BS EN 9101:2018

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Quality Management Systems - Audit Requirements for Aviation, Space, and Defence Organisations

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National foreword

This British Standard is the UK implementation of EN 9101:2018. It supersedes BS EN 9101:2015, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee ACE/1, International and European Aerospace Policy and Processes.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Quality Management Systems - Audit Requirements for Aviation, Space, and Defence Organisations

Systèmes de Management de la Qualité - Exigences d'Audits pour les Organisations de l'Aéronautique, l'Espace et la Défense

Qualitätsmanagementsysteme - Audit-Anforderungen für Organisationen der Luftfahrt, Raumfahrt und Verteidigung

This European Standard was approved by CEN on 10 March 2017.

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European foreword

This document (EN 9101:2018) 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of an identical text or by endorsement, at the latest by November 2018, and conflicting national standards shall be withdrawn at the latest by November 2018.

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.

This document supersedes EN 9101:2015.

According to the CEN-CENELEC Internal Regulations, the national standards organisations 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, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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Rationale

This standard has been revised to incorporate the requirements for accredited Certification Bodies (CBs) introduced by International Organization for Standardization (ISO) / International Electrotechnical Commission EN ISO/IEC 17021-1:2015, the 2016 changes to International Aerospace Quality Group EN 9100-series standards Quality Management System (QMS) requirements, and inputs received from interested parties relating to process-based auditing methods and the evaluation of process effectiveness.

Foreword

To assure customer satisfaction, aviation, space, and defence organizations must provide and continually improve safe and reliable products and services that meet or exceed customer and applicable statutory and regulatory requirements. The globalization of the industry and the resulting diversity of regional and national requirements and expectations have complicated this objective. Organizations have the challenge of purchasing products and services from suppliers, throughout the world, at all levels of the supply chain. Suppliers have the challenge of delivering products and services to multiple customers having varying quality requirements and expectations.

Industry established the IAQG, with representatives from aviation, space, and defence companies in the Americas, Asia/Pacific, and Europe, to implement initiatives that make significant improvements in quality and reductions in cost throughout the value stream.

This document has been prepared by the IAQG and standardizes the requirements for conducting and reporting of QMS audits. It can be used at all levels of the supply chain by organizations around the world.

It provides requirements for an audit and reporting process, based on the:

- process and continual improvement approach defined in EN 9100-series standards;
- specific aviation, space, and defence additions in EN 9100-series standards;
- use of common audit tools; and
- uniform, transparent, and standardized reporting of audit results.

In this standard, the following terms are used:

- “shall” indicates a requirement;
- “should” indicates a recommendation;
- “may” indicates a permission; and
- “can” indicates a possibility or capability.

Words “typical”, “example”, or “e. g.” indicate suggestions given for guidance. Information marked “NOTE” is for guidance in understanding or clarifying the associated requirement.

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0 Introduction

0.1 General

Auditing is a basic tool to assess effective implementation of and conformity to QMS requirements. In addition to assessing conformity, this standard focuses on the evaluation of effectiveness (see EN ISO 9000 clause 3.7.11) of the QMS and its associated processes.

An organization is not only required to be in conformity with QMS requirements, but to be effective in meeting customer expectations and delivering products and services that meet those expectations.

Additionally, this standard takes into account the requirements presented in the 2016 revisions of the EN 9100-series standards.

0.2 Auditing approach

This standard supports the engagement and evaluation of an organization's QMS process approach, as required by the EN 9100-series standards. When evaluating an organization's QMS, there are basic questions that should be asked of every process, for example:

a) Is the process appropriately determined?

b) Are responsibilities assigned?

c) Are the processes adequately implemented and maintained?

d) Is the process effective in achieving the desired results?

The collective answers to these and other associated questions will contribute to the evaluation results.

In addition, product and service quality (as delivered), customer satisfaction, and QMS effectiveness can be considered as interrelated. This relationship should be reflected in the audit process and associated results.

0.3 Audit records and reports

This standard defines the audit records and reports to be generated, during the audit process. They are critical in providing the organization and its customers with objective evidence on the conformity and effectiveness of the QMS (including process effectiveness), and reporting the audit results in a standard format/structure.

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1 Scope

1.1 General

This document defines requirements for the preparation and execution of the audit process. In addition, it defines the content and composition for the audit reporting of conformity and process effectiveness to the EN 9100-series standards, the organization's QMS documentation, and customer and statutory/regulatory requirements.

The requirements in this document are additions or represent changes to the requirements and guidelines in the standards for conformity assessment, auditing, and certification as published by ISO/IEC (i. e., EN ISO/IEC 17000, EN ISO/IEC 17021-1). When there is conflict with these standards, the requirements of the EN 9101 standard shall take precedence.

NOTE 1 In this standard, the term "EN 9100-series standards" comprises the following Aerospace Quality Management System (AQMS) standards: EN 9100, EN 9110, and EN 9120; developed by the IAQG and published by various national standards bodies.

NOTE 2 In addition to this standard, the IAQG publishes deployment support material on the IAQG website (see http://www.sae.org/iaqg/) that can be used by audit teams, when executing the audit process.

1.2 Application

This document shall be used for audits of EN 9100-series standards by CBs for certification of organizations, under the auspices of the aviation, space, and defence industry certification scheme [also known as the Industry Controlled Other Party (ICOP) scheme]. The ICOP scheme requirements are defined in the EN 9104-series standards (i. e., EN 9104-001, EN 9104-002, EN 9104-003).

NOTE Relevant parts of this standard can also be used by an organization in support of internal audits (1st party) and external audits at suppliers (2nd party).

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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[1], *Quality Management Systems — Requirements for Aviation, Space and Defence Organizations*

EN 9102[1], *Aerospace First Article Inspection Requirement*

EN 9104-001[1], *Aerospace series — Quality management systems — Part 001: Requirements for Aviation, Space, and Defence Quality Management System Certification Programs*

EN 9104-002[1] , *Aerospace series — Quality management systems — Part 002: Requirements for Oversight of Aerospace Quality Management System Registration/Certification Programs*

EN 9104-003[1], *Aerospace series — Quality management systems — Part 003: Requirements for Aerospace Quality Management System (AQMS) Auditor Training and Qualification*

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[1] As developed under the auspice of the IAQG and published by various standards bodies [e. g., SAE International, European Committee for Standardization (CEN), Japanese Standards Association/Society of Japanese Aerospace Companies (JSA/SJAC), Brazilian Association for Technical Norms (ABNT)].

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EN 9110[1], *Quality Management Systems — Requirements for Aviation Maintenance Organizations*

EN 9115[1], *Quality Management Systems — Requirements for Aviation, Space and Defence Organizations — Deliverable Software (Supplement to EN 9100:2016)*

EN 9120[1], *Quality Management Systems — Requirements for Aviation, Space and Defence Distributors*

EN 9131[1], *Aerospace series — Quality Management Systems — Nonconformance Data Definition and Documentation*

EN ISO 9000:2015, *Quality management systems — Fundamentals and vocabulary*

EN ISO/IEC 17000, *Conformity assessment — Vocabulary and general principles (ISO/IEC 17000:2004)*

EN ISO/IEC 17021-1, *Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 1: Requirements (ISO/IEC 17021-1:2015)*

IAQG Procedure 105.6, *IAQG Forms Management*

IAF MD 3:2008, *IAF Mandatory Document for Advanced Surveillance and Recertification Procedures*

IAF MD 4:2008, *IAF Mandatory Document for the Use of Computer Assisted Auditing Techniques ("CAAT") for Accredited Certification of Management Systems*

3 Terms and definitions

For the purpose of this standard, the terms and definitions provided in EN ISO 9000, EN ISO/IEC 17000, EN 9100-series standards, EN 9104-001 standard, and the following apply. Furthermore, an acronym log for this standard is presented in Annex A.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1
containment
action to control and mitigate the impact of a nonconformity and protect the customer's operation (stop the problem from getting worse); includes correction, immediate corrective action, immediate communication, and verification that the nonconforming situation does not further degrade

3.2
Key Performance Indicator
KPI
measures associated with goals or targets showing how well an organization is achieving its objectives or critical success factors for a particular project. KPIs are used to objectively define a quantifiable and measurable indication of the organization's progress towards achieving its goals

Note 1 to entry: KPIs relating to an organization's financial performance are not in the scope of the EN 9101 standard; however, economic measures (e. g., sales quotas, scrap value reduction) can be considered acceptable measures for process improvement.

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3.3
major nonconformity
The requirements of EN ISO/IEC 17021-1 clause 3.12 apply.

In addition, a major nonconformity can be one or more of the following situations:

- a nonconformity where the effect is judged to be detrimental to the integrity of the product or service;
- the absence of or total breakdown of a system to meet a EN 9100-series standard requirement, a customer QMS requirement, or documented information defined by the organization;
- any nonconformity that can result in the probable delivery of nonconforming product or service; and
- a condition that can result in the failure or reduce the usability of the product or service and its intended purpose.

3.4
minor nonconformity
The requirements of EN ISO/IEC 17021-1 clause 3.13 apply.

In addition a minor nonconformity can be a single system failure or lapse in conformity to meet a EN 9100-series standard requirement, customer QMS requirement, or documented information defined by the organization.

3.5
Nonconformity Report
NCR
a document stating results and providing objective evidence of nonconformity against audit criteria, including the following information: containment, correction, root cause, corrective action implementation, and closure

3.6
Online Aerospace Supplier Information System
OASIS
web-based IAQG database containing information on participating IAQG member companies, National Aerospace Industry Associations (NAIA), National Accreditation Bodies (NAB), accredited CBs, authenticated Aerospace Experience Auditors (AEAs), Aerospace Auditors (AAs) certified suppliers, certificates, and audit results

3.7
planned activities
the means, methods, and internal requirements by which the organization intends to achieve planned results of a given process to meet customer requirements. Planned activities include conformity to process requirements and maintained documented information

3.8
planned results
the intended performance of a process as determined and measured by the organization. Planned results include product and service conformity and On-time Delivery (OTD) to meet customer requirements, and may include other elements related to the process, as defined by the organization

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3.9
Process Effectiveness Assessment Report
PEAR
a document stating process evaluation results; providing evidence of conformity to requirements and process effectiveness

4 Auditing and reporting

The audit and reporting process established to assess conformity, including the determination of QMS effectiveness to the EN 9100-series standards, shall meet the requirements of EN ISO/IEC 17021-1, as stated in each relevant clause of this standard. Additional audit requirements for the aviation, space, and defence industry are invoked by this standard.

For combined and integrated audits, the requirements of EN 9104-001 clause 8.2.3 apply.

4.1 General

The audit process and associated activities (see clause 4.1.1) shall be followed when auditing and certifying organizations to AQMS standards in the aviation, space, and defence industry.

The audit process requirements consist of three main parts:

a) the phases of the audit process (see clause 4.1.1);

b) the common activities (see clause 4.2) that shall be used to support the audit phases; and

c) the specific requirements for each audit phase (see clause 4.3).

4.1.1 Audit process

The audit process consists of the following phases:

a) Pre-audit activities (see clause 4.3.1);

b) Stage 1 audit (see clause 4.3.2);

c) Stage 2 audit (see clause 4.3.3);

d) Surveillance audit (see clause 4.3.4); and

e) Recertification audit (see clause 4.3.5).

Pre-audit activities and Stage 1/Stage 2 audits are applicable for initial certification. A Stage 1 audit can also be utilized for recertification audits and during CB transfer.

NOTE 1 Although “Special Audit” is not listed as a part of the audit program, it can be applicable after initial certification, when directed by special request. The requirements for special audits are addressed in clause 4.3.6.

NOTE 2 The requirements for certification are defined by the EN 9104-001 standard.

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