

Quality System Assessment

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## SAE AS9101

### 1. SCOPE:

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

### 2. QUALITY SYSTEM ASSESSMENT REPORT CONTENT:

The Assessment Report is made up of:

- Page 3 (required)  
General Assessment Information
- Page 4 (required)  
Assessment Conclusions
- Page 5 (optional)  
General Company Information
- Page 6  
Assessment Result Summary
- Page 7  
Assessment Scoring Chart
- Page 8  
Corrective Action Request Form
- Appendix 1  
Quality System Questionnaire
- Appendix 2 (*Supplied by Auditor*)  
Documents regarding the company:
  - Organization charts
  - Copies of agreements and certifications

*One of these 2 pages is required, the other one is optional.*

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	<b>ASSESSMENT REPORT</b>	<i>(Member logo)</i>
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<b>GENERAL ASSESSMENT INFORMATION</b>
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**1. Supplier & Work Address**

Company Name : Parent Name : Supplier Identification : Site Address :	Fax Number : E-Mail : CAGE code : Assessment Representative & Title :  Management Representative & Title :
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**2. ISO Registration**

<input type="checkbox"/> ISO Registered <input type="checkbox"/> ISO Standard / Revision Product Codes :	Registrar Name : Expiration Date :
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**3. Assessment Team**

<b>Lead Assessor Name :</b> <input type="checkbox"/> Certified Auditor <input type="checkbox"/> Qualified Auditor (e.g., ISO10011-2)	<b>Other Assessor Members :</b>
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**4. Assessment Dates**

Begin Date :	End Date :
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**5. Assessment Scope**

<input type="checkbox"/> Total facility assessed <input type="checkbox"/> Partial facility assessed <input type="checkbox"/> Other :	<input type="checkbox"/> Initial assessment <input type="checkbox"/> Re-assessment	<input type="checkbox"/> All AS9100 / EN9100 elements assessed <input type="checkbox"/> Partial AS9100 / EN9100 elements assessed Elements not assessed :
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**6. Assessment Disposition**

<input type="checkbox"/> Compliant <input type="checkbox"/> Non compliant <input type="checkbox"/> Compliant with minor corrective actions	Scoring result :
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**7. Assessment Approval**

Assessing Company	Date	Lead Assessor Name	Signature

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**ASSESSMENT CONCLUSIONS**  
(To be completed in English)

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

**Strong points :**

**Weak points :**

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## GENERAL SUPPLIER 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 ( )
<b>Sales</b>				
<b>Earnings</b>				
<b>Earnings used for Re-Investment</b>				
<b>Workforce</b>				

### 2. Turnover breakdown and main Customers

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

### 3. Clearances or Approvals granted by Authorities

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

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## ASSESSMENT RESULT SUMMARY

**Supplier:**

**Assessment Results :**

Elements (AS9100 / EN9100 Standard)	Result				Corrective Action Request Number (MA/mi)
	S	MA	mi	N/A	
1. Management Responsibility					
2. Quality System					
3. Contract Review					
4. Design Control					
5. Document and Data Control					
6. Purchasing					
7. Control of Customer-supplied Product					
8. Product Identification and Traceability					
9. Process Control					
10. Inspection and Testing					
11. Control of Inspection, Measuring & Test Equipment					
12. Inspection and Test Status					
13. Control of Non-conforming Product					
14. Corrective and Preventive Actions					
15. Handling, Storage, Packaging, Preservation & Delivery					
16. Control of Quality Records					
17. Internal Quality Audits					
18. Training					
19. Servicing					
20. Statistical Techniques					
<b>Results Summary</b>					Assessing Company : Lead Assessor Name : Signature

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## ASSESSMENT SCORING CHART

Supplier:		Result				Coef. Item	Result	Max. Result	Observation Corrective Action Request No. (MA/mi)
Elements (AS9100 / EN9100 Standard)		3	2	1	0				
1.	Management Responsibility					2			
2.	Quality System					2			
3.	Contract Review					2			
4.	Design Control					5			
5.	Document and Data Control					2			
6.	Purchasing					2			
7.	Control of Customer-supplied Product					1			
8.	Product Identification and Traceability					2			
9.	Process Control					5			
10.	Inspection and Testing					2			
11.	Control of Inspection, Measuring & Test Equipment					1			
12.	Inspection and Test Status					1			
13.	Control of Non-conforming Product					2			
14.	Corrective and Preventive Action					2			
15.	Handling, Storage, Packaging, Preservation & Delivery					2			
16.	Control of Quality Records					1			
17.	Internal Quality Audits					2			
18.	Training					2			
19.	Servicing					2			
20.	Statistical Techniques					1			
<b>R ⇔</b>								<b>⇔ M</b>	

QUALITY SYSTEM RATING :  $\frac{20 \times R}{M} =$

Note : Non-conformities to major requirements in Elements 4 or 9 prevent classification A (see Questionnaire)

20	19	18	17	16	15	14	13	12	11	10	9	8	7	6	5	4	3	2	1	0
<b>A</b> GOOD					<b>B</b> MEDIUM					<b>C</b> POOR					<b>D</b> UNACCEPTABLE					

**Cross according to the Quality System Rating**

<b>The assessed Supplier agrees on the Quality System scoring and the Corrective Action Request</b>		
Supplier Representative :	Signature :	Date :

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	<b>CORRECTIVE ACTION REQUEST (C.A.R.)</b>	<i>(Member logo)</i>
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Supplier:	Identification C.A.R. No.:
Site:	Date issued:
Reference Standard :	Referenced Standard Element concerned :

Action No.	Criticality MA / mi	Non-Conformance Description

Assessor Name :	Assessor Signature :
-----------------	----------------------

<b>Assessed Supplier 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.</b>	Due date :
---	------------

	Action No.:	Root Cause :		Planned completion date of Corrective Action :	Completion date :
		1st Step	Action No. :		
	Supplier Representative Name :		Signature :	Current date :	
2nd Step	Supplier Representative Name :		Signature :	Current date :	

<b>Verification of the implementation of the completed Corrective Action to be filled out by the Assessing Company</b>			
Completed on :	Accepted : Yes <input type="checkbox"/> No <input type="checkbox"/>	Name :	Signature :

To be filled out by the Assessed Supplier Representative

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APPENDIX 1  
QUALITY SYSTEM QUESTIONNAIRE

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## SAE AS9101

### 1. SCOPE:

The purpose of this document is to present the questionnaire to be used during the "on site" quality system assessment of suppliers in order to ensure common practices for these assessments.

### 2. USE OF THE QUESTIONNAIRE:

The use of this questionnaire is mandatory and will be a part of the Assessment Report.

The questionnaire is based on the AS9100/EN9100 standard, which is relative to:

- ISO 9001 requirements (1994)
- Additional Aerospace specific requirements are shown in bold and italics

Important questionnaire elements are defined below:

- Critical (C)  
The levels of criticality are used for the scoring, and determines the level of corrective action (Major if the level of criticality is critical, otherwise minor).
- Reference and revision  
If needed, write the number and the revision level of the considered procedures.
- Document  
Mark the appropriate box for each requirement with:
  - Satisfactory (S)
  - Corrective action required (CA)
  - Not applicable (N/A)
- Use  
Mark the appropriate box for each requirement with:
  - Satisfactory (S)
  - Corrective action needed (CA)
  - Not applicable (N/A)
  - Not evaluated (N/E)

The criticality of the corrective action is either Major (MA) or Minor (mi) depending whether the discrepancy is related to a critical requirement identified by the capital letter "C" in the 1st column.

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### 2. (Continued):

- Objective evidence assessed

Write the objective evidence reviewed during the assessment. Guidance is provided for certain questions, as indicated in the S column by a small number (for example: 1).

- Discrepancy with Standard's requirement

Write the identified deviation or the number of corrective action request.

- Observations/Comments

Write as appropriate in this box, the observations and comments that could be helpful for the supplier (e.g., clarification, continuous improvement, safety issue). This is not a deviation.

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**Summary**

<b>Section headings</b>	<b>Page numbers</b>
1. <i>Management responsibility</i>	<b>4 - 5</b>
2. <i>Quality system</i>	<b>6 - 7</b>
3. <i>Contract review</i>	<b>8</b>
4. <i>Design control</i>	<b>9 - 12</b>
5. <i>Document and data control</i>	<b>13 - 14</b>
6. <i>Purchasing</i>	<b>15 - 17</b>
7. <i>Control of customer-supplied product</i>	<b>18</b>
8. <i>Product identification and traceability</i>	<b>19</b>
9. <i>Process control</i>	<b>20 - 22</b>
10. <i>Inspection and testing</i>	<b>23 - 25</b>
11. <i>Control of inspection, measuring and test equipment</i>	<b>26 - 28</b>
12. <i>Inspection and test status</i>	<b>29</b>
13. <i>Control of nonconforming product</i>	<b>30 - 31</b>
14. <i>Corrective and preventive action</i>	<b>32</b>
15. <i>Handling, storage, packaging, preservation and delivery</i>	<b>33 - 34</b>
16. <i>Control of quality records</i>	<b>35</b>
17. <i>Internal quality audits</i>	<b>36</b>
18. <i>Training</i>	<b>37</b>
19. <i>Servicing</i>	<b>38</b>
20. <i>Statistical techniques</i>	<b>39</b>

**Abbreviations used**

<i>S</i>	: Satisfactory
<i>CA</i>	: Corrective action required
<i>MA</i>	: Major corrective action
<i>mi</i>	: Minor corrective action
<i>N/A</i>	: Not applicable
<i>N/E</i>	: Not evaluated

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<b>QUALITY SYSTEM QUESTIONNAIRE</b>			

ASSESSMENT QUESTIONS	CRITICAL	REFERENCE and Revision	DOCUMENT			USE			
			S	CA MA/ml	N/A	S	CA MA/ml	N/A	N/E

## 4.1. Management responsibility

4.1.1. Quality policy									
01 Has the supplier's management with executive responsibility defined and documented the quality policy including objectives and the commitment to quality?	C		1)						
02 Is the quality policy relevant to the supplier's organizational goals and the expectations and needs of its customers?	C		2)						
03 Does the supplier ensure that the quality policy is understood, implemented and maintained at all levels of the organization?	C					3)			
4.1.2. Organization									
4.1.2.1. Responsibility and authority									
04 Are the responsibility, authority and interrelation between the people who manage, perform and verify work affecting quality defined and documented?	C		4)						
05 Do the documented definitions address personnel which:									
a) Initiate actions to prevent the occurrence of any nonconformance relating to product, process and quality system?	C								
b) Identify and record any problems relating to product, process and quality system?	C								
c) Initiate, recommend or provide solutions through designated channels?	C								
d) Verify the implementation of solutions?	C								
e) Control further processing, delivery or installation of nonconforming product until the deficiency or unsatisfactory condition has been corrected?	C								
4.1.2.2. Resources									
06 Has the supplier identified resource requirements and provided adequate resources which includes the assignment of trained personnel for:									
a) management?									
b) performance of work?									
c) verification activities?									
d) internal quality audit?									

- 1) Management commitment written and issued (quality manual or other documents).  
 2) Yearly objectives (current and previous year).  
 3) Formalized issue (information notice to the personnel or meeting report).  
 4) Organizational notice, organizational charts, job description.

**Objective evidence assessed**

**Discrepancy with Standard's requirements (corrective action request numbers)**

**Recommendations/Observations**

C : Critical - S : Satisfactory; - CA : Corrective action required - MA : Major corrective action  
 ml : Minor corrective action - N/A : Not applicable - N/E: Not evaluated

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<b>QUALITY SYSTEM QUESTIONNAIRE</b>			

ASSESSMENT QUESTIONS	CRITICAL	REFERENCE and Revision	DOCUMENT			USE			
			S	CA MA/mi	N/A	S	CA MA/mi	N/A	N/E

## 4.1. Management responsibility (continued)

<b>4.1.2.3. Management Representative</b>									
07 Has the supplier's management with executive responsibility appointed a member of the supplier's own management who, irrespective of other responsibilities, has defined authority for:									
a) ensuring that a quality system in accordance with <b>AS9100/EN9100</b> is established, implemented and maintained?									
b) reporting on the performance of the quality system to the supplier's management for review and improvements ?									
<b>08 Does the management representative have the necessary authority and the organizational freedom to resolve matters pertaining to quality?</b>									
<b>4.1.2.4. Process performer</b>									
09 (applicable to suppliers having a quality assurance activity performed by an individual process performer (e.g. operator, buyer, planner)) Does the supplier have procedures that define the specific tasks and responsibilities of an individual process performer performing quality assurance activities, that are authorized and the corresponding requirements and training necessary to perform a quality assurance activity?									
<b>4.1.3. Management review</b>									
10 Is the quality system reviewed by the supplier's management with executive responsibility at defined intervals sufficient to ensure its continued suitability and effectiveness in satisfying the requirements of <b>AS9100/EN9100</b> and the supplier's stated quality policy and objectives?									
10 Are records of such reviews maintained?							1)		

1) Minutes, topics dealt on the reviews, availability of improvement plans.

**Objective evidence assessed**

**Discrepancy with Standard's requirements (corrective action request numbers)**

**Recommendations/Observations**

C : Critical - S : Satisfactory; - CA : Corrective action required - MA : Major corrective action  
 mi : Minor corrective action - N/A : Not applicable - N/E: Not evaluated

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ASSESSMENT QUESTIONS	CRITICAL	REFERENCE and Revision	DOCUMENT			USE			
			S	CA MA/mi	N/A	S	CA MA/mi	N/A	N/E

## 4.2. Quality system

4.2.1. General									
01 Has the supplier established, documented and does he maintain a quality system as a means of ensuring that product conforms to specified requirements?	C		1)						
02 Has the supplier prepared a Quality Manual: a) covering the requirements of AS9100/EN9100? b) which includes or makes reference to the quality system procedures? c) which includes an outline of the structure of the documentation used in the quality system?									
	C		2)						
03 Are other quality system requirements imposed by the applicable regulatory authorities included or referenced in the quality system documentation?									
4.2.2. Quality system procedures									
04 Has the supplier prepared procedures consistent with the requirements of AS9100/EN9100 and the supplier's stated quality policy?									
05 Has the supplier effectively implemented the quality system and its documented procedures?									
06 Has the supplier ensured that quality system procedures are readily accessible to personnel who are responsible for performing work in conformance to requirements, and to customer and/or regulatory authorities representatives?									
07 Are the range and detail of the procedures that form part of the quality system dependent upon the complexity of the work, the methods used, and the skills and training needed by personnel involved in carrying out the activity?									

- 1) Quality manual and associated documents.  
2) System structure

**Objective evidence assessed**

**Discrepancy with Standard's requirements (corrective action request numbers)**

**Recommendations/Observations**

C : Critical - S : Satisfactory - CA : Corrective action required - MA : Major corrective action  
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ASSESSMENT QUESTIONS	CRITICAL	REFERENCE and Revision	DOCUMENT			USE			
			S	CA MA/mi	N/A	S	CA MA/mi	N/A	N/E

## 4.2. Quality system (continued)

4.2.3. Quality planning	CRITICAL	REFERENCE and Revision	S	CA MA/mi	N/A	S	CA MA/mi	N/A	N/E
08 Has the supplier a formalized planning system in accordance with his own quality system, which documents product, project or contract requirements?						1)			
09 Does the planning system include the following activities for:									
a) the preparation of quality plans?									
b) the identification and acquisition of any controls, processes, equipment (including inspection and test equipment), fixtures, resources and skills that may be needed to achieve the required quality? <i>the design, manufacture, and use of tooling so that variable measurements can be taken, particularly for key characteristics?</i>									
c) ensuring the compatibility of the design, the production process, installation, servicing, inspection and test procedures and the applicable documentation?									
d) the updating, as necessary, of quality control, inspection and testing techniques, including the development of new instrumentation?									
e) the identification of any measurement requirement involving capability that exceeds the known state of the art, in sufficient time for the needed capability to be developed?									
f) the identification of suitable verification at appropriate stages in the realization of product? <i>the identification of in-process verification points when adequate verification of conformance cannot be performed at a later stage of realization?</i>									
g) the clarification of acceptance standards for all features and requirements, including those which contain a subjective element?									
h) the identification and preparation of quality records?									
i) <i>the identification and selection of subcontractors?</i>									
j) <i>the establishment of appropriate process controls and development of control plans where key characteristics have been identified?</i>									
<b>4.2.4. CONFIGURATION MANAGEMENT</b>									
10 Has the supplier established, documented and does he maintain a configuration management system appropriate to the product?									

1) Quality plan.

**Objective evidence assessed**

**Discrepancy with Standard's requirements (corrective action request numbers)**

**Recommendations/Observations**

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ASSESSMENT QUESTIONS	CRITICAL	REFERENCE and Revision	DOCUMENT			USE			
			S	CA MA/mi	N/A	S	CA MA/mi	N/A	N/E

### 4.3. Contract review

<b>4.3.1. General</b>										
01 Has the supplier established and does he maintain documented procedures of contract review and for the coordination of these activities?										
02 <i>Has the supplier established and does he maintain documented procedures for tender review and for the coordination of these activities?</i>										
<b>4.3.2. Review</b>										
03 Before submission of a tender, or the acceptance of a contract order (statement of requirement), does the supplier review the tender, contract or order to ensure:										2)
a) the requirements are adequately defined and documented?	C									
Where no written statement of requirement is available for an order received by verbal means, does the supplier ensure that the order requirements are agreed before their acceptance?	C									
b) any differences between the contract and the order requirements and those in the tender are resolved?	C									
c) the supplier has the capability to meet contractual requirements?	C									
d) <i>risk associated with a new technology and/or a short delivery time scale have been evaluated?</i>										
<b>4.3.3. Amendment to a contract</b>										
04 Does the supplier identify how an amendment to a contract is made and correctly transferred to the functions concerned within the supplier's organization?										
05 <i>Are contract review requirements also applied to contract amendments?</i>										
<b>4.3.4. Records</b>										
07 Are records of such contract reviews maintained?										

1) Procedure or document that specifies the organization of these reviews.  
 2) Examples of examined files.

**Objective evidence assessed**

**Discrepancy with Standard's requirements (corrective action request numbers)**

**Recommendations/Observations**

C : Critical - S : Satisfactory - CA : Corrective action required - MA : Major corrective action  
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ASSESSMENT QUESTIONS	CRITICAL	REFERENCE and Revision	DOCUMENT			USE			
			S	CA MA/ml	N/A	S	CA MA/ml	N/A	N/E

### 4.4. Design control

<b>4.4.1. General</b>									
01 Has the supplier established and does he maintain documented procedures to control and verify the design of the product in order to ensure that specified requirements are met?			1)						
02 Are the responsibilities and authorities for the approval of the design data defined?									
03 When the supplier subcontracts design or development activities, does he control the subcontracted activity consistent with the requirements of AS9100/EN9100, section 4.4 ?									
<b>4.4.2. Design and development planning</b>									
04 Has the supplier prepared plans for each design and development activity?	C						2)		
05 Do the plans describe or reference such activities and define responsibility for their implementation?	C								
06 Are the design and development activities assigned to qualified personnel?	C								
07 Are the design and development personnel equipped with adequate resources?	C								
08 Are such plans updated as the design evolves?	C								
<b>4.4.2.1. Design and development management planning</b>									
09 Does the supplier plan the different phases used to carry out the design and development, in respect of the organization, task sequence, mandatory steps, significant stages and method of configuration control?	C								
10 Does the supplier give consideration to the following activities as appropriate: - structure of the design effort into significant elements according to the complexity? - for each element, analysis of the tasks and the necessary resources for its design and development? (Does this analysis consider an identified responsible person, design content, planning constraints, and performance conditions?)	C								
	C								
<b>4.4.2.2. Reliability, maintainability, safety</b>									
11 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?	C						3)		
1) Examined procedures.									
2) Design and development plannings achieved or in process with planning of tasks and key events.									
3) Functional safety analysis (providing the ability to conduct reliability analysis).									

<b>Objective evidence assessed</b>
------------------------------------

<b>Discrepancy with Standard's requirements (corrective action request numbers)</b>
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<b>Recommendations/Observations</b>
-------------------------------------

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ASSESSMENT QUESTIONS	CRITICAL	REFERENCE and Revision	DOCUMENT			USE			
			S	CA MA/mi	N/A	S	CA MA/mi	N/A	N/E

**4.4. Design control (continued)**

<b>4.4.3. Organizational and technical interfaces</b>									
12 Are the organizational and technical interfaces between different groups which input into the design process defined?									
13 Is the necessary information:									
a) documented?									
b) transmitted?									
c) regularly reviewed?									
<b>4.4.4. Design input</b>									
14 Are the design input requirements relating to the product including applicable statutory and regulatory requirements identified and documented?	C						1)		
15 Is their selection reviewed by the supplier for adequacy?	C								
16 Are incomplete, ambiguous or conflicting requirements resolved with those responsible for imposing these requirements?	C								
17 Does the design input take into consideration the results of all contract review activities?									
<b>18 Are input data to the design defined and documented in terms of functional requirements?</b>									
<b>19 In the case of a product requiring design and development planning, does the supplier establish the input data specific to each element and review to ensure consistency with requirements?</b>									
<b>4.4.5. Design output</b>									
20 Is the design output documented and expressed in terms that can be verified and validated against design input requirements?							2)		
21 Does the supplier's design output:									
a) meet the design input requirements?							3)		
b) contain or make references to acceptance criteria?									
c) identify those characteristics of the design that are crucial to the safe and proper functioning of the product (e.g., operating, storage, handling, maintenance and disposal requirements)?									
22 Are the design output documents reviewed before release?									
<b>23 Has the supplier defined all pertinent data required to allow the product to be identified, manufactured, inspected, used and maintained?</b>									

- 1) Customer data formalization.
- 2) File allowing to identify, manufacture, procure, inspect, use and maintain the product. Provide an example.
- 3) File allowing a verification with regard to the input.

**Objective evidence assessed**

**Discrepancy with Standard's requirements (corrective action request numbers)**

**Recommendations/Observations**

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ASSESSMENT QUESTIONS	CRITICAL	REFERENCE and Revision	DOCUMENT			USE			
			S	CA MA/ml	N/A	S	CA MA/ml	N/A	N/E

### 4.4. Design control (continued)

4.4.6. Design review										
24 At appropriate stages of design, does the supplier plan and conduct formal documented reviews of the design results?	C								1)	
25 Do these reviews include representatives of all functions concerned with the design stage being reviewed as well as other specialist personnel, as required?	C									
26 Are records of such reviews maintained?	C									
<b>27 Is consideration given to:</b>										
<b>a) the validity of design in relation to the objectives of the design stage?</b>										
<b>b) actions which need to be taken in the event of any identified deviation?</b>										
<b>c) decision necessary for progression to the next stage?</b>										
4.4.7. Design verification										
28 At appropriate stages of design, is design verification performed to ensure that the design stage output meets the design stage input requirements?	C								2)	
29 Are the design verification measures recorded?	C									
4.4.8. Design validation										
30 Is the design validation performed to ensure that product conforms to defined user needs and/or requirements?										
4.4.8.1 Documentation of design verification and validation										
31 At the completion of development, does the supplier ensure that reports, calculations, test results, etc. demonstrate that the product definition meets the specification requirements for all identified operational conditions and the product will function correctly?										

- 1) Formalized and planned reviews.  
 2) Records of the verifications (calculation, comparisons, justificative file, tests result, document review prior to issue).

**Objective evidence assessed**

**Discrepancy with Standard's requirements (corrective action request numbers)**

**Recommendations/Observations**

C : Critical - S : Satisfactory - CA : Corrective action required - MA : Major corrective action  
 ml : Minor corrective action - N/A : Not applicable - N/E : Not evaluated

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### 4.4. Design control (continued)

#### 4.4.8.2. Design verification and validation testing

32 Where tests are necessary for verification and validation, are these tests planned, controlled, reviewed, and documented to ensure and prove the following:

- 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?
- test procedures describe the method of operation, the performance of the test, and the recording of the results?
- the correct configuration standard of the product is submitted for the test?
- the requirements of the test plan and the test procedures are observed?
- the acceptance criteria are met?


#### 4.4.9. Design changes

33 Does the supplier ensure that before their implementation, all design changes and modifications are:

- a) identified?
- b) documented?
- c) reviewed?
- d) approved by authorized personnel?

C																			
C						1)													
C																			
C																			

#### Design change approval

34 Does the supplier's design control provide for customer and/or regulatory authority approval of changes, when required by contract or regulatory requirement?

C																			
---	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

1) Configuration control: arrangements taken to ascertain that the product definition and its evolutions are known at any moment.

#### Objective evidence assessed

#### Discrepancy with Standard's requirements (corrective action request numbers)

#### Recommendations/Observations

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### 4.5. Document and data control

4.5.1. General									
01 Has the supplier established and does he maintain documented procedures to control all documents and data that relate to the requirements of this document?	C		1)						
02 Does these procedures include (to the extent applicable) documents of external origin such as standards and customer drawings?									
4.5.2. Document and data approval and issue									
03 Does the supplier ensure that documents and data are reviewed and approved for adequacy by authorized personnel prior to issue?									
04 Has the supplier established a master list or equivalent document control procedure identifying the current revision status of documents?						2)			
05 Is the master list or equivalent document control procedure readily available to preclude the use of invalid and/or obsolete documents?									
06 Does the supplier's quality system ensure that:									
a) the pertinent issues of appropriate documents are available at all locations where operations essential to the effective functioning of the quality system are performed?									
b) invalid and/or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use?									
c) any obsolete documents retained for legal and/or knowledge-preservation purposes suitably identified?									
<b>07 When customer furnished digital data is used for design, production and/or inspection, does the supplier establish system controls in accordance with customer requirements?</b>									
4.5.3. Document and data changes									
08 Are changes to documents and data reviewed and approved by the same functions/organizations that performed the original review and approval, unless specifically designated otherwise?						3)			
09 Have the designated functions/organizations access to pertinent background information upon which to base their review and approval?									

- 1) Examined procedures.  
 2) Lists, files (or other documents) examined.  
 3) Traceability and review changes.

**Objective evidence assessed**

**Discrepancy with Standard's requirements (corrective action request numbers)**

**Recommendations/Observations**

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**4.5. Document and data control (continued)**

10 Where practicable, is the nature of the change identified in the document or the appropriate attachments?										
<b>DOCUMENT CHANGE INCORPORATION</b>										
11 Does the supplier establish a process to ensure the timely review, distribution, implementation and maintenance of all authorized and released drawings, standards, specifications, planning, and changes?										
12 Does the supplier maintain a record of change incorporation and, when required, does he coordinate these incorporations with the customer and/or regulatory authority?										

**Objective evidence assessed**

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**Discrepancy with Standard's requirements (corrective action request numbers)**

**Recommendations/Observations**

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## 4.6. Purchasing

<b>4.6.1. General</b>									
01 Has the supplier established and does he maintain documented procedures to ensure that purchased product conforms to specified requirements?	C								
<b>02 Is the supplier responsible for the quality of all products purchased from subcontractors, including customer-designated sources?</b>									
<b>4.6.2. Evaluation of subcontractors</b>									
03 Does the supplier :									
a) evaluate and select his subcontractors on the basis of their ability to meet the subcontract requirements including the quality system and any specific quality assurance requirements?							1)		
b) define the type and extent of control exercised by the supplier over subcontractors?									
b1) Is the control dependent upon the type of product, the impact of subcontracted product on the quality of final product, and where applicable, on the quality audit reports and/or quality records of the previously demonstrated capability and performance of subcontractors?									
c) establish and maintain quality records of acceptable subcontractors?									
d) ensure where required that both the supplier and all subcontractors use customer-approved special process sources?									
e) ensure that the organization having responsibility for approving subcontractor quality systems has the authority to disapprove the use of sources?									
f) periodically review subcontractor performance to establish supplier's level of control? <i>Are record of these reviews maintained and used as a basis for establishing the level of supplier controls to be implemented?</i>							2)		
g) maintain procedures that define the necessary actions to be taken when dealing with subcontractors which do not meet requirements?									
04 Does the supplier maintain a list of approved subcontractors and specify the scope of approval?					3)			4)	

- |   |  |
|---|--|
| 1) Examined files. Explain the method for selecting the Subcontractors. | 2) Suppliers performance/measurement system. |
| 3) Latest updating of the approved subcontractors' list.                | 4) Updated list of approved Subcontractors.  |

**Objective evidence assessed**

**Discrepancy with Standard's requirements (corrective action request numbers)**

**Recommendations/Observations**

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## 4.6. Purchasing (continued)

4.6.3. Purchasing data									
05 Do purchasing documents contain data clearly describing the product ordered, including where applicable:									
a) the type, class, grade or other precise identification?						1)			
b) the title or other positive identification, and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data, including requirements for approval or qualification of product, procedures, process equipment and personnel?									
c) the title, number and issue of the quality system standard to be applied?									
d) <i>design, test examination, inspection and customer acceptance requirements and any related instructions and requirements?</i>									
e) <i>right of access by the purchaser, their customer and regulatory authorities to all facilities involved in the order and all applicable quality records?</i>									
f) <i>requirements for test specimens (production method, number, storage conditions, etc.) for design approval, inspection, investigation or auditing?</i>									
g) <i>requirements relative to the notification of anomalies, changes in definition and the approval of their processing?</i>									
h) <i>requirement to flow down to subtier suppliers the applicable requirements in the purchasing documents, including key characteristics where required?</i>									
06 Does the supplier review and approve purchasing documents for adequacy of the specified requirements prior to release?									

1) Purchase Orders that apply to several types of procurements.

### Objective evidence assessed

### Discrepancy with Standard's requirements (corrective action request numbers)

### Recommendations/Observations

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N/A	N/A	N/A

## 4.6. Purchasing (continued)

4.6.4. Verification of purchased products	CRITICAL	REFERENCE and Revision	DOCUMENT	USE	S	CA MA/mi	N/A	S	CA MA/mi	N/A	N/A
07 Does the supplier implement procedures to verify purchased products, they may include obtaining objective evidence of the quality of the product from subcontractors (e.g., accompanying documentation, certificate of conformity, test reports, statistical records, process control), inspection and audit at source, review of the required documentation, inspection of the products at delivery, and delegation of verification to the subcontractor, or subcontractor certification?								1)			
08 When delegation is used, does the supplier define the requirements for delegation and maintain a list of delegations?											
<b>4.6.4.1. Supplier verification at subcontractor's premises</b>											
09 Where the supplier proposes to verify purchased product at the subcontractor's premises, does the supplier specify verification arrangements and the method of product release in the purchasing documents?											
<b>4.6.4.2. Customer Verification of Subcontracted Product</b>											
10 When specified in the contract, is the supplier's customer or the customer's representative afforded the right to verify at the subcontractor's premises and the supplier's premises that subcontracted product conforms to specified requirements?											
11 Does the supplier not use such verification as evidence of effective control of quality by the subcontractor?											

1) Explanation of who does what.

**Objective evidence assessed**

**Discrepancy with Standard's requirements (corrective action request numbers)**

**Recommendations/Observations**

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## 4.9. Process control

4.9.1. General									
01 Does the supplier identify and plan the production, installation and servicing processes which directly affect quality?	C		1)						
02 Does the supplier ensure that the processes are carried out under controlled conditions in terms of:									
a) documented procedures defining the manner of production, installation and servicing, where the absence of such instructions could adversely affect quality?	C								
b) use of suitable production, installation and servicing equipment and a suitable working environment (e.g. temperature, humidity, lighting and cleanness, etc.)?	C								
c) compliance with reference standards/codes, quality plans and/or documented procedures?	C								
d) monitoring and control of suitable process parameters and product characteristics; <b>monitoring and control of key characteristics where required by purchase order/contract?</b>	C								
e) approval of process and equipment, as appropriate?	C								
f) criteria for workmanship, which shall be stipulated in the clearest practical manner (e.g., written standards, representative samples or illustrations)?	C								
g) suitable maintenance of equipment to ensure continuing process capability?	C								
h) <b>accountability for all product during manufacture (e.g. parts quantities, split orders, nonconformities)?</b>									
i) <b>evidence that all manufacturing and inspection operations have been completed as planned, or as otherwise documented and authorized?</b>									
j) <b>provision for the prevention, detection and removal of foreign objects?</b>	C								
k) <b>utilities and supplies such as water, compressed air, electricity and chemical products to the extent they affect product quality?</b>									

1) Detail of the organization and its functioning. Application field of the topic (production, implementation of servicing).

**Objective evidence assessed**

**Discrepancy with Standard's requirements (corrective action request numbers)**

**Recommendations/Observations**

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### 4.9. Process control (continued)

<b>4.9.1.1 Production Documentation</b>									
<b>03</b> Are production operations carried out in accordance with approved data, and 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?	C						1)		
b) the list of specific or non-specific tools and numerical control (NC) machine programs?	C								
c) documents associated with specific tools enabling the tools to be designed, produced, validated, controlled, used and maintained?	C								
<b>4.9.1.2. Control of production process changes</b>									
<b>04</b> Are persons required to approve changes to production processes identified and authorized?							2)		
<b>05</b> Has the supplier identified those changes which require customer acceptance in accordance with contractual requirements prior to making any change?									
<b>06</b> Are changes affecting processes, production equipment, tools and programs documented?									
<b>07</b> Are procedures available to control their implementation?									
<b>08</b> Does the supplier assess the results of changes to production processes to confirm that the desired effect has been achieved without adverse effects to product quality?									
<b>4.9.1.3. Control of production equipment, tools, numerical control (NC) machine programs</b>									
<b>09</b> Are production equipment, tools and programs validated prior to use, maintained and inspected periodically according to documented procedures?	C						3)		
<b>10</b> Does validation prior to production use include verification of the first article produced to the design data/specification?	C								
<b>11</b> Are the storage requirements, including periodic preservation/condition checks, established for production equipment or tooling in storage?	C								
1) Examples examined.									
2) Clearly defined list.									
3) Examples examined.									

<b>Objective evidence assessed</b>
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<b>Discrepancy with Standard's requirements (corrective action request numbers)</b>
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<b>Recommendations/Observations</b>
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**4.9. Process control (continued)**

<b>4.9.1.4. Control of work occasionally performed outside the supplier's facilities</b>									
<b>12</b> When planning to carry out work at a location other than its normal facilities, does the supplier define the procedure to validate the location and to control the work?									
<b>4.9.2. Special processes</b>									
<b>13</b> Where the results of processes cannot be fully verified by subsequent inspection and testing of the product, and where, for example, processing deficiencies may become apparent only after the product is in use, are the processes carried out by qualified operators and/or do they require continuous monitoring and control of process parameters to ensure that the specific requirements are met?	C						1)		
<b>14</b> Are the requirements for any qualification of process operations, including associated equipment and personnel specified?	C								
<b>15</b> Are records maintained for qualified processes, equipment and personnel, as appropriate?	C								
<b>16</b> When production operations call for special processes :									
<b>a) are the special processes to be implemented identified and qualified prior to use?</b>	C						2)		
<b>b) does the supplier control applicable aspects of special processes, as defined by the process specifications (this includes special process changes)?</b>	C								
<b>c) are significant operations and parameters in the process to be controlled during production clearly defined?</b>	C								

- 1) Detail of what is achieved (facilities, operators, etc.).  
 2) List of special processes.

**Objective evidence assessed**

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## 4.10. Inspection and testing

4.10.1. General									
01 Has the supplier established and does he maintain documented procedures for inspection and testing activities in order to verify that specified requirements for the product are met?									
02 Are the required inspection and testing, and the records to be established, detailed in the quality plan or documented process?									
03 Do these procedures specify the resources and methods to be implemented, and the methods of recording the results?	C								
04 Do these procedures include:									1)
▪ identification of authorized personnel?	C								
▪ limits of authorization?	C								
▪ training and qualification requirements?	C								
05 Does the supplier maintain and control inspection documentation, which includes at least:									
a) criteria for acceptance and rejection?									
b) where in the sequence inspection and testing operations are performed?									
c) documents recording inspection results?									
d) identification of production inspection instruments?									
e) documents associated with specific inspection instruments enabling them to be designed, produced, validated, controlled, used and maintained?									
06 When the supplier subcontracts inspection or test activities, does the supplier control the subcontracted activity consistent with the requirements of AS9100/EN9100, section 4.6?									
<b>4.10.2. Receiving inspection and testing</b>									
07 Does the supplier ensure that incoming product is not used or processed (except in the circumstances described in AS9100/EN9100, section 4.10.2.3) until it has been inspected or otherwise verified as conforming to specified requirements?	C								
08 Are verifications of conformance to the specific requirements in accordance with the quality plan and/or documented procedures?	C								
09 In determining the amount and nature of receiving inspection, is consideration given to the amount of control exercised at the subcontractor's premises and the recorded evidence of conformance provided?	C								

1) Operators' certification / qualification.

<b>Objective evidence assessed</b>
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<b>Discrepancy with Standard's requirements (corrective action request numbers)</b>
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<b>Recommendations/Observations</b>
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**4.10. Inspection and testing (continued)**

<p>10 Does the quality plan or the documented procedures specify that where incoming product is released for urgent production purposes prior to verification, it shall be positively identified and recorded in order to permit immediate recall and replacement in the event of nonconformity to specified requirements?</p>										
<p>11 <i>When certification test reports are utilized to accept material, does the supplier assure that data in said reports are acceptable per applicable specifications?</i></p>										
<p>12 <i>Does the supplier periodically validate test reports?</i></p>										
<b>4.10.3. In-process inspection and testing</b>										
<p>13 Are products inspected and tested as required by the quality plan and/or documented procedures?</p>										
<p>14 Are products held until the required inspection and tests have been completed or necessary reports have been received and verified, except when product is released under positive-recall procedures (see <b>AS9100/EN9100, section 4.10.2.3</b>)?</p>										
<b>4.10.4. Final inspection and testing</b>										
<p>15 Does the supplier carry out all final inspection and testing in accordance with the quality plan and/or documented procedures to complete the evidence of conformance of the finished product to the specified requirements?</p>										
<p>16 Does the quality plan and/or procedures for final inspection and testing require that all specified inspection and tests, including those specified either on receipt of product or in-process, have been carried out and that the results meet specified requirements?</p>										
<p>17 Does the supplier ensure that no product is dispatched until:</p>										
<p>a) all the activities specified in the quality plan and/or documented procedures have been satisfactorily completed?</p>	C									
<p>b) associated data and documentation are available and authorized?</p>	C									
<b>4.10.5. Inspection and test records</b>										
<p>18 Has the supplier established and does he maintain records which show clearly whether the product has passed or failed the inspections and/or tests according to defined acceptance criteria?</p>										

**Objective evidence assessed**

**Discrepancy with Standard's requirements (corrective action request numbers)**

**Recommendations/Observations**

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**4.10. Inspection and testing (continued)**

19 Do the records identify the inspection authority responsible for release of the product?										
20 Do test records show actual test results data when required by specification or acceptance test plan?										
21 When required to demonstrate product qualification, does the supplier ensure that quality records provide evidence that the product meets the defined requirements?										
<b>4.10.6. First Article Inspection</b>										
22 Does the supplier's system provide a process, as appropriate, for the inspection, verification, and documentation of the first production article.										
23 Is First Article Inspection documentation retained and does it include a list of the characteristics required by the design data and any required tolerances, the actual results, and when testing is required, the results of the tests?										
24 Are the First Article Inspections updated to include production process changes or configuration changes?										

**Objective evidence assessed**

**Discrepancy with Standard's requirements (corrective action request numbers)**

**Recommendations/Observations**

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## 4.11. Control of inspection, measuring and test equipment

4.11.1. General										
01 Has the supplier established and does he maintain documented procedures to control, calibrate and maintain inspection, measuring and test equipment (including test software) used by the supplier to demonstrate the conformance of the product to the specified requirements?	C									1)
02 Is the supplier's inspection, measuring and test equipment used in a manner which ensures that measurement uncertainty is known and is consistent with the required measurement capability?	C									
03 Where test software or comparative references such as test hardware are used as suitable forms of inspection, does the supplier ensure they are checked to prove that they are capable of verifying the acceptability of product prior to release for use during production, installation or servicing?										
04 Does the supplier perform rechecks at prescribed intervals?										
05 Has the supplier established the extent and frequency of such checks and does he maintain records as evidence of control?										
06 Where the availability of technical data pertaining to the inspection, measuring and test equipment is a specified requirement, is such data made available, when required by the customer or customer's representative, for verification that the inspection, measuring and test equipment is functionally adequate?										
07 <i>Has the supplier defined responsibilities regarding the control of inspection, measuring and test equipment, including those used by operators as well as, where appropriate, test devices and tools supplied by the customer?</i>	C									
4.11.2. Control procedures										
08 Has the supplier:										
a) determined the measurements to be made?										
b) determined the accuracy required?										
c) selected the appropriate inspection, measuring and test equipment that is capable of the necessary accuracy and precision?										

1) Specified responsibilities.

**Objective evidence assessed**

**Discrepancy with Standard's requirements (corrective action request numbers)**

**Recommendations/Observations**

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**4.11. Control of inspection, measuring and test equipment (continued)**

15 Does the supplier ensure that the environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out?										
16 Does the supplier ensure that the handling, preservation and storage of inspection, measuring and test equipment is such that the accuracy and fitness for use are maintained?										
17 Does the supplier safeguard inspection, measurement and test facilities, including both test hardware and test software, from adjustments which would invalidate the calibration setting?										
18 Does the supplier define the method for recall of measuring devices that require calibration?										

**Objective evidence assessed**

**Discrepancy with Standard's requirements (corrective action request numbers)**

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<b>QUALITY SYSTEM QUESTIONNAIRE</b>			

ASSESSMENT QUESTIONS	CRITICAL	REFERENCE and Revision	DOCUMENT			USE			
			S	CA MA/mi	N/A	S	CA MA/mi	N/A	N/E

**4.12. Inspection and test status**

01 Is the inspection and test status identified by suitable means, which indicate the conformance or nonconformance of products with regard to inspection and tests performed?	C		1)			2)				
02 Is the identification of inspection and test status maintained, as defined in the quality plan and/or documented procedures, throughout production, installation and servicing of the product to ensure that only product that have passed the required inspections and tests (or released under an authorized concession) is dispatched, used or installed?										
<b>4.12.1. Authorized personnel</b>										
04 Does the supplier have records which identify personnel authorized to verify, certify and release products?										
<b>4.12.2. Acceptance authority media</b>										
05 When acceptance authority media are used (e.g.: stamps, electronic signatures or passwords), does the supplier establish and document controls for the media?										

- 1) Examined documents that specify the rules.  
2) Method in use (at each stage).

**Objective evidence assessed**

**Discrepancy with Standard's requirements (corrective action request numbers)**

**Recommendations/Observations**

C : Critical - S : Satisfactory; - CA : Corrective action required - MA : Major corrective action  
mi : Minor corrective action - N/A : Not applicable - N/E : Not evaluated