SAE Aerospace
An SAE International Group

AEROSPACE STANDARD

SAE AS9101
Technically equivalent to AECMA prEN 9101

REV. B

Issued 2000-09
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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.

Contents

SECTION 1:
QUALITY MANAGEMENT SYSTEMS – ASSESSMENT

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

ASSESSMENT REPORT	*Assessing company logo*

GENERAL ASSESSMENT INFORMATION

1 Organization & Work Address

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

2 ISO Registration

[ ] ISO Registered	Registrar Name:
[ ] ISO Standard / Revision	Expiration Date (If applicable):
[ ] Aerospace Standard / Revision	

3 Assessment Team

Lead Assessor Name:	Other Assessor Team Members:
[ ] Certified Auditor – Type & No.	
[ ] Qualified Auditor	

4 Assessment Dates:

5 Assessment Scope

[ ] Total facility assessed	[ ] Initial assessment	[ ] All 9100 elements assessed
[ ] Partial facility assessed	[ ] Re-assessment	[ ] Partial 9100 elements assessed
[ ] Other:		Elements not assessed:
[ ] Activity assessed:		

6 Assessment Disposition

[ ] Conforming
[ ] Conforming with minor (mi) corrective action
[ ] Non conforming with Major (MA) corrective action

7 Scoring

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 _____

ASSESSMENT REPORT	*Assessing company logo*

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

ASSESSMENT REPORT	*Assessing company logo*

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	*Assessing company logo*

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 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: 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							(Member logo)
Organization :		**Result**					
	SCORING CHART	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**					**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	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						
731	*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	Product 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 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	*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	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 = $\frac{\text{RESULT X 100}}{880}$

CORRECTIVE ACTION REQUEST (C.A.R.)	*Assessing company logo*

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

Verification date :	Accepted:	Assessor Name :	Assessor Signature :
	Yes ☐ No ☐		

List of Recommendations/Observations/Comments	*Assessing company logo*

Organization :	Audit report number
Site :	Issued date :

Item Number	Section	Description

Lead Assessor Name:	Signature:

***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*

APPENDIX A
AS9101

***

QUALITY SYSTEM QUESTIONNAIRE

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 : 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

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) ? ***e) The identification of resources to support operation and maintenance of the product ?***	P

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 ASESSMENT 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

- 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

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

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

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

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

QUALITY SYSTEM QUESTIONNAIRE					
ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
4.2. Documentation requirements (continued)					
4.2.3 Control of documents					
10 Are the documents required by the quality management system controlled ?	M				
11 Are records controlled according to the requirements given in 4.2.4 ?					
12 Has a documented procedure been established to define the controls needed to : a) approve documents for adequacy prior to issue ? b) review and update as necessary and re-approve documents ? c) ensure that changes and the current revision status of documents are identified ? d) ensure that relevant versions of applicable documents are available at points of use ? e) ensure that documents remain legible and readily identifiable ? f) ensure that documents of external origin are identified and their distribution controlled ? and g) prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose ?					
13 Does the organization coordinate document changes with customers and/or regulatory authorities in accordance with contract or regulatory requirements ?					
4.2.4 Control of records					
14 Are records established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system ?					
15 Do records remain legible, readily identifiable and retrievable (1) ?					
16 Has a documented procedure been established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records ?					
17 Does the documented procedure define the method for controlling records that are created by and/or retained by suppliers ?					
18 Are records available for review by customers and regulatory authorities in accordance with contract or regulatory requirements ?					
4.3 Configuration management					
19 Has the organization established, documented and maintained a configuration management process appropriate to the product ?	**P**				

Guidance Note

1) List records reviewed

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*

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) : 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 ?	M				
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 (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

***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*

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

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

07 Has Top management ensured that the responsibilities and authorities are defined and communicated within the organization (1) ?

5.5.2 Management representative

08 Has Top management appointed a member of management who, irrespective of other responsibilities, has responsibility and authority that includes :

a) ensuring that processes needed for the quality management system are established, implemented and maintained ?

b) reporting to top management on the performance of the quality management system and any need for improvement ?

c) ensuring the promotion of awareness of customer requirements throughout the organization ? and

d) the organizational freedom to resolve matters pertaining to quality ?

M

5.5.3 Internal communication

09 Has Top management ensured that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system ?

Guidance Note

1) Identify and records method of communication within the organization

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

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

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

6. RESOURCE MANAGEMENT

6.1 Provision of resources

01 Has the organization determined and provided the resources needed:
- a) to implement and maintain the quality management system and continually improve its effectiveness ? And
- b) to enhance customer satisfaction by meeting customer requirements ?

6.2 Human resources

6.2.1 General

02 Are personnel performing work affecting product quality competent on the basis of appropriate education, training, skills and experience (1) ?

6.2.2 Competence, awareness and training

03 Does the organization :
- a) determine the necessary competence for personnel performing work affecting product quality (2) ? P
- b) provide training or take other actions to satisfy these needs ?
- c) Evaluate the effectiveness of the actions taken ?
- d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives ?
- e) maintain appropriate records of education, training, skills and experience (see 4.2.4) (3) ?

6.3 Infrastructure

04 Does the organization determine, provide and maintain the infrastructure needed to achieve conformity to product requirements ?
Infrastructure includes, as applicable :
- a) buildings, workspace and associated utilities ?
- b) process equipment (both hardware and software) ? And
- c) supporting services (such as transport or communication) ?

6.4 Work environment

05 Does the organization determine and manage the work environment needed to achieve conformity to product requirements ? P

Note : Factors that may affect the conformity of the product include temperature, humidity, lighting, cleanliness, protection from electrostatic discharge, etc.

Guidance Notes

1) Review training Records and Plan (status of the current year and of the previous year)
2) Give examples of methods used to determine competence (e.g.: competence matrix, multiskill, …)
3) Review training certificates for the certified personnel and training records (internal and external training courses)

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

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

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

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

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 ?					

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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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) ? - ***in respect of organization, task sequence, mandatory steps, significant stages and method of configuration control,*** 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 Where appropriate, due to complexity, does the organization give consideration to the following activities : - ***structuring the design effort into significant elements ?*** - ***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 ?***					
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 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) ?	**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

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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 (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) ?					

Note : Design and/or development verification may include activities such as :
- **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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QUALITY SYSTEM QUESTIONNAIRE					
ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E

7.3 Design and development (continued)

7.3.6 Design and development validation

29 Is design and development validation performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known ?	P					
30 Wherever practicable, is validation completed prior to the delivery or implementation of the Product ?						
31 Are records of the results of validation and any necessary actions maintained (see 4.2.4) ?						

Note:
- Design and/or development validation follows successful design and/or development verification.
- Validation is normally performed under operating conditions.
- Validation is normally performed on the final product, but may be necessary in the earlier stages prior to product completion.
- Multiple validations may be performed if there are different intended uses.

7.3.6.1 Documentation of design and/or development verification and validation

32 At the completion of design and/or development, does the organization ensure that reports, calculations, test results, etc., demonstrate that the product definition meets the specification requirements for all identified operational conditions?	**M**					

7.3.6.2 Design and/or development verification and validation testing

33 Where tests are necessary for verification and validation, are these tests planned, controlled, reviewed, and documented to ensure and prove the following (1) : ***a) test plans or specifications identify the product being tested and the resources being used, define test objectives and conditions, parameters to be recorded, and relevant acceptance criteria ?*** ***b) test procedures describe the method of operation, the performance of the test, and the recording of the results ?*** ***c) the correct configuration standard of the product is submitted for the test ?*** ***d) the requirements of the test plan and the test procedures are observed ?*** ***e) the acceptance criteria are met ?***	P					

Guidance Note

1) Give an example of a qualification report

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

7.3 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	***Does the organization's change control process provide for customer and/or regulatory authority approval of changes, when required by contract or regulatory requirement ?***					
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 Is the organization responsible for the quality of all products purchased from suppliers, including customer-designated sources ?						
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 Does the organization :	M					
a) Maintain a register of approved Suppliers that includes the scope of the approval (1) ?						
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) ?						
c) Define the necessary actions to take when dealing with Suppliers that do not meet requirements ?						
d) Ensure where required that both the organization and all Suppliers use customer-approved special process sources ?						
e) Ensure that the function having responsibility for approving Supplier quality systems has the authority to disapprove the use of sources ?						

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

7.4 Purchasing (continued)

7.4.2 Purchasing information

46 Does purchasing information describe the product to be purchased, including where appropriate (1) : *a) requirements for approval of product, procedures, processes and equipment ?* *b) requirements for qualification of personnel ?* *c) quality management system requirements ?* ***d) the name or other positive identification, and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data ?*** ***e) requirements for design, test, examination, inspection and related instructions for acceptance by the Organization ?*** ***f) requirements for test specimens (e.g., production method, number, storage conditions) for design approval, inspection, investigation or auditing ?*** ***g) requirements relative to :*** ***- supplier notification to Organizationr of nonconforming product ? and*** ***- arrangements for Organizationr approval of supplier nonconforming material ?*** ***h) requirements for the supplier to notify the Organization of changes in product and/or process definition and, where required, obtain organization approval ?*** ***i) right of access by the organization, their customer, and authorities to all facilities involved in the order and to all applicable records ? and*** ***j) requirements for the supplier to flow down to subtier suppliers the applicable requirements in the purchasing documents, including key characteristics where required ?***	P				
47 Does the organization ensure the adequacy of specified purchase requirements prior to their communication to the supplier ?					

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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QUALITY SYSTEM QUESTIONNAIRE					
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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QUALITY SYSTEM QUESTIONNAIRE					
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

56 Does planning consider, as applicable : - ***the establishment of process controls and development of control plans where key characteristics have been identified*** - ***the identification of in-process verification points when adequate verification of conformance cannot be performed at a later stage of realization*** **P** - ***the design, manufacture, and use of tooling so that variable measurements can be taken, particularly for key characteristics, and*** - ***special processes (see 7.5.2).***					
57 Does the organization plan and carry out production and service provision under controlled conditions (1). Do these controlled conditions include, as applicable : 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 ?*** **P** ***i) provision for the prevention, detection, and removal of foreign objects ?*** **P** ***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) ?***					

Guidance Notes

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

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

7.5 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

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

7.5 Production and service provision (continued)

7.5.1.5 Control of service operations					
69 Where servicing is a specified requirement, do service operation processes provide for : ***a) a method of collecting and analyzing in-service data ?*** ***b) 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) ?*** ***c) the control and updating of technical documentation ?*** ***d) the approval, control, and use of repair schemes (3) ? and,*** ***e) the controls required for off-site work (e.g., organization's work undertaken at the customer's facilities) ?***					
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 ? ***-qualification and approval of special processes prior to use ?*** b) approval of equipment and qualification of personnel ? c) use of specific methods and procedures ? ***- control of the significant operations and parameters of special processes in accordance with documented process specifications and changes thereto (5) ?*** d) requirements for records (see 4.2.4) ? e) and 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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QUALITY SYSTEM QUESTIONNAIRE					
ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E

7.5 Production and service provision (continued)

7.5.3 Identification and traceability					
73 Where appropriate, has the organization identified the product by suitable means throughout product realization ?					
74 Does the organization maintain the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration ? **P**					
75 Has the organization identified the product status with respect to monitoring and measurement requirements ?					
76 When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), does the organization establish and document controls for the media (1) ?					
77 Where traceability is a requirement, does the organization control and record the unique identification of the product (see 4.2.4) ?					
78 According to the level of traceability required by contract, regulatory, or other established requirement, does the organization's system provide for (2) : **P** ***a) identification to be maintained throughout the product life ?*** ***b) all the products manufactured from the same batch of raw material or from the same manufacturing batch to be traced, as well as the destination (delivery, scrap) of all products of the same batch ?*** ***c) in any assembly, the identity of its components and those of the next higher assembly to be traced?*** ***d) in any given product, a sequential record of its production (manufacture, assembly, inspection) to be retrieved ?***					

Note: In some industry sectors, configuration management is a means by which identification and traceability is maintained.

7.5.4 Customer property					
79 Does the organization exercise care with customer property while it is under the organization's control or being used by the organization (3) ?					
80 Has the organization identified, verified, protected and safeguarded customer property provided for use or incorporation into the product ?					
81 Does the organization define methods to identify and record customer products that are lost, damaged or otherwise made unusable and report such to the customer ?					

Note: Customer property can include intellectual property, ***including customer furnished data used for design, production and/or inspection***.

Guidance Notes

1) Give examples of method(s) used
2) Give examples of traceability level applied (up and down)
3) Identify types of product supplied by the customer.

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

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