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

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

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Série aérospatiale - Systèmes de management de la qualité - Partie 001: Exigences applicables aux processus de certification des systèmes de management de la qualité dans le domaine aéronautique, spatial et de défense

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This European Standard was approved by CEN on 10 November 2012.

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EUROPEAN COMMITTEE FOR STANDARDIZATION COMITÉ EUROPÉEN DE NORMALISATION EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This document (EN 9104-001:2013) 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of an identical text or by endorsement, at the latest by September 2013, and conflicting national standards shall be withdrawn at the latest by September 2013.

This document supersedes EN 9104:2006.

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.

According to the CEN-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 Yugoslay, 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.

Introduction

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.

The IAQG developed specific requirements for aviation, space, and defence (interchangeably referred to as 'aerospace') quality management systems that are to be implemented and maintained throughout the supply chain for the design, manufacture, and maintenance of products used in aviation, space, and defence applications. These requirements are published simultaneously as the EN 9100-series standards (i.e., EN 9100, EN 9110, EN 9120) by SAE International in the Americas, AeroSpace and Defence Industries Association of Europe - Standardization (ASD-STAN) in Europe, and Japanese Standards Association (JSA) and Society of Japanese Aerospace Companies (SJAC) in Asia/Pacific.

Another initiative of the IAQG was the development of a global scheme for the acceptance and recognition of audits performed by Certification Bodies (CBs), using the EN 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:

- the use of a 3rd party audit certification scheme with specific aviation, space, and defence elements and requirements, under the guidance and oversight of the aviation, space, and defence industry; and
- the use of a harmonized approach with the CBs for the purpose of improving the quality and process control throughout the entire supply chain standards.iteh.ai)

Rationale

After the initial publication of International Aerospace Quality Group (IAQG) EN 9104 standard 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.

The requirements for oversight and AQMS auditor qualification information (EN 9104-002 and EN 9104-003 respectively) were removed from the original EN 9104 text. This effort necessitated the total rewrite of the initial standard, now re-designated as EN 9104-001, which is the keystone document of the EN 9104-series trilogy.

This standard defines the basic requirements for managing the AQMS certification scheme (commonly referred to as the 'ICOP scheme'). Two other standards in this series (i.e., EN 9104-002, EN 9104-003) provide specific requirements for defining the oversight process, and the AQMS auditor qualification and training requirements, respectively. These three standards together are commonly referred to as the ICOP certification management system 'Trilogy'.

This standard establishes provisions for the individual IAQG sector schemes controlled use of audit results provided by CBs, based on three primary criteria.

- the use of accredited CBs;
- the CB's use of qualified and authenticated AQMS auditors; and
- the use of international aviation, space, and defence standards for quality management systems.

This standard addresses the following elements necessary for the ICOP scheme:

- a) the approval of Accreditation Bodies (ABs), Auditor Authentication Bodies (AABs), and Training Provider Approval Bodies (TPABs);
- b) the qualification, accreditation, and recognition of CBs;
- c) the audits of quality management systems by accredited CBs;
- d) the criteria for determining the certification structure, content, and duration of audits;
- e) the recording and disposition of nonconformities generated by the audits;
- f) the posting of audit results, findings, and certification;
- g) the entry of data into the Online Aerospace Supplier Information System (OASIS) database; and
- h) the use of International Accreditation Forum (IAF) guidance and mandatory documents for established processes (e.g. audit duration calculations, multiple site certifications).

Additionally, this standard references the other standards in the EN 9104-series (i.e., EN 9104-002, EN 9104-003) that specify:

- i) the minimum standards of qualification and experience for AQMS auditors;
- j) the authentication of AQMS auditors by AABs and recognition by IAQG sectors;
- k) the oversight of ABs, CBs, TPABs, AABs, and AQMS auditors by applicable Sector Management Structure (SMS) and IAQG Original Equipment Manufacturers (OEMs), and other organizations and their representatives who participate in the management of the ICOP scheme; and
- I) the operation of the IAQG oversight function.

This standard also provides guidance for the use of the required audit process reporting tools (see EN 9101), and provides clarifications and process improvements resulting from the lessons learned during the initial operation of the ICOP scheme.

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1 Scope

This European Standard defines the requirements and industry-accepted practices for managing the ICOP scheme, which provides confidence to aviation, space, and defence customers and organizations that their suppliers with certification of their quality management systems, issued by accredited CBs, meet the applicable AQMS standard requirements. The requirements established in this standard are applicable to the IAQG and its three sectors for managing AQMS certification and associated activities. The requirements are applicable to IAQG working groups [e.g. SMS, Other Party Management Team (OPMT)], IAQG member companies, ABs, CBs, Certification Body Management Committees (CBMCs), AABs, TPABs, Training Providers (TPs), and organizations seeking/obtaining AQMS standard certification.

The AQMS standard adopted by the organization should be EN 9100, EN 9110, and/or EN 9120, as appropriate to the organization's activities; these standards are referred to throughout this writing as 'AQMS standards'. IAQG member companies have committed to recognize the certification of a supplier's quality management system to all equivalent AQMS standards (e.g. AS, EN, JISQ, NBR). IAQG sectors may expand the application of the requirements defined in this standard for other standards approved by the IAQG and its three sectors [i.e., Americas Aerospace Quality Group (AAQG), European Aerospace Quality Group (EAQG), Asia/Pacific Aerospace Quality Group (APAQG)].

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, Quality management systems — Requirements for aviation, space and defence organizations

EN 9101, Quality management systems — Audit requirements for aviation, space, and defence organizations https://standards.iteh.ai/catalog/standards/sist/4d3f8299-edbf-4df8-93b4-

EN 9104-002, Aerospace series — Quality management systems 001 Part 002: Requirements for oversight of aerospace quality management system certification/registrations programs

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

EN 9110, Quality management systems — Requirements for aviation maintenance organizations

EN 9120, Quality management systems — Requirements for aviation space and defence distributors

NOTE Equivalent versions (e.g. AS, EN, JISQ, SJAC, NBR) of the IAQG standards listed above are published internationally in each IAQG sector.

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

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

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

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

EN ISO/IEC 17024:2003, Conformity assessment — General requirements for bodies operating certification of persons (ISO/IEC 17024:2012)

EN ISO 19011:2011, Guidelines for auditing management systems (ISO 19011:2011)

IAF GD 3:2003, IAF Guidance on cross frontier accreditation

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 (ASRP)

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 ML 4:2011, Policies and procedures for a multilateral recognition arrangement on the level of accreditation bodies and on the level of regional groups

3 Terms and definitions

Definitions for general terms can be found in EN ISO 9000 and the IAQG International Dictionary, which is located on the IAQG website. An acronym log for this standard is presented in Appendix A. For the purposes of this document, the following terms and definitions apply.

3.1

Accreditation Body (AB) that has the primary responsibility for the accreditation of CBs to issue certifications to AQMS standards (standards.iteh.ai)

3.2

aerospace

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

3.3

Aerospace Quality Management System (AQMS)

quality management system based upon EN ISO 9001 that includes additional aviation, space, and defence requirements, as established in IAQG standards EN 9100, EN 9110, and EN 9120

3.4

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 aviation, space, and defence organizations. An AQMS auditor is defined as either an Aerospace Experience Auditor (AEA) or an Aerospace Auditor (AA), and shall have met the requirements set forth in EN 9104-003 and Clause 7 of this standard

Note 1 to entry: The term 'Aerospace Auditor' (AA) is the same as the term 'auditor' defined in EN 9104-003. IAQG sectors may use other names for an AQMS auditor as long as the requirements of this standard and EN 9104-003 are applied.

3.5

assessment

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

3.6

audit

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

3.7

Auditor Authentication Body (AAB)

body approved by the IAQG sector that has the primary responsibility for authenticating AQMS auditors, in accordance with specific requirements

3.8

central office (also referred to as central function)

organization location/activity that controls the 'common' quality management system for the organization under a single AQMS standard certificate

3.9

Certification Body (CB)

body that performs audit and certification services, and is subject to accreditation with respect to AQMS standards and any supplementary documentation required under the ICOP scheme

3.10

Certification Body Management Committee (CBMC)

organization within an SMS that functions on a national level (e.g. Italy, France, Germany, Spain, United Kingdom, Austria) responsible for EN 9104-series standards conformance in their respective countries. They perform the same functions as the SMS, under control of the SMS within their sector EVIEW.

3.11

certification structure

term utilized to describe how the certification activities of an aviation, space, and defence organization will be structured and managed by the contracted CB. The defined structure will assist CBs with the development of a robust and conforming audit program, and provide industry with visibility of the structure within the OASIS database. These structures are defined below, further description is provided in Appendix B.

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- a) Single Site An organization having one location. The organization may be operating under one large building or several buildings at that location. The organization may have one or multiple products or product families flowing though one or multiple processes.
- b) Multiple Site An organization having an identified central function (the central office, but not necessarily the headquarters of the organization) at which certain activities are planned, controlled, or managed and a network of sites at which such activities are fully or partially carried out. With the exception of the central office the processes within each of the sites are substantially the same and are operated to the same methods and procedures (see IAF MD 1, "Multi-site Organization" definition and eligibility requirements).
- c) Campus An organization having an identified central function (the central office, but not necessarily the headquarters of the organization) at which certain activities are planned, controlled, or managed; and that has a decentralized, sequential, linked product realization process. For the purposes of this standard, it is referred to as a value stream where the outputs from one site are an input to another site, which ultimately results in the final product or service.
- d) Several Sites An organization having an identified central function (the central office, but not necessarily the headquarters of the organization) at which certain activities are planned, controlled, or managed and a network of sites, that do not meet the criteria for either a multiple site or a campus organization.
- e) Complex An organization having an identified central function (the central office, but not necessarily the headquarters of the organization) at which certain activities are planned, controlled, or managed and a network of locations that are any combination of multiple site, campus, several sites, or more than one campus.

3.12

combined audit

audit of an organization's management system(s) against two or more AQMS standards conducted at the same time

3.13

cross frontier accreditation

policy that allows for an AB to conduct assessments/oversight on CBs operating in countries other than the country in which the AB accreditation or lead office of the CB is based. The AB performing the assessment/oversight has to be recognized by the IAQG and listed in the OASIS database

3.14

Industry Controlled Other Party (ICOP)

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

3.15

Integrated Management System (IMS)

organization methodology using a single quality management system to manage multiple aspects of organizational performance to meet the requirements of multiple AQMS standards (e.g. EN 9100 and EN 9110)

Management systems may exhibit different levels of integration (see 8.2.3). Note 1 to entry:

3.16

International Aerospace Quality Group (IAQG) A RD PREVE V body of prime aviation, space, and defence OEMs. This group is chartered to develop common requirements and guidelines for use by the aviation, space, and defence industry for quality improvement

3.17

International Aerospace Quality Group (IAQG) Other Party Management Team (OPMT)

body of prime aerospace OEMs that has the primary responsibility for the management of the ICOP scheme

3.18

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)

3.19

lead office

single office of a CB that has the responsibility for the implementation of the EN 9104-series standard's requirements

3.20

office assessment

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

3.21

Online Aerospace Supplier Information System (OASIS) database

web-based IAQG application containing information on participating National Aerospace Industry Associations (NAIAs), ABs, TPABs, AABs, accredited CBs, AQMS auditors, certified suppliers, and audits, which are approved and recognized by the SMS through the ICOP scheme

3.22

organization

any legal entity or defined part of a legal entity with a quality management system that is subject to an ICOP audit and the associated certification process

3.23

Pre-audit

activities undertaken by a CB with its client, after initial contact or application, before commencement of the initial certification audit (i.e., Stage 1 and Stage 2 audit activities)

3.24

Sector Management Structure (SMS)

organization established in an IAQG sector that manages the application and oversight of the ICOP scheme as defined by this standard. Each sector may use a different name for this organization li.e., Registration Management Committee (RMC) in the Americas and Asia/Pacific, EAQG OPMT and national CBMCs in Europe]

3.25

site

permanent location where an organization carries out work or a service

3.26

Training Provider Approval Body (TPAB)

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

3.27

value stream

end-to-end business process which delivers a product or service to a customer. The process steps may use and produce intermediate goods, services, and information to achieve the end product or service

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3.28

witness assessment (standards.iteh.ai) 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 and EN 9104-002

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3.29 witness audit

evaluation of an auditor's ability and competency to perform AQMS audits to the applicable standard and associated requirements

4 Requirements of the sector management structure

4.1 The SMS has the responsibility for the management, review, approval, implementation, and modification of their sector operating procedure(s). The SMS shall be the governing body by which the requirements for and recognition of CBs and authentication of auditors to AQMS standards are determined; consistent with the requirements of this standard.

4.2 The SMS has the responsibility to review and recognize new AB accreditations of CBs. This is to be initially evaluated by the SMS or CBMC, if applicable, ensuring that an AB meets the requirements defined in Clause 5; particularly with respect to the decision-making process and defined competence requirements, which is annually verified through oversight of the AB to the requirements of this standard.

Where agreed upon between the AB and the SMS or CBMC, if applicable, there can be an additional review, as part of the AB's accreditation decision-making process, by the SMS or an industry expert endorsed by the SMS ensuring that the AB fully meets the competence requirements of 5.4.2.

The SMS shall determine and approve CBMCs, when utilized. CBMCs operate as an extension of the SMS, 4.3 performing the same functions on a national level to the requirements of this standard.

4.4 The SMS and CBMC, if applicable, shall report to the IAQG OPMT, OASIS database administrator, and other parts of the SMS notification of suspension or withdrawal of ABs, CBs, AAB, and TPABs.

4.5 The SMS shall identify which ABs are approved to accredit CBs for AQMS standard certification in accordance with this standard. The method and results of approval shall be documented and records maintained. ABs approved by the SMS shall be identified in the OASIS database.

4.6 The SMS shall recognize CBs that are accredited to certify an organization's AQMS. The accreditation of CBs for AQMS standards shall be granted and surveillance performed by the AB in accordance with this standard. The method and results of recognition shall be documented and records maintained. CBs recognized by the SMS shall be identified in the OASIS database.

4.7 Each SMS shall define a process for the approval, suspension, and withdrawal of approval of AABs and TPABs in accordance with the requirements of EN 9104-003 and this standard. Only AABs approved by an SMS shall qualify for AQMS auditor evaluation, authentication, and re-authentication.

Those who participate in the evaluation or make the decision to approve, suspend, or withdraw an AAB or TPAB shall not have participated in the development of the management systems or processes or in the work of the AAB or TPAB for a minimum period of two years before the decision. Furthermore, they shall not have any personal, contractual, voluntary, or formal relationship with the AAB or TPAB that would present a potential conflict of interest to the impartiality of the decision.

4.8 Where an AAB or TPAB's approval is withdrawn, any application to an SMS for re-approval shall be rejected for a period of 12 months from the date of withdrawal. The AAB or TPAB has the right to appeal this decision to the IAQG OPMT.

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4.9 The SMS shall approve, as appropriate, AABs that authenticate AQMS auditors. The authentication of auditors to AQMS standards shall be granted by the AAB in accordance with the requirements of EN 9104-003 and this standard. The method and results of approval shall be documented and records maintained. AABs approved by the SMS shall be identified in the OASIS database.04-001:2014

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4.10 The SMS shall approve, as appropriate,b/TRABs/Ithat/review and approve the AQMS standard training courses and TPs. The approval of training courses and TPs for AQMS standards shall be granted by the TPAB in accordance with the requirements of EN 9104-003 and this standard. The method and results of approval shall be documented and records maintained. TPABs approved by the SMS shall be identified in the OASIS database.

4.11 The SMS shall recognize the authentication by AABs of auditors that perform AQMS audits of organizations. This shall be documented by a formal process by each SMS in accordance with the requirements of EN 9104-003 and this standard. The method and results of SMS approval shall be documented and records maintained. AQMS auditors recognized by the SMS shall be identified in the OASIS database.

4.12 The approval, recognition, certification, or authentication of ABs, AABs, TPABs, TPs, CBs, and AQMS auditors by any IAQG sector to the requirements of this standard shall be recognized by the other IAQG sectors.

4.13 Each SMS has the right to withdraw or suspend the approval, recognition, or authentication of ABs, CBs, AABs, TPABs, or AQMS auditors based on, but not limited to poor performance, nonconformity to requirements, or falsification of data.

4.14 Each SMS shall establish and maintain operating procedures, which support implementation and conformance to the SMS requirements established by this standard. The procedures shall include record retention requirements.

4.15 Each SMS shall report essential data that describes deployment activities to the IAQG OPMT. Essential data includes information on the AQMS auditor population (i.e., approvals, disapprovals, numbers of AAs and AEAs), the CB population (i.e., approvals, disapprovals), auditor training and authentication organizations, the number of AQMS standard certifications issued, and oversight activities by the SMS and IAQG OEMs.

NOTE AB, CB, AAB, and TPAB approval documents and procedures may be reviewed by the IAQG OPMT.