SLOVENSKI STANDARD
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Aeronavtika - Sistemi vodenja kakovosti - 001. del: Zahteve za certificiranje sistemov vodenja kakovosti v letalstvu, vesoljskih dejavnostih in obrambi

Aerospace series - Quality management systems - Part 001: Requirements for Certification of Aviation, Space, and Defense Quality Management Systems

Luft- und Raumfahrt - Qualitätsmanagementsysteme - Teil 001: Anforderungen an Zertifizierungsverfahren für Qualitätsmanagementsysteme der Luftfahrt, Raumfahrt und Verteidigung

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Luft- und Raumfahrt - Qualitätsmanagementsysteme - Teil 001: Anforderungen an Zertifizierungsverfahren für Qualitätsmanagementsysteme der Luftfahrt, Raumfahrt und Verteidigung

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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prEN 9104-001:2022 (E)

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prEN 9104-001:2022 (E)

European foreword

This document (prEN 9104-001:2022) 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 9104-001:2013.

In early 2000, the International Aerospace Quality Group (IAQG) developed the Industry Controlled Other Party (ICOP) scheme to support the certification of Aviation, Space, and Defence (ASD) organization's Aerospace Quality Management System (AQMS). The scheme was built upon the existing International Accreditation Forum (IAF) and International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) requirements for certification of an organization's Quality Management System (QMS).

The ICOP scheme and ISO/IEC requirements have changed over time, this revision incorporates those changes and strengthens the alignment between industry and current IAF requirements. Furthermore, this standard was revised to align with the latest revisions to the other ICOP scheme requirements documents.

Introduction

To ensure customer satisfaction, ASD organizations have to provide, and continually improve, safe and reliable products and services that meet or exceed customer and applicable statutory and regulatory requirements. The globalization of the industry and the resulting diversity of regional and national requirements and expectations have complicated this objective. Organizations have the challenge of purchasing products and services from external providers throughout the world and at all levels of the supply chain. External providers have the challenge of delivering products and services to multiple customers having varying quality requirements and expectations.

Industry established the IAQG, with representatives from 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 standard has been prepared by the IAQG.

The IAQG develops documents that standardize QMS requirements to the greatest extent possible and can be used at all levels of the supply chain by organizations around the world. Their use should result in improved quality, cost, and delivery performance through the reduction or elimination of organization-unique requirements, effective implementation of the QMS, and wider application of good practices. While primarily developed for the ASD industry, these EN 9100-series standards (i.e. EN 9100, EN 9110, and EN 9120) can also be used in other industry sectors when a QMS with supplemental requirements, beyond an EN ISO 9001 system, is needed.

Subsequently, the IAQG developed a global scheme for the acceptance and recognition of certification of an organization's AQMS performed by Certification Bodies (CBs), using the EN 9100-series standards, and taking into account the existing schemes for QMS certification. The scheme relies on:

- the use of CBs with specific ASD elements and requirements, under the guidance and oversight of the ASD industry; and

- the use of a harmonized approach with the CBs for improving the quality and process control throughout the entire supply chain.

This document defines the scheme requirements for managing AQMS certification (commonly referred to as the 'ICOP scheme'). Other standards in this series (i.e. EN 9104-002, EN 9104-003) provide specific requirements for defining the industry oversight process, and the AQMS requirements for ASD auditor training, development, competence, and authentication, respectively. The three ICOP scheme requirements documents are:

- EN 9104-001, *Aerospace series — Quality Management Systems — Part 001: Requirements for Certification of Aviation, Space, and Defence*;

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

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

In this document, the following terms are used:

- "shall" indicates a requirement;

- "should" indicates a recommendation;

- "may" indicates a permission;

- "can" indicates a possibility or capability;

- "annual" or "annually" indicates a 12-month period beginning January 1st and ending December 31st; and

- "days" are calendar days, unless otherwise specified.

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

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1 Scope

This document defines the industry-accepted requirements for the ICOP scheme, which provides confidence to ASD customers, that organizations with certification of their QMS, issued by accredited CBs, meet applicable AQMS standard requirements. The requirements in this document are applicable to all participants in the ICOP scheme. If there is a conflict between the requirements of this document, and customer or applicable statutory/regulatory requirements, the latter has to take precedence.

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,[1] *Quality Management Systems — Requirements for Aviation, Space, and Defense Organizations*

EN 9101[1], *Quality Management Systems — Audit Requirements for Aviation, Space, and Defence Organisations*

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

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

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

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

EN ISO 9000, *Quality management systems - Fundamentals and vocabulary (ISO 9000)*

EN ISO 9001, *Quality management systems - Requirements (ISO 9001)*

EN ISO 19011, *Guidelines for auditing management systems (ISO 19011)*

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

EN ISO/IEC 17011, *Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies (ISO/IEC 17011)*

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

IAF MD 1, *IAF Mandatory Document for the Audit and Certification of a Management System Operated by a Multi-Site Organization*

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

IAF MD 4, *IAF Mandatory Document for the Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes*

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[1] As developed under the auspices of the IAQG and published by various standards bodies [e.g., 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)].

IAF MD 5, *IAF Mandatory Document — Determination of Audit Time of Quality, Environmental, and Occupational Health & Safety Management Systems*

IAF MD 11, *IAF Mandatory Document for the Application of ISO/IEC 17021 for Audits of Integrated Management Systems*

IAF ML 4, *IAF Multilateral Recognition Arrangements — Policies and Procedures for a MLA on the Level of Single Accreditation Bodies and on the Level of Regional Accreditation Groups*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN ISO 9000, EN ISO/IEC 17000, the IAQG International Dictionary (located on the IAQG website www.iaqg.org) and the following apply.

NOTE   An acronym log for this document is presented in Annex A.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at https://www.iso.org/obp

- IEC Electropedia: available at https://www.electropedia.org/

3.1
Aerospace Quality Management System
AQMS
QMS based upon EN ISO 9001 that includes additional ASD requirements, as established in EN 9100, EN 9110, and EN 9120 standards

3.2
Aerospace Quality Management System (AQMS) Auditor
person with the demonstrated attributes (i.e., training, audit experience, industry experience) and competence to conduct an audit on ASD organizations. An AQMS auditor is either an Authenticated Experienced Auditor (AEA) or an Authenticated Auditor (AA), and shall have met the requirements set forth in EN 9104-003

3.3
Industry Controlled Other Party (ICOP) Scheme
IAQG and industry managed scheme for the audit and certification of an organization's AQMS by accredited other party CBs, in accordance with the requirements defined in the EN 9104-series standards

3.4
International Aerospace Quality Group
IAQG
non-profit global association comprised of member companies from the ASD industries, whose mission is to achieve significant performance improvements world-wide in terms of quality, delivery, and cost, through the development and deployment of standards, industry oversight, and guidance materials for use at all levels of the global supply chain

3.5
International Aerospace Quality Group (IAQG) Other Party Management Team (OPMT)
organization comprised of member companies within the ASD industries who design, develop, manufacture, and support original equipment at system or subsystem levels; established by the IAQG to manage the ICOP scheme

3.6
International Aerospace Quality Group (IAQG) Sector
sub-structure of the IAQG that consists of members in a specific geographic area (i.e., Americas, Europe, Asia/Pacific)

3.7
Online Aerospace Supplier Information System (OASIS™) Database
web-based IAQG application containing information on participating National Aerospace Industry Associations (NAIAs), Accreditation Bodies (ABs), Training Provider Approval Bodies (TPABs), Auditor Authentication Bodies (AABs), accredited CBs, AQMS auditors, certified organizations, and audits, which are approved and recognized by the Sector Management Structure (SMS) through the ICOP scheme

3.8
Organization Certification Analysis Process
OCAP
interactive process between the organization and CB to determine the organization's AQMS scope and associated certification audit program, and conduct a risk assessment for certification within the ICOP scheme

3.9
Performance Based Surveillance/Recertification Process
PBS/RP
ICOP scheme AQMS surveillance and recertification optional process based on objective evidence and demonstration that a certified organization continually maintains a conforming, effective, and high performing AQMS

3.10
Regional Management Structure
RMS
committee within a SMS that operates at the regional level, responsible for EN 9104-series standards conformance in their respective regions. They perform the same functions as the SMS, under control of the SMS within their sector

3.11
Sector Management Structure
SMS
committee established in an IAQG sector that manages the application and oversight of the ICOP scheme

Note 1 to entry: Each sector may use a different name for this organization.

3.12
Training Provider Approval Body
TPAB
body approved by the SMS or RMS that has the primary responsibility to conduct the review and approval of training courses and Training Providers (TPs)

4 Principles

4.1 The ICOP scheme (see Annex B) is globally recognized, and includes AQMS certifications, auditor authentications, and the bodies and entities approved in accordance with the EN 9104-series of standards (i.e. EN 9104-001, EN 9104-002, and EN 9104-003) and all published resolutions.

4.2 The IAQG has established the IAQG Other Party Management Team (OPMT) to act as the scheme owner that develops, implements, maintains, and improves the requirements of the ICOP scheme.

4.3   The IAQG OPMT is supported by a SMS for each sector (i.e. Americas, Europe, Asia-Pacific).

4.4   The IAQG has established the OASIS database as the mandated repository for ICOP scheme certification data.

4.5   The OASIS database supports the collection, issuance, and management of feedback between various stakeholders in the ICOP scheme, as depicted in Annex C.

a)   OASIS database users can provide feedback to ICOP scheme stakeholders (e.g. CBs, ABs, IAQG Leadership, Document Representatives).

b)   Feedback can include ICOP scheme information, complaints, questions, or suggestions users have with respect to:

- management of the ICOP scheme;

- AQMS certificates;

- AQMS audit data;

- certified organization performance;

- clarification of standards; or

- support needed.

4.6   The ICOP scheme participants identified within the OASIS database have demonstrated their initial and continuing conformance to the applicable requirements.

a)   The OASIS database identifies the status of ICOP scheme participants.

b)   ICOP scheme entities that are suspended are at risk and their status is temporarily invalid.

c)   ICOP scheme participants that are expired, withdrawn, or deleted are no longer in conformance with the scheme requirements.

5   General requirements

5.1 Policy and ethics

5.1.1   IAQG member company representatives and other ICOP scheme participants shall be in compliance with local and national laws and anti-trust regulations.

5.1.2   All participants in the IAQG ICOP scheme shall report conduct that adversely affects the integrity of the scheme to the appropriate entity(ies).

5.1.3   When an AB, CB, SMS, or Regional Management Structure (RMS) representative encounters an AQMS auditor misconduct issue, they shall share relevant documented information detailing the misconduct with the AAB responsible for the subject auditor's AQMS authentication.

5.2 Oversight

5.2.1   The ICOP scheme oversight process and associated activities, including the management and performance of oversight, shall be in accordance with the requirements defined in EN 9104-002.

5.2.2 Entities participating in the ICOP scheme shall agree to EN 9104-002 oversight by the IAQG OPMT and the applicable SMS or RMS.

5.2.3 Complaints generated from the ICOP scheme shall be directed to the entity of the complaint. If not resolved, the complaint may be escalated in accordance with Table 1.

Escalated complaints should focus on process issues and not process decisions.

Table 1 — Complaint resolution escalation

If complaint is against the:	Certified Organization	Auditor	Assessor	AB	CB	RMS	SMS
The issue shall be communicated to the:	CB	CB	Assessor's Organization	SMS or RMS	AB	SMS	IAQG OPMT

5.3 Documented information

5.3.1 Documented information and data in the form of audit reports, nonconformities, checklists, or other company specific information, generated by the application of this standard, shall be considered confidential (also referred to as proprietary or sensitive) between the parties generating, collecting, or using the data; and be managed as such, except as required by law.

a) Organizations using this information shall keep it confidential (both internally and externally), unless otherwise agreed by the consenting parties.

b) IAQG OPMT ICOP scheme participants shall not be provided with access to records of their competitors.

NOTE   Documented information retained by ABs and CBs on certified organizations may be subject to an audit or review, at any time, by applicable ABs, SMS, RMS, government, or regulatory authorities.

5.3.2 Access to documented information required by the ICOP scheme, shall be available to the IAQG OPMT, SMS, or RMS (if applicable) for evaluating operation of the scheme and conformance with this standard.

5.3.3 Records demonstrating conformance to the ICOP scheme requirements of the EN 9104-series standards shall be retained by the originator for a minimum period of ten years.

6   Requirements for Industry Controlled Other Party Scheme management structure

6.1 General requirements

6.1.1 The IAQG SMS may be supported by a RMS. When established, a RMS shall operate as a part of the SMS, performing the same functions on a regional level.

6.1.2 The IAQG OPMT, SMS, and RMS (if applicable) shall be in conformance with IAQG published policies and Operating Management System (OMS) written rules and procedures that pertain to the ICOP scheme.

6.2 Structure and resource requirements

6.2.1   The IAQG OPMT shall be composed of the following:

a)   three IAQG member company representatives with voting rights, which are members of and appointed by each SMS;

b)   alternate voting members from IAQG member companies, appointed by each SMS, to ensure full representation at all meetings or votes; and

c)   other non-voting stakeholder representatives that may include sector AB representatives, sector CB representatives, regulatory authorities, IAF representatives, IAQG sector member companies, IAQG strategy streams representatives, and other invited organizations or persons (as necessary) to support the operations of the IAQG OPMT.

6.2.2   All IAQG OPMT, SMS, or RMS voting, alternate members, non-voting stakeholder representatives and observers shall have completed an IAQG confidentiality agreement and conflict of interest declaration.

6.2.3   IAQG OPMT, SMS, or RMS members that have an employment relationship (direct or contractual) with an ICOP scheme recognized CB are prohibited from being an ICOP scheme voting member.

6.2.4   Each SMS and RMS (if applicable) shall be composed of the following:

a)   representatives from the IAQG sector member companies or RMS, as voting members; and

b)   other non-voting stakeholders that may include representatives from ABs, CBs, AABs, TPABs, interested parties (e.g. regulatory, customer, governmental agencies), and other invited organizations or persons, as necessary, to support the operations of the SMS.

6.2.5   At least one annual meeting shall be held by the IAQG OPMT, each sector SMS, and each RMS (if applicable). Meetings may be open to all stakeholders (per the stated agenda), or restricted to voting members and invited members for industry-specified topics.

6.3 Operational process requirements for the Other Party Management Team, Sector Management Structure, and Regional Management Structure

6.3.1   The IAQG OPMT shall develop and implement processes to:

a)   develop, implement, maintain, and improve the requirements of the ICOP scheme;

b)   operate an effective oversight program in accordance with EN 9104-002 standard requirements, including the oversight of each SMS;

c)   establish resolutions for the interpretation, clarification, and changes to the ICOP scheme requirements;

d)   define SMS reporting requirements;

e)   conduct reviews of ICOP scheme activities to identify lessons learned, improvement opportunities, and manage risks;

f)   review and respond to any issues, queries, or feedback from ICOP scheme stakeholders;

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NOTE   The IAQG OPMT may establish alleviations for extraordinary events in accordance with guidance defined in IAF ID 3.

g) resolve appeals and complaints directed or elevated to the IAQG OPMT; and

h) elevate complaints which cannot be resolved by the IAQG OPMT to the IAQG Executive Committee for final disposition.

6.3.2   The SMS shall develop and implement processes to:

a) ensure conformity to the requirements of this standard in their sector;

b) report the status and activities of the SMS to the IAQG OPMT in accordance with IAQG OPMT requirements; and

c) determine if one or more RMS is needed as part of the SMS, including defining the geographic area of each RMS utilized.

6.3.3   When one or more RMS are determined to be needed, there shall be:

a) a definition of the structure and interface established between the SMS and RMS;

b) an approval of any RMS operating within the SMS in accordance with applicable requirements; and

c) an acceptance of the voluntary suspension or withdrawal of a RMS.

6.3.4   Each SMS or RMS shall develop and implement processes to:

a) approve an applicant AB, AAB, or TPAB in accordance with applicable requirements;

b) suspend or withdraw the approval of an AB, AAB, or TPAB;

c) recommend the suspension or withdrawal of:

   1) a CB that is accredited for the ICOP scheme by an AB;

   2) an AQMS auditor authenticated by an AAB;

   3) a TP or training course approved by a TPAB; or

   4) an organization certified for an AQMS standard by a CB operating in the ICOP scheme;

d) review and recognize AB accreditation decisions (i.e. accreditation, extensions of AQMS scope, suspension, or withdrawal);

e) recognize the authentication of AQMS auditors, and approval of TPs and training courses in the SMS or RMS;

f) ensure the status (i.e. approved, suspended, expired, or withdrawn) of the participating entities is correctly recorded in the OASIS database within 10 days of the status change;

g) operate an effective oversight program in accordance with EN 9104-002 standard requirements;

h) manage appeals and complaints directed to either the RMS or SMS; and