AS9100C Differences

The differences in AS9100C versus AS9100B are described in the sections below. Additions based on the changes from ISO 9001:2008 are underlined and highlighted in yellow. Additions in the unique AS9100C parts of the text are underlined and highlighted in green. All the unique AS9100C text is shown in **bold**.

The underlining of new text will allow readers to spot the additions, even if this paper is printed without color. AS9100C and ISO 9001:2008 texts are shown inside *boxes* and in Italics to help separate the text from the comments. Deleted text from ISO 9001:2000 and AS9100B is indicated by ~~strikethroughs~~.

Most of the text in AS9100B (and ISO 9001:2000) was not affected by AS9100C (and ISO 9001:2008). The unaffected parts of AS9100B, carried over unchanged into AS9100C, are not repeated in this paper.

Note: This paper on the changes in AS9100C (and ISO 9001:2008) has been reproduced by permission of the author, Larry Whittington. You can contact him at <Larry@WhittingtonAssociates.com>.

AS9100C - Introduction

0.1 General

In the Introduction, ISO 9001:2008 adds “organizational environment”, “change”, and “risk” to the list of factors that influence the design and implementation of a quality management system. The other changes to this text are minor revisions to the other factors, as well as, the use of a bulleted list.

The design and implementation of an organization's quality management system is influenced by

- its organizational environment, change in that environment, and the risks associated with that environment,
- its varying needs,
- its particular objectives,
- the products it provides ~~provided~~,
- the processes it employs ~~employed~~, ~~and~~
- its ~~the~~ size and organizational structure ~~of the organization~~.

Later in section 0.1, ISO 9001:2008 changes "regulatory" to "statutory and regulatory” and clarifies that the customer, statutory, and regulatory requirements are those applicable to the product.

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.

AS9100C Differences

AS9100C - Scope

1. Scope

1.1 General

AS9100C expanded the scope to include Defense, along with Aviation and Space. And, if in conflict, legal requirements take precedence over AS9100C requirements.

This standard includes ISO 9001:2008 quality management system requirements and specifies additional aviation, space and defense industry requirements, definitions and notes ~~for a quality management system for the aerospace industry. The additional aerospace requirements are~~ as shown in bold, italic text.

It is emphasized that the ~~quality management system~~ requirements specified in this standard are complementary (not alternative) to contractual and applicable ~~law~~ statutory and regulatory requirements. Should there be a conflict between the requirements of this standard and applicable statutory or regulatory requirements, the latter shall take precedence.

The ISO 9001:2008 part of AS9100C has expanded the uses of "regulatory" to "statutory and regulatory" to fully address legal requirements.

a) needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements, and

b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

The Note at this General section used to say the term "product" applied only to the product intended for, or required by, a customer. The ISO 9001:2008 part of AS9100C has expanded Product to include any intended output resulting from the product realization processes.

NOTE 1: In this International Standard, the term "product" only applies ~~only~~ to
- a ~~the~~ product intended for, or required by, a customer,
- any intended output resulting from the product realization processes.

A second Note has been added to explain that "statutory and regulatory" requirements can be expressed as "legal" requirements.

NOTE 2: Statutory and regulatory requirements can be expressed as legal requirements.

AS9100C Differences

1.2 Application

AS9100B stated that a requirement exclusion cannot affect the organization's ability, or responsibility, to provide product that meets customer and applicable regulatory requirements. The ISO 9001:2008 part of AS9100C replaces "regulatory" with "statutory and regulatory".

> *Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within Clause 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable statutory and regulatory requirements.*

AS9100C adds a description of the audience for the **AS9100** standard:

> ***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.***

AS9100C adds a description of the audience for the **AS9110** standard:

> ***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).***

AS9100C adds a description of the audience for the **AS9120** standard:

> ***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).***

AS9100C - Normative References

2. Normative Reference

Although the text at this section has been significantly reduced (the deleted text is not shown), the key change is to refer to ISO 9000:2005 instead of the old ISO 9000:2000.

> *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:~~2000~~2005, Quality management systems - Fundamentals and vocabulary*

AS9100C Differences

AS9100C - Terms and Definitions

3. Terms and Definitions

The ISO 9001:2008-based change at this section was to no longer explain the supply chain terms, including that "supplier" replaced "subcontractor" and "organization" replaced "supplier". The old explanation was needed for the transition from ISO 9001:1994 to ISO 9001:2000, but not now.

The remaining text from ISO 9001:2008 is shown below:

For the purposes of this document ~~International Standard~~, the terms and definitions given in ISO 9000 apply.

Throughout the text of this International Standard, wherever the term "product" occurs, it can also mean "service".

AS9100B defined Key Characteristics. AS9100C revised that definition and added three new terms .

The term, Risk, is used in the standard at clauses 7.1.1, 7.1.2, 7.2.2.e, 7.4.1.f, and 8.5.3 Note.

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

The term, Special Requirements, is used in the standard at clause 7.2.2.d.

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 use din 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.

The terms, Critical Items and Key Characteristic, are used at clauses, 7.3.3.e, 7.4.2.e, 7.5.1, and 8.2.4.

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 Characteristics
~~The~~ An attribute or features ~~of a material, process, or part~~ whose variation has a significant ~~influence~~ effect on product fit, form, function, performance, service life, or ~~manufacturability~~ producibility, that requires specific actions for the purpose of controlling variation.

AS9100C - Clause 4

4. Quality Management System

4.1 General Requirements

AS9100C inserts the following sentence to add customer and legal requirements to those of AS9100C. The rational for this addition is to indicate that these requirements apply at the quality management system level, not just at the previously stated documentation level.

The organization's quality management system shall also address customer and applicable statutory and regulatory quality management system requirements.

In 4.1, sub-clause (a), the word "Identify" has been replaced with "Determine".

a) ~~Identify~~ Determine the processes needed for the quality management system and their application throughout the organization (see 1.2),

Although similar, the words "Identify" and "Determine" have slightly different meanings. To identify is to recognize or establish something as being a particular thing. To determine is to apply reason and reach a decision. To determine the processes implies more analysis and judgment than merely identifying them.

e) monitor, measure where applicable, and analyze these processes, and ...

Processes are monitored, but may not need to be measured. Therefore, the requirement change above indicates processes are only measured where applicable.

Later in clause 4.1, regarding outsourcing:

Where an organization chooses to outsource any process that affects product conformity ~~with~~ to requirements, the organization shall ensure control over such processes. ~~Control of such~~ The type and extent of control to be applied to these outsourced processes shall be ~~identified~~ defined within the quality management system.

This addition clarifies that specific controls are to be defined and applied, not just identified. See the new Note 3 below for an explanation of the type and extent of controls for an outsourced process.

The current Note under clause 4.1 has been expanded and two new Notes have been added:

NOTE 1: Processes needed for the quality management system referred to above ~~should~~ include processes for management activities, provision of resources, product realization, ~~and~~ measurement, analysis, and improvement.

The text above expands from "measurement" to "measurement, analysis, and improvement" to match the title for clause 8. And, by deleting "should", it clearly states that these processes are included.

The new Note below provides an explanation of what is considered an outsourced process.

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.

The new Note below identifies the factors influencing the control of an outsourced process.

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 clause 7.4.

Outsourcing a process to another organization typically involves the purchase of those services. As a result, the requirements of clause 7.4, including the controls mentioned in 7.4.1, apply equally to the supplier selected to perform the outsourced process.

4.2 Documentation Requirements

4.2.1 General

The changes in this section are basically just a restructuring of the sub-clauses c), d), and e).

c) documented procedures and records required by this International Standard, and

d) documents, including records, ~~needed~~ determined by the organization to be necessary to ensure the effective planning, operation and control of its processes. ~~,and~~

~~*e) records required by this International Standard (see 4.2.4).*~~

You can see that adding "records" to sub-clause (c) allowed sub-clause (e) to be dropped. Sub-clause (d) has been expanded to include the necessary records.

AS9100C removed sub-clause (f) because its new general requirement in clause 4.1 more broadly states that the system must address the applicable statutory and regulatory quality management system requirements :

~~**f) quality system requirements imposed by the applicable regulatory authorities.**~~

AS9100C reworded the first sentence of this paragraph and deleted the second sentence. It makes sense that personnel have not just access, but be made aware of the documentation and changes.

The organization shall ensure that personnel have access to, and are aware of, relevant quality management system documentation and changes. ~~are aware of relevant procedures. Customer and/or regulatory authorities representatives shall have access to quality management system documentation.~~

The first Note for clause 4.2.1 has added two more sentences:

A single document may include the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.

An example for the first sentence would be satisfying the requirements for documented procedures in 8.5.2, Corrective Action, and 8.5.3, Preventive Action, through one combined Corrective and Preventive Action procedure. An example for the second sentence would be splitting the required procedure for the Control of Documents into two separate documented procedures.

4.2.2 Quality Manual

AS9100C deleted this entry under 4.2.2, sub-clause (b) regarding the relationship between requirements and documented procedures. It was too prescriptive and didn't really contribute to product quality.

~~when referencing the documented procedures, the relationship between the requirements of this International Standard and the documented procedures shall be clearly shown.~~

4.2.3 Control of Documents

The opening sentence of this clause in ISO 9001:2008 still states that documents required by the quality management system are to be controlled. The only revision to clause 4.2.3 is shown below:

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

The change in sub-clause (f) clarifies that not all external documents have to be identified and controlled; only those needed for the planning and operation of the quality management system.

AS9100C deleted this sentence because the 4.1 addition in General Requirements addresses customer and legal requirements for the entire system:

~~The organization shall coordinate document changes with customers and/or regulatory authorities in accordance with contract or regulatory requirements.~~

4.2.4 Control of Records

The opening sentence for clause 4.2.4 has expanded from records being "maintained" to having them "controlled". Maintaining records would simply keep them in good condition. Controlling the records means to regulate their use.

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

~~Records shall remain legible, readily identifiable and retrievable.~~

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

Records shall remain legible, readily identifiable, and retrievable.

The requirement for a documented Record Control procedure has been rewritten, but the content is basically the same. It is now a separate paragraph for emphasis and moved up in the section.

Note that "retention time" has been reduced to "retention". And, you can see that records must still remain legible, readily identifiable, and retrievable. This requirement is now a separate paragraph and moved to the end of clause 4.2.4.

AS9100C deleted the following sentence from clause 4.2.4 because the 4.1 addition in General Requirements addresses customer and legal requirements for the entire system:

~~Records shall be available for review by customers and regulatory authorities in accordance with contract or regulatory requirements.~~

The Configuration Management clause 4.3 in AS9100B has been moved to clause 7.1.3 in AS9100C.

~~4.3 Configuration Management~~

AS9100C - Clause 5

5. Management Responsibility

5.1 Management Commitment

No changes in AS9100C clause 5.1.

5.2 Customer Focus

AS9100C added this requirement to measure product conformity and on-time delivery performance. It establishes a clear link between the quality management system and organizational performance.

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
5.4 Planning
No changes in AS9100C clauses 5.3 or 5.4.

5.5 Responsibility, Authority, and Communication
5.5.1 Responsibility and Authority
No changes in AS9100C clause 5.5.1.

5.5.2 Management Representative
Most organizations already appoint a Management Representative that is a member of their own management team. The change below clarifies that requirement.

Top management shall appoint a member of the organization's management who, irrespective of other responsibilities, shall have responsibility and authority that includes:

Some companies in the past have outsourced the Management Representative role to someone in a different organization, or even to their consultant. This text change may be aimed at that practice.

AS9100C revised sub-clause (d) to ensure the appointed Management Representative has sufficient clout in the organization to be listened to by top management:

d) the organizational freedom and unrestricted access to top management to resolve ~~matters pertaining to~~ quality management issues.

5.5.3 Internal Communication
No changes in AS9100C clause 5.5.3.

5.6 Management Review
No changes in AS9100C clause 5.6.

AS9100C - Clause 6
6. Resource Management
6.1 Provision of Resources
No changes in AS9100C clause 6.1.

6.2 Human Resources
6.2.1 General
The revision below changes from work affecting "product quality" to work affecting "conformity to product requirements". Since quality is the degree to which a set of inherent characteristics fulfils requirements, then product quality would be the degree of conformity to product requirements.

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

The revision above should not be viewed as a new requirement. Anyone performing, verifying, or managing work within the scope of the quality management system, including supporting services, can affect conformity to product requirements. A new Note has been added to 6.2.1 to explain this point.

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~~, and Training~~

This clause title has been changed from "Competence, Awareness, and Training" to "Competence, Training, and Awareness". Awareness comes from some form of training and should be last in the title. And, that is also the sequence of the requirements as listed within clause 6.2.2.

The change in 6.2.1 from “product quality” to “product requirements” has been made to this sub-clause:

a) determine the necessary competence for personnel performing work affecting conformity to product ~~quality~~ requirements,

Use below of the phrase "where applicable" recognizes that training or other actions may not be necessary, since individuals may already have the necessary competence. And, since "these needs" could be taken out of context, the requirement has been revised to specifically mention competence.

b) where applicable, provide training or take other actions to ~~satisfy these needs~~ achieve the necessary competence,

6.3 Infrastructure

The only change in 6.3 was to add "information systems" as an example of a supporting service.

c) supporting services (such as transport, ~~or~~ communication, or information systems).

6.4 Work Environment

AS9100B included a Note that listed factors that may affect product conformity. When ISO 9001:2008 added this Note below (included in AS9100C), there was no longer a need for a separate AS9100 Note.

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).

~~NOTE: Factors that may affect the conformity of the product include temperature, humidity, lighting, cleanliness, protection from electrostatic discharge, etc.~~

AS9100C Differences

AS9100C - Clause 7

7. Product Realization

7.1 Planning of Product Realization

AS9100C added this Note under 7.1, sub-clause (a) on what to consider for product quality objectives:

In planning product realization, the organization shall determine the following, as appropriate:

a) quality objectives and planning 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.

The ISO 9001:2008 portion of AS9100C added "measurement" as one of the required activities to be determined during the planning of product realization.

In planning product realization, the organization shall determine the following, as appropriate:

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;

AS9100C added a new requirement at sub-clause (e) and moved the old (e) to become the basis for the new sub-clause (f). Remember, configuration management moved from clause 4.3 to clause 7.1.3.

In planning product realization, the organization shall determine the following, as appropriate:

(e) configuration management appropriate to the product;

(f) ~~the identification of~~ resources to support the use ~~operation~~ and maintenance of the product.

7.1.1 Project Management

AS9100C added this new clause on project management and acceptable risk (see new clause 7.1.3). Adds focus on upfront planning and the ongoing management of project plans.

As appropriate to the organization and the product, the organization shall plan and manage product realization in a structured and controlled manner to meet the requirements at acceptable risk, within resource and schedule constraints.

7.1.2 Risk Management

AS9100C added this new clause on risk management. In AS9100B, "risk" was only mentioned at clause 7.2.2 (d) on reviewing product requirements for risks such as new technology and short delivery times. Placement in this clause will cause more focus on product risk during product realization.

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

AS9100C moved this clause from 4.3 to 7.1.3 and expanded it to describe what might be included in a configuration management process. Placement at this clause is to focus configuration management on the product and to sustain that focus throughout product realization.

The organization shall establish, ~~document~~ 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: ~~Guidance on configuration management is given in~~ See ISO 10007 for guidance.

7.1.4 Control of Work Transfers

AS9100C moved this requirement for the control of work transfers from clause 7.5.1.4 to 7.1.4. The rewording clarifies the types of work transfers and points out it could be temporary or permanent.

~~Control of Work Transferred, on a Temporary Basis, Outside the Organization's Facilities:~~
~~When planning to temporarily transfer work to a location outside the Organization's facilities, the organization shall define the process to control and validate the quality of the work.~~

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

The change below from "related" to "applicable" shifts from determining legal requirements that are merely associated with the product to those that are relevant and can be applied to the product.

The organization shall determine:

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

Since the bulleted list for 7.2.1 begins with "The organization shall determine", the use of the word "determined" again in the entry below was not appropriate. The new text clarifies that the additional requirements "considered necessary" must be determined.

d) any additional requirements ~~determined~~ considered necessary by the organization.

AS9100C added this new Note. See clause 3.2 of AS9100C for the definition of "special requirements".

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

Organizations may not have considered the breadth of post-delivery activities as described by the new Note below.

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

AS9100C added a new requirement at sub-clause (d) on special requirements, and moved the old sub-clause (d) requirement on risks to a new sub-clause (e).

This review … and shall ensure that

d) special requirements of the product are determined, and

e) ~~d~~) risks (e.g., new technology, short delivery time ~~scale~~ frame) have been ~~evaluated~~ identified (see 7.1.2).

7.2.3 Customer Communication

No changes in AS9100C clause 7.2.3.

7.3 Design and Development
7.3.1 Design and Development Planning

AS9100C removed the entry under sub-clause (a) since the topics are addressed in other sections:

During the design and development planning, the organization shall determine
a) the design and development stages,

~~***- in respect of organization, task sequence, mandatory steps, significant stages and method of configuration control,***~~

AS9100C deleted text on design planning considerations and restated it in a new sentence:

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.

~~***Where appropriate, due to complexity, the organization shall give consideration to the following activities:***~~
~~***- structuring the design effort into significant elements;***~~
~~***- for each element, analyzing the tasks and the necessary resources for its design and development. This analysis shall consider an identified responsible person, design content, input data, planning constraints, and performance conditions. The input data specific to each element shall be reviewed to ensure consistency with requirements.***~~

AS9100C moved the following text from the end of clause 7.3.1 to the middle of clause 7.3.1.

The different design and development tasks to be carried out shall be ~~***defined according to specified***~~ ***based on the safety*** ~~***or***~~ ***and functional objectives of the product in accordance with customer, statutory and*** ~~***/or***~~ ***regulatory*** ~~***authority***~~ ***requirements.***

AS9100C added this requirement to have product designers consider more than just product function:

Design and development planning shall consider the ability to produce, inspect, test and maintain the product.

Clause 7.3.1.b continues to state that the organization must determine the review, verification, and validation appropriate for each design and development stage. The new Note below explains that although review, verification, and validation have distinct goals, they can be carried out separately or in any combination.

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

This clause continues to require the design and development inputs to be determined and records to be maintained. It lists several types of requirements to be included. The revision below simply changes from "These inputs" to "The inputs".

~~These~~ The inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.

7.3.3 Design and Development Outputs

The change below removes the unnecessary word, "provided". It also switches from "a form that enables verification" to "a form suitable for verification". To enable something is to make it possible. However, to be suitable means it is meant for use, or in this case, for verification.

The outputs of design and development shall be ~~provided~~ in a form ~~that enables~~ suitable for verification against the design and development input and shall be approved prior to release.

The change below was to simply remove the word “for”.

b) provide appropriate information for purchasing, production, and ~~for~~ service provision,

AS9100C expanded sub-clause (e) to include “critical items” (see definition in clause 3.3), not just “key characteristics” (see definition in clause 3.4):

e) ~~identify~~ specify, as applicable, any critical items, including any key characteristics, ~~when applicable, in accordance with design or contract requirement~~ and specific actions to be taken for these items.

AS9100C revised this text at the end of section 7.3.4:

The organization shall define the ~~All pertinent~~ data required to allow the product to be identified, manufactured, inspected, used and maintained ~~shall be defined by the organization~~; including for example:
~~- drawings, part lists, specifications;~~
- ~~a listing of those~~ the drawings, part lists, and specifications necessary to define the configuration and the design features of the product; and
- ~~information on~~ the material, processes~~, type of manufacturing~~ and assembly data needed ~~of the product necessary~~ to ensure ~~the~~ conformity of the product.

The new Note below reminds the reader that clause 7, Production and Service Provision, includes sub-clause 7.5.5, Preservation of Product. Why do that? To indicate that the design output should consider product preservation, e.g., product packaging.

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

7.3.4 Design and Development Review

No changes in AS9100C clause 7.3.4.

7.3.5 Design and Development verification

AS9100C deleted the Note from this section. Since Notes are added for clarification, they can be deleted when they are no longer necessary.

~~***NOTE: Design and/or development verification may include activities such as:***~~
~~***- performing alternative calculations,***~~
~~***- comparing the new design with a similar proven design, if available,***~~
~~***- undertaking tests and demonstrations, and***~~
~~***- reviewing the design stage documents before release.***~~

7.3.6 Design and Development Validation

AS9100C deleted the Notes from this section. Since Notes are added for clarification, they can be deleted when they are no longer necessary.

~~***NOTES:***~~
~~***- Design and/or development validation follows successful design and/or development verification.***~~
~~***- Validation is normally performed under defined operating conditions.***~~
~~***- Validation is normally performed on the final product, but may be necessary in earlier stages prior to product completion.***~~
~~***- Multiple validations may be performed if there are different intended uses.***~~

7.3.6.1 Design and Development Verification and Validation Testing

AS9100C did not change the content moved to this section from the old clause 7.3.6.2.

7.3.6.2 Design and Development Verification and Validation Documentation

AS9100C did not change the content moved to this section from the old clause 7.3.6.1.

7.3.7 Control of Design and Development Changes

ISO 9001:2008 merged the first and last paragraph of this section into one paragraph with no text changes. AS9100C added the sentence below:

Design and development changes shall be controlled in accordance with the configuration management process (see 7.1.3).

AS9100C deleted the following text since the new requirement in clause 4.1 requires that applicable statutory and regulatory requirements be addressed throughout the quality management system.

~~***The organization's change control process shall provide for customer and/or regulatory authority approval of changes, when required by contract or regulatory requirement.***~~

7.4 Purchasing
7.4.1 Purchasing Process

AS9100C modified the second paragraph in this section for clarity reasons:

The organization shall be responsible for the ~~quality~~ conformity of all products purchased from suppliers, including ~~customer-designated~~ product from sources defined by the customer.

AS9100C revised the section below to give examples of approval status and approval scope:

a) maintain a register of ~~approved~~ its suppliers that includes approval status (e.g., approved, conditional, disapproved) and the scope of the approval (e.g., product type, process family);

AS9100C revised the section below to replace the use of "records" with "results":

b) periodically review supplier performance; ~~records~~ the results of these reviews shall be used as a basis for establishing the level of controls to be implemented;

AS9100C rewrote and expanded the requirement in sub-clause (e), and added a requirement in (f) in keeping with the new focus on risk management.

~~e) ensure that the function having responsibility for approving supplier quality systems has the authority to disapprove the use of sources.~~

e) define the process, responsibilities and authority for the approval status decision, changes of the approval status and conditions for a controlled use of suppliers depending on the supplier's approval status, and

f) determine and manage the risk when selecting and using suppliers (see 7.1.2)

7.4.2 Purchasing Information

AS9100C revised 7.4.2 sub-clauses (d) and (e). There were no changes to sub-clauses (a), (b), (c), or (f).

Purchasing information shall describe the product to be purchased, including where appropriate

d) the ~~name or other positive~~ identification and revision status~~, and applicable issues~~ of specifications, drawings, process requirements, inspection/verification instructions and other relevant technical data,

e) requirements for design, test, ~~examination,~~ 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,

AS9100C moved the old AS9100B entries (h) and (j) to be the 3rd and 4th entries under sub-clause (g):

g) requirements ~~relative~~ regarding the need for the supplier to

- ~~supplier notification to~~ notify the organization of nonconforming product ~~and~~

- ~~arrangements for~~ obtain organization approval ~~of supplier~~ for nonconforming ~~material,~~ product disposition,

- ~~requirements for the supplier to~~ notify the organization of changes in product and/or process ~~definition~~ , changes of suppliers, changes of manufacturing facility location and, where required, obtain organization approval, and

- ~~requirements for the supplier to~~ flow down to ~~sub-tier suppliers~~ the supply chain the applicable requirements ~~in the purchasing documents,~~ including ~~key characteristics where required~~ customer requirements.

AS9100C replaced the old sub-clause (h) with a new entry regarding record retention, and revised the existing sub-clause (i):

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~~, and~~.

7.4.3 Verification of Purchased Product

AS9100C used the last paragraph of clause 7.4.3 to create a new Note:

NOTE 1: ~~Verification by the~~ 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 ~~by the supplier~~ and ~~shall~~ does not absolve the organization of ~~the~~ its responsibility to provide acceptable product~~, nor shall it preclude subsequent rejection by the customer~~ and comply with all requirements .

AS9100C moved requirements (a) through (e) to a second new Note. The only revised text appears in the first entry [old sub-clause (a)] under the note:

NOTE 2: Verification activities ~~may~~ can include

~~a)~~ - obtaining objective evidence of the ~~quality~~ conformity of the product from the suppliers~~ (e.g., accompanying documentation, certificate of conformity, test reports, statistical records, process control records),

AS9100C rewrote the requirement in clause 7.4.3 for a positive recall procedure as shown below:

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.

~~***Purchased product shall not be used or processed until it has been verified as conforming to specified requirements unless it is released under positive recall procedure.***~~

AS9100C deleted the following requirement from the standard because it was viewed as too prescriptive and not applicable to all organization sizes and product types.

~~***Where the organization utilizes test reports to verify purchased product, the data in those reports shall be acceptable per applicable specifications. The organization shall periodically validate test reports for raw material.***~~

AS9100C also deleted:

~~***Where specified in the contract, the customer or the customer's representative shall be afforded the right to verify at the supplier's premises and the organization's premises that subcontracted product conforms to specified requirements.***~~

7.5 Production and Service Provision
7.5.1 Control of Production and Service Provision

AS9100C moved the opening text about planning, along with its four entries, to the end of clause 7.5.1. New Notes have been added under sub-clauses (a), (b), and (c):

a) the availability of information that describes the characteristics of the product,

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

b) the availability of work instructions, as necessary,

NOTE: Work instructions can include process flow charts, production documents, (e.g., manufacturing plans, travelers, routers, work orders, process cards) and inspection documents.

c) the use of suitable equipment,

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

AS9100C Differences

Clause 7.5.1, sub-clauses (d) and (f) were modified by ISO 9001:2008. The title of clause 7.6 was changed to refer to the control of monitoring and measuring "equipment" instead of "devices", therefore, the terminology has been changed below:

d) the availability and use of monitoring and measuring ~~devices~~ equipment,

The change below simply clarifies that implementation activities are those related to the "product".

f) the implementation of product release, delivery, and post-delivery activities.

AS9100C revised sub-clauses (g), (h), (j), and (k):

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

h) evidence that all ~~manufacturing~~ production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized,

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

k) criteria for workmanship, ~~which shall be stipulated~~ specified in the clearest practical manner (e.g., written standards, representative samples, ~~or~~ illustrations).

AS9100C revised and moved this planning text from the top of the section to the end of the section:

Planning shall consider, as ~~applicable~~ appropriate

- the establishment of process controls and development of control plans where key characteristics have been identified,

- ~~the~~ designing, manufacturing, and using ~~of~~ tooling to measure variable data, ~~so that variable measurements can be taken, particularly for key characteristics, and~~

- ~~the identification of~~ identifying in-process inspection/verification points when adequate verification of conformance cannot be performed at ~~a~~ later stages of realization,

- special processes (see 7.5.2).

AS9100C Differences

AS9100C dropped the old section 7.5.1.1 on Production Documentation. A revised version of that old text, 7.5.1.1 (a), was moved under 7.5.1 (a) as a new Note. Likewise, a revised version of old clause 7.5.1.1 (b) was moved under 7.5.1 (b) as a new Note.

The new 7.5.1.1 is titled, Production Process Verification, and includes revised text from clause 8.2.4.2 regarding first article inspection (FAI). Placing the text in clause 7 acknowledges that FAI is not primarily a monitoring and measuring process, but one that is used to assure product realization under controlled conditions. And, being in clause 7, it can now be excluded for unique and individual products.

7.5.1.1 Production Process Verification

The organization~~'s system~~ shall ~~provide~~ use ~~a process for the inspection, verification, and documentation of~~ 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 ~~or following~~ when ~~any subsequent~~ changes occur that invalidates ~~the previous~~ original ~~first article inspection~~ results (e.g., engineering changes, manufacturing process changes, tooling changes).

NOTE: This activity is often referred to as first article inspection. ~~See (AS) (EN) (SJAC) 9102 for guidance.~~

AS9100C retained the placement and title for clause 7.5.1.2. It has been revised to clarify that the referenced programs to be controlled and documented are "software" programs. Also, the changes made by ISO 9001:2008 elsewhere to refer to product "conformity" instead of product "quality" are likewise made in this section for consistency.

7.5.1.2 Control of Production Process Changes:

Personnel ~~Persons~~ authorized to approve changes to production processes shall be identified.

The organization shall identify and obtain acceptance of changes that require customer and/or regulatory authority approval in accordance with contract or regulatory requirements.

The organization shall control and document changes affecting processes, production equipment, tools ~~and~~ or software programs ~~shall be documented~~. ~~Procedures shall be available to control their implementation.~~

The results of changes to production processes shall be assessed to confirm that the desired effect has been achieved without adverse effects to product ~~quality~~ conformity.

AS9100C changed the title for this clause to refer to the broader term, “software” programs, instead of using the more limited term, “numerical control” programs.

7.5.1.3 Control of Production Equipment, Tools and ~~Numerical Control (NC) Machine~~ Software Programs:

Production equipment, tools and software programs used to automate and control/monitor product realization processes, shall be validated prior to ~~use~~ release for production and shall be maintained ~~and inspected periodically according to documented procedures. Validation prior to production use shall include verification of the first article produced to the design data/specification.~~

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

AS9100C revised and moved clause 7.5.1.4 to clause 7.1.4, with a new title, “Control of Work Transfers”.

~~7.5.1.4 Control of Work Transferred, on a Temporary Basis, Outside the Organization’s Facilities:~~

~~When planning to temporarily transfer work to a location outside the Organization’s facilities, the organization shall define the process to control and validate the quality of the work.~~

AS9100C changed the title of this clause to Post Delivery Support.

7.5.1.5 ~~Control of Service Operations~~ Post Delivery Support:

~~Where servicing is a specified requirement, service operation processes shall provide for~~

Post-delivery support shall provide as applicable the

a~~) a method of collecting~~ collection and ~~analyzing~~ analysis of in-service data,
b) actions to be taken, including investigation and reporting, ~~where~~ when problems are ~~identified~~ detected after delivery, ~~including investigation, reporting activities, and actions on service information consistent with contractual and/or regulatory requirements,~~
c) ~~the~~ control and updating of technical documentation,
d) ~~the~~ approval, control, and use of repair schemes, and
e) ~~the~~ controls required for off-site work (e.g., organization’s work undertaken at the customer’s facilities).

7.5.2 Validation of Processes for Production and Service Provision

The revised text in this clause makes clear that any process output that can't be verified may result in deficiencies becoming known only after the product is in use or the service has been delivered.

The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement~~. This includes any processes where~~ and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.

AS9100C slightly changed the note below:

NOTE: These processes are ~~frequently~~ often referred to as special processes.

AS9100C dropped the AS additions under 7.5.2 (a) and (c):

The organization shall establish arrangements for these processes including, as applicable

a) defined criteria for review and approval of the processes,
~~- qualification and approval of special processes prior to use,~~

c) use of specific methods and procedures,
~~- control of the significant operations and parameters of special processes in accordance with documented process specifications and changes thereto,~~

7.5.3 Identification and Traceability

This clause continues to state that, where appropriate, the organization must identify the product by suitable means "throughout product realization". The text below refers to inspection and test status of the product, and some organizations may have thought it only applied to the final product. The revision below clarifies that identifying the product monitoring and measurement status applies throughout product realization, from received product to final product, including in-process product.

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

By moving the "records" reference to the end of the sentence below, the meaning has expanded from recording the product identification, to keeping any type of record associated with product traceability.

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

AS9100C moved the section on traceability from a requirement to this new Note:

Note: Traceability requirements can include ~~According to the level of traceability required by contract, regulatory, or other established requirement, the organization's system shall provide for:~~

a) identification to be maintained throughout the product life;
b) the ability to trace all ~~the~~ products manufactured from the same batch of raw material, or from the same manufacturing batch, ~~to be traced, as well as~~ to the destination (e.g., delivery, scrap) ~~of all products of the same batch~~;
c) for an assembly, the ability to ~~identity~~ trace ~~of~~ its components to the assembly and then to ~~those of~~ the next higher assembly ~~to be traced~~;
d) for a ~~given~~ product, a sequential record of its production (manufacture, assembly, inspection/verification) to be ~~retrieved~~ retrievable.

AS9100B included a reference to clause 4.3, Configuration Management, in the ISO 9001:2008 Note below. Since AS9100C moved Configuration Management to clause 7.1.3, the reference was modified.

NOTE: In some industry sectors, configuration management is a means by which identification and traceability are maintained ***(see ~~4.3~~ 7.1.3)***.

7.5.4 Customer Property

The change below reads better, but hasn't changed the requirement to report customer property issues to the customer and keep records.

If any customer property is lost, damaged, or otherwise found to be unsuitable for use, ~~this shall be reported~~ the organization shall report this to the customer and ~~records maintained~~ maintain records (see 4.2.4).

The existing Note in 7.5.4 has been revised to include "personal data" as an example of customer property, broadening its applicability to more organizations, especially service organizations.

The AS9100B addition to this ISO 9001:2000-based Note was removed by AS9100C after ISO 9001:2008 made the highlighted change.

*NOTE: Customer property can include intellectual property and personal data. **~~including customer furnished data used for design, production and/or inspection.~~***

7.5.5 Preservation of product

If anyone was confused over the meaning of "conformity of product" in the old text, using "conformity to requirements" should be easier to understand in the new text.

The organization shall preserve the ~~conformity of~~ product during internal processing and delivery to the intended destination in order to maintain conformity to requirements.

The current requirement that begins with, "This preservation shall include", doesn't give the flexibility to include, or not include, the identification, handling, packaging, storage, and protection of the product. The change below allows product preservation to be applied as applicable.

~~This~~ As applicable, preservation shall include identification, handling, packaging, storage, and protection. Preservation shall also apply to the constituent parts of a product.

AS9100C revised the text below to add “statutory” to “regulatory” requirements for consistency with ISO 9001:2008 and its combined use of statutory and regulatory to address “legal” requirements. The requirement on accompanying documentation was deleted.

Preservation of product shall also include, where applicable in accordance with product specifications and~~/or~~ applicable statutory and regulations, provisions for:

a) cleaning;
b) prevention, detection and removal of foreign objects;
c) special handling for sensitive products;
d) marking and labeling including safety warnings;
e) shelf life control and stock rotation;
f) special handling for hazardous materials.

AS9100C moved the requirement below from clause 7.5.5 to clause 8.2.4 since its focus is to monitor the product to ensure all the documents required to accompany the product are present at delivery.

~~***The organization shall ensure that documents required by the contract/order to accompany the product are present at delivery and are protected against loss and deterioration.***~~

7.6 Control of Monitoring and Measuring ~~Devices~~ Equipment

The second clause title to change in ISO 9001:2008 is clause 7.6, where "devices" has been changed to "equipment". The term equipment was already used in several places in clause 7.6. The term “devices” has a broader scope and could include non-equipment types of tools. Equipment is the better choice for this calibration clause.

The changes to the clause below are to replace "devices" with "equipment" and to remove the reference to clause 7.2.1, Determination of Requirements Related to the Product.

The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring ~~devices~~ equipment needed to provide evidence of conformity of product to determined requirements ~~(see 7.2.1)~~.

AS9100C revised this text to refer to equipment instead of devices, and to include verification.

The organization shall maintain a register of these monitoring and measuring ~~devices~~ 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.

AS9100C revised this Note to refer to equipment instead of devices.

NOTE: Monitoring and measuring ~~devices~~ equipment includes, but ~~are~~ 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.

AS9100C Differences

AS9100C slightly revised the text below, but did not change the requirement:

The organization shall ensure that environmental conditions are suitable for the calibrations~~,~~ inspections~~, measurements~~ and ~~tests~~ testing being carried out.

A minor change to 7.6 (a) is shown below. This requirement went from "calibrated or verified" to "calibrated or verified, or both", meaning a type of equipment might be calibrated and/or verified.

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);

AS9100C moved the recall requirement from sub-clause (f) to be a standalone sentence below the list.

~~***f) be recalled to a defined method when requiring calibration.***~~

The organization shall establish, implement and maintain a process for the recall of monitoring and measuring equipment requiring calibration or verification.

The statement below, that measuring equipment must "be identified" sounded like the organization was to add identification. However, measuring equipment may come with the identification already in place.

c) ~~be identified~~ have identification ~~to enable~~ in order to determine ~~the~~ its calibration status ~~to be determined~~;

The text below was split from its old paragraph and made a standalone sentence for emphasis.

Records of the results of calibration and verification shall be maintained (see 4.2.4).

Software development organizations may have been unsure how to “confirm”, per clause 7.6, that software used for monitoring and measurement has the ability to satisfy the intended application.

A new Note was added to explain that confirmation of software would typically include verification and configuration management.

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.

This old Note for clause 7.6 was dropped. It referred the reader to the ISO 10012-1 and ISO 10012-2 standards for guidance. Although these standards have been replaced with ISO 10012:2003, the reference was not retained.

~~*NOTE: See ISO 10012-1 and ISO 10012-2 for guidance.*~~

AS9100C - Clause 8

8. Measurement, Analysis, and Improvement

8.1 General

The prior use of "conformity of the product" has been revised to "conformity to product requirements".

The organization shall plan and implement the monitoring, measurement, analysis, and improvement processes needed *a) to demonstrate conformity ~~of the~~ to product requirements,*

AS9100C modified the Note below to switch from “may” to “can”, indented four of the entries under “process control”, and added “criticality” to the last entry regarding analysis.

NOTE: According to the nature of the product and depending on the specified requirements, statistical techniques ~~may~~ 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 - ~~matching sampling rate to the criticality of the product and to the process capability~~;*** ***- failure mode, ~~and~~ effect and criticality analysis.***

8.2 Monitoring

8.2.1 Customer Satisfaction

AS9100C expanded on the customer satisfaction requirement to include specific types of measurements and to require plans be implemented to improve the customer’s satisfaction. This change establishes a clear link between the quality management system and organizational performance.

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.

A new Note has been added to clause 8.2.1 to provide examples of monitoring customer perceptions.

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, dealer reports.

8.2.2 Internal Audit

AS9100C added a Note under clause 8.2.2 (a) to clarify that "planned arrangements" includes customer contractual requirements:

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.

The change below was to simply add the word "The" at the beginning of the sentence.

The ~~S~~selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process.

The requirement below was edited to emphasize the need for a documented procedure (by placing it first in the sentence). Also, "establishing records" has been moved ahead of "reporting results" in the list of topics to be defined in the procedure. Records are being captured throughout the audit and should be listed before the reporting of results.

A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.

~~The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure.~~

The new sentence below highlights the need to maintain records of the audit and its results. The reference in the old text to 4.2.4 for record control was moved to this new sentence.

Records of the audits and their results shall be maintained (see 4.2.4).

Expanding from "actions" to "any necessary corrections and corrective actions" reminds us that an immediate correction might be needed before determining the cause of the nonconformity and taking corrective action to prevent its recurrence. Clause 8.2.3 also refers to corrections and corrective actions.

The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes.

The reference in the Note below to the withdrawn ISO 10011 standard has been replaced with a reference to ISO 19011, Guidelines for Quality and/or Environmental Management Systems Auditing.

NOTE: See ~~ISO 10011-1, ISO 10011-2 and ISO 10011-3~~ ISO 19011 for guidance.

AS9100C deleted the following text from clause 8.2.2, because it was viewed as too prescriptive:

~~Detailed tools and techniques shall be developed such as checksheets, process flowcharts, or any similar method to support audit of the quality management system requirements. The acceptability of the selected tools will be measured against the effectiveness of the internal audit process and overall organization performance.~~

AS9100C could delete this text because a general statement to this effect was added to clause 4.1 for application across the entire quality management system. Plus, a new Note was added earlier in the section about internal audit planned arrangements including customer contractual requirements.

~~Internal audits shall also meet contract and/or regulatory requirements.~~

8.2.3 Monitoring and Measurement of Processes

This clause requires applying suitable methods for monitoring and measuring processes to demonstrate their ability to achieve planned results. For some supporting processes, these results are only indirectly related to product conformity. Therefore, the reference to product conformity was moved from this paragraph to the new Note below.

When planned results are not achieved, correction and corrective action shall be taken, as appropriate~~, to ensure conformity of the product~~.

What is a "suitable" method for monitoring and measuring processes? The Note below says to consider the type and extent of monitoring or measurement based on the impact of the process on conformity to product requirements and system effectiveness.

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.

AS9100C added a new sub-clause to the activities performed in the event of a process nonconformity:

In the event of process nonconformity, the organization shall

a) take appropriate action to correct the nonconforming process,
b) evaluate whether the process nonconformity has resulted in product nonconformity, ~~and~~
c) 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 the nonconforming product ~~in accordance with clause~~ (see 8.3).

8.2.4 Monitoring and Measurement of Product

The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained.

The requirement to maintain evidence of conformity with acceptance criteria has been moved from the paragraph below to the first paragraph above. And, the release of product is not to the next in-process stage, but for delivery to the customer.

~~Evidence of conformity with the acceptance criteria shall be maintained~~. Records shall indicate the person(s) authorizing release of product for delivery to the customer (see 4.2.4).

AS9100C removed clause 8.2.4.1 and left most of that section as an embedded part of clause 8.2.4:

~~8.2.4.1 Inspection Documentation:~~

Measurement requirements for product ~~or service~~ acceptance shall be documented~~. This documentation may be part of the production documentation, but~~ and shall include

a) criteria for acceptance and/or rejection,
b) where in the sequence measurement and testing operations are performed,
c) ~~a~~ required record~~s~~ of the measurement results (at a minimum, indication of acceptance or rejection), and
d) ~~type of~~ any specific measurement instruments required and any specific instructions associated with their use.

~~Test records shall show actual test results data when required by specification or acceptance test plan.~~

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

AS9100C expanded this section to apply to critical items, not just key characteristics:

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

AS9100C clarified this section on sampling inspection and the appropriateness of the sampling plan:

When the organization uses sampling inspection as a means of product acceptance, the plan shall be ~~statistically valid~~ 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)~~. The plan shall preclude the acceptance of lots whose samples have known nonconformities. When required, the plan shall be submitted for customer approval.~~

AS9100C revised this section on the positive recall process:

~~Product shall not be used until it has been inspected or otherwise verified as conforming to specified requirements, except when product is released under positive recall procedures~~ Where product is released for production use pending completion of all required measurement and monitoring activities, it shall be identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.

This requirement was edited to clarify the release of product and delivery of service is to the customer.

The release of product ~~release~~ and delivery of service ~~delivery~~ 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.

AS9100C moved this requirement from clause 7.5.5 to clause 8.2.4 since it is more a product monitoring issue that one of product preservation.

The organization shall ensure that all documents required ~~by the contract/order~~ to accompany the product are present at delivery ~~and are protected against loss and deterioration~~.

8.3 Control of Nonconforming Product

The sentence below has been edited to begin with (instead of end with) the requirement for a documented procedure.

A documented procedure shall be established to define ~~T~~the controls and related responsibilities and authorities for dealing with nonconforming product. ~~shall be defined in a documented procedure.~~

AS9100C made a slight change to this existing Note:

NOTE: The term "nonconforming product" includes nonconforming product returned ~~from~~ by a customer.

AS9100C changed this text to define both responsibility and authority, for both review and disposition.

The organization's documented procedure shall define the responsibility ~~for review~~ and authority for the review and disposition of nonconforming product and the process for approving personnel making these decisions.

The requirement below adds "where applicable", meaning where relevant and suitable, to deal with nonconforming product in one or more of the ways listed.

Where applicable, ~~T~~the organization shall deal with nonconforming product by one or more of the following ways:

AS9100C Differences

The new entry below is edited text from the last sentence in clause 8.3 that has been moved to become part of the list of ways to deal with nonconforming product.

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.

AS9100C moved this requirement, and Note, forward in the section and placed them under 8.3 (d):

~~In addition to any contract or regulatory authority reporting requirements, t~~The organization's ~~system~~ product control process shall provide for timely reporting of delivered nonconforming product ~~that may affect reliability or safety~~.

NOTE: Parties requiring notification of nonconforming product ~~may~~ can include suppliers, internal organizations, customers, distributors, and regulatory authorities.

AS9100C added a new sub-clause entry (e) to the list of ways to deal with a nonconforming product:

e) by taking actions necessary to contain the effect of the nonconformity on other processes or products.

AS9100C clarified the dispositions of "use-as-is" and "repair", and added a new Note to describe the authorized representative:

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

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

~~Unless otherwise restricted in the contract, organization-designed product which is controlled via a customer specification may be dispositioned by the organization as use-as-is or repair, provided the nonconformity does not result in a departure from customer-specified requirements.~~

AS9100C modified one requirement and deleted another one:

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

~~Notification shall include a clear description of the nonconformity, which includes as necessary parts affected, customer and/or organization part numbers, quantity, and date(s) delivered.~~

The requirement below is from an earlier paragraph. No changes were made. Since it includes "subsequent actions", e.g., re-verification, it is appropriate for recordkeeping to be last in the section.

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

The deleted text below was moved to entry (d) in the list of ways to deal with nonconforming product.

~~*When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.*~~

8.4 Analysis of Data

The analysis of data provides information on customer satisfaction, conformity to product requirements, characteristics and trends of processes and products, and suppliers. The changes below were to revise a reference (from 7.2.1 to 8.2.4) and to add new references (8.2.3, 8.2.4, and 7.4).

The analysis of data shall provide information relating to

a) customer satisfaction (see 8.2.1)

b) conformity to product requirements ~~*(see 7.2.1)*~~ *(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

AS9100C added this requirement, and new Note.

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

The requirement below switched from "cause" to "causes" to match with "nonconformities" and to be consistent with a similar sentence in 8.5.3, Preventive Action.

The organization shall take action to eliminate the ~~cause~~ causes of nonconformities in order to prevent recurrence.

ISO 9000:2005 defines "review" as an activity to determine the effectiveness of a subject to achieve established objectives. However, the "reviewing" in the requirement below was often interpreted as checking to see if an action was taken, instead of determining its effectiveness. It has been clarified.

f) reviewing the effectiveness of the corrective action taken.

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g) flowing down ~~of the~~ corrective action requirements to a supplier when it is determined that the supplier is responsible for the ~~root cause~~ nonconformity , ~~and~~

h) specific actions where timely and/or effective corrective actions are not achieved, and

AS9100C added a new requirement to go beyond the detected problem to see if more nonconforming product might exist, and then to do something about it:

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

As explained under 8.5.2, Corrective Action, the "reviewing" of the action has been clarified to include determining the effectiveness of the action.

e) reviewing the effectiveness of the preventive action taken.

AS9100C added a new Note to clause 8.5.3 to give examples of preventive action opportunities:

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 Bibliography for AS9100C has been updated to reflect new standards, new editions of standards, and withdrawn standards since the publication of AS9100B.

~~*AS/EN/SJAC 9102 Aerospace First Article Inspection Requirement*~~

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~~:2000~~ Quality management systems - Fundamentals and vocabulary

ISO 9001~~:2000~~ Quality management systems - Requirements

ISO 9004:~~2000~~ ~~Quality management systems - Guidelines for performance improvements~~ Managing for the sustained success of an organization - A quality management approach

ISO 10007~~:1995~~ Quality management systems . Guidelines for configuration management

ISO 19011~~:2002~~ Guidelines for quality and/or environmental management systems auditing