



SLOVENSKI STANDARD

SIST EN 9111:2008

01-junij-2008

Aeronavtika - Sistemi vodenja kakovosti - Ocenjevanje, ki se uporablja v vzdrževalnih organizacijah (na podlagi ISO 9001:2000)

Aerospace series - Quality management systems - Assessment applicable to maintenance organizations (based on ISO 9001:2000)

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

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Série aérospatiale - Systèmes de management de la qualité - Évaluation applicable aux organismes d'entretien (basé sur ISO 9001:2000)

<https://standards.iteh.ai/catalog/standards/sist/3a57e3ca-60d1-4579-9c6e-0ac896a8d4e/sist-en-9111-2008>

Ta slovenski standard je istoveten z: EN 9111:2005

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 9111:2008

en,fr,de

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ICS 03.120.10; 49.020

English Version

Aerospace series - Quality management systems - Assessment
applicable to maintenance organizations (based on ISO
9001:2000)

Série aérospatiale - Systèmes de management de la
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Luft- und Raumfahrt - Qualitätsmanagementsystems -
Audit für Wartungsfirmen (basiert auf ISO 9001:2000)

This European Standard was approved by CEN on 28 October 2005.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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

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

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Foreword

This European Standard (EN 9111:2005) has been prepared by the European Association of Aerospace Manufacturers - Standardization (AECMA-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 AECMA, 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 June 2006, and conflicting national standards shall be withdrawn at the latest by June 2006.

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.

In December 1998, the Aerospace Industry established the International Aerospace Quality Group (IAQG) with the purpose of achieving significant improvements in quality and reductions in cost throughout the value stream.

This organization, with representation from Aerospace companies in Americas, Asia and Europe and sponsored by SAE, SJAC and AECMA has agreed to take responsibility for the technical contents of this standard.

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

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

1 Purpose

The purpose of this standard is to define the content and the presentation of the Assessment Report of the EN 9110 (based on ISO 9001:2000).

2 Quality System Assessment Report content

The Assessment Report is made up of:

- Page 5 (*required*)
General Assessment Information
- Page 6 (*required*)
Assessment Conclusions
- Page 7 (*optional*)
General Organization Information
- Page 8 (*required*)
Assessment Result Summary
- Page 9 (*required*)
Quality System Scoring
- Page 10
Corrective Action Request (when required)
- Page 11
List of Recommendations/Observations/Comments
- Annex
MAINTENANCE ORGANIZATIONS – Quality System Questionnaire associated to the International Quality Management System Standard EN 9110 (based on ISO 9001:2000)
- Annex
Documents regarding the company:
 - Organization charts,
 - Copies of agreements and certifications ...

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ASSESSMENT REPORT Standards 9110/9111		<i>Assessing company logo</i>	
GENERAL ASSESSMENT INFORMATION			
1 Maintenance Organization & Work Address			
Company Name:		Tel Number:	
Subsidiary of:		Fax Number:	
Organization Identification:		e-mail:	
Assessed Site Address:		CAGE code:	
		Assessment Representative & Title:	
		Quality Manager Representative & Title:	
Main activities:			
Product Types or Codes:			
2 ISO Registration			
<input type="checkbox"/> ISO Registered		Registrar Name:	
<input type="checkbox"/> ISO Standard / Revision		Expiration Date (If applicable):	
<input type="checkbox"/> Aerospace Standard / Revision			
3 Assessment Team			
Lead Assessor Name:		Other Assessor Team Members:	
<input type="checkbox"/> Certified Auditor – Type & No.			
<input type="checkbox"/> Qualified Auditor			
4 Assessment Dates:			
5 Assessment Scope			
<input type="checkbox"/> Total facility assessed		<input type="checkbox"/> Initial assessment	
<input type="checkbox"/> Partial facility assessed		<input type="checkbox"/> Re-assessment	
<input type="checkbox"/> Other:		<input type="checkbox"/> All 9110 elements assessed	
<input type="checkbox"/> Activity assessed:		<input type="checkbox"/> Partial 9110 elements assessed	
		Elements not assessed:	
6 Assessment Disposition		7 Scoring	
<input type="checkbox"/> Conforming		Scoring result:	
<input type="checkbox"/> Conforming with minor (mi) corrective action			
<input type="checkbox"/> Nonconforming with Major (MA) corrective action			
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 _____

ASSESSMENT REPORT	<i>Assessing company logo</i>
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ASSESSMENT CONCLUSIONS
(To be completed in English)

General comments about the organization and the quality system of the assessed organization:

Strong points:

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Improvement Opportunities:

ASSESSMENT REPORT			<i>Assessing company logo</i>	
GENERAL ORGANIZATION INFORMATION				
1 Legal and Financial Aspects				
<input type="checkbox"/> Date of Formation: <input type="checkbox"/> Legal Status: <input type="checkbox"/> Capital: <input type="checkbox"/> Other Data:				
	Third Prior Financial Year ()	Second Prior Financial Year ()	First Prior Financial Year ()	Current Financial Year ()
Sales	iTeh STANDARD PREVIEW (standards.iteh.ai)			
Earnings	SIST EN 9111:2008 https://standards.iteh.ai/catalog/standards/sist/3a57e3ca-60d1-4579-9c6e-0ac896a8d4e/sist-en-9111-2008			
Earnings used for Re-Investment	SIST EN 9111:2008 https://standards.iteh.ai/catalog/standards/sist/3a57e3ca-60d1-4579-9c6e-0ac896a8d4e/sist-en-9111-2008			
Workforce				
2 Turnover breakdown and main Customers				
Activities	Main Customers		Sales Percentage	
Aircraft, Space and Defence Industry				
Other Activity (be specific)				
3 Clearances or Approvals granted by Authorities				
Name of the Authority	Types and References		End of Validity (date)	

ASSESSMENT REPORT	<i>Assessing company logo</i>
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ASSESSMENT RESULT SUMMARY

Organization:

Elements* (EN 9110 – 9111)	Result				Observation / Corrective Action Request Number (Ma/mi)
	S	Ma	mi	N/A	
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:
Rep's name:	Results				Lead Assessor Name:
Signature:					Signature:

* For each element, cross results of assessment: "S" for Satisfactory, "Ma" for major corrective action, "mi" for minor or "N/A" for non applicable

ASSESSMENT SCORING	<i>(Member logo)</i>
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Organization:		Result					
	SCORING CHART Standards 9110/9111	Major CAR or minor CAR on Key requirement		Minor CAR on non Key requirement		NO CAR	RESULT
		Multiple findings	Single finding	Multiple findings	Single finding		
4	Quality management system (Max. 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 (Max. 150)						
5.1	Management commitment						
5.2	Customer focus	0	5	15	20	30	
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 (Max. 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 (Max.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	D & D Planning	0	5	15	20	30	
7.3.2-3-4	Inputs, outputs & review	0	5	15	20	30	
7.3.5-6	D&D 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 (Max. 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	
						Total Points Possible	
						Total Points Achieved	
						Score (pt achieved/pts × 100)	
The assessed Organization agrees on the Quality System scoring and Corrective Action requests							
Organization Representative:		Signature:		Date:			

CORRECTIVE ACTION REQUEST (C.A.R.)		<i>Assessing company logo</i>	
Organization:		Identification C.A.R. No.:	
Site:		Date issued:	
Reference Standard:		Referenced Standard Element concerned:	
Criticality MA / mi	Non-Conformance Description		
Assessor Name:		Assessor Signature:	
Assessed Organization to complete the Corrective Action Request 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: <div style="text-align: center;"> <p>STANDARD PREVIEW</p> <p>(standards.iteh.ai)</p> <p>SIST EN 9111:2008</p> <p>https://standards.iteh.ai/catalog/standards/sist/3a57e3ca-60d1-4579-9c6e-0ac896a8d4e/sist-en-9111-2008</p> </div>		
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			
<u>Verification date:</u>	Accepted: Yes <input type="checkbox"/> No <input type="checkbox"/>	<u>Assessor Name:</u>	<u>Assessor Signature:</u>

List of Recommendations/Observations/Comments	<i>Assessing company logo</i>
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Organization: Site:	Audit report number: Issued date:
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Item Number	Section	Description
<p>iTeh STANDARD PREVIEW (standards.iteh.ai)</p> <p><u>SIST EN 9111:2008</u> https://standards.iteh.ai/catalog/standards/sist/3a57e3ca-60d1-4579-9c6e-0ac896a8d4e/sist-en-9111-2008</p>		

Lead Assessor Name:	Signature:
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Annex A
(normative)

**Maintenance Organizations
Quality System Questionnaire**

**associated to the International Quality Management System Standard
EN 9110 (based on ISO 9001:2000)**

1 Purpose

The purpose of this standard is to present the questionnaire to be used during the “on site” quality system assessment of Organizations in order to ensure common practices for these assessments. This questionnaire is relative to EN 9110 standard (based on ISO 9001:2000).

2 Use of the questionnaire

The use of this questionnaire is mandatory and will be a part of the Assessment Report. The questionnaire is based on the EN 9110 standard, section 4, which is relative to:

- **ISO 9001:2000 requirements**
- **Additional Aerospace specific requirements are shown in bold and italics.**

The audit is undertaken by review against the requirements of the questionnaire and the findings are recorded as appropriate by annotation of respective columns,

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

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

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 16 is considered as a key requirement.

16 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				
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In the second example below only part of question 03, i.e. d) is considered Key Requirement.

<p>03 In planning product realization, does the organization determine the following, as appropriate:</p> <p>a) Quality objectives and requirements for the product?</p> <p>b) the need to establish processes, documents, and provide resources specific to the product?</p> <p>c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance?</p> <p>d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4)?</p> <p>e) the identification of resources to support operation and maintenance of the product?</p>	P				
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Guidance notes: Under Key requirements column certain questions will have a numeric reference that refers to additional guidance notes which are detailed within the 'Guidance notes' section located after the questions on each page. The guidance notes provide the Auditor with further insight on type of objective evidence and/or review expectations etc. In the example below, note 1) refers the auditor to additional notes pertaining to question 51 part a).

<p>51 Does the analysis of data provide information relating to :</p> <p>a) customer satisfaction (see 8.2.1) (1) ?</p> <p>b) conformity to product requirements (see 7.2.1)?</p> <p>c) characteristics and trends of processes and products including opportunities for preventive action? And</p> <p>d) organizations?</p>					
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Guidance Note *iTeh STANDARD PREVIEW*
 1) Give examples and check how the organization measures the effectiveness.
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References: When a reference (e.g. 4.1) is added to a question, it is linked to the appropriate chapter (e.g. 4.1) of EN 9110 standard. [SIST EN 9111:2008](http://standards.iteh.ai/catalog/standards/sist/en-9111-2008)

Objective evidence assessed / Observations / Comments / N/A explanation

Record the objective evidence reviewed during the assessment or reason for not applicable.

Nonconformities:

Major : The absence of, or total breakdown of a management element specified in the EN 9110 standard or any nonconformities where the effect is judged to be detrimental to the integrity of the product or service.

Minor : A single system failure or lapse in conformance with a procedure relating to the EN 9110 standard.

NOTE A number of minor nonconformities against one requirement can represent a total breakdown of the system and this can be considered as a major nonconformity

3 Use of the Assessment Scoring chart

Following completion of the Quality System Questionnaire the Assessment Scoring chart can now be completed. The findings of each section and sub-section of the completed Quality System Questionnaire are reviewed and the Assessment Scoring sheet completed as follows.

- If, multiple findings (i.e. greater than 1) with Major (Ma) Corrective Action Request (CAR) or minor (mi) CAR on Key requirement in a section, e.g. 4.1 General Requirements then score in Major CAR or minor CAR on Key Requirement (i.e. any questions with 'M' or 'P' indicator) "Multiple findings" column (result = 0), or
- If, single finding with Major (Ma) CAR or minor (mi) CAR on key requirements in a section, e.g. 4.1 General Requirements then score in Major CAR or minor CAR on Key Requirement "Single finding" column (result = 10), or