

AEROSPACE STANDARD

SAE AS9101
Technically equivalent to
AECMA prEN 9101

REV.
B

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Superseding AS9101A

Quality Management Systems Assessment

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FOREWORD

In December 1998, the Aerospace Industry has 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.

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SECTION 1

* * *

QUALITY MANAGEMENT SYSTEMS ASSESSMENT

1 PURPOSE

The purpose of this document is to define the content and the presentation of the Assessment Report of the section 1 of AS9100.

2 QUALITY 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*)
General Organization Information
- Page 9 (*required*)
Assessment Result Summary
- Page 10 (*required*)
Assessment Scoring
- Page 11
Corrective Action Request (when required)
- Page 12
List of Recommendations/Observations/Comments
- **Appendix A**
Quality System Questionnaire relative to the section 1 of AS9100

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ASSESSMENT REPORT	
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GENERAL ASSESSMENT INFORMATION

1 Organization & Work Address

Company Name: Subsidiary of: Organization Identification: Assessed Site Address: Main activities: Product Types or Codes:	Tel Number: Fax Number: e-mail: CAGE code: Assessment Representative & Title: Quality Manager Representative & Title:
--------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------

2 ISO Registration

<input type="checkbox"/> ISO Registered <input type="checkbox"/> ISO Standard / Revision <input type="checkbox"/> Aerospace Standard / Revision	Registrar Name: Expiration Date (If applicable):
-------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------

3 Assessment Team

Lead Assessor Name: <input type="checkbox"/> Certified Auditor – Type & No. <input type="checkbox"/> Qualified Auditor	Other Assessor Team Members:
-------------------------------------------------------------------------------------------------------------------------------------	------------------------------

4 Assessment Dates:

5 Assessment Scope

<input type="checkbox"/> Total facility assessed <input type="checkbox"/> Partial facility assessed <input type="checkbox"/> Other: <input type="checkbox"/> Activity assessed:	<input type="checkbox"/> Initial assessment <input type="checkbox"/> Re-assessment	<input type="checkbox"/> All 9100 elements assessed <input type="checkbox"/> Partial 9100 elements assessed Elements not assessed:
------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------

6 Assessment Disposition	7 Scoring
---------------------------------	------------------

<input type="checkbox"/> Conforming <input type="checkbox"/> Conforming with minor (mi) corrective action <input type="checkbox"/> Non conforming with Major (MA) corrective action	Scoring result:
-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------

8 Assessment Approval

Assessing Company	Date	Lead Assessor Name	Signature
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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



ASSESSMENT CONCLUSIONS

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

Strong points:

Improvement Opportunities:

ASSESSMENT REPORT



GENERAL 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)

ASSESSMENT REPORT



ASSESSMENT RESULT SUMMARY

Organization :

Elements* (AS9100 – Section 1)	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					
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: Signature:	Results				Lead Assessor Name: 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




Organization :		Result						
	SCORING CHART	Major CAR or minor CAR on Key requirement		Minor CAR on <u>non</u> Key requirement		NO CAR	RESULT	
		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							
5.2	Customer focus	0	5	15	20	30		
5.3	Quality policy							
5.4	Planning							
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							
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	<i>D&D Planning</i>	0	5	15	20	30		
7.3.2-3-4	<i>Inputs, outputs & review</i>	0	5	15	20	30		
7.3.5-6	<i>D&D verification & validation</i>	0	5	15	20	30		
7.3.7	<i>Control of design and development changes</i>	0	5	15	20	30		
7.4	Purchasing	0	10	30	50	60		
7.5	Product and service provision							
7.5.1	<i>Control of production and service provision</i>	0	10	25	40	50		
7.5.2	<i>Validation of processes for production and service provision</i>	0	10	20	30	40		
7.5.3	<i>Identification and traceability</i>	0	10	20	30	40		
7.5.4-5	<i>Customer property & preservation of product</i>	0	5	15	20	30		
7.6	Control of monitoring and measuring device	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	<i>Customer satisfaction</i>	0	5	10	15	20		
8.2.2	<i>Internal audit</i>	0	5	15	20	30		
8.2.3	<i>Monitoring and measurement of processes</i>	0	5	15	20	30		
8.2.4	<i>Monitoring and measurement of product</i>	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	880 ⁽¹⁾ or 1000	
						SCORE	/ 100	

The assessed Organization agrees on the Quality System scoring and Corrective Action requests		
Organization Representative :	Signature :	Date :

(1) When 7.3 is not assessed : SCORE = $\frac{\text{RESULT} \times 100}{880}$

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CORRECTIVE ACTION REQUEST (C.A.R.)			
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:		
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



Organization :	Audit report number
Site :	Issued date :

Item Number	Section	Description

Lead Assessor Name:	Signature:
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S : Satisfactory - **CAR** : Corrective action required – **Ma** : Major corrective action – **mi** : Minor corrective action
N/A : Not applicable - **NE**: Not evaluated - **P** : Product - **M** : Management

**APPENDIX A
AS9101**

* * *

QUALITY SYSTEM QUESTIONNAIRE

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1. PURPOSE

The purpose of this document 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 the section 1 of AS9100.

2. USE OF THE QUESTIONNAIRE

The use of this questionnaire is mandatory and will be a part of the Assessment Report. The questionnaire is used to evaluate AS9100 standard, section 1.

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 14 is considered as a key requirement.

14	Does the output from the management review include any decisions and actions related to :	M				
	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 ?					

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

03	In planning product realization, does the organization determine the following, as appropriate :					
	a) Quality objectives and requirements for the product ?					
	b) The need to establish processes, documents, and provide resources specific to the product ?					
	c) Required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance ?					
	d) Records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4) ?	P				
	e) <i>The identification of resources to support operation and maintenance of the product ?</i>					

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Guidance notes: 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 1 part a).

48 Does the analysis of data provide information relating to : a) Customer satisfaction (see 8.2.1) (1) ? b) Conformity to product requirements (see 7.2.1) e ? c) Characteristics and trends of processes and products including opportunities for preventive action ? And d) Organizations ?					
------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--	--	--	--	--

Guidance Note

1) Give examples and check how the organization measures the effectiveness.

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 AS9100.

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

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

Non-conformities :

Major : The absence of, or total breakdown of a management element specified in the 9100 standard or any non-conformities 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 9100 standard.

Note : A number of minor non-conformities against one requirement can represent a total breakdown of the system and this can be considered as a major non-conformity

3. USE OF THE ASSESSMENT SCORING CHART

Following completion of each chapter of the Quality System Questionnaire the nomenclature 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
- If, multiple findings on non Key requirement (i.e. greater than 1) with Minor (mi) (CAR) in a section, e.g. 4.1 General Requirements then score in Minor CAR on non Key requirement “Multiple findings” column (result=25), or

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- If, single finding on non Key requirement with Minor (mi) CAR in a section, e.g. 4.1 General Requirements then score in Minor CAR on non Key requirement “Single findings” column (result = 40), or
- If, no CAR in a section, e.g. 4.1 General Requirements then score in “NO CAR” column (result=50)
- When a single finding occurred on several questions affecting the same section of the scoring table (e.g. 4.2 & 4.3 or 5.1-5.2-5.3), then score as “multiple findings”.

Further notes on scoring

The above review criteria should be considered sequentially.

Maximum audit total can be,

1000, where audit review comprises whole Quality System Questionnaire or,

880, where audit review comprises Quality System Questionnaire less Design and Development. In this case, the final score = $\frac{\text{TOTAL X 100}}{880}$

If a complete section line of the score sheet has not been assessed (N/A or N/E) the score will be calculated as follow:

$$\text{Score} = \frac{\text{TOTAL x 100}}{\text{Sum of maximum possible score}}$$

The higher the score the greater the level of compliance acknowledged by the audit activity.

Summary

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QUALITY SYSTEM QUESTIONNAIRE					
ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E

4.2.4 QUALITY MANAGEMENT SYSTEM

4.1 General requirements					
01 Has the organization established, documented, implemented and maintained a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard ?					
02 Does the organization : a) identify the processes needed for the quality management system and their application throughout the organization (1) ? b) determine the sequence and interaction of these processes (1) ? c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective ? d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes ? e) monitor, measure and analyze these processes ? and f) implement actions necessary to achieve planned results and continual improvement of these processes ?					
03 Are these processes managed by the organization in accordance with the requirements of this International Standard ?					
04 Where an organization chooses to outsource any process that affects product conformity with requirements, does the organization ensure control over such processes ?	P				
05 Is the control of such outsource processes identified within the quality management system ?					

Note : Processes needed for the quality management system referred to above should include processes for management, provision, product realization and measurement.

Guidance Note
1) Main process formally identified e.g. : list, flow diagram, etc.

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

*S: Satisfactory - CAR: Corrective action required - Ma: Major corrective action - mi: Minor corrective action
N/A: Not applicable - N/E: Not evaluated - P: Product - M: Management*

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QUALITY SYSTEM QUESTIONNAIRE					
ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E

4.2. 4.2 Documentation requirements

4.2.1 General					
06 Does the quality management system documentation include : a) documented statements of a quality policy and quality objectives ? b) a quality manual ? c) documented procedures required by this International Standard ? d) documents needed by the organization to ensure the effective planning, operation and control of its processes ? e) records required by this International Standard (see 4.2.4) ? and f) quality system requirements imposed by the applicable Regulatory Authorities ?					
07 Does the organization ensure that personnel have access to quality management system documentation and are aware of relevant procedures ?					
08 Do Customer and/or regulatory authority representatives have access to quality management system documentation ?					
4.2.2 Quality manual					
09 Has the organization established and maintained a quality manual that includes (1) : a) the scope of the quality management system, including details of, and justification for, any exclusions ? b) the documented procedures established for the quality management system, or reference to them, and when referencing the documented procedures, is the relationship between the requirements of this International Standard and the documented procedures clearly shown (2) ? c) a description of the interaction between the processes of the quality management system ?					

Note 1 : Where the term “documented procedure” appears within this International Standard, this means that the procedure is established, documented, implemented and maintained.

Note 2 : The extent of the quality management system documentation can differ from one organization to another due to

- a) the size of organization and type of activities,
- b) the complexity of processes and their interactions, and
- c) the competence of personnel

Guidance Notes

- 1) Quality manual reference and issue
- 2) Check the procedure list

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

S: Satisfactory - **CAR:** Corrective action required – **Ma:** Major corrective action – **mi:** Minor corrective action
N/A: Not applicable - **N/E:** Not evaluated - **P:** Product - **M:** Management

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QUALITY SYSTEM QUESTIONNAIRE						
ASSESSMENT QUESTIONS		KEY Requirements	S	CAR Number Ma or mi	N/A	N/E

5 MANAGEMENT RESPONSIBILITY

5.1 Management commitment						
01	Has Top management provided evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by (1) :	M				
	a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements ?					
	b) establishing the quality policy ?					
	c) ensuring that quality objectives are established ?					
	d) conducting management reviews ? And					
	e) ensuring the availability of resources ?					
5.2 Customer focus						
02	Has Top management ensured that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1) ?					
5.3 Quality policy						
03	Has Top management ensured that the quality policy :					
	a) is appropriate to the purpose of the organization ?					
	b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system ?					
	c) provides a framework for establishing and reviewing quality objectives ?					
	d) is communicated and understood within the organization (2) ? and					
	e) is reviewed for continuing suitability ?					
5.4 Planning						
5.4.1 Quality objectives						
04	Has Top management ensured that quality objectives, including those needed to meet requirements for product [see 7.1 a)] are established at relevant functions and levels within the organization (3) ?					
05	Are the quality objectives measurable and consistent with the quality policy ?	M				
5.4.2 Quality management system planning						
06	Has Top management ensured that :					
	a) the planning of the quality management system is carried out in order to meet the requirements given in(see 4.1), as well as the quality objectives ? and					
	b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented ?					

Guidance Notes

- 1) Evidence of management commitment
- 2) Identify and records method of communication
- 3) Review objectives and status of their implementation

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

Empty space for objective evidence, observations, comments, and N/A explanation

*S: Satisfactory - CAR: Corrective action required – Ma: Major corrective action – mi: Minor corrective action
N/A: Not applicable - N/E: Not evaluated - P: Product - M: Management*

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QUALITY SYSTEM QUESTIONNAIRE								
ASSESSMENT QUESTIONS				KEY Requirements	S	CAR Number Ma or mi	N/A	N/E

5.6 Management review

5.6.1 General									
10	Has Top management reviewed the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness (1) ?								
11	Does this review include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives ?								
12	Are records from management reviews maintained (see 4.2.4) ?								
5.6.2 Review input									
13	Does the input to management review include information on (2) : a) results of audits? b) customer feedback? c) process performance and product conformity? d) status of preventive and corrective actions? e) follow-up actions from previous management reviews? f) changes that could affect the quality management system? And g) recommendations for improvement?				M				
5.6.3 Review output									
14	Does the output from the management review include any decisions and actions related to (2) : d) improvement of the effectiveness of the quality management system and its processes? e) improvement of product related to customer requirements? And f) resource needs?				M				

Guidance Notes
1) Records management review frequency and functions involved (e.g : quality, production, etc.)
2) Verify the availability of input / output data such as: statistical data; graphics; summary tables; reports; etc.

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

*S: Satisfactory - CAR: Corrective action required – Ma: Major corrective action – mi: Minor corrective action
N/A: Not applicable - N/E: Not evaluated - P: Product - M: Management*

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QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS					KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
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7. PRODUCT REALIZATION

7.1 Planning of product realization

01	Does the organization plan and develop the processes needed for product realization ? (see 4.1)							
02	Is planning of product realization consistent with the requirements of the other processes of the quality management system (see 4.1) ?							
03	In planning product realization, does the organization determine the following, as appropriate : a) quality objectives and requirements for the product ? b) the need to establish processes, documents, and provide resources specific to the product ? c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance ? d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4) ? e) the identification of resources to support operation and maintenance of the product ?	P						
04	Is the output of this planning in a form suitable for the organization's method of operations?							

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

*S: Satisfactory - CAR: Corrective action required – Ma: Major corrective action – mi: Minor corrective action
N/A: Not applicable - N/E: Not evaluated - P: Product - M: Management*

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QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
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7.2 Customer-related processes

7.2.1 Determination of requirements related to the product					
05 Does the organization determine : a) requirements specified by the customer, including the requirements for delivery and post-delivery activities ? b) requirements not stated by the customer but necessary for specified or intended use, where known ? c) statutory and regulatory requirements related to the product ? and d) any additional requirements determined by the organization ?	M				
7.2.2 Review of requirements related to the product					
06 Does the organization review the requirements related to the product ?					
07 Is the review conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and does it ensure that (1) : a) product requirements are defined ? b) contract or order requirements differing from those previously expressed are resolved ? c) the organization has the ability to meet the defined requirements ? And d) risks (e.g., new technology, short delivery time scale) have been evaluated ?	P				
08 Are records of the results of the review and actions arising from the review maintained (see 4.2.4) (2) ?					
09 Where the customer provides no documented statement of requirement, are the customer requirements confirmed by the organization before acceptance ?					
10 Where product requirements are changed, does the organization ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements ?	P				

Note : In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover the relevant product information such as catalogues or advertising material.

7.2.3 Customer communication

11 Does the organization determine and implement effective arrangements for communicating with customers in relation to : a) product information ? b) enquiries, contracts or order handling, including amendments ? and c) customer feedback, including customer complaints ?					
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Guidance Notes

- 1) Check that all affected functions are involved in the review
- 2) Give examples

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

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S: Satisfactory - **CAR:** Corrective action required – **Ma:** Major corrective action – **mi:** Minor corrective action
N/A: Not applicable - **N/E:** Not evaluated - **P:** Product - **M:** Management

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QUALITY SYSTEM QUESTIONNAIRE						
ASSESSMENT QUESTIONS		KEY Requirements	S	CAR Number Ma or mi	N/A	N/E

7.3 Design and development

7.3.1 Design and development planning						
12	Does the organization plan and control the design and development of product ?					
13	During the design and development planning, does the organization determine : a) the design and development stages (1) ? - <i>in respect of organization, task sequence, mandatory steps, significant stages and method of configuration control,</i> b) the review, verification and validation that are appropriate to each design and development stage ? and c) the responsibilities and authorities for design and development ?	M				
14	<i>Where appropriate, due to complexity, does the organization give consideration to the following activities :</i> - <i>structuring the design effort into significant elements ?</i> - <i>for each element, analyzing the tasks and the necessary resources for its design and development. Does This analysis consider an identified responsible person, design content, input data, planning constraints, and performance conditions. Is the input data specific to each element reviewed to ensure consistency with requirements ?</i>					
15	Does the organization manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility ?					
16	Is planning output updated, as appropriate, as the design and development progresses ?					
17	<i>Are the different design and development tasks to be carried out defined according to specified safety or functional objectives of the product in accordance with customer and/or regulatory authority requirements (2) ?</i>	P				
7.3.2 Design and development inputs						
18	Are inputs relating to product requirements determined and are records maintained (see 4.2.4) (3) ? Do these inputs include : a) functional and performance requirements ? b) applicable statutory and regulatory requirements ? c) where applicable, information derived from previous similar designs ? and d) other requirements essential for design and development ?	M				
19	Are these inputs reviewed for adequacy ?					
20	Are requirements completed, unambiguous and not in conflict with each other ?					

Guidance Notes

- 1) Give at least an example of a completed design & development plan, or an example of one in progress, that identifies the planning of tasks and key events.
- 2) Give an example
- 3) Review applicable input data (give examples)

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

<p>Objective evidence assessed / Observations / Comments / N/A explanation</p>

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ASSESSMENT QUESTIONS					KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
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7.3 Design and development (continued)

7.3.3 Design and development outputs									
21	Are the outputs of design and development provided in a form that enables verification against the design and development input and approved prior to release ?								
22	Do the design and development outputs : a) meet the input requirements for design and development ? b) provide appropriate information for purchasing, production and for service provision ? c) contain or reference product acceptance criteria ? d) specify the characteristics of the product that are essential for its safe and proper use ? and e) identify key characteristics, when applicable, in accordance with design or contract requirements ?	M							
23	Is all pertinent data required to allow the product to be identified, manufactured, inspected, used and maintained defined by the organization; for example: - drawings, part lists, specifications ? - a listing of those drawings, part lists, and specifications necessary to define the configuration and the design features of the product ? - information on material, processes, type of manufacturing and assembly of the product necessary to ensure the conformity of the product ?	M							
7.3.4 Design and development review									
24	At suitable stages, are systematic reviews of design and development performed in accordance with planned arrangements (see 7.3.1) to (1) : a) evaluate the ability of the results of Design and development to meet requirements ? b) identify any problems and propose necessary actions ? and c) authorize progression to the next stage ?	M							
25	Do participants in such reviews include representatives of functions concerned with the design and development stage(s) being reviewed ?								
26	Are records of the results of the reviews and any necessary actions maintained (see 4.2.4) ?								
7.3.5 Design and development verification									
27	Is verification performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements ?								
28	Are records of the results of the reviews and any necessary actions maintained (see 4.2.4) ?								
<p>Note : Design and/or development verification may include activities such as :</p> <ul style="list-style-type: none"> - performing alternative calculations - comparing the new design with a similar proven design, if available - undertaking tests and demonstrations, and - reviewing the design stage documents before release. 									
Guidance Notes									
1) Give evidence of reviews									
Objective evidence assessed / Observations / Comments / N/A explanation									

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7.3 Design and development (continued)

7.3.7 Control of design and development changes					
34	Are design and development changes identified and records maintained ?				
35	Are the changes reviewed, verified and validated, as appropriate, and approved before implementation (1) ?	P			
36	Does the review of design and development changes include evaluation of the effect of the changes on constituent parts and product already delivered ?	P			
37	<i>Does the organization's change control process provide for customer and/or regulatory authority approval of changes, when required by contract or regulatory requirement ?</i>				
38	Records of the results of the review of changes and any necessary actions maintained (see 4.2.4) ?				

Guidance Note

- 1) Give an example

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

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QUALITY SYSTEM QUESTIONNAIRE						
ASSESSMENT QUESTIONS		KEY Requirements	S	CAR Number Ma or mi	N/A	N/E

7.4 Purchasing

7.4.1 Purchasing process						
39	Does the organization ensure that purchased product conforms to specified purchase Requirements ?	P				
40	Is the type and extent of control applied to the Supplier and the purchased product dependent upon the effect of the purchased product on subsequent product realization or the final product ?					
41	<i>Is the organization responsible for the quality of all products purchased from suppliers, including customer-designated sources ?</i>					
42	Does the organization evaluate and select Suppliers based on their ability to supply product in accordance with the organization's requirements ?					
43	Are criteria for selection, evaluation and re-evaluation established ?					
44	Are records of the results of evaluations and any necessary actions arising from the evaluation maintained (see 4.2.4) ?					
45	<i>Does the organization :</i> <i>a) Maintain a register of approved Suppliers that includes the scope of the approval (1) ?</i> <i>b) Periodically review Suppliers performance and use the records of these reviews as a basis for establishing the level of controls to be implemented (2) ?</i> <i>c) Define the necessary actions to take when dealing with Suppliers that do not meet requirements ?</i> <i>d) Ensure where required that both the organization and all Suppliers use customer-approved special process sources ?</i> <i>e) Ensure that the function having responsibility for approving Supplier quality systems has the authority to disapprove the use of sources ?</i>	M				

Guidance Notes
1) Review current list of approved Suppliers 2) Review suppliers performance / measurement system (e.g.: supplier rating, etc.)

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

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ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
7.4 Purchasing (continued)					
7.4.2 Purchasing information					
<p>46 Does purchasing information describe the product to be purchased, including where appropriate (1) :</p> <p>a) requirements for approval of product, procedures, processes and equipment ?</p> <p>b) requirements for qualification of personnel ?</p> <p>c) quality management system requirements ?</p> <p>d) the name or other positive identification, and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data ?</p> <p>e) requirements for design, test, examination, inspection and related instructions for acceptance by the Organization ?</p> <p>f) requirements for test specimens (e.g., production method, number, storage conditions) for design approval, inspection, investigation or auditing ?</p> <p>g) requirements relative to :</p> <p style="padding-left: 20px;">- supplier notification to Organizationr of nonconforming product ? and</p> <p style="padding-left: 20px;">- arrangements for Organizationr approval of supplier nonconforming material ?</p> <p>h) requirements for the supplier to notify the Organization of changes in product and/or process definition and, where required, obtain organization approval ?</p> <p>i) right of access by the organization, their customer, and authorities to all facilities involved in the order and to all applicable records ? and</p> <p>j) requirements for the supplier to flow down to subtier suppliers the applicable requirements in the purchasing documents, including key characteristics where required ?</p>	P				
<p>47 Does the organization ensure the adequacy of specified purchase requirements prior to their communication to the supplier ?</p>					
Guidance Note					
1) Examine purchase orders that apply to several types of procurement.					
Objective evidence assessed / Observations / Comments / N/A explanation					

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ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
7.4 Purchasing (continued)					
7.4.3 Verification of purchased product					
48 Does the organization establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements, they may include obtaining objective evidence of the quality of the product from suppliers (e.g., accompanying documentation, certificate of conformity, test reports, statistical records, process control, inspection and audit at supplier's premises, review of the required documentation, inspection of products upon receipt, and, delegation of verification to the supplier, or supplier certification ?	P				
49 Is purchased product held until it has been verified as conforming to specified requirements unless it is released under positive recall procedure ?					
50 Where the organization utilizes test reports to verify purchased product, is the data in those reports acceptable per applicable specifications (1) ?					
51 Does the organization periodically validate test reports for raw material (1) ?					
52 Where the organization delegates verification activities to the supplier, are the requirements for delegation defined and a register of delegations maintained (1) ?					
53 Where the organization or its customer intends to perform verification at the supplier's premises, does the organization state the intended verification arrangements and method of product release in the purchasing information?					
54 Where specified in the contract, is the customer or the customer's representative afforded the right to verify at the supplier's premises and the organization's premises that subcontracted product conforms to specified requirements ?					
55 It is ensured that verification by the customer is not used by the organization as evidence of effective control of quality by the supplier (it does not absolve the organization of the responsibility to provide acceptable product, nor shall it preclude subsequent rejection by the customer) ?					
Guidance Note					
1) Give an example					
Objective evidence assessed / Observations / Comments / N/A explanation					

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ASSESSMENT QUESTIONS		KEY Requirements	S	CAR Number Ma or mi	N/A	N/E

7.5 Production and service provision

7.5.1 Control of production and service provision

<p>56 Does <i>planning</i> consider, as applicable :</p> <ul style="list-style-type: none"> - <i>the establishment of process controls and development of control plans where key characteristics have been identified</i> - <i>the identification of in-process verification points when adequate verification of conformance cannot be performed at a later stage of realization</i> - <i>the design, manufacture, and use of tooling so that variable measurements can be taken, particularly for key characteristics, and</i> - <i>special processes (see 7.5.2).</i> 	P				
<p>57 Does the organization plan and carry out production and service provision under controlled conditions (1). Do these controlled conditions include, as applicable :</p> <ul style="list-style-type: none"> a) the availability of information that describes the characteristics of the product ? b) the availability of work instructions, as necessary ? c) the use of suitable equipment ? d) the availability and use of monitoring and measuring devices ? e) the implementation of monitoring and measurement ? f) the implementation of release, delivery and post-delivery activities ? g) accountability for all product during manufacture (e.g., parts quantities, split orders, nonconforming product) ? h) evidence that all manufacturing and inspection operations have been completed as planned, or as otherwise documented and authorized ? i) provision for the prevention, detection, and removal of foreign objects ? j) monitoring and control of utilities and supplies such as water, compressed air, electricity and chemical products to the extent they affect product quality ? and k) criteria for workmanship, which shall be stipulated in the clearest practical manner (e.g., written standards, representative samples or illustrations) ? 	P P				

Guidance Notes
1) List the Part Number(s) used for this review

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

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ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
7.5 Production and service provision (continued)					
7.5.1.1 Production documentation					
58 Are production operations carried out in accordance with approved data ?					
59 Does the data contain as necessary : a) drawings, parts lists, process flow charts including inspection operations, production documents (e.g., manufacturing plans, traveler, router, work order, process cards); and inspection documents (see 8.2.4.1) ? and b) a list of specific or non-specific tools and numerical control (NC) machine programs required and any specific instructions associated with their use ?	P				
7.5.1.2 Control of production process changes					
60 Are persons authorized to approve changes to production processes identified (1) ?	M				
61 Has the organization identified and obtained acceptance of changes that require customer and/or regulatory authority approval in accordance with contract or regulatory requirements ?					
62 Are changes affecting processes, production equipment, tools and programs documented ?	P				
63 Are procedures available to control their implementation ?					
64 Are the results of changes to production processes assessed to confirm that the desired effect has been achieved without adverse effects to product quality ?	P				
7.5.1.3 Control of production equipment, tools and numerical control (N.C.) machine programs					
65 Are production equipment, tools and programs validated prior to use and maintained and inspected periodically according to documented procedures ?	P				
66 Does validation prior to production use include verification of the first article produced to the design data/specification ?	P				
67 Are storage requirements, including periodic preservation/condition checks, established for production equipment or tooling in storage ?					
7.5.1.4 Control of work transferred, on a temporary basis, outside the organization's facilities					
68 When planning to temporarily transfer work to a location outside the organization's facilities, does the organization define the process to control and validate the quality of the work ?	M				

Guidance Notes
1) Clearly defined list or procedures

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ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
7.5 Production and service provision (continued)					
7.5.1.5 Control of service operations					
69 <i>Where servicing is a specified requirement, do service operation processes provide for :</i> a) <i>a method of collecting and analyzing in-service data ?</i> b) <i>actions to be taken where problems are identified after delivery, including investigation, reporting activities, and actions on service information consistent with contractual and/or regulatory requirements (1) (2) ?</i> c) <i>the control and updating of technical documentation ?</i> d) <i>the approval, control, and use of repair schemes (3) ? and,</i> e) <i>the controls required for off-site work (e.g., organization's work undertaken at the customer's facilities) ?</i>					
7.5.2 Validation of processes for production and service provision					
70 Does the organization validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement (This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered) (4) ? Note : These processes are frequently referred to as special processes.	P				
71 Does validation demonstrate the ability of these processes to achieve planned results ?					
72 Has the organization established arrangements for these processes including, as applicable : a) defined criteria for review and approval of the processes ? <i>-qualification and approval of special processes prior to use ?</i> b) approval of equipment and qualification of personnel ? c) use of specific methods and procedures ? <i>- control of the significant operations and parameters of special processes in accordance with documented process specifications and changes thereto (5) ?</i> d) requirements for records (see 4.2.4) ? e) and Re-evaluation/revalidation ?	M				
Guidance Notes 1) Review reports issued following visits to the customer (technical support). Comment on method of collection of in service data. Examine some investigation reports 2) Review evidence of implementation of corrective and preventive actions. 3) Review evidence of what has been assessed (e.g.: maintenance manual, repair manual, information to customer) 4) Verify the existence of list of special processes. 5) Give examples					
Objective evidence assessed / Observations / Comments / N/A explanation					

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ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
7.5 Production and service provision (continued)					
7.5.5 Preservation of product					
82 Does the organization preserve the conformity of product during internal processing and delivery to the intended destination ?					
83 Does the preservation include identification, handling, packaging, storage and protection ?					
84 Does preservation also apply to the constituent parts of a product ?					
85 Does preservation of product also include, where applicable in accordance with product specifications and/or regulations, provisions for : a) <i>cleaning ?</i> b) <i>prevention, detection and removal of foreign objects ?</i> c) <i>special handling for sensitive products ?</i> d) <i>marking and labeling including safety warnings ?</i> e) <i>shelf life control and stock rotation ?</i> f) <i>special handling for hazardous materials ?</i>	P				
86 Does the organization ensure that documents required by the contract/order to accompany the product are present at delivery and are protected against loss and deterioration ?					
Objective evidence assessed / Observations / Comments / N/A explanation					

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ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E

8 MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 General					
01 Does the organization plan and implement the monitoring, measurement, analysis and improvement processes needed (1) : a) to demonstrate conformity of the product ? b) to ensure conformity of the quality management system, and ? c) to continually improve the effectiveness of the quality management system ?	M				
02 Does this include determination of applicable methods, including statistical techniques, and the extent of their use ?					

Note : According to the nature of the product and depending on the specified requirements, statistical techniques may be used to support :

- design verification (e.g., reliability, maintainability, safety) ;*
- process control :*
 - *selection and inspection of key characteristics;*
 - *process capability measurements;*
 - *statistical process control;*
 - *design of experiment;*
- inspection – matching sampling rate to the criticality of the product and to the process capability ;*
- failure mode and effect analysis.*

Guidance Notes

1) Give examples of data

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QUALITY SYSTEM QUESTIONNAIRE					
ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
8.2 Monitoring and measurement (continued)					
8.2.1 Customer satisfaction					
03 As one of the measurements of the performance of the quality management system, does the organization monitor information relating to customer perception as to whether the organization has met customer requirements (1) ?					
04 Are the methods for obtaining and using this information determined?					
8.2.2 Internal audit					
05 Does the organization conduct internal audits at planned intervals to determine whether the quality management system (2) : a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization? and b) is effectively implemented and maintained?	M				
06 Is an audit program planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits?					
07 Is the audit criteria, scope, frequency and methods defined?					
08 Does the selection of auditors and conduct of audits ensure objectivity and impartiality of the audit process (3) ?					
09 Does the organization ensure internal auditors do not audit their own work ?					
10 Are the responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) defined in a documented procedure ?					
11 Do the management responsible for the areas being audited ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes ?	M				
12 Do follow-up activities include the verification of the actions taken and the reporting of verification results (see 8.5.2) (4) ?					
13 Are detailed tools and techniques developed such as check sheets, process flowcharts, or any similar method to support audit of the quality management system requirements ?					
14 Are the selected internal audit tools acceptable in measuring the effectiveness of the internal audit and overall organization performance ?					
15 Do internal audits also meet contract and/or regulatory requirements ?					
Guidance Notes					
1) Give examples of how customer's satisfaction is measured, committed, and acted upon. 2) Review of audit plan (status of the previous year and progress of the current year). 3) Check the list of approved auditors. 4) Review type of audits (questionnaire, synthesis, circulation, request for corrective actions, corrective actions follow-up).					
Objective evidence assessed / Observations / Comments / N/A explanation					

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ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
8.2 Monitoring and measurement (continued)					
8.2.3 Monitoring and measurement of processes					
16 Does the organization apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes ?					
17 Do these methods demonstrate the ability of the processes to achieve planned results ?					
18 When planned results are not achieved, is correction and corrective action taken, as appropriate, to ensure conformity of the product ?					
19 In the event of process nonconformity, does the organization (1) : a) take appropriate action to correct the nonconforming process ? b) evaluate whether the process nonconformity has resulted in product nonconformity ? and c) identify and control the nonconforming product in accordance with clause 8.3 ?	P				
8.2.4 Monitoring and measurement of product					
20 Does the organization monitor and measure the characteristics of the product to verify that product requirements have been met ?	P				
21 Is this carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1) ?					
22 When key characteristics have been identified, are they monitored and controlled ?	P				
23 When the organization uses sampling inspection as a means of product acceptance, is the plan statistically valid and appropriate for use ?					
24 Does the plan preclude the acceptance of lots whose samples have known nonconformities ?					
25 When required, is the plan submitted for customer approval ?					
26 Is product held until it has been inspected or otherwise verified as conforming to specified requirements, except when product is released under positive-recall procedures pending completion of all required measurement and monitoring activities ?	P				
27 Is evidence of conformity with the acceptance criteria maintained ?					
28 Do records indicate the person(s) authorizing release of product (see 4.2.4) ?					
29 Is product release and service delivery held until all the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer ?					
Guidance Note					
1) Give examples of non conformity (product, process, ...).					
Objective evidence assessed / Observations / Comments / N/A explanation					

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ASSESSMENT QUESTIONS			KEY Requirements	S	CAR Number Ma or mi	N/A	N/E

8.4 Analysis of data

46 Does the organization determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made ?	M				
47 Does this include data generated as a result of monitoring and measurement and from other relevant sources ?					
48 Does the analysis of data provide information relating to : a) customer satisfaction (see 8.2.1) (1) ? b) conformity to product requirements (see 7.2.1) ? c) characteristics and trends of processes and products including opportunities for preventive action ? And d) suppliers ?					

Guidance Note

- 1) Give examples and check how the organization measures the effectiveness.

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

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ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
8.5 Improvement					
8.5.1 Continual improvement					
49 Does the organization continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review ?					
8.5.2 Corrective action					
50 Does the organization take action to eliminate the cause of nonconformities in order to prevent recurrence (1) ?	P				
51 Are Corrective actions appropriate to the effects of the nonconformities encountered ?					
52 Is a documented procedure established to define requirements for : a) reviewing nonconformities (including customer complaints) ? b) determining the causes of nonconformities ? c) evaluating the need for action to ensure that nonconformities do not recur ? d) determining and implementing action needed ? e) recording of the results of the action taken (see 4.2.4) ? f) reviewing corrective action taken ? g) <i>flow down of the corrective action requirement to a supplier, when it is determined that the supplier is responsible for the root cause ? and</i> h) <i>specific actions where timely and/or effective corrective actions are not achieved ?</i>					
8.5.3 Preventive action					
53 Does the organization determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence (2) ?	M				
54 Are preventive actions appropriate to the effects of the potential problems ?					
55 Is a documented procedure established to define requirements for : a) determining potential nonconformities and their causes ? b) evaluating the need for action to prevent occurrence of nonconformities ? c) determining and implementing action needed ? d) recording of the results of the action taken (see 4.2.4) ? and e) reviewing preventive action taken ?					
Guidance Notes 1) Select a non-conforming part and use 52 a) through h) to check for effectiveness. 2) Select a non-conforming part and use 55 a) through e) to check for effectiveness.					
Objective evidence assessed / Observations / Comments / N/A explanation					

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Annex A (informative)

Bibliography

ISO 9000: 2000	Quality management systems – Fundamentals and vocabulary
ISO 9001: 2000	Quality management systems – Requirements
ISO 10011	Guidelines for auditing quality systems
EN 9100 – Section 1	Aerospace series – Quality management systems – Requirements (based on ISO 9001: 2000)