SAE Aerospace
An SAE International Group

AEROSPACE STANDARD

SAE AS9121
Technically equivalent to
AECMA prEN 9101

Issued 2003-08

Aerospace Series
Quality Systems
Quality System Assessment Applicable to Stockist Distributors

TO PLACE A DOCUMENT ORDER:
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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

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1 PURPOSE

The purpose of this document is to define the content and the presentation of the Assessment Report of AS9120.

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)*
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Page 9 *(required)*
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Page 10 *(required)*
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STOCKIST DISTRIBUTORS - Quality System Questionnaire relative to the section 1 of AS9120 (based on ISO 9001:2000)

Appendix B
Documents regarding the company:

- Organization charts
- Copies of agreements and certifications

ASSESSMENT REPORT Standards 9120/9121	*Assessing company logo*

GENERAL ASSESSMENT INFORMATION

1 Distributor organization & Work Address

Company Name:	Tel Number:
	Fax Number:
Subsidiary of:	e-mail:
Organization Identification:	CAGE code:
Assessed Site(s) Addresse(s):	Assessment Representative & Title:
Headquarter:	
Warehouse(s):	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 9120 elements assessed
☐ Partial facility assessed	☐ Re-assessment	☐ Partial 9120 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
(To be completed in English)

General comments about the organization, distributed products and sources, traceability and the quality system of the assessed organization.

Strong points:

Weak 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* (EN/AS 9120-9121)	**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					*Non applicable*
7.2 Customer-related processes					
7.3 Design and development					*Non applicable*
7.4 Purchasing					
7.5 Production and service provision					*7.5.2 Non applicable*
7.6 Control of monitoring and measuring devices					
8 - Measurement, analysis and improvement					
8.1 General					
8.2 Monitoring and measurement					
8.3 Control of nonconforming product					
8.4 Analysis of data					
8.5 Improvement					
Assessed Organization:					Assessing Company:
Rep's name:	**Results**				Lead Assessor Name:
Signature:					Signature:

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

ASSESSMENT SCORING								(Member logo)
Organization :								**Result**
IAQG 9120	SCORING CHART Standards 9120/9121	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**					**80**	
4.1	General requirements	0	5	20	30	40	
4.2 & 4.3	Documentation requirements & Configuration management	0	5	20	30	40	
5	**Management responsibility**					**80**	
5.1	Management commitment	0	5	10	15	20	
5.2	Customer focus						
5.3	Quality policy						
5.4	Planning	0	5	10	15	20	
5.5	Responsibility, authority and communication	0	5	15	15	20	
5.6	Management review	0	5	10	15	20	
6	**Resource Management**					**80**	
6.1	Provision of resources	0	5	10	20	30	
6.2	Human resources						
6.3	Infrastructure	0	10	25	40	50	
6.4	Work environment						
7	**Product realization**					**480**	
7.1	Planning of product realization	**Not required**					
7.2	Customer related processes	0	10	20	40	60	
7.3	Design and development	**Not required**					
7.4	Purchasing	0	5	30	40	100	
7.5	Product and service provision						
7.5.1	*Control of production and service provision*	0	5	30	60	80	
7.5.2	*Validation of processes for production and service provision*	**Not required**					
7.5.3	*Identification and traceability*	0	5	40	50	100	
7.5.4	*Customer property*	0	5	10	15	20	
7.5.5	*Preservation of product*	0	5	20	40	100	
7.6	Control of monitoring and measuring device	0	5	10	15	20	
8	**Measurement analysis and improvement**					**280**	
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	10	15	20	
8.2.3	*Monitoring and measurement of processes*	0	5	20	25	30	
8.2.4	*Monitoring and measurement of product*	0	5	15	15	20	
8.2.5	*Evidence of conformance – Certificate of conformity*	0	5	N/A	N/A/	100	
8.3	Control of nonconforming product	0	5	20	25	30	
8.4	Analysis of Data	0	5	10	15	20	
8.5	Improvement	0	5	10	15	20	
						TOTAL	1000
						SCORE	/ 100

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

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
AS9121

***

STOCKIST DISTRIBUTORS

QUALITY SYSTEM QUESTIONNAIRE

Associated to the International Quality System Standard
AS/EN 9120

(based on ISO 9001: 2000)

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 AS9120 (based on ISO 9001: 2000).

2 USE OF THE QUESTIONNAIRE

The use of this questionnaire is mandatory and will be a part of the Assessment Report. The questionnaire is based on the AS / EN /JISQ 9120 standard, which is relative to:

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

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

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

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

Additional information on questionnaire

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

“P” direct link with product

“M” direct link with Management

The extent of Key Requirement applicability is determined by the location of the ‘M’ or ‘P’. In the example below all of question 12 is considered as a key requirement.

12 Does the output from the management review include any decisions and actions related to (2) : 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 04, i.e. a) is considered Key Requirement.

04 Does the organization : a) determine the necessary competence for personnel performing work affecting product quality (2) ? 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) ?	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 46 part a).

46) 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) 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 AS / EN /JISQ 9120.

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 9120 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 9120 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 =5), 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=20), 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 = 30), or
- If, no CAR in a section, e.g. 4.1 General Requirements then score in "NO CAR" column (result=40)
- 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**

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 conformance 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 (2) ?	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 (list, flow diagram, etc.)
2) List external processes that can affect product conformity

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 (2) ***when referencing the documented procedures, is the relationship between the requirements of this International Standard and the documented procedures clearly shown (3) ?*** 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
3) Reference of Standards used as part of the system

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 maintain appropriate documentation to verify the status of the products, e.g.: manufacturer's data, standards, airworthiness data (1) ?.	***P***				
14 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 (2) ?					
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 Are records included where applicable (3) : ***a) manufacturer, distributor, repair station, test and inspection reports,*** ***b) original certificates of conformity (manufacturer, sub-tier distributor), copies of airworthiness certificates,*** ***c) non-conformance, concession and corrective action records,*** ***d) lot traceability records,*** ***e) environmental or shelf life condition records.***	***P***				
18 Are records are stored in an electronic form, the integrity of the system and the back-up procedures shall be appropriately validated. ***Are these records without possibility of change by software traceable to the original documentation.***					
19 Are records of product origin, conformity and shipment maintain for a minimum of seven years, or as required by contract (4) ?	***M***				
21 Are records available for review by customers and regulatory authorities in accordance with contract or regulatory requirements?					

Guidance Note

1) List updated manufacturer's documentation, standard, and airworthiness data
2) List records reviewed
3) Examples reviewed
4) Period of records retention

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) ? ***Note Reference to Clause 7.1 a is not required***					
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) : 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				

Guidance Notes

1) Records management review frequency and functions involved (e.g : quality, sales, warehouse, 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: f) determine the necessary competence for personnel performing work affecting product quality (2) ? g) provide training or take other actions to satisfy these needs? h) evaluate the effectiveness of the actions taken? i) 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? j) maintain appropriate records of education, training, skills and experience (see 4.2.4) (3) ?	P				
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 (4) ?	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)
4) Explain management methods of work environment adapted to stored and distributed products

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

Note: This section not required for compliance to this standard

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product						
01 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? d) and any additional requirements determined by the organization?	M					
7.2.2 Review of requirements related to the product						
02 Does the organization review the requirements related to the product?						
03 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? **d) *risks (e.g., new technology, short delivery time scale) have been evaluated?***	P					
04 Are records of the results of the review and actions arising from the review maintained (see 4.2.4) (2) ?						
05 Where the customer provides no documented statement of requirement, are the customer requirements confirmed by the organization before acceptance?						
06 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						
07 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

Note: This section not required for compliance to this standard

7.4 Purchasing

7.4.1	**Purchasing process**					
08	Does the organization ensure that purchased product conforms to specified purchase requirements?	P				
09	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?					
10	Does the organization evaluate and select Suppliers based on their ability to supply product in accordance with the organization's requirements?					
11	Are criteria for selection, evaluation and re-evaluation established?					
12	Are records of the results of evaluations and any necessary actions arising from the evaluation maintained (see 4.2.4)?					
13	***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 (3) ?					
	d) prevent the purchase of counterfeit / suspect unapproved products ?					

Guidance Notes

1) Review current list of approved Suppliers
2) Review suppliers performance / measurement system (e.g.: supplier rating, etc.)
3) Describe the rules applied

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

14	Does purchasing information describe the product to be purchased, including where appropriate (1) (2) : a) requirements for approval of product, procedures, processes and equipment? b) requirements for qualification of personnel? c) quality management system requirements? ***d) the name/product description or other positive identification, and other relevant technical data (e.g., revision level),*** ***e) requirements relative to supplier notification to organization of nonconforming product*** ***f) requirements for the supplier to notify the organization of changes in product definition,*** ***g) right of access by the organization, their customer, and regulatory authorities to all facilities involved in the order and to all applicable records, and*** ***h) requirements for a certificate of conformity or airworthiness approval from the approved manufacturer or approved repair station.***	P				
15	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.
2) Note the purchase order numbers and the text of requirements, applicable issue for specifications, drawings, and product conformity requirements

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					
16 Does the organization establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements, ***they may include (1) :*** ***a) obtaining objective evidence of the quality of the product from suppliers and verifying the authenticity of the accompanying documentation, e.g. certificate of conformity from the manufacturer, airworthiness certificate, test reports, statistical records, process control;*** ***b) review of the required documentation,*** ***c) inspection of products upon receipt.***	P				
17 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?					
18 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?					
19 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)?					

7.5 Production and service provision

7.5.1 Control of production and service provision					
20 Does the organization plan and carry out production and service provision under controlled conditions (2) . 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 (3) ? 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?	P				

Guidance Note

1) List examples, P/N, batch number, manufacturers, prove of documentation authenticity, COC numbers
2) List the nature of product under production operations (splitting operations, cutting operations of raw material, bars, sheets, …)
3) List of work instructions used in workshop to cut at the sizes raw materials

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)

7.5.2 Validation of processes for production and service provision - Note: This section not required for compliance to this standard

7.5.3 Identification and traceability					
21 Where appropriate, has the organization identified the product by suitable means throughout product realization?					
22 Has the organization identified the product status with respect to monitoring and measurement requirements?					
23 When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), does the organization establish and document controls for the media (1) ?					
24 Where traceability is a requirement, does the organization control and record the unique identification of the product (see 4.2.4)?					
25 Does the organization establish and maintain documented procedures for product identification and traceability, by suitable means (e.g., labels, bar codes or other) from receipt, during splitting, storage packaging, and preservation operations, and until delivery (including where handling or packing operations are subcontracted) (2) ?	***P***				
26 Does the organization's processes provide for:					
a) maintaining the manufacturer's identification and batch/lot of traceability (3) ?	***P***				
b) the ability to identify and trace products manufactured from the same batch of raw material or from the same manufacturing batch, as well as the ability to identify, the ultimate destination (delivery, scrap) of all products of the same batch (4) ?	***P***				
c) maintaining the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration (5) ?	***P***				

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

7.5.4 Customer property					
27 Does the organization exercise care with customer property while it is under the organization's control or being used by the organization (6) ?					
28 Has the organization identified, verified, protected and safeguarded customer property provided for use or incorporation into the product?					
29 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 an example of authority media used
2) Give the method used
3) Give examples of traceability identification
4) Give examples of traceability of the management of batches from manufacturer's products, incoming, stock deliveries, scraps
5) Give examples how the identification is maintained and changes of documentation and/or product are traced
6) Identify types of property supplied by the customer, if applicable

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)

7.5.5 Preservation of product					
30 Does the organization preserve the conformity of product during internal processing and delivery to the intended destination?					
31 Does the preservation include identification, handling, packaging, storage and protection?					
32 Does preservation also apply to the constituent parts of a product?					
33 Does preservation of product also include, where applicable in accordance with product specifications and/or regulations, provisions for (1) : ***a) cleaning?*** ***b) prevention, detection and removal of foreign objects?*** ***c) special handling for sensitive products?*** ***d) marking and labeling including safety warnings?*** ***e) shelf life control and stock rotation?*** ***f) special handling for hazardous materials?*** ***g) environmental controls (e.g., temperature, humidity).***	***P***				
34 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?					

Guidance Note

1 Give examples adapted to the nature of the products

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

7.6 Control of monitoring and measuring devices

35 Does the organization determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1) (1) ?	P				
36 Does the organization maintain a register of these monitoring and measuring devices, and define the process employed for their calibration including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria?	**M**				
37 Does the organization establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements?					
38 Does the organization ensure that environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out?					
39 Where necessary to ensure valid results, is measuring equipment: a) calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist is the basis used for calibration or verification recorded (2) ? b) adjusted or re-adjusted as necessary? c) identified to enable the calibration status to be determined? d) safeguarded from adjustments that would invalidate the measurement result? e) protected from damage and deterioration during handling, maintenance and storage? ***f) recalled to a defined method when requiring calibration?***					
40 Does the organization assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements?					
41 Does the organization take appropriate action on the equipment and any product affected?	P				
42 Are records of the results of calibration and verification maintained (see 4.2.4)?					
43 When used in the monitoring and measurement of specified requirements, is the ability of computer software to satisfy the intended application confirmed?	P				
44 Is this undertaken prior to initial use and reconfirmed as necessary?					

Guidance Notes

1) Review that the organization has a process for ensuring the capability of measurement system (e.g. Interval Analysis, Resolution Analysis, Gage Repeatable & Reproducibility, etc.)
2) Ensure the links to the recognized international / national standard.

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

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