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A Joint ACI U.S.A. & CAI Division of Canada White Paper

AS9100:2009 Revision C Overview

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Overview:

On July 1, 2012, *The SAE Aerospace Standard AS9100:2009 Revision C* shall be enforced globally. This version was designed by a 16-member team from 10 different countries which comprised the International Aerospace Quality Group (I.A.Q.G.) from years 2005 through 2009. It was released and published in early 2010.

The *SAE Aerospace Standard AS9100:2009 Revision C* supersedes and replaces *AS9100:2004 Revision B*. Aerospace Original Equipment Manufacturers (O.E.M.s) shall require valid and verifiable certification from their supply chain members. Those manufacturers who have not upgraded to version C by July 1, 2012 shall be decertified until compliant and suspended from the *Online Aerospace Supplier Information System* (O.A.S.I.S.)

The Stakeholders of the Aerospace Standard AS9100:2009 Revision C:

The following parties will be the main beneficiaries of the specific revisions that occurred beginning in 2005 with developmental input and output planned and determined by the *International Aerospace Quality Group (I.A.Q.G.):*

- *The Civil Authorities*
- *The Defense Industry and Authorities*
- *The Space Industry and Authorities*
- *Various Trade Associations*
- *Suppliers*
- *I.A.Q.G. Member Companies*
- *I.A.Q.G. Strategy Streams and Teams*

The Main Objectives of AS9100:2009 Revision C:

The first objective incorporates specific changes that had been done for the new *ISO9001:2008*.

The second objective expands the scope of the Aerospace standard to include not only the *Aviation* and *Space* Industries but also the *Defense* industry as well.

The third objective ensures the alignment of the *I.A.Q.G.* strategy for *On-time Delivery* and *On-time Performance.*

The fourth objective develops and adopts new requirements within the standard based on the needs of the *Stakeholders*.

The fifth objective improves the existing requirements where the *Stakeholders* have a need for clarification, including when a documented procedure would be required.

Per the *International Aerospace Quality Group (I.A.Q.G.)* the changes and improvements to *AS9100:2009 Revision C* may offer the additional recognitions and synergies with the *N.A.T.O. Allied Quality Assurance Publications (A.Q.A.P.).*

N.B.: The *International Aerospace Quality Group (I.A.Q.G.)* took more than four years with officers representing different countries and companies to review, develop, improve and publish the new standard. Moreover, because the standard provides the Aerospace industry *Original Equipment Manufacturers* and their Supplier Manufacturers a rigorous framework by which their supply products and quality can be judged, overall quality and customer satisfaction is therefore expected to substantially increase.

Key Changes, Additions, and Revisions within AS9100:2009 Revision C:

Foreword:

The *Foreword* section of the standard introduces the terms "*Space*" and "*Defense Organizations*" to the scope of the standard. The standard now reads "*Aviation, Space, and Defense Organizations.*" This allows for the *AS9100:2009 Revision C* to be applicable to other industries where the need for *Quality* is important.
There have been other minor clarifications completed throughout this section. See below:

> "*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." AS9100:2009 Revision C - Foreword*

Revision Summary / Rationale:

The *Revision Summary* now changes to *Revision Summary / Rationale* in the heading.

This section of *AS9100:2009 Revision C* includes the changes to *ISO9001:2008* and other changes to meet the needs of S*takeholders*.

Introduction and General 0.1:

The *I.A.Q.G.* restores the numbering system to the standards starting with "*0.1.*" Also, the standard states that *ISO9001:2008* adds clarification that the "*business environment*" which is inclusive of "*risk*" is an aspect that bears on the *Quality Management System (Q.M.S.) Design and Implementation*.

> *Webster's New World College Dictionary, Fourth Edition Copyright © 2000* defines the word "*risk*" which is derived from the Vulgar Latin "riscare" as "(*n.)* 1. the chance of injury, damage, or loss; dangerous chance; hazard; 2. Insurance a) the chance of loss; b) the degree of probability of loss; c) the amount of possible loss to the insuring company; d) a person or thing with reference to the risk involved in providing insurance; e) the type of loss that a policy covers, as fire, storm, etc. (*vt.)* which is derived from the French "*risquer.*" 1. to expose to the chance of injury, damage, or loss; hazard [*to risk* one's life]; 2. to incur the risk of [to risk a fight]. SYN. *Danger:* at r*isk,* in danger of damage, injury, loss, etc."

ISO9001:2008 also adds the term "*statutory requirements*" in addition to *"risk"* throughout the *AS9100:2009 Revision C Standard. See below:*

> *"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." AS9100:2009 Revision C General 0.1.*

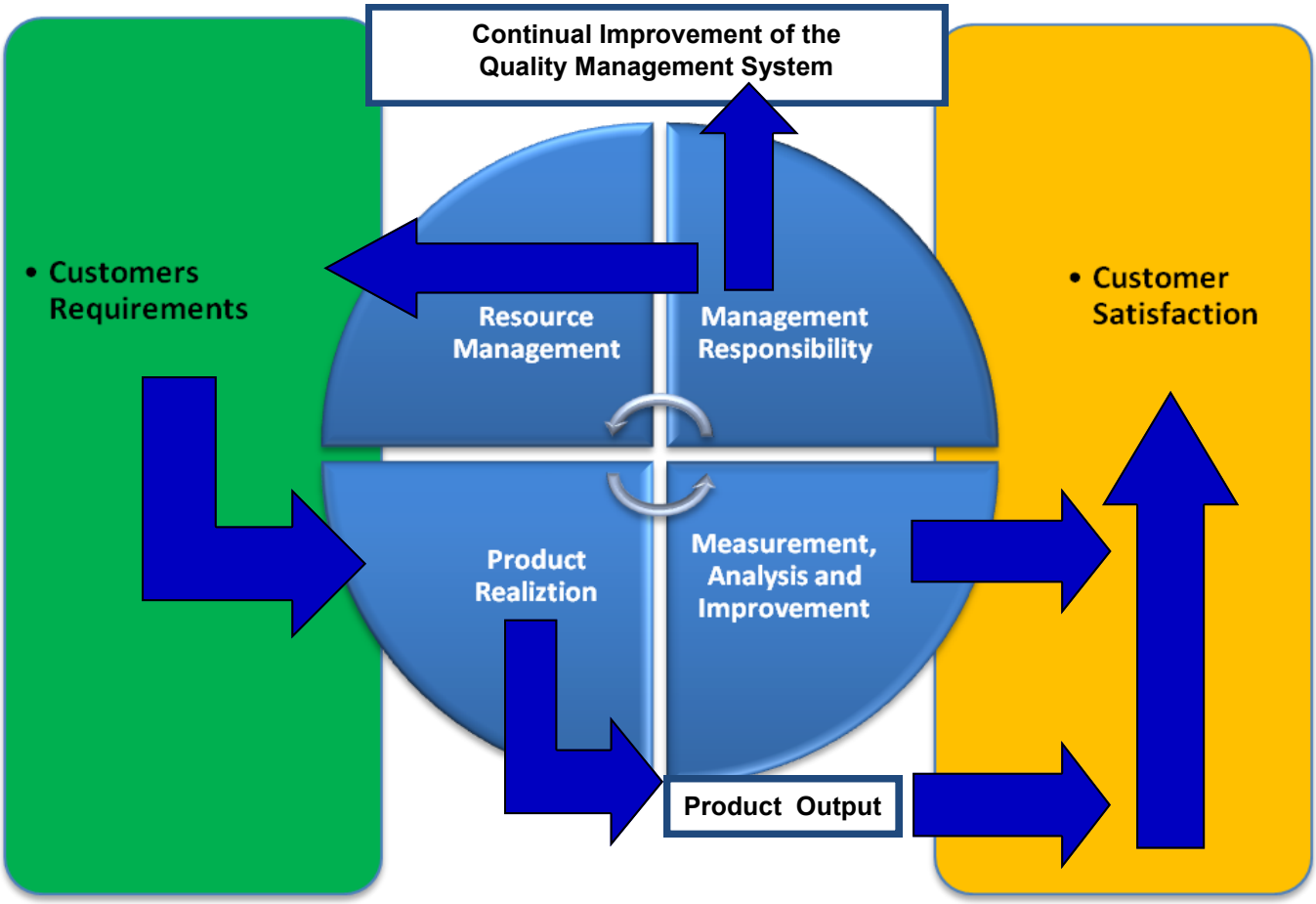
"This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, statutory and regulatory requirements applicable to the product, and the organization's own requirements." AS9100:2009 Revision C General 0.1.

AS9100:2009 Revision C Clause 0.2

In *Clause 0.2, ISO 9001:2008* replaces the word *"identify"* with *"determine."* The word "*determine*" is a much stronger and more precise word than to "i*dentify."* See definition below:

Webster's New World College Dictionary, Fourth Edition Copyright © 2000 defines "*determine*" (vt.) [from Old French "*determiner*" and Latin "*determinare*" to bound limit] as "1. to set limits to; bound, define; 2. to settle (a dispute, question, etc.) conclusively; decide; 3. to reach a decision about after thought and investigation; decide upon; 4. to establish or affect the nature, kind, or quality of; fix [genes *determine* heredity]; 5. to find out exactly; calculate precisely; ascertain [to *determine* a ship's position]; 6. to give direction to; shape or affect; 7. *Law* to end; terminate *(vi.)* 1. to decide; resolve; 2. *(Law)* to come to an end. *SYN*. decide, learn."

ISO 9001:2008 also emphasizes that processes and their interactions should "*produce the desired outcome*." This indicates that if the processes are correct, the desired outcome would occur. See figure below from *ISO 9001:*



N.B.: According to the *I.A.Q.G.* the above diagram which illustrates the relationship to between *ISO9001* requirements and Documented Procedures is deleted in *AS9100:2009 Revision C.* The *I.A.Q.G.* indicated that the document provides no value that assures product quality. Auditors must review documented procedures.

AS9100:2009 Revision C 1.1 General:

In Clause 1.1, it must be noted that *AS9100:2009 Revision C* includes all requirements of *ISO9001:2008* as well as the additional industry requirements for the *aviation, space and defense organization* industries that are consistent with the revised scope of the document. If a conflict occurs between *AS9100* and Federal and/or State Laws, the Legal Requirement or Law shall take precedence.

ISO 9001:2008 clarifies that the term "*product*" applies not only to product for a customer, but also to product needed for realization processes. Also, the statement "*statutory and regulatory*" refer to legality.

1.2 Application:

In Section 1.2, AS9100 Revision C now provides clarification on the scopes of three *aviation, space and defense* standards:

- *AS9100 is for organizations that design, develop and produce products.*
- *AS9110 is for organizations that provide maintenance, repair and overhaul services.*
- *AS9120 is for organizations that buy products and resell them.*

AS9100:2009 Revision C Section 1.2 incorporates the above information with the following statement below:

> *"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.*
>
> *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).*
>
> *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)."*

2 Normative References:

AS9100:2009 Revision C as was stated earlier includes *ISO9001:2008* which supersedes and replaces *ISO9001:2000*. Also note the reference to *ISO9000:2005*. See below:

> *"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."*

3.0 - 3.4 Terms and Definitions:

As was noted earlier, *AS9100:2009 Revision C* includes the terms "*Risk,"* "*Special Requirements,"* and "*Critical Items."* These terms are utilized throughout the standard. Understanding of these terms is important to understanding the scope of the standard with its requirements. For the definitions see page 6:

"3.1 Risk

An undesirable situation or circumstance that has both a likelihood of occurring and a potentially negative consequence.

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.

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.

3.4 Key Characteristic

An attribute or feature whose variation has a significant effect on product fit, form, function, performance, service life or producibility, that requires specific actions for the purpose of controlling variation.

NOTE: Special requirements and critical items are new terms and, along with key characteristics, are interrelated. Special requirements are identified when determining and reviewing requirements related to the product (see 7.2.1 and 7.2.2). Special requirements can require the identification of critical items. Design output (see 7.3.3) can include identification of critical items that require specific actions to ensure they are adequately managed. Some critical items will be further classified as key characteristics because their variation needs to be controlled."

4.0 Quality Management System - 4.1 General Requirements:

In this section, we again see certain words or phrases that have been replaced with more specific language, e.g., "*Determine the Processes*" supersedes and replaces "*Identify the Processes*." As was discussed earlier, "*determine*" is a more precise action word than "*Identify*." The former carries more weight with implied directive control of the process whereas the latter only "*identifies*" the processes, i.e., takes notice of the processes more passively or without subsequent action.
Also, note within Section 4.1 that *AS9100:2009 Revision C* provides precise definition of "*outsourced processes*." See below:

"*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 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.

These processes shall be managed by the organization in accordance with the requirements of this International Standard.

Where an organization chooses to outsource any process that affects product conformity to requirements, the organization shall ensure control over such processes.

The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system.

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.

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.

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 (Purchasing Clause)"

4.2 Documentation Requirements:

4.2.1 General:

This section provides amplification superseding *AS9100:2004 Revision B* for what exactly *Aviation, Space*, or *Defense Organizations* must have in order to comprise the *Quality Management System*.

Also note that within this section of the standard that the term "*documented procedure*" is clearly defined as inclusive of "*establishing, documenting, implementing, and maintaining it."*

Additionally, the standard states that a "*document*" may address more than one procedure and that a "*documented procedure*" may be covered by one or more "*documents."*

"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. The organization shall ensure that personnel have access to, and are aware of, relevant quality management system documentation and changes."

"The organization shall ensure that personnel have access to, and are aware of, relevant quality management system documentation and changes.

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 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."

4.2.2 Quality Manual:

As was previously indicated, after thorough review and consideration, the *I.A.Q.G.* deleted the requirement from *4.2.2.* that required documentation which showed the relationship between *AS9100 Requirements* and the documented procedures of the organization.

The Rationale that the *I.A.Q.G.* provided in their revision of *AS9100* is that the requirement provided no value for the purpose of assurance of quality and that the requirement was "*prescriptive*" in that it specified a manner by which the requirements for the standard were met.

The *AS9100:2009 Revision C* stated that the appropriately designated and "d*ocumented procedures*" need to be identified by Auditors as an "*inherit part*" of carrying on the audits. The standard is stated below in *4.2.2*:

"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."

4.2.3: Control of Documents:

In this section, the *I.A.Q.G*. reiterates that which is stated in *ISO9001:2008* with regard to "*documents of external origin*." As far as the Auditor is concerned, the Auditor will wish to review any documents that are distributed by the organization that are of external origin. Conversely, the Auditor will also look for adherence to the standard that documents of internal origin that relate directly the standard are not dispersed nor distributed outside of the organization that could affect quality in any way, shape, manner. This is where "*risk*" is highly important. Issues of legality, confidentiality, etc., of the documents and who and what are exposed to distribution may be reviewed by the Auditor.
The standard states this below:

"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.

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."

4.2.4 Control of Records:

Basically, the organization must show in its records "*evidence of conformity*,"procedures for storage and retrieval of the records, and that any records that are "*created*" by its suppliers must also be accounted for in the same procedure.

"*Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled.*

The organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.

The documented procedure shall define the method for controlling records that are created by and/or retained by suppliers.

Records shall remain legible, readily identifiable and retrievable."

5.0 Management Responsibility (See below)

5.1. Management Commitment:

There have been no changes to this section in *AS9100:2009 Revision C* from *AS9100:2004 Revision B*.

"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."

5.2 Customer Focus:

AS9100:2009 Revision C adds requirements for the measurement of the *conformity of the product* and the *on-time delivery performance*. Additionally, if the *on-time delivery and/or conformity specifications* required by the customer are not achieved, documentations of the corrective actions must occur.

"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 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.

5.3 Quality Policy:

There have been no changes to this section from *AS9100:2004 Revision B*.

"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.

5.4 Planning

5.4.1 Quality Objectives:

There have been no changes to this section of the standard.

"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.

The quality objectives shall be measurable and consistent with the quality policy."

5.4.2 Quality Management System Planning:

There have been no changes to this section of the standard.

"Top management shall ensure that

a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and

b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented."

5.5 Responsibility, Authority, and Communication

5.5.2. Management Representative:

This section of the standard is very clear and specific in that the **Management Representative** must be a member of the management of the organization. Additionally, the Title or Level of the *Management Representative* is not important. The important part of this standard is that the *Management Representative* must have the freedom to resolve all matters of Quality. In other words, the *Management Representative* must have the freedom to resolve matters of Quality on their authority separate from the fact that the person reports to top management. This is not to say that communication must not take place, but the authority or first authority to deal with issues of Quality must be dealt with by the *Management Representative* who must also advise top management of resolution or actions. This part of the standard is often troublesome in some organizations. The *Management Representative* can also include an Outside Source "*Liaison*" to Top Management.

"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.

NOTE: The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system."

5.5.3 Internal Communication:

There have been no changes to this section of the standard from *AS9100:2004 Revision B*.

> *"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."*

5.6 Management Review

5.6.1 General:

There have been no changes to this section of the standard from *AS9100:2004 Revision B*.

> *"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."*

5.6.2 Review Input:

There have been no changes to this section of the standard from *AS9100:2004 Revision B*.

> *"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."*

5.6.3 Review Output:

There have been no changes to this section of the standard from *AS9100:2004 Revision B*.

> *"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."*

6.0 Resource Management

6.1 Provision of Resources:

There have been no changes to this section of the standard from *AS9100:2004 Revision B*.

> *"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."*

6.2 Human Resources

6.2.1 General:

It is important to note here that *ISO9001:2008* makes clear that "*Product Quality*" is the "*conformity*" to the product requirements. Thus, any and all personnel within an organization can and do have a direct bearing on the quality of the product.

"Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience.

NOTE: Conformity to product requirements can be affected directly or indirectly by personnel performing any task within the quality management system."

6.2.2 Competence, training and awareness:

It is important to note that in this section of the standard the order of the words was changed from "*Competence, Awareness and Training*" in *AS9100:2004 Revision B* to the heading above. The *I.A.Q.G. AS9100:2009 Revision C Standard* requires that the organization properly organize records of their employees from their demonstration of competence, additional training that may be required, and the awareness of the employee of the product quality.

"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)."

6.3 Infrastructure:

ISO9001:2008 adds "*Information Systems*" as an example to "*Support Service*." Another example is software that can properly track and trace a product from inception to delivery.

"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)."

6.4 Work Environment:

Section 6.4 is very clear and precise. The work environment must conform to the requirements to fulfill product realization. This implies that organizations must have personnel who are trained for that part of product realization and they must have fully functional equipment, machinery, etc., in order to manufacture in conformance to a customer's requirements.

"The organization shall determine and manage the work environment needed to achieve conformity to product requirements.
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)."

7 Product Realization

7.1 Planning of Product Realization:

AS9100:2009 Revision C in this section provides additional guidance on aspects to consider when determining the *product quality objectives and requirements*. This section, also per the *I.A.Q.G.*, adds "*appropriate measurement activities*." Thirdly per the *I.A.Q.G.*, the standard adds "*Configuration Management*" to the "*Product Planning Realization Process*."

"The organization shall plan and develop the processes needed for product realization.

Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1).

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 output of this planning shall be in a form suitable for the organization's method of operations.

NOTE 1: A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract can be referred to as a quality plan.

NOTE 2: The organization may also apply the requirements given in 7.3 to the development of product realization processes.

7.1.1 Project Management:

AS9100 Revision C adds new *Project Management* requirements to mitigate risk per the *I.A.Q.G*. and to meet the resource and schedule restraints.

"AS9100 adds new project management requirements to mitigate risks and meet resource and schedule restraints."

7.1.2 Risk Management:

AS9100:2009 Revision C adds *Risk Management* requirements which include *responsibilities*; the *risk criteria*; *identification, assessment, and communication of risks*; *the actions to mitigate the risks*; *and the acceptance of the unmitigated risks*. The Auditors will wish to verify if the organization has a *risk management* process that addresses all of the requirements. Also, the Auditors will wish to know if the definition of risk is understood. See below:

"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."

7.1.3 Configuration Management:

The *AS9100 Management clause* was moved by the *I.A.Q.G*. from *Section 4* to *Section 7* of the standards. This was done because it was felt that this should be applied throughout the product realization process. The ISO standard which provides guidance for this is *ISO10007*. (*Contact Aerospace Consultants International LLC for a PDF Copy of this Standard*). The Auditors will expect that some level of Configuration Management will have been expected for all products at all levels of the supply chain per the *I.A.Q.G*.

"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.

NOTE: See ISO10007 for guidance."

7.1.4 Control of Work Transfers:

This section of *AS9100* was moved from *Section 7.5* to this location due to the fact that it includes "*planning."* It also addresses "*permanent transfers*" and provides clarified details.

"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."

7.2 Customer-related Processes

7.2.1 Determination of Requirements Related to the Product:

ISO9001:2008 provides very minor clarifications of this section of the standard.

AS9100 adds a note in Section 3.2 and *ISO9001:2008* adds a note to clarify what is meant by post-delivery activities.

"The organization shall determine:

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,

b) requirements not stated by the customer but necessary for specified or intended use, where known,

c) statutory and regulatory requirements applicable to the product, and

d) any additional requirements considered necessary by the organization.

NOTE: Requirements related to the product can include special requirements.

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."

7.2.2 Review of Requirements Related to the Product:

AS9100:2009 Revision C adds clarification that "*requirements reviews*" include a "*review*" to determine "*special product requirements*." Additionally, there are minor changes in the text to clarify "*risk review*."

"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).

Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.

Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

NOTE: In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material."

7.2.3 Customer Communication:

There have been no changes from *AS9100:2004 Revision B* to *AS9100:2009 Revision C* for this section.

"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 complaint ."

7.3 Design and Development

7.3.1 Design and Development Planning:

"The organization shall plan and control the design and development of product.

During the design and development planning, the organization shall determine:

a) the design and development stages,

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.

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."

With regard to the above paragraph, this particular requirement of *AS9100:2009 Revision C* was reworded to provide clarity. The *I.A.Q.G*. notes that previously it was only required to "*give consideration to*" these activities. It is now more strongly worded that these activities shall be done, where appropriate.

"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."

AS9100:2009 Revision C adds "*statutory*" to be consistent with *ISO9001:2008*. This requirement has been moved and slightly reworded.

AS9100:2009 Revision C also adds the requirement for planning to consider downstream processes and customers.

> *"Design and development planning shall consider the ability to produce, inspect, test and maintain 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.*
>
> *Planning output shall be updated, as appropriate, as the design and development progresses."*

ISO9001:2008 adds a note per the *I.A.Q.G*. clarifying that reviews, *verification and validation* can be conducted and recorded separately or combined according to the needs of the organization.

> *"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."*

7.3.2 Design and Development Inputs:

> *"Inputs relating to product requirements shall be determined and records maintained (see4.2.4). 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.*
>
> *The inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other."*

There was a minor change at the beginning of the last statement. "*These inputs*" was changed in *ISO9001:2008* to "*The changes*".

7.3.3 Design and Development Outputs:

> *"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."*

In the above opening statement of this section, the *I.A.Q.G*. changed the phrase from *AS9100:2004 Revision B* "*enables verification*" to "*suitable for verification*." This is interpreted as that any outputs would be ready for verification. The prior *AS9100 Revision B* in this section was ambiguous.

In the next paragraph of this section, one will note that words such as "*identify*" which had hitherto been discussed were replaced with "*specify*." There were also minor changes to subsection *"e)."* See below:

> *"Design and development outputs shall:*
>
> *a) meet the input requirements for design and development,*
>
> *b) provide appropriate information for purchasing, production and service provision,*
>
> *c) contain or reference product acceptance criteria,*
>
> *d) specify the characteristics of the product that are essential for its safe and proper use, and*
>
> *e) specify, as applicable, any critical items, including any key characteristics, and specific actions to be taken for these items."*

In the next part of this section several changes are also noted from *AS9100:2004 Revision B*. Again, we see that the passive phrase "*shall be identified*" was replaced by "*shall define."* The data requirements are thus defined more clearly. See below:

"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.

NOTE: Information for production and service provision can include details for the preservation of product."

7.3.4 Design and Development Review:

There were no changes to this section of *AS9100 in Revision C.*

"At suitable stages, systematic review 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.

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 nay necessary actions shall be maintained (4.2.4)."

7.3.5 Design and Development Verification:

The only change in this section was the deletion from *AS9100:2004 Revision B* of "*notes*" which offered examples of 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 in put requirement. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4.).

7.3.6 Design and Development Validation:

The only change in this section was the deletion from *AS9100:2004 Revision B* of "*notes*" which offered examples of validation.

"Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1.) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4.)."

7.3.6.1 Design and Development Verification and Validation Testing:

In *AS9100:2004 Revision B* this section came after "*Design and Development Verification and Validation Documentation*." In *AS9100:2009 Revision C*, "*Verification and Validation Testing*" was placed in logical order before "*Verification and Validation Documentation."*

"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 planand the test procedures are observed, and
e) the acecptance criteria are met."

7.3.6.2 Design and Development Verification and Validation Documentation:

As was just stated above, this section now follows "*Testing*." There were no other changes to this section.

"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."

7.3.7 Control of Design and Development Changes:

In this section it is stated that the *Design and Development* changes must be in accordance with section (7.1.3) which is the *Configuration Management Process (ISO 10007)*. Additionally, the regulatory reference now implied in 4.1 is taken out from this section. Note the changed Standard below:

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 controlled in accordance with the configuration management process (see 7.1.3).
Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4)."

7.4 Purchasing

7.4.1 Purchasing Process:

There were some minor amplifications to this section to provide additional clarity with the insertion of "*conformity*" and "*product*" sources that have been designated by the customer.

"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 be responsible for the conformity of all products purchased from suppliers, including product from sources defined by the customer.

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)."

An additional note is placed at the end of this section. This pertains to organizations deciding to outsource certain aspects of the product realization process. They must assure the quality of the outsourced part of the process conforms to customer requirements at the time of finish. The outside or sub-source must therefore be evaluated. The standard then provides detailed advisement for utilizing third party qualifying organizations for the outside source. Data from the assessment can provide the determinants for whether or not to continue utilizing a particular outside or sub-source. See below:

> *"NOTE: One factor that can be used during supplier selection and evaluation is supplier quality data from objective and reliable external sources, as evaluated by the organization (e.g., information from accredited quality management system or process certification bodies, organization approvals from government authorities). Use of such data would be only one component of an organization's supplier control process and the organization remains responsible for verifying that purchased product meets specified purchase requirements."*

In the last part of this section, *I.A.Q.G.* made several changes from *AS9100:2004 Revision B.*

First is the requirement that the supplier register must indicate supplier approval status. This is a categorization by which the organization organizes its supplier base with the designations of "*Approved, Conditional, and Disapproved*." Many companies utilize slightly different terminologies such as "*Favorable, Conditional, Unfavorable*" status. The standard uses the former as an example. However, the latter is still valid.

Secondly, there are changes from *AS9100:2004 Revision B* where in this section the word "*results*" is inserted and the word "*records*" is removed. This implies that the suppliers are being judged on their supply "*results."* For example, is the supplier manufacturing with poor quality? Are their deliveries late? etc.

Thirdly, the procedures for defining the status of a supplier must be properly defined followed by those responsible and with the authority to change the status of the given supplier.

> "*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)."*

7.4.2 Purchasing Information:

This section is of particular importance. There were several changes that the *I.A.Q.G.* instituted to make the Purchasing Process more accountable and precise in conforming with the standards.

First is the "*revision status*" of any *customer specifications* and requirements for purchasers as to the inspection, verification process, etc., of any source that will be applied to the manufacturing of the final product.

Secondly, the supplier must notify the purchasing organization of any and all non-conforming product that is scheduled to arrive and any other additional changes that are or have occurred at the supplier location that could affect the quality of the processing of the product.

"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.

7.4.3 Verification of the Purchased Product:

"The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements."

This section of the standard and the note that follows the above passage discuss the fact that inspection activities of or at a supplier source are still not in and of themselves a guarantee of quality. The responsibility is clearly on the supplier to comply completely with all requirements so that proper evidence of quality is both documented and recorded.

Additionally, this section also notes that when a purchased product is utilized in the production process, that the purchased part that is part of that process is identified and recorded.

"NOTE 1: Customer verification activities performed at any level of the supply chain should not be used by the organization or the supplier as evidence of effective control of quality and does not absolve the organization of its responsibility to provide acceptable product and comply with all requirements.

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,

- inspection of products upon receipt, and

- delegation of verification to the supplier or supplier certification.

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."

"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 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."

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision:

This section has some minor wording changes but provides additional notes with examples of *Product Information*, *Work Instructions* and certain *Suitable Equipment*. See below:

"The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable:

-the availability of information that describes the characteristics of the product,

NOTE: This information can include drawings, parts lists, materials and process specifications.

-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.

-the use of suitable equipment,

NOTE: Suitable equipment can include product specific tools (e.g., jigs, fixtures, molds) and software programs.

-the availability and use of monitoring and measuring equipment,

-the implementation of monitoring and measurement,

-the implementation of product release, delivery and post-delivery activities,

-accountability for all product during production (e.g., parts quantities, split orders, nonconforming product),

-evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized,

-provision for the prevention, detection and removal of foreign objects,

-monitoring and control of utilities and supplies (e.g., water, compressed air, electricity, chemical products) to the extent they affect conformity to product requirements, and

-criteria for workmanship, specified in the clearest practical way (e.g., written standards, representative samples, illustrations).

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)."

7.5.1.1 Production Process Verification:

This section mainly discusses the fact that a sample of the production run should be extricated and inspected in order to verify that the production is occurring accurately and according to customer requirements and specifications. If there is any change in the engineering of the part which transforms it in any way, then another sample must be taken from that production run as well.

> *"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).*
>
> *NOTE: This activity is often referred to as first article inspection."*

7.5.1.2 Control of Production Process Changes:

There were three areas of changes in this section from *AS9100:2004 Revision B*. First, the word "*persons*" is replaced by "*personnel*" for those who are identified to make any authorized changes to a process. Secondly, the standard makes it more imperative that processes should not only be documented but controlled. Thirdly, in the discussion of changes to the processing of the product that without "adverse effect to quality" was changed to without "*adverse effect to conformity*." See below:

> *"Personnel authorized to approve changes to production processes shall be identified.*
>
> *The organization shall control and document changes affecting processes, production equipment, tools, or software programs.*
>
> *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. "*

7.5.1.3 Control of Production Equipment, Tools, and Software Programs:

There were minor changes in this section from *AS9100:2004 Revision B. I.A.Q.G*. removed specific requirements for the periodic inspection of various equipment, tooling, etc. See below:

> *"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.*
>
> *Storage requirements, including periodic preservation/condition checks, shall be defined for production equipment or tooling in storage."*

7.5.1.4 Post-Delivery Support:

The *I.A.Q.G*. emphasizes the message of this section by changing the title from "*Control of Service Operations*" to "*Post-delivery Support*." The differences in the meaning are subtle but specific. Service operations are implied to be effective after a problem has been identified. This again is more of a passive approach. The newer title in *AS9100:2009 Revision C* is more proactive. "*Post-delivery Support*" is indicative of support to the customer regardless of the positivity or negativity associated with the delivery. This approach helps organizations maintain positive relationships with their clients and promotes communication which helps to maintain quality.

> *"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."*

7.5.2 Validation of Processes for Production and Service Provision:

This section presents the requirement which may come across as ambiguous. Any unique process that cannot be generally monitored or a process that is also not necessarily repeated is described in this section note as a "*special process." Any special processes*" that are or will become part of the production process must be validated prior to its implementation. See below:

"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.

NOTE: These processes are often referred to as special processes."

Ambiguity can result from the reference to the standard as "*special processes."* However, the word "special" as it would apply in a manufacturing processing situation shall be defined here. According to *Webster's New World College Dictionary 4th Edition © 2000*, "special" is defined as:

"special (adj.). [Old Fr. Especial < Lat. Specialis < species, kind, sort] *1. of a kind different from others; distinctive, peculiar, or unique; 2. exceptional, extraordinary; 3. highly regarded or valued; 4. of or for a particular person, occasion, purpose, etc.; 5. not general nor regular; specific or limited* [special legislation]*."*

Therefore, for the purposes of the standard, definition number "5" is understandable and applicable. The "special process" is a process that is not general nor regular. Any part of the process that is not regular must therefore be validated as a failure in that part of the process can directly and negatively affect quality when used by the customer.

"Validation shall demonstrate the ability of these processes to achieve planned results .

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."

7.5.3 Identification and Traceability:

This section requires that the "*status*" of the product and the identification of the product itself must occur throughout the product realization process. Thus, the status of all phases of the *product realization process* must produce agreement that actual and final processed *configuration of the product* must agree and be consistent with final *customer specifications* of the product.

Other minor changes also occurred in this section from *AS9100:2004 Revision B* with the deletion of the requirement for documented controls of stamps, passwords, etc., and utilizes the terms "appropriate controls for media" with regard to the identification and control of the stamps, passwords, etc.

"Where appropriate, the organization shall identify the product by suitable means throughout product realization.

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 identify the product status with respect to monitoring and measurement requirements throughout product realization.

When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), the organization shall establish appropriate controls for the media."

"Where traceability is a requirement, the organization shall control the unique identification of the product and maintain records (see 4.2.4).

NOTE: Traceability requirements may include:

− identification to be maintained throughout the product life,

− the ability to trace all products manufactured from the same batch of raw material, or from the same manufacturing batch, to the destination (e.g., delivery, scrap),

− for an assembly, the ability to trace its components to the assembly and then to the next higher assembly, and

− for a product, a sequential record of its production (manufacture, assembly, inspection/verification) to be retrievable.

NOTE: In some industry sectors, configuration management is a means by which identification and traceability are maintained (see 7.1.3)."

This section also emphasizes one of the most important aspects of the *product realization process*. *Tracking and tracing* as the standard indicates must inculcate "*control*" of the unique identification of the product and that the records must be maintained. This is an area of extreme importance in that the Auditors will request to verify how well an organization tracks and traces its *product realization process*.

7.5.4 Customer Property:

The only change in this section is that it was rewritten as a active mandate rather than a passive mandate. See below:

"The organization shall exercise care with customer property while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records (see 4.2.4).

NOTE: Customer property can include intellectual property and personal data."

7.5.5 Preservation of Product:

There were minor amplifications to this section. It states that the organization must preserve the product during the *product realization process* and during the shipping to its destination. See below:

"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.

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."

7.6. Control of Monitoring and Measuring Equipment:

There were a number of changes in this section. First, the word "*devices*" was interchanged with "*equipment*" for the purposes of measurement. Secondly, the word "*verificati*on" is added into the context where the word "*equipment*" was added. This was done to align the text precisely with *ISO9001:2008*. Thirdly, the requirement was made to be more clear and authoritative with regard to recall of monitoring and measurement equipment that requires calibration and verification. Finally, the note toward the end of the section that referred the organization to *ISO10012 1 and ISO10012 2* for guidance in *AS9100:2004 Revision B* was deleted.

"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.

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.

NOTE: Monitoring and measuring equipment includes, but is not limited to: test hardware, test software, automated test equipment (ATE) and plotters used to produce inspection data. It also includes personally owned and customer supplied equipment used to provide evidence of product conformity.

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 ensure that environmental conditions are suitable for the calibration, inspection, measurement and testing being carried out.

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.

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).

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.

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."

8 Measurement, Analysis and Improvement

8.1 General:

Two changes occurred in this section of the standard from *AS9100:2004 Revision B*. First, the *I.A.Q.G.* changed the wording in the context of *Measurement, Analysis and Improvement* from "*conformity of the product*" to "*conformity to product requirements*." It is clearer and more precise now. Secondly, *Failure Mode Effect Analysis (FMEA)* was changed to *Failure Mode Effect and Criticality Analysis (FMECA).*

"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.

This shall include determination of applicable methods, including statistical techniques, and the extent of their use.

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"

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction:

This section was enhanced by the *I.A.Q.G.* Additional notes were added as to how customer satisfaction must be monitored. Auditors should expect to see a minimum of twelve to eighteen months of supporting data as to how customer satisfaction is measured. The organization with the utilization of specific measurement media must then glean from this data any information that obviates deficiencies. The organization must then show evidence of utilizing this data to correct these deficiencies. Failing to provide data of this may result in a major non-compliancy and thus delay certification. See below:

"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.

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.

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."

8.2.2 The Internal Audit:

This section has had some wording changes such as "*program*" to "*programme*" for consistency with the original ISO standard. Next, "*corrective actions*" is now utilized and the standard makes more precise the requirements of which the internal audit should consist. Moreover, the section for "*detailed tools* and "*techniques*" such as flow charts was deleted from *AS9100:2004 Revision B*.

> *"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.*
>
> *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.
>
> *NOTE: See ISO 19011 for guidance."*

8.2.3: Monitoring and Measurement of Processes:

This section has been enhanced with advisement that the monitoring and measurement system must be properly evaluated for its extent in each phase of the *product realization process*. Its overall effectiveness must be evaluated. And moreover, if non-conformities are determined in an area of the process, it must be determined if the non-conformity in one area of the process could affect other areas of the process as well.

> *"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.*
>
> *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.*
>
> *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 (see 8.3)."*

8.2.4 Monitoring and Measurement of Product:

There are numerous enhancements, amplifications and movements from *AS9100:2004 Revision B* that were done by the *I.A.Q.G.* in order to make this section more precise and provide the specific advisement that is appropriate for implementing this section in an organization's *Quality Management System*.

The first part of this section provides the requirements for the measurement and acceptance of a product during the product realization process. The term "*critical items*" is added. And, inspection is required by the utilization of statistical sampling system that is appropriate. At the end of the sampling, the organization must document, record, and be able to provide all evidence that the product meets the defined requirements of the customer.

"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.

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 records 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.

When critical items, including key characteristics, have been identified the organization shall ensure they are controlled and monitored in accordance with the established processes.

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)."

In the following part of this section, it is mandated that organizations record and identify all *measurement and monitoring activities* so if a recall of the product from the customer occurs, a proper record of that particular product can be produced and reviewed.

"Where product is released or 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.

Records shall indicate the person(s) authorizing release of product for delivery to the customer (see 4.2.4).

Where required to demonstrate product qualification, the organization shall ensure that records provide evidence that the product meets the defined requirements.

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 organization shall ensure that all documents required to accompany the product are present at delivery."

8.3 Control of Non-conforming Product:

The standard requires organizations to have in place a documented procedure to establish the methodology for controlling *non-conforming product*. This clarifies this section from *AS9100:2004 Revision B*.

The term "*where applicable*" is added in the next part where the organization must deal with *non-conforming product* and its subsequent procedures thereof.

Following that are other minor wording and text changes from *AS9100:2004 Revision B.*

"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.

NOTE: The term "nonconforming product" includes nonconforming product returned bya customer.

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.

"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."

In the next part, the disposition of a product "*use-as-is or repair*" must be decided by an *approved management representative* who has the authority to make design changes if and only if this has been approved by the customer.

"Dispositions of use-as-is or repair shall only be used after approval by an authorized representative of the organization responsible for design.

NOTE: Authorized representative includes personnel having delegated authority from the design organization.

The organization shall not use dispositions of use-as-is or repair, unless specifically authorized by the customer, if the nonconformity results in a departure from the contract requirements.

Product dispositioned for scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable.

When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4)."

8.4 Analysis of Data

The standard provides the requirements for analyzing data from the several areas such as *customer satisfaction*, *conformity to product requirements, characteristics and trends in the products and processes*. This is a very important part of the standard from which the Auditors will wish to review records going back twelve to eighteen months. Trending data includes data that occurs from any sub-sourced suppliers to the organization. Note the references to *8.2.3, 8.2.4, and 7.4* respectively.

"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 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)."

8.5 Improvement

8.5.1 Continual Improvement:

The *I.A.Q.G.* in *AS9100:2009 Revision C* adds changes from *AS9100:2004 Revision B*. In this section, the standard requires the monitoring of improvement activities. The results of these activities then must be evaluated. An additional note provides guidance for this.

> *"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 monitor the implementation of improvement activities and evaluate the effectiveness of the results.*
>
> *NOTE: Continual improvement opportunities can result from lessons learned, problem resolutions and the benchmarking of best practices."*

8.5.2 Corrective Action:

There are several enhancements for this section of the standard from *AS9100:2004 Revision B*. First, the word "*cause*" is changed to the plural "*causes*". *I.A.Q.G*. recognizes that the reasons of *nonconformities* may be several thus there can be more than one cause. Secondly, the standard requires that the effectiveness of the *corrective action or corrective actions* to any non-conformity must be evaluated for effectiveness. Thirdly, if the cause or causes of the *non-conformity* or *non-conformities* are emanating from one or more suppliers, then corrective action or actions must occur at the supplier level as well and evaluated as to their effectiveness. See below:

> *"The organization shall monitor the implementation of improvement activities and evaluate the effectiveness of the results.*
>
> *NOTE: Continual improvement opportunities can result from lessons learned, problem resolutions and the benchmarking of best practices.*
>
> *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."*

8.5.3 Preventive Action:

There are amplifications in this section of the standard. The *I.A.Q.G.* also states that not only should the organization develop appropriate *preventive action* for protection of the conformity of a product during the product realization process, but that the effectiveness of the *preventive action* must also be evaluated. The *I.A.Q.G*. includes a note as to examples of this for guidance.

"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.

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.

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."

Bibliography:

The *I.A.Q.G*. notes that the sources from which *AS9100:2009 Revision C* were created came from the following sources:

"AS/EN 9110 Quality Management Systems – Requirements for Aviation Maintenance Organizations

AS/EN 9120 Quality Management Systems – Requirements for Aviation, Space and Defense Distributors

ISO 9000 Quality management systems – Fundamentals and vocabulary

ISO 9001 Quality management systems – Requirements

ISO 9004 Managing for the sustained success of an organization – A quality management approach*

ISO 10007 Quality management systems – Guidelines for configuration management

ISO 19011 Guidelines for quality and/or environmental management systems auditing

** To be published. (Revision of ISO 9004:2000)"*

This overview with accompanying explanation and commentary was provided by Aerospace Consultants International LLC of Grosse Pointe, Michigan.

ACI and CAI of Canada provide our clients complete expertise in preparing them for the implementation and enforcement of the new *AS9100:2009 Revision C*.

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Over the course of the next year in 2012, revisions of the ISO/TS 16949:2009 and AS9100:2009 standards become “Live” on July 1, 2012 and shall be fully enforced. All Original Equipment Manufacturers alike shall require verifiable compliancy to these standards from their supply chain. Revising your current company Quality Management System is difficult enough without the added pressures of increased competition, demands to lower the prices of the products you provide your clients, and the high level of costs for receiving certification from your Registrar.

ACI has a better way. Our company can assist you as a team coach. We assess your needs exactly. We help your company to fully prepare for the new standards. ACI identifies your successes and non-conformities per the new standards before the Registrar comes. When they arrive, your company will pass your final audits more easily. With ACI guiding your company through the process, you will be confident with the expertise you need with the benefit of substantial cost savings. In this way, ACI is of superior value to your company.

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