <p>Where necessary to ensure valid results, measuring equipment shall</p> <p>a) 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>);</p> <p>b) be adjusted or re-adjusted as necessary;</p> <p>c) <u>have identification in order to determine its</u> calibration status;</p> <p>d) be safeguarded from adjustments that would invalidate the measurement result;</p> <p>e) be protected from damage and deterioration during handling, maintenance and storage.</p> <p><u>The organization shall establish, implement and maintain a process for the recall of monitoring and measuring equipment requiring calibration or verification.</u></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>NOTE Confirmation of the ability of computer software to satisfy the intended <u>application would typically include its verification and configuration management to maintain its suitability for use.</u></p>

AS9100B	Changes	AS9100:2009
<p>8 Measurement, analysis and improvement</p> <p>8.1 General</p> <p>The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed</p> <p>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.</p> <p>This shall include determination of applicable methods, including statistical techniques, and the extent of their use.</p> <p>NOTE: According to the nature of the product and depending on the specified requirements, statistical techniques may be used to support:</p> <ul style="list-style-type: none"> - 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. 	<p>ISO 9001 now confirms that the intent is conformity of the product to requirements.</p> <p>AS9100 removes confusing text in this note.</p> <p>AS9100 modified the note changing failure mode, effect and criticality analysis (FMECA) to failure mode and effect analysis (FMEA).</p>	<p>8 Measurement, analysis and improvement</p> <p>8.1 General</p> <p>The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed</p> <p>a) to demonstrate conformity to product requirements, b) to ensure conformity of the quality management system, and c) to continually improve the effectiveness of the quality management system.</p> <p>This shall include determination of applicable methods, including statistical techniques, and the extent of their use.</p> <p>NOTE According to the nature of the product and depending on the specified requirements, statistical techniques <u>can</u> be used to support design verification (e.g., reliability, maintainability, safety),</p> <ul style="list-style-type: none"> - process control, - selection and inspection of key characteristics, - process capability measurements, - statistical process control, - design of experiment, - inspection, <u>and</u> - failure mode, effect <u>and criticality</u> analysis.
<p>8.2 Monitoring and measurement</p> <p>8.2.1 Customer satisfaction</p> <p>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.</p>	<p>AS9100 recognizes customer satisfaction as a key inclusion in this update and has defined mandatory measures (e.g. customer performance indicators) that all organizations of regardless of sizes and complexity must monitor, analyze and review to assess if improvement is needed. If action is needed, improvements must be planned and implemented and the results of the action must be evaluated to check their performance and effectiveness.</p> <p>ISO 9001 adds a guidance note for on input sources for customer satisfaction</p>	<p>8.2 Monitoring and measurement</p> <p>8.2.1 Customer satisfaction</p> <p>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.</p> <p><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></p> <p>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.</p>

AS9100B	Changes	AS9100:2009
<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>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>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>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>Detailed tools and techniques shall be developed such as check sheets, 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>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>AS9100 includes an advisory note that audits must include contractual requirements</p> <p>ISO 9001 provides rewording for a documented procedure requirement and clarifies the audit record requirements.</p> <p>ISO 9001 uses the proper terminology "correction" and "corrective action" as defined in ISO 9000.</p> <p>AS9100 removes the confusing requirement for detailed tools and techniques and the requirement to measure their effectiveness.</p> <p>AS9100 removes reference for contract & regulatory requirements now included in the new note under 8.2.2a and implied in 4.1.</p> <p>ISO 9001 updates the audit guidance document from ISO 10011 to ISO 19011.</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><u>NOTE Planned arrangements include customer contractual requirements.</u></p> <p>b) is effectively implemented and maintained.</p> <p>An audit programme 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><u>A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.</u></p> <p><u>Records of the audits and their results shall be maintained</u> (see 4.2.4).</p> <p>The management responsible for the area being audited shall ensure that <u>any necessary corrections and corrective actions</u> 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>(NOTE See ISO <u>19011</u> for guidance.)</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>ISO 9001 removed the misleading reference to only product conformity</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.</p>

AS9100B	Changes	AS9100:2009
<p><i>In the event of process nonconformity, the organization shall</i></p> <p><i>a) take appropriate action to correct the nonconforming process,</i></p> <p><i>b) evaluate whether the process nonconformity has resulted in product nonconformity, and</i></p> <p><i>c) identify and control the nonconforming product in accordance with clause 8.3.</i></p>	<p>ISO 9001 offers additional guidance with a note to instructing appropriate process monitoring and measurement methods.</p> <p><i>AS9100 provides direction to broaden the scope of evaluation when process nonconformities occur to determine the magnitude of the problem.</i></p> <p><i>AS9100 also provides clarification for nonconforming product control.</i></p>	<p><u>NOTE</u> 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.</p> <p><i>In the event of process nonconformity, the organization shall</i></p> <p><i>a) take appropriate action to correct the nonconforming process,</i></p> <p><i>b) evaluate whether the process nonconformity has resulted in product nonconformity,</i></p> <p><i>c) <u>determine if the process nonconformity is limited to a specific case or whether it could have affected other processes or products, and</u></i></p> <p><i>d) <u>identify and control any nonconforming product (see 8.3).</u></i></p>
<p>8.2.4 Monitoring and measurement of product</p>		<p>8.2.4 Monitoring and measurement of product</p>
<p>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).</p> <p><i>When key characteristics have been identified, they shall be monitored and controlled.</i></p> <p><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></p> <p><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></p> <p>Evidence of conformity with the acceptance criteria shall be maintained.</p> <p>Records shall indicate the person(s) authorizing release of product (see 4.2.4).</p>	<p><i>AS9100 moved the requirements for product acceptance from the deleted paragraph 8.2.4.1. It clarified the minimum for records of measurement results, and further clarifies requirements for specific measurement equipment.</i></p> <p><i>AS9100 includes the new term “critical items” (see paragraph 3) for determining criticality of product. It also adds the requirement for establishing processes for the control and monitoring of these items.</i></p> <p><i>AS9100 clarifies the need for sampling plans to be justified and based on the based on recognized statistical principles.</i></p>	<p>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.</p> <p><i>Measurement requirements for product acceptance shall be documented <u>and</u> shall include</i></p> <p><i>a) criteria for acceptance and/or rejection,</i></p> <p><i>b) where in the sequence measurement and testing operations are performed,</i></p> <p><i>c) <u>required records of the measurement results (at a minimum, indication of acceptance or rejection), and</u></i></p> <p><i>d) <u>any specific measurement instruments required and any specific instructions associated with their use.</u></i></p> <p><i>When <u>critical items, including key characteristics, have been identified the organization shall ensure they are controlled and monitored in accordance with the established processes.</u></i></p> <p><i>When the organization uses sampling inspection as a means of product acceptance, the <u>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).</u></i></p>



AS9100B	Changes	AS9100:2009
<p>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.</p>	<p>AS9100 added additional instructions to “identify and record” product issued pending completion of verification.</p> <p>ISO 9001 clarifies that the person responsible for releasing product must be identified and recorded</p> <p>AS9100 added the requirement for records of product qualification from the deleted paragraph 8.2.4.1.</p> <p>ISO 9001 clarifies that planned arrangements must be met prior to delivery.</p> <p>AS9100 moved the requirement for documentation to be present at delivery from 7.5.5.</p>	<p><u>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.</u></p> <p>Records shall indicate the person(s) authorizing release of product for delivery to the customer (see 4.2.4).</p> <p>Where required to demonstrate product qualification, the organization shall ensure that records provide evidence that the product meets the defined requirements.</p> <p>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.</p> <p>The organization shall ensure that <u>all</u> documents required to accompany the product are present at delivery.</p>
<p>8.2.4.1 Inspection Documentation</p> <p>Measurement requirements for product or service acceptance shall be documented. This documentation may be part of the production documentation, but shall include</p> <p>a) criteria for acceptance and/or rejection,</p> <p>b) where in the sequence measurement and testing operations are performed,</p> <p>c) a record of the measurement results, and</p> <p>d) type of measurement instruments required and any specific instructions associated with their use.</p> <p>Test records shall show actual test results data when required by specification or acceptance test plan.</p> <p>Where required to demonstrate product qualification the organization shall ensure that records provide evidence that the product meets the defined requirements</p>	<p>AS9100 eliminated this section and transferred the remainder of this requirement to paragraph 8.2.4</p>	
<p>8.2.4.2 First Article Inspection</p> <p>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.</p> <p>NOTE: See (AS) (EN) (SJAC) 9102 for guidance.</p>	<p>AS9100 eliminated this section and transferred the remainder of this requirement to paragraph 7.5.1.1.</p>	

AS9100B	Changes	AS9100:2009
<p>8.3 Control of nonconforming product</p> <p>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.</p> <p>NOTE: The term “nonconforming product” includes nonconforming product returned from a customer.</p> <p>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.</p> <p>The organization shall deal with nonconforming product by one or more of the following ways:</p> <p>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.</p> <p>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.</p>	<p>ISO 9001 adds “where applicable” to the ways that organizations deal with nonconforming product.</p> <p>ISO 9001 moves text from the end of this section to enhance the list of methods to deal with nonconforming product.</p> <p>AS9100 rearranged the text of this section and a moved note from below to deal with nonconforming product.</p> <p>AS9100 adds containment of effects of nonconforming product to the list of ways to deal with nonconforming product.</p> <p>AS9100 rewords and clarifies the conditions under which dispositions of “use-as-is” and “repair” may be used.</p> <p>AS9100 also adds to this section a note introducing the new term “authorized representative.”</p>	<p>8.3 Control of nonconforming product</p> <p>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 the controls and related responsibilities and authorities for dealing with nonconforming product.</u></p> <p>NOTE The term “nonconforming product” includes nonconforming product returned by a customer.</p> <p>The organization’s documented procedure shall define the responsibility and authority for the review and disposition of nonconforming product, and the process for approving personnel making these decisions.</p> <p><u>Where applicable,</u> the organization shall deal with nonconforming product by one or more of the following ways:</p> <p>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) <u>by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started;</u></p> <p>The organization’s <u>nonconforming product control process</u> shall provide for timely reporting of delivered nonconforming product;</p> <p>NOTE Parties requiring notification of nonconforming product can include suppliers, internal organizations, customers, distributors and regulatory authorities.</p> <p><u>e) by taking actions necessary to contain the effect of the nonconformity on other processes or products</u></p> <p><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></p> <p><u>NOTE Authorized representative includes personnel having delegated authority from the design organization.</u></p> <p>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.</p>

AS9100B	Changes	AS9100:2009
<p>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.</p> <p>Product dispositioned for scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable.</p> <p>Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).</p> <p>When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements</p> <p>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.</p> <p>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.</p> <p>NOTE: Parties requiring notification of nonconforming product may include suppliers, internal organizations, customers, distributors, and regulatory authorities.</p>	<p>ISO 9001 has extensively restructured the sequence of this section to better define the intent of the requirement</p> <p>ISO 9001 appropriately placed the requirement for records at the end of the section.</p> <p>AS9100 has extensively refined the wording of this section and moved the remaining requirements elsewhere in this section.</p> <p>AS9100 has moved this note to the beginning of this section</p>	<p>Product dispositioned for scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable</p> <p>When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.</p> <p><u>Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).</u></p>
<p>8.4 Analysis of data</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>The analysis of data shall provide information relating to</p> <ol style="list-style-type: none"> customer satisfaction (see 8.2.1), conformity to product requirements (see 7.2.1), characteristics and trends of processes and products including opportunities for preventive action, and suppliers. 	<p>ISO 9001 changed the references to the more appropriate sections to reflect the changes to the current structure</p>	<p>8.4 Analysis of data</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>The analysis of data shall provide information relating to</p> <ol style="list-style-type: none"> customer satisfaction (see 8.2.1), conformity to product requirements <u>(see 8.2.4),</u> characteristics and trends of processes and products, including opportunities for preventive action <u>(see 8.2.3 and 8.2.4),</u> and suppliers<u>(see 7.4).</u>
AS9100B	Changes	AS9100:2009

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>AS9100 directs the monitoring of the implementation of improvement activities and to appraise the effectiveness of the results.</p> <p>AS9100 adds a new note and gives specific guidance for improvement opportunities.</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>The organization shall monitor the implementation of improvement activities and evaluate the effectiveness of the results.</p> <p>NOTE Continual improvement opportunities can result from lessons learned, problem resolutions and the benchmarking of best practices.</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>A documented procedure shall be established to define requirements for</p> <ol style="list-style-type: none"> reviewing nonconformities (including customer complaints), determining the causes of nonconformities, evaluating the need for action to ensure that nonconformities do not recur, determining and implementing action needed, records of the results of action taken (see 4.2.4), reviewing corrective action taken, flow down of the corrective action requirement to a supplier, when it is determined that the supplier is responsible for the root cause, and specific actions where timely and/or effective corrective actions are not achieved. 	<p>ISO 9001 makes “cause” plural, recognizing that there may be multiple causes for each nonconformity.</p> <p>ISO 9001 clarifies that the effectiveness of the action should be reviewed, not just the action.</p> <p>AS9100 clarifies the intent of this requirement. Corrective action will be directed to a supplier when the supplier is responsible for a <u>nonconformity</u> - rather than the root cause.</p> <p>AS9100 adds the requirement to determine the extent of the nonconformity by determining if other nonconforming product exists which is the result of the identified causes and to take further action if appropriate.</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>A documented procedure shall be established to define requirements for</p> <ol style="list-style-type: none"> reviewing nonconformities (including customer complaints), determining the causes of nonconformities, evaluating the need for action to ensure that nonconformities do not recur, determining and implementing action needed, records of the results of action taken (see 4.2.4), reviewing <u>the effectiveness of the</u> corrective action taken, flowing down corrective action requirements to a supplier when it is determined that the supplier is responsible for the <u>nonconformity</u>, specific actions where timely and/or effective corrective actions are not achieved, and <u>determining if additional nonconforming product exists based on the causes of the nonconformities and taking further action when required.</u>
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>

AS9100B	Changes	AS9100:2009
<p>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>ISO 9001 explains that the action taken should be reviewed for effectiveness - rather than just the action itself</p> <p><i>AS9100 includes a note which provides examples of methods, sources and opportunities for preventive action</i></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 <u>the effectiveness of the</u> preventive action taken. <p><i><u>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.</u></i></p>

Dead Line

- *All management system transitions must be completed no later than July 1,2012 including;*
- *Closure of all findings; with completed corrective action with in-depth root cause identification, which must be verified by NQA-USA.*

AS9100B	Changes	AS9100:2009
<p><i>Bibliography</i></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>²Superseded by ISO 19011, Guidelines for quality and/or environmental management systems auditing</p> <p>³Superseded by ISO 10012, Measurement management systems – Requirements for measurement processes and measuring equipment</p>	<p><i>AS9100 identifies the other two standards in the AS industry trilogy of management standards; AS9110 and AS9120.</i></p> <p><i>AS9100 removes all version dates from standards listed.</i></p> <p><i>AS9100 deletes reference to first article and measurement system guidance documents and it also deletes reference to obsolete standards.</i></p>	<p><i>Bibliography</i></p> <p><u>AS/EN 9110</u> <i>Quality Management Systems – Requirements for Aviation Maintenance Organizations</i></p> <p><u>AS/EN 9120</u> <i>Quality Management Systems – Requirements for Aviation, Space and Defense Distributors</i></p> <p>ISO 9000 <i>Quality management systems – Fundamentals and vocabulary</i></p> <p>ISO 9001 <i>Quality management systems – Requirements</i></p> <p>ISO 9004² <i><u>Managing for the sustained success of an organization – A quality management approach</u></i></p> <p>ISO 10007 <i>Quality management <u>systems</u> – Guidelines for configuration management</i></p> <p>ISO 19011 <i>Guidelines for quality and/or environmental management systems auditing</i></p> <p>²<u>To be published. (Revision of ISO 9004:2000)</u></p>



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AS9100:2009 Transition Guidance Handbook