International Aerospace Quality Group (IAQG)
9100:2000 to 9100:2009 Comparison

9100:2000	9100:2009	Summary
Title	**Title**	
Quality Management Systems - Aerospace – Requirements	*Quality Management Systems – Requirements for Aviation, Space and Defense Organizations*	*Expanded scope to aviation, space and defense organizations to better reflect the full range of users of 9100.*
Foreword	**Foreword**	
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.	*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.*	*Reworded to include aviation, space and defense; and applicable statutory requirements. Minor rewording to enhance clarity.*
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.	*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.*	*Removed aerospace specific reference. Minor rewording.*

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.	***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***	***Limiting aerospace specific verbiage changed to aviation, space and defense, while inviting other industrial sectors to use the standard if applicable.***
Revision summary	**Revision Summary/Rationale**	Added Rationale to header.
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.	**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.**	**Summary statement updated to reflect the incorporation of ISO9001:2008 and industry requirements, definitions and notes.**
Introduction	**Introduction**	
General	**0.1 General**	Added number.
The adoption of a quality management system should be a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by varying needs, particular objectives, the products provided, the processes employed and the size and structure of the organization. It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.	The adoption of a quality management system should be a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by a) its organizational environment, changes in that environment, and the risks associated with that environment, b) its varying needs, c) its particular objectives, d) the products it provides, e) the processes it employs, f) its size and organizational structure. It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.	Added organizational environment and its potential risks as quality management system design and implementation influencing factors.
The quality management system requirements specified in this International Standard are complementary to requirements for products. Information marked “NOTE” is for guidance in understanding or clarifying the associated requirement.	The quality management system requirements specified in this International Standard are complementary to requirements for products. Information marked “NOTE” is for guidance in understanding or clarifying the associated requirement.	No change.
This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, regulatory and the organization's own requirements.	This International Standard can be used by internal and external parties, including certification bodies, to assess the organization’s ability to meet customer, statutory and regulatory requirements applicable to the product, and the organization’s own requirements.	Statutory added in conjunction with regulatory requirements and clarification that they are applicable to the product.

The quality management principles stated in ISO 9000 and ISO 9004 have been taken into consideration during the development of this International Standard.	The quality management principles stated in ISO 9000 and ISO 9004 have been taken into consideration during the development of this International Standard.	No change.
Process Approach	0.2 **Process Approach**	Added number.
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.	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.	No change.
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.	For an organization to function effectively, it has to determine and manage numerous linked activities. An activity or set of activities using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one process directly forms the input to the next.	Minor change from "identify" to "determine" the processes. Determine adds an action after the identification.
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”.	The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management to produce the desired outcome, can be referred to as the “process approach”.	Process approach expanded to include "produce the desired outcome".
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.	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.	No change.
When used within a quality management system, such an approach emphasizes the importance of 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.	When used within a quality management system, such an approach emphasizes the importance of 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.	No change.
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.	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.	No change.

NOTE: In addition, the methodology known as “Plan-Do-Check-Act” (PDCA) can be applied to all processes. PDCA can be briefly described as follows. Plan: establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization’s policies. Do: implement the processes. Check: monitor and measure processes and product against policies, objectives and requirements for the product and report the results. Act: take actions to continually improve process performance.	NOTE: In addition, the methodology known as “Plan-Do-Check-Act” (PDCA) can be applied to all processes. PDCA can be briefly described as follows. Plan: establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization’s policies. Do: implement the processes. Check: monitor and measure processes and product against policies, objectives and requirements for the product and report the results. Act: take actions to continually improve process performance.	No change.
FIGURE 1 - Model of a Process-Based Quality Management System	FIGURE 1 - Model of a Process-Based Quality Management System	No change.
1. Scope	**1. Scope**	
1.1 General	**1.1 General**	
This standard includes ISO 9001:20001 quality management system requirements and specifies additional requirements for a quality management system for the aerospace industry. The additional aerospace requirements are shown in bold, italic text	***This standard includes ISO 9001: 2008 quality management system requirements and specifies additional aviation, space and defense industry requirements, definitions and notes as shown in bold, italic text***	***Revised to include ISO 9001:2008 changes and additional industry requirements for aviation, space and defense.***
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. If a conflict exists between IAQG 9100 and legal requirements, the legal requirements take precedence.	***It is emphasized that the requirements specified in this standard are complementary (not alternative) to contractual and applicable statutory and regulatory requirements. Should there be a conflict between the requirements of this standard and applicable statutory or regulatory requirements, the latter shall take precedence***	***Statutory requirements added to stay consistent with ISO text and to meet the needs of the expansion of scope to aviation, space and defense.*** ***Additional minor rewording.***
This International Standard specifies requirements for a quality management system where an organization a) needs to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements, and 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.	This International Standard specifies requirements for a quality management system where an organization a) needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements, and b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.	Statutory requirements added.
NOTE: In this International Standard, the term “product” applies only to the product intended for, or required by, a customer.	NOTE 1 In this International Standard, the term “product” only applies to a) product intended for, or required by, a customer, b) any intended output resulting from the product realization processes.	Product applies not only to product for a customer, but also any intended output of the product realization processes.
	NOTE 2 Statutory and regulatory requirements may be expressed as legal requirements.	Note added to clarify that statutory and regulatory requirements may be in the form of legal requirements.

1.2 Application	1.2 Application	
All requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product provided.	All requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product provided.	No change.
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.	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.	No change.
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.	Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within clause 7, and such exclusions do not affect the organizations ability, or responsibility, to provide product that meets customer and applicable statutory and regulatory requirements.	Statutory requirements added.
	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.	***New applicability statement for 9100 provides users and potential users guidance on standard applicability.***
	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).	***New applicability statement for 9110 provides users and potential users guidance on standard applicability.***
	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).	***New applicability statement for 9120 provides users and potential users guidance on standard applicability.***
1 With the permission of the International Organization for Standardization (ISO). The complete standard may be obtained from any ISO member or from the ISO Central Secretariat, Case Postale 56, 1211 Geneva 20, Switzerland. Copyright remains with ISO.	***1 With the permission of the International Organization for Standardization (ISO). The complete standard can be obtained from any ISO member or from the ISO Central Secretariat: 1, ch. de la Voie-Creuse, Case postale 56, CH-1211 Geneva 20, SWITZERLAND, or visit www.iso.org. Copyright remains with ISO.***	***Minor addition and web address.***
2. Normative reference	**2. Normative references**	

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. ISO 9000:2000, Quality management systems - Fundamentals and vocabulary.	The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies. ISO 9000:2005, Quality management systems — Fundamentals and vocabulary.	Simplified text. Updated the normative reference from ISO 9000:2000 to ISO 9000:2005.
3. Terms and definitions	**3. Terms and definitions**	
For the purposes of this International Standard, the terms and definitions given in ISO 9000 apply. The following terms, used in this edition of ISO 9001 to describe the supply chain, have been changed to reflect the vocabulary currently used: Supplier - Organization - Customer 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”.	For the purposes of this document, the terms and definitions given in ISO 9000 apply. Throughout the text of this International Standard, wherever the term “product” occurs, it can also mean “service”.	Text outlining changes from the ISO 9001:1994 version has been deleted.
	3.1 Risk	
	An undesirable situation or circumstance that has both a likelihood of occurring and a potentially negative consequence.	***Definition of "Risk" added to support the introduction of Risk Management. The understanding of risk is important for an organization to develop a proactive quality management system***
	3.2 Special requirements	

	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.	*Definition of "Special Requirements" added to support the introduction of the requirement in clause 7. The rationale is to improve understanding of "Special Requirements" and the potential chain of flow to "Critical Items" and to "Key Characteristics" and to ensure these important requirements are systemically addressed and linked to risk management activities by the organization.*
	3.3 Critical items	
	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.	*Definition of "Critical Items" added to support the introduction of the requirement in clause 7. The rationale is to improve understanding of "Critical Items" coming from Special Requirements and ensure these items are systemically addressed and linked to risk management activities by the organization.*
Key Characteristic	*3.4 Key Characteristic*	
The feature s of a material, process, or part whose variation has a significant influence on product fit, performance, service life, or manufacturability .	*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.*	*An expanded Key Characteristic definition is more specific and adds clarity.*
	NOTE Special requirements and critical items are new terms and, along with key characteristics, are interrelated. Special requirements are identified when determining and reviewing requirements related to the product (see 7.2.1 and 7.2.2). Special requirements can require the identification of critical items. Design output (see 7.3.3) can include identification of critical items that require specific actions to ensure they are adequately managed. Some critical items will be further classified as key characteristics because their variation needs to be controlled.	*Note added to provide insight on the interrelationship between special requirements, critical items and key characteristics and in what type of scenario they might be applied.*
4 Quality management system	**4 Quality management system**	
4.1 General requirements	**4.1 General requirements**	

The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.	The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard. ***The organization's quality management system shall also address customer and applicable statutory and regulatory quality management system requirements.***	***The 9100 text was moved in the revised 9100 standard from clause 4.2.1 to 4.1 to clarify that the requirement is placed at the QMS level and not only at the documentation level. Replaces detailed references in 9100 to "statutory and regulatory requirements" with one requirement to apply statutory and regulatory requirements throughout the standard.***
The organization shall a) identify the processes needed for the quality management system and their application throughout the organization (see 1.2), b) determine the sequence and interaction of these processes, c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective, d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes, e) monitor, measure and analyse these processes, and f) implement actions necessary to achieve planned results and continual improvement of these processes.	The organization shall a) determine the processes needed for the quality management system and their application throughout the organization (see 1.2), b) determine the sequence and interaction of these processes, c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective, d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes, e) monitor, measure where applicable, and analyse these processes, and f) implement actions necessary to achieve planned results and continual improvement of these processes.	Minor change from "identify" to "determine" the processes. Determine adds an action after the identification. Added "where applicability".
These processes shall be managed by the organization in accordance with the requirements of this International Standard.	These processes shall be managed by the organization in accordance with the requirements of this International Standard.	No change.
Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes.	Where an organization chooses to outsource any process that affects product conformity to requirements, the organization shall ensure control over such processes.	Minor change.
Control of such outsourced processes shall be identified within the quality management system.	The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system.	Strengthened verbiage by adding "type and extent" of control and changing "identify" to "define" outsourced processes within the QMS.
NOTE Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement.	NOTE 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.	The word "should" was deleted to enhance clarity of the Note and linkage established to the "analysis" and "improvement" processes.
	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.	Guidance provided on what an outsourced process is.

	NOTE 3 Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory and regulatory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such as a) the potential impact of the outsourced process on the organization's capability to provide product that conforms to requirements, b) the degree to which the control for the process is shared, c) the capability of achieving the necessary control through the application of 7.4.	Note outlines outsourced process organizational responsibility and provides examples of influencing factors associated with its control.
4.2 Documentation requirements	**4.2 Documentation requirements**	
4.2.1 General	**4.2.1 General**	
The quality management system documentation shall include 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.***	The quality management system documentation shall include a) documented statements of a quality policy and quality objectives, b) a quality manual, c) documented procedures and records required by this International Standard, and d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes.	Minor restructuring of the records requirement from e) to c). **Deleted regulatory requirement, which is covered in 4.1.**
The organization shall ensure that personnel have access to quality management system documentation and are aware of relevant procedures.	***The organization shall ensure that personnel have access to, and are aware of, relevant quality management system documentation and changes.***	***This requirement has had some words moved around and adds "documentation and changes". Addressing "Changes" in documentation is the primary delta here.***
Customer and/or regulatory authorities representatives shall have access to quality management system documentation.		***Deleted regulatory authority access requirement now included in 4.1.***
NOTE 1 Where the term "documented procedure" appears within this International Standard, this means that the procedure is established, documented, implemented and maintained.	NOTE 1 Where the term "documented procedure" appears within this International Standard, this means that the procedure is established, documented, implemented and maintained. 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.	Note 1 provides clarification that a single "documented procedure" may apply to more than one procedures. Multiple procedures may be included in a single document based on the organization's needs.

NOTE 2 The extent of the quality management system documentation can differ from one organization to another due to a) the size of organization and type of activities, b) the complexity of processes and their interactions, and c) the competence of personnel.	NOTE 2 The extent of the quality management system documentation can differ from one organization to another due to a) the size of organization and type of activities, b) the complexity of processes and their interactions, and c) the competence of personnel.	No change.
NOTE 3 The documentation can be in any form or type of medium.	NOTE 3 The documentation can be in any form or type of medium.	No change.
4.2.2 Quality manual	**4.2.2 Quality manual**	
The organization shall establish and maintain a quality manual that includes a) the scope of the quality management system, including details of and justification for any exclusions (see 1.2), b) the documented procedures established for the quality management system, or reference to them, and ***- when referencing the documented procedures, the relationship between the requirements of this International Standard and the documented procedures shall be clearly shown.*** c) a description of the interaction between the processes of the quality management system.	The organization shall establish and maintain a quality manual that includes 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.	***Deleted the requirement that quality manual references to procedures include linkage to 9100 requirements. The requirement adds 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.***
4.2.3 Control of documents	**4.2.3 Control of documents**	
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.	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.	No change.
A documented procedure shall be established to define the controls needed 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.	A documented procedure shall be established to define the controls needed a) to approve documents for adequacy prior to issue, b) to review and update as necessary and re-approve documents, c) to ensure that changes and the current revision status of documents are identified, d) to ensure that relevant versions of applicable documents are available at points of use, e) to ensure that documents remain legible and readily identifiable, f) to ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.	Added that external documents needed by the organization for their QMS must be identified and distribution controlled.

The organization shall coordinate document changes with customers and/or regulatory authorities in accordance with contract or regulatory requirements.		***Deleted, now addressed in 4.1.***
4.2.4 Control of records	**4.2.4 Control of records**	
Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system.	Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled.	The requirement to maintain QMS records has been replaced by control.
Records shall remain legible, readily identifiable and retrievable.		Moved to below.
A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.	The organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.	Minor rewording.
The documented procedure shall define the method for controlling records that are created by and/or retained by suppliers.	***The documented procedure shall define the method for controlling records that are created by and/or retained by suppliers.***	***No change.***
Records shall be available for review by customers and regulatory authorities in accordance with contract or regulatory requirements.		***Deleted, now addressed in 4.1.***
	Records shall remain legible, readily identifiable and retrievable.	Moved from above.
4.3 Configuration Management		***Moved to 7.1.3***
The organization shall establish, document and maintain a configuration management process appropriate to the product.		***Moved configuration management clause to 7.1.3 as part of product realization. Adds focus and addresses interpretation issues arising from it being in clause 4.***
NOTE: Guidance on configuration management is given in ISO 10007.		***Moved to 7.1.3***
5 Management responsibility	**5 Management responsibility**	
5.1 Management commitment	**5.1 Management commitment**	
Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements, b) establishing the quality policy, c) ensuring that quality objectives are established, d) conducting management reviews, and e) ensuring the availability of resources.	Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements, b) establishing the quality policy, c) ensuring that quality objectives are established, d) conducting management reviews, and e) ensuring the availability of resources.	No change.
5.2 Customer focus	**5.2 Customer focus**	

Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1).	Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1).	No change.
	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.	***Added to promote continuous improvement of customer satisfaction, to establish clear relationship between the QMS and organizational performance (on-time delivery performance), and establish action requirement if results are not achieved that are linked with top management.***
5.3 Quality policy	**5.3 Quality policy**	
Top management shall ensure that the quality policy a) is appropriate to the purpose of the organization, b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system, c) provides a framework for establishing and reviewing quality objectives, d) is communicated and understood within the organization, and e) is reviewed for continuing suitability.	Top management shall ensure that the quality policy a) is appropriate to the purpose of the organization, b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system, c) provides a framework for establishing and reviewing quality objectives, d) is communicated and understood within the organization, and e) is reviewed for continuing suitability.	No change.
5.4 Planning	**5.4 Planning**	
5.4.1 Quality objectives	**5.4.1 Quality objectives**	
Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within the organization.	Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within the organization.	No change.
The quality objectives shall be measurable and consistent with the quality policy.	The quality objectives shall be measurable and consistent with the quality policy.	No change.
5.4.2 Quality management system planning	**5.4.2 Quality management system planning**	
Top management shall ensure that a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.	Top management shall ensure that a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.	No change.
5.5 Responsibility, authority and communication	**5.5 Responsibility, authority and communication**	
5.5.1 Responsibility and authority	**5.5.1 Responsibility and authority**	
Top management shall ensure that responsibilities and authorities are defined and communicated within the organization.	Top management shall ensure that the responsibilities and authorities are defined and communicated within the organization.	No change.
5.5.2 Management representative	**5.5.2 Management representative**	

Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes a) ensuring that processes needed for the quality management system are established, implemented and maintained, b) reporting to top management on the performance of the quality management system and any need for improvement, c) ensuring the promotion of awareness of customer requirements throughout the organization, and ***d) the organizational freedom to resolve matters pertaining to quality.***	Top management shall appoint a member of the organization's management who, irrespective of other responsibilities, shall have responsibility and authority that includes a) ensuring that processes needed for the quality management system are established, implemented and maintained, b) reporting to top management on the performance of the quality management system and any need for improvement, c) ensuring the promotion of awareness of customer requirements throughout the organization, and ***d) the organizational freedom and unrestricted access to top management to resolve quality management issues.***	Added that the management representative shall be a member of the organization's management. ***The words 'and unrestrictive access' have been added at this update to avoid the possibility of the Management Representative being unable to directly access top management to ensure they are aware of and involved in resolving quality management issues.***
NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.	NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.	No change.
5.5.3 Internal communication	**5.5.3 Internal communication**	
Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.	Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.	No change.
5.6 Management review	**5.6 Management review**	
5.6.1 General	**5.6.1 General**	
Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.	Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.	No change.
Records from management reviews shall be maintained (see 4.2.4).	Records from management reviews shall be maintained (see 4.2.4).	No change.
5.6.2 Review input	**5.6.2 Review input**	
The input to management review shall include information on a) results of audits, b) customer feedback, c) process performance and product conformity, d) status of preventive and corrective actions, e) follow-up actions from previous management reviews, f) changes that could affect the quality management system, and g) recommendations for improvement.	The input to management review shall include information on a) results of audits, b) customer feedback, c) process performance and product conformity, d) status of preventive and corrective actions, e) follow-up actions from previous management reviews, f) changes that could affect the quality management system, and g) recommendations for improvement.	No change.
5.6.3 Review output	**5.6.3 Review output**	

The output from the management review shall include any decisions and actions related to a) improvement of the effectiveness of the quality management system and its processes, b) improvement of product related to customer requirements, and c) resource needs.	The output from the management review shall include any decisions and actions related to a) improvement of the effectiveness of the quality management system and its processes, b) improvement of product related to customer requirements, and c) resource needs.	No change.
6 Resource management	**6 Resource management**	
6.1 Provision of resources	**6.1 Provision of resources**	
The organization shall determine and provide the resources needed a) to implement and maintain the quality management system and continually improve its effectiveness, and b) to enhance customer satisfaction by meeting customer requirements.	The organization shall determine and provide the resources needed a) to implement and maintain the quality management system and continually improve its effectiveness, and b) to enhance customer satisfaction by meeting customer requirements.	No change.
6.2 Human resources	**6.2 Human resources**	
6.2.1 General	**6.2.1 General**	
Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.	Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience.	Added conformity to product requirements.
	NOTE Conformity to product requirements can be affected directly or indirectly by personnel performing any task within the quality management system.	Note has been added to provide guidance all personnel, directly or indirectly, may affect conformity to product. Often the focus of conformity is on the actual build process, but it applies throughout product realization.
6.2.2 Competence, awareness and training	**6.2.2 Competence, training and awareness**	Header reworded.
The organization shall a) determine the necessary competence for personnel performing work affecting product quality, b) provide training or take other actions to satisfy these needs, c) evaluate the effectiveness of the actions taken, d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and e) maintain appropriate records of education, training, skills and experience (see 4.2.4).	The organization shall a) determine the necessary competence for personnel performing work affecting conformity to product requirements, b) where applicable, provide training or take other actions to achieve the necessary competence, c) evaluate the effectiveness of the actions taken, d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and e) maintain appropriate records of education, training, skills and experience (see 4.2.4).	a) Reworded from personnel performing "product quality" to "conformity to product requirements." b) "where applicable" has been added to provide flexibility, since training may not always be necessary if personnel already are competent.
6.3 Infrastructure	**6.3 Infrastructure**	

The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable a) buildings, workspace and associated utilities, b) process equipment (both hardware and software), and c) supporting services (such as transport or communication).	The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable a) buildings, workspace and associated utilities, b) process equipment (both hardware and software), and c) supporting services (such as transport, communication or information systems).	"Information systems" has been added as another "such as" example of a supporting service.
6.4 Work environment	**6.4 Work environment**	
The organization shall determine and manage the work environment needed to achieve conformity to product requirements.	The organization shall determine and manage the work environment needed to achieve conformity to product requirements.	No change.
	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).	ISO Note added to enhance guidance on "work environment" and provide examples. Similar in intent to the 9100 note that was deleted.
NOTE: Factors that may affect the conformity of the product include temperature, humidity, lighting, cleanliness, protection from electrostatic discharge, etc.		***Replaced by ISO Note.***
7 Product realization	**7 Product realization**	
7.1 Planning of product realization	**7.1 Planning of product realization**	
The organization shall plan and develop the processes needed for product realization.	The organization shall plan and develop the processes needed for product realization.	No change.
Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1).	Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1).	No change.

In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4); ***e) the identification of resources to support operation and maintenance of the product.***	In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; ***NOTE Quality objectives and requirements for the product include consideration of aspects such as*** ***- product and personal safety,*** ***- reliability, availability and maintainability,*** ***- producibility and inspectability,*** ***- suitability of parts and materials used in the product,*** ***- selection and development of embedded software, and*** ***- recycling or final disposal of the product at the end of its life.*** b) the need to establish processes and documents, and to provide resources specific to the product; c) required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4); ***e) configuration management appropriate to the product;*** ***f) resources to support the use and maintenance of the product.***	***The note was added to emphasize the importance of considering relevant requirements at the earliest point in the product lifecycle.*** ***The new clause e) was added to improve product quality through the use of structured configuration management methods.*** Also added "measurement" as one of the criteria for product acceptance.
The output of this planning shall be in a form suitable for the organization's method of operations.	The output of this planning shall be in a form suitable for the organization's method of operations.	No change.
NOTE 1 A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan.	NOTE 1 A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract can be referred to as a quality plan.	No change.
NOTE 2 The organization may also apply the requirements given in 7.3 to the development of product realization processes.	NOTE 2 The organization may also apply the requirements given in 7.3 to the development of product realization processes.	No change.
	7.1.1 Project Management	***New header.***
	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.	***Project management has been added to the standard outlining requirements on planning and managing product realization risks, resources and schedule. Most aviation, space and defense products are complex and involve multi-tier partners and suppliers and project management provides additional focus on upfront planning and the management of project plans throughout product realization***

	7.1.2 Risk Management	**New header.**
	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 ***a) assignment of responsibilities for risk management,*** ***b) definition of risk criteria (e.g., likelihood, consequences, risk acceptance),*** ***c) identification, assessment and communication of risks throughout product realization,*** ***d) identification, implementation and management of actions to mitigate risks that exceed the defined risk acceptance criteria, and*** ***e) acceptance of risks remaining after implementation of mitigating actions.***	***Risk Management was placed in clause 7.1.2 to provide additional focus on product risk during product realization.***
	7.1.3 Configuration Management	***(Moved from 4.3)***
	The organization shall establish, implement and maintain a configuration management process that includes, as appropriate to the product ***a) configuration management planning,*** ***b) configuration identification,*** ***c) change control,*** ***d) configuration status accounting, and*** ***e) configuration audit***	***Configuration management moved from clause 4.3 to 7.1.4. The move and expanded scope provides focus of configuration management during product realization. Added ISO 10007 sections (a-e).***
	NOTE See ISO 10007 for guidance.	No change.
	7.1.4 Control of work transfers	***(Moved from 7.5.1.4)***

	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.	***"Work Transfer" clause moved from 7.51.4. The rationale is that "Work Transfer" can occur at anytime during product realization. These requirements, originally included as clause 7.5.1.4, have been significantly expanded to-*** ***• apply to transfers throughout the whole lifecycle (not just for Production)*** ***• require that the work transfer process includes the planning of proposed moves*** ***• cover permanent (as well as temporary) transfers include moves from one supplier to another and moves from one of the organizations facilities to another.***
7.2 Customer-related processes	**7.2 Customer-related processes**	
7.2.1 Determination of requirements related to the product	**7.2.1 Determination of requirements related to the product**	
The organization shall determine a) requirements specified by the customer, including the requirements for delivery and post-delivery activities, b) requirements not stated by the customer but necessary for specified or intended use, where known, c) statutory and regulatory requirements related to the product, and d) any additional requirements determined by the organization.	The organization shall determine a) requirements specified by the customer, including the requirements for delivery and post-delivery activities, b) requirements not stated by the customer but necessary for specified or intended use, where known, c) statutory and regulatory requirements related to the product, and d) any additional requirements considered necessary by the organization.	Minor rewording.
	NOTE Requirements related to the product can include special requirements.	***This new note points out that when defining the overall product requirements the user should also consider any special requirements identified by the customer and the organization.***
	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.	ISO 9001:2008 adds a note to clarify what is meant by post-delivery activities.
7.2.2 Review of requirements related to the product	**7.2.2 Review of requirements related to the product**	

The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that a) product requirements are defined, b) contract or order requirements differing from those previously expressed are resolved, c) the organization has the ability to meet the defined requirements, ***and*** ***d) risks (e.g., new technology, short delivery time scale) have been evaluated.***	The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that a) product requirements are defined, b) contract or order requirements differing from those previously expressed are resolved, c) the organization has the ability to meet the defined requirements, ***d) special requirements of the product are determined, and*** ***e) risks (e.g., new technology, short delivery time frame) have been identified (see 7.1.2).***	***d) has been added to this clause to incorporate the addition of special requirements into the review of requirements related to the product.*** ***e) has been updated to reference the clause added for risk management 7.1.2.***
Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).	Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).	No change.
Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.	Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.	No change.
Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.	Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.	No change.
NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.	NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.	No change.
7.2.3 Customer communication	**7.2.3 Customer communication**	
The organization shall determine and implement effective arrangements for communicating with customers in relation to a) product information, b) enquiries, contracts or order handling, including amendments, and c) customer feedback, including customer complaints.	The organization shall determine and implement effective arrangements for communicating with customers in relation to a) product information, b) enquiries, contracts or order handling, including amendments, and c) customer feedback, including customer complaints.	No change.
7.3 Design and development	**7.3 Design and development**	
7.3.1 Design and development planning	**7.3.1 Design and development planning**	
The organization shall plan and control the design and development of product.	The organization shall plan and control the design and development of product.	No change.

During the design and development planning, the organization shall determine a) the design and development stages, ***- in respect of organization, task sequence, mandatory steps, significant stages and method of configuration control,*** b) the review, verification and validation that are appropriate to each design and development stage, and c) the responsibilities and authorities for design and development.	During the design and development planning, the organization shall determine a) the design and development stages, b) the review, verification and validation that are appropriate to each design and development stage, and c) the responsibilities and authorities for design and development.	***Removed redundant text under a).***
Where appropriate, due to complexity, the organization shall give consideration to the following activities: ***- structuring the design effort into significant elements;*** ***- for each element, analyzing the tasks and the necessary resources for its design and development. This analysis shall consider an identified responsible person, design content, input data, planning constraints, and performance conditions. The input data specific to each element shall be reviewed to ensure consistency with requirements.***	***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.***	***This clause has been simplified to provide clarity. The deletion of "give consideration to" will more clearly focus the organizations determination of when the requirement is appropriate.***
	The different design and development tasks to be carried out shall be based on the safety and functional objectives of the product in accordance with customer, statutory and regulatory requirements.	***Moved from below.*** ***Statutory added to be consistent with ISO 9001:2008. This requirement has also been moved and slightly reworded.***
	Design and development planning shall consider the ability to produce, inspect, test and maintain the product.	***Added the requirement for planning to consider product realization capability and the maintenance of the product.***
The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.	The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.	No change.
Planning output shall be updated, as appropriate, as the design and development progresses.	Planning output shall be updated, as appropriate, as the design and development progresses.	No change.
The different design and development tasks to be carried out shall be defined according to specified safety or functional objectives of the product in accordance with customer and/or regulatory authority requirements.		***moved to above.***
	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.	This note clarifies that reviews, verification and validation can be conducted and recorded separately or combined according to the organization's needs.
7.3.2 Design and development inputs	**7.3.2 Design and development inputs**	

Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include a) functional and performance requirements, b) applicable statutory and regulatory requirements, c) where applicable, information derived from previous similar designs, and d) other requirements essential for design and development.	Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include a) functional and performance requirements, b) applicable statutory and regulatory requirements, c) where applicable, information derived from previous similar designs, and d) other requirements essential for design and development.	No change.
These inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.	The inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.	Minor wording change.
7.3.3 Design and development outputs	**7.3.3 Design and development outputs**	
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.	The outputs of design and development shall be in a form suitable for verification against the design and development input and shall be approved prior to release.	Deleted "provided" and added "suitable for verification" as an expectation.

Design and development outputs shall a) meet the input requirements for design and development, b) provide appropriate information for purchasing, production and for service provision, c) contain or reference product acceptance criteria, d) specify the characteristics of the product that are essential for its safe and proper use, ***and*** ***e) identify key characteristics, when applicable, in accordance with design or contract requirements.***	Design and development outputs shall a) meet the input requirements for design and development, b) provide appropriate information for purchasing, production and for service provision, c) contain or reference product acceptance criteria, d) specify the characteristics of the product that are essential for its safe and proper use, ***and*** ***e) specify, as applicable, any critical items, including any key characteristics, and specific actions to be taken for these items.***	***The text in e) has been updated to include "critical items" as defined in clause 3. It also adds the requirement to specify actions to be taken.***

All pertinent data required to allow the product to be identified, manufactured, inspected, used and maintained shall be defined by the organization; for example: ***- drawings, part lists, specifications;*** ***- a listing of those drawings, part lists, and specifications 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.***	***The organization shall define the data required to allow the product to be identified, manufactured, inspected, used and maintained; including for example*** ***− the drawings, part lists, and specifications necessary to define the configuration and the design features of the product, and*** ***− the material, process, manufacturing and assembly data needed to ensure conformity of the product.***	***Restructured and removed redundant text..***
	NOTE Information for production and service provision can include details for the preservation of product.	Added visibility on product preservation.
7.3.4 Design and development review	**7.3.4 Design and development review**	
At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1) 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.***	At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1) 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.***	***No change.***
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).	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).	No change.
7.3.5 Design and development verification	**7.3.5 Design and development verification**	
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).	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).	No change.
NOTE: Design and/or development verification may include activities such as: ***- performing alternative calculations,*** ***- comparing the new design with a similar proven design, if available***		***Deleted note providing examples of verification activities. The text was determined to be more in line with a "how to" than a requirement.***
7.3.6 Design and development validation	**7.3.6 Design and development validation**	

Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).	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).	No change.
NOTES: ***- Design and/or development validation follows successful design and/or development verification.*** ***- Validation is normally performed under defined operating conditions.*** ***- Validation is normally performed on the final product, but may be necessary in earlier stages prior to product completion.*** ***-Multiple validations may be performed if there are different intended uses***		***"Note" deleted. The text was found to be redundant.***
	7.3.6.1 Design and development verification and validation testing	***IAQG 9100 moves the header from 7.3.6.2.***
	Where tests are necessary for verification and validation, these tests shall be planned, controlled, reviewed and documented to ensure and prove the following: ***a) test plans or specifications identify the product being tested and the resources being used, define test objectives and conditions, parameters to be recorded, and relevant acceptance criteria,*** ***b) test procedures describe the method of operation, the performance of the test and the recording of the results,*** ***c) the correct configuration of the product is submitted for the test,*** ***d) the requirements of the test plan and the test procedures are observed, and*** ***e) the acceptance criteria are met.***	***Realigned to reflect a more sequential order.***
7.3.6. 1 Documentation of design and/or development verification and validation	***7.3.6. 2 Design and development verification and validation documentation***	***Moved down from 7.3.6.1 to 7.3.6.2.*** ***Minor wording of the header.***
At the completion of design and/or development, the organization shall ensure that reports, calculations, test results, etc., demonstrate that the product definition meets the specification requirements for all identified operational conditions	***At the completion of design and/or development, the organization shall ensure that reports, calculations, test results, etc., demonstrate that the product definition meets the specification requirements for all identified operational conditions***	***No change.***
7.3.6.2 Design and/or development verification and validation testing:		***Moved above - 7.3.6.1.***

Where tests are necessary for verification and validation, these tests shall be planned, controlled, reviewed, and documented to ensure and prove the following: ***a) test plans or specifications identify the product being tested and the resources being used, define test objectives and conditions, parameters to be recorded, and relevant acceptance criteria;*** ***b) test procedures describe the method of operation, the performance of the test, and the recording of the results;*** ***c) the correct configuration standard of the product is submitted for the test;*** ***d) the requirements of the test plan and the test procedures are observed;*** ***e) the acceptance criteria are met.***		***Moved above - 7.3.6.1.*** ***Removed "standard" to reduce confusion and misinterpretation.***
7.3.7 Control of design and development changes	**7.3.7 Control of design and development changes**	
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.	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.	No change.
The organization's change control process shall provide for customer and/or regulatory authority approval of changes, when required by contract or regulatory requirement.	***Design and development changes shall be controlled in accordance with the configuration management process (see 7.1.3).***	***Removed the regulatory reference now in 4.1. This new requirement provides a link to the enhanced (and moved) requirement for Configuration management included in clause 7.1.3.***
Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).	Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).	No change.
7.4 Purchasing	**7.4 Purchasing**	
7.4.1 Purchasing process	**7.4.1 Purchasing process**	
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.	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.	No change.
The organization shall be responsible for the quality of all products purchased from suppliers, including customer-designated sources.	***The organization shall be responsible for the conformity of all products purchased from suppliers, including product from sources defined by the customer.***	***This clause has been reworded to simplify and clarify the originally intended wording- no additional requirements have been included. "Quality" changed to "conformity" in alignment with ISO text (ref. 6.2.1, 6.2.2)***

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).	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).	No change.
	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	***This new note emphasizes that the organization should obtain and use as much reliable supplier performance 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, independent of where this performance data was obtained.***
The organization shall: ***a) maintain a register of approved suppliers that includes the scope of the approval;*** ***b) periodically review supplier performance; records of these reviews shall be used as a basis for establishing the level of controls to be implemented;*** ***c) define the necessary actions to take when dealing with suppliers that do not meet requirements;*** ***d) ensure where required that both the organization and all suppliers use customer-approved special process sources;*** ***e) ensure that the function having responsibility for approving supplier quality systems has the authority to disapprove the use of sources.***	***The organization shall:*** ***a) maintain a register of its suppliers that includes approval status (e.g., approved, conditional, disapproved) and the scope of the approval (e.g., product type, process family),*** ***b) periodically review supplier performance; the results of these reviews shall be used as a basis for establishing the level of controls to be implemented,*** ***c) define the necessary actions to take when dealing with suppliers that do not meet requirements,*** ***d) ensure where required that both the organization and all suppliers use customer-approved special process sources,*** ***e) define the process, responsibilities and authority for the approval status decision, changes of the approval status and conditions for a controlled use of suppliers depending on their approval status, and*** ***f) determine and manage the risk when selecting and using suppliers (see 7.1.2).***	***Added requirements that outline the conditions for using a supplier depends on its approval status, the results of supplier performance reviews are to be used to establish supplier controls and risk management will be utilized in determining and selecting suppliers.*** ***a) Clause 7.4.1 a) now requires inclusion of supplier status in the supplier register, examples of supplier scope are also provided.*** ***b) The new text of clause b) improves the wording of the previous version to state that it is the results of the review (rather than the records) that are used to establish the level of controls to be used.*** ***e) This revised clause requires the organization to treat supplier approval as a defined (but not necessarily documented) process and to define the responsibilities and authorities for each activity in that process.*** ***f) Clause f) provides a link to the new clause 7.1.2- addressing risk when selecting and using suppliers.***
7.4.2 Purchasing information	**7.4.2 Purchasing information**	

Purchasing information shall describe the product to be purchased, including where appropriate a) requirements for approval of product, procedures, processes and equipment, b) requirements for qualification of personnel, c) quality management system requirements, ***d) the name or other positive identification, and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data,*** ***e) requirements for design, test, examination, inspection and related instructions for acceptance by the organization,*** ***f) requirements for test specimens (e.g., production method, number, storage conditions) for design approval, inspection, investigation or auditing,*** ***g) requirements relative to*** ***- supplier notification to organization of nonconforming product and*** ***- arrangements for organization approval of supplier nonconforming material,*** ***h) requirements for the supplier to notify the organization of changes in product and/or process definition and, where required, obtain organization approval,*** ***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*** ***j) requirements for the supplier to flow down to sub-tier suppliers the applicable requirements in the purchasing documents, including key characteristics where required.***	Purchasing information shall describe the product to be purchased, including, where appropriate a) requirements for approval of product, procedures, processes and equipment, b) requirements for qualification of personnel, c) quality management system requirements, ***d) the identification and revision status of specifications, drawings, process requirements, inspection/verification instructions and other relevant technical data,*** ***e) 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,*** ***f) requirements for test specimens (e.g., production method, number, storage conditions) for design approval, inspection/verification, investigation or auditing,*** ***g) requirements regarding the need for the supplier to*** ***- notify the organization of nonconforming product,*** ***- obtain organization approval for nonconforming product disposition,*** ***- 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*** ***- flow down to the supply chain the applicable requirements, including customer requirements*** ***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.***	***d) Revision status added as a requirement in conjunction with the identification of specifications.*** ***e) Verification and the use of statistical techniques for product acceptance has been added and as applicable critical items and key characteristics.*** ***f) Verification added as an alternative to inspection of the appropriate test specimens.*** ***g) Clarifies and adds requirements for suppliers to notify the organization of nonconforming product and changes, and for suppliers to flow down requirements.*** ***h) Requirement has been added to communicate supplier record retention requirements consistent with clause 4.2.4.*** ***i) clarifies that the right of access requirements are to be in applicable areas and apply to any level of the supply chain.***
The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.	The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.	No change.
The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.	The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.	No change.
7.4.3 Verification of purchased product	**7.4.3 Verification of purchased product**	

The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.	The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.	No change.
Moved from below.	***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.***	***This subject has been changed from a requirement to a Note because the need for customer verification would be a contractual requirement and additional to those requirements contained in 9100.***
Verification activities may include ***a) obtaining objective evidence of the quality of the product from supplier s (e.g., accompanying documentation, certificate of conformity, test reports, statistical records, process control),*** ***b) inspection and audit at supplier's premises,*** ***c) review of the required documentation,*** ***d) inspection of products upon receipt, and*** ***e) delegation of verification to the supplier, or supplier certification***	***NOTE 2 Verification activities can include*** ***- 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,*** ***d) inspection of products upon receipt, and*** ***e) delegation of verification to the supplier, or supplier certification***	***Changed to a guidance note. No shall statement existed, so a note is more appropriate. "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.***
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.	***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.***	***This clause has been significantly reworded adding verbiage that is more specific and proactive. Requirements have been added to "identify and record" product issued pending completion of verification to allow recall and replacement. This replaces "positive recall."***
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.		***Deleted the requirement to validate supplier test reports. Test reports are a tool and prescriptive, suggesting a "how to" and are not applicable to all stakeholders and for all types of products. Often misinterpreted***
Where the organization delegates verification activities to the supplier, the requirements for delegation shall be defined and a register of delegations maintained.	***Where the organization delegates verification activities to the supplier, the requirements for delegation shall be defined and a register of delegations maintained.***	***No change.***
Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.	Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.	No change.
Where specified in the contract, the customer or the customer's representative shall be afforded the right to verify at the supplier's premises and the organization's premises that subcontracted product conforms to specified requirements.		***Deleted contractual language. Covered in clause 4.1.***

Verification by the customer shall not be used by the organization as evidence of effective control of quality by the supplier and shall not absolve the organization of the responsibility to provide acceptable product, nor shall it preclude subsequent rejection by the customer.		***Moved to Note above.***
7.5 Production and service provision	**7.5 Production and service provision**	
7.5.1 Control of production and service provision	**7.5.1 Control of production and service provision**	
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, - special processes (see 7.5.2).		Moved to below.

The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable 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 th representative samples or illustrations).***	The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable a) the availability of information that describes the characteristics of the product, ***NOTE This information can include drawings, parts lists, materials and process specifications.*** b) the availability of work instructions, as necessary, ***NOTE Work instructions can include process flow charts, production documents (e.g., manufacturing plans, travelers, routers, work orders, process cards) and inspection documents.*** c) the use of suitable equipment, ***NOTE Suitable equipment can include product specific tools (e.g., jigs, fixtures, molds) and software programs.*** d) the availability and use of monitoring and measuring equipment, e) the implementation of monitoring and measurement, f) the implementation of product release, delivery and post-delivery activities, ***g) accountability for all product during production (e.g. , parts quantities, split orders, nonconforming product),*** ***h) evidence that all production and inspection /verificatio 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., wa compressed air, electricity, chemical products) to the ext they affect conformity to product requirements, and*** ***k) criteria for workmanship, specified in the clearest prac way (e.g., written standards, representative samples, illustrations).***	***Notes have been added under a), b), and c) to provide additional guidance and examples to the stakeholders. Some of these were taken from the deleted 7.5.1.1 Production Documentation clause.*** d) Changes measuring “devices” to “equipment” wherever it appears. ***g) Changes "manufacture" to "production" - consistent throughout this revision.*** ***j) Changes "quality" to "conformity" - consistent throughout this revision.***

Moved from above.	Planning shall consider, as applicable, - establishing, implementing and maintaining appropriate processes to manage critical items, including process controls where key characteristics have been identified, - designing, manufacturing and using tooling to measure variable data, - identifying in-process inspection/verification points when adequate verification of conformance cannot be performed at later stages of realization, and - special processes (see 7.5.2).	*This requirement has been moved from above and changes text to be consistent with the new term "critical items."*
Was in 8.2.4.2 – First article.	*7.5.1.1 Production process verification*	*Header moves from 8.2.4.2 and changes text from "First Article" to "Production Process Verification."*
Was in 8.2.4.2 – First article.	*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).*	*The "First Article Inspection" (FAI) clause was moved from 8.2 monitoring and measurement, to 7.5.1.1 production and service provision. 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.*
	NOTE This activity is often referred to as first article inspection.	*Note added to provide a guide post for those familiar with FAI.*
7.5.1.1 Production Documentation		*Header deleted.*
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.		*Deleted this clause* *Moved text in 7.5.1.1 to 7.5.1a) and b).*
7.5.1.2 Control of production process changes	*7.5.1.2 Control of production process changes*	
Persons authorized to approve changes to production processes shall be identified.	*Personnel authorized to approve changes to production processes shall be identified.*	*Minor wording change from "persons" to "personnel."*
The organization shall identify and obtain acceptance of changes that require customer and/or regulatory authority approval in accordance with contract or regulatory requirements.		*Deleted.* *In line with the policy adopted throughout the updated Standard, additional customer (contractual) or regulatory requirements have been removed. See 4.1*

Changes affecting processes, production equipment, tools and programs shall be documented. Procedures shall be available to control their implementation.	The organization shall control and document changes affecting processes, production equipment, tools, or software programs.	The need to document changes has been added at this update and removes the requirement for "procedures to control their implementation." Also "programs" is clarified as "software."
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.	The results of changes to production processes shall be assessed to confirm that the desired effect has been achieved without adverse effects to product conformity.	Revised "quality" to "conformity" to be consistent with ISO 9001:2008 text.
7.5.1.3 Control of production equipment, tools and numerical control (NC) machine programs	**7.5.1.3 Control of production equipment, tools and software programs**	**IAQG 9100 changes the header to include all software, not just NC programs.**
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.	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.	The scope of this clause has been changed from NC programs to software. This is in recognition that software is a product unto itself and often utilized throughout product realization. The scope has been defined as "software programs used to automate and control/monitor product realization processes." The new clause has removed the requirement for a documented procedure.
Storage requirements, including periodic preservation/condition checks, shall be established for production equipment or tooling in storage.	Storage requirements, including periodic preservation/condition checks, shall be defined for production equipment or tooling in storage.	Storage requirements changed from "established" to "defined."
7.5.1.4 Control of work transferred, on a temporary basis, outside the organization's facilities		**Moved – see 7.1.4 above.**
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.		Moved – see 7.1.4 above.
7.5.1. 5 Control of Service Operations	**7.5.1. 4 Post-delivery support**	**Header simplified.**
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).	Post-delivery support shall provide as applicable for the a) collection and analysis of in-service data, b) actions to be taken, including investigation and reporting, when problems are detected after delivery, c) control and updating of technical documentation, d) approval, control and use of repair schemes, and e) controls required for off-site work (e.g., organization's work undertaken at the customer's facilities).	This clause has some minor text changes to enhance clarity. Verbiage on contractual and regulatory requirements deleted consistent with this revision and can be found in 4.1.
7.5.2 Validation of processes for production and service provision	**7.5.2 Validation of processes for production and service provision**	

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.	The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered	Minor change.
NOTE: These processes are frequently referred to as special processes.	***NOTE These processes are often referred to as special processes.***	***Minor change.***
Validation shall demonstrate the ability of these processes to achieve planned results.	Validation shall demonstrate the ability of these processes to achieve planned results.	No change.
The organization shall establish arrangements for these processes including, as applicable a) defined criteria for review and approval of the processes, ***- qualification and approval of special processes prior to use,*** b) approval of equipment and qualification of personnel, c) use of specific methods and procedures ***-control of the significant operations and parameters of special processes in accordance with documented process specifications and changes thereto,*** d) requirements for records (see 4.2.4), and e) revalidation.	The organization shall establish arrangements for these processes including, as applicable 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.	***Redundant and unnecessary text removed.***
7.5.3 Identification and traceability	**7.5.3 Identification and traceability**	
Where appropriate, the organization shall identify the product by suitable means throughout product realization.	Where appropriate, the organization shall identify the product by suitable means throughout product realization.	No change.
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.	***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.***	***No change.***
The organization shall identify the product status with respect to monitoring and measurement requirements.	The organization shall identify the product status with respect to monitoring and measurement requirements throughout product realization.	Added that product must be identified "throughout product realization."
When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), the organization shall establish and document controls for the media.	***When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), the organization shall establish appropriate controls for the media.***	***This revision of the standard removes the requirement for "documented" controls for stamps, signatures, passwords, etc. and instead requires "appropriate" controls. The intent is to offer flexibility to the stakeholders and acknowledge there are many ways to accomplish the control of media and these should be "appropriate" to the use.***
Where traceability is a requirement, the organization shall control and record the unique identification of the product (see 4.2.4).	Where traceability is a requirement, the organization shall control the unique identification of the product and maintain records (see 4.2.4).	Maintenance of records added to the record requirement.

According to the level of traceability required by contract, regulatory, or other established requirement, the organization's system shall provide for: ***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***	***NOTE Traceability requirements can include*** ***− identification to be maintained throughout the product life,*** ***− the ability to trace all products manufactured from the same batch of raw material, or from the same manufacturing batch, to the destination (e.g., delivery, scrap),*** ***− for an assembly, the ability to trace its components to the assembly and then to the next higher assembly, and*** ***− for a product, a sequential record of its production (manufacture, assembly, inspection/verification) to be retrievable.***	***This requirement has been changed to a Note ("shall provide" to "can include".) The text is prescriptive and not applicable to all organizations, so it has been changed to guidance to be used in conjunction with the ISO requirement above. The text has been revised removing the contract and regulatory references. This is consistent with the overall strategy to state the requirement in 4.1 and have it reflect incorporation throughout the standard.***
NOTE In some industry sectors, configuration management is a means by which identification and traceability are maintained (see 4.3).	NOTE In some industry sectors, configuration management is a means by which identification and traceability are maintained (see 7.1.3).	The reference to configuration management changes from 4.3 to the new clause number 7.1.3.
7.5.4 Customer property	**7.5.4 Customer property**	
The organization shall exercise care with customer property while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained (see 4.2.4).	The organization shall exercise care with customer property while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records(see4.2.4).	The text near the bottom of the clause has been changed to specifically identify the "organization" as being responsible for reporting to the customer issue with customer property.
NOTE: Customer property can include intellectual property ***including customer furnished data used for design, production and/or inspection.***	NOTE Customer property can include intellectual property and personal data.	***"Customer furnished data used for the design" has been removed from this note*** and has been simplified in the ISO text to say "personal data."
7.5.5 Preservation of product	**7.5.5 Preservation of product**	
The organization shall preserve the conformity of product during internal processing and delivery to the intended destination. This preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.	The organization shall preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.	A statement of intent has been added to the preservation of product stating "in order to maintain conformity to requirements." "As applicable" added prior to the list of ways preservation of product may be accomplished.

Preservation of product shall also include, where applicable in accordance with product specifications and/or applicable regulations, provisions for: ***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.***	***Preservation of product shall also include, where applicable in accordance with product specifications and applicable statutory and regulatory requirements, provisions for*** ***a) cleaning,*** ***b) prevention, detection and removal of foreign objects,*** ***c) special handling for sensitive products,*** ***d) marking and labeling including safety warnings,*** ***e) shelf life control and stock rotation, and*** ***f) special handling for hazardous materials.***	***Added "statutory" to be consistent with ISO 9001:2008.***
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.		***Moved to 8.2.4***
7.6 Control of monitoring and measuring devices	**7.6 Control of monitoring and measuring equipment**	Header change deletes devices and adds equipment
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).	The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.	Measuring "devices" has been changed to "equipment" throughout the standard.
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.	***The organization shall maintain a register of the monitoring and measuring equipment and define the process employed for their calibration/verification including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria.***	***Measuring "devices" has been changed to "equipment" throughout the standard. The word verification has been added next to calibration/ consistent with ISO 9001:2008.***
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.	***NOTE Monitoring and measuring equipment include s, 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.***	***Measuring "devices" has been changed to "equipment" to be consistent with ISO9001:2008.***
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.	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.	No change.
The organization shall ensure that environmental conditions are suitable for the calibration s, inspection s, measurement s and test s being carried out.	***The organization shall ensure that environmental conditions are suitable for the calibration, inspection, measurement and test ing being carried out.***	***Minor editorial changes.***

Where necessary ensure valid results, measuring equipment shall 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; b) be adjusted or re-adjusted as necessary; c) be identified to enable the calibration status to be determined; d) be safeguarded from adjustments that would invalidate the measurement result; e) be protected from damage and deterioration during handling, maintenance and storage; ***f) be recalled to a defined method when requiring calibration.***	Where necessary to ensure valid results, measuring equipment shall a) be calibrated or verified, or both, 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 (see 4.2.4); b) be adjusted or re-adjusted as necessary; c) have identification in order to determine its calibration status; d) be safeguarded from adjustments that would invalidate the measurement result; e) be protected from damage and deterioration during handling, maintenance and storage. ***The organization shall establish, implement and maintain a process for the recall of monitoring and measuring equipment requiring calibration or verification.***	***f) has been changed to a separate requirement following e) and strengthens the requirement for the organization to establish a process for recall of equipment in need of calibration and verification.***
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).	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).	No change.
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.	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.	No change.
NOTE See ISO 10012-1 and ISO 10012-2 for guidance.		Deleted the note referencing the ISO 10012-1 and ISO10012-2.
	NOTE Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.	Note added with guidance for software confirmation.
8 Measurement, analysis and improvement	**8 Measurement, analysis and improvement**	
8.1 General	**8.1 General**	

The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed a) to demonstrate conformity of the product, b) to ensure conformity of the quality management system, and c) to continually improve the effectiveness of the quality management system.	The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed a) to demonstrate conformity to product requirements, b) to ensure conformity of the quality management system, and c) to continually improve the effectiveness of the quality management system.	Clarified that conformity is based on the product "requirements".
This shall include determination of applicable methods, including statistical techniques, and the extent of their use.	This shall include determination of applicable methods, including statistical techniques, and the extent of their use.	No change.
NOTE: According to the nature of the product and depending on the specified requirements, statistical techniques may be used to support: ***- 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;***	***NOTE According to the nature of the product and depending on the specified requirements, statistical techniques can be used to support*** ***- 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, and*** ***- failure mode, effect and criticality analysis.***	***This note removes prescriptive verbiage and adds failure mode, effect and criticality analysis (FMECA) in place of failure mode and effect analysis (FMEA).***
8.2 Monitoring and measurement	**8.2 Monitoring and measurement**	
8.2.1 Customer satisfaction	**8.2.1 Customer satisfaction**	
As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.	As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.	No change.
	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.	***Customer satisfaction is a key inclusion in this update to the Standard and this clause defines mandatory measures that all organizations of all 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 effectiveness. It also follows that should the action not be effective, further action must be taken until customer satisfaction performance is as required***

	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.	This note has been added to provide guidance on various input sources that may be utilized to support customer satisfaction.
8.2.2 Internal audit	**8.2.2 Internal audit**	
The organization shall conduct internal audits at planned intervals to determine whether the quality management system 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 b) is effectively implemented and maintained.	The organization shall conduct internal audits at planned intervals to determine whether the quality management system 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 ***NOTE Planned arrangements include customer contractual requirements.*** b) is effectively implemented and maintained.	***A Note has been added as a reminder to include customer contractual requirements in planned arrangements.***
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.	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. The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.	Minor change.
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.	A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results. Records of the audits and their results shall be maintained (see 4.2.4).	Text has been restructured. The intent remains the same.
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).	The management responsible for the area being audited shall ensure that any necessary corrections and corrective 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).	Clarification has been provided as to the type of actions to be taken are "any necessary correction and corrective" actions.
Detailed tools and techniques shall be developed such as checksheets, process flowcharts, or any similar method to support audit of the quality management system requirements. The acceptability of the selected tools will be measured against the effectiveness of the internal audit process and overall organization performance.		***Deleted.*** ***Deleted the requirement for detailed tools and techniques. The requirement was too prescriptive and reference to specific tools in a "such as" statement is more appropriate as guidance material.***

Internal audits shall also meet contract and/or regulatory requirements.		***Deleted.*** ***Reference to contract & regulatory requirements has been deleted. Reference note under 8.2.2a and clause 4.1.***
NOTE: See ISO 10011-1, ISO 10011-2 and ISO 10011-3 for guidance.	NOTE See ISO 19011 for guidance.	The reference for an audit guidance document has been changed from ISO 10011 (cancelled) to ISO 19011.
8.2.3 Monitoring and measurement of processes	**8.2.3 Monitoring and measurement of processes**	
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.	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" has been removed. Not all processes directly affect product conformity, but may still impact how an organization would demonstrate the ability of the processes to achieve planned results.
	NOTE When determining suitable methods, it is advisable that the organization consider the type and extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to product requirements and on the effectiveness of the quality management system.	This note has been added to provide guidance on how an organization may go about determining appropriate process monitoring and measurement methods.
In the event of process nonconformity, the organization shall ***a) take appropriate action to correct the nonconforming process,*** ***b) evaluate whether the process nonconformity has resulted in product nonconformity, and*** ***c) identify and control the nonconforming product in accordance with clause 8.3.***	***In the event of process nonconformity, the organization shall*** ***a) take appropriate action to correct the nonconforming process,*** ***b) evaluate whether the process nonconformity has resulted in product nonconformity,*** ***c) determine if the process nonconformity is limited to a specific case or whether it could have affected other processes or products, and*** ***d) identify and control any nonconforming product***	***A new line item has been added as c). It requires that the organization determine if the nonconformity is limited or if it has affected other processes or products. This expends the scope towards the identification of how the nonconformance has affected not only the product, but also other processes.***
8.2.4 Monitoring and measurement of product	**8.2.4 Monitoring and measurement of product**	
The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1).	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.	Moved bottom sentence from below. "Evidence of conformity with the acceptance criteria shall be maintained."

	Measurement requirements for product acceptance shall be documented and shall include ***a) criteria for acceptance and/or rejection,*** ***b) where in the sequence measurement and testing operations are performed,*** ***c) required record s of the measurement results (at a minimum, indication of acceptance or rejection), and*** ***d) any specific measurement instruments required and any specific instructions associated with their use.***	***Moved from 8.2.4.1.*** ***No change other than the alignment.***
When key characteristics have been identified, they shall be monitored and controlled.	***When critical items, including key characteristics, have been identified the organization shall ensure they are controlled and monitored in accordance with the established processes.***	***"Critical items" has been added in conjunction with key characteristics. This is consistent with the new terms added in clause 3. This clause also adds a requirement that processes are in place to control and monitor the critical items and key characteristic that have been identified.***
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.	***When the organization uses sampling inspection as a means of product acceptance, the sampling plan shall be justified on the basis of recognized statistical principles and appropriate for use (i.e., matching the sampling plan to the criticality of the product and to the process capability).***	***Reworded to clarify often misinterpreted requirements. Added that sampling plans must be justified based on recognized statistical principles. "Customer approval" was deleted and was seen as a contractual requirement. If customers need this they must flow contractually.***
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.	***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.***	***The text of this clause has been rewritten enhance clarity and add requirements for product pending completion to be "identified and recorded", so replacement can be done if the product ends up not meeting requirements.***
Evidence of conformity with the acceptance criteria shall be maintained.		Moved to top paragraph of 8.2.4
Records shall indicate the person(s) authorizing release of product (see 4.2.4).	Records shall indicate the person(s) authorizing release of product for delivery to the customer (see 4.2.4).	This clause has been clarified by adding specific verbiage that it is only the product "for delivery to the customer" that requires a person be identified to authorize its release.
	Where required to demonstrate product qualification, the organization shall ensure that records provide evidence that the product meets the defined requirements.	***Moved from 8.2.4.1.*** ***The requirement for records of product qualification has been moved to clause 8.2.4 from the deleted clause 8.2.4.1.***
Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.	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.	The "customer" has been added to indicate who the product will be released and delivered to.

	The organization shall ensure that all documents required to accompany the product are present at delivery.	***This requirement moves from 7.5.5 to 8.2.4.***
8.2.4.1 Inspection Documentation		***IAQG 9100 deletes this header.***
Measurement requirements for product or service acceptance shall be documented. This documentation may be part of the production documentation , but shall include a) criteria for acceptance and/or rejection, b) where in the sequence measurement and testing operations are performed, c) a record of the measurement results, and d) type of measurement instruments required and any		***Moved to 8.2.4 above. No change other than the alignment.***
Test records shall show actual test results data when required by specification or acceptance test plan.		***Deleted.***
Where required to demonstrate product qualification the organization shall ensure that records provide evidence that the product meets the defined requirements.		***Moved to 8.2.4 above.***
8.2.4.2 First Article Inspection		***IAQG 9100 deletes this header.***
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		***Moved to 7.5.1.1 and renamed.***
NOTE: See (AS) (EN) (SJAC) 9102 for guidance.		***Deleted.***
8.3 Control of nonconforming product	**8.3 Control of nonconforming product**	
The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.	The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.	Reworded for clarity. The intent remains the same.
NOTE: The term "nonconforming product" includes nonconforming product returned from a customer.	***NOTE The term "nonconforming product" includes nonconforming product returned by a customer.***	***Minor editorial change.***

The organization's documented procedure shall define the responsibility for review and authority for the disposition of nonconforming product and the process for approving personnel making these decisions.	***The organization's documented procedure shall define the responsibility and authority for the review and disposition of nonconforming product, and the process for approving personnel making these decisions.***	***Minor editorial change.***
The organization shall deal with nonconforming product by one or more of the following ways: a) by taking action to eliminate the detected nonconformity; b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer; c) by taking action to preclude its original intended use or application. (d is moved from below)	Where applicable, the organization shall deal with nonconforming product by one or more of the following ways: a) by taking action to eliminate the detected nonconformity; b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer; c) by taking action to preclude its original intended use or application; d) by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started; ***– The organization's nonconforming product control process shall provide for timely reporting of delivered nonconforming product;*** ***NOTE Parties requiring notification of nonconforming product can include suppliers, internal organizations, customers, distributors and regulatory authorities.*** ***e) by taking actions necessary to contain the effect of the nonconformity on other processes or products.***	"Where applicable" has been added. ***The organizations nonconforming product control "system" has been replaced by "process", in the text below d), consistent with a general strategy to use process in place of references to document, policy, system, etc. The text following b) has been moved up from the end of the clause to provide a cleaner structure and flow of the requirements. e) has been added to containment action to be taken on nonconformities.***
	Dispositions of use-as-is or repair shall only be used after approval by an authorized representative of the organization responsible for design.	***Moved from below.*** ***This clause has been simplified and redundant text removed. The new requirement focuses on having a authorized representative of the design organization. This is intended to provide continuity of the design responsibility and integrity of the product***
	NOTE Authorized representative includes personnel having delegated authority from the design organization.	***Moved text and a note from below to the ways of dealing with nonconforming product.***

The organization shall not use dispositions of use-as-is or repair, unless specifically authorized by the customer, if ***- the product is produced to customer design, or*** ***- the nonconformity results in a departure from the contract requirements.***	***The organization shall not use dispositions of use-as-is or repair, unless specifically authorized by the customer, if the nonconformity results in a departure from the contract requirements.***	***This clause has removed text pertaining to the use-as-is or on repair dispositions on product produced to customer design. The emphasis is placed on nonconformities that depart from contract requirements and that they are approved by the customer***
Unless otherwise restricted in the contract, organization-designed product which is controlled via a customer specification may be dispositioned by the organization as use-as-is or repair, provided the nonconformity does not result in a departure from customer-specified requirements		***Moved to above.***
Product dispositioned for scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable.	***Product dispositioned for scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable.***	***No change.***
	When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.	Moved from below. No change other than moving up in sequence.
Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).	Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).	No change.
When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.		Moved to above.
When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.		Moved above to 8.3.d.
In addition to any contract or regulatory authority reporting requirements, the organization's system shall provide for timely reporting of delivered nonconforming product that may affect reliability or safety. Notification shall include a clear description of the nonconformity, which includes as necessary parts affected, customer and/or organization part numbers, quantity, and date(s) delivered		***Moved to 8.3d.***
NOTE: Parties requiring notification of nonconforming product may include suppliers, internal organizations, customers, distributors, and regulatory authorities.		***Moved as note under 8.3d.***
8.4 Analysis of data	**8.4 Analysis of data**	

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.	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.	No change.
The analysis of data shall provide information relating to a) customer satisfaction (see 8.2.1), b) conformity to product requirements (see 7.2.1), c) characteristics and trends of processes and products including opportunities for preventive action, and d) suppliers.	The analysis of data shall provide information relating to a) customer satisfaction (see 8.2.1), b) conformity to product requirements (see 8.2.4), c) characteristics and trends of processes and products, including opportunities for preventive action (see 8.2.3 and 8.2.4), and d) suppliers (see 7.4).	Clause references have been updated to and expanded to provide applicable reference points to the other clauses.
8.5 Improvement	**8.5 Improvement**	
8.5.1 Continual improvement	**8.5.1 Continual improvement**	
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.	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.	No change.
	The organization shall monitor the implementation of improvement activities and evaluate the effectiveness of the results.	***This clause widens the requirements of the ISO text and 'closes the loop' of the improvement cycle by requiring the organization to (periodically) monitor the implementation of improvement actions and evaluate their effectiveness. Where action hasn't been effective, the ISO text requires that further action is taken until it is.***
	NOTE Continual improvement opportunities can result from lessons learned, problem resolutions and the benchmarking of best practices.	***This new Note in clause 8.5.1 provides a few examples where opportunities for improvement can be identified; there are many other improvement opportunities that could also be used***
8.5.2 Corrective action	**8.5.2 Corrective action**	
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.	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.	"Cause" changed to the plural "causes" of nonconformities. An editorial change.

A documented procedure shall be established to define requirements for a) reviewing nonconformities (including customer complaints), b) determining the causes of nonconformities, c) evaluating the need for action to ensure that nonconformities do not recur, d) determining and implementing action needed, e) records of the results of action taken (see 4.2.4), f) reviewing corrective action taken, ***g) flow down of the corrective action requirement to a supplier, when it is determined that the supplier is responsible for the root cause, and*** ***h) specific actions where timely and/or effective corrective actions are not achieved.***	A documented procedure shall be established to define requirements for a) reviewing nonconformities (including customer complaints), b) determining the causes of nonconformities, c) evaluating the need for action to ensure that nonconformities do not recur, d) determining and implementing action needed, e) records of the results of action taken (see 4.2.4), f) reviewing the effectiveness of the corrective action taken, ***g) flowing down corrective action requirements to a supplier when it is determined that the supplier is responsible for the nonconformity,*** ***h) specific actions where timely and/or effective corrective actions are not achieved, and*** ***i) determining if additional nonconforming product exists based on the causes of the nonconformities and taking further action when required.***	f) Clarifies that the effectiveness of the action should be reviewed, not just the action. ***g) The rewording changes the requirement from the supplier responsible for the "root cause" to "nonconformance", recognizing the two are not always the same and placing the responsibility on the originator.*** ***i) Requirement has been added to determine not only if other nonconforming product exists resulting from the causes, but also that further action must be taken as required.***
8.5.3 Preventive action	**8.5.3 Preventive action**	
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.	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.	No change.
A documented procedure shall be established to define requirements for 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.	A documented procedure shall be established to define requirements for 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 the effectiveness of the preventive action taken.	The addition of "effectiveness" of the preventive action provides more emphasis on the performance of the preventive action, not just the initial action.
	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.	***This new note provides examples of preventive action opportunities, sources and tools that may be utilized by organizations. Stakeholder feedback indicated that additional guidance has been needed in the preventive action area, so to avoid being overly prescriptive a note was seen as the optimal way to provide the organizations some options and enhance their success in this clause.***
Bibliography	**Bibliography**	

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