



SLOVENSKI STANDARD
oSIST prEN 9104-002:2022
01-januar-2022

Aeronavtika - Sistemi vodenja kakovosti - 2. del: Zahteve za nadzor programov certificiranja sistemov vodenja kakovosti v letalstvu, pri vesoljskih dejavnostih in obrambi

Aerospace series - Quality management systems - Part 2: Requirements for the Oversight of Aviation, Space, and Defense Quality Management System Certification Programs

Luft- und Raumfahrt - Qualitätsmanagementsysteme - Teil 2: Ergänzendes Element
(standards.iteh.ai)

Série aérospatiale - Systèmes de management de la qualité - Partie 2 :Exigences relatives à la supervision des programmes de certification des systèmes de management de la qualité de l'aéronautique, l'espace et la défense

Ta slovenski standard je istoveten z: prEN 9104-002

ICS:

03.100.70	Sistemi vodenja	Management systems
03.120.10	Vodenje in zagotavljanje kakovosti	Quality management and quality assurance
49.020	Letala in vesoljska vozila na splošno	Aircraft and space vehicles in general

oSIST prEN 9104-002:2022 **en,fr,de**

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

DRAFT
prEN 9104-002

November 2021

ICS

Will supersede EN 9104-002:2016

English Version

**Aerospace series - Quality management systems - Part 2:
Requirements for the Oversight of Aviation, Space, and
Defense Quality Management System Certification
Programs**

Série aérospatiale - Systèmes de management de la
qualité - Partie 2 :Exigences relatives à la supervision
des programmes de certification des systèmes de
management de la qualité de l'aéronautique, l'espace et
la défense

Luft- und Raumfahrt - Qualitätsmanagementsysteme -
Teil 2: Ergänzendes Element

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.

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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 9104-002:2021) has been prepared by the Aerospace and Defence Industries Association of Europe — Standardization (ASD-STAN).

This document will supersede EN 9104-002:2016.

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.

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Introduction

Industry established the IAQG, with representatives from ASD companies in the Americas, Asia-Pacific, and European sectors, 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 to define an oversight process that monitors and reviews the ICOP certification scheme deployment and ensures conformance to established ASD industry 9104-series requirements for accreditation and AQMS certification. This standard also provides a means of initial and ongoing evaluation of participating other parties e.g. Certification Bodies (CBs), for IAQG members and other approved organizations that utilize ASD authorities' recognition of the ICOP scheme as part of the requirements for supplier, vendor, and/or subcontractor control.

This document provides requirements for an oversight process based on:

- the establishment of harmonized risk-based oversight processes at the international level and within all three global sectors (i.e. Americas, Asia-Pacific, and Europe);
- the shared review and assessment of ICOP certification scheme participants including Sector Management Structures (SMSs), Regional Management Structures (RMSs), Accreditation Bodies (ABs), CBs, Auditor Authentication Bodies (AABs), and Training Provider Approval Bodies (TPABs);
- the use of qualified and approved Other Party (OP) Assessors;
- the use of common assessment tools; and
- the reporting and review of oversight results.

In this standard, the following terms are used:

- “shall” indicates a requirement;
- “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.

The term “e.g.” indicate suggestions given for guidance, and information marked “NOTE” is for guidance in understanding or clarifying the associated requirement.

Rationale

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 ICOP certification scheme was built upon the existing International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) and International Accreditation Forum (IAF) requirements for the accredited certification of an organization's Quality Management System (QMS).

This standard has been revised to align with the latest revisions of the IAQG 9104-1 and 9104-3 standards; the EN ISO/IEC 17000, 17011, and 17021-1 standards; and to incorporate lessons learned from past oversight activities, including feedback from interested parties.

1 Scope

This document defines the ICOP certification scheme risk-based, shared, oversight process applicable to the IAQG and associated sectors for managing oversight of the ASD industry established requirements contained in 9104-series standards (i.e. 9104-1, 9104-2, 9104-3). The oversight process provides objective evidence of conformance to the 9104-series standards and the associated requirements for accreditation and AQMS certification. If there is a conflict between the requirements of this document and applicable statutory or regulatory requirements, the latter takes 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 9104-1, Aerospace series — Quality management systems — Part 1: Requirements for Aviation, Space, and Defence Quality Management System Certification Programs 1)

EN 9104-3, Aerospace series — Quality management systems — Part 3: Requirements for Aviation, Space, and Defence Auditor Training, Development, Competence, and Authentication 1)

3 Terms and definitions

For the purposes of this document, the terms and definitions in EN 9104-1, EN 9101, the IAQG International Dictionary (located on the IAQG website), and the following apply.

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/>

NOTE 1 An acronym log for this standard is presented in Annex A.

NOTE 2 see also the terms and definitions listed in EN ISO 9000, EN ISO/IEC 17000 and EN ISO/IEC 17021-1

3.1

activity review

oversight assessment activity, applicable to entities participating in the ICOP scheme determined to be of low or medium risk that is focused on harmonization and improvement. This includes a review of an internal or self-assessment against applicable requirements, and successes, opportunities, failures, and threats

3.2

file review

review of the documented information pertaining to a given accreditation, certification, authentication, or approval file, against applicable standards, requirements, and entity procedures to evaluate the conformance and effectiveness of their deployed processes

3.3

joint team assessment

office or witness assessment of a CB conducted in accordance with the requirements of this standard by a team comprised of AB and OP Assessors

Note 1 to entry: observers may attend joint team assessments.

prEN 9104-002:2021 (E)**3.4****observation**

statement, comment, or remark raised to an assessed entity based on something that was observed, heard, or noticed during an oversight assessment

3.5**office assessment**

oversight assessment of the management office of an entity participating in the ICOP scheme to applicable requirements using the evaluation tools and methods defined in the 9104-series standards

3.6**Opportunity for Improvement****OPI**

identified harmonization, improvement, or clarification opportunity agreed between an OP Assessor and the assessed entity that needs to be addressed within a defined timeframe

3.7**Other Party (OP) Assessor**

full-time employee (not a contractor or retired staff member) from either an IAQG member company or National Aerospace Industry Association (NAIA) member company actively participating in the ICOP scheme oversight process

Note 1 to entry: an OP Assessor may be categorized as an OP Assessor or an Experienced OP Assessor based on their level of experience and training.

3.8**oversight assessment**

systematic process to assess the conformance to applicable requirements of an entity participating in the ICOP scheme, based on applicable requirements. The following are types of oversight assessment activities:

- activity review;
- office assessment;
- witness assessment;
- post-audit assessment;
- file review;
- market surveillance (reference IAF ID 4)

3.9**post-audit assessment**

technical review of a published audit report that includes an interview with the audit team leader and the audit team. The objective being to assess the conformance and effectiveness of the deployed audit processes and associated procedures to the applicable requirements

3.10**shared oversight**

IAQG Other Party Management Team (OPMT) managed process that assures conformance and global harmonization of the ICOP scheme across all IAQG sectors. Shared oversight includes assessments of approved, accredited, and authenticated stakeholders and prevents duplication of effort and allows IAQG member companies to share results

3.11**supplemental oversight**

additional oversight activity conducted by IAQG member companies in accordance with this standard, using qualified OP Assessors that does not duplicate SMS or RMS shared oversight activities

Note 1 to entry: supplemental oversight may be used to address supply chain risk or increase IAQG member company confidence in the ICOP scheme effectiveness.

3.12**witness assessment**

oversight assessment that includes observation of an AB or CB conducting an assessment or AQMS certification audit

4 General

4.1 Requirements for the oversight of the IAQG ICOP certification scheme are contained within this standard.

4.2 Documented information (e.g. guidance documents) to support the conduct and reporting of oversight assessments shall be provided by the IAQG through the IAQG website and Online Aerospace Supplier Information System (OASIS) database. <https://standards.iteh.ai/catalog/standards/sist/8803ea02-0132-4bf2-b07d-67788726-9104-002-2022>

4.3 The IAQG OPMT, SMS, or RMS may revise oversight assessment activities in response to identified risks, opportunities, and significant changes, including items such as an extraordinary event or circumstance (reference IAF ID 3).

4.4 Any IAQG member company wishing to recognize AQMS certification shall participate in shared oversight assessment activities and provide resources to support the ICOP scheme.

5 Resource requirements**5.1 General**

5.1.1 OP Assessors shall ensure they have the training, experience, and competence required by this standard.

5.1.2 OP Assessors shall complete the appropriate IAQG declaration to document fulfilment of the OP Assessor competence requirements.

5.1.3 OP Assessors shall be approved by their respective employers in accordance with the requirements of this standard. Approval includes:

- a. the authorization and allocation of appropriate resources (e.g. training, budget, time);
- b. the necessary tools (e.g. published standards, computer equipment, access to applicable IAQG data) to allow effective participation;

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c. documentation within the appropriate IAQG declaration.

5.1.4 When OP Assessors are employed by an NAIA member company, the respective SMS or RMS Oversight Chair shall review, and when approved, document the approval within the appropriate IAQG declaration.

5.1.5 An approved OP Assessor shall be eligible to conduct office assessments, activity reviews, and file reviews. An approved Experienced OP Assessor shall be eligible to conduct all type of oversight assessments including AQMS witness, post audit reviews, and AQMS market surveillance assessments.

5.1.6 OP Assessors and their employing organization shall retain documented information to support the qualification and approval of OP Assessors, in accordance with the requirements of this standard. Retained documented information supporting qualification and approval shall be made available to the respective SMS, RMS, and the IAQG OPMT, upon request or for the purposes of oversight.

5.2 Other Party Assessor competence

5.2.1 OP Assessors shall be categorized as follows:

- a. OP Assessors;
- b. experienced OP Assessors.

5.2.2 OP Assessors and experienced assessors shall have knowledge of the ICOP scheme (i.e. EN 9104-series standards requirements, relevant AQMS and ISO standards, applicable IAF documents, IAQG OPMT resolutions) sufficient to be able to effectively assess conformity.

NOTE Table 1 provides a summary of the qualification requirements for becoming an OP Assessor.

<https://standards.iteh.ai/catalog/standards/sist/8803ea02-0132-4bf2-b07d-1906676d6268/pr-en-9104-002-2022>
Table 1 — Other Party Assessor competence summary

Element	OP Assessor	Experienced OP Assessor
Baseline Knowledge	Knowledge of the ICOP scheme	
Work Experience	Evidence of two years ASD knowledge and work experience	Evidence of four years ASD knowledge and work experience that includes an understanding of the processes and controls needed for conformance to the applicable AQMS standard
Audit Experience	Conducted at least three QMS audits (1st, 2nd, or 3rd party) or OP assessments for a minimum of nine assessment days within the last three years	Conducted at least three AQMS audits (1st, 2nd, or 3rd party) or OP assessments for a minimum of nine assessment days within the last three years
IAQG OPMT Mandated Training	Evidence of successful completion (including examination, as applicable) of any IAQG OPMT mandated OP Assessor training	
Other Training	None required	Evidence of training for each AQMS standard being assessed, and the EN 9101
Continual Professional Development (CPD)	Evidence of 15 h within the last three years related to changes in the ASD industry and ICOP scheme	Evidence of 24 h within the last three years related to changes in the ASD industry and ICOP scheme

5.2.3 OP Assessors shall initially and in each three-year period fulfil ASD knowledge and work experience, auditing, and training requirements as follows:

- a. work Experience: Two years aviation, space, or defence industry work experience.

Work experience shall be full time work experience in the aviation, space, or defence industry for an IAQG or NAIA member company; directly involved in engineering, design, manufacturing, quality, or process control for any of the following types of organizations:

- a major equipment manufacturer or integrator organization that designs, produces, and delivers complete vehicles or systems for ASD applications (e.g. aircraft, ships, submarines, major weapon systems, launchers, spacecraft),
- a direct supplier to a major equipment manufacturer or integrator,
- a prime organization that designs and/or produces a major assembly, major subassembly, or major component of an ASD end item (e.g. cabins, wings, fuselages, propulsion systems, control systems, health monitoring systems, ordnance management systems, radar systems, emergency or backup systems),
- ASD regulatory agency (i.e. a civil, military, or space organization that is a public authority or government agency responsible for exercising autonomous authority over ASD activities in a regulatory or supervisory capacity);

- b. audit experience: have conducted at least three QMS audits (1st, 2nd, or 3rd party) or OP assessments for a minimum of nine assessment days;

- c. training: successful completion of IAQG OPMT mandated OP Assessor training courses;

NOTE 1 Completion of IAQG OPMT mandated training courses is only required once for each identified training course.

- d. Continual Professional Development (CPD): a minimum of 15 hours related to changes in the ASD industry and ICOP scheme.

NOTE 2 Mandated OP Assessor training courses may be used in support of CPD requirements.

5.2.4 Experienced OP Assessors shall initially, and in each three-year period, fulfil ASD knowledge and work experience, auditing, and training requirements as follows:

- a. work experience: a minimum of four years ASD industry work experience (see paragraph 5.2.3.a) that includes an understanding of the processes and controls needed for conformance to the applicable AQMS standard;
- b. auditing experience: have conducted at least three AQMS audits (1st, 2nd, or 3rd party) or OP assessments for a minimum of nine assessment days;
- c. training: successful completion of IAQG OPMT mandated OP Assessor training courses. Evidence of attending training for each AQMS standard being assessed and the EN 9101 standard;
- d. Continual Professional Development (CPD): evidence of a total of 24 hours related to changes in the ASD industry and ICOP scheme.

NOTE Each hour of structured learning activity is equivalent to one CPD hour.