

Supplier Quality System Assessment

General Supplier Information

Supplier Name: _____

Address of Facility Audited: _____

Telephone: _____

Website: _____

Type of Audit (check one)

☐ Supplier Self Audit

☐ MED On-Site Audit

Audit Date: _____

Person's name(s) completing this audit:

Name: _____ Company: _____ Title: _____ Phone: _____

Name: _____ Company: _____ Title: _____ Phone: _____

Supplier Senior Company Official's Name: _____ Title: _____

Supplier Senior Quality Official's Name: _____ Title: _____

Supplier Products: _____

Number of years in business: _____ Approximate Annual Sales: _____

Ownership: ☐ Partnership; ☐ Private; ☐ Public; Stock symbol if applicable: _____

Number of buildings: _____ Total square footage: _____ Total MFG square footage: _____

Total Employees: _____ Production: _____ Engineering: _____ Quality: _____ Office: _____

ISO Certified: ☐ Yes ☐ No Level: _____ ISO Registrar: _____ Date of last audit: _____

List top five customers: _____

Where is/would MED be on that list (i.e., percent of business): _____

COMMENTS:

Supplier Overall Audit Rating _____ % (From Page 8 Calculations)

Audit Rating Recommendations:

- ≥ 95 % = Outstanding quality system and performance.
- ≥ 80 % = Meets requirements with above average to superior quality system and performance.
- ≥ 65 % = Requires improvements in meeting quality system standards and performance.
- < 65 % = Requires significant improvement in meeting quality system standards and performance.
- ≤ 45 % = No quality system in place.

Supplier Quality System Assessment

Instructions for completing Sections 1 through 8:

Using the following rating system, answer each question by writing or typing in the number that best describes your response. For Supplier Self Audits, suppliers do not complete the shaded boxed questions, although the supplier should be prepared to answer all them during an actual MED on-site audit. The shaded questions are additional items only for MED personnel use during on-site audits. MED auditors will complete all questions as applicable.

- 3** = Procedure or system is thoroughly documented and consistently adhered to.
2 = Procedure or system exists though may be inadequate and/or is not consistently followed.
1 = Procedure or system exists but is rarely followed and/or is not accurate.
0 = No procedure or system exists at this time.
N/A = Not applicable.

- Where indicated with " ***", please attach a one-page example from your supporting document.
- Space is provided after each section for any comments. Please provide any details not described by documents. Additional example documentation may be attached.

1.0 Contract Review & Document Control

		Rating System	Score
1.1	Is there a Quality Manual available that describes quality-related procedures and policies? (<i>Attach an uncontrolled copy</i>)	0 1 2 3 N/A	
1.2	Is there a procedure to ensure that revision levels are verified for each manufacturing/sales order against the customer purchase order beginning from order entry? ***	0 1 2 3 N/A	
1.3	Is there a procedure or policy requiring customer notification and approval of material, process or supplier/manufacturing site location changes?	0 1 2 3 N/A	
1.4	Is there a procedure for maintaining and distributing drawings, drawing revisions, and specifications? ***	0 1 2 3 N/A	
1.5	Is there a master listing identifying current procedures or work instructions and their latest revisions? ***	0 1 2 3 N/A	
1.6	Is there a procedure for the removal of obsolete documents that includes part master files?	0 1 2 3 N/A	
1.A	Is there evidence that correct document revisions are available at all locations where relevant activities take place?	0 1 2 3 N/A	
1.B	Is there evidence that controlled documents are approved by authorized personnel prior to use?	0 1 2 3 N/A	
1.C	Do document changes/revisions include or reference the nature and date of the changes made?	0 1 2 3 N/A	
1.D	Is there an up-to-date organization chart? (<i>Attach a copy</i>)	0 1 2 3 N/A	

Section 1 Comments:

2.0 Control of Inspection, Measuring & Test Equipment

		Rating System	Score
2.1	Is there a procedure that describes calibration intervals and maintenance requirements for all measurement equipment that is used to measure part or product conformance?	0 1 2 3 N/A	
2.2	Are all measurement equipment clearly labeled with the last date of calibration and when due for recalibration?	0 1 2 3 N/A	

2.3	Is all measurement equipment that is not used to measure part or product conformance (may include employee owned tools and reference tools) identified with a "NO CALIBRATION REQUIRED" label or words to that effect?	0 1 2 3 N/A	
2.4	Are calibration records maintained for all measurement equipment? Who performs the calibrations? ***	0 1 2 3 N/A	
2.5	Are all calibrations performed using equipment and shop masters traceable to the National Institute for Standards and Technology (NIST) or other suitable standards?	0 1 2 3 N/A	
2.6	If equipment is found to be out of tolerance during calibration, are there procedures or policies to evaluate the impact it may have had on manufactured material?	0 1 2 3 N/A	
2.A	Is there evidence that all inspections are being performed using calibrated measurement equipment with sufficient precision and accuracy?	0 1 2 3 N/A	
2.B	If calibrations are being performed by supplier personnel, are there written instructions for each measurement and test equipment being serviced?	0 1 2 3 N/A	
2.C	Is there evidence that test equipment that is over-due for calibration is being removed from service until calibration has been performed?	0 1 2 3 N/A	
2.D	Are there adequate environmental, handling, preservation and storage conditions for measuring, inspection and test equipment?	0 1 2 3 N/A	

Section 2 Comments:

3.0 Incoming Inspection		Rating System	Score
3.1	Are incoming materials inspected to all requirements of a purchase order, general specifications, and/or applicable drawings?	0 1 2 3 N/A	
3.2	Are there inspection procedures for incoming materials? ***	0 1 2 3 N/A	
3.3	Are statistically valid sampling plans with AQL's based upon customer requirements utilized? ***	0 1 2 3 N/A	
3.4	Is there a procedure for the disposition of discrepant incoming materials? ***	0 1 2 3 N/A	
3.5	Are there procedures and practices to insure that incoming materials as well as rejected materials are kept segregated and secured from accepted material?	0 1 2 3 N/A	
3.6	Is there a procedure that describes how long inspection records are retained?	0 1 2 3 N/A	
3.A	Is there evidence that test reports, certificates of conformance or chemical and physical certifications of materials or parts are received with the individual material lots and are retained?	0 1 2 3 N/A	
3.B	Is there evidence (records) that the material has passed inspection and tests as defined by the acceptance criteria?	0 1 2 3 N/A	
3.C	Is there evidence that first article inspections are performed on new parts/materials or when materials, processes or suppliers are changed?	0 1 2 3 N/A	
3.D	Is there evidence that correction action requests are being routinely issued to suppliers due to rejected material or other supplier performance issues?	0 1 2 3 N/A	

Section 3 Comments:

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4.0 Manufacturing & Process Control		Rating System	Score
4.1	Are there written procedures for all manufacturing processes and do the procedures indicate workmanship criteria, special handling or process conditions, and the specific equipment to be used? ***	0 1 2 3 N/A	
4.2	Is a lot traveler (or router) utilized and does it clearly define all processing and inspection steps for each product lot as it progresses through manufacturing and test? Do the records indicate the completed manufacturing processes with the quantities, names and dates of those who performed each identified step? ***	0 1 2 3 N/A	
4.3	Are all software changes validated before approval and issuance and are there effective controls to insure that only the most current version can be used? How is this documented? ***	0 1 2 3 N/A	
4.4	Are important part and process characteristics clearly defined for each part/product, and are they effectively monitored during production to insure that specified requirements are met? Are any statistical process control methods utilized that would contribute to final product acceptance? ***	0 1 2 3 N/A	
4.5	Is there a preventive maintenance schedule established for all production equipment and tooling and is it suitable to ensure continuing process capability? Does it include a system for monitoring tool life and the number of parts produced from a tool before maintenance and/or replacement?	0 1 2 3 N/A	
4.6	Are there procedures and practices to prevent contamination or degradation of parts from ESD, dust, oil, hazardous substances or other environmental contaminants?	0 1 2 3 N/A	
4.A	Are there procedures and policies for housekeeping and are there any safety conditions that could jeopardize the work environment?	0 1 2 3 N/A	
4.B	Is there evidence that all Material Certifications, Process Certifications and Certifications of Compliance are traceable to a manufacturing lot number?	0 1 2 3 N/A	
4.C	Does the manufacturing equipment and technology being utilized appear adequate and suitable for the intended purposes?	0 1 2 3 N/A	
4.D	Is there any evidence that process capability studies, design of experiments, etc., are being performed and communicated to the customer?	0 1 2 3 N/A	
Section 4 Comments:			
5.0 In-Process & Final Inspection		Rating System	Score
5.1	Is in-process and/or final inspection being performed on each lot to insure compliance to all requirements of the customer purchase order, general specifications, and/or applicable drawings?	0 1 2 3 N/A	
5.2	Where inspection and testing is being performed, are there written procedures with statistically valid AQL based sampling plans being utilized? ***	0 1 2 3 N/A	
5.3	Is there a procedure and policy to insure that a first article inspection is performed for all applicable dimensions when a part revision, material, or manufacturing process has changed?	0 1 2 3 N/A	
5.4	Is inspection and test data maintained on file and traceable to each lot? If yes, for how long?	0 1 2 3 N/A	
5.5	Can inspection and test data collected for key specified parameters be summarized to indicate statistical control/consistency for each lot shipped to the customer?	0 1 2 3 N/A	

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5.6	Is there a procedure for the identification, segregation and disposition of discrepant parts and assemblies? ***	0 1 2 3 N/A	
5.A	Is there evidence of adequate identification, including inspection and test status throughout the process?	0 1 2 3 N/A	
5.B	Do retained quality records demonstrate conformance to product requirements?	0 1 2 3 N/A	
5.C	Is there evidence that customer authorizations are being requested and approved prior to shipment of any parts or assemblies that may not fully meet all specifications?	0 1 2 3 N/A	
5.D	Is there evidence that repaired or reworked parts are being fully re-inspected to all applicable requirements?	0 1 2 3 N/A	

Section 5 Comments:

6.0 Packaging, Storage & Shipping		Rating System	Score
6.1	Is there a procedure that describes proper handling, packaging, storage, preservation, and shipping methods?	0 1 2 3 N/A	
6.2	Are raw materials/parts stored and used on a first-in, first-out (FIFO) basis?	0 1 2 3 N/A	
6.3	Are all materials stored in a secure area?	0 1 2 3 N/A	
6.4	Is there a procedure that describes the handling and expiration date coding of limited life materials such as adhesives (Loctite), etc.?	0 1 2 3 N/A	
6.5	Are finished goods effectively segregated with a manufacturing lot number or a date coding system that includes the part number and completion status?	0 1 2 3 N/A	
6.6	Are labeling, certifications, and packaged finished product inspected and verified to insure compliance with customer requirements prior to shipment? ***	0 1 2 3 N/A	
6.A	Is there evidence that excess issued material returned from manufacturing to raw materials storage is being properly identified and part marked?	0 1 2 3 N/A	
6.B	Is there evidence that material/parts are handled, stored and packaged in a way to prevent damage?	0 1 2 3 N/A	
6.C	Is there evidence that customer specific packaging requirements are available to shipping personnel for each part or assembly?	0 1 2 3 N/A	
6.D	If MED provides material or parts to the supplier, is there evidence of appropriate storage, segregation and preservation of parts while under the supplier's control?	0 1 2 3 N/A	

Section 6 Comments:

7.0 Corrective and Preventive Action		Rating System	Score
7.1	Is there a procedure for implementing corrective and preventive actions? ***.	0 1 2 3 N/A	
7.2	Is there a follow-up system to identify, evaluate effectiveness, and close corrective actions?	0 1 2 3 N/A	
7.3	Is there a log, database or other system used for trending and/or history of corrective actions? ***	0 1 2 3 N/A	

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7.4	Is there a procedure for the receipt and evaluation of customer complaints?	0 1 2 3 N/A	
7.5	Does the above procedure include the issuance of return material authorizations (RMA's) and corrective action requests (CAR's) to the customer?	0 1 2 3 N/A	
7.6	Is quality cost data (scrap, rework, customer returns, etc.) collected, analyzed and shared throughout the organization to drive process improvement and part variability reduction activities? ***	0 1 2 3 N/A	
7.A	Is there evidence that the corrective action system is up-to-date with issues closed in a uniform and timely manner?	0 1 2 3 N/A	
7.B	Is there evidence that implemented changes resulting from corrective action have been appropriately documented and is being effectively disseminated to those who are directly responsible for assuring product quality and the prevention of future problems?	0 1 2 3 N/A	
7.C	Is there evidence of timely customer RMA and CAR issuances?	0 1 2 3 N/A	
7.D	Is there evidence that there is a regular and adequate management review of corrective and preventive actions?	0 1 2 3 N/A	

Section 7 Comments:

8.0 Training		Rating System	Score
8.1	Is there a procedure that defines the responsibilities and training requirements for each position? ***	0 1 2 3 N/A	
8.2	Have training and development plans been implemented for all employees who have an impact on quality?	0 1 2 3 N/A	
8.3	Are processes operated/performed by qualified employees?	0 1 2 3 N/A	
8.4	Are training records maintained on each employee that includes the training course/subject, completion date and trainer name? ***	0 1 2 3 N/A	
8.5	Are individual training records easily accessible to each employee?	0 1 2 3 N/A	
8.6	Is training being provided to changes that would affect the form, fit or function within the area?	0 1 2 3 N/A	
8.A	Do employees appear to be adequately trained for their assigned tasks?	0 1 2 3 N/A	
8.B	Is there evidence that the people being trained are made aware of the defects that may occur from improper performance of their job function?	0 1 2 3 N/A	
8.C	If in-house trainers are utilized, is there evidence that the trainers have adequate experience and expertise to perform the assigned training?	0 1 2 3 N/A	
8.D	Is there evidence that the quality policy and mission statement is known and understood by all employees?	0 1 2 3 N/A	

Section 8 Comments:

Supplier Quality System Audit Summary

A. Summary of items that we liked

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B. Summary of items that require immediate attention (corrective action)

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C. Summary of items that are of concern

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Supplier Quality System Assessment

Supplier Quality System Audit Scorecard

Instructions for use:

1. Transfer the rating scores from the individual questions within each section to the corresponding areas within the table below.
2. Calculate the *Total Section Score* by adding together the ratings of each applicable question score per section.
3. Calculate the *Maximum Possible Score* by multiplying the number of applicable questions rated per section by 3.
4. Calculate the *Average Section Score* by dividing the *Total Section Score* by the *Maximum Possible Score*.
5. Calculate the *Supplier Overall Audit Rating* by dividing the sum of the *Total Section Scores* by the sum of the *Maximum Possible Scores*.
6. Record the *Supplier Overall Audit Rating* on Page 1 of audit form in the assigned area.

Note: Deficiencies in any critical quality system area may warrant corrective action and a change to the supplier's approval status. Flexibility may be granted to a supplier at the discretion of the MED audit team based upon material function, sourcing availability or other key considerations.

Survey Section	Individual Question Scores										Total Section Score	Max Possible Score	Average Section Score
	.1	.2	.3	.4	.5	.6	.A	.B	.C	.D			
1. Contract Review & Document Control													
2. Control of Inspection, Measuring & Test Equipment													
3. Incoming Inspection													
4. Manufacturing and Process Control													
5. In-Process & Final Inspection													
6. Packaging, Storage & Shipping													
7. Corrective and Preventive Action													
8. Training													
SUPPLIER OVERALL AUDIT RATING													

Audit Rating Recommendations:

- ≥ 95 % = Outstanding quality system and performance.
- ≥ 80 % = Meets requirements with above average to superior quality system and performance.
- ≥ 65 % = Requires improvements in meeting quality system standards and performance.
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