

IA9110 KEY CHANGES CLAUSE BY CLAUSE VIEW

June 2024



This <u>Clause-by-Clause view</u> describes the new or revised IA9110 specific requirements, compared to AS9110:2016.

It has been completed after the IA9100 CD comments disposition. All the <u>common</u> comments have been already analyzed and:

- if accepted, they have been implemented in IA9110
- if rejected, they will not be included in IA9110

Rationale, Foreword

Intended application

Introduction

0.1 General

0.2 Quality management principles

0.3 Process approach

0.4 Relationship with other management system standards

IA9100 changes ---

IA9110 changes ---

Explanation of single Standards Development Organization and new IA prefix

QMS implemented & correctly maintained using process approach, managing risk, & identifying opportunities = effectiveness

IA9110 intended application standalone.

Replaced "business" with "activity"

Note revised to remove the "e.g." and adding "Other IAQG supporting standards".

Removed reference to 9115 standard.

IA9100 and IA9120 intended application deleted and will be included in those standards.

NOTE for supporting information in Annex C and improvement standards

Importance of organizational culture and ethical behavior to an effective QMS and its ability to achieve intended results (*)

Definition proposed for the terms "as appropriate" and "as applicable"

Importance of organizational culture on the QMS (*)

Implementation of QMS is a cornerstone to establishing a culture of quality

^{* -} Development of Support Materials and SCMH Content

Requirements

- 1. Scope
- 2. Normative references
- 3. Terms and definitions
 - Counterfeit part
 - Article
 - Product
 - First Process Evaluation (FPE)

Incorporation of clarification: if conflict...the most stringent requirement take precedence

Definition: An unauthorized copy, imitation, substitute, or modified item which is knowingly misrepresented as a specified genuine item from an authorized manufacturer or a previously used item which has been represented as new.

Examples of software and electronic device added to modified part.

- Article definition removed
- Product definition revised to include also the definition of Article.
 IA9110 reviewed to adhere to this new definitions
- First Process Evaluation new definition (clause 8.5.1.4)

4. Context of the organization

- 4.1 Understanding the organization and its context
- 4.2 Understanding the needs and expectations of interested parties
- 4.3 Determining the scope of the quality management system
- 4.4 Quality management system and its processes

NOTE: The determination of processes is an organizational decision as to the level of detail needed to adequately manage the QMS

Former AS9110 clause 4.4.2.c now become 4.4.3 and the list has been identified by letters.

Added Note for Quality Plan

5. Leadership

5.1 Leadership and commitment

5.2 Policy

5.3 Organizational roles, responsibilities and authorities

6. Planning

- 6.1 Actions to address risks and opportunities
- 6.2 Quality objectives and planning to achieve them
- 6.3 Planning of changes

Leadership to ensures goals and objectives enhance organizational culture

Leadership to promote an ethical work environment with note added (e.g. no retaliatory action)

Both requirements included in IA9110 clause 5.1.1 k. and l. Former clauses moved to 5.5.1 m. and n.

IA9110 clause 5.1.1.n revised:

n. ensuring that the corrective actions are implemented in due time, and taking necessary actions when timely and effective corrective actions are not achieved (see 10.2.1.h and 9.3.2.c.4).

IA9110 clause 5.2.3 Safety Policy revised for safety objective setting, confidential safety reporting (no retaliatory actions) and safety continual improvement

IA9110 clause 5.3.3 Other Appointed Managers revised: "responsible for assuring that all required operational and compliance activities are carried out

NOTE: Risks receive additional controls in Operational Risk Management with reference to clause 8.1.1

7. Support

7.1 Resources

7.1.1 General

7.1.2 People

7.1.3 Infrastructure

7.1.4 Environment for the operation of processes

7.1.5 Monitoring and measuring resources

7.1.6 Organizational knowledge

7.1.7 Information Security

7.2 Competence

7.3 Awareness

7.4 Communication

7.5 Documented information

7.5.1 General

7.5.2 Creating and updating

7.5.3 Control of documented information

Clause 7.1.1 c - revision from "tasks are accomplished" to "work is being performed"

Clarifying that lists of monitoring & measurement equipment be placed on documented information that could be a register.

7.1.7 Information Security (NEW)

Information security, appropriate to the organization, to safeguard the achievement of QMS intended results. NOTE updated. (Definition to be added to Dictionary)

IA9110 clause 7.2.h revised "prior to personnel qualification or certification" instead of "prior to performing unsupervised work

IA9110 clause 7.5.1.c "safety processes" instead of "product safety management"

Further refined requirements when documented information is managed electronically

8. Operation

8.1 Operational planning and control

8.1.1 Operation risk management

8.1.2 Configuration management

8.1.3 Product safety

8.1.4 Prevention of counterfeit parts

8.1.5 Prevention of Susp. Un. Parts

8.1.a. Information security and data protection added to the NOTE. 8.1.k. (New) Operations to prevent, detect and mitigate the risk of foreign objects

Clause under 8.1.j added "regulatory requirements"

Note: (Revised) to include APQP is one method for operational planning and control

Added Transfer of Work, previously not included in 9110 and additional Note 3 regarding the inclusion of changing location, housings or facilities.

IA9110 clause 8.1.2 revised to include "CAMO" as stakeholder

8.1.3 Product Safety: NOTE elevated to requirement.

New clause 8.1.3.h (confidential reporting system with a note to an anonymous reporting)

Change adopted in IA9100 8.1.4 and reflected in IA9110 8.1.5

NOTE items now requirements, including training, parts obsolescence monitoring program, traceability of parts, test methodologies, monitoring counterfeit parts, and segregation/containment/ reporting of suspected or detected counterfeit parts. Removal of e.g. for training.

8. Operation

- 8.2 Requirements for products and services
 - 8.2.1 Customer communication
 - 8.2.2 Determining the requirements related to products and services
 - 8.2.3 Review of the requirements related to products and services
 - 8.2.4 Changes to requirements for products and services

8. Operation

- 8.3 Design and development of products and services
 - 8.3.1 General
 - 8.3.2 Design and development planning
 - 8.3.3 Design and development inputs
 - 8.3.4 Design and development controls
 - 8.3.5 Design and development outputs
 - 8.3.6 Design and development changes

IA9110 Clause after 8.3.6 revised to include reference to configuration management (clause 8.1.2)

8. Operation

8.4 Control of externally provided processes, products and services

8.4.1 General

8.4.2 Type and extent of control

8.4.3 Information for external providers

Former statement from IA9100 included in IA9110 8.4.1 on:

- Responsibility for the conformity of all externally provided processes
- Application of appropriate controls to their direct and sub-tier Restructured NOTE in 8.4.1

Changed NOTES order.

Allow remote inspections.

Included new statement on the verification (not delegation) of contracted activities

Organization to "implement a process" (not "determine a method") for qualifying and overseeing non cert. external providers.

Contracted activities verification to be retained as documented information (requirement coming from IA9100)

Restructured clause to increase understanding including adding direct and sub-tier control

In IA9110 the clause is the 8.4.3.g, restructured in line with IA9100 and numbered.

Also the IA9110 clause 8.4.3.i now numbered

8. Operation

8.5 Production and service provision

8.5.1 Control of production and service provision

8.5.2 Identification and traceability

8.5.3 Property belonging to customers or external providers

8.5.4 Preservation

8.5.5 Post-delivery activities

8.5.6 Control of changes

8.6 Release of products and services

8.7 Control of nonconforming outputs

8.5.1.d NOTE revised in alignment with IA9100.

8.5.1.1 included software.

8.5.1.2 Note reference to clause 8.4.

8.5.1.3 Production Process Verification is "Not used" (was "not applicable")

8.5.1.4 Evaluation of a New Capability and reference to the First Process Evaluation (FPE). New requirement added in 9110 (*)

Clarification added for product "during and after maintenance"

8.5.5.f revised to include other examples of product/customer support

Change Clause 8.7.1 - defining corrective actions for nonconforming products and services including those detected after delivery, as appropriate to their impacts (see 10.2). Clarification that clause 10.2.1.b.1-3 are to be viewed as sequential activities.

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^{*} guidance and supporting material on FPE being developed to create a new SCMH section

9. Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

9.1.2 Customer satisfaction

9.1.3 Analysis and evaluation

9.2 Internal audit

9.3 Management review

10. Improvement

10.1 General

10.2 Nonconformity and corrective action

10.3 Continual improvement

Revised this IA9110 clause: "The organization shall evaluate safety objectives performance"

Revised this IA9110 clause to add a numbered list

IA9110 clause 9.1.3.h "Product safety" instead of "product safety management"

Reviewing performance indicators change from NOTE to requirement

IA9110 clause 9.2.1 revised to change NOTE to a requirement

Ensuring risks are included when establishing an audit program

IA9110 clause 9.2.2.g added

IA9110 clause 9.1.3.h "Product safety" instead of "product safety management"

NOTE: One method to achieve continual improvement can be through periodic QMS maturity assessments and setting improvement goals and objectives (see 5.1.1.b) as appropriate to the strategic needs of the organization.

Added new NOTE 1 in IA9110 10.3

