SLOVENSKI STANDARD
SIST EN 9101:2008

01-julij-2008

Aeronavtika - Sistemi vodenja kakovosti - Ocenjevanje (na podlagi ISO 9001:2000)

Aerospace series - Quality management systems - Assessment (based on ISO 9001:2000)

Luft- und Raumfahrt - Qualitätsmanagementsysteme - Audit (basiert auf ISO 9001:2000)

Série aérospatiale - Systèmes de management de la qualité - Évaluation (basé sur ISO 9001:2000)

Ta slovenski standard je istoveten z: **EN 9101:2008**

ICS:

03.120.10	Vodenje in zagotavljanje kakovosti	Quality management and quality assurance
49.020	Letala in vesoljska vozila na splošno	Aircraft and space vehicles in general

SIST EN 9101:2008 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 9101

April 2008

ICS 03.120.10; 49.020

English Version

Aerospace series - Quality management systems - Assessment (based on EN ISO 9001:2000)

Série aérospatiale - Systèmes de management de la qualité - Évaluation (basé sur EN ISO 9001:2000)

Luft- und Raumfahrt - Qualitätsmanagementsysteme - Audit (basiert auf EN ISO 9001:2000)

This European Standard was approved by CEN on 28 December 2007.

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 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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, 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.

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN 9101:2008: E

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Foreword

This document (EN 9101:2008) 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 October 2008, and conflicting national standards shall be withdrawn at the latest by October 2008.

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.

To assure customer satisfaction, aerospace industry organizations must produce, and continually improve, safe, reliable products that meet or exceed customer and regulatory authority requirements. The globalization of the aerospace industry, and the resulting diversity of regional/national requirements and expectations, has complicated this objective. End-product organizations face the challenge of assuring the quality of, and integrating, product purchased from suppliers throughout the world and at all levels within the supply chain. Aerospace suppliers and processors face the challenge of delivering product to multiple customers having varying quality expectations and requirements.

The aerospace industry has established the International Aerospace Quality Group (IAQG) for the purpose of achieving significant improvements in quality and safety, and reductions in cost, throughout the value stream. This organization includes representatives from aerospace companies in the Americas, Asia/Pacific, and Europe. This international standard has been prepared by the IAQG.

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, 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.

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1 PURPOSE

The purpose of this document is to define the content and the presentation of the Assessment Report for the EN 9100 standard.

2 QUALITY MANAGEMENT SYSTEM ASSESSMENT REPORT CONTENT

The Assessment Report is made up of:

- Page 6 *(required)*
  General Assessment Information
- Page 7 *(required)*
  Assessment Conclusions
- Page 8 *(optional)*
  Specific Organization Information
- Page 9 *(required)*
  QMS Assessment Result Summary
- Page 10 *(required)*
  QMS Assessment Scoring
- Page 11 *(required when nonconformities are identified during assessment)*
  Corrective Action Request
- Page 12 *(required when observations/comments are identified during assessment)*
  Observations/Comments
- Annex A
  Quality Management System Questionnaire

Audit Report No.:	ASSESSMENT REPORT	*Assessing company logo*

GENERAL ASSESSMENT INFORMATION	
1 Organization & Work Address	
Company Name: Subsidiary of: Organization Identification: Assessed Site Address: Main activities:	Tel Number: Fax Number: E-mail: CAGE code: Assessment Representative & Title: Management Representative & Title: Product Types or Codes: No. of employees at assessed site:
2 QMS Registration	
[ ] ISO Standard / Revision: Expiration Date (if applicable): Registrar Name:	[ ] Aerospace Standard / Revision: Expiration Date (if applicable): Registrar Name:
3 Assessment Team	
Lead Assessor Name: [ ] Certified Auditor – Type & No. [ ] Qualified Auditor	Other Assessment Team Members:
4 Assessment Dates:	
5 Assessment Scope	
[ ] Total facility assessed [ ] Initial assessment [ ] Partial facility assessed [ ] Re-assessment [ ] Other: [ ] Activity assessed:	[ ] All EN 9100 clauses assessed [ ] Partial EN 9100 clauses assessed Clauses not assessed:
6 Assessment Disposition	**7 Scoring**
[ ] Conforming [ ] Conforming with minor (mi) corrective action [ ] Nonconforming with Major (Ma) corrective action	Scoring result:

8 Assessment Approval			
Assessing Company	Date	Lead Assessor Name	Signature

Distribution Agreement

This Assessment Report is the property of the Assessed Organization and the Assessing Company. Distribution to other companies or individuals is authorized only after written agreement of the assessed Organization and of the Assessing Company.

To that end, a signature below by an Authorized Representative of the Assessing Company indicates that this report may be copied by the Organization for other customers.
If copied, the report must be disclosed in full including findings and any corrective actions.

Authorized Representative
Assessing Company Name ________________________ Signature ________________________________ Date ___________

Audit Report No.:	ASSESSMENT REPORT	*Assessing company logo*

ASSESSMENT CONCLUSIONS
General comments about the organization and the quality management system of the assessed organization:
Strong points:
Improvement Opportunities:

Audit Report No.:	ASSESSMENT REPORT	*Assessing company logo*

SPECIFIC ORGANIZATION INFORMATION

1 Legal and Financial Aspects

- ❒ Date of Formation:
- ❒ Legal Status:
- ❒ Capital:
- ❒ Other Data:

	Third Prior Financial Year ( )	Second Prior Financial Year ( )	First Prior Financial Year ( )	Current Financial Year ( )
Sales				
Earnings				
Earnings used for Re-Investment				
Workforce				

2 Turnover breakdown and main Customers

Activities	Main Customers	Sales Percentage
Aircraft, Space and Defense Industry		
Other Activity (be specific)		

3 Clearances or Approvals granted by Authorities

Name of the Authority	Types and References	End of Validity (date)

Audit Report No.:	**ASSESSMENT REPORT**	*Assessing company logo*

QMS ASSESSMENT RESULT SUMMARY

Organization:

Clauses*	**Result**					**Observation / Corrective Action Request Number (Ma/mi)**
	S	Ma	mi	N/A	N/E	
4 - Quality Management System						
4.1 General requirements						
4.2 Documentation requirements						
4.3 Configuration management						
5 - Management responsibility						
5.1 Management commitment						
5.2 Customer focus						
5.3 Quality policy						
5.4 Planning						
5.5 Responsibility, authority and communication						
5.6 Management review						
6 - Resource management						
6.1 Provision of resources						
6.2 Human resources						
6.3 Infrastructure						
6.4 Work environment						
7 - Product realization						
7.1 Planning of product realization						
7.2 Customer-related processes						
7.3 Design and development						
7.4 Purchasing						
7.5 Production and service provision						
7.6 Control of monitoring and measuring devices						
8 - Measurement, analysis and improvement						
8.1 General						
8.2 Monitoring and measurement						
8.3 Control of nonconforming product						
8.4 Analysis of data						
8.5 Improvement						
Assessed Organization:						Assessing Company:
Management Rep's name:	**Results**					Lead Assessor Name:
Signature:						Signature:

* For each clause, indicate with an "X" the results of assessment: "S" for Satisfactory, "Ma" for major corrective action, "mi" for minor, "N/A" for not applicable, or N/E for not evaluated.

Audit Report No.:	**QMS ASSESSMENT SCORING**	*Assessing company logo*

Organization:		**Result**					
	SCORING CHART	Major CAR or minor CAR on Key requirement		Minor CAR on **non** Key requirement		NO CAR	RESULT
		(Col. A)	**(Col. B)**	**(Col. C)**	**(Col. D)**		
		Multiple findings	Single finding	Multiple findings	Single finding		
4	**Quality management system**					**(100)**	
4.1	General requirements	0	10	25	40	50	
4.2 & 4.3	Documentation requirements & Configuration management	0	10	25	40	50	
5	**Management responsibility**					**(150)**	
5.1	Management commitment	0	5	15	20	30	
5.2	Customer focus						
5.3	Quality policy						
5.4	Planning	0	10	20	30	40	
5.5	Responsibility, authority and communication	0	5	15	20	30	
5.6	Management review	0	10	25	40	50	
6	**Resource Management**					**(100)**	
6.1	Provision of resources	0	10	25	40	50	
6.2	Human resources						
6.3	Infrastructure	0	10	25	40	50	
6.4	Work environment						
7	**Product realization**					**(450)**	
7.1	Planning of product realization	0	5	15	20	30	
7.2	Customer-related processes	0	10	30	50	60	
7.3	Design and development						
7.3.1	Design and development planning	0	5	15	20	30	
7.3.2-3-4	Inputs, outputs & review	0	5	15	20	30	
7.3.5-6	Design and development verification & validation	0	5	15	20	30	
7.3.7	Control of design and development changes	0	5	15	20	30	
7.4	Purchasing	0	10	30	50	60	
7.5	Production and service provision						
7.5.1	Control of production and service provision	0	10	25	40	50	
7.5.2	Validation of processes for production and service provision	0	10	20	30	40	
7.5.3	Identification and traceability	0	10	20	30	40	
7.5.4-5	Customer property & Preservation of product	0	5	15	20	30	
7.6	Control of monitoring and measuring devices	0	5	10	15	20	
8	**Measurement, analysis and improvement**					**(200)**	
8.1	General	0	5	10	15	20	
8.2	Monitoring and measurement						
8.2.1	*Customer satisfaction*	0	5	10	15	20	
8.2.2	*Internal audit*	0	5	15	20	30	
8.2.3	*Monitoring and measurement of processes*	0	5	15	20	30	
8.2.4	*Monitoring and measurement of product*	0	5	15	20	30	
8.3	Control of nonconforming product	0	5	15	20	30	
8.4	Analysis of data	0	5	10	15	20	
8.5	Improvement	0	5	10	15	20	

The assessed organization agrees on the quality management system scoring and corrective action requests		
Name of Representative:	Signature:	Date:

Total Points Possible	
Total Points Achieved	
Score (pts achieved/pts possible) × 100	

Audit Report No.:	**CORRECTIVE ACTION REQUEST (CAR)**	*Assessing company logo*

Organization: Site:	Identification C.A.R. No.: Date issued:
Reference Standard:	Referenced Standard Clause concerned:

Criticality Ma / mi	Nonconformance Description

Assessor Name:	Assessor Signature:

Assessed Organization to complete the CAR with root cause analysis, corrective action, and planned completion date of corrective action, and return to the Assessing Company by due date.	Due date:

Action No.:	Root Cause:	
Action No.:	Corrective Action:	Planned completion date of corrective action:

Organization Representative Name:	Signature:	Current date:
Verification of the implementation of the completed Corrective Action by the Assessed Organization		
Organization Representative Name:	Signature:	Current date:

Verification of the implementation of the completed Corrective Action to be filled out by the Assessing Company			
Verification date:	Accepted: Yes ❒ No ❒	Assessor Name:	Assessor Signature:

__S__: Satisfactory – __CAR__: Corrective action request – __Ma__: Major corrective action – __mi__: Minor corrective action
__N/A__: Not applicable – __N/E__: Not evaluated – __P:__ Product – __M__: Management

Audit Report No.:	**OBSERVATIONS/COMMENTS**	*Assessing company logo*
Organization:		
Site:	Issued date:	

Item Number	Section	Observation/Comment

Lead Assessor Name:	Signature:

Annex A
(normative)

QUALITY MANAGEMENT SYSTEM QUESTIONNAIRE

1 PURPOSE

The purpose of this annex is to present the questionnaire to be used during the “on-site” quality management system assessment of Organizations in order to ensure common practices for these assessments.

2 USE OF THE QUESTIONNAIRE

The use of this questionnaire is mandatory and will be a part of the Assessment Report.
The audit is undertaken by review of the organization’s QMS against the requirements of the EN 9100 standard, using the questionnaire as a guide. Findings are recorded as appropriate by the following annotations in the respective columns of the questionnaire:

- Satisfactory (S)
- Not applicable (N/A) the reason shall be documented at the bottom of the page
- Not evaluated (N/E)
- Corrective Action Request (CAR) Major (Ma) or Minor (mi) nonconformity:

The CAR number shall be referenced in the “CAR number” column. The category Ma for Major CAR or mi for Minor CAR shall also be included.

Additional information on questionnaire

Key Requirements: Some requirements are deemed to be very significant and are so identified by the presence of “P” or “M” against the specific section or question within the questionnaire:

- “P” – direct link with Product
- “M” – direct link with Management

The extent of Key Requirement applicability is determined by the location of the “M” or “P”.
In the example below all of question 14 is considered as a Key Requirement.

14 Does the output from the management review include any decisions and actions related to: a) Improvement of the effectiveness of the quality management system and its processes? b) Improvement of product related to customer requirements? and c) Resource needs?	M				