

## **Quality Management Systems - Audit Requirements for Aviation, Space, and Defence Organizations**

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## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 9101:2011 sisaldab Euroopa standardi EN 9101:2011 ingliskeelset teksti.

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English Version

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

Systèmes de management de la Qualité - Exigences  
d'audit pour les Organismes 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 28 March 2011.

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 CEN-CENELEC Management Centre 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 CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, 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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EUROPÄISCHES KOMITEE FÜR NORMUNG

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## Contents

Page

|  |           |
|--|-----------|
| Foreword.....  | 3         |
| <b>0 Introduction.....</b>   | <b>5</b>  |
| <b>0.1 General.....</b>  | <b>5</b>  |
| <b>0.2 Auditing Approach .....</b>   | <b>5</b>  |
| <b>0.3 Audit Records and Reports .....</b>   | <b>5</b>  |
| <b>1 Scope .....</b>   | <b>6</b>  |
| <b>1.1 General.....</b>  | <b>6</b>  |
| <b>1.2 Application .....</b>   | <b>6</b>  |
| <b>2 Normative references .....</b>  | <b>6</b>  |
| <b>3 Terms and definitions .....</b>   | <b>7</b>  |
| <b>4 Auditing and reporting .....</b>  | <b>8</b>  |
| <b>4.1 General.....</b>  | <b>8</b>  |
| <b>4.1.1 Audit Process.....</b>  | <b>9</b>  |
| <b>4.1.2 Audit Methodology .....</b>   | <b>11</b> |
| <b>4.2 Common Audit Activities .....</b>   | <b>15</b> |
| <b>4.2.1 Audit Planning .....</b>  | <b>15</b> |
| <b>4.2.2 On-site Audits .....</b>  | <b>16</b> |
| <b>4.2.3 Audit Reporting.....</b>  | <b>19</b> |
| <b>4.2.4 Nonconformity Management .....</b>  | <b>19</b> |
| <b>4.2.5 Audit Records .....</b>   | <b>20</b> |
| <b>4.3 Audit Phase Specific Requirements .....</b>   | <b>20</b> |
| <b>4.3.1 Pre-audit Activities .....</b>  | <b>20</b> |
| <b>4.3.2 Stage 1 Audit.....</b>  | <b>21</b> |
| <b>4.3.3 Stage 2 Audit.....</b>  | <b>24</b> |
| <b>4.3.4 Surveillance.....</b>   | <b>25</b> |
| <b>4.3.5 Recertification .....</b>   | <b>25</b> |
| <b>4.3.6 Special Audits .....</b>  | <b>26</b> |
| <b>Annex A (normative) Objective Evidence Record (OER) .....</b>   | <b>28</b> |
| <b>Annex B (normative) Nonconformity Report (NCR) .....</b>  | <b>53</b> |
| <b>Annex C (normative) Process Effectiveness Assessment Report (PEAR) .....</b>                            | <b>56</b> |
| <b>Annex D (normative) QMS Process Matrix Report .....</b>   | <b>58</b> |
| <b>Annex E (normative) Audit Report (Stage 2, Surveillance, Recertification/Approval and Special).....</b> | <b>62</b> |
| <b>Annex F (normative) Audit Report (Stage 1) .....</b>  | <b>69</b> |
| <b>Annex G (normative) Supplemental Audit Report .....</b>   | <b>76</b> |

## Foreword

This document (EN 9101:2011) has been prepared by the Aerospace and Defence Industries Association of Europe - Standardization (ASD-STAN).

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 January 2012, and conflicting national standards shall be withdrawn at the latest by January 2012.

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 9101:2008.

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 standard was reviewed by the Domain Technical Coordinator of ASD-STAN's Quality Domain.

To assure customer satisfaction, aviation, space, and defence organizations must produce and continually improve, safe, reliable products 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 from suppliers throughout the world and at all levels of the supply chain. Suppliers have the challenge of delivering products to multiple customers having varying quality requirements and expectations.

Industry has established the International Aerospace Quality Group (IAQG), with representatives from 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 standard has been prepared by the IAQG.

This document standardizes the requirements for conducting and reporting of quality management system audits. It provides requirements for an audit and reporting process based on:

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

It can be used by aviation, space, and defense organizations at all levels throughout the global supply chain.

In this European Standard, the word "shall" indicates a requirement and the word "should" a recommendation to meet the intent of the standard. Words "typical", "example", or "e.g." indicate suggestions given for guidance. Information marked "NOTE" is for guidance in understanding or clarifying the associated requirement.

This standard has been completely rewritten to incorporate the 2009 changes to IAQG 9100-series standard quality management system requirements, the requirements for accredited Certification Bodies (CBs) introduced by International Organization for Standardization (ISO) / International Electrotechnical Commission (IEC) 17021, and inputs received from industry stakeholders associated to process based auditing methods

and the evaluation of process effectiveness. It replaces the existing versions of 9101, 9111, and 9121 (e.g., AS9101C, AS9111, AS9121, EN 9101:2006, EN 9111:2005, EN 9121:2005, SJAC 9101C).

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, 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.

## 0 Introduction

### 0.1 General

Auditing is a basic tool to assess effective implementation of and conformity to quality management system requirements. In addition to the determination of conformity, this standard focuses on the evaluation of effectiveness of the quality management system and its associated processes.

An organization is not only required to be in conformity with quality management system requirements, but to be effective in meeting customer expectations and delivering products that meet those expectations. In other words, an organization must not only meet the requirements of the quality management system standard, but at the same time deliver products that satisfy customer expectations.

Additionally, this standard takes into account the new requirements presented in the 2009 revisions of the 9100-series standards [e.g., critical items, special requirements, On-time Delivery (OTD) performance, risk management, project management].

### 0.2 Auditing Approach

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

- a) Is the process identified and appropriately defined?
- b) Are responsibilities assigned?
- c) Are the processes 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.

Additionally, product quality (as delivered), customer satisfaction, and quality management system 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 and maintained. They are critical in providing objective evidence on the conformity and effectiveness of the quality management system (including process effectiveness), and reporting the audit results. They can be used to inform the organization and its customers in a standard format/structure.

Records and reports to be generated are identified within this standard as annexes and shall be used to fulfill the reporting requirements.

NOTE Electronic templates of these documents will be made available by the IAQG.

# 1 Scope

## 1.1 General

This European standard defines requirements for the preparation and execution of the audit process. Additionally, it defines the content and composition for the audit reporting of conformity and process effectiveness to the 9100-series standards, the organization's quality management system documentation, and customer/regulatory requirements.

The requirements in this standard 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., ISO/IEC 17000, ISO 19011, ISO/IEC 17021). When there is conflict with these standards, the requirements of the 9101 standard shall take precedence.

NOTE 1 In this standard, the term "9100-series standards" comprises the following quality management system standards: 9100, 9110, and 9120; developed by the IAQG and published by various national standards bodies.

NOTE 2 In addition to this standard, IAQG publishes recommended practices that can be used by audit teams when executing the audit process.

## 1.2 Application

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

NOTE 1 Conflicts between 9104-series standards and this standard will be escalated to IAQG and resolved by an IAQG decision(s).

NOTE 2 Relevant parts of this standard (e.g., 4.2.1, 4.2.2, 4.2.3, and 4.2.4) can be used by an organization in support of internal audits (1<sup>st</sup> party) and external audits at suppliers (2<sup>nd</sup> party). This includes the audit methodology, guidance material, and document formats [e.g., audit reports, Nonconformity Reports (NCRs), other documents described in the Annexes]. In such case, the words "Certification Body" or "CB" should be read as "auditor" or "auditing organization" as appropriate.

# 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, *Quality Management Systems — Requirements for Aviation, Space and Defence Organizations*<sup>1)</sup>

EN 9110, *Quality Management Systems — Requirements for Aviation Maintenance Organizations*<sup>1)</sup>

EN 9120, *Quality Management Systems — Requirements for Aviation Space and Defence Distributors*<sup>1)</sup>

EN 9104, *Aerospace series — Quality management systems — Requirements for Aerospace Quality Management System Certification/Registrations Programs*<sup>1)</sup>

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1) As developed under the auspice of the IAQG and published by various standards bodies (e.g., ASD-STAN, SAE, CEN, JSA/SJAC, ABNT).



EN 9104-002, *Aerospace series — Quality management systems — Part 002: Requirements for Oversight of Aerospace Quality Management System Certification/Registrations Programs*<sup>1)</sup>

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

IAF MD 2:2007, *IAF Mandatory Document for the Transfer of Accredited Certification of Management Systems*

ISO 9000:2005, *Quality management systems — Fundamentals and vocabulary*

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

ISO/IEC 17021:2006, *Conformity assessment — Requirements for bodies providing audit and certification of management systems*

ISO 19011:2002, *Guidelines for quality and/or environmental management systems auditing*

### 3 Terms and definitions

For the purpose of this standard, the terms and definitions provided in ISO 9000, ISO/IEC 17000, 9100-series standards, 9104-series standards (i.e., 9104, 9104-002, 9104-003), and the following apply.

#### 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

##### **major nonconformity**

a non-fulfilment of a requirement which is likely to result in the failure of the quality management system or reduce its ability to assure controlled processes or compliant products; it can be one or more of the following situations:

- a) a nonconformity where the effect is judged to be detrimental to the integrity of the product or service;
- b) the absence of or total breakdown of a system to meet a 9100-series standard requirement, an organization procedure, or customer quality management system requirement;
- c) any nonconformity that would result in the probable shipment of nonconforming product; and/or
- d) a condition that could result in the failure or reduce the usability of the product or service and its intended purpose

#### 3.3

##### **minor nonconformity**

a non-fulfilment of a requirement which is not likely to result in the failure of the quality management system or reduce its ability to assure controlled processes or compliant products; it can be either one of the following situations:

- a) a single system failure or lapse in conformance with a 9100-series standard or customer quality management system requirement; or
- b) a single system failure or lapse in conformance with a procedure associated to the organization's quality management system