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





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NATIONAL FOREWORD

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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

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

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

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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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Jon	tents	Page
orew	ord	4
ntrod	uction	5
Ratior	nale	6
	Scope	8
2	Normative references	8
3	Terms and definitions	9
ı.	Requirements of the sector management structure	12
5	Requirements for accreditation bodies	14
6	Requirements for certification bodies	20
7	For aerospace requirements quality management system auditors	23
3	Requirements for audits and reporting	23
)	Requirements for oversight process	36
10	Requirements for auditor authentication bodies	36
11	Requirements for training provider approval bodies	38
12	Online aerospace supplier information system database	40
13	Requirements of the other party management team	41
14	Online aerospace supplier information system database feedback process	42
15	Sector management structure	43
16	Cross frontier policy for EN 9104/2 oversight activity	45
17	Records	45
18	Requirements for certified organizations	46
19	Confidentiality and conflicts of interest	46
20	Fees and financials	47
21	NOTES	47
Appen	ndix A ACRONYM LOG	48
Appen	ndix B Industry controlled other party scheme certification structures matrix for 9100/9110/9120:2009 certification audits	49
Appen	ndix C Information to be uploaded into the online aerospace supplier information system database	51

Figures and Tables	Page
Table 1 — Accreditation body assessment requirements of certification bodies	17
Table 2 — Audit duration requirements	25
Table 3 — Multiple site organization audit frequency	27
Table 4 — Permissible reductions for reduced SCOPE / complexity for several site organizations.	28
Table 5 — Online aerospace supplier information system database data responsibility	40
Figure 1 — Illustration of the customer – Supplier – Certification body feedback loops within the online aerospace supplier information system database	43
Figure 2 — Sector management structure diagram	44



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 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.



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.



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.



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

EN 9104-002, Aerospace series — Quality management systems — 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)

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

3.2

aerospace

business of design, manufacture, maintenance, distribution, or 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)