Quality Manual

Multilayer Prototypes

Compliant to
ISO 9001-2008 / AS9100 Rev C

This Quality Manual sets forth the quality system policies and
Defines compliance with the ISO 9001-2008 SAE AS 9100 REV C requirements.

Reviewed & Dated:		Approved & Dated:	
ISO Management Representative	12/15/2016	ISO Management Representative	12/15/2016

1.0 INTRODUCTION AND SCOPE

1.1 Scope:

1.1.1 This quality manual describes the policies and organization-wide control system of Multilayer Prototypes quality management system. The quality system meets the requirements of AS 9100 Revision C as defined by the SAE and also conforms to ISO 9001-2008 as defined by the International Organization for Standardization and the American National Standards Institute.

1.1.2 The scope of this quality management system includes processes for continual improvement of the system and the assurance of conformity to customer contractual documentation and applicable regulatory requirements. Should there be a conflict between the requirements of this manual and applicable statutory or regulatory requirements, the latter shall take precedence.

1.1.3 Excluded from the scope of this manual and the quality system is “Design and Development.” Design and Development has been excluded because Multilayer Prototypes does not design their products. Further excluded is 7.5.2 Validation of Processes for Production and Service Provision as Multilayer Prototypes outsources these special processes.

1.2 Multilayer Prototypes Overview:

1.2.1 The name of this organization is Multilayer Prototypes, Inc. It is located in Newbury Park, California.

1.2.2 The primary business of Multilayer Prototypes, Inc. is the fabrication of Prototype PCB as well as PCB layout and design using its manufacturing expertise and equipment. Multilayer Prototypes, Inc. employs approximately 15 employees.

1.3 Mission:

1.3.1 Multilayer Prototypes is the product brand-imaging champion for our customers. Our comprehensive product line, superior manufacturing, quality and innovations in research and development help our customers build sustained value to meet the increasingly complex demands of their unique markets worldwide.

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1.4 Corporate Quality Policy:

1.4.1 Top management assures that the quality policy is appropriate to the purpose of the organization and provides a framework for establishing and reviewing quality objectives.

2.0 REFERENCES

2.1 ANSI/ASQ 9001-2008, Quality Management Systems – Requirements.

2.2 AS 9100 Revision C, Quality Management Systems – Requirements.

3.0 DEFINITIONS

- *For the purpose of this document the terms and definitions given in ISO9000 will apply.*

3.1 Contract: An accepted order from the customer.

3.2 Controlled Document: Any document that is reviewed and approved before release for use or for reference.

3.3 Customer: The recipient of a product provided by the Multilayer Prototypes.

3.4 Multi-disciplinary Approach: Typically includes management, sales, production, engineering, quality, and other appropriate personnel.

3.5 Organization: Multilayer Prototypes.

3.6 Product: The result of Multilayer Prototypes activities or processes.

3.7 Proposal: Offer made by an organization in response to an invitation to satisfy a contract award to provide product.

3.8 Supplier: An organization that provides materials or information to Multilayer Prototypes.

3.9 Key Characteristics: The features of a material, process, or part whose variation has a significant influence on product fit, performance, service life, or manufacturability.

3.10 Risk: An undesirable situation or circumstance that has both a likelihood of occurring and potentially negative consequence.

3.11 Special Requirements: Those requirements identified by the customer, or determined by the organization, which have high risk to being achieved, thus requiring their inclusion in the risk management process. Factors used in the determination of special requirements include product or process complexity, past experience and product or process maturity. Examples of special requirements include performance requirements imposed by the customer that are at the limit of the industry's capability, or requirements determined by the organization to be at the limit of its technical or process capabilities.

3.12 Critical Items: Those items (e.g., functions, parts, software, characteristics, and processes) having significant effect on the product realization and use of the product: including safety, performance, forms, fit, function, producibility, service life, etc.: that require specific actions to ensure they are adequately managed. Examples of critical items include safety critical items, fracture critical items, mission critical items, key characteristics, etc.

3.13 Outsource Process: Is a process that the organization needs for its quality management system and which the organization chooses to have performed by an external party.

4.0 QUALITY MANAGEMENT SYSTEM

4.1 General Requirements:

4.1.1 This Quality Manual describes the Multilayer Prototypes' AS 9100 Revision C quality system and how it is implemented to ensure the product meets and/or exceeds specified requirements. This manual includes and/or makes reference to the quality system procedures, (QP) and outlines the structure of the documentation used in the quality system.

4.1.2 The Level I and Level II Master Document List identifies the different procedures, quality records, and forms used to implement the Multilayer Prototypes quality policy. A screenshot of the file explorer window on the computer may serve as the master document control list.

4.1.3 Multilayer Prototypes:

4.1.3.1 Identifies the processes needed for the quality management system and their application throughout the organization refer to "**Attachment A**".

4.1.3.2 Determines the sequence and interaction of these processes in "**Attachment A**".

4.1.3.3 Determines criteria and methods needed to ensure that both the operation and control of these processes are effective.

4.1.3.4 Ensures the availability of resources and information necessary to support the operation and monitoring of these processes.

4.1.3.5 Monitors, measures, and analyzes these processes.

4.1.3.6 Implements actions necessary to achieve planned results and continual improvement of these processes.

4.1.3.7 These processes are managed in accordance with the requirements of ISO-9001-2008 and AS 9100 Revision C.

4.1.4 Where Multilayer Prototypes chooses to outsource any process that affects product conformity to requirements, Multilayer Prototypes ensures control over such processes. The type and extent of control to be applied to these outsourced processes shall be defined within our quality management system. The capability of achieving the necessary control will be through the purchasing documentation. Outsourced processe(s) include: Plating

4.2 Documentation Requirements

4.2.1 General:

4.2.1.1 Multilayer Prototypes established and maintains procedures to control all documents and data in all format (Electronic or hard copy) that relate to the requirements of AS 9100 Revision C, including documents of external origin, such as customer standards or master drawings.

4.2.1.2 The following documents form the basis of the Multilayer Prototypes Quality Management System:

4.2.1.2.1 Quality Policy and Quality Objectives.

4.2.1.2.2 Quality Manual **(Level I Document)**.

4.2.1.2.3 Quality Procedures **(Level II Documents)**.

4.2.1.2.4 Work Instructions and Quality Records **(Level III and Level IV Documents)**.

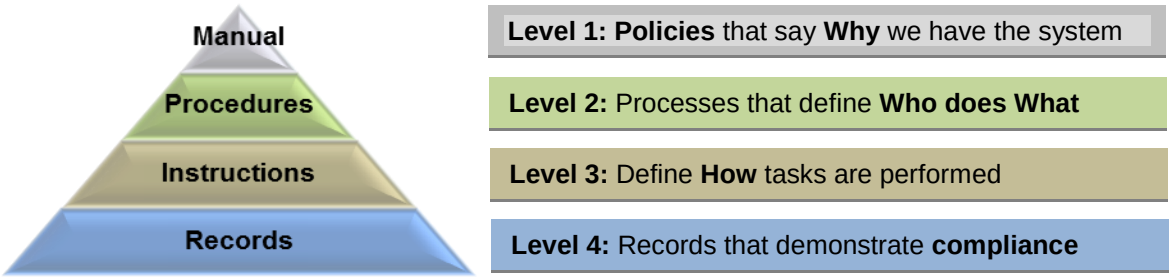
4.2.1.2.5 Documents including records, needed to ensure the effective planning, operation and control of processes.

4.2.1.2.6 Requirements imposed by the applicable regulatory authorities.

4.2.1.2.7 Procedures and quality records may be created and/or maintained in the form of paper copy, electronic copy, or in other media as deemed appropriate.

4.2.1.3 Multilayer Prototypes ensures that personnel have access to Quality Management System documentation and are aware of relevant procedures. Multilayer Prototypes Company also ensures that Customers and/or regulatory authorities have access to Quality Management System documentation.

QUALITY SYSTEM DOCUMENTATION STRUCTURE



4.2.2 Quality Manual:

4.2.2.1 This Quality Manual establishes the scope of the quality management system including associated procedures, work instructions, forms, and work aids. The integration of the documented system is found within each procedure. The Quality Manual includes details of and justification for exclusions, if appropriate. **"Attachment A"** of this manual is a description of the interaction between processes of the quality management system.

4.2.2.2 The responsibility to effectively implement the quality system procedures necessary to meet AS 9100 Revision C requirements is held by the process owners as defined on the specific procedure or work instruction. Procedure and work instruction detail depends upon the complexity of the work, methods used, and the skills and training needed by personnel to carry out the activity. For example, a procedure may consist of only a flowchart of process elements.

4.2.2.3 The management level or levels closest to the actual users of the specific document review and approve the procedures.

All Level I and Level II controlled documents receive final approval from the document owner and either the Management Representative or President/CEO, or other designated member of the executive staff.

4.2.2.4 All managers and supervisors affected by the controlled document is responsible to ensure that their personnel are adequately informed and trained, as necessary, to ensure the proper implementation of the procedure.

4.2.3 Control of Documents:

4.2.3.1 Quality system documents may be initiated by managers, and are issued after review and approval by authorized personnel. All documents are reviewed for adequacy prior to issue. The document owner or others approve work instructions, as designated by the Management Representative.

4.2.3.2 Master Lists of controlled documents are maintained, identify the current revision status, and are readily available to preclude the use of invalid and/or obsolete documents. All documents will remain legible and readily identifiable.

4.2.3.3 Electronic or hard copy documents are distributed to personnel and locations where they are used. Invalid or obsolete documents are removed from points of use to prevent unintentional use. Any obsolete documents retained for legal or knowledge preservation purposes are suitably identified.

4.2.3.4 Documents are reviewed, updated, and re-authorized by the same function or department that issued the original document, unless specifically designated otherwise. Designated functions have access to pertinent background information upon which to base their review and approval.

4.2.3.5 The nature of the change is identified in the document or the appropriate attachments. Engineering documents (such as drawings and assembly procedures) are controlled according to documented procedures.

4.2.3.6 Electronic or hard copy documents of external origin are controlled, including distribution, to ensure that the applicable revision level is being used. The process owner of that document controls standards and/or regulatory documents of external origin. External drawings, schematics, and/or other documents used in the manufacture of product are verified for the applicable revision level during Contract Review.

4.2.3.7 Multilayer Prototypes ensures that obsolete documents are suitably identified and/or prevented from unintended use.

4.2.3.8 Document changes are coordinated with customers and/or regulatory authorities in accordance with contract or regulatory requirements, as applicable.

4.2.4 Control of Records:

4.2.4.1 There are documented procedures for identification, controlling, storage, protection, retrieval, retention time, and disposition of records.

4.2.4.2 Records are established and maintained to demonstrate conformance to specified requirements and the effective operation of the quality system. Pertinent records from the subcontractor are an element of this data, and shall be audit on regular bases.

4.2.4.3 All records (hard copy or electronically) are legible, readily identifiable and are stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss.

4.2.4.4 Records may be in the form of any type of media, such as hard copy or electronic media.

4.2.4.5 Retention time of records is established and recorded. Where agreed contractually, records are available for review by customers and regulatory authorities in accordance with contract or regulatory requirements. Quality records shall be retained for ten years minimum unless a customer requires a longer retention time.

4.2.5 List of Quality Procedures (Level II):

- QP-04-01, Document Control
- QP-04-02, Control of Records
- QP-05-01, Management Review
- QP-05-02, Organizational Chart
- QP-06-01, Competence, Awareness and Training Procedure
- QP-07-01, Review of Requirements Related to the Product
- QP-07-02, Purchase Process and Information
- QP-07-03, Control of Monitoring and Measuring Devices
- QP-07-04, Risk Management
- QP-07-05, Preservation of Product
- QP-08-01, Internal Quality Audit
- QP-08-02, Control of Nonconforming Product
- QP-08-03, Corrective and Preventive Action
- QP-08-04, Customer Satisfaction Procedure
- QP-08-05, Monitoring and Measuring of Product

5.0 MANAGEMENT RESPONSIBILITY

5.1 Management Commitment:

5.1.1 Top management provides evidence of its commitment to the development and implementation of the quality management system and continually improves its effectiveness by:

5.1.1.1 Communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements.

5.1.1.2 Establishing the quality policy.

5.1.1.3 Ensuring that quality objectives are established.

5.1.1.4 Conducting management reviews.

5.1.1.5 Ensuring the availability of resources.

5.2 Customer Focus:

5.2.1 Multilayer Prototypes management is committed to ensuring that customer requirements are determined and are met with the aim of enhancing customer satisfaction.

5.2.2 Multilayer Prototypes incorporate a commitment to ensure that product conformity and on-time-delivery performance are continually measured and that appropriate action is taken if planned results are not achieved.

5.3 Quality Policy:

5.3.1 The quality policy of Multilayer Prototypes incorporates a commitment to comply with the quality system requirements and continually improve the effectiveness of the quality management system.

5.3.2 The quality policy provides management with a framework for establishing and reviewing quality objectives. The policy is a company commitment to comply with requirements and continually improve the effectiveness of the quality management system.

5.3.3 During the Management Review of The Quality Meeting, management meets to review and revise (as necessary) the quality policy, pertinent business strategies, objectives and goals for the year.

5.3.4 The policy is communicated to all employees through training and is posted throughout the facility to promote customer satisfaction. The following is the quality policy for Multilayer Prototypes:

QUALITY POLICY STATEMENT

Multilayer Prototypes, Inc. is committed to meeting statutory, regulatory and customer requirements, including on-time delivery and product quality through continuous improvement of the Quality Management System.

5.4 Planning:

5.4.1 Quality Objectives – The management of Multilayer Prototypes ensures that the quality policy, objectives, and goals are established at relevant functions and level throughout the company. The objectives are quantified and will be measurable and consistent with the quality policy.

5.4.1.1 The following are the Quality Objectives:

5.4.1.1.1 Improve Customer Satisfaction:
5.4.1.1.1.1 Improve On-time Delivery
5.4.1.1.1.2 Product Quality

5.4.2 Quality Management System Planning:

5.4.2.1 Top management reviews the appropriateness of the quality management system on an annual basis; the records of which can be found in Management Review minutes. Top management ensures that:

5.4.2.1.1 The planning of the quality management system is carried out in order to meet the requirements given in paragraph 4.1, as well as the quality objectives.

5.4.2.1.2 The integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.5 Responsibility, Authority, and Communication:

5.5.1 Responsibility and Authority – The organization charts and job descriptions define the responsibility, level of authority, and the interrelation of personnel who manage the quality system. At each department level within Multilayer Prototypes supporting organization charts indicate the personnel who perform and verify work affecting quality (refer to controlled document **QP-05-02, Organization Charts**). These responsibilities and authorities are communicated within Multilayer Prototypes.

5.5.2 Management representative – Multilayer Prototypes has identified an individual for the position of Management Representative, who reports directly to the President/CEO, and who is irrespective of other responsibilities;

5.5.2.1 Ensures that processes needed for the quality system is established, implemented, and maintained in accordance with AS 9100 Revision C requirements.

5.5.2.2 Evaluates and reports on the performance of the quality system to management for review and as a basis for improvement of the quality system.

5.5.2.3 Has an adequate organization to support this responsibility.

5.5.2.4 Reviews internal process audits to verify the effectiveness of the quality system processes.

5.5.2.5 Ensures the promotion of awareness of customer requirements throughout the company.

5.5.2.6 Has the organizational freedom and unrestricted access to top management to resolve matters pertaining to quality.

5.5.3 Internal Communication:

5.5.3.1 Multilayer Prototypes have identified the Management Representative, who reports at Management Review meetings, with responsibility and authority to ensure **communication processes** are established and utilized throughout the company regarding the effectiveness of the quality management system.

5.5.3.2 Examples of the communication processes include email, verbal and all employee meetings.

5.6 Management Review:

5.6.1 **General** – Quality system reviews are held, at a minimum of, annual intervals to assess continuing suitability, adequacy and effectiveness of the quality system in relation to AS9100 Revision C and this Quality Manual. Executive management representing each area of the operation is present at these reviews. The reviews include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Documented procedures define the system for management review and tracking of reviews is typically performed by recording minutes of the meetings and/or records of reviews and action items. Corrective actions from management reviews are entered into the corrective action system for tracking. Management review records are maintained for no less than two years.

5.6.2 **Review Input:** The activities reviewed include, but are not limited to the following:

5.6.2.1 Follow-up to previous management review activities.

5.6.2.2 Internal and external audit results.

5.6.2.3 Customer feedback, complaints and field problem reports.

5.6.2.4 Continuing suitability of the Quality Policy and Quality Objectives.

5.6.2.5 Customer satisfaction surveys.

5.6.2.5 Process performance and product conformity.

5.6.2.6 Quantify quality objectives.

5.6.2.7 Status of preventive and corrective actions.

5.6.2.8 Organizational and process changes that could affect the quality system.

5.6.2.9 Discussion of infrastructure requirements and appropriate work environment.

5.6.2.10 Review prior actions to improve competency (may include training).

5.6.2.11 Recommendations for improvement.

5.6.2.12 Changes that could effect the quality management system.

5.6.3 **Review Output**: The output from management review activities include decisions and action's relating to:

5.6.3.1 Improving the effectiveness of the quality management system and its processes.

5.6.3.2 Improving the product related to customer requirements.

5.6.3.3 Resource needs

5.6.3.4 Updating the policy and quality objectives, as applicable.

6.0 RESOURCE MANAGEMENT

6.1 Provision of Resources:

Each manager and/or supervisor has the responsibility and authority to ensure, there are adequate resources to support the quality system throughout their functional responsibilities. Each manager and/or supervisor is to:

6.1.1 Provide adequate resources.

6.1.2 Prioritize assignments.

6.1.3 Place trained personnel in the right place at the right time to ensure Multilayer Prototypes meets its company goals and objectives.

6.1.4 Implement and maintain the quality management system and continually improve its effectiveness.

6.1.5 Enhance customer satisfaction by meeting customer requirements.

6.2 Human Resources:

6.2.1 General – Personnel performing specific tasks are qualified on the basis of appropriate education, training, skills and/or experience, as required.

6.2.2 Employees of Multilayer Prototypes employed on or prior to the issue date of this manual are considered qualified to perform their work assignments based on previous satisfactory performance of that work.

6.2.3 Competence, Training, and Awareness – Multilayer Prototypes has established and maintains job descriptions and personnel files to:

6.2.3.1 Determine competency/training needs for personnel performing activities affecting product quality.

6.2.3.2 Provide training or take actions to satisfy these needs.

6.2.3.3 Provide evidence of actions taken/performed and its effectiveness.

6.2.3.4 Evaluate employee's competencies at defined intervals.

6.2.3.5 Provide evidence that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

6.2.3.6 Maintain records of education, training, skills and experience.

6.3 Infrastructure:

Multilayer Prototypes management utilizes a systematic approach to facilities, equipment, and process planning by incorporating multi-disciplinary teams to optimize performance. The multi-disciplinary teams determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable:

6.3.1 Buildings, workspace and associated utilities.

6.3.2 Process equipment (both hardware and software).

6.3.3 Supporting services (such as transportation, communication), or information system.

6.4 Work Environment:

Premises are maintained in a state of order, temperature, humidity, lighting, protected from electrostatic discharge, manufactured to ensure product conformity and consistency. Cleanliness and repair appropriate to the products.

Contingency plans are established based on situation as a result of emergency management meetings to address situations as they arise.

7.0 PRODUCT REALIZATION

7.1 Planning of Product Realization

Multilayer Prototypes plans and develops the processes needed for product realization. The planning of product realization is consistent with the requirements of the other processes of the quality management system.

In planning product realization, Multilayer Prototypes determines the following, as appropriate:

1. Quality objectives and requirements for the product were considered, by the following attributes:

    - Product and personal safety.
    - Suitability of parts and materials used.
    - Producibility and inspectability.
    - Reliability, availability, and maintainability.
    - Selection and development of embedded software.
    - Recycling or final disposal of the product at the end of its life.

2. The need to establish processes, documents, and provide resources specific to the product as applicable.

3. Required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance.

4. Records needed to provide evidence that the realization processes and resulting product meet requirements.

5. Quality planning is documented through the quality manual, procedures, and other integral parts of the quality system.

6. The identification of resource to support operation and maintenance of the product.

7.1.1 Project Management:

Multilayer Prototypes plans and manage product realization in a structured and controlled manner to meet requirements at acceptable risk within our resources and production constraints.

7.1.2 Risk Management:

Multilayer Prototypes, established, implement, and maintain process for managing risk to the achievement of applicable requirements, including:

1. Assignment of risk management responsibilities.
2. Definition of risk criteria.
3. Identification, assessment, and communication of risk throughout product realization.
4. Identification, implementation and management of actions to mitigate risks that exceed the defined risk acceptance criteria.
5. Acceptance of risk remaining after implementation of mitigation actions.

7.1.3 Configuration Management:

Also, Multilayer Prototypes implement and maintain a configuration management process as specify and determined by our customer that includes:

1. Configuration Identification
2. Change Control
3. Configuration audit

7.1.4 Control of Work Transfers:

Multilayer Prototypes established, implemented a procedure to plan and control the transfer of work (from one organization facility to another, from the organization to a supplier, from one supplier to another supplier) and to verify the conformity of the work to requirements. See QP-07-02

7.2 Customer-Related Processes:

7.2.1 Determination of Requirements Related to the Product:

The generation and review of each proposal, contract, or order ensures that:

7.2.1.1 Customer requirements, including the requirements for delivery and post-delivery activities, and contract scope are adequately defined and documented including verbal specifications.

7.1.2.2 Requirements not stated by the customer but necessary for specified or intended use, where known, are determined.

7.1.2.3 Statutory and regulatory requirements related to the product are adequately defined and documented as applicable.

7.1.2.4 Any **additional** requirements determined by Multilayer Prototypes.

7.1.2.5 Requirements related to the product can include special requirements.

7.2.2 Review of Requirements Related to the Product:

Multilayer Prototypes reviews customer requirements prior to the commitment to supply a product to the customer and ensures that:

1. Product requirements, and special requirements and/or amendment approval are defined
2. Any contract or accepted order requirements differing from those in the quotation tender are resolved, documented, and acknowledged by the customer.
3. Multilayer Prototypes has the ability to meet the contract or accepted order requirements.
4. Risks (e.g., new technology, short delivery time) are evaluated.
5. Customer requirements, including the requirements for delivery and post-delivery activities, and contract scope are adequately defined and documented including verbal communications.

4. Product requirement **changes** are amended on relevant documents and relevant personnel are made aware of the changed requirements.

7. Records of order reviews and actions arising from the review are maintained.

7.2.3 Customer Communication:

Continued communication with the customer before, at, and after contract closure is maintained by the Sales Department. Customer communication includes handling product information, inquiries, contracts, order handling, order amendments, customer feedback, and customer complaints.

The systems employed at Multilayer Prototypes may include but are not limited to:

1. Written quotations or enquiries
2. Telephone conversations
3. Written correspondences
4. Company literature
5. Customer samples
6. Fax
7. Email
8. Customer feedback, including customer complaints.
9. Any other means of communication that is available and appropriate.

7.3 Design and Development:

Excluded, as Multilayer Prototypes does not design their products.

7.4 Purchasing:

7.4.1 Purchasing Process:

Purchasing will ensure that purchased product conforms to specified purchase requirements. Purchasing will receive a form of written communication to ensure the correct product is ordered. This process can take place by a Purchase Requisition, Estimate, or a Purchase Order.
Multilayer Prototypes is responsible for the conformity of all products purchased from suppliers, including customer-designated sources. The type and extent of control applied to the supplier and the purchased product is dependent upon the effect of the purchased product on subsequent product realization or the final product.

Multilayer Prototypes maintains a register of **approved suppliers** that includes the scope of the approval. Periodic supplier performance review is made and records of these reviews are used as a basis for establishing the level of controls to be implemented. A documented procedure itemizes the criteria for selection, evaluation and re-evaluation and includes the following:

1. Defines the necessary actions to be taken when dealing with suppliers that do not meet requirements.

2. Ensures where required that both the organization and all suppliers use customer-approved special process sources.

3. Ensures that the function having responsibility for approving supplier quality systems has the authority to disapprove the use of sources.

4. Determine and manage the **risk** when selecting and using suppliers.

7.4.2 Purchasing information:

Purchasing documents are describe clearly and completely identifies, the product to be purchased, including where appropriate:

1. Any requirements for approval of product procedure, processes and equipment.

2. Any requirements for qualification of personnel.

3. Quality management system requirements.

4. The name or identification, and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data.

5. Requirements for test, examination, inspection and related instructions for acceptance by the organization.

6. Requirements for test specimens for inspection, investigation or auditing.

7. Requirements relative to:

    7.1 Supplier notification to the organization of nonconforming product
    7.2 Arrangements for the organization's approval of supplier nonconforming material.

8. Requirements for the supplier to notify the organization of changes in product and/or process definition and, where required, obtain organization approval.

9. Right of access by Multilayer Prototypes, customer, statutory and regulatory authorities to all facilities involved in the order and to all applicable records.

10. Requirements for the supplier to flow down to the sub-tier suppliers the applicable requirements in the purchasing documents, including key characteristics where required.

11. Requirements for record retention.

7.4.3 Verification of Purchased Product:

7.4.3.1 All material shall be inspected upon receipt for defects, visual damage, conformance to specified purchase requirements and proper documentation. Depending on the status of the supplier, the material may be deemed conforming upon receipt. Any defects or nonconforming product shall be controlled as per the

Control of Non-conforming Product Quality Procedure.

7.4.3.2 If purchased product is released for production use pending completion of all required verification, it will be identified [recorded] labeled to allow recall and replacement, if it is subsequently found that the product does not meet requirements.

7.4.3.3 Certificates of Conformance are maintained for reference purposes as appropriate.

7.4.3.4 When Multilayer Prototypes delegates verification activities to the supplier, the requirements for delegation are defined and a register of delegations mainlined.

7.4.3.5 When verifying purchased product at the supplier's premises (source inspection) the verification arrangements and the methods of product release are stated in the purchasing information.

7.5 Production and Service Provision:

7.5.1 Control of Production and Service Provision:

Multilayer Prototypes planning processes consider, as applicable:

1 The establishment of process controls and development of control plans where key characteristics have been identified.

2. The identification of in-process verification points when adequate verification of conformance cannot be performed at a later stage of realization.

3. The manufacture and use of tooling so that variable measurements can be taken, particularly for key characteristics.

4. Special processes need to be clearly identified.

Also Multilayer Prototypes plans and carries out production and service provision under controlled conditions. Controlled conditions include:

1. The availability of information that describes the characteristics of the product can include drawings, materials and process specification.

2. The availability of work instructions, as necessary, such as process flow, charts and travelers.

3. The use of suitable equipment.

4. The implementation of monitoring and measurement.

5. The implementation of release, delivery and post-delivery activities.

6. Accountability for all products during manufacture.

7. Evidence that all manufacturing and inspection verification operations have been completed as planned, or as otherwise documented and authorized.

8. Provision for the prevention, detection, and removal of foreign objects.

9. Monitoring and control of utilities and supplies such as water, compressed air, electricity and chemical products to the extent they affect product quality.

10. Criteria for workmanship, which is stipulated in the clearest practical manner.

11. Manage, identify and control the critical characteristic.

12. Using appropriate tooling to measure variable data.

13. Identify in process inspection/verification point, where conformance cannot performed at later stages.

7.5.1.1 Production Process Verification:

Production operations are carried out in accordance with **approved data**. The data may contain:

1. Drawings, parts lists, process flow charts including inspection operations, production documents and inspection documents.

2. A list of specific or non-specific tools and numerical control machine programs required and any specific instructions associated with their use. When applicable, Multilayer Prototypes will use a representative item from the first production run of a new part or assembly to verify that the production process, documentation and tooling are capable to produce parts that meet all requirements. These processes were repeated when changes occur that invalidate the original results.

7.5.1.2 Control of Production Process Changes:

The Production Manager or President are authorized to approve **changes** to production processes and they are documented. Multilayer Prototypes obtains acceptance when these changes require customer and/or statutory and regulatory authority approval. The results of changes are assessed to confirm that the desired effect has been achieved, without adverse effect to product conformity.

7.5.1.3 Control of Production Equipment, Tools and Software Programs:

Production equipment and tools are validated prior to use, maintained and inspected periodically. Also, storage and preservative condition are defined and documented.

7.5.1.4 Post-Delivery Support:

Post-delivery support shall provide as applicable for the

a) collection and analysis of in-service data,

b) actions to be taken, including

c) control and updating of technical documentation, investigation and reporting, when problems are detected after delivery,

d) approval, control and use of repair schemes, and

e) controls required for off-site work (e.g., organization's work undertaken at the customer's facilities).

7.5.2 Validation of Processed for Production and Service Provision:

Excluded as Multilayer Prototypes outsources these processes.

7.5.3 Identification and Traceability:

Multilayer Prototypes has established and maintained methods for identifying the product by suitable means throughout product realization. Product configuration is maintained, in order to identify any differences between the actual configuration and the agreed configuration. These methods include but are not limited to:

- Finished goods labels
- Work Order number
- Product identification number
- UPC Code
- Product Code
- Stock location

7.5.3.1 The location of the product in the production, packaging and storage process identifies the status of the product with respect to monitoring and measurement requirements.

7.5.3.2 Multilayer Prototypes establishes and document controls acceptance authority media when used.

7.5.3.3 Unique identification of the product is controlled and recorded when traceability is a requirement. In accordance with the level of traceability required by contract, regulatory, or other established requirement, Multilayer Prototypes provides for:

1. Identification to be maintained throughout the product life;
2. 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 of all products of the same batch.
3. For a given product, a sequential record of its production to be retrieved.

7.5.4 Customer Property:

The use of customer consigned materials or customer supplied third party material is controlled within the quality management system. Multilayer Prototypes identifies, verifies, protects and safeguards customer property that has been provided for use or incorporation into the product.

7.5.4.1 Any such property that is lost, damaged, or is otherwise unsuitable for use shall be

reported to the customer and records maintained.

7.5.5 Preservation of Product:

Employees and suppliers are responsible for preserving the conformity of product and constituent parts during internal processing and delivery to the intended destination. This preservation includes, where appropriate:

1. Identification
2. Handling
3. Packaging
4. Storage
5. Protection
6. Cleaning
7. Prevention, detection and removal of foreign objects
8. Special handling for sensitive products
9. Marking and labeling including safety warnings
10. Shelf life control and stock rotation
11. Special handling for hazardous material.

7.5.5.1 Documents required by the contract/order to accompany the product are present at delivery and are protected against loss and deterioration.

7.5.5.2 **Customer Packaging Standards** – Packing, packaging, and marking processes (including materials used) are controlled to the extent necessary to ensure conformance to specified requirements.

7.6 Control of Monitoring and Measuring Equipment:

Multilayer Prototypes maintain a register of the monitoring and measuring equipment type, identification, location, frequency, of checks and check method. Also, the environmental conditions are suitable for the calibration. Multilayer Prototypes has established and maintains a system for the calibration and maintenance of measuring and monitoring devices used to demonstrate conformance of products to specified requirements.

7.6.1 The devices are used in a manner that ensures that measurement certainty, including accuracy and precision, is known and is consistent with the required measurement capability.

7.6.2 The system provides for the following activities:

1. Calibrate, adjust and re-adjust measuring and monitoring devices at specified intervals and prior to use, against equipment traceable to international or national standards. Where no such standards exist, the basis used for calibration will be determined and recorded.

2. Identify, measuring and monitoring devices with a suitable indicator or approved

identification record to show calibration status.

3. Determine the method for calibration of measuring and monitoring devices.

4. Record the results of calibration and verification activities are maintained.

5. Ensure environmental conditions are suitable for calibrations, measurements, inspections and tests.

6. Safeguard measuring and monitoring devices from adjustments that would validate the calibration.

7. Recalled to a defined method when requiring calibration.

8. Protection of devices from damage or deterioration during handling, maintenance and storage.

7.6.3 Assess and record the validity of previous measuring results when a device is found to be out of calibration and take appropriate actions on the equipment and any product affected.

7.6.4 When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application is confirmed prior to initial use and reconfirmed as necessary.

8.0 MEASUREMENT, ANALYSIS, AND IMPROVEMENT

8.1 General:

Multilayer Prototypes has planned, developed and implemented processes designed to monitor, measure, analyze and improve processes needed including determination of applicable methods, including statistical techniques, and the extent of their use:

1. To demonstrate product conformity utilizing test and measurement activities.

2. To ensure conformity of the quality management system via internal audits.

3. Improve continually the quality management system effectiveness utilizing continuous improvement, customer satisfaction data, and management review activities.

8.1.1 Depending on specified requirements, statistical techniques can be used to support:

8.1.4.1 New configuration or tooling verification

8.1.4.2 Process Control:

- Selection / Inspection of key characteristic
- Process capability measurements
- Design of experiment
- Statistical process control

8.1.4.3 Inspection

8.1.4.4 Failure mode, effect and critical analysis (FMEA)

8.2 Monitoring and Measurement:

8.2.1 Customer Satisfaction:

Multilayer Prototypes has established a system for monitoring information such as product conformity, on time delivery performance, customer satisfaction and/or dissatisfaction. It includes:

8.2.1.1 Handling of customer complaints through the corrective/preventive action system.

8.2.1.2 Employee inputs into the corrective/preventive action system based on perceived customer expectations.

8.2.1.3 Monitoring quality objectives that signal customer satisfaction levels.

8.2.1.4 Direct solicitation of customer needs expectations and satisfaction levels.

8.2.1.5 Any other means available to Multilayer Prototypes.

8.2.2 Internal Audit:

Procedures are documented to plan and implement internal quality audits at planned intervals to verify whether quality activities and related results conform to planned arrangements, including customer contractual requirements, and the requirements of AS-9100 Revision C and to the quality management system requirements established by Multilayer Prototypes, and its effective implementation and maintenance.

8.2.2.1 Internal quality audits are planned and scheduled on the basis of the status and importance of the processes and areas to be audited as well as the results of previous audits. The audit criteria, scope, frequency and methods are documented and defined. Selection of auditors and the conduct of audits ensure objectivity and impartiality of the audit process. Auditors do not audit processes or areas where they have responsibility.

8.2.2.2 Documented procedures define audit responsibilities and requirements for planning and conducting audits, and for reporting the results and maintaining records.

8.2.2.3 Multilayer Prototypes management responsible for the area being audited ensures that actions are taken promptly to eliminate detected nonconformities and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results.

8.2.3 Monitoring and Measurement of Processes:

Multilayer Prototypes applies suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective actions are taken to ensure conformity of the product.

8.2.3.1 In the event of process nonconformity, Multilayer Prototypes

1. Correct the non-conforming process.

2. Evaluate whether the process has resulted in production nonconformity.

3. Determine the effect on other process or product.

4. Identify and control any nonconforming product.

8.2.4 Monitoring and Measurement of Products:

8.2.4.1 Multilayer Prototypes has monitor and measure the characteristic of the product to verify that the product requirements have been met. These test / measurements are carried out at proper stages of the product realization process in accordance with the planned arrangements.

8.2.4.2 Required inspection / testing records are established, maintained and show evidence of conformity with the acceptance criteria.

8.2.4.3 Measurement requirements for product acceptance has been established, documented and maintained by including:

a. Criteria for acceptance and/or rejection

b. Determine sequence of measurement and testing.

c. Required records of the measurement results.

d. Any specific measurement instrument required with their use.

8.2.4.4 All critical items, including key characteristics, are identified, controlled and monitored in accordance with established process.

8.2.4.5 Acceptance criteria for variable/attribute data sampling plans are established and detail in the document procedures and / or quality plan. The sampling plans are justified on the basis of recognized statistical principles as appropriate for use.

8.2.4.6 In planning product realization, Multilayer Prototypes identify the following as appropriate:

8.2.4.6.1 Incoming inspection and testing:
Multilayer Prototypes utilizes receiving inspection and subcontractors certifications as the metrologies to ensure incoming product meets requirements.

8.2.4.6.2 In-process inspection and testing:
Product is inspected / tested in order to verify that specific requirements for the product are met. Required inspection / test and the records to be established are detailed in the production travelers.

8.2.4.6.3 Final inspection and testing:
All final inspection is conducted in accordance with the production travelers and customer documentation. The details process requires that:

1. All associated documentation created and the results are recorded.

2. Final inspection may include accumulation for in-process inspection.

3 Production release and delivery are not implemented until all specified actions have been completed, unless authorized by the customer.

8.2.4.7 Inspection and Test Records:

All testing is recorded and signed-off by the personnel performing the inspection and/or testing to provide evidence the product has been inspected and/or tested.

1. These records show clearly whether the product has passed or failed the inspections and/or tests according to defined acceptance criteria.

2. Traceability exists between the test records, the product tested and the test environment employed.

3. Where the product fails to pass any inspection and/or test, the procedure for control of nonconforming product shall apply.

4. The system provides for the recording of evidence of conformity with the acceptance criteria, where in the sequence measurement and testing operations are performed, record of the measurement results, and type of measurement instruments required and any specific instructions associated with their use.

5. Records indicate the authority responsible for the release of products.

6. For production qualification, the records provide evidence that the product meets the defined requirements.

8.2.4.8 Packaging Verification:

Verification of packaged final product is conducted in accordance with the Career lot number, product code, testing documentation, bill of lading, and packing slip to confirm the correct product, quantity, packaging and delivery information prior to shipment are met.

8.3 Control of Nonconforming Product:

Multilayer Prototypes has established and maintains a documented procedure for control of non-conforming products and/or services to prevent unintended use or delivery. Non conforming product returned by a customer.

8.3.1 The system provides for identifying, recording and reviewing the nature and extent of the nonconformity encountered. When non-conforming product is detected after delivery or use has started, Multilayer Prototypes will take appropriate action regarding the consequences of the non-conformity.

8.3.2 The non-conformance system provides for the review (investigation where required) and disposition of non-conformances as follows:

1. Taking action to eliminate the detected nonconformity

2 Taking acting necessary to contain the nonconformity effect on other processes.

3. Authorizing its use, release or acceptance under concession by relevant authority and, where applicable, by the customer.
4. Taking action to preclude its original intended use or application.

5. Taking action appropriate to the effects of nonconformity when nonconforming product is detected after delivery.

8.3.3 Responsibility and authority for the review and resolving of non-conformities is defined in the system and when required by contract, the proposed use or repair of non-conforming product shall be timely reported for concession to the customer, the end user, regulatory body or other body. The description of any such correction or adjustment, accepted nonconformity, product repair or service modification will be recorded.

8.3.4 When nonconforming product is corrected it shall be subject to re-evaluation to demonstrate conformity to the requirements.

8.3.5 Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, are maintained.

8.3.6 Product dispositioned for scrap shall be permanently marked until physically rendered unusable.

8.4 Analysis of Data:

Multilayer Prototypes determines, collects and analyzes 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. This includes data generated as a result of monitoring and measurement and from other relevant sources. The analysis of data provides information relating to:

8.4.1 Customer Satisfaction

8.4.2 Conformity to product requirements.
8.4.3 Characteristics and trends of processes and products including opportunities for preventive action.

8.4.4 Suppliers

8.5 Improvement:

8.5.1 Continual Improvement:

Multilayer Prototypes continually improves 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. Multilayer Prototypes monitors the implementation activities and evaluate the effectiveness of the results.

8.5.2 Corrective Action:

Corrective actions are appropriate to the effects of the nonconformities encountered. The Corrective Action system procedure includes consideration of the following:

1. Reviewing nonconformities (including customer complaints).
2. Determining the causes of nonconformities.
3. Evaluating the need for action to ensure that nonconformities do not recur.
4. Determining and implementing action needed.
5. Records of the results of action taken.
6. Reviewing corrective action taken.
7. Flowing down corrective action requirement to a supplier when it is determined that the supplier is responsible.
8. Specific actions where timely and effective corrective actions are not achieved.
9. Determined if additional corrective action is required.

8.5.3 Preventative Action:

Preventive actions are appropriate to the effects of the potential problems. Examples or preventive action include risk management, error proofing, failure mode and effect analysis, and information on product problems reported by external sources. The Preventive Action system procedure defines requirements for the following:

1. Determining potential nonconformities and their causes.
2. Evaluating the need for action to prevent occurrence of nonconformities.
3. Determining and implementing action needed.
4. Records of results of action taken.
5. Reviewing preventive action taken.

Attachment A