

## SLOVENSKI STANDARD kSIST FprEN 9101:2015

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Sistemi vodenja kakovosti - Zahteve za presojo organizacij zračnega prometa, vesoljskih poletov in obrambe

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

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

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# EUROPEAN STANDARD NORME EUROPÉENNE EUROPÄISCHE NORM

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#### **English Version**

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

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

This draft European Standard is submitted to CEN members for formal vote. It has been drawn up by the Technical Committee ASD-STAN.

If this draft becomes a European Standard, 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.

This draft European Standard was established by CEN 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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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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

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## **Foreword**

This document (FprEN 9101:2014) 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 document is currently submitted to the Formal Vote.

This document will supersede EN 9101:2011.

#### **RATIONALE**

This standard has been revised to incorporate the requirements for accredited Certification Bodies (CBs) introduced by International Organisation for Standardisation (ISO) / International Electrotechnical Commission (IEC) 17021:2011, 9104/1:2012, and inputs received from industry stakeholders associated to process-based auditing methods and the evaluation of process effectiveness.

#### **FOREWORD**

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

Industry 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 document has been prepared by the IAQG and standardises the requirements for conducting and reporting of Quality Management System (QMS) audits. It can be used by aviation, space, and defence organisations at all levels throughout the global supply chain.

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 standardised reporting of audit results.

In this 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.

## Introduction

#### General

Auditing is a basic tool to assess effective implementation of and conformity to QMS requirements. In addition to the determination of conformity, this standard focuses on the evaluation of effectiveness (see ISO 9000 subclause 3.2.14) of the QMS and its associated processes.

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

### Auditing approach

This standard supports the engagement and evaluation of an organisation's QMS process approach, as required by the 9100-series standards. When evaluating an organisation's QMS, 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 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 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.

### 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 organisation 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.