SLOVENSKI STANDARD
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Zahteve za presojo sistemov vodenja kakovosti organizacij zračnega prometa, vesoljskih poletov in obrambe

Requirements for Conducting Audits of Aviation, Space, and Defence Quality Management Systems

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

Ta slovenski standard je istoveten z: **prEN 9101**

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Requirements for Conducting Audits of Aviation, Space, and Defence Quality Management Systems

This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee ASD-STAN.

If this draft becomes a European Standard, 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.

This draft European Standard was established by CEN 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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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (prEN 9101:2021) 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 document has received the approval of the National Associations and the Official Services of the member countries of ASD-STAN, prior to its presentation to CEN.

This document is currently submitted to the CEN Enquiry.

This document will supersede EN 9101:2018.

This standard has been revised to align with the latest revision of the International Aerospace Quality Group (IAQG) 9104-1 standard, incorporating inputs received from interested parties, standard clarifications, and Other Party Management Team (OPMT) resolutions.

0 Introduction

0.1 General

Industry established the IAQG, with representatives from Aviation, Space, and Defence (ASD) 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 standardizes the requirements for conducting audits of ASD Quality Management Systems (QMS). It can be used at all levels of the supply chain by organizations around the world.

This document supplements the existing International Organization for Standardization (ISO) / International Electrotechnical Commission (IEC) 17021-1 conformity assessment standard and provides requirements for an audit and reporting process, based on the

a) process and continual improvement approach defined in 9100-series standards,

b) specific ASD additions in 9100-series standards,

c) use of common audit tools, and

d) uniform, transparent, and standardized reporting of audit results.

In this standard, the following terms are used:

- "shall" indicates a requirement;
- "should" indicates a recommendation;
- "may" indicates a permission;
- "can" indicates a possibility or capability; and
- "days" are calendar days.

Words "example" or "e.g." indicate suggestions given for guidance, and information marked "NOTE" is for guidance in understanding or clarifying the associated requirement.

Auditing is a basic tool to assess effective implementation of and conformity to QMS requirements. In addition to assessing conformity, this standard focuses on the evaluation of effectiveness (see ISO 9000:2015, 3.7.11) 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 and services that meet those expectations.

0.2 Auditing Approach

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

e) Is the process appropriately determined?

f) Are responsibilities assigned?

g) Are the processes adequately implemented and maintained?

h) 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 and service 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 Documented Information

This standard defines the documented information to be generated, during the audit process. The documented information is 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.

AUDIT REQUIREMENTS

1 Scope

1.1 General

This document 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 9100-series standards, the organization's QMS documentation, and customer and statutory/regulatory requirements.

The requirements in this document 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 17021-1). When there is conflict with these standards, the requirements of 9101 standard take precedence.

NOTE 1 In this document, the term "9100-series standards" comprises the 9100, 9110, and 9120 standards; developed by the IAQG and published by various national standards bodies.

NOTE 2 In addition to this document, 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 document is intended to be used for audits of 9100-series standards by Certification Bodies (CBs) for certification of organizations, under the auspices of the ASD industry certification scheme [also known as the Industry Controlled Other Party (ICOP) scheme]. The ICOP scheme requirements are defined in the 9104-series standards (i.e. EN 9104-001, EN 9104-002, EN 9104-003).

NOTE Relevant parts of this document can also 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 are referred to in the text in such a way that some or all of their content constitutes requirements 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.

EN 9100:2018, *Quality Management Systems — Requirements for Aviation, Space, and Defence Organizations*[1]

EN 9110:2018, *Quality Management Systems — Requirements for Aviation Maintenance Organizations*[1]

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

EN 9104-001:2013, *Aerospace series — Quality management systems — Part 001: Requirements for Aviation, Space, and Defence Quality Management System Certification Programs*[1]

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

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

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

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

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

ISO/IEC 17021-1:2015, *Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 1: Requirements*

IAQG Procedure 105.6, IAQG Forms Management

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000, ISO/IEC 17000, 9100-series, 9104-series, the IAQG International Dictionary (located on the IAQG website) and the following apply. An acronym log for this document is presented in Annex A.

3.1
containment
action to control and mitigate the impact of a nonconformity to protect the customer, organization, or product (i.e., stop the problem from getting worse)

Note 1 to entry: This includes immediate action, immediate communication, and verification to ensure that the nonconforming situation does not further degrade

3.2
key performance indicator
KPI

measure associated with goals or targets showing how well an organization is achieving its objectives or critical success factors, used to objectively define a quantifiable and measurable indication of performance

3.3
major nonconformity
nonconformity that affects the capability of the management system to achieve the intended results

Note 1 to entry: Nonconformities could be classified as major in the following circumstances:

- if there is a significant doubt that effective process control is in place, or that products or services will meet specified requirements;
- a number of minor nonconformities associated with the same requirement or issue could demonstrate a systemic failure and thus constitute a major nonconformity.

Note 2 to entry: In addition, a major nonconformity can be one or more of the following situations:

- a nonconformity where the effect is judged to be detrimental to the integrity or safe use of the product or service;
- the absence of or total breakdown of a system to meet a 9100-series standard requirement, a customer QMS requirement, or documented information defined by the organization;
- any nonconformity that can result in the probable delivery of nonconforming product or service;

- a condition that can result in the failure or reduce the usability of the product or service for its intended purpose.

[SOURCE: ISO/IEC 17021-1:2015, 3.12, modified – Note 2 to entry has been added.]

3.4
minor nonconformity
nonconformity that does not affect the capability of the management system to achieve the intended results

Note 1 to entry: In addition, a minor nonconformity can be a single system failure or lapse in conformity to meet a 9100-series standard requirement, customer QMS requirement, or documented information defined by the organization.

[SOURCE: ISO/IEC 17021-1:2015, 3.13, modified – Note 1 to entry has been added.]

3.5
nonconformity report
NCR
document that provides details of the nonconformity, organization's planned actions, and auditor verification/closure

Note 1 to entry: See Form 4.

3.6
planned activity
criteria and methods by which the organization plans to achieve the intended results of, and conformity to, a given process to meet requirements

3.7
planned result
intended performance of a process as determined and measured by the organization

Note 1 to entry: Performance measures include product/service conformity and On-time Delivery (OTD), and may include other measures related to the process defined by the organization.

3.8
process effectiveness assessment report
PEAR
document that provides details of a given process, process results, process realization, and the level of process effectiveness

Note 1 to entry: See Form 3.

3.9
repeat nonconformity
trend of identical nonconformities reported against the same requirement, indicating that previous corrective action attempt(s) failed to prevent recurrence of the nonconforming situation

4 Auditing and reporting

4.1 General

4.1.1 The audit and reporting process established to assess conformity, including the determination of QMS effectiveness to the 9100-series standards, shall meet the requirements of ISO/IEC 17021-1, as stated in each relevant clause of this standard.

4.1.2 For Integrated Management System (IMS) audits, the requirements of EN 9104-001:2013, 8.5.2 apply.

4.1.3 The audit program and associated activities (see 4.2) shall be followed when auditing and certifying organizations to 9100-series standards in the ASD industry.

4.1.4 The audit process requirements consist of three main parts:

a) the phases of the audit process (see 4.2.1);

b) the common audit activities (see Clause 5) used to support each audit phase;

c) the specific requirements for each audit phase (see Clause 6).

4.2 Audit Program

4.2.1 The audit program consists of the following phases:

a) Pre-audit activities (see 6.2);

b) Stage 1 audit (see 6.3);

c) Stage 2 audit (see 6.4);

d) Surveillance audit (see 6.5);

e) Recertification audit (see 6.6).

4.2.2 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 defined in 6.7.

NOTE 2 The requirements for certification are defined by the 9104-001 standard.