SAE The Engineering Society For Advancing Mobility Land Sea Air and Space®
INTERNATIONAL
400 Commonwealth Drive, Warrendale, PA 15096-0001

AEROSPACE STANDARD

SAE AS9101
Technically equivalent to AECMA prEN 9101

REV. A

Issued 2000-09
Revised 2002-04

Superseding AS9101

Quality System Assessment

LICENSE AGREEMENT

The purchase price of this document includes a license to duplicate the forms included within only for the internal use of the organization which purchased the document. Further duplication or licensing is prohibited.

SECTION 1
Associated to the AS9100/EN9100/JISQ9100
Section 1 based on ISO 9001-2000

1. SCOPE:

The purpose of this document is to define the content and the presentation of the Assessment Report of the section 1 of the AS/EN/JISQ 9100, based on ISO 9001-2000.

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 Organizational Information
- Page 6 (optional if Quality Scoring Appendix 2 is used)
  Assessment Result Summary
- Page 7
  Corrective Action Request (when required)
- Page 8
  List of Recommendations/Observations/Comments
- Appendix 1
  Quality System Questionnaire relative to the section 1 of the AS/EN/JISQ 9100
- Appendix 2
  Quality System Scoring (Optional)
- Appendix 3
  Documents regarding the company:

  - Organization charts
  - Copies of agreements and certifications

ASSESSMENT REPORT	*Assessing company logo*

GENERAL ASSESSMENT INFORMATION

1. Organization & Work Address

Company Name:
Subsidiary of :
Organization Identification :
Assessed Site Address :
Main activities :
Product Types or Codes :

Tel Number
Fax Number :
e-mail :
CAGE code :
Assessment Representative & Title :
Quality Manager Representative & Title :

2. ISO Registration

[ ] ISO Registered
[ ] ISO Standard / Revision
[ ] Aerospace Standard / Revision

Registrar Name :
Expiration Date (If applicable) :

3. Assessment Team

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

Other Assessor Team Members :

4. Assessment Dates :

5. Assessment Scope

[ ] Total facility assessed
[ ] Partial facility assessed
[ ] Other :
[ ] Activity assessed :

[ ] Initial assessment
[ ] Re-assessment

[ ] All 9100 elements assessed
[ ] Partial 9100 elements assessed
Elements not 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 and the quality system of the assessed organization:

Strong points :

Improvement Opportunities :

ASSESSMENT REPORT	*Assessing company logo*

GENERAL ORGANIZATION INFORMATION

1. Legal and Financial Aspects

- Date of Formation :
- Legal Status :
- Capital :
- Other Data :

	Third Prior Financial Year ( )	Second Prior Financial Year ( )	First Prior Financial Year ( )	**Current Financial Year ( )**
Sales				
Earnings				
Earnings used for Re-Investment				
Workforce				

2. Turnover breakdown and main Customers

Activities	**Main Customers**	**Sales Percentage**
Aircraft, Space and Defense Industry		
Other Activity (be specific)		

3. Clearances or Approvals granted by Authorities

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

ASSESSMENT REPORT	*Assessing company logo*

ASSESSMENT RESULT SUMMARY

Organization:

Elements* (AS / EN / JISQ9100 Standard)	**Result** S	MA	mi	N/A	**Observation / Corrective Action Request Number (MA/mi)**
4- Quality Management System					
4.1 General requirements					
4.2 Documentation requirements					
4.3 Configuration Management					
5 - Management responsibility					
5.1 Management commitment					
5.2 Customer focus					
5.3 Quality policy					
5.4 Planning					
5.5 Responsibility, authority and communication					
5.6 Management review					
6 - Resource management					
6.1 Provision of resources					
6.2 Human resources					
6.3 Infrastructure					
6.4 Work environment					
7 - Product realization					
7.1 Planning of product realization					
7.2 Customer-related processes					
7.3 Design and development					
7.4 Purchasing					
7.5 Production and service provision					
7.6 Control of monitoring and measuring devices					
8 - Measurement, analysis and improvement					
8.1 General					
8.2 Monitoring and measurement					
8.3 Control of nonconforming product					
8.4 Analysis of data					
8.5 Improvement					
Assessed Organization :					Assessing Company :
Rep's name :	**Results**				Lead Assessor Name :
Signature :					Signature :

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

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 : Yes ☐ No ☐	Assessor Name :	Assessor Signature :

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 1
9101
QUALITY SYSTEM QUESTIONNAIRE

Associated to the International Quality System Standard
AS9100/JISQ9100/EN9100 Section 1, based on ISO 9001-2000

LICENSE AGREEMENT

1. SCOPE:

The purpose of this document is to present the questionnaire to be used during the "on site" quality system assessment of Organizations in order to ensure common practices for these assessments. This questionnaire is relative to the section 1 of the AS/EN/JISQ 9100 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 9100 standard, section 1, which is relative to:

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

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 9100.

Important questionnaire elements are defined below:

- Key requirements
  The questions which are marked by:
  - "P" have a direct link with the products
  - "M" have a direct link with the management

- Mark the appropriate box for each requirement with:
  - Satisfactory (S)
  - Not applicable (N/A)
  - Not evaluated (N/E)

- Corrective Action Request (CAR) are categorized Major (MA) or Minor (mi.):
  Major: The absence of, or total breakdown of a management element specified in the 9100 standard or any non-conformities where the effect is judged to be detrimental to the integrity of the product or service which are identified as Key Requirements in significant sections of AS/EN/JISQ 9100 ("P" or "M") in the questionnaire.
  Minor: Other deviation.

  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.

  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.

- Objective evidence assessed/Observations/Comments
  Record the objective evidence reviewed during the assessment. Guidance is provided for certain questions, as indicated in the Key Requirements column by a small number (for example: 1).

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

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?						
Does the organization : identify the processes needed for the quality management system and their application throughout the organization ?	1)					
determine the sequence and interaction of these processes?	1)					
determine criteria and methods needed to ensure that both the operation and control of these processes are effective?						
ensure the availability of resources and information necessary to support the operation and monitoring of these processes?						
monitor, measure and analyze these processes? and						
implement actions necessary to achieve planned results and continual improvement of these processes?						
Are these processes managed by the organization in accordance with the requirements of this International Standard?						
Where an organization chooses to outsource any process that affects product conformity with requirements, does the organization ensure control over such processes?	P					
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.

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?***					

1) Main process formally identified (list, flow diagram, etc.)

Objective evidence assessed / Observations / Comments

***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

4.2.2 Quality manual

09 Has the organization established and maintained a quality manual that includes : a) the scope of the quality management system, including details of, and justification for, any exclusions ? b) the documented procedures established for the quality management system, or reference to them, and ***when referencing the documented procedures, is the relationship between the requirements of this International Standard and the documented procedures clearly shown?*** c) a description of the interaction between the processes of the quality management system?	1) 2) 3)				

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

4.2.3 Control of documents

10 Are the documents required by the quality management system controlled?					
11 Are records controlled according to the requirements given in 4.2.4?					
12 Has a documented procedure been established to define the controls needed to: a) approve documents for adequacy prior to issue? b) review and update as necessary and re-approve documents? c) ensure that changes and the current revision status of documents are identified? d) ensure that relevant versions of applicable documents are available at points of use? e) ensure that documents remain legible and readily identifiable? f) ensure that documents of external origin are identified and their distribution controlled? and g) prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose?					
13 Does the organization coordinate document changes with customers and/or regulatory authorities in accordance with contract or regulatory requirements?					

1) Quality manual reference and issue
2) Check the procedure list
3) International standard used as referential

Objective evidence assessed / Observations / Comments

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)					
4.2.4 Control of records					
14 Are records established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system?					
15 Do records remain legible, readily identifiable and retrievable?	1)				
16 Has a documented procedure been established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records?					
17 Does the documented procedure define the method for controlling records that are created by and/or retained by suppliers?					
18 Are records available for review by customers and regulatory authorities in accordance with contract or regulatory requirements?					
4.3 Configuration management					
19 Has the organization established, documented and maintained a configuration management process appropriate to the product ?	P				

1) Records examples

Objective evidence assessed / Observations / Comments

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 : 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?	1) 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? and e) is reviewed for continuing suitability?	2)				
5.4. Planning					
5.4.1. Quality objectives					
04 Has Top management ensured that quality objectives, including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within the organization.	3)				
05 Are the quality objectives measurable and consistent with the quality policy.	M				
5.4.2. Quality management system planning					
06 Has Top management ensured that : a) the planning of the quality management system is carried out in order to meet the requirements (see 4.1), as well as the quality objectives? and b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented?					

1) Evidence of management commitment
2) Identify and records method of communication
3) Yearly objectives (current and previous year) and status of their implementation

Objective evidence assessed / Observations / Comments

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.					

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?	2)				
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)?					

1) Identify and records method of communication within the organization
2) Records management review frequency and attendees

Objective evidence assessed / Observations / Comments

***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 (Continued)

5.6.2. Review input

13	Does the input to management review include information on:	1) M
	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?	

5.6.3. Review output

14	Does the output from the management review include any decisions and actions related to :	1) M
	a) improvement of the effectiveness of the quality management system and its processes?	
	b) improvement of product related to customer requirements? and	
	c) resource needs?	

1) Verify the availability of input / output data such as : statistical data; graphics; summary tables; reports; etc.

Objective evidence assessed / Observations / Comments

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

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

6 Resource management

6.1. Provision of resources

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

6.2. Human resources

6.2.1. General

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

6.2.2. Competence, awareness and training

03	Does the organization : a) determine the necessary competence for personnel performing work affecting product quality? 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)?	2) P 3)				

6.3. Infrastructure

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

6.4. Work environment

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

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

1) 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) Training certificates for the certified personnel and training records (internal and external training courses)

Objective evidence assessed / Observations / Comments

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

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

7 Product realization

7.1. Planning of product realization

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

7.2. Customer-related processes

7.2.1. Determination of requirements related to the product

04	Does the organization determine : a) requirements specified by the customer, including the requirements for delivery and post-delivery activities? b) requirements not stated by the customer but necessary for specified or intended use, where known? c) statutory and regulatory requirements related to the product? and d) any additional requirements determined by the organization ?	M

Objective evidence assessed / Observations / Comments

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

QUALITY SYSTEM QUESTIONNAIRE					
ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
7.2.2. Review of requirements related to the product					
06 Does the organization review the requirements related to the product?					
07 Is the review conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and does it ensure that : a) product requirements are defined? b) contract or order requirements differing from those previously expressed are resolved? c) the organization has the ability to meet the defined requirements? ***and*** ***d) risks (e.g., new technology, short delivery time scale) have been evaluated?***	1) P				
08 Are records of the results of the review and actions arising from the review maintained (see 4.2.4)?	2)				
09 Where the customer provides no documented statement of requirement, are the customer requirements confirmed by the organization before acceptance?					
10 Where product requirements are changed, does the organization ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements?	P				

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

7.2.3. Customer communication

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

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

Objective evidence assessed / Observations / Comments

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 (continued)

7.3.1.1. Design and development

7.3.1. Design and development planning

12 Does the organization plan and control the design and development of product?	
13 During the design and development planning, does the organization determine : a) the design and development stages? ***- in respect of organization, task sequence, mandatory steps, significant stages and method of configuration control,*** b) the review, verification and validation that are appropriate to each design and development stage? and c) the responsibilities and authorities for design and development?	1) M
14 Where appropriate, due to complexity, does the organization give consideration to the following activities : - ***structuring the design effort into significant elements?*** - ***for each element, analyzing the tasks and the necessary resources for its design and development. Does This analysis consider an identified responsible person, design content, input data, planning constraints, and performance conditions. Is the input data specific to each element reviewed to ensure consistency with requirements?***	
15 Does the organization manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility?	
16 Is planning output updated, as appropriate, as the design and development progresses?	
17 Are the different design and development tasks to be carried out defined according to specified safety or functional objectives of the product in accordance with customer and/or regulatory authority requirements?	2) **P**

7.3.2. Design and development inputs

18 Are inputs relating to product requirements determined and are records maintained (see 4.2.4)? Do these inputs include : a) functional and performance requirements? b) applicable statutory and regulatory requirements? c) where applicable, information derived from previous similar designs? and d) other requirements essential for design and development?	3) M
19 Are these inputs reviewed for adequacy?	
20 Are requirements completed, unambiguous and not in conflict with each other?	

7.3.3. Design and development outputs

21 Are the outputs of design and development provided in a form that enables verification against the design and development input and approved prior to release?	

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

Objective evidence assessed / Observations / Comments

***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 (continued)

7.3.3. Design and development outputs (continued)

22	Do the design and development outputs : a) meet the input requirements for design and development? b) provide appropriate information for purchasing, production and for service provision? c) contain or reference product acceptance criteria? d) specify the characteristics of the product that are essential for its safe and proper use? ***and*** ***e) identify key characteristics, when applicable, in accordance with design or contract requirements?***	M				
23	***Is all pertinent data required to allow the product to be identified, manufactured, inspected, used and maintained defined by the organization; for example:*** ***a) - Drawings, part lists, specifications?*** ***b) - a listing of those drawings, part lists, and specifications necessary to define the configuration and the design features of the product?*** ***- information on material, processes, type of manufacturing and assembly of the product necessary to ensure the conformity of the product?***	**M**				

7.3.4. Design and development review

24	At suitable stages, are systematic reviews of design and development performed in accordance with planned arrangements (see 7.3.1) to: a) evaluate the ability of the results of design and development to meet requirements? b) identify any problems and propose necessary actions? ***and*** ***c) authorize progression to the next stage?***	1)M				
25	Do participants in such reviews include representatives of functions concerned with the design and development stage(s) being reviewed?					
26	Are records of the results of the reviews and any necessary actions maintained (see 4.2.4)?					

7.3.5. Design and development verification

27	Is verification performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements?					
28	Are records of the results of the reviews and any necessary actions maintained (see 4.2.4)?					

Note: Design and/or development verification may include activities such as:
- **performing alternative calculations,**
- **comparing the new design with a similar proven design, if available**
- **undertaking tests and demonstrations, and**
- **reviewing the design stage documents before release.**

1) Give evidence of review

Objective evidence assessed / Observations / Comments

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 (continued)

7.3.6. Design and development validation

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

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

7.3.6.1. Documentation of design and/or development verification and validation

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

7.3.6.2. Design and/or development verification and validation testing

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

1) Give an example of a qualification report

Objective evidence assessed / Observations / Comments

***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 (continued)

7.3.7. Control of design and development changes

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

7.4 Purchasing

7.4.1. Purchasing process

39	Does the organization ensure that purchased product conforms to specified purchase requirements?					
40	Is the type and extent of control applied to the Supplier and the purchased product dependent upon the effect of the purchased product on subsequent product realization or the final product?					
41	Does the organization evaluate and select Suppliers based on their ability to supply product in accordance with the organization's requirements?					
42	Are criteria for selection, evaluation and re-evaluation established?					
43	Are records of the results of evaluations and any necessary actions arising from the evaluation maintained (see 4.2.4)?					
44	***Does the organization :***	M				
	a) maintain a register of approved Suppliers that includes the scope of the approval?	2)				
	b) Periodically review Suppliers performance and use the records of these reviews as a basis for establishing the level of controls to be implemented?					
	c) define the necessary actions to take when dealing with Suppliers that do not meet requirements?	3)				
	d) ensure where required that both the organization and all Suppliers use customer-approved special process sources?					
	e) ensure that the function having responsibility for approving Supplier quality systems has the authority to disapprove the use of sources?					

1) Give an example
2) Current list of approved Suppliers
3) Suppliers performance / measurement system (e.g.: supplier rating, etc..)

Objective evidence assessed / Observations / Comments

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 (continued)

7.4. Purchasing (continued)

7.4.2. Purchasing information

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

1) Examine purchase orders that apply to several types of procurement.

Objective evidence assessed / Observations / Comments

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 (continued)

7.4. Purchasing (continued)

7.4.3. Verification of purchased product

47	Does the organization establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements, they may include ***obtaining objective evidence of the quality of the product from suppliers (e.g., accompanying documentation, certificate of conformity, test reports, statistical records, process control, inspection and audit at supplier's premises, review of the required documentation, inspection of products upon receipt, and, delegation of verification to the supplier, or supplier certification***?	P				
48	***Is purchased product held until it has been verified as conforming to specified requirements unless it is released under positive recall procedure?***					
49	***Where the organization utilizes test reports to verify purchased product, is the data in those reports acceptable per applicable specifications?***	1)				
50	***Does the organization periodically validate test reports for raw material?***	1)				
51	***Where the organization delegates verification activities to the supplier, are the requirements for delegation defined and a register of delegations maintained?***	1)				
52	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?					
53	***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?***					
54	***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)?***					

1) Give an example

Objective evidence assessed / Observations / Comments

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 (continued)

7.5. Production and service provision

7.5.1. Control of production and service provision

55	***Does planning consider, as applicable :***					
	a)	***- the establishment of process controls and development of control plans where key characteristics have been identified***				
	b)	***- the identification of in-process verification points when adequate verification of conformance cannot be performed at a later stage of realization***				
	c)	***- the design, manufacture, and use of tooling so that variable measurements can be taken, particularly for key characteristics, and***				
	d)	***- special processes (see 7.5.2).***				
56	Does the organization plan and carry out production and service provision under controlled conditions.	1)				
	Do these controlled conditions include, as applicable :					
	a)	the availability of information that describes the characteristics of the product?				
	b)	the availability of work instructions, as necessary?				
	c)	the use of suitable equipment?				
	d)	the availability and use of monitoring and measuring devices?				
	e)	the implementation of monitoring and measurement,				
	f)	the implementation of release, delivery and post-delivery activities?				
	g)	***accountability for all product during manufacture (e.g., parts quantities, split orders, nonconforming product)?***				
	h)	***evidence that all manufacturing and inspection operations have been completed as planned, or as otherwise documented and authorized?***	P			
	i)	***provision for the prevention, detection, and removal of foreign objects?***	P			
	j)	***monitoring and control of utilities and supplies such as water, compressed air, electricity and chemical products to the extent they affect product quality? and***				
	k)	***criteria for workmanship, which shall be stipulated in the clearest practical manner (e.g., written standards, representative samples or illustrations)?***				

1) Give an example

Objective evidence assessed / Observations / Comments

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 (continued)

7.5.1.1. Production documentation

57	*Are Production operations carried out in accordance with approved data?*					
58	*Does the data contain as necessary :* *a) drawings, parts lists, process flow charts including inspection operations, production documents (e.g., manufacturing plans, traveler, router, work order, process cards); and inspection documents (see 8.2.4.1)? and* *b) a list of specific or non-specific tools and numerical control (NC) machine programs required and any specific instructions associated with their use?*					

7.5.1.2. Control of production process changes

59	*Are persons authorized to approve changes to production processes identified?*	1) M				
60	*Has the organization identified and obtained acceptance of changes that require customer and/or regulatory authority approval in accordance with contract or regulatory requirements?*					
61	*Are changes affecting processes, production equipment, tools and programs documented?*	P				
62	*Are procedures available to control their implementation?*					
63	*Are the results of changes to production processes assessed to confirm that the desired effect has been achieved without adverse effects to product quality?*	P				

7.5.1.3. Control of production equipment, tools and numerical control (N.C.) machine programs

64	*Are production equipment, tools and programs validated prior to use and maintained and inspected periodically according to documented procedures?*	P				
65	*Does validation prior to production use include verification of the first article produced to the design data/specification?*	P				
66	*Are storage requirements, including periodic preservation/condition checks, established for production equipment or tooling in storage?*					

7.5.1.4. Control of work transferred, on a temporary basis, outside the organization's facilities

67	*When planning to temporarily transfer work to a location outside the organization's facilities, does the organization define the process to control and validate the quality of the work?*	M				

1) Clearly defined list

Objective evidence assessed / Observations / Comments

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 (continued)

7.5.1.5. Control of service operations

68 Where servicing is a specified requirement, do service operation processes provide for : ***a) a method of collecting and analyzing in-service data?*** ***b) actions to be taken where problems are identified after delivery, including investigation, reporting activities, and actions on service information consistent with contractual and/or regulatory requirements?*** ***c) the control and updating of technical documentation?*** ***d) the approval, control, and use of repair schemes? and,*** ***e) the controls required for off-site work (e.g., organization's work undertaken at the customer's facilities)?***	1) 2) 3)

7.5.2 Validation of processes for production and service provision

69 Does the organization validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement (This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered)? **Note: These processes are frequently referred to as special processes.**	4) P
70 Does validation demonstrate the ability of these processes to achieve planned results?	
71 Has the organization established arrangements for these processes including, as applicable : a) defined criteria for review and approval of the processes? b) qualification and approval of special processes prior to use? c) approval of equipment and qualification of personnel? d) use of specific methods and procedures? e) ***Control of the significant operations and parameters of special processes in accordance with documented process specifications and changes thereto?*** f) requirements for records (see4.2.4)? and g) revalidation?	M 5)

1) Review reports issued following visits to the customer (technical support). Comment on method of collection of in service data. Examine some investigation reports
2) Evidence of implementation of corrective and preventive actions.
3) Evidence of what has been assessed (e.g.,: maintenance manual, repair manual, information to customer)
4) List of special processes.
5) Give examples

Objective evidence assessed / Observations / Comments

***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 (continued)

7.5.3. Identification and traceability

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

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

7.5.4. Customer property

78	Does the organization exercise care with customer property while it is under the organization's control or being used by the organization?	3)
79	Has the organization identified, verified, protected and safeguarded customer property provided for use or incorporation into the product?	P
80	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***.

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

Objective evidence assessed / Observations / Comments

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 (continued)

7.5.5. Preservation of product

81	Does the organization preserve the conformity of product during internal processing and delivery to the intended destination?					
82	Does the preservation include identification, handling, packaging, storage and protection?					
83	Does preservation also apply to the constituent parts of a product?					
84	***Does preservation of product also include, where applicable in accordance with product specifications and/or regulations, provisions for :***	**P**				
	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?					
85	***Does the organization ensure that documents required by the contract/order to accompany the product are present at delivery and are protected against loss and deterioration?***					

Objective evidence assessed / Observations / Comments

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 (continued)

7.6. Control of monitoring and measuring devices

86	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)?	
87	***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?*** ***Note: Monitoring and measuring devices include, but are not limited to: test hardware, test software, automated test equipment (ATE) and plotters used to produce inspection data. It also includes personally owned and customer supplied equipment used to provide evidence of product conformity.***	
88	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?	
89	***Does the organization ensure that environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out?***	
90	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, the basis used for calibration or verification shall be recorded? 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?***	1)
91	Does the organization assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements?	
92	Does the organization take appropriate action on the equipment and any product affected?	P
93	Are records of the results of calibration and verification maintained (see 4.2.4)?	
94	When used in the monitoring and measurement of specified requirements, is the ability of computer software to satisfy the intended application confirmed?	P
95	Is this undertaken prior to initial use and reconfirmed as necessary?	

1) Ensure the links to the recognized international / national standard.

Objective evidence assessed / Observations / Comments

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

8 Measurement, analysis and improvement

8.1. General

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

Note: According to the nature of the product and depending on the specified requirements, statistical techniques may be used to support:
- **design verification (e.g., reliability, maintainability, safety);**
- **process control:**
  - **selection and inspection of key characteristics;**
  - **process capability measurements;**
  - **statistical process control;**
  - **design of experiment;**
- **inspection – matching sampling rate to the criticality of the product and to the process capability;**
- **failure mode and effect analysis.**

8.2. Monitoring and measurement

8.2.1. Customer satisfaction

04 As one of the measurements of the performance of the quality management system, does the organization monitor information relating to customer perception as to whether the organization has met customer requirements?	2) M				
05 Are the methods for obtaining and using this information determined?					

8.2.2. Internal audit

06 Does the organization conduct internal audits at planned intervals to determine whether the quality management system : a) conforms to the planned arrangements (see 7.1) to the requirements of this International Standard and to the quality management system requirements established by the organization? and b) is effectively implemented and maintained?					

1) Give examples of data
2) Give examples of how customer's satisfaction is measured, committed, and acted upon.

Objective evidence assessed / Observations / Comments

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

8 Measurement, analysis and improvement (continued)

Internal audit (continued)

07	Is an audit program planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits?	1) M				
08	Is the audit criteria, scope, frequency and methods defined?					
09	Does the selection of auditors and conduct of audits ensure objectivity and impartiality of the audit process?	2)				
10	Does the organization ensure internal auditors do not audit their own work?					
11	Are the responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) defined in a documented procedure?					
12	Do the management responsible for the areas being audited ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes?	3) M				
13	Do follow-up activities include the verification of the actions taken and the reporting of verification results (see 8.5.2)?	3)				
14	***Are detailed tools and techniques developed such as check sheets, process flowcharts, or any similar method to support audit of the quality management system requirements?***					
15	***Are the selected internal audit tools acceptable in measuring the effectiveness of the internal audit and overall organization performance?***					
16	***Do internal audits also meet contract and/or regulatory requirements?***					

8.2.3. Monitoring and measurement of processes

17	Does the organization apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes?					
18	Do these methods demonstrate the ability of the processes to achieve planned results?					
19	When planned results are not achieved, is correction and corrective action taken, as appropriate, to ensure conformity of the product?					
20	***In the event of process nonconformity, does the organization :***	4) P				
a)	***take appropriate action to correct the nonconforming process?***					
b)	***evaluate whether the process nonconformity has resulted in product nonconformity? and***					
c)	***identify and control the nonconforming product in accordance with clause 8.3.?***					

1) Audit plan (status of the previous year and progress of the current year).
2) List of approved auditors.
3) Evidence of a sample of audits (questionnaire, synthesis, circulation, request for corrective actions, corrective actions follow-up).
4) Give examples of non conformity (product, process,…).

Objective evidence assessed / Observations / Comments

***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

8 Measurement, analysis and improvement (continued)

8.2.4. Monitoring and measurement of product

21	Does the organization monitor and measure the characteristics of the product to verify that product requirements have been met?	P				
22	Is this carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1)?					
23	***When key characteristics have been identified, are they monitored and controlled?***	P				
24	***When the organization uses sampling inspection as a means of product acceptance, is the plan statistically valid and appropriate for use?***					
25	***Does the plan preclude the acceptance of lots whose samples have known nonconformities?***					
26	***When required, is the plan submitted for customer approval?***					
27	***Is product held until it has been inspected or otherwise verified as conforming to specified requirements, except when product is released under positive-recall procedures pending completion of all required measurement and monitoring activities?***	P				
28	Is evidence of conformity with the acceptance criteria maintained?					
29	Do records indicate the person(s) authorizing release of product (see 4.2.4)?					
30	Is product release and service delivery held until all the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer?					

Objective evidence assessed / Observations / Comments

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

8 Measurement, analysis and improvement (continued)

8.2.4.1. Inspection documentation

31	*Are measurement requirements for product or service acceptance documented?*	
32	*Does this documentation ,which may be part of the production documentation, include :*	P
a)	*criteria for acceptance and/or rejection?*	
b)	*where in the sequence measurement and testing operations are performed?*	
c)	*a record of the measurement results? and*	
d)	*type of measurement instruments required and any specific instructions associated with their use?*	
33	*Do test records show actual test results data when required by the specification or acceptance test plan?*	
34	*When required to demonstrate product qualification does the organization ensure that records provide evidence that the product meets the defined requirements?*	

8.2.4.2. First article inspection

35	*Does the organization's system provide a process for the inspection, verification, and documentation of a representative item from the first production run of a new part, or following any subsequent change that invalidates the previous first article inspection result?*	P 1)

1) Give examples of first article (new product and change).

Objective evidence assessed / Observations / Comments

***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

8 Measurement, analysis and improvement (continued)

8.3. Control of nonconforming product

Note: The term "nonconforming product" includes nonconforming product returned from a customer.

36	Does the organization ensure that product which does not conform to requirements is identified and controlled to prevent its unintended use or delivery?	P
37	Are the controls and related responsibilities and authorities for dealing with nonconforming product defined in a documented procedure?	
38	***Does the organization's documented procedure define the responsibility for review and authority for the disposition of nonconforming product and the process for approving personnel making these decisions?***	
39	Does the organization deal with nonconforming product in one or more of the following ways by:	P
a)	taking action to eliminate the detected nonconformity?	
b)	authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer?	
c)	taking action to preclude its original intended use or application?	
40	***Does the organization prevent dispositions of use-as-is or repair, unless specifically authorized by the customer, if***	
	- ***the product is produced to customer design? or***	
	- ***the nonconformity results in a departure from the contract requirements?***	
	(Unless otherwise restricted in the contract, is organization-designed product, which is controlled via a customer specification, dispositioned by the organization as use-as-is or repair, provided the nonconformity does not result in a departure from customer-specified requirements ?)	

Objective evidence assessed / Observations / Comments

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

8 Measurement, analysis and improvement (continued)

8.3. Control of nonconforming product (continued)

41	***Is product dispositioned for scrap conspicuously and permanently marked, or positively controlled, until physically rendered unusable?***	P
42	Are records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, maintained (see 4.2.4)?	
43	When nonconforming product is corrected is it subject to re-verification to demonstrate conformity to the requirements?	
44	When nonconforming product is detected after delivery or use has started, does the organization take action appropriate to the effects, or potential effects, of the nonconformity?	P
45	***In addition to any contract or regulatory authority reporting requirements, does the organization's system provide for timely reporting of delivered nonconforming product that may affect reliability or safety?***	P
46	***Does notification include a clear description of the nonconformity, which includes as necessary, parts affected, customer and/or organization part numbers, quantity, and date(s) delivered?***	

Note: The term "nonconforming product" includes nonconforming product returned from a customer.

8.4 Analysis of data

47	Does the organization determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made?	M
48	Does this include data generated as a result of monitoring and measurement and from other relevant sources?	
49	Does the analysis of data provide information relating to:	1)
a)	customer satisfaction (see 8.2.1)?	
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?	

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

Objective evidence assessed / Observations / Comments

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

8 Measurement, analysis and improvement (continued)

8.5. Improvement

8.5.1. Continual improvement

50	Does the organization continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review?	

8.5.2. Corrective action

51	Does the organization take action to eliminate the cause of nonconformities in order to prevent recurrence?	
52	Are Corrective actions appropriate to the effects of the nonconformities encountered?	
53	Is a documented procedure established to define requirements for :	1)
a)	reviewing nonconformities (including customer complaints)?	
b)	determining the causes of nonconformities?	
c)	evaluating the need for action to ensure that nonconformities do not recur?	
d)	determining and implementing action needed?	
e)	recording of the results of the action taken (see 4.2.4)?	
f)	reviewing corrective action taken?	
g)	***flow down of the corrective action requirement to a supplier, when it is determined that the supplier is responsible for the root cause? and***	**M**
h)	***specific actions where timely and/or effective corrective actions are not achieved?***	

8.5.3. Preventive action

54	Does the organization determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence?	M
55	Are preventive actions appropriate to the effects of the potential problems?	
56	Is a documented procedure established to define requirements for :	2)
a)	determining potential nonconformities and their causes?	
b)	evaluating the need for action to prevent occurrence of nonconformities?	
c)	determining and implementing action needed?	
d)	recording of the results of the action taken (see 4.2.4)? and	
e)	reviewing preventive action taken?	

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

Objective evidence assessed / Observations / Comments

***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 2
9101
QUALITY SYSTEM SCORING

Associated to the International Quality System Standard
AS9100/JISQ9100/EN9100 Section 1, issued in 2002
based on ISO 9001-2000

LICENSE AGREEMENT

ASSESSMENT SCORING							*(Member logo)*
Organization :		**Result**					
IAQG	SCORING CHART	Major CAR "M" or "P"		Minor CAR		NO CAR	RESULT
		Several	Single	Several	Single		
4	**Quality management system**						
4.1	General requirements	0	10	25	40	50	
4.2 & 4.3	Documentation requirements & Configuration management	0	10	25	40	50	
5	**Management responsibility**						
5.1	Management commitment	0	5	15	20	30	
5.2	Customer focus						
5.3	Quality policy						
5.4	Planning	0	10	20	30	40	
5.5	Responsibility, authority and communication	0	5	15	20	30	
5.6	Management review	0	10	25	40	50	
6	**Resource Management**						
6.1	Provision of resources	0	10	25	40	50	
6.2	Human resources						
6.3	Infrastructure	0	10	25	40	50	
6.4	Work environment						
7	**Product realization**						
7.1	Planning of product realization	0	5	15	20	30	
7.2	Customer related processes	0	10	30	50	60	
7.3	Design and development						
731	*D& D Planning*	0	5	15	20	30	
732-3-4	*Inputs, outputs & review*	0	5	15	20	30	
735-6	*D&D verification & validation*	0	5	15	20	30	
737	*Control of design and development changes*	0	5	15	20	30	
7.4	Purchasing	0	10	30	50	60	
7.5	Product and service provision						
751	*Control of production and service provision*	0	10	25	40	50	
752	*Validation of processes for production and service provision*	0	10	20	30	40	
753	*Identification and traceability*	0	10	20	30	40	
754-5	*Customer property & preservation of product*	0	5	15	20	30	
7.6	Control of monitoring and measuring device	0	5	10	15	20	
8	**Measurement analysis and improvement**						
8.1	General	0	5	10	15	20	
8.2	Monitoring and measurement						
821	*Customer satisfaction*	0	5	10	15	20	
822	*Internal audit*	0	5	15	20	30	
823	*Monitoring and measurement of processes*	0	5	15	20	30	
824	*Monitoring and measurement of product*	0	5	15	20	30	
8.3	Control of nonconforming product	0	5	15	20	30	
8.4	Analysis of Data	0	5	10	15	20	
8.5	Improvement	0	5	10	15	20	
					TOTAL	880[1] or 1000	
					RATING		/ 100

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

(1) When 7.3 is not assessed

SECTION 2
Associated to the AS9100/EN9100/JISQ9100
Section 2 based on ISO 9001-1994

1. SCOPE:

   The purpose of this document is to define the content and the presentation of the Assessment Report of the section 2 of the AS/EN/JISQ 9100, based on ISO 9001-1994.

2. QUALITY SYSTEM ASSESSMENT REPORT CONTENT:

   The Assessment Report is made up of:

   - Page 42 (required)
     General Assessment Information
   - Page 43 (required)
     Assessment Conclusions
   - Page 44 (optional)
     General Supplier Information
   - Page 45
     Assessment Result Summary
   - Page 46
     Assessment Scoring Chart

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

   - Page 47
     Corrective Action Request
   - Appendix 1
     Quality System Questionnaire relative to the section 2 of the AS/EN/JISQ 9100
   - Appendix 2
     Documents regarding the company:

     - Organization charts
     - Copies of agreements and certifications

ASSESSMENT REPORT	*(Member logo)*

GENERAL ASSESSMENT INFORMATION

1 Supplier & Work Address

Company Name:	Fax Number:
Parent Name:	E-Mail:
Supplier Identification:	CAGE code:
Assessed Site Address:	Duns No.:
	Assessment Representative & Title:
	Management Representative & Title:

2 ISO Registration

[ ] ISO Registered	Registrar Name:
[ ] ISO Standard / Revision	Expiration Date:
[ ] Aerospace Standard / Revision	Product Types or Codes:

3 Assessment Team

Lead Assessor Name:	Other Assessor Team Members:
[ ] Certified Auditor – Type & No.	
[ ] Qualified Auditor (e.g., ISO10011-2)	

4 Assessment Dates

Begin Date:	End Date:

5 Assessment Scope

[ ] Total facility assessed [ ] Initial assessment	[ ] All AS9100 / EN9100 elements assessed
[ ] Partial facility assessed [ ] Re-assessment	[ ] Partial AS9100 / EN9100 elements assessed
[ ] Other :	Elements not assessed:

6 Assessment Disposition	**7 Scoring**
[ ] Non conforming	Scoring result:
[ ] Conforming with minor corrective actions	

8 Assessment Approval

Assessing Company	Date	Lead Assessor Name	Signature

Distribution Agreement

This Assessment Report is the property of the assessed Supplier and the assessing Company. Full or partial distribution to other companies or individuals is authorized only after written agreement of the assessed Supplier 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 supplier 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	*(Member logo)*

ASSESSMENT CONCLUSIONS (To be completed in English)
General comments about the organization and the quality system of the assessed Supplier:
Strong points:
Weak points:

ASSESSMENT REPORT	*(Member logo)*

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 ( )**
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	*(Member logo)*

ASSESSMENT RESULT SUMMARY

Supplier:

Assessment Results:

	Elements (AS9100 / EN9100 Standard)	Result				Observation / 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					
	Results Summary					Assessing Company: Lead Assessor Name: Signature:

ASSESSMENT REPORT	*(Member logo)*

ASSESSMENT SCORING CHART

Supplier:

Elements (AS9100 / EN9100 Standard)		Result 3	2	1	0	Coef. Item	Result	Max. Result	Observation / Corrective Action Request Number (MA/mi)
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			
					R ⇨			⇦ M	

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

Note : Non-conformitites 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
A GOOD					B MEDIUM				C POOR				D UNACCEPTABLE							

Cross according to the Quality System Rating

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

CORRECTIVE ACTION REQUEST (C.A.R.)	*(Member logo)*

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:

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. Due date:

To be filled out by the Assessed Supplier Representative

1st Step

Action No.:	Root Cause:

Action No. :	Corrective Action:	Planned completion date of Corrective Action :	Completion date :

Supplier Representative Name:	Signature:	Current date:

2nd Step

Supplier Representative Name:	Signature:	Current date:

Verification of the implementation of the completed Corrective Action to be filled out by the Assessing Company

Completed on:	Accepted: Yes ☐ No ☐	Name:	Signature:

APPENDIX 1
AS9101/EN9101
QUALITY SYSTEM QUESTIONNAIRE

Associated to the International Quality System Standard
AS9100/JISQ9100/EN9100 Section 2 based on ISO 9001-1994

LICENSE AGREEMENT

1. SCOPE:

   The purpose of this document is to present the questionnaire to be used during the "on site" quality system assessment of Organizations in order to ensure common practices for these assessments. This questionnaire is relative to the section 2 of the AS/EN/JISQ 9100 based on ISO 9001-1994.

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, section 2, 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 required (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.

   • 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.

Summary

Section headings	Page numbers
1. Management responsibility	52 - 53
2. Quality system	54 - 55
3. Contract review	56
4. Design control	57 - 60
5. Document and data control	61 - 62
6. Purchasing	63 - 65
7. Control of customer-supplied product	66
8. Product identification and traceability	67
9. Process control	68 - 70
10. Inspection and testing	71 - 73
11. Control of inspection, measuring and test equipment	74 - 76
12. Inspection and test status	77
13. Control of nonconforming product	78 - 79
14. Corrective and preventive action	80
15. Handling, storage, packaging, preservation and delivery	81 - 82
16. Control of quality records	83
17. Internal quality audits	84
18. Training	85
19. Servicing	86
20. Statistical techniques	87

Abbreviations used

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

QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	CRITICAL	REFERENCE and Revision	DOCUMENT S	DOCUMENT CA MA/mi	DOCUMENT N/A	USE S	USE CA MA/mi	USE N/A	USE 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*
***mi** : Minor corrective action - **N /A** : Not applicable - **N/E**: Not evaluated*

QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	CRITICAL	REFERENCE and Revision	DOCUMENT S	DOCUMENT CA MA/mi	DOCUMENT N/A	USE S	USE CA MA/mi	USE N/A	USE N/E
4.1. Management responsibility (continued)									
4.1.2.3. Management Representative									
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 ***AS9100/EN9100*** is established, implemented and maintained?									
b) reporting on the performance of the quality system to the supplier's management for review and improvements ?									
08 Does the management representative have the necessary authority and the organizational freedom to resolve matters pertaining to quality?									
4.1.2.4. Process performer									
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?***									
4.1.3. Management review									
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 ***AS9100/EN9100*** and the supplier's stated quality policy and objectives?									
10 Are records of such reviews maintained?									

1) Minutes, topics dealt with 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*

QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	CRITICAL	REFERENCE and Revision	DOCUMENT S	DOCUMENT CA MA/mi	DOCUMENT N/A	USE S	USE CA MA/mi	USE N/A	USE 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		2)						
c) which includes an outline of the structure of the documentation used in the quality system?									
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*
***mi** : Minor corrective action - **N /A** : Not applicable - **N/E**: Not evaluated*

QUALITY SYSTEM QUESTIONNAIRE

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									
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? ***the design, manufacture, and use of tooling so that variable measurements can be taken, particularly for key characteristics?***									
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? ***the identification of in-process verification points when adequate verification of conformance cannot be performed at a later stage of realization?***									
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) the identification and selection of subcontractors?									
j) the establishment of appropriate process controls and development of control plans where key characteristics have been identified?									
4.2.4. CONFIGURATION MANAGEMENT									
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

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

QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	CRITICAL	REFERENCE and Revision	DOCUMENT S	DOCUMENT CA MA/mi	DOCUMENT N/A	USE S	USE CA MA/mi	USE N/A	USE N/E
4.3. Contract review									
4.3.1. General									
01 Has the supplier established and does he maintain documented procedures of contract review and for the coordination of these activities?			1)						
02 Has the supplier established and does he maintain documented procedures for tender review and for the coordination of these activities?									
4.3.2. Review									
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) risk associated with a new technology and/or a short delivery time scale have been evaluated?									
4.3.3. Amendment to a contract									
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 Are contract review requirements also applied to contract amendments?									
4.3.4. Records									
06 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*
***mi** : Minor corrective action - **N /A** : Not applicable - **N/E**: Not evaluated*

QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	CRITICAL	REFERENCE and Revision	DOCUMENT S	DOCUMENT CA MA/mi	DOCUMENT N/A	USE S	USE CA MA/mi	USE N/A	USE N/E
4.4. Design control									
4.4.1. General									
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 ?									
4.4.2. Design and development planning									
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								
4.4.2.1. Design and development management planning									
2.1.1. 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								
2.1.2. 10 Does the supplier give consideration to the following activities as appropriate:									
- structure of the design effort into significant elements according to the complexity?	C								
- 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								
4.4.2.2. Reliability, maintainability, safety									
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).

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*

QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	CRITICAL	REFERENCE and Revision	DOCUMENT S	DOCUMENT CA MA/mi	DOCUMENT N/A	USE S	USE CA MA/mi	USE N/A	USE N/E
4.4. Design control (continued)									
4.4.3. Organizational and technical interfaces									
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?									
4.4.4. Design input									
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?									
18 Are input data to the design defined and documented in terms of functional requirements?									
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?									
4.4.5. Design output									
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? 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)?						3)			
22 Are the design output documents reviewed before release?									
23 Has the supplier defined all pertinent data required to allow the product to be identified, manufactured, inspected, used and maintained?									

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

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

QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	CRITICAL	REFERENCE and Revision	DOCUMENT S	DOCUMENT CA MA/mi	DOCUMENT N/A	USE S	USE CA MA/mi	USE N/A	USE 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								
27 Is consideration given to:									
a) the validity of design in relation to the objectives of the design stage?									
b) actions which need to be taken in the event of any identified deviation?									
c) decision necessary for progression to the next stage?									
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*
***mi** : Minor corrective action - **N /A** : Not applicable - **N/E**: Not evaluated*

QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	CRITICAL	REFERENCE and Revision	DOCUMENT S	DOCUMENT CA MA/mi	DOCUMENT N/A	USE S	USE CA MA/mi	USE N/A	USE N/E
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 ubmitted 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?	C								
b) documented?	C		1)						
c) reviewed?	C								
d) approved by authorized personnel?	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

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

QUALITY SYSTEM QUESTIONNAIRE

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

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

QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	CRITICAL	REFERENCE and Revision	DOCUMENT			USE			
			S	CA MA/mi	N/A	S	CA MA/mi	N/A	N/E
4.5. Document and data control (continued)									
10 Where practicable, is the nature of the change identified in the document or the appropriate attachments?									
DOCUMENT CHANGE INCORPORATION									
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

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*

QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	CRITICAL	REFERENCE and Revision	DOCUMENT S	DOCUMENT CA MA/mi	DOCUMENT N/A	USE S	USE CA MA/mi	USE N/A	USE N/E
4.6. Purchasing									
4.6.1. General									
01 Has the supplier established and does he maintain documented procedures to ensure that purchased product conforms to specified requirements?	C								
02 Is the supplier responsible for the quality of all products purchased from subcontractors, including customer-designated sources?									
4.6.2. Evaluation of subcontractors									
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?	C					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? Are record of these reviews maintained and used as a basis for establishing the level of supplier controls to be implemented?						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

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

QUALITY SYSTEM QUESTIONNAIRE

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

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) design, test examination, inspection and customer acceptance requirements and any related instructions and requirements?	
e) right of access by the purchaser, their customer and regulatory authorities to all facilities involved in the order and all applicable quality records?	
f) requirements for test specimens (production method, number, storage conditions, etc.) for design approval, inspection, investigation or auditing?	
g) requirements relative to the notification of anomalies, changes in definition and the approval of their processing?	
h) requirement to flow down to subtier suppliers the applicable requirements in the purchasing documents, including key characteristics where required?	
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

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

QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	CRITICAL	REFERENCE and Revision	DOCUMENT S	DOCUMENT CA MA/mi	DOCUMENT N/A	USE S	USE CA MA/mi	USE N/A	USE N/E
4.6. Purchasing (continued)									
4.6.4. Verification of purchased products									
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?									
4.6.4.1. Supplier verification at subcontractor's premises									
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?									
4.6.4.2. Customer Verification of Subcontracted Product									
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

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

QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	CRITICAL	REFERENCE and Revision	DOCUMENT S	DOCUMENT CA MA/mi	DOCUMENT N/A	USE S	USE CA MA/mi	USE N/A	USE N/E
4.7. Control of customer-supplied product									
01 Has the supplier established and does he maintain documented procedures for the control of customer-supplied product?		1)							
02 Does the supplier define methods to:									
a) verify acceptability of supplied product?	C					1)			
b) segregate and store customer supplied product?	C					1)			
c) assure product is properly maintained during storage?	C					1)			
03 Does the supplier define methods to identify and record customer products that are lost, damaged or otherwise made unusable and report such to the customer?	C					2)			

1) Types of products supplied by the customers.
2) Example examined. Explanation of who does what (inspection, acceptance, refusal, reserve).

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*

QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	CRITICAL	REFERENCE and Revision	DOCUMENT S	DOCUMENT CA MA/mi	DOCUMENT N/A	USE S	USE CA MA/mi	USE N/A	USE N/E
4.8. Product identification and traceability									
01 Where appropriate, has the supplier established and does he maintain documented procedures for identifying the product by suitable means:		1)							
a) from receipt?									
b) during all stages of production?									
c) during delivery?									
d) during installation?									
02 Where and to the extent that traceability is a specified requirement, has the supplier established and does he maintain documented procedures for unique identification of individual product or batches?	C					2)			
03 Is such identification recorded?	C								
04 According to the level of traceability required by contract, regulatory, or other established requirement, does the supplier's system provide for:									
a) identification to be maintained throughout the product life?	C								
b) all the products manufactured from the same batch of raw material or from the same manufacturing batch to be traced, as well as the destination (delivery, scrap) of all products of the same batch?	C					3)			
c) for an assembly, the identity of its components and those of the next higher assembly to be traced?	C					4)			
d) for a given product, a sequential record of its production (manufacture, assembly, inspection) to be retrieved?	C								
05 Does the supplier maintain the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration?	C								

1) Retained identification principles.
2) Traceability principles retained by the supplier.
3) Examined example.
4) Examined example.

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*

QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	CRITICAL	REFERENCE and Revision	DOCUMENT S	DOCUMENT CA MA/mi	DOCUMENT N/A	USE S	USE CA MA/mi	USE N/A	USE N/E
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; ***monitoring and control of key characteristics where required by purchase order/contract?***	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) accountability for all products during manufacture (e.g. parts quantities, split orders, nonconformities)?									
i) evidence that all manufacturing and inspection operations have been completed as planned, or as otherwise documented and authorized?									
j) provision for the prevention, detection and removal of foreign objects?	C								
k) utilities and supplies such as water, compressed air, electricity and chemical products to the extent they affect product quality?									

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

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

QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	CRITICAL	REFERENCE and Revision	DOCUMENT S	DOCUMENT CA MA/mi	DOCUMENT N/A	USE S	USE CA MA/mi	USE N/A	USE N/E
4.9. Process control (continued)									
4.9.1.1 Production Documentation									
03 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								
4.9.1.2. Control of production process changes									
04 Are persons required to approve changes to production processes identified and authorized?						2)			
05 Has the supplier identified those changes which require customer acceptance in accordance with contractual requirements prior to making any change?									
06 Are changes affecting processes, production equipment, tools and programs documented?									
07 Are procedures available to control their implementation?									
08 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?									
4.9.1.3. Control of production equipment, tools, numerical control (NC) machine programs									
09 Are production equipment, tools and programs validated prior to use, maintained and inspected periodically according to documented procedures?	C					3)			
10 Does validation prior to production use include verification of the first article produced to the design data/specification?	C								
11 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.

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*