



NSAI
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Irish Standard
I.S. EN 9104-001:2013

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

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

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

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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of an identical text or by endorsement, at the latest by September 2013, and conflicting national standards shall be withdrawn at the latest by September 2013.

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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
- l) 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)

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

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.

- 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 through 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.

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