9100 Change & Rationale

Title

Expanded scope from aerospace to aviation, space and defense organizations to better reflect the full range of users of 9100.

Foreword

Limiting aerospace specific text has been changed to aviation, space and defense, while inviting other industrial sectors to use the standard if applicable. Minor rewording has been done to enhance clarity.

Revision Summary/Rationale

Summary statement updated to reflect the incorporation of ISO9001:2008 and industry requirements, definitions and notes.

Introduction

0.1 General

Added organizational environment and its potential risks as quality management system design and implementation influencing factors.

Statutory added in conjunction with regulatory requirements and clarification that they are applicable to the product.

0.2 Process Approach

Minor change from "identify" to "determine" the processes. Determine adds an action after the identification. Identify could mean to record.

Process approach expanded to include "produce the desired outcome".

1.0 Scope

1.1 General

Revised to include ISO 9001:2008 changes and additional industry requirements for aviation, space and defense.

Statutory requirements added to stay consistent with ISO text and to meet the needs of the expansion of scope to aviation, space and defense.

Product applies not only to product for a customer, but also any intended output of the product realization processes.

Note added to clarify that statutory and regulatory requirements may be in the form of legal requirements.

1.2 Application

Statutory requirements added.

New applicability statement for 9100 provides users and potential users guidance on standard applicability.

Minor addition and web address.

2. Normative References

Simplified text. Updated the normative reference from ISO 9000:2000 to ISO 9000:2005.

3. Terms and Conditions
Text outlining changes from the ISO 9001:1994 version has been deleted.
3.1 Risk
Definition of "Risk" added to support the introduction of Risk Management. The understanding of risk is important for an organization to develop a proactive quality management system.
3.2 Special Requirements
Definition of "Special Requirements" added to support the introduction of the requirement in clause 7. The rationale is to improve understanding of "Special Requirements" and the potential chain of flow to "Critical Items" and to "Key Characteristics" and to ensure these important requirements are systemically addressed and linked to risk management activities by the organization.
3.3 Critical Items
Definition of "Critical Items" added to support the introduction of the requirement in clause 7. The rationale is to improve understanding of "Critical Items" coming from Special Requirements, design output, and/or risk analyses to ensure these items are systemically addressed and adequately managed during product realization.
3.4 Key Characteristic
An expanded Key Characteristic definition is more specific and adds clarity (see IAQG 9103). ***Note added to provide insight on the interrelationship between special requirements, critical items and key characteristics and in what type of scenario they might be applied.***
4 Quality Management System
4.1 General Requirements
The shall statement was moved in the revised 9100 standard from clause 4.2.1 to 4.1 to clarify that the requirement is placed at the QMS level and not only at the documentation level. Clause 4.1 is the overall QMS general requirements that are applicable across the entire QMS. So all 9100 requirements shall address customer and applicable statutory and regulatory requirements as applicable. Minor change from "identify" to "determine" the processes. Determine adds an action after the identification. Added "where applicable" since it is not always possible to measure every process. Strengthened text by adding "type and extent" of control and changing "identify" to "define" outsourced processes within the QMS. The word "should" was deleted to enhance clarity of the Note and linkage established to the "analysis" and "improvement" processes. Guidance provided on what an outsourced process is. Note outlines outsourced process organizational responsibility and provides examples of influencing factors associated with its control.

4.2 Documentation Requirements

4.2.1 General

Minor restructuring of the records requirement from e) to c).

Deleted regulatory requirement, which is covered in 4.1.

The requirement has had some words moved around and adds "documentation and changes". Addressing "Changes" in documentation is the primary delta here.

The change requires staff to have access to and awareness of all relevant parts of management system documentation (and changes), not just awareness of procedures as in the previous version of the Standard.

Deleted regulatory authority access requirement now included in 4.1.

Note 1 provides clarification that a single “documented procedure” may apply to more than one procedure. Multiple procedures may be included in a single document based on the organization’s needs.

4.2.2 Quality Manual

Deleted the requirement that quality manual references to procedures include linkage to 9100 requirements. The requirement adds no value to assuring product quality and was viewed as prescriptive in that it specifies a particular method of assuring the requirements of the standard have been met.

4.2.3 Control of Documents

Added that external documents needed by the organization for their QMS must be identified and distribution controlled.

Deleted "The organization shall coordinate document changes with customers and/or regulatory authorities in accordance with contract or regulatory requirements." now addressed in 4.1.

4.2.4 Control of Records

The requirement to maintain QMS records has been replaced by control.

Deleted "Records shall be available for review by customers and regulatory authorities in accordance with contract or regulatory requirements." now addressed in 4.1.

The additional text- "Records shall be available for review by customers and regulatory authorities ..." has been removed because these are contractual or regulatory in nature (and clause 4.1 already requires that contractual and regulatory requirements shall be addressed by the QMS.)

4.3 Configuration Management

Moved configuration management clause to 7.1.3 as part of product realization. Adds focus and addresses interpretation issues arising from it being in clause 4.

Moved "NOTE: Guidance on configuration management is given in ISO 10007." to 7.1.3.

5 Management Responsibility
5.1 Management Commitment
No Change.
5.2 Customer Focus
Product improvement is a key addition in this update and this requirement places the accountability for product conformity and on-time delivery improvement directly with top management (see also clause 8.2.1).
5.3 Quality Policy
No Change.
5.4 Planning
5.4.1 Quality Objectives
No Change.
5.4.2 Quality Management System Planning
No Change.
5.5 Responsibility, Authority and Communication
5.5.1 Responsibility and Authority
No Change.
5.5.2 Management Representative
Added that the management representative shall be a member of the organization's management. ***The words "and unrestrictive access" have been added at this update to avoid the possibility of the Management Representative being unable to directly access top management to ensure they are aware of and involved in resolving quality management issues.*** ***The term "matter" was replaced by "issues" for clarity.***
5.5.3 Internal Communication
No Change.
5.6 Management Review
5.6.1 General
No Change
5.6.2 Review Input
No Change
5.6.3 Review Output
No Change
6 Resource Management
6.1 Provision of Resources
No Change
6.2 Human Resources
6.2.1 General
Added conformity to product requirements. Note has been added to provide guidance all personnel, directly or indirectly, may affect conformity to product. Often the focus of conformity is on the actual build process, but it

applies throughout product realization.

6.2.2 Competence, Training and Awareness

a) Reworded from personnel performing "product quality" to "conformity to product requirements."
b) "where applicable" has been added to provide flexibility, since training may not always be necessary if personnel already are competent.

6.3 Infrastructure

"Information systems" has been added as another "such as" example of a supporting service.

6.4 Work Environment

ISO Note added to enhance guidance on "work environment" and provide examples. Similar in intent to the 9100 note that was deleted.

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

7 Product Realization

7.1 Planning of Product Realization

The note was added to emphasize the importance of considering relevant requirements at the earliest point in the product lifecycle.

The new clause e) was added to improve product quality through the use of structured configuration management methods.

Added “measurement” as one of the criteria for product acceptance.

7.1.1 Project Management

Project management has been added to the standard outlining requirements on planning and managing product realization risks, resources and schedule. Most aviation, space and defense products are complex and involve multi-tier partners and suppliers and project management provides additional focus on upfront planning and the management of project plans throughout product realization.

Project management is an important new topic introduced at this update- important because every type and size of organization carries out ‘project management’ in some form or other. Project management is included in clause 7.1 because its requirements apply to all phases of the lifecycle.

7.1.2 Risk Management

Risk Management was placed in clause 7.1.2 to provide additional focus on product risk during product realization.

The concept of risk could be viewed from two perspectives, risk management processes and risk based decisions.

Risk Management, as with any process can be viewed as a series of steps, with sequences and interactions (IAQG 9100 – 4.1.b). The wording added to this section defines the steps, sequences and interactions an organization needs to perform to

ensure risks are properly handled. This risk process can be applied in various ways dependent on the business approach and integrated into key points of the organizations product realization processes.

Once Risks are identified (7.1.2.c) from various potential sources (customer, organization, Statutory/Regulatory, etc.) the risks need to be communicated to various departments or individuals within the organization. As this risk communication is received, an assessment of these risks must be performed to determine potential impacts. Where most organizations have options on how to complete these processes, the individuals that work with these processes will need to determine which of the process options are the most appropriate choice to support the goal of mitigating the risks.

This concept can be applied throughout the standard where risk identification, assessment and mitigations might be performed. A key example of this can be found with the new requirements added to the purchasing process in section 7.4.1.f and direct links to risk can be found in 3.1, 7.1.1, 7.2.2 & 8.5.3.

Additional information on Risk Management within a Management System approach can found in various ISO standards including:
IAQG 9134 Supply Chain Risk Management
ISO Guide 73 Risk Management Vocabulary
ISO 17666 Space Systems - Risk Management
ISO 16085 Systems-Software Engineering - Risk Management
ISO 31000 Risk Management (under development)
Project Management Institute

7.1.3 Configuration Management

Configuration management moved from clause 4.3 to 7.1.4. The move and expanded scope provides focus of configuration management during product realization. Added ISO 10007 sections (a-e).

Configuration management is included now in clause 7.1 because its requirements apply to all phases of the lifecycle of products realization and use. Configuration management is aimed to know at any time the as designed and the as built configuration of products in order to ensure fit for use of these products.

7.1.4 Control of Work Transfers

"Work Transfer" clause moved from 7.5.1.4. The rationale is that "Work Transfer" can occur at anytime during product realization. These requirements, originally included as clause 7.5.1.4, have been significantly expanded to-
• apply to transfers throughout the whole lifecycle (not just for Production)
• require that the work transfer process includes the planning of proposed moves
• cover permanent (as well as temporary) transfers include moves from one supplier to another and moves from one of the organizations facilities to another.

7.2 Customer Related Processes

7.2.1 Determination of Requirements Related to the Product

Minor rewording in bullet d) "determined" revised to "considered necessary".

The new Note points out that when defining the overall product requirements the user should also consider any special requirements identified by the customer and the organization.

ISO 9001:2008 adds a note to clarify what is meant by post-delivery activities.

7.2.2 Review of Requirements Related to the Product

d) has been added to this clause to incorporate the addition of special requirements into the review of requirements related to the product.
e) has been updated to reference the clause added for risk management 7.1.2.

7.2.3 Customer Communication

No Change.

7.3 Design and Development

7.3.1 Design and Development Planning

Removed redundant text under a).

The "Where appropriate" clause has been simplified to provide clarity. The deletion of "give consideration to" will more clearly focus the organizations determination of when the requirement is appropriate. The "Where appropriate" clause details planning requirements for the design and development phase of a project. This clause could include a work breakdown structure, how work packages are identified and their content.

Statutory added to be consistent with ISO 9001:2008. This requirement has also been moved and slightly reworded. It is emphasized that as part of the design input and to be integrated in the requirements related to the product functional and operational requirements as applicable including reliability, safety, maintainability and statutory/regulatory requirements.

Added the requirement for planning to consider product realization capability and the maintenance of the product.
It is emphasized that design and development planning should account for production preparation, ability to test (as applicable), verify, maintain and repair, etc. and associated risks to be mitigated from the early design stage.

The note clarifies that reviews, verification and validation can be conducted and recorded separately or combined according to the organization's needs.

7.3.2 Design and Development Inputs

Minor wording change.

7.3.3 Design and Development Outputs

Deleted "provided" and added "suitable for verification" as an expectation.

The text in e) has been updated to include "critical items" as defined in clause 3. It also adds the requirement to specify actions to be taken.

Special Requirements (SR) and Critical Items (CI) is a new theme that is added to numerous sections within the AS9100c standard (3.2, 3.3, 3.4, 7.2.1, 7.2.2, 7.4.2, 7.5.1, 8.2.4). As discussed in the Risk Management section (7.1.2) an output of the risk management process is prioritization. An example of risk based prioritization can historically be seen with Key Characteristics (KC). This is the idea that one characteristic of a design is more critical than another. The identification of a KC should result in activities, behavior and decisions that ensure enhanced attention is applied to this KC within the organizations realization process and product acceptance. With this concept in mind SR & CI were developed to be an evolution of the KC concept. ***"Where KC is basically the communication of the criticality of a design characteristic from engineering to production, SR is intended to be the communication of criticality of requirements from the customer to the organization, or identification of criticality by the organization to meeting customer requirements. CI is intended to be an expansion of the KC concept. CI is the identification of criticality of any type of requirement by the design organization. CI can be the traditional identification of a KC as identified in AS 9103. The expansion of the KC concept comes when the design organization defines other types of Criticality as part of Design Output. Identification of Critical components within a system Identification of Product Safety concerns. Identification of Critical Safety Items as defined by Civil Aviation, Defense or Space Customers (See soon to be released AS 9017). Identification of design requirement(s) that are determined to be more critical than another. As with KC, when a SR or CI is identified by the customer or the organization, the relevant personnel within the organizations realization process are expected to understand the nature of the SR/CI.*** ***They are also expected to apply appropriate actions to ensure that the SR/CI is addressed in the realization process in accordance with the organizations risk handling processes."*** Restructured and removed redundant text. Added visibility on product preservation.
7.3.4 Design and Development Review
No Change.
7.3.5 Design and Development Verification
Deleted Note providing examples of verification activities. The text was determined to be more in line with a "how to" than a requirement.
7.3.6 Design and Development Validation
"Notes" deleted. The text was found to be redundant.
7.3.6.1 Design and Development Verification and Validation Testing
Realigned to reflect a more sequential order.
7.3.6.2 Design and Development Verification and Validation Documentation
Minor wording of the header.
7.3.6.2 Design and/or Development Verification and Validation Testing

Moved above - 7.3.6.1.
Removed "standard" to reduce confusion and misinterpretation.

7.3.7 Control of Design and Development Changes

Removed the regulatory reference now in 4.1.

The new requirement provides a link to the enhanced (and moved) requirement for Configuration management included in clause 7.1.3.

7.4 Purchasing

7.4.1 Purchasing Process

The clause has been reworded to simplify and clarify the originally intended wording- no additional requirements have been included. "Quality" changed to "conformity" in alignment with ISO text (ref. 6.2.1, 6.2.2)

The new note emphasizes that the organization should obtain and use as much reliable supplier quality (e.g. audit, OASIS, on time/on quality) data as possible when making a selection decision and provides a number of examples where this data might be found. The last sentence points out that accountability for supplier remains the responsibility of the organization, independent of where this performance data was obtained.

Added requirements that outline the conditions for using a supplier depends on its approval status, the results of supplier performance reviews are to be used to establish supplier controls and risk management will be utilized in determining and selecting suppliers.
a) Clause 7.4.1 a) now requires inclusion of supplier status in the supplier register, examples of supplier scope are also provided.
b) The new text of clause b) improves the wording of the previous version to state that it is the results of the review (rather than the records) that are used to establish the level of controls to be used.
e) This revised clause requires the organization to treat supplier approval as a defined (but not necessarily documented) process and to define the responsibilities and authorities for each activity in that process.
f) Clause f) provides a link to the new clause 7.1.2- addressing risk when selecting and using suppliers.

7.4.2 Purchasing Information

d) editorial change only – "the identification and revision status" replaces "the name or other positive identification, and applicable issues of" also "inspection" now is "inspection/ verification" to recognize the difference between the 2 terms (See ISO 9000:2005) and that both can apply to this paragraph – the intent of "d" remains the same: to clearly identify the flow-down data in the purchasing info.
e) Paragraph scope (not intent) has been expanded slightly to specifically recognize "statistical techniques for product acceptance" and requirements for "critical items including key characteristics" as part of the product/acceptance requirements that need to be flowed on the purchasing documents (if they exist) for the product being procured.
f) "inspection" now is "inspection/ verification" to recognize the difference between the 2 terms (See ISO 9000:2005) and that both terms can apply to this paragraph – the

intent of "f" remains unchanged.
g) was significantly revised editorially to make it easier to understand and incorporate former paragraphs "h" and "j" under the requirements for the supplier to act under certain circumstances (i.e. if parts are nonconforming, if certain changes occur, and when mandated to flow requirements down to sub-tiers). Material change to this paragraph is the addition of "change of suppliers", and "change of manufacturing facility location" to the list of notification required in the purchasing information if the organization deems it appropriate per 7.4.2 lead paragraph.
h) This is an added requirement to prescribe in the purchasing documentation supplier records retention requirements. This addition is complementary (and the execution portion) to paragraph 4.2.4 requirement that the required records procedure "define the method for controlling records that are created by and/or retained by suppliers". Presumably, once described per 4.2.4, the organization will need to notify the supplier of those requirements in the purchasing documentation (this paragraph) for their execution.
i) Clarification revision that the right of access only applies "to the applicable areas" where the product is realized and "to all the applicable records" (not necessarily the records storage areas or other areas of a facility not germane to product realization). "At any level of the supply chain" replaces "involved in the order" for clarification.

7.4.3 Verification of Purchased Product

The subject has been changed from a requirement to a Note because the need for customer verification would be a contractual requirement and additional to those requirements contained in 9100.

Changed to a guidance note. No shall statement existed, so a note is more appropriate. "Quality" changed to "conformity" in alignment with ISO text (ref. 6.2.1, 6.2.2). Test reports changed to test records to provide flexibility for the stakeholders.

The clause has been significantly reworded adding text that is more specific and proactive. Requirements have been added to "identify and record" product issued pending completion of verification to allow recall and replacement. This replaces "positive recall."

Deleted the requirement to validate supplier test reports. Test reports are a tool and prescriptive, suggesting a "how to" and are not applicable to all stakeholders and for all types of products. Often misinterpreted. An item for consideration in risk management.

Deleted contractual language. Covered in clause 4.1.

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

Notes have been added under a), b), and c) to provide additional guidance and examples to the stakeholders. Some of these were taken from the deleted 7.5.1.1 Production Documentation clause.
d) Changes measuring "devices" to "equipment" wherever it appears. Consistent with 7.6.

g) Changes "manufacture" to "production" - consistent throughout this revision.
j) Changes "quality" to "conformity" - consistent throughout this revision.

Text was changed to be consistent with the new term "critical items."

For key characteristic management statistical process control may be used (ref. IAQG 9103).

7.5.1.1 Production Process Verification

The "First Article Inspection" (FAI) clause was moved from 8.2 monitoring and measurement, to 7.5.1.1 production and service provision. The move acknowledges that this requirement is not primarily a measuring and monitoring process, but a process that will be used to assure product realization capability under controlled conditions. Being in clause 7 also allows justifiable exclusion for unique and individual products.

Previously covered by clause 8.2.4.2- First article inspection (under monitoring and measurements), these requirements have been moved into clause 7 to emphasize that they are integral to the production part of the lifecycle- confirming that production processes are capable of consistently producing products that meet requirements. Examples are provided when it is expected that production verification will need to be repeated.

Note added to provide a guide post for those familiar with FAI.

7.5.1.1 Production Documentation

Deleted clause
Moved text in 7.5.1.1 to 7.5.1 a), b) and c).

7.5.1.2 Control of Production Process Changes

Minor wording change from "persons" to "personnel."

In line with the policy adopted throughout the updated Standard, additional customer (contractual) or regulatory requirements have been removed. See 4.1.

The need to document changes has been added at this update and removes the requirement for "procedures to control their implementation." Also "programs" is clarified as "software."

Revised "quality" to "conformity" to be consistent with ISO 9001:2008 text.

7.5.1.3 Control of Production Equipment, Tools and Software Programs

The scope of the clause has been changed from NC programs to software. This is in recognition that non-deliverable software is a product unto itself and often utilized throughout product realization. The scope has been defined as "software programs used to automate and control/monitor product realization processes." The new clause has removed the requirement for a documented procedure.

Storage requirements changed from "established" to "defined."

7.5.1.4 Control of Work Transferred, on a Temporary Basis, Outside the Organization's Facilities

Moved – see 7.1.4 above.

7.5.1.4 Post-Delivery Support

The clause has some minor text changes to enhance clarity. text on contractual and regulatory requirements deleted consistent with this revision and can be found in 4.1.

7.5.2 Validation of Processes for Production and Service Provision

Removed text requiring qualification and approval prior to use.

7.5.3 Identification and Traceability

Added that product must be identified "throughout product realization."

This revision of the standard removes the requirement for "documented" controls for stamps, signatures, passwords, etc. and instead requires "appropriate" controls. The intent is to offer flexibility to the stakeholders and acknowledge there are many ways to accomplish the control of media and these should be "appropriate" to the use.

Maintenance of records added to the record requirement.

This requirement has been changed to a Note ("shall provide" to "can include".) The text is prescriptive and not applicable to all organizations, so it has been changed to guidance to be used in conjunction with the ISO requirement above. The text has been revised removing the contract and regulatory references. This is consistent with the overall strategy to state the requirement in 4.1 and have it reflect incorporation throughout the standard. The new Note provides guidance on what should be considered when an organization is defining identification and traceability requirements.

The reference to configuration management changes from 4.3 to the new clause number 7.1.3.

7.5.4 Customer Property

The text near the bottom of the clause has been changed to specifically identify the "organization" as being responsible for reporting to the customer issue with customer property.

The 9100 "Customer furnished data used for the design" has been removed from this note since it is often contractual and understanding that these items are included in intellectual property.

ISO text has added text "personal data."

7.5.5 Preservation of Product

A statement of intent has been added to the preservation of product stating "in order to maintain conformity to requirements." "As applicable" added prior to the list of ways preservation of product may be accomplished.

Added "statutory" to be consistent with ISO 9001:2008.

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

deterioration" moved to 8.2.4

7.6 Control of Monitoring and Measuring Equipment

Measuring "devices" has been changed to "equipment" throughout the standard. The word verification has been added next to calibration/ consistent with ISO 9001:2008.

f) has been changed to a separate requirement following e) and strengthens the requirement for the organization to establish a process for recall of equipment in need of calibration and verification.

Deleted the Note referencing the ISO 10012-1 and ISO10012-2.

Note added with guidance for software confirmation.

8 Measurement, Analysis and Improvement

8.1 General

Clarified that conformity is based on the product "requirements".

The note removes prescriptive text and adds failure mode, effect and criticality analysis (FMECA) in place of failure mode and effect analysis (FMEA).

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

Customer satisfaction is a key inclusion in this update to the Standard and this clause defines mandatory measures (e.g. customer performance indicators) that all organizations of all sizes and complexity must monitor), analyze and review to assess if improvement is needed. If action is needed, improvements must be planned and implemented and the results of the action must be evaluated to check their effectiveness. It also follows that should the action not be effective, further action must be taken until customer satisfaction performance is as required.

A note has been added to provide guidance on various input sources that may be utilized to support customer satisfaction.

8.2.2 Internal Audit

A Note has been added as a reminder to include customer contractual requirements in planned arrangements.

This note is to emphasize that all the QMS requirements are under the scope of the internal audit. The customer contractual requirements should be consider as QMS requirements for the internal audit purpose.

Minor changes, some text has been restructured. The intent remains the same.

Clarification has been provided as to the type of actions to be taken are "any necessary correction and corrective" actions.

Deleted the requirement for detailed tools and techniques. The requirement was too prescriptive and reference to specific tools in a "such as" statement is more appropriate as guidance material.

Reference to contract & regulatory requirements has been deleted. Reference note under 8.2.2a and clause 4.1.

The reference for an audit guidance document has been changed from ISO 10011 (cancelled) to ISO 19011.

8.2.3 Monitoring and Measurement of Processes

"to ensure conformity of the product" has been removed. Not all processes directly affect product conformity, but may still impact how an organization would demonstrate the ability of the processes to achieve planned results.

A note has been added to provide guidance on how an organization may go about determining appropriate process monitoring and measurement methods.

A new line item has been added as c). It requires that the organization determine if the nonconformity is limited or if it has affected other processes or products. This expends the scope towards the identification of how the nonconformance has affected not only the product, but also other processes.

8.2.4 Monitoring and Measurement of Product

Moved bottom sentence from below.
"Evidence of conformity with the acceptance criteria shall be maintained."

"Critical items" has been added in conjunction with key characteristics. This is consistent with the new terms added in clause 3. This clause also adds a requirement that processes are in place to control and monitor the critical items and key characteristic that have been identified.

Reworded to clarify often misinterpreted requirements. Added that sampling plans must be justified based on recognized statistical principles.
"Customer approval" was deleted and was seen as a contractual requirement. If customers need this they must flow contractually.

The text of the clause has been rewritten enhance clarity and add requirements for product pending completion to be "identified and recorded", so replacement can be done if the product ends up not meeting requirements.

The clause has been clarified by adding specific text that it is only the product "for delivery to the customer" that requires a person be identified to authorize its release.

The requirement for records of product qualification has been moved to clause 8.2.4 from the deleted clause 8.2.4.1.

The "customer" has been added to indicate who the product will be released and delivered to.

The requirement "The organization shall ensure that all documents required to

accompany the product are present at delivery" was moved from 7.5.5 to 8.2.4.

8.2.4.1 Inspection Documentation

Some content was moved to 8.2.4 above.

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

8.2.4.2 First Article Inspection

Moved to 7.5.1.1 and renamed. Deleted Note.

8.3 Control of Nonconforming Product

Minor editorial change for clarity. The intent remains the same.

This clause is applicable to all non conforming product, even those returned by the customer.

A documented procedure describing the control of non conforming product is required. The procedure may include:
- Definition of the responsibility and authority.
- Requirements for personnel making decisions.
- Process for approving personnel.
- Process for review and disposition for the product.
All of this shall be arranged according to the company, product, the type of non conformances/defects and following the requirements establish in this standard.
The documented procedure must outline the requirements to prevent the unintended use or delivery of nonconforming product.

"Where applicable" has been added.

The organizations nonconforming product control "system" has been replaced by "process", in the text below d), consistent with a general strategy to use process in place of references to document, policy, system, etc. The text following b) has been moved up from the end of the clause to provide a cleaner structure and flow of the requirements. e) has been added to containment action to be taken on nonconformities.

Note: This is an example. Notification of nonconforming product should be addressed to the parties according to and the applicable requirements (ie. Contractual requirements or regulatory authorities requirements could request to be informed for a type of nonconformance).

e) Is important to avoid the nonconformance or its effects appears in other processes or products. All necessary actions must be taken.

The clause has been simplified and redundant text removed. The new requirement focuses on the identification and authorization of a representative from the design organization for the purpose of use-as-is or repair disposition/s. This is intended to provide continuity of the design responsibility and integrity of the product.

The clause emphasized the concept of any difference from the designed configuration should be authorized/approved for the adequate responsible of the design organization.

Moved text and a note from below to the ways of dealing with nonconforming product.

Should be clearly stated the authorized representative and their authority.

The clause has removed text pertaining to the use-as-is or on repair dispositions on product produced to customer design. The emphasis is placed on nonconformities that depart from contract requirements and that they are approved by the customer.

The clause emphasized the concept of any difference from the agreed/contractual configuration should be authorized for the customer. In some cases contractual requirements establish the process/ responsible for communication and authorization (ie. The GQAR as acquirer representative for NATO contracts).

To emphasize the intent of the clause of the standard: "to prevent the unintended use or delivery of non conforming product".

8.4 Analysis of Data

Clause references have been updated to and expanded to provide applicable reference points to the other clauses.

8.5 Improvement

8.5.1 Continual Improvement

This clause widens the requirements of the ISO text and 'closes the loop' of the improvement cycle by requiring the organization to (periodically) monitor the implementation of improvement actions and evaluate their effectiveness. Where action hasn't been effective, the ISO text requires that further action is taken until it is.

The new Note in clause 8.5.1 provides a few examples where opportunities for improvement can be identified; there are many other improvement opportunities that could also be used.

8.5.2 Corrective Action

"Cause" changed to the plural "causes" of nonconformities. An editorial change.

f) Clarifies that the effectiveness of the action should be reviewed, not just the action.
g) The rewording changes the requirement from the supplier responsible for the "root cause" to "nonconformance", recognizing the two are not always the same and placing the responsibility on the originator of the nonconformity.
i) Requirement has been added to determine not only if other nonconforming product exists resulting from the causes, but also that further action must be taken as required.

8.5.3 Preventive Action

The addition of "effectiveness" of the preventive action provides more emphasis on the performance of the preventive action, not just the initial action.

This new Note provides examples of preventive action opportunities, sources and tools that may be utilized by organizations. Stakeholder feedback indicated that additional

guidance has been needed in the preventive action area, so to avoid being overly prescriptive a note was seen as the optimal way to provide the organizations some options and enhance their success in this clause.
Bibliography
The bibliography adds 9110 and 9120 to the list of standards, removes version year from standards listed, deletes reference to first article and measurement system guidance documents and deletes reference to obsolete standards.

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