EMPIRICAL TESTING CORP.

Supplier Quality Manual

INTRODUCTION

Welcome to Empirical Testing Corp

Empirical Testing Corp specializes in providing consulting, design, machine and testing of Aerospace and Defense components and Medical Implants.

Introduction to Manual

In today's manufacturing environment, product that is found to be non-conforming at receiving, or during production, causes serious disruptions of the production and shipping schedules, resulting in high production costs. Even the best Receiving Inspection program cannot detect all defective material. Empirical Testing Corp requires suppliers to control the quality of material shipped so that it meets the acceptance criteria when it is received.

This manual describes Empirical Testing Corp expectations for its suppliers in order to ensure that purchased material meets the specified requirements.

Scope

This information applies to suppliers who have interest in doing business with Empirical Testing Corp. It also applies to our outsourced partners or subsidiaries. Please review the classification levels to see what classification level that your business falls into based upon the deliverables your company is contracted to supply. Our procurement specialist will add the classification level to the PO so as to remove any ambiguity for the vendor.

Classification levels:

Level-3; General merchandise, consumables, office supplies, personal use items, non-critical hardware and maintenance items, etc.
Level-2; Requires the vendor to be ISO certified and have a viable Quality Management System in place as well as quality personnel dedicated to ISO and quality compliance. As an example, items under this classification have to meet material, quality, ISO, ASTM or Military Standards or have to meet quality specifications or standards described by our internal engineering or other staff. These items generally have to have certificates of compliance or material certifications shipped with them to comply with our quality management system. This could be hardware, software, materials, metals, components, pre-manufactured parts, machine maintenance parts, or any parts or material designated by our engineering or procurement staff as needing to validate compliance.
Level-1; Articles of any type under the Level-1 classification are deemed critical and require an on-site audit of the vendor Quality Management System by Empirical Testing Corp quality personnel. However, the on-site audit may be waived under the following circumstances.

1.The vendor can supply all the necessary documentation and/or certifications of compliance to ISO-9001, AS9100, or ASTM requirements. The documentation and/or certifications must specifically indicate when the certification was received and when the certifications are up for renewal. The shipment will also require the certification of compliance for the parts, materials or

assemblies etc. The waiver is not be construed to waive any quality requirement or certification but only the on-site quality audit. In the event a waiver is placed with a PO, the procuring agent and chief engineer must sign the PO.

2. Empirical Testing Corp. reserves the right to issue a waiver when an Emergency Material Release is required to meet an aggressive schedule or a test is deemed "at risk". This is not be construed as a waiver of the quality or certification requirements, only the on-site quality audit. The vendor may supply the certifications or documentation of compliance via email or facsimile.

Quality Management System Requirements

1.1 Quality Management System

Each of Empirical Testing Corp supplier is required to maintain an effective quality management system, preferably one that conforms to ISO 9001:2000 Quality Management System – requirements. In addition, the supplier must meet the requirements of this manual as directed by the PO.

1.2 Quality Manual and Procedures

The supplier, as requested, will furnish Empirical Testing Corp with a copy of the supplier's Quality Manual and supporting procedures. This will also require the supplier to complete a Empirical Testing Corp supplier approval questionnaire and submit it for review.

1.3 Control of Sub-tier Suppliers

Suppliers are responsible for the quality of materials and components provided by their sub-tier suppliers and sub-contractors. Empirical Testing Corp suppliers may impose controls on their sub-tier suppliers that provide quality results and documentation comparable to the controls applied to suppliers by Empirical Testing Corp. The extent of the controls may vary, depending on the nature and complexity of the product and processes, but should normally include:

- Evaluation and qualification of sub-tier supplier facilities
- Control to ensure that raw materials used meet Empirical Testing Corp requirements
- Controls to ensure that the sub-tier suppliers of components used are those approved by Empirical Testing Corp, where applicable.
- Ensure that sub-tier suppliers have an ESD control program that meets or exceeds the needs of Empirical Testing Corp if the parts or materials are ESD sensitive.
- Part qualification, including first article inspection and process capability studies of as applicable.
- Control of drawings/revisions
- Control of nonconforming material
- Corrective action and preventive action programs
- A continuous quality improvement program

Where appropriate, Empirical Testing Corp may specify the sub-tier suppliers that may be used, evaluate and qualify the sub-tier supplier's facilities, and assist the

supplier in controlling the sub-tier supplier. Typically, this occurs when the sub-tier supplier is an essential component of the supply-chain process. *Empirical Testing Corp reserves the prerogative to evaluate the quality system and records of such sub-tier suppliers as necessary. In the event of Empirical Test Corp involvement, it does not absolve suppliers of the ultimate responsibility for the quality performance of their sub-tier suppliers.*

2.0 Supplier Qualification Process

All suppliers of production materials to Empirical Testing Corp must be qualified suppliers. The extent of the qualification process is dependent upon the criticality of product purchased and other factors determined by Empirical Testing Corp. The qualification process in its most complete form consists of three parts:

- A questionnaire completed by the supplier.
- A quality management system self-assessment completed by the supplier, using the Empirical Testing Corp supplier assessment survey form. This is returned, along with the supplier's quality certifications and documentation for review by Empirical Testing Corp.
- An on-site assessment by Empirical Testing Corp personnel or their authorized agents may be requested at our discretion. (If directed by PO)

Empirical Testing Corp periodically reevaluates suppliers through the use of quality performance data and/or on-site assessments.

2.1 New Supplier Questionnaire

In the early stages of the supplier selection process, potential level one and level two suppliers are sent a questionnaire. This questionnaire solicits general information about the company such as location(s), size, capabilities, and financial stability as well as detailed questions regarding the Company's quality management system and quality history.

2.2 New Supplier Self Assessment

When a new supplier is being considered, they are sent a quality management system self-assessment survey form. The supplier completes the self-assessment and returns it along with a copy of their quality certifications and/or supporting documents. Empirical Testing Corp quality manager will review the quality manual, procedures, and survey to determine if the documented quality system meets our requirements.

2.3 On-Site Assessment (If directed by PO) Level-3 only.

For suppliers of critical components, an on-site assessment of the supplier's facility may be performed. The on-site assessment includes three components:

- A quality assessment to determine whether the supplier's quality management system is in place and functioning effectively.
- A business assessment to determine whether the supplier has financial resources, production capacity, and other business resources needed to fulfill Empirical Testing Corp production needs.
- A technology assessment to determine whether the supplier has the needed technical resources, including production and inspection equipment, facilities, engineering resources, etc.

If the assessment team determines that the supplier meets Empirical Testing Corp, our approval qualifies the supplier to bid on new business and supply production materials.

2.4 Periodic Re-evaluation

Empirical Testing Corp periodically reevaluates current production suppliers through the use of quality performance data and/or on-site assessments. If requested, the supplier shall make their facility available for on-site process verification by Empirical Testing Corp personnel, with reasonable notice.

3.0 Part Qualification (If directed by PO)

The supplier is responsible for submitting all First Article data requested by Empirical Testing Corp on the first article requirements checklist (if requested). Empirical Testing Corp and the supplier will agree on the number of the samples to be checked and submitted with the first article data. Where possible, all First Article documents should be submitted to the supplier quality engineer in electronic format (preferably Adobe Acrobat or Microsoft Office) if the First Article documents are requested by the Quality Manager.

In rare cases, Empirical Testing Corp personnel may wish to be present during the initial production run. This will allow Empirical Testing Corp to validate and verify the process before any product is shipped.

3.1 First Article Requirements Checklist (If directed by PO)

For each new or changed part, Empirical Testing Corp sends the supplier a First Article Requirements Checklist, listing the steps and information that must be submitted for qualification of the component or assembly for production. The checklist items selected are based on the type of component or assembly to be supplied. If Empirical Testing Corp does not send a First Article checklist then it is not necessary on the particular component.

3.2 Dimensional Inspection Report (If directed by PO)

Empirical Testing Corp notifies the supplier of the quantity of parts to be inspected when necessary, typically five from each tool or cavity. The supplier inspects or tests each sample for all dimensions, drawing notes, and specification requirements listed on the current revision of the Empirical Testing Corp drawing and/or specification. The supplier records the results on the First Article Report form or equivalent. The supplier numbers a copy of Empirical Testing Corp drawing and/or specification to correspond with the supplier's results.

The dimensional inspection report must include the specification number, specified requirements, and the inspection/test results. Each report must be traceable to the supplier's material, through lot/heat/coil/batch numbers or equivalent, and must be signed by the organization that performed the testing. For any requirements that the supplier does not have the equipment to inspect or test, the supplier may obtain reports from their sub-supplier or other test agency.

Parts inspected for the dimensional inspection report are randomly selected from a production run of parts. The minimum quantity for the production run is agreed upon between the supplier and Empirical Testing Corp.

3.3 Material Certification/Test Report

When requested, the supplier must provide a material certification/test report. This report must include the specification number, specified material and/or physical requirements, and the inspection/test results. Each report must be

traceable to the supplier's material, and must be signed by the organization that performed the testing.

3.4 Gage Repeatability & Reproducibility (R&R) Studies (If directed by PO)

Empirical Testing Corp will indicate on the PO if R&R studies are required. For those characteristics specified by Empirical Testing Corp, the supplier must perform gage R&R studies using procedures described in Measurement Systems Analysis published by an acceptable source. Empirical Testing Corp must approve R&R values greater than 10 percent of the tolerance.

Normally for variable gages, three different operators measure ten samples three times each. For attribute gages, the Attribute Gage Study (long method) is required. Empirical Testing Corp must approve any alternative methods.

3.5 Gage Correlation Studies (If directed by PO)

If gage studies are required they will be indicated on the PO. For characteristics specified by Empirical Testing Corp the supplier must perform a gage correlation study. This consists of the supplier identifying, measuring and recording a specified number of production parts. The supplier then sends the parts to Empirical Testing Corp for measurement. Empirical Testing Corp compares their measurements with the supplier's measurements to determine the correlation between the gages.

3.6 Process Capability Studies (If directed by PO)

If process capabilities Process Capability (C_{pk}) is a comparison of the inherent variability of a process output to specification limits *under statistically stable conditions*. There are a number of techniques for assessing the capability of processes. Empirical Testing Corp suppliers must use methods defined in Statistical Process Control (SPC) published by American Society of Quality for determining process capability and process performance, unless an alternate method is approved in writing by Empirical Testing Corp.

A Cpk of at least 1.33 is required for Company XX critical dimensions.

When required to submit process capability data to Company XX, the supplier must calculate process capability using the following method, unless an alternate method is approved by Company XX:

C_p = Process capability ignoring process centering = $\frac{USL - LSL}{6\hat{s}}$

C_{pk} = Process capability including centering = the minimum of either: $\frac{USL - Avg.}{3\hat{s}}$ or $\frac{Avg. - LSL}{3\hat{s}}$

USL = Upper Specification Limit
LSL = Lower Specification Limit

Avg. = Process Average = $\overline{\overline{X}}$

$\hat{s}$ = Estimated Standard Deviation = $\hat{s} = \frac{\overline{R}}{d_2}$

$\overline{R}$ = Average Range

d_2 = Constant from statistical tables

For unilateral tolerances, the same logic is employed, except that only the specified side of the tolerance is used to calculate C_{pk}. When $\overline{X}$ & R charts are used for capability studies, the subgroups must contain pieces taken consecutively from the process and the subgroups must be arranged sequentially in the order they were produced.

3.7 Failure Modes and Effects Analysis (FMEA) (If directed by PO)

When requested, the supplier must perform a Process Failure Modes and Effects Analysis (PFMEA), and submit it for approval. For parts and assemblies that are designed by the supplier, the supplier should also perform a Design Failure Modes and Effects Analysis. The PFMEA considers all reasonably foreseeable potential failure modes of each process. Based on the potential seriousness and likelihood of the problem, the supplier develops manufacturing controls. The PFMEA should be a living document, and should be updated when process changes occur, or when defective material is produced. PFMEA methods and examples can be found in Potential Failure Mode and Effects Analysis published by AIAG.

3.8 Control Plan (If directed by PO)

If requested, the supplier must develop a control plan. The control plan and is a detailed description of the supplier's proposed processing steps required to produce the part, and the controls that are put into place to control the quality at each step. The control plan must include all in-house processing, external processing, inspection, packaging, and shipping. Suppliers may use their own format. Measuring devices and fixtures designed and built to check Empirical Testing Corp parts must be identified with a gage number and drawing, and must be listed on the control plan.

The control plan must include all critical characteristics. Where detailed instructions are required, the supplier details those instructions in a work instruction, or equivalent, which must be listed in the control plan. Inspection methods, sample sizes, and sampling frequencies should be based on the process capabilities, seriousness and likelihood of potential non-conformances, and process stability. Critical characteristics that do not meet Empirical Testing Corp process capability requirements must be inspected 100%, unless Empirical Testing Corp approves alternate control methods in writing.

3.9 Electrostatic Discharge (ESD) Susceptibility (If directed by PO)

When components or assemblies supplied to Empirical Testing Corp are susceptible to ESD, the supplier shall establish ESD susceptibility information for them. Procedures, methods, and equipment used for determining the ESD susceptibility shall be provided to Empirical Testing Corp. ESD failure modes shall be considered in PFMEAs, and ESD controls shall be included in control plans and packaging.

3.10 Material Safety Data Sheets (MSDS)

As applicable, Material Safety Data Sheets (MSDS) must be provided during First Article process.

3.11 Agency Approvals and Compatibility Reports

The supplier is responsible to provide the proper agency approval test reports per Empirical Testing Corp, if required. Examples are UL, CE, FCC, TUV, etc. The supplier is also responsible for agency test reports from their sub-supplier or other outside test agencies.

The suppler is responsible to submit test results that verify compatibility as required. Testing may be done by the supplier or by a test facility certified by the supplier.

3.12 Packaging & Labeling

The supplier must adequately plan for packaging of material shipped to Empirical Testing Corp. The supplier will provide a documented packaging plan including container size, number of parts per container, packaging configuration, when requested. Packaging will be designed to provide protection from any damage that may occur. For static sensitive components, ESD packaging shall be provided. Packaging, labeling, and shipping materials must comply with the requirements of common carriers to secure the least transportation costs. Unless otherwise stated packaging should be by “best practice”.

3.13 Traceability

The supplier must plan for traceability of components. The supplier will provide a written plan, when requested, specifying how components will be marked with serial or lot numbers and date codes if required, or how containers will be identified with lot numbers or date codes if component marking is not required. The plan will also include sizes of lots or batches. Where possible, batch sizes should be minimized to aid in containment should quality problems be found.

4.0 Manufacturing Control

4.1 Process Control (If directed by PO)

Empirical Testing Corp suppliers are required to control all manufacturing processes in accordance with the control plan, which is approved during part qualification.

4.2 Statistical Process Control (If directed by PO)

If specified in the PO, the supplier is required to apply effective statistical process controls. Effective controls must include:

- The control chart displays control limits that are correctly calculated (specification limits may not be used as control limits).

- The control chart is at the process area, visible to the operator, or persons who are responsible for controlling the process.
- For each out-of-control condition, actions are taken to bring the process back into control. Actions taken to bring the process back into control are recorded.
- Product produced during any out-of-control condition is sorted, scrapped, reworked or dispositioned through the supplier's material review process

4.3 Process Performance Requirements (If directed by PO)

Process Performance (P_{pk}) is the comparison of the actual process variation to the specification limits. When required to submit process performance data to Company XX, the supplier must report process performance using the following method:

Critical Characteristics: A P_{pk} at least 1.33 is required. Any critical characteristic failing to meet the minimum requirement requires a containment plan and an improvement plan.

Other Characteristics: A P_{pk} of at least 1.00 is required. The supplier is not required to calculate and report process performance for non-critical characteristics, unless requested by Company XX. When specified by Company XX, other characteristics failing to meet the minimum requirement also require a containment and improvement plan.

P_{pk} = the minimum of either $\frac{USL - Avg.}{3s}$ or $\frac{Avg. - LSL}{3s}$

USL = Upper Specification Limit
LSL = Lower Specification Limit
Avg. = Process Average = $\bar{\bar{x}}$

s = Estimated Standard Deviation $s = \sqrt{\frac{\sum_{i=1}^{n} (x_i - \bar{\bar{x}})^2}{(n-1)}}$

n = Total number of parts inspected

For unilateral tolerances, the same logic is employed, except that only the side of the tolerance that is specified is used in to calculate P_{pk}.

4.4 Process Improvement (If directed by PO)

Out-of-control or unstable processes (which have assignable causes) and processes that do not meet the minimum C_{pk}/ P_{pk} requirements must be identified and corrected. The Supplier must also improve processes with low yield rates.

4.5 Lot Control

A lot consists of product of one part number and revision that are made at the same time, under the same processing conditions, from the same lot of raw

materials. The primary purpose for identifying lots is to determine the scope of actions that must be taken when problems arise during further manufacturing or with customers. Each container of material shipped to Empirical Testing Corp must be identified with the Supplier's lot number. Inspection records must be traceable to lot numbers.

The following are typical conditions that result in a change of lot numbers:

Change of part number or revision
Change of part number or revision of components
Interruption of continuous production (typically for more than a few hours)
Repairs or modification to the tooling or equipment
Tooling changes (other than minor adjustment or replacement of consumable tooling)
Change to a different lot of raw materials
Process changes

4.6 Traceability

Traceability ties finished product back to the components used in the product. When traceability is specified, the traceability marking should be effective down to the individual component, i.e., lot code, batch or serial should be identifiable throughout Empirical Testing Corp processes.

4.7 Workmanship

When workmanship standards are not referenced on Empirical Testing Corp drawings or specifications, the supplier is expected to follow industry-accepted standards (e.g. ANSI, IPC). When in doubt, consult with Empirical Testing Corp for clarification.

4.8 Safety

At no time should any customer, or person at a Empirical Testing Corp facility, be exposed to hazardous material or situations that are not inherent in a component's structure. Residues, films, out-gassing products and packaging materials should comply with OSHA (Occupational Safety & Health Association) standards. For items with inherent hazards, safety notices must be clearly observable. As applicable, MSDS sheets must be provided during the First Article process.

4.9 Maintenance

The supplier must maintain all facilities, manufacturing machines, tools, measuring devices, and other equipment in such a manner that the supplier can support production requirements, and the quality of parts manufactured for Empirical Testing Corp is not degraded in any way.

4.10 Electrostatic Discharge (ESD) Controls

If the supplier furnishes ESD-sensitive materials, the supplier must maintain an effective ESD program that meets all requirements for the material produced.

5.0 Drawings/Changes

5.1 Drawing and Change Control

The supplier must have a documented system for assuring that the latest Empirical Testing Corp drawings are in effect at their facility. The supplier's quality management system must contain a documented procedure that describes the method used for the receipt, review, distribution, and implementation of all changes to drawings and specifications. In addition, the procedure must address control of obsolete drawings and specifications. A documented procedure should also detail the method used to contain new or modified parts until approved by the customer.

5.2 Process Changes, Engineering Changes

Suppliers must have systems in place to control changes to drawings, specifications, processes, or produced parts. Systems should be capable of handling changes being requested by the customer, and also changes requested by the supplier.

5.3 Supplier Process Change Request (SPCR) (If directed by the PO)

A Supplier Process Change Request (SPCR) is used to request a change to a released part, process, drawing, or specification. Empirical Testing Corp encourages SPCRs for process improvement with the stipulation that before an SPCR is submitted, the supplier thoroughly reviews their FMEA and control plan to assure that all process-related issues have been addressed and resolved.

The originator of an SPCR includes the following information:

- Drawing or part number
- Drawing or part title
- Description of problem or recommended change
- Reason for change or "rationale"
- Proposed effective date

The supplier submits the SPCR with the revised FMEA and control plan (if applicable) to Empirical Testing Corp for evaluation of the following:

- Supplier-demonstrated process capability and stability
- Comparison to First Article data
- Industry standards
- Supplier process engineering capabilities
- Supplier's adherence to control plan

After Empirical Testing Corp has completed the review, and concurs with the supplier, Empirical Testing Corp will notify the supplier as to the final disposition of the SPCR and part submittal requirements and dates.

When monitoring is required, the appropriate markings must be identified on the lots etc. for a specified time frame as decided jointly with Empirical Testing Corp and the supplier.

Supplier Deviation Request

A supplier is never permitted to knowingly ship product that deviates from the print, specification limits, or design intent without written authorization from Empirical Testing Corp. If such a condition exists, the supplier may request Empirical Testing Corp to allow shipment of the product. This is accomplished by initiating a Deviation Request.

If directed by Empirical Testing Corp, the supplier must send samples of non-conforming items to Empirical Testing Corp for evaluation. The cost of any testing required to determine the acceptability of the product will be charged to the supplier. Empirical Testing Corp will determine the item's acceptability and what corrective actions (if any) are required beyond the deviation. If approved, Empirical Testing Corp will send a written deviation approval to the supplier.

The deviation is only intended to be an interim action and **is not** to be construed as an engineering change. The supplier must begin work immediately to correct the condition in question. This must be accomplished within the time frame stated on the deviation. Failure to comply with the mutually agreed upon closure date for the deviation may result in the supplier's rating being affected.

In all cases, the supplier must fully contain all product suspected of being non-conforming at their facility. In addition, the supplier may be required to sort any suspect product at Empirical Testing Corp.

Any parts sent to Empirical Testing Corp that have been approved on a deviation must be clearly identified on the box, container, or other packaging method with the appropriate markings as instructed jointly by Empirical Testing and the supplier.

6.0 Packaging & Labeling

6.1 Packaging

Each supplier must adequately plan for packaging. Empirical Testing Corp encourages supplier-initiated packaging improvements. Suppliers will provide packaging that provides protection from any damage that may occur. Packaging, labeling, and shipping materials must comply with the requirements of common carriers, in a manner to secure the lowest transportation costs.

Packaging for ESD sensitive items must meet appropriate ESD packaging requirements. Contamination is a serious concern to Empirical Testing Corp. Packaging must protect the components from contamination, including fibers from the packaging materials.

Expendable materials and packaging must be legal and safe for standard "light industry" disposal. The preferred maximum weight of manually handled packs is 40 lbs.

Whenever possible, only one part number and one supplier lot is to be packaged in a shipping container. When more than one part number or lot number is packaged in a shipping container, each part number and/or lot number must be separately packaged (i.e. bags or boxes) inside the container, with each labeled as to the contents.

6.2 Labeling

Each shipping container or inside package must contain the following information:

- Empirical Testing Corp part number (if no Empirical Testing Corp) number exists, supplier part number is used)
- Quantity
- Supplier's Name
- Purchase Order Number
- Lot identification (if required)

7.0 Corrective Action System

Empirical Testing Corp requires suppliers to utilize a closed-loop corrective action system when problems are encountered in their manufacturing facility, or after nonconforming product has been shipped to Empirical Testing Corp.

7.1 Corrective Action Process Approach

The corrective action system utilized should be similar to the process outlined below. The focus should be on identifying the root cause(s) of the problem and taking action to prevent its recurrence.

- Use a team approach
- Describe the problem
- Contain the problem
- Identify and verify root causes(s)
- Implement permanent corrective actions
- Verify corrective action effectiveness
- Close the corrective action

7.2 Supplier Corrective Action

Empirical Testing Corp issues a Corrective Action Request (CAR) to a supplier when non-conforming parts are found at incoming inspection, in production, in test, or by a Empirical Testing Corp customer. They can also be issued as a result of a supplier audit. The supplier is required to respond by returning the CAR back to Empirical Testing Corp with the "Team Response" fields completed. The following provides a brief outline of the CAR procedure that suppliers to Empirical Testing Corp should comply with:

- Empirical Testing Corp requires that the supplier take immediate containment action upon notification of the nonconformance. The supplier must submit a written response to Empirical Testing Corp, reporting the Supplier's initial observation and defining the interim containment plan within 48 hours of notification. The Supplier's Initial Observation is an acknowledgement that the Supplier has been informed of the problem, and has begun to gather information about the problem.

- The containment plan must clearly define the containment actions at the supplier's facility to assure that no nonconforming product is shipped to Empirical Testing Corp. If suspect product has already been shipped, the supplier must address all suspect stock in transit and any stock at Empirical Testing. The supplier will assist Empirical Testing Corp in identifying customer risk by identifying all suspect lot numbers and associated quantities involved.

- Within 2 weeks after the original notification, the supplier must report the results of the Supplier's investigation into the cause of the problem.

- Within 3 weeks from the initial notification date, the supplier must submit the corrective action to be taken to prevent recurrence of the problem, and the effectivity date (the date the corrective action will be implemented.). Actions such as “train the operator,” “discipline the operator,” or “increase inspection,” are typically not acceptable corrective actions.

- The supplier is required to keep Empirical Testing Corp informed of progress towards implementing the corrective action. When corrective action implementation is complete, the supplier and Empirical Testing Corp verify that the corrective action is effective in preventing the problem’s recurrence.

8.0 Supplier Monitoring (If directed by PO)

Empirical Testing Corp continually monitors its suppliers to ensure they continue to meet Empirical Testing Corp requirements, and to ensure that the supplier continues to ship acceptable parts. This may consist of:

- A quality management system surveillance audit at the supplier's facility
- An on-site audit of the supplier's control plan
- A random incoming inspection audit of a batch of product
- Source inspection of product at the supplier's facility
- 10th First Article Inspection
- Review of supplier-furnished data packages
- A supplier progress review meeting conducted periodically at the supplier's site or Empirical Testing Corp to review supplier performance and progress

8.1 Supplier Audits (If directed by PO)

Periodically, Empirical Testing Corp may audit the supplier's quality management system. The supplier must make their facility available for on-site process verification by Empirical Testing Corp personnel at any time, with reasonable notice. This may be a full or abbreviated documentation and on-site audit. The purpose is to evaluate any changes that may have occurred in the supplier's quality management system, and to assess the supplier's continuing commitment to quality improvement.

Periodically, Empirical Testing Corp may also audit the supplier's continuing conformance to the control plan approved in the First Article process.

8.2 Supplier-Furnished Lot Documentation (If directed by PO)

Empirical Testing Corp may require the supplier to furnish inspection, test, process performance, or other quality data with each shipment to ensure that the product meets Empirical Testing Corp requirements. When data submission is required, the data must accompany each shipment, or be e-mailed or faxed to Empirical Testing Corp at the same time the lot is shipped. All documentation must be clearly identified with Empirical Testing Corp part number, and the supplier's lot number.

When specified by Empirical Testing Corp, the supplier must submit monthly data packages. Data packages typically consist of copies of control charts and process capability calculations for specified characteristics.

Once the supplier has completed two consecutive quarters of data submissions, the supplier may request elimination of the data submission if records show that the characteristic consistently satisfies Empirical Testing Corp requirements for process stability and process performance, and if the characteristic has caused no problems in Empirical Testing Corp production. Empirical Testing Corp will notify the supplier in writing if the data submission may be discontinued.

Appendix 1

C = 0 SAMPLING PLAN

	.010	.015	.025	.040	.065	.10	.15	.25	.40	.65	1.0	1.5	2.5	4.0	6.5	10.0
LOT SIZE	**SAMPLE SIZE**															
2 to 8	*	*	*	*	*	*	*	*	*	*	*	*	5	3	2	2
9 to 15	*	*	*	*	*	*	*	*	*	*	13	8	5	3	2	2
16 to 25	*	*	*	*	*	*	*	*	*	20	13	8	5	3	3	2
26 to 50	*	*	*	*	*	*	*	*	32	20	13	8	5	5	5	3
51 to 90	*	*	*	*	*	*	80	50	32	20	13	8	7	6	5	4
91 to 150	*	*	*	*	*	125	80	50	32	20	13	12	11	7	6	5
151 to 280	*	*	*	*	200	125	80	50	32	20	20	19	13	10	7	6
281 to 500	*	*	*	315	200	125	80	50	48	47	29	21	16	11	9	7
501 to 1200	*	800	500	315	200	125	80	75	73	47	34	27	19	15	11	8
1201 to 3200	1250	800	500	315	200	125	120	116	73	53	42	35	23	18	13	9
3201 to 10,000	1250	800	500	315	200	192	189	116	86	68	50	38	29	22	15	9
10,001 to 35,000	1250	800	500	315	300	294	189	135	108	77	60	46	35	29	15	9
35,001 to 150,000	1250	800	500	490	476	294	218	170	123	96	74	56	40	29	15	9
150,001 to 500,000	1250	800	750	715	476	345	270	200	156	119	90	64	40	29	15	9
500,001 and over	1250	1200	1112	715	556	435	303	244	189	143	102	64	40	29	15	9

*Indicates entire lot must be inspected
NOTE: The Acceptance Number in all cases is ZERO.

Appendix 2

Supplier Questionnaire

Please fill out the questionnaire and return it to clissy@empiricaltech.com. It will be reviewed promptly and you will be contacted to inform you of the status of the approval process.

1. Contact Information	
Company name	
Company address	
Company website	
Quality contact name, phone number, and email address	
Customer service contact name, phone number, and email address	

2. General Information	
Number of employees	
Number of quality employees	
Years in business	
Years at present facility	
ISO or equivalent certified? If yes, please list accrediting body and certificate number (Attach copy of certificate)	
Has your company been audited by a third party inspection agency in the past calendar year? (If yes, which agency?)	
Will you allow onsite visits of your work site?	

3. Management System; Internal Audits	Y	N	N/A	Comments
Is a quality manual in place? (Attach copy)				
Are written procedures in place for critical processes?				
If a quality manual and written procedures are in place, are they available at all locations where operations are performed?				
Is a quality policy statement in place?				
Is an organization chart in place? (Attach copy)				
Are management reviews periodically performed?				
If yes, are corrective actions and customer complaints discussed?				
Are internal audits periodically performed?				

If yes, are the internal audit findings recorded and a corrective action procedure implemented?				
4. Document Control; Control of Records and Data	**Y**	**N**	**N/A**	**Comments**
Is there a written document control process?				
Are critical documents (including new and revised) reviewed and approved for use prior to being put into the quality system?				
If yes, is this approval documented?				
Does the system ensure that the most up-to-date documentation is readily available to personnel?				
Are obsolete documents removed from active work areas so that they are not accessed?				
Are obsoleted documents maintained for historical purposes?				
Is there a written document outlining retention durations for manufacturing and quality records?				
Are electronic files backed-up on a regular basis?				

5. Review of Requests and Contracts; Purchasing	**Y**	**N**	**N/A**	**Comments**
Is there a written procedure for handling requests, tenders, and contracts?				
Are records of reviews, including significant changes and communication, maintained?				
Is the customer notified of any deviations from the request?				
Is there a written procedure for purchasing services and supplies?				
Are critical vendors/ subcontractors evaluated?				
Is there a document containing a list of approved vendors/subcontractors?				
Are purchased supplies not used until they have been inspected and verified?				
If yes, is the inspection documented?				
Are certificates of analysis for raw materials available upon request?				

6. Non-conformance; Corrective and Preventative Actions	**Y**	**N**	**N/A**	**Comments**
Is there a written procedure for handling non-conforming items?				
Are non-conforming items quarantined?				
Are customers notified in the case of a part/material recall?				
Is there a written procedure for handling corrective and				

preventative actions?				
Does a root cause analysis take place in the event of a corrective action?				
Are records of customer complaints and subsequent corrective actions maintained?				
Is an internal audit performed if a corrective action casts doubts on compliance with in-house policies/procedures?				

7. Training	**Y**	**N**	**N/A**	**Comments**
Is there a training program in place?				
Are records of training documented separately per employee?				
Is there a written document containing job descriptions for key personnel?				

8. Environmental Control	**Y**	**N**	**N/A**	**Comments**
Are good housekeeping processes in place?				
Are the appropriate environmental values recorded?				

9. Calibration	**Y**	**N**	**N/A**	**Comments**
Are there written procedures for the use and operation of relevant calibration equipment?				
Are non-standard methods of calibration validated prior to use?				
Is there a written procedure for estimating measurement uncertainty?				
Are reference standards periodically checked according to a defined schedule to maintain confidence?				
Are written procedures in place for the safe handling, transport, and storage of reference standards and materials?				

10. Calibration Reporting	**Y**	**N**	**N/A**	**Comments**
Are deviations from methods included on calibration reports where applicable?				
Is the estimated uncertainty included on calibration reports?				
Is evidence that measurements are traceable included on calibration reports?				

11. Equipment	**Y**	**N**	**N/A**	**Comments**
Are up-to-date instructions on the use and maintenance of equipment readily available?				
Are items of equipment uniquely identified and labeled?				
Are records of maintenance, malfunction, modification, and calibration kept for unique items of equipment?				
Are items of equipment that are calibrated clearly marked as such?				
Are items of equipment used for testing, calibration,				

and/or sampling calibrated?				

12. Sampling; Handling of Items	**Y**	**N**	**N/A**	**Comments**
Are written procedures in place defining a statistically appropriate sampling plan?				
Are written procedures in place for the safe handling, transport, and storage of customer items?				
Are customer orders uniquely identified?				
Upon receipt of customer items, are abnormalities recorded and the customer notified?				

13. Closing	
Completed By: Signature	
Completed By: Print Name	
Completed By: Title	
Completed By: Date	

14. FOR EMPIRICAL TESTING CORP. USE ONLY	
Supplier Reviewed and Approved By: Signature	
Completed By: Print Name	
Completed By: Title	
Completed By: Date	
Comments:	

Reference Documentation List.

<List applicable reference documents (associated forms, etc). Write NA on fist line of table if there are none.>

The key documents associated with this operation are:

Document Name	Doc #

Track Changes

Revision #	Date of Change	Change Owner	Change Details
A	18Dec18	D. Turner	Create Document