SLOVENSKI STANDARD
SIST EN 9101:2015

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Sistemi vodenja kakovosti - Zahteve za presojo organizacij zračnega prometa, vesoljskih poletov in obrambe

Quality Management Systems - Audit Requirements for Aviation, Space, and Defence Organisations

Qualitätsmanagementsysteme - Audit-Anforderungen für Organisationen der Luftfahrt, Raumfahrt und Verteidigung

Série aérospatiale - Systèmes de management de la Qualité - Exigences d'Audits pour les Organisations de l'Aéronautique, l'Espace et la Défense

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03.120.10	Vodenje in zagotavljanje kakovosti	Quality management and quality assurance
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Quality Management Systems - Audit Requirements for Aviation, Space, and Defence Organisations

Systèmes de management de la Qualité - Exigences d'Audits pour les Organisations de l'Aéronautique, l'Espace et la Défense

Qualitätsmanagementsysteme - Audit-Anforderungen für Organisationen der Luftfahrt, Raumfahrt und Verteidigung

This European Standard was approved by CEN on 20 March 2015.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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European foreword

This document (EN 9101:2015) has been prepared by the Aerospace and Defence Industries Association of Europe - Standardization (ASD-STAN).

After enquiries and votes carried out in accordance with the rules of this Association, this European Standard has received the approval of the National Associations and the Official Services of the member countries of ASD, prior to its presentation to CEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2016, and conflicting national standards shall be withdrawn at the latest by March 2016.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 9101:2011.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

RATIONALE

This European standard has been revised to incorporate the requirements for accredited Certification Bodies (CBs) introduced by International Organization for Standardization (ISO) / International Electrotechnical Commission (IEC) ISO/IEC 17021:2011, EN 9104/1:2012, and inputs received from industry stakeholders associated to process-based auditing methods and the evaluation of process effectiveness.

FOREWORD

To assure customer satisfaction, aviation, space, and defence organisations must produce and continually improve safe reliable products that meet or exceed customer and applicable statutory/regulatory requirements. The globalization of the industry and the resulting diversity of regional and national requirements and expectations have complicated this objective. Organisations have the challenge of purchasing products from suppliers, at all levels of the supply chain, throughout the world. Suppliers have the challenge of delivering products to multiple customers having varying quality requirements and expectations.

Industry established the International Aerospace Quality Group (IAQG), with representatives from companies in the Americas, Asia/Pacific, and Europe, to implement initiatives that make significant improvements in quality and reductions in cost throughout the value stream.

This document has been prepared by the IAQG and standardises the requirements for conducting and reporting of Quality Management System (QMS) audits. It can be used by aviation, space, and defence organisations at all levels throughout the global supply chain.

It provides requirements for an audit and reporting process, based on:

- the process and continual improvement approach defined in EN 9100-series standards;
- the specific aviation, space, and defence additions in EN 9100-series standards;
- the use of common audit tools; and
- the uniform, transparent, and standardised reporting of audit results.

In this European Standard, the word “shall” indicates a requirement and the word “should” a recommendation to meet the intent of the standard. Words “typical”, “example”, or “e.g.” indicate suggestions given for guidance. Information marked “NOTE” is for guidance in understanding or clarifying the associated requirement.

0 Introduction

0.1 General

Auditing is a basic tool to assess effective implementation of and conformity to QMS requirements. In addition to the determination of conformity, this European Standard focuses on the evaluation of effectiveness (see ISO 9000, subclause 3.2.14) of the QMS and its associated processes.

An organization is not only required to be in conformity with QMS requirements, but to be effective in meeting customer expectations and delivering products that meet those expectations.

Additionally, this European Standard takes into account the new requirements presented in the 2009 revisions of the EN 9100-series standards [e.g. critical items, special requirements, On-time Delivery (OTD) performance, risk management, project management].

0.2 Auditing approach

This European Standard supports the engagement and evaluation of an organization's QMS process approach, as required by the EN 9100-series standards. When evaluating an organization's QMS, there are basic questions that should be asked of every process, for example:

a) Is the process identified and appropriately defined?

b) Are responsibilities assigned?

c) Are the processes adequately implemented and maintained?

d) Is the process effective in achieving the desired results?

The collective answers to these and other associated questions will contribute to the evaluation results.

In addition, product quality (as delivered), customer satisfaction, and QMS effectiveness can be considered as interrelated. This relationship should be reflected in the audit process and associated results.

0.3 Audit records and reports

This European Standard defines the audit records and reports to be generated, during the audit process. They are critical in providing the organization and its' customers with objective evidence on the conformity and effectiveness of the QMS (including process effectiveness), and reporting the audit results in a standard format/structure.

1 Scope

1.1 General

This European Standard defines requirements for the preparation and execution of the audit process. In addition, it defines the content and composition for the audit reporting of conformity and process effectiveness to the EN 9100-series standards, the organization's QMS documentation, and customer and statutory/regulatory requirements.

The requirements in this European Standard are additions or represent changes to the requirements and guidelines in the standards for conformity assessment, auditing, and certification as published by ISO/IEC (i.e. ISO/IEC 17000, ISO/IEC 17021). When there is conflict with these standards, the requirements of the EN 9101 standard shall take precedence.

NOTE 1 In this European Standard, the term "EN 9100-series standards" comprises the following Aerospace Quality Management System (AQMS) standards: EN 9100, EN 9110, and EN 9120; developed by the IAQG and published by various national standards bodies.

NOTE 2 In addition to this European Standard, the IAQG publishes deployment support material on the IAQG website (see http://www.sae.org/iaqg/) that can be used by audit teams, when executing the audit process.

1.2 Application

This European Standard shall be used for audits of EN 9100-series standards by CBs for certification of organisations, under the auspices of the aviation, space, and defence industry certification scheme [also known as Industry Controlled Other Party (ICOP) scheme]. The ICOP scheme requirements are defined in the EN 9104-series standards (i.e. EN 9104/1, EN 9104/2, EN 9104/3).

NOTE Relevant parts of this European Standard can be used by an organization in support of internal audits (1st party) and external audits at suppliers (2nd party).

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 9100[1)], *Quality Management Systems — Requirements for Aviation, Space and Defence Organisations*

EN 9102[1)], *Aerospace series — Quality systems — First article inspection*

EN 9104-001[1)], *Aerospace series — Quality management systems — Part 001: Requirements for Aviation, Space, and Defence Quality Management System Certification Programs*

EN 9104-002[1)], *Aerospace series — Quality management systems — Part 002: Requirements for Oversight of Aerospace Quality Management System Certification/Registrations Programs*

EN 9104-003[1)], *Aerospace series — Quality management systems — Part 003: Requirements for Aerospace Quality Management System (AQMS) — Auditor Training and Qualification*

[1)] As developed under the auspice of the IAQG and published by various standards bodies [e.g., SAE International, European Committee for Standardisation (CEN), Japanese Standards Association/Society of Japanese Aerospace Companies (JSA/SJAC), Brazilian Association for Technical Norms (ABNT)].

EN 9110[1)], *Quality Management Systems — Requirements for Aviation Maintenance Organisations*

EN 9115[1)], *Quality Management Systems — Requirements for Aviation, Space and Defence Organisations — Deliverable Software (Supplement to EN 9100)*

EN 9120[1)], *Quality Management Systems — Requirements for Aviation Space and Defence Distributors*

EN 9131[1)], *Aerospace series — Quality Management Systems — Nonconformance Data Definition and Documentation*

IAF MD 2:2007, *IAF Mandatory Document for the Transfer of Accredited Certification of Management Systems*

IAF MD 3:2008, *IAF Mandatory Document for Advanced Surveillance and Recertification Procedures*

IAF MD 4:2008, *IAF Mandatory Document for the Use of Computer Assisted Auditing Techniques ("CAAT") for Accredited Certification of Management Systems*

IAQG Procedure 119, *Forms Management*

ISO 9000:2005, *Quality management systems — Fundamentals and vocabulary*

ISO/IEC 17000:2004, *Conformity assessment — Vocabulary and general principles*

ISO/IEC 17021:2011, *Conformity assessment — Requirements for bodies providing audit and certification of management systems*

3 Terms and definitions

For the purpose of this European Standard, the terms and definitions provided in ISO 9000, ISO/IEC 17000, EN 9100-series standards, EN 9104/1 standard, and the following apply. Furthermore, an acronym log for this European Standard is presented in Appendix A.

3.1
containment
action to control and mitigate the impact of a nonconformity and protect the customer's operation (stop the problem from getting worse); includes correction, immediate corrective action, immediate communication, and verification that the nonconforming situation does not further degrade

3.2
Key Performance Indicator (KPI)
measures associated with goals or targets showing how well an organisation is achieving its' objectives or critical success factors for a particular project. KPIs are used to objectively define a quantifiable and measurable indication of the organisation's progress towards achieving its goals

3.3
major nonconformity
a non-fulfilment of a requirement which is likely to result in the failure of the QMS or reduce its ability to assure controlled processes or compliant products/services; it can be one or more of the following situations:

- a nonconformity where the effect is judged to be detrimental to the integrity of the product or service;

- the absence of or total breakdown of a system to meet a EN 9100-series standard requirement, an organization procedure, or customer QMS requirement;
- any nonconformity that would result in the probable shipment of nonconforming product; and
- a condition that could result in the failure or reduce the usability of the product or service and its intended purpose.

3.4
minor nonconformity
a non-fulfilment of a requirement which is not likely to result in the failure of the QMS or reduce its ability to assure controlled processes or compliant products/services; it can be a single system failure or lapse in conformance with one of the following conditions:

- a EN 9100-series standard requirement;
- a customer QMS requirement; or
- a procedure associated to the organization's QMS.

Note 1 to entry: A number of minor nonconformities against one requirement (e.g. similar nonconformities associated to different sites or different departments/functions/processes within a single site) can represent a total breakdown of the system and thus be considered a major nonconformity.

3.5
Nonconformity Report (NCR)

a document stating results and providing objective evidence of nonconformity against audit criteria, including the following information: containment, correction, root cause, corrective action implementation, and closure.

3.6
Online Aerospace Supplier Information System (OASIS)
Web-based IAQG database containing information on participating IAQG member companies, National Aerospace Industry Associations (NAIA), National Accreditation Bodies (NAB), accredited CBs, authenticated Aerospace Experience Auditors (AEAs), Aerospace Auditors (AAs) certified suppliers, certificates, and audit results

3.7
planned activities
the means, methods, and internal requirements by which the organisation intends to achieve planned results of a given process to meet customer requirements. Planned activities include conformity to process requirements and procedures

3.8
planned results
the intended performance of a process, as defined and measured by the organisation. Planned results include product conformity and OTD to meet customer requirements, and may include other elements related to the process, as defined by the organisation

3.9
Process Effectiveness Assessment Report (PEAR)
a document stating process evaluation results; providing evidence of conformity to requirements and process effectiveness

4 Auditing and reporting

The audit and reporting process established to assess conformity, including the determination of QMS effectiveness to the EN 9100-series standards, shall meet the requirements of ISO/IEC 17021, as stated in each relevant clause of this European Standard. Additional audit requirements for the aviation, space, and defence industry are invoked by this European Standard.

For combined and integrated audits, the requirements of EN 9104/1, subclause 8.2.3 apply.

4.1 General

The audit process and associated activities (see subclause 4.1.1) shall be followed when auditing and certifying organisations to AQMS standards in the aviation, space, and defence industry.

The audit process requirements consist of three main parts:

a) the phases of the audit process (see subclause 4.1.1);

b) the common activities (see subclause 4.2) that shall be used to support the audit phases; and

c) the specific requirements for each audit phase (see subclause 4.3).

4.1.1 Audit process

The audit process consists of the following phases (see Figure 1):

a) Pre-audit activities (see subclause 4.3.1);

b) Stage 1 audit (see subclause 4.3.2);

c) Stage 2 audit (see subclause 4.3.3);

d) Surveillance audit (see subclause 4.3.4); and

e) Recertification audit (see subclause 4.3.5).

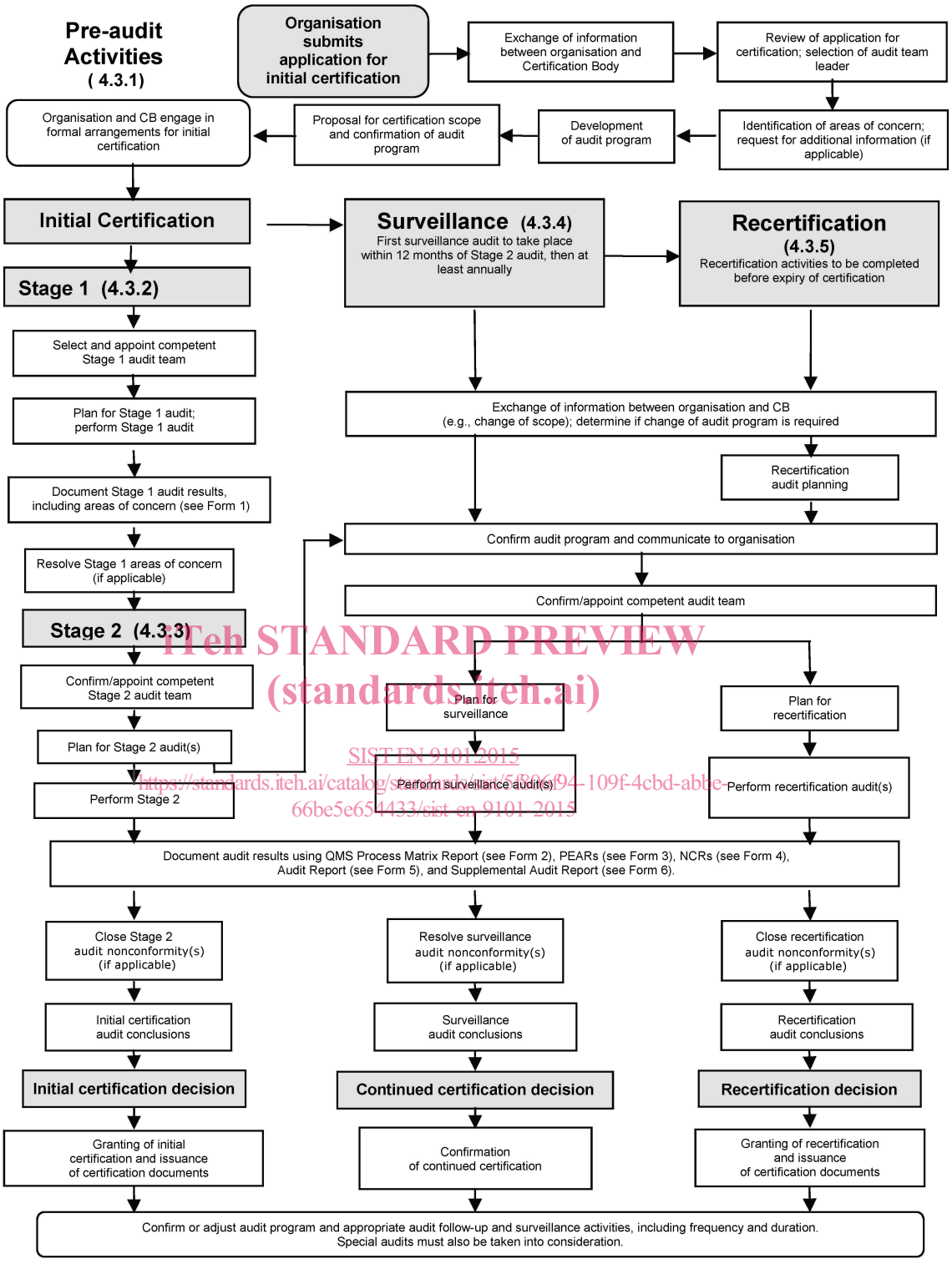

Figure 1 — Overview of audit process flow

(see ISO/IEC 17021:—, Figure E.1)

Pre-audit activities and Stage 1 / Stage 2 audits are applicable for initial certification. A Stage 1 audit can also be utilized for recertification audits and during CB transfer.

NOTE 1 Although 'Special Audit' is not listed as a part of the audit program, it can be applicable after initial certification, when directed by special request. The requirements for special audits are addressed in subclause 4.3.6.

NOTE 2 The requirements for certification are defined by the EN 9104/1 standard.

4.1.2 Audit approaches

The following approaches (see subclauses 4.1.2.1 thru 4.1.2.6) shall be used, as appropriate, to conduct each on-site audit.

4.1.2.1 Customer focus

The audit team shall determine that customer satisfaction is being evaluated and appropriate actions are taken by the organization based on available performance information (e.g. nonconformity data, corrective action requests, results of satisfaction surveys, complaints regarding product quality, OTD, service provision, responsiveness to customer and internal requests) provided by the organization's customers (e.g. scorecards, report cards).

4.1.2.2 Organisational leadership

There shall be an interview(s) with top management to evaluate the:

a) establishment and continued relevance of the organization's quality policy and objectives;

b) establishment of performance measures aligned to quality objectives;

c) QMS development, implementation, and continual improvement;

d) top management commitment;

e) QMS performance and effectiveness;

f) performance to customer expectations (e.g. supplier rating, scorecard, audit results); and

g) actions taken to address issues that are not meeting customer performance expectations.

4.1.2.3 Quality management system performance and effectiveness

The audit of QMS performance and effectiveness shall include a review of the following:

a) the processing of customer complaints, customer feedback data (e.g. periodic performance reports received from customers), and other relevant customer data (e.g. results of customer surveys);

b) results and actions from internal and external audits of the QMS, including their associated records;

c) stakeholder feedback (e.g. feedback from regulatory authorities or other interested parties);

d) the processing of process/product nonconformities, including review of associated corrective actions and evaluation on the effectiveness of actions taken;

e) the processing of preventive actions, including evaluation on the effectiveness of actions taken;

f) management review conduct, including associated records (e.g. process inputs/outputs, actions taken);

g) internal performance monitoring, measurement, reporting, and reviews against stakeholder and internal performance objectives and targets, including continual improvement activities and associated records;

h) the organization's current performance against targets, including customer specific targets and associated records of applicable actions taken where targets are not being met; and

i) the status and effectiveness of the organization's process performance improvement activities and their outcomes related to product quality.

4.1.2.4 Process management

The audit team shall conduct QMS audits using a method that focuses on process performance and effectiveness; this ensures that priority is given to the following:

a) reviewing the organization's processes, their sequence and interactions, the identification of functions and assignment of responsibilities, and performance against requirements and defined measures, with focus on processes that directly impact the customer;

b) reviewing the process for validation and approval of processes and process changes;

c) reviewing the availability of resources and information required to operate and support associated activities, including appropriate training and competency of personnel;

d) reviewing the process-based management techniques, including the examination of process measures (e.g. quality, takt time, cycle time, output effectiveness, control limits, process capability determination);

e) reviewing plans in place to ensure performance objectives/targets are monitored, measured, and analysed in order to realize the planned activities and achieve the planned results (e.g. verify performance information availability, percentage of nonconforming parts/products, percentage OTD);

f) reviewing applicable action taken when objectives/targets are not met to promote continual improvement; and

g) pursuing audit trails addressing customer concerns or requests for corrective actions, performance against objectives, and relevant process controls.

The audit team shall audit processes to sufficient depth and detail to evaluate if the organization's processes are capable of meeting planned results and performance levels, including applicable customer specific targets.

NOTE 1 KPIs are used to identify an organization's progress towards achieving its' performance goals.

NOTE 2 KPIs relating to financial information are not in the scope of the EN 9101 standard.

NOTE 3 The audit team should pursue process-based audit trails by following actual products, customer orders, and related documents (e.g. customer contracts, drawings, shop orders, inspection records) through the organization's product realization and associated processes. Verifying the interfaces between processes and the linked documentation requirements (see EN 9100-series standards subclause 4.2); resource management (see EN 9100-series standards Clause 6); and measurement, analysis, and improvement (see EN 9100-series standards, Clause 8).