

FACTORY ASSESSMENT QUESTIONNAIRE

Factory: ***
Assessor: ***

Assessment Date: YYYY-MM-DD
Number: ***

ELEMENT 1. MANAGEMENT RESPONSIBILITY

Question	Comments	Result
1. * Are there clearly defined and documented responsibilities and authorities for all personnel affecting quality?	YES	CI
2. * Is there a periodic top management review of quality system effectiveness supported by appropriate records?	YES	CI
3. * Is there a documented business plan(s) that considers the QS-9000 requirements including, as applicable - competitive product analysis, - benchmarking, - R & D plans Internal quality and operational performance measures.	YES	CI
SCORE		3

ELEMENT 2. QUALITY SYSTEM

Question	Comments	Result
<p>1. * Is there a quality manual meeting QS-9000 requirements for documentation of a comprehensive quality system, including Note: This can be done prior to site visit.</p> <ul style="list-style-type: none"> - Management Responsibility <ul style="list-style-type: none"> - Quality Policy - Organisation - Quality Planning <ul style="list-style-type: none"> - Cross Functional Teams - Feasibility Reviews - Control Plans - Process FMEAs - Contract Review - Design Control, if applicable (QS9000) <ul style="list-style-type: none"> - Design Review - Design Verification - Design Validation - Design Changes (all suppliers) - Document/Data Control <ul style="list-style-type: none"> - Document Changes - Purchasing <ul style="list-style-type: none"> - Subcontractor evaluation - Product Identification/Traceability - Process Control <ul style="list-style-type: none"> - Process Monitoring - Capability/Performance Indices - Verification of Set-ups - Process Changes - Planned Preventive Maintenance - Inspection and Testing <ul style="list-style-type: none"> - Appearance, if applicable - Accredited Laboratories <p>Inspection, Measuring & Test Equipment</p> <ul style="list-style-type: none"> - Measurement Systems Analysis - Inspection & Test Status <p>-Control of Nonconforming Product</p> <ul style="list-style-type: none"> - Control of Reworked Product - EAPAs (see QSR) <ul style="list-style-type: none"> - Corrective and Preventive Actions - Handling, Storage, Packaging and Delivery - Control of Quality Records - Internal Audits - Training - Statistical Techniques <p>Are there adequate supporting procedures for each element?</p>	<p>YES</p>	<p>CI</p>
<p>2. * Is the Quality Planning process consistent with the elements of the quality system that addresses:</p> <ul style="list-style-type: none"> - Product Program Plan preparation <ul style="list-style-type: none"> - Identification and acquisition of the appropriate resources 	<p>YES</p>	<p>CI</p>

3. *	Are feasibility reviews conducted to confirm the compatibility of design with the manufacturing process, including capacity planning and utilisation?	YES	CI
4. *	Are control plans revised when appropriate for product and process changes or when processes are found to be unstable or non-capable?	YES	CI
5. *	Do control plans cover three phases: prototype, pre-launch, production unless exempted by the customer?	YES	CI
6. *	Are there adequate supporting procedures for each element of the quality manual?	YES	CI
SCORE			3

ELEMENT 3. CONTRACT REVIEW

Question	Comments	Result
1. * Are records of contract reviews maintained?	<i>Without signed date and name.</i>	M
SCORE		1

ELEMENT 4. DESIGN CONTROL (*No design request, not assessed*)

Question	Comments	Result
1. * Are appropriate resources and facilities available to use computer aided design, engineering and analysis? If CAD/CAE is sub-contracted, has the supplier provided technical leadership?		-
2. * Have formal documented design reviews been conducted per the design plan?		
3. * Is performance testing (life, durability, reliability) tracked for timely completion and conformance?		-
4. * Does the supplier have a comprehensive prototype program (unless waived by the customer or made unnecessary by the generic nature of the product supplied)?		-
SCORE		-

ELEMENT 5. DOCUMENT AND DATA CONTROL

Question	Comments	Result
1. * Are new and revised documents reviewed and approved by authorised personnel prior to issue?	YES	CI
2. * Is there a master list (or equivalent) identifying document revision status?	YES	CI
SCORE		3

ELEMENT 6. PURCHASING

Question	Comments	Result
1. * Are subcontractors evaluated and selected based on their ability to meet quality system and quality assurance requirements?	YES	CI
2. * Does the supplier have a procedure to define the appropriate level of control over subcontractors?	YES	CI
3. * Are quality records of subcontractors kept up to date and used to evaluate performance?	YES	CI
SCORE		3

ELEMENT 7. PRODUCT IDENTIFICATION AND TRACEABILITY

Question	Comments	Result
1. * Is traceability maintained and recorded when so required by the customer?	<i>Have but not continuum</i>	C
SCORE		2

ELEMENT 8. PROCESS CONTROL

Question	Comments	Result
1.* Have documented job instructions been developed that : (I.4.9))	<i>Have</i>	C
- Are accessible at the workstation?		
- Communicate requirements to all employees involved in this process?		
- Provide for verification of job set-ups and tool change intervals?		
- Specify monitoring of special characteristics?		
- List requirements for inspection, testing, gauging and recording results?		
- Provide sample size and frequency?		
- Establish approval and rejection criteria?		
- List required tools and gauges (with mastering at required frequency)?		
- Document the identification and handling of non-conforming material?		
- Specify appropriate notifications and corrective actions (including plans for unstable/non-capable processes)?		
- Specify applications of statistical methods required by control plans?		
- Identify relevant engineering and manufacturing standards and the latest engineering change affecting the inst.?		
- Appropriate approvals and date?		
- Operation name and number?		
- Keyed to process flow chart?		
- Part name and number?		
- Revision date for instructions?		
- Visual controls?		

<p>2.* Are process control requirements being met?</p> <hr/> <p>- Have the customer preliminary process capability requirements been met?</p> <hr/> <p>- Have the customer outgoing performance requirements been met?</p> <hr/> <p>- Are special causes of variation investigated and appropriate actions taken?</p> <hr/> <p>- Are control charts annotated with significant process events?</p> <hr/> <p>- Are control charts maintained and reviewed with highest priority given to special characteristics?</p>	<p><i>One worker didn't wear glove on picking process.</i></p>	<p>M</p>
<p>3* Is there an effective planned preventive maintenance system which includes:</p> <ul style="list-style-type: none"> - A maintenance schedule established with specific responsibilities assigned? - Maintenance evaluated for process capability improvement? - Evaluation for reduction of machine/process downtime? - Maintenance conducted at the prescribed frequencies for all equipment? - Availability of replacement parts for key manufacturing equipment? <p>Predictive maintenance methods?</p>	<p><i>Have</i></p>	<p>C</p>
<p>4.* Does the supplier have appropriate governmental certificates indicating compliance to the identified applicable regulations?</p>	<p><i>Have</i></p>	<p>C</p>
<p>5.* Is the work environment clean and well organised?</p>	<p><i>Yes</i></p>	<p>CI</p>
	<p>SCORE</p>	<p>1</p>

ELEMENT 9. INSPECTION AND TESTING

Question	Comments	Result
1.* Incoming Parts and Materials and Purchased Services - Is purchased material controlled and verified per the selected system prior to release to production? - Is positive identification provided for material used in production but not verified - Where specified as the control method, do suppliers submit statistical data as required?	YES	CI
2.* In-process Inspection and Testing Does the supplier : - Inspect and test product as required by the documented procedures? - Hold product until the required inspections and tests have been completed? - Utilise defect prevention methods, such as statistical process control, error proofing, visual controls, rather than defect detection.	YES	CI
3.* Final Inspection and Testing Does the supplier: - Conduct final inspection and testing in accordance with documented procedures? - Assure that no product is shipped until all activities specified in the documented procedures have been satisfactorily completed?	YES	CI
4.* Does the supplier use accredited laboratory facilities when required by the customer?		
SCORE		3

ELEMENT 10. INSPECTION, MEASURING AND TEST EQUIPMENT

Question	Comments	Result
1.* Is measurement system analysis conducted (Gauge R & R) for all gauges, measuring and test equipment, noted on the control plan?	YES	CI
2.* Is each item of inspection, measurement and test equipment identified with a unique designation (including employee owned equipment)?	YES	CI
3.* Is each such piece of equipment calibrated at prescribed intervals and in the correct environment (including employee-owned equipment)?	YES	CI
4.* Are inspection, measurement and test equipment properly handled, preserved and stored to maintain calibration and fitness for use?	YES	CI
SCORE		3

ELEMENT 11. CONTROL OF NONCONFORMING PRODUCT

Question	Comments	Result
1. * Is there identification, documentation, separation (where possible) to a designated area and disposition of nonconforming and suspect product?	YES	CI
2. Are reworked products reinspected and/or tested according to the Control Plan?	YES	CI
SCORE		3

ELEMENT 12. CORRECTIVE AND PREVENTIVE ACTION

Question	Comments	Result
1. * Are appropriate corrective actions developed to eliminate the causes of the non-conformances?	YES	CI
2. * Does the supplier use a disciplined problem solving method?	YES	CI
3. * Are the customer complaints and reports of non-conformances handled effectively?	YES	CI
4. * Is the effectiveness of corrective action verified?	YES	CI
5. * Is the relevant information on actions taken including changes to procedure submitted for management review?	YES	CI
SCORE		3

ELEMENT 13. HANDLING, STORAGE, PACKAGING, PRESERVATION AND DELIVERY

Question	Comments	Result
1. * Do supplier's material handling methods prevent product damage or deterioration?	HAVE	C
2. * Are applicable customer packaging standards complied with?	HAVE	C
3. * Is the supplier's delivery performance 100% to schedule, are there appropriate analyses and corrective actions?	<i>Finding shortage one drum in one shipment. Having correction action.</i>	0
4. * Is there an inventory management system to optimise inventory turns and stock rotation?	HAVE	C
SCORE		0

ELEMENT 14. CONTROL OF QUALITY RECORDS

Question	Comments	Result
1. * Are these records available to the customer for evaluation upon request?	HAVE	C
SCORE		2

ELEMENT 15. INTERNAL QUALITY AUDITS

Question	Comments	Result
1. * Does the supplier carry out internal quality system audits as planned?	YES	CI
2. * Are the audits scheduled on the basis of the status and importance of the activity?	YES	CI
3. * Are the audit results documented and brought to the attention of the responsible personnel?	YES	CI
4. * Are corrective actions timely, recorded and evaluated for effectiveness?	YSE	CI
5. * Does the audit include work environment and general housekeeping?	YES	CI
SCORE		3

ELEMENT 16. TRAINING

Question	Comments	Result
1. * Do qualifications for jobs affecting quality include identification of appropriate education, training needs and experience?	HAVE	C
SCORE		2

ELEMENT 17. CONTINUOUS IMPROVEMENT

Question	Comments	Result
1. * Is there evidence that continuous quality and productivity improvement efforts are a key element of the supplier's business?	YES	CI
SCORE		3

ELEMENT 18. MANUFACTURING CAPABILITIES

Question	Comments	Result
1. * Does the plant layout minimise material travel and handling, facilitate synchronous material flow, and maximise value added use of floor space?	YES	CI
2. * Are resources available for tool and gauge maintenance and repair?	YES	CI
SCORE		3