

SLOVENSKI STANDARD SIST EN 9104-002:2016

01-september-2016

Nadomešča:

SIST EN 9104-002:2008

Aeronavtika - Sistemi vodenja kakovosti - 2. del: Zahteve za nadzor postopkov registracije sistemov vodenja kakovosti na področju aeronavtike/Programi certificiranja

Aerospace series - Quality management systems - Part 002: Requirements for Oversight of Aerospace Quality Management System Registration/Certification Programs

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Ta slovenski standard je istoveten z: EN 9104-002:2016

ICS:

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

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EN 9104-002

June 2016

ICS 03.120.10; 49.020

Supersedes EN 9104-002:2008

English Version

Aerospace series - Quality management systems - Part 002: Requirements for Oversight of Aerospace Quality Management System Registration/Certification Programs

Série aérospatiale - Systèmes de management de la qualité - Partie 002: Exigences relatives à la supervision des processus de certification des Systèmes de Management de la qualité dans le domaine aérospatial

Luft- und Raumfahrt - Qualitätsmanagementsysteme -Teil 002: Anforderungen an Überwachung/Kontrolle von Zertifizierungsverfahren für Qualitätsmanagementsysteme der Luft- und Raumfahrt

This European Standard was approved by CEN on 17 December 2015.

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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 9104-002:2016) 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 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 December 2016, and conflicting national standards shall be withdrawn at the latest by December 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 9104-002:2008.

According to the 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. https://standards.itch.ai/catalog/standards/sist/61d28270-562f-427b-9139-

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RATIONALE

After the initial publication of International Aerospace Quality Group (IAQG) standard EN 9104 in 2004, it became evident that a single standard containing all aspects of the Industry Controlled Other Party (ICOP) Aerospace Quality Management System (AQMS) was too complex. It was decided that the standard be broken into three sections:

- EN 9104-001 Requirements for Aviation, Space, and Defence Quality Management System Certification Programs;
- EN 9104-002 Requirements for Oversight of Aerospace Quality Management System Registration/Certification Programs; and
- EN 9104-003 Requirements for Aerospace Auditor Competency and Training Courses.

This document is written to define a robust shared oversight process to ensure conformance to established aviation, space, and defence industry EN 9100-series accreditation/certification requirements. The purpose of this revision is to align with the respective EN 9104-001 and EN 9104-003 standards and incorporate lessons learned from past oversight activities.

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FOREWORD

In December 1998, the aviation, space, and defence industry established the IAQG with the goal of achieving significant improvements in quality and reductions in cost throughout the value stream.

This document details the operating processes of the IAQG Other Party Management Team (OPMT) that monitors and reviews the Aerospace Supplier Quality System Accreditation/Certification Programs of each Sector Management Structure (SMS).

This document provides requirements for a shared oversight process based on the:

- establishment of oversight committees at the international and global sector levels;
- use of joint team assessments;
- use of qualified and approved IAQG member Other Party (OP) assessors;
- use of common assessment tools; and
- reporting of oversight results.

This document addresses the following activities:

- a) Establishment of standard oversight processes in all three global sectors (i.e., Europe, Asia Pacific, and the Americas). The management of these global sector schemes is referred to as SMS.

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- b) Oversight of SMS, Certification Body Management Committees (CBMCs), Accreditation Bodies (ABs), Certification Bodies (CBs), Auditors Authentication Bodies (AABs), Training Provider Approval Bodies (TPABs), and training classes alog/standards/sist/61d28270-562f-427b-9139
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1 Scope

The requirements established in this document are applicable to the IAQG and associated sectors for managing oversight to established requirements contained in EN 9104-series standards (i.e., EN 9104-001, EN 9104-002, EN 9104-003). The requirements are applicable to IAQG working groups for oversight.

NOTE All required forms are depicted in Appendix A. These form exhibits are provided for reference only; the current versions of these forms are available on the IAQG website.

1.1 Purpose

The purpose of this standard is to document the ICOP oversight process and define a robust shared oversight process which provides objective evidence of conformance to established aerospace industry EN 9100-series standards (i.e., EN 9100, EN 9110, EN 9120) requirements and associated accreditation/certification.

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 Organizations (Standards.iteh.ai)

EN 9101 1), Quality Management Systems — Audit Requirements for Aviation, Space, and Defence Organizations — SIST EN 9104-002:2016

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

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

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m EN~9110~^{1}}$), Quality Management Systems — Requirements for Aviation Maintenance Organizations

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

IAQG Operating Procedure 119, "IAQG Forms Management"

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

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

ISO/IEC 17011:2004, Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies

¹⁾ As developed under the auspice of the IAQG and published by various standards bodies [e.g., AeroSpace and Defence Industries Association – 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)].

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

ISO 19011:2011, Guidelines for auditing management systems

IAF ID 4:2012, IAF Informative Document — Market Surveillance Visits to Certified Organizations

IAF MD 1:2007, IAF Mandatory Document for the Certification of Multiple Sites Based on Sampling

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

IAF MD 5:2009, IAF Mandatory Document for Duration of QMS and EMS Audits

IAF MD 10:2013, IAF Mandatory Document for Assessment of Certification Body Management of Competence in Accordance with ISO/IEC 17021:2011

IAF MD 11:2013, IAF Mandatory Document for the Application of ISO/IEC 17021 for Audits of Integrated Management Systems

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3 Terms and definitions

Definitions for general terms can be found in ISO 9000, ISO/IEC 17000, ISO 19011, EN 9104-001, and the IAQG International Dictionary (located on the IAQG website). An acronym log for this document is presented in Appendix B. For the purpose of this standard, the following definitions apply:

3.1

aerospace

the business of design, manufacture, maintenance, distribution, or support of aviation, space, and defence vehicles or engines, accessories, or component parts; and all ancillary and allied businesses, including vehicle maintenance and parts distribution operations

3.2

appeal

request by the provider of the object of conformity assessment to the conformity assessment body or AB for reconsideration by that body of a decision it has made relating to that object (see ISO/IEC 17000). An appeal can be lodged by any entity within the ICOP scheme.

3.3

assessment

a systematic process to assess the competence of an AB or a conformity assessment body (e.g., AB, CB, AAB, TPAB), based on the assessment criteria (see ISO/IEC 17011)

3.4

audit

a systematic, independent, and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled

3.5

complaint

expression of dissatisfaction, other than appeal, by any person or organization to a conformity assessment body or AB, relating to the activities of that body, where a response is expected (see ISO/IEC 17000 and section 9 of this standard). A complaint can be lodged against any entity within the ICOP scheme.

3.6

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

3.7

Industry Controlled Other Party (ICOP)

the AQMS standard certification scheme, under IAQG and industry management, for the assessment and certification of organization quality management systems by other parties, in accordance with the requirements defined in the EN 9104-series standards

3.8

joint team assessment

an oversight assessment conducted in accordance with the requirements of this standard by a team of representatives, which may be comprised of AB assessors, OP assessors, and observers

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nonconformity (also referred to as 'nonconformance')

the non-fulfilment of a <u>requirement</u> that is stated, generally implied, or obligatory (see EN 9101 standard for definitions of major and minor nonconformities)

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3.10

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office assessment 16e399aeba23/sist-en-9104-002-2016

an on-site evaluation of an AB, AAB, or TPAB management office or CB lead office to the applicable requirements using the evaluation tools and methods contained in the EN 9104-series standards

3.11

Other Party (OP) assessor

a full-time employee (not a contractor or retired staff member) from either an IAQG member company or from an National Aerospace Industry Association (NAIA) member company [i.e., Aviation, Space, or Defence Original Equipment Manufacturer (OEM) or direct supplier to an OEM] that is actively participating in the ICOP oversight process, who has been qualified and approved in accordance with this standard, and conducts shared oversight assessment or supplementary IAQG member company oversight activity in accordance with this standard

3.12

shared oversight

the IAQG OPMT managed process that assures conformance and global harmonisation of the ICOP scheme across all IAQG sectors. Shared oversight includes assessments of approved, accredited, and authenticated stakeholders, as defined in the EN 9104-001 standard. Shared oversight prevents duplication of effort and allows IAQG member companies to share results.

3.13

supplemental oversight

additional oversight conducted by IAQG member companies in accordance with this standard, using qualified OP assessors. Supplemental oversight activity does not duplicate SMS or CBMC shared oversight activities. Supplemental oversight may be used to increase IAQG member company confidence in the ICOP scheme effectiveness. Supplemental oversight can also be used to address supply chain risk.

3.14

suspension

temporary invalidation of the statement of conformity for all or part of the specified scope of attestation (see ISO/IEC 17000)

3.15

witness assessment

an evaluation of an assessment or audit team's (e.g., AB, CB) conduct during an on-site assessment or audit to applicable criteria (i.e., requirements defined in AQMS standards and an assessment or audit team's procedures), using the evaluation tools and methods defined in this standard

4 General

- **4.1** ICOP oversight assessment requirements are contained within this standard. Aviation, space, and defence sector accreditation/certification and Training Provider (TP) approval/auditor authentication requirements are contained within the referenced published EN 9104-series standards.
- **4.2** The overall IAQG ICOP oversight process is depicted in the process model contained in Appendix C. This model includes the interrelationship between the processes and associated oversight activities.
- **4.3** The forms and check sheets used for conducting oversight assessments shall be controlled, updated, and maintained by the IAQG OPMT. They shall be made available to all stakeholders via the IAQG website. **iTeh STANDARD PREVIEW**
- **4.4** The forms presented in this standard are for reference only; technically equivalent forms may be developed and utilized to support oversight activities.

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5 Requirements for oversight and assessment personnel

5.1 General

- **5.1.1** OP assessors are responsible for ensuring they have the training, experience, and competence, as required by this standard, and they have been authorized by their employing company. They shall complete Form A, "Other Party (OP) Assessor Industry Controlled Other Party (ICOP) Declaration Form", to confirm fulfilment of the requirements and declare any potential conflicts of interest.
- **5.1.2** OP assessors shall be approved in accordance with this standard by their respective employers or SMS Oversight Chair. They shall verify continued support and provide objective evidence every three years, via submission of a completed declaration form (see Form A). This form shall be submitted to the respective SMS, which shall retain copies of all completed forms.
- **5.1.3** AB assessors shall be competent and qualified, as required by the EN 9104-001 standard. ABs shall ensure that AB assessors receive training as it relates to their roles and responsibilities described in this standard.

5.2 Other party assessor

- **5.2.1** OP assessor conducting oversight assessments shall have knowledge of the ICOP scheme [i.e., knowledge of all parts of the EN 9104-series standards requirements, knowledge of the relevant AQMS and ISO standards, applicable International Accreditation Forum (IAF) documents, and IAQG OPMT resolutions] sufficient to be able to effectively assess conformity.
- **5.2.2** OP assessors shall initially and in each three year period fulfil auditing, training, and work experience requirements as follows:
- a) Auditing experience: have conducted at least three AOMS audits (1st, 2nd or 3rd party) or OP assessments for a minimum of nine assessment days within the last three years.
- b) Work experience: four years aviation, space, or defence industry experience within the prior 10 calendar years.
 - NOTE Work experience to include four years full time in the aviation, space, or defence industry directly involved in engineering, design, manufacturing, quality, or process control for an IAQG member company, OEM, or tier one supplier to an OEM and/or appropriate official civil, military, or space organization, such as National Aviation Authorities (NAAs), European Space Agency (ESA)/National Aeronautics and Space Administration (NASA), Ministry of Defence (MoD), Department of Defence (DoD).
- c) A minimum of 15 hours of continuing education related to changes in the aviation, space, and defence industry and the ICOP scheme within the last three years.
- d) Successful completion of any IAOG OPMT mandated OP assessor training courses.

NOTE The OPMT mandated courses should address the minimum requirements contained in 5.2.3.

- **5.2.3** OP assessor training shall include knowledge of the standards and documents referenced within this standard, including the following documentation:
- EN 9104-series standards (i.e., EN 9104-001, EN 9104-002, EN 9104-003);
- AQMS standards (i.e., EN 9100, EN 9110, EN 9120);
- EN 9101;

- ISO/IEC 17011;
- ISO/IEC 17021;
- IAF mandatory documents (i.e., IAF MD 1, IAF MD 2, IAF MD 3, IAF MD 4, IAF MD 5, IAF MD 10, IAF MD 11); and
- applicable IAQG sector SMS documents or procedures that apply.

5.3 Confidentiality and conflicts of interest

- **5.3.1** All IAQG OPMT, SMS, CBMC members, and OP assessors shall complete the appropriate declaration form (see Forms A and B) for confidentiality and conflicts of interest, prior to membership or assignment. The SMS shall retain copies of all completed forms.
- **5.3.2** These forms shall be provided to any assessed organization (e.g., AB, CB, AAB, TPAB, certified organization), upon request.
- **5.3.3** Auditors, that have an employment relationship with a CB, can be neither OP assessors nor voting members of any IAQG OPMT, SMS, or CBMC committees.
- **5.3.4** Certain data in the form of audit reports, nonconformities, checklists, or other company specific information, generated by the application of this standard, shall be handled as confidential (commonly referred to as proprietary or sensitive) between the parties generating, collecting, or using the data (see EN 9104-001 [section 19]).

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5.3.5 OP assessors shall not disclose the assessed organization's performance data with the assessed organization's clients without written permission (e.g., AB performance to CB or CB performance to certified organization). https://standards.iteh.ai/catalog/standards/sist/61d28270-562f-427b-9139-

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- **5.3.6** Conflicts of interest that shall prevent participation as an OP assessor in an oversight assessment activity shall include:
- a) Employment or engagement by a CB in any role, including participation in a CB's committee for safeguarding impartiality, for any oversight activity.
- b) Employment or engagement by an AB in any role, including participation in an AB's committee for safeguarding impartiality, for any AB oversight activity.
- c) Employment or engagement by an AB (i.e., technical advisor), during an industry shared oversight assessment.
- d) Employment or engagement in any role by an AAB, where the oversight activity is scheduled for an AAB, TPAB, or witnessing an auditor authenticated by the associated AAB.
- e) Auditor authentication or certification by an AAB, where the oversight activity is scheduled for the AAB that has authenticated or certificated the assigned OP assessor.
- f) Employment or engagement in any role by a TPAB, where the oversight activity is scheduled for a TPAB, TP, or AAB.
- g) Employment or engagement in any role by a TP, where the oversight activity is scheduled for a TPAB or TP.
- h) A contractual relationship between the OP assessor's company and the assessed CB organization, where the OP assessor is directly involved in the relationship (e.g., direct interface with CB sales and

audit personnel). The employment or engagement activity shall not have occurred within the last two years.

5.3.7 OP assessors shall declare any perceived potential or actual conflicts of interest, prior to acceptance of an oversight assignment. Potential conflicts of interest shall be recorded on the "Other Party (OP) Assessor Industry Controlled Other Party (ICOP) Declaration Form" (see Form A), as described in Section 10.

Responsibilities

6.1 General

- **6.1.1** The IAQG OPMT, each SMS or CBMC, and participating organizations shall ensure that all participants in oversight are aware of their roles and responsibilities.
- **6.1.2** All participants shall ensure that they have an agreed arrangement with their employing organization, prior to participation in oversight of the ICOP scheme. Such an arrangement shall provide participants with the appropriate authority and resources, including training, budget, and time, to allow effective participation.
- **6.1.3** Oversight assessment team members shall declare any conflicts of interest that may exist for a particular assessment assignment (e.g., OP assessor contracted by AB). Any such conflicts shall be reviewed and resolved between all affected parties, prior to any oversight activity taking place. An update of the completed "Other Party (OP) Assessor Industry Controlled Other Party (ICOP) Declaration Form" (see Form A) may be needed as a result of this activity; eh. ai)

6.2 Oversight assessment team leader SIST EN 9104-002:2016

- https://standards.iteh.ai/catalog/standards/sist/61d28270-562f-427b-9139-**6.2.1** For joint team assessments (AB and OP assessor), a participating AB assessor shall be the oversight assessment team leader. For non-joint team assessments (assessment without an AB assessor), a participating OP assessor shall be the oversight assessment team leader.
- **6.2.2** Prior to the conduct of an oversight assessment, the oversight assessment team leader shall be identified and their role communicated to all affected parties.
- **6.2.3** The oversight assessment team leader shall ensure the oversight activity is accomplished in accordance with the requirements of this standard by:
- a) establishing and documenting assessment objectives:
- b) documenting and communicating an assessment plan for all assessments (except witness assessments) and communicating the plan to all affected parties;
- c) leading the assessment activity;
- d) conducting opening and closing meetings:
- e) documenting the assessment results, generation of assessment reports that include all required forms:
- deciding on the appropriate grading (major or minor, refer to EN 9101 Terms and Definitions) of any nonconformity raised as a result of the assessment:
- deciding on appropriate conclusions for the assessment in line with the assessment objectives set and making related recommendations to the AB, SMS, or CBMC, as appropriate (e.g., follow-up assessments, approval, maintenance, suspension, withdrawal);

- h) containment, correction, and corrective action review and acceptance; and
- i) notification of closure of nonconformities to the assessed organization.
- **6.2.4** Additional responsibilities of the oversight assessment team leader include the following:
- a) Management and resolution of any identified conflicts of interest between all affected parties.
- b) Protection of confidential information obtained during the assessment.
- c) When issues cannot be resolved with the assessed organization or team members, the assessment team leader shall elevate complaints or issues to the AB, CBMC, SMS, or IAQG OPMT, as appropriate, in accordance with complaint resolution process defined in Section 9.

6.3 Other party assessor

- **6.3.1** OP assessors are responsible to ensure they have been authorised and approved by their respective IAQG member company or SMS Oversight Chair, and shall submit an "Other Party (OP) Assessor Industry Controlled Other Party (ICOP) Declaration Form" (see Form A) to the applicable SMS or CBMC, prior to conducting an assessment.
- **6.3.2** The OP assessor and their employing organization shall maintain records to support the qualification of OP assessors, in accordance with the requirements of this standard. Records supporting qualification and approval shall be made available to the respective SMS and/or CBMC, and the IAQG OPMT, upon request for the purposes of oversight.

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6.3.3 OP assessors shall declare any potential or actual conflicts of interest (see 5.3), prior to acceptance of each oversight assignment.

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- **6.3.4** Additional OP assessor responsibilities include the following:
- a) support the assessment team to meet the assessment objectives:
- b) accept and complete assessment assignments from the oversight assessment team leader;
- c) document the assessment results:
- d) generate applicable assessment reports, including all required forms; and
- e) elevate any complaints/issues to the AB, CBMC, SMS, or IAQG OPMT, if needed, in accordance with complaint resolution process defined in Section 9.

6.4 International aerospace quality group other party management team

- **6.4.1** The responsibility of the IAQG OPMT is to manage the EN 9104-series standards application on a global level, including monitoring that each SMS has implemented their sector schemes and is in conformance with EN 9104-series standards requirements. The IAQG OPMT shall appoint an Oversight Chair who shall declare any potential conflicts of interest, prior to acceptance of the assignment.
- **6.4.2** The IAQG OPMT Oversight Chair manages the IAQG OPMT oversight activities; these activities include the following:
- a) communication within the IAOG OPMT and between all global SMSs regarding oversight activities: