

SLOVENSKI STANDARD SIST EN 9104-002:2008

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

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

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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

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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 1 May 2008.

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Foreword

This document (EN 9104-002:2008) 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of an identical text or by endorsement, at the latest by February 2009, and conflicting national standards shall be withdrawn at the latest by February 2009.

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.

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Introduction

This document is written to define a robust shared oversight process to ensure conformance to established aerospace industry 9100-series accreditation/certification requirements.

In December 1998, the Aerospace Industry established the International Aerospace Quality Group (IAQG) with the purpose 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 Schemes 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;
- the use of qualified and approved IAQG member Other Party (OP) assessors;
- the use of common assessment tools;
- the reporting of oversight results h STANDARD PREVIEW

This document addresses the following issues: and ards. iteh.ai)

- a) Establishment of standard oversight processes in all three global sectors (Europe, Asia Pacific and the Americas). The management of these global sector schemes is referred to as SMS. https://standards.iteh.ai/catalog/standards/sist/351dfb24-daba-46e7-81fc-
- b) Oversight of SMS, Certification Body Management Committees (CBMCs), Accreditation Bodies (ABs), Certification Bodies (CBs), Auditor Authentication Bodies (AABs), Training Provider Approval Bodies (TPABs) and training providers.

1 Scope

1.1 General

These requirements are applicable to IAQG global sectors when utilizing Aerospace Industry Controlled Other Party (ICOP) schemes for the assessment and certification of supplier quality systems in accordance with the requirements contained in EN 9104.

IAQG member companies have committed to perform sufficient oversight of the Aerospace accreditation/certification assessment processes in order to ensure conformance to established requirements contained in EN 9104.

NOTE The IAQG OPMT oversight structure is depicted graphically in Annex A.

1.2 Purpose

The purpose of this standard is to document the process for oversight of the 9100-series certification of Aerospace Quality Management Systems (AQMS) program. This process shall be implemented by participating IAQG member companies, ABs, CBs, AABs, TPABs and training providers to ensure consistent conformance with the requirements of EN 9104.

2 Normative references iTeh STANDARD PREVIEW

The following referenced documents are indispensable for the application 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.

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EN 9100, Aerospace series — Quality management systems — Requirements (based on ISO 9001:2000) and Quality systems — Model for quality assurance in design, development, production, installation and servicing (based on ISO 9001:1994)¹⁾

EN 9104:2006, Aerospace series — Quality management systems — Requirements for Aerospace Quality Management System Certification/Registrations Programs¹⁾

EN 9104-003, Aerospace series — Quality management systems — Part 003: Requirements for Aerospace Quality Management System (AQMS) Auditor Training and Qualification^{1) 2)}

EN 9110, Aerospace series — Quality systems — Model for quality assurance applicable to maintenance organizations¹⁾

EN 9120, Aerospace series — Quality management systems — Requirements for stockist distributors (based on ISO 9001:2000)¹⁾

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

EN ISO 9001, Quality management systems — Requirements (ISO 9001:2000)

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

¹⁾ Or the corresponding AAQG standards (e.g. AS, ARP, etc.) or APAQG (e.g. JISQ, SJAC, HB, etc.)

²⁾ In preparation at the date of publication of this standard.

EN ISO/IEC 17021, Conformity assessment — Requirements for bodies providing audit and certification of management systems (ISO/IEC 17021:2006)

EN ISO/IEC 17024:2003, Conformity assessment — General requirements for bodies operating certification of persons (ISO/IEC 17024:2003)

EN ISO 19011:2002, Guidelines for quality and/or environmental management systems auditing (ISO 19011:2002)

IAF, Guidance on the Application of ISO/IEC Guide 61:1996

IAF, Guidance on the Application of ISO/IEC Guide 62:1996

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

accreditation body (AB)

body recognized by an IAQG sector that has the primary responsibility for the accreditation of CBs to issue certifications/registrations to AQMS standards

3.2

aerospace

business of design, manufacture, maintenance, distribution, and support of aviation vehicles and engines, accessories and component parts, all ancillary and allied businesses including aerospace vehicle operations

This also includes Space and Defence.

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aerospace experience auditor (AEA) 3) ced8bfc7cbe9/sist-en-9104-002-2008

auditor that has met the requirements set forth in EN 9104 and EN 9104-003

3.4

auditor authentication body (AAB)

body recognized by an IAQG sector that has the primary responsibility for certifying or approving persons (e.g. auditors) against specific requirements

3.5

other party (OP) assessor

IAQG member representative that has been qualified and approved in accordance with this standard, and supports a joint team assessment or conducts supplementary IAQG member oversight activity in accordance with this standard

3.6

certification body (CB)

body that audits and certifies/registers the conformity of the quality management system of organizations with respect to published AQMS standards and any supplementary documentation required under the system

Also, referred to as Certification Registration Body (CRB).

³⁾ Sectors may use other names for 'Auditor', Aerospace Auditor' and 'Aerospace Experienced Auditor' (AEA) as long as the requirements of EN 9104 are applied.

3.7

certification bodies management committee (CBMC)

organization within an SMS that functions on a national level (e.g. Italy, France, Germany, Spain, UK, Austria); responsible for EN 9104 conformance in their respective countries

They perform the same functions as the SMS under the control of their global SMS.

3.8

international aerospace quality group (IAQG)

body of prime aerospace Original Equipment Manufacturers (OEMs)

This group is chartered to develop and implement common requirements and guidelines for use by the space, aviation and defense industry for quality improvement.

3.9

international aerospace quality group (IAQG) sector or sector

sub-structure of the IAQG, consisting of the members in a specific area, such as Americas, Europe and Asia/Pacific

3.10

joint team assessment

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

3.11

nonconformity iTeh STANDARD PREVIEW

non-fulfilment of a requirement (see EN ISO 9000)

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major: the absence of, or the failure to implement and maintain, one or more requirements which would, on the basis of available objective evidence raise significant doubt as to the credibility of conformance; or a number of minor nonconformities against one or more requirements, which when combined, can represent a breakdown of the system or process. Available 4-daba-46e7-81 ic
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minor: an observed lapse in conformance to a requirement

3.12

office assessment

on-site evaluation of an AB, CB, AAB or TPAB, at the management office, to the applicable aerospace requirements, using the evaluation tools and methods contained in this standard

2 12

sector management structure (SMS)

organization established in a sector that manages the application of the sector scheme based on EN 9104

Each sector may use a different name for this organization, (e.g. Registration Management Committee in the Americas and Asia Pacific, OPMT in Europe within the AeroSpace & Defense Industrires Association of Europe [ASD]).

3.14

training provider

body that has the primary responsibility for providing aerospace training against specific requirements

3.15

training provider approval body (TPAB)

body recognized by the SMS that has the primary responsibility to conduct the review and approval of training course content and training provider administration

3.16

witness assessment

evaluation of an audit team conducting an on-site audit, to the applicable aerospace requirements, using the evaluation tools and methods contained in this standard

4 General

- **4.1** Aerospace ICOP oversight requirements are contained within this standard. Aerospace sector accreditation/certification/auditor authentication requirements are contained within the referenced published standards (e.g. EN 9104). The check sheets contained in this standard (see Annexes B thru H) are provided, as guidance, for conducting oversight assessments. These check sheets may be expanded by the IAQG OPMT or respective SMS to cover additional requirements in their sectors or provide additional clarification, as needed.
- **4.2** Any IAQG member company wishing to recognize AQMS certification shall conduct oversight.
- **4.3** Participating IAQG member companies shall provide the necessary resources to support the SMS committees and oversight activities.
- **4.4** Industry auditors that have an employment relationship with a CB, can be neither OP assessors nor voting members of SMS committees.
- **4.5** The IAQG OPMT and each global SMS shall annually conduct a review and evaluation of the scheme to ensure its continued effectiveness. The evaluation shall include review and analysis of the following:
- Data reported by participants in this process (i.e. IAQG member, AB, CB).
- b) IAQG On-line Aerospace Supplier Information System (OASIS) database information (e.g. number of findings, breakdown of findings based on majors vs. minors):2008
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- International Accreditation Forum (IAF) peer review activity on the ABs in each sector.
- d) Complaints (i.e. AB, CB, SMS, IAQG member).
- e) Assessment activity conducted by SMS recognized ABs at accredited CBs.
- f) Joint team assessment oversight activities conducted by the SMS, which include:
 - On-site office assessments of ABs.
 - On-site office assessments of CBs.
 - On-site witness assessments of AB/CB at client's facilities.
 - On-site office assessments of AABs.
 - On-site office assessments of TPABs.
 - Approval of training courses, when required.

- **4.6** Each AB shall report annually to the SMS the following information, for each CB they have accredited:
- date accredited;
- number of AEAs employed/contracted;
- date of last CB office assessment and witness assessment, including type, quantity of major/minor nonconformities, and observations issued.
- **4.7** Each AB shall report annually to the SMS the results of any IAF Peer Evaluations, IAQG member or Regulatory Authority assessments conducted for AB conformance to EN 9104.
- **4.8** The AB shall report CB performance data and/or trends to the voting members of the SMS and designated SMS representatives.
- **4.9** The AB may provide the data above to the SMS during the AB office assessment conducted by the SMS.

5 Requirements for participating international aerospace quality group member companies

5.1 Other party assessor

- **5.1.1** IAQG member companies shall ensure that assigned representatives who support IAQG OPMT and/or SMS activities have the necessary tools (e.g. published standards, computer equipment) and resources to accomplish committed tasks.
- **5.1.2** IAQG member companies shall ensure that their designated OP assessors are qualified in accordance with this standard and they shall provide objective evidence of such every three years, via submission of a completed declaration form (see Annex I) to the respective SMS.

5.1.3 IAQG member companies shall ensure that only qualified individuals are assigned to conduct oversight assessments or participate in joint team assessments supporting the SMS.

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- **5.1.4** Assessor qualification shall include comprehensive training on the following:
- EN 9104.
- EN 9104-002.
- EN 9104-003.
- AQMS standards (e.g. EN 9100, EN 9110, EN 9120).
- EN ISO 19011.
- ISO/IEC Guide 61 (Superseded by EN ISO 17011 on January 01, 2006).
- IAF Guidance on the Application of ISO/IEC Guide 61:1996.
- ISO/IEC Guide 62 (Superseded by EN ISO 17021 on August 01, 2006).
- IAF Guidance on the Application of ISO/IEC Guide 62:1996.
- Conflict of interest and confidentiality requirements.
- Complaint resolution process.
- Any applicable global sector SMS documents that apply (e.g. AS9014).

- **5.1.5** OP Assessors shall, as a minimum, meet the education and training requirements of EN ISO 19011 and continually meet the following requirements:
- Auditing Experience: to have conducted at least three AQMS audits or OP assessments for a minimum of nine assessment days, within the last three years.
- NOTE 1 Joint team assessments and/or oversight assessments may be considered for meeting the above audit criteria.
- b) Work Experience: four years aerospace industry experience within the prior ten calendar years.
- NOTE 2 Work experience to include four years full time in the aerospace industry directly involved in Engineering, Design, Manufacturing, Quality or Process Control for a major airframe manufacturer, prime supplier, auxiliary equipment supplier and/or appropriate official civil, military or space organization, such as National Aviation Authorities (NAA), European Space Agency (ESA)/National Aeronautics and Space Administration (NASA), Ministry of Defense (MoD), Department of Defense (DoD).

5.2 Supplemental international aerospace quality group member oversight

IAQG member companies may conduct additional oversight, above the minimum EN 9104-002 requirements and outside the SMS shared oversight schedule.

- a) This oversight activity must not be a duplication of SMS activity, but may be linked to IAQG member analysis of internal ICOP recognition activity (e.g. number of CB clients, complaints, number of auditors).
- b) IAQG members shall ensure that only qualified OP assessors are assigned to conduct supplemental oversight assessments. **Teh STANDARD PREVIEW**
- c) The oversight activity must be scheduled and coordinated with all affected parties in advance of assessment conduct.
- d) When applicable, the oversight assessment tools contained in this standard shall be used.
- e) Any nonconformity identified shall be recorded on an Oversight Nonconformity Record (see Annex J) and resolved in accordance with the complaint process defined in this standard.
- f) IAQG member companies shall maintain records of supplemental oversight.
- g) Supplemental IAQG member oversight activities shall be summarized and reported to the member's global SMS on an annual basis.

NOTE The intent of supplemental oversight is not to duplicate SMS activities, but to ensure that if an IAQG member company conducts ICOP oversight that it shall be accomplished using trained OP assessors and the tools contained within this standard shall be utilized.

6 Requirements for international aerospace quality group other party management team

6.1 Responsibilities of the other party management team

- **6.1.1** The IAQG OPMT is the committee responsible for managing EN 9104 application on a global level.
- **6.1.2** Monitor that each SMS is implementing their sector schemes and is in conformance with EN 9104.
- **6.1.3** Provide a mechanism for a periodic review of the lessons learned by each of the sector schemes and a review of any proposed changes.
- **6.1.4** Ensure that the OASIS database operates effectively and is accessible to the IAQG members.

6.2 Other party management team actions required to fulfil the responsibilities defined in EN 9104

- **6.2.1** Review regular status reports from each SMS.
- **6.2.2** Perform a review of the operation and conformance of each sector scheme at least once every two years.
- **6.2.3** Monitor feedback from IAQG members, CBs, and suppliers regarding overall process performance.
- **6.2.4** Review the operation of the OASIS database.
- **6.2.5** Review SMS procedures and processes.

6.3 Oversight of the on-line aerospace supplier information system database

- **6.3.1** The IAQG OPMT shall conduct an annual oversight assessment of the operation, maintenance, and configuration control of the OASIS database. The assessment shall be accomplished utilizing the OASIS Management Assessment Check Sheet as guidance (see Annex B). The assessment may be performed at the SAE office.
- **6.3.2** The results of the assessment shall be recorded on an Oversight Assessment Summary Report (see Annex K).
- **6.3.3** Any nonconformity identified during the assessment, shall be recorded on an Oversight Nonconformity Record (see Annex J).
- 6.3.4 The review of database operations shall include:
- Reviewing SAE operating procedure for the OASIS database.
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- Reviewing reports from the database administrator of any input rejections.
- Checking that each SMS has a process of assuring the accuracy of data being generated and maintained in their sector.
- Monitoring feedback from IAQG members, ABs, CBs, and suppliers regarding the effectiveness and accessibility of the database.
- Reviewing backup data and security processes.
- Reviewing the financial health condition of the OASIS database.

6.4 Oversight of sector management structure

- **6.4.1** The IAQG OPMT shall conduct an oversight assessment of the operation of each SMS. The assessment shall be accomplished utilizing the SMS Assessment Check Sheet, as guidance (see Annex C).
- **6.4.2** The IAQG OPMT shall conduct assessments of the host SMS operation during face to face meetings held in that SMS's global sector.
- **6.4.3** The results of the assessment shall be recorded on an Oversight Assessment Summary Report (see Annex K).
- **6.4.4** Any nonconformity identified, during the assessment, shall be recorded on an Oversight Nonconformity Record (see Annex J).