



SLOVENSKI STANDARD

SIST EN 9104:2009

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Aeronavtika - Sistemi vodenja kakovosti - Zahteve za postopke certificiranja sistemov vodenja kakovosti na področju aeronavtike/Programi registracije

Aerospace series - Quality management systems - Requirements for Aerospace Quality Management System Certification/Registrations Programs

Luft- und Raumfahrt - Qualitätsmanagementsysteme - Anforderungen an Zertifizierungsverfahren für Qualitätsmanagementsysteme der Luft- und Raumfahrt

Série aérospatiale - Systèmes de management de la qualité - Exigences applicables aux processus de certification des Systèmes de Management de la Qualité dans le domaine aérospatial

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 9104

April 2006

ICS 03.120.10; 49.020

English Version

**Aerospace series - Quality management systems -
Requirements for Aerospace Quality Management System
Certification/Registrations Programs**

Série aérospatiale - Systèmes de management de la
qualité - Exigences applicables aux processus de
certification des Systèmes de Management de la Qualité
dans le domaine aérospatial

Luft- und Raumfahrt - Qualitätsmanagementsysteme -
Anforderungen an Zertifizierungsverfahren für
Qualitätsmanagementsysteme der Luft- und Raumfahrt

This European Standard was approved by CEN on 3 February 2006.

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. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.



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Foreword

This European Standard (EN 9104:2006) has been prepared by the European Association of Aerospace Manufacturers - Standardization (AECMA-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 AECMA, 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 October 2006, and conflicting national standards shall be withdrawn at the latest by October 2006.

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.

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.

The IAQG has developed specific requirements for quality systems that are to be implemented and maintained throughout the supply chain in the design, manufacture and maintenance of products used in aviation and space applications. These requirements are published simultaneously as AS/EN/JISQ 9100-series by SAE in the Americas, AECMA in Europe and JISQ in Asia/Pacific. Other countries will follow with technically identical national standards.

In this European Standard, these standards are indicated as Aerospace Quality Management Systems (AQMS) Standards.

A further initiative of the IAQG was the development of a truly global scheme for the use of assessment results performed by Certification/Registration Bodies (CRBs), based on the 9100-series standards and taking into account the schemes already in use or under development in the various IAQG sectors.

All these schemes have two major elements in common:

- Use of a voluntary certification/registration scheme with specific aerospace elements and requirements, under the supervision and control of the aerospace industry.
- A harmonized approach to the CRBs with the purpose to improve the quality level and control throughout the whole supply chain.

This European Standard provides requirements for sectorial/regional schemes for the controlled use of assessment results of CRBs, based on three fundamentals:

- Use of accredited CRBs.
- Use of qualified and approved aerospace auditors.
- Use of international aerospace standards for quality management systems in aerospace industry.

This European Standard addresses the following issues:

- a) Qualification and accreditation of CRBs.
- b) Assessment of quality systems by accredited CRBs.
- c) The principles for determining the content and duration of assessments.

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- d) Reporting and control of nonconformities.
- e) The form of registration recommendations.
- f) Minimum standards of qualification and experience for aerospace auditors employed by CRBs.
- g) Authentication of auditors by CRBs, Accreditation Bodies (ABs) and the IAQG sectors.
- h) Oversight of ABs by applicable Sector Management Structure (SMS).
- i) Oversight of CRBs by applicable SMS and IAQG Original Equipment Manufacturers (OEM).
- j) Operation of the IAQG oversight function.

This European Standard introduces certification/registration to the 9110 (maintenance organizations) and 9120 (stockist/distributors) standards, use of ISO 19011, mandatory use of the scoring process, as well as a number of clarifications and detail improvements resulting from the initial operation of the scheme. The requirements of this document are effective upon publication.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

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1 Scope

1.1 General

These requirements are applicable to IAQG sector schemes when making use of ABs, CRBs and their auditors, for the assessment and certification/registration of supplier quality systems in accordance with the requirements of this document.

The quality management system standard used by the CRB shall be EN 9100/9110/9120, as appropriate to the supplier's activities. It shall be applied to the supplier's complete Quality System that covers aerospace products. Sectors may use these requirements for other standards.

IAQG members have committed to recognize the equivalence of certification/registration of a suppliers quality management system to either of the AS, EN or JISQ/SJAC standards.

1.2 Purpose

The purpose of this European Standard is to give requirements on the process for providing aerospace companies and their suppliers with assessment and certification/registration of their quality systems, by accredited CRBs.

2 Normative references

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.

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 9110, *Aerospace series — Quality systems — Model for quality assurance applicable to maintenance organizations*.¹⁾

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

NOTE 1 The above standards are referred throughout this document as AQMS Standards.

EN 9101, *Aerospace series — Quality management systems — Assessment (based on ISO 9001:2000)*.^{1) 2)}

EN 9111, *Aerospace series — Quality management systems — Assessment applicable to maintenance organizations (based on ISO 9001:2000)*.¹⁾

EN 9121, *Aerospace series — Quality management systems — Assessment applicable to stockist distributors (based on ISO 9001:2000)*.¹⁾

NOTE 2 The above standards are referred throughout this document as the Aerospace Assessment Report and Questionnaires.

EN 9102, *Aerospace series — Quality Systems — First article inspection*.¹⁾

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

2) Published as AECMA Prestandard at the date of publication of this standard.

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EN 9103, *Aerospace series — Quality management systems — Variation management of key characteristics*.¹⁾

ISO 9001, *Quality management systems — Requirements*.

ISO 19011, *Guidelines for quality and/or environmental management systems auditing*.

ISO/IEC Guide 61, *General requirements for assessment and accreditation of certification/registration bodies*.

ISO/IEC Guide 62, *General requirements for bodies operating assessment and certification/registration of quality systems*.

IAF Guidance on the Application of ISO/IEC Guide 61.

IAF Guidance on the Application of ISO/IEC Guide 62.

3 Terms and definitions

For the purposes of this standard, 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 CRBs 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

3.3**aerospace experience auditor**³⁾

auditor that has met the requirements set forth in 7.2, 7.3 or 7.4 of this document

3.4**aerospace product**

aircraft, rotorcraft, guided weapon, launcher, spacecraft or other product designed to travel through the air, inside or outside the ground effect, or to travel outside the influence of the earth's atmosphere or major components of these products such as engines or major sub-systems or parts, appliances, equipment and materials as contained in these

3.5**auditor**³⁾

person that has met the requirements set forth in 7.1 of this document

3.6**Certification/Registration Body (CRB)**

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

3.7**International Aerospace Quality Group (IAQG)**

body of prime aerospace OEMs. This group is chartered to develop common requirements for use by the aerospace industry for quality improvement.

3) Sectors may use other names for "Auditor", "Aerospace Auditor" and "Aerospace Experienced Auditor" as long as the requirements of this document are applied.

3.8**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

3.9**nonconformity**

absence of, or the failure to implement and maintain, one or more quality management system requirements, or a situation that would, on the basis of available objective evidence, raise significant doubt as to the quality of what the organization is supplying

major: the absence of, or total breakdown of a quality management system element specified in the AQMS standard or any non-conformities where the effect is judged to be detrimental to the integrity of the product, processes or service.

minor: a single system failure or lapse in conformance with a procedure relating to the AQMS standard.

NOTE A number of minor non-conformities against one requirement can represent a total breakdown of the system and this can be considered as a major nonconformity.

Any finding (e.g., comments, observations) that equates to the above definition shall be documented as a nonconformity, categorized as major or minor, and dealt with in accordance with 8.3.

3.10**On Line Aerospace Supplier Information System (OASIS)**

web-based IAQG database containing information on participating National Aerospace Industry Associations, ABs, accredited CRBs, authenticated Aerospace Experience Auditors, Certified Suppliers and Assessments

3.11**Sector Management Structure (SMS)**

organization established in a sector that manages the application of the sector scheme based on this document. Each sector may use a different name for this organization (e.g., Registrar Management Committee in the Americas and Asia/Pacific, Certification Body Management Committee in Europe within AECMA).

4 General

4.1 The requirements stated herein shall be based on the latest versions of the documents listed in Clause 2.

4.2 Aerospace additional requirements are identified in the AQMS Standards as bold italic items. These elements are in addition to ISO 9001 elements and should also be applied in the organization's quality system.

4.3 Data, in the form of checklists, approvals or other company specific information, generated in the application of this document shall be handled as "confidential, proprietary and sensitive" between the parties generating, collecting, or using the data. Companies using this data shall keep its usage confidential both internally and externally, unless otherwise agreed in writing by the consenting parties. Data resident at the ABs and CRBs on OEMs shall not be shared with OEM competitors. However, this data may be subject to audit or review at any time by applicable ABs, SMS, government or regulatory bodies and the IAQG Oversight Team (OT) (see Clause 14).

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5 Requirements for accreditation bodies

5.1 The responsibilities of the AB shall be to review and recommend accreditation of the CRBs to the requirements of this document. The AB shall approve the use of “marks” and logos for use on certificates of approval. The AB shall work with the IAQG sector to give assurance that CRBs continue to perform in a manner consistent with the requirements contained herein and in the IAQG sector scheme. ABs shall be members of the IAF (International Accreditation Forum) and signatories of the IAF MLA (Multi-lateral Agreement) to participate in this process. ABs shall be in conformance to ISO/IEC Guide 61 and IAF Guidance on the Application of ISO/IEC Guide 61.

5.2 ABs shall have a person(s) with aerospace background on their advisory group, as defined in ISO/IEC Guide 61.

5.3 The basis for AB accreditation of CRBs to AQMS shall include an initial full system witness audit of an AQMS certification/registration per the AB’s operating procedures.

5.4 AB audit teams who are conducting assessments of CRBs for the purposes of this scheme shall include an auditor with aerospace experience (same as 7.2, 7.3 or 7.4) or have aerospace industry expert(s) with experience (same as 7.2, 7.3 or 7.4) as part of the audit team.

5.5 The AB shall have the specific procedures, tools and techniques in its systems for granting, maintaining, suspending and withdrawing accreditation of CRBs (e.g., AQMS Standards and Aerospace Assessment Report and Questionnaires, briefing notes) and for compliance with Clause 8 of this document.

5.6 The AB shall agree to periodic surveillance and witness audits by IAQG sectors. IAQG member companies shall perform oversight of scheme involved National Accreditation Bodies (NABs) and report results to the SMS as established in each sector.

5.7 The AB shall agree to the “Right of Access” by IAQG member companies, IAF and other regulatory or Government bodies for the purpose of establishing that the correct criteria and methods were used in accrediting CRBs. This includes information or records pertaining to IAF approval of the AB.

6 Requirements for certification/registration bodies

6.1 CRBs seeking qualification under the sectorial procedures based on these requirements shall first be accredited in accordance with ISO/IEC Guide 62 and IAF Guidance on the Application of ISO/IEC Guide 62 for ISO 9001 for at least one year prior to submitting an application. As such, the CRB shall have been successfully assessed for conformance to ISO/IEC Guide 62 and ISO 19011.

6.2 ABs shall accredit the CRB’s audit management program for each AQMS standard in accordance with the requirements of this document.

6.3 Accreditation requirements shall include, among other things, evidence that the CRB’s management committee or advisory group have a person(s) with aerospace background and knowledge. A CRB may or may not already be approved by the AB for the scope category of aerospace represented by Scope Sector 21 (NACE DM 35.3) (formerly U.S. SIC Code 372 and 376) in accordance with AB procedures and requirements. The CRB shall have qualified auditors and/or technical experts engaged in registration activities.

6.4 Requirements for CRBs to obtain AQMS Standards accreditation shall include as a minimum:

- a) The CRB's certification function shall have a person(s) with aerospace background and knowledge involved in the certification decisions of the CRB.

- b) The CRB shall use an auditor training program that complies with detailed requirements per IAQG sector and records thereof for quality system requirements. Minimum content of this training program is:
- AQMS Standards.
 - The Aerospace Assessment Report and Questionnaires.
 - The scheme as used in the specific sector for Certification/Registration of AQMS.
 - The scoring process and use of nonconformity reports.
 - Additional sectorial training requirements.
 - Civil Aviation Authority (CAA) requirements (such as Federal Aviation Administration [FAA] Title 14 CFR Part 21, Joint Aviation Requirements (JAR) 21 or equivalent per the national CAA) and applicable advisory material.
 - Applicable Space and Defense organizations requirements.
- c) CRB shall document their auditor-training program and it shall be reviewed and approved by the AB during the accreditation process.
- d) The CRB shall utilize qualified auditors as defined in Clause 7 of this document. The CRB audit team shall meet the requirements of Clause 8 of this document.
- e) The CRB shall have the specific procedures, tools and techniques in its systems for granting, maintaining, extending, reducing, suspending and withdrawing certification/registration at aerospace organizations per AB and IAQG requirements (e.g., AQMS Standards and Aerospace Assessment Report and Questionnaires, briefing notes) and Clause 8 of this document.
- f) The CRB shall agree to periodic surveillance and witness audits by the ABs and by IAQG sectors. ABs shall conduct annual witness audits of CRBs holding AQMS accreditation. IAQG member companies shall perform oversight of CRBs used by their suppliers and report results to the SMS as established in each sector. <https://standards.iteh.ai/catalog/standards/sist/025b56d4-abfe-45e0-9e93-3b2702521cca/sist-en-9104-2009>
- g) The CRB shall agree to the "Right of Access" by IAQG member companies, ABs and other regulatory or Government bodies for the purpose of establishing that the correct criteria and methods were used in issuing organization approvals to AQMS Standards. This includes information or records pertaining to AB approval of the CRB.
- h) The CRB shall be responsible for entering assessment data into the OASIS database by following a process defined by their SMS or by providing the information to a designated database administrator, in accordance with subclause 8.4.
- i) No CRB shall be allowed to certify an organization to an AQMS Standard with which the CRB or a related body has provided consulting services related to registration within the past two years. In addition, any individual who has, in the past two years, provided consulting services to an organization, shall have no involvement with the AQMS Standard certification/registration of that organization. Where there might appear to be a conflict of interest, either through consulting or the offering of training to a potential client this shall be disclosed to the AB and the SMS prior to performing the registration process to determine if there is a conflict of interest.

NOTE If a CRB performs training for an organization for which it will provide registration services, the training shall be conducted and managed separately from the CRB's certification/registration program and in full conformance with ISO/IEC Guide 62 and IAF Guidance on the Application of ISO/IEC Guide 62. In addition any training of auditors for AQMS Standards shall be conducted in accordance with sectorial schemes.

6.5 An accredited CRB is responsible for ensuring the continued integrity and validity of the certificates it issues and for drawing up and implementing a procedure to enable it to carry out this responsibility.