

Title Multilayer Prototypes Quality Manual		
Document Identification QM	Revision 008	Page 1 of 41

Quality Manual



Multilayer Prototypes

**Compliant to
ISO 9001-2015 / AS9100 Rev D**

This Quality Manual sets forth the quality system policies and Defines compliance with the ISO 9001-2015 SAE AS 9100 REV D requirements.

Reviewed & Dated: ISO Management Representative 10/25/17	Approved & Dated: ISO Management Representative 10/25/17
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UNCONTROLLED IF PRINTED

Title Multilayer Prototypes Quality Manual		
Document Identification QM	Revision 008	Page 2 of 41

Table of Contents

1.0	INTRODUCTION AND SCOPE	5
1.1	SCOPE:	5
1.2	MULTILAYER PROTOTYPES OVERVIEW:	5
1.3	MISSION:.....	5
1.4	CORPORATE QUALITY POLICY:	5
2.0	REFERENCES	6
3.0	DEFINITIONS.....	6
4.0	CONTEXT OF THE ORGANIZATION.....	7
4.1	UNDERSTANDING THE ORGANIZATION AND ITS CONTEXT	7
4.2	UNDERSTANDING THE NEEDS AND EXPECTATIONS OF INTERESTED PARTIES	7
4.3	DETERMINING THE SCOPE OF THE QUALITY MANAGEMENT SYSTEM	8
4.4	QUALITY MANAGEMENT SYSTEM AND ITS PROCESSES	8
5.	LEADERSHIP.....	9
5.1	LEADERSHIP AND COMMITMENT.....	9
5.1.1	<i>General.....</i>	9
5.1.2	<i>Customer Focus</i>	10
5.2	POLICY.....	11
5.2.1	<i>Establishing the Quality Policy</i>	11
5.2.2	<i>Communicating the Quality Policy</i>	11
5.3	ORGANIZATIONAL ROLES, RESPONSIBILITIES, AND AUTHORITIES	11
6.	PLANNING	12
6.1	ACTIONS TO ADDRESS RISKS AND OPPORTUNITIES	12
6.1.2	<i>Multilayer Prototypes plans:</i>	12
6.2	QUALITY OBJECTIVES AND PLANNING TO ACHIEVE THEM	13
6.3	PLANNING OF CHANGES	14
7.	SUPPORT	14
7.1	RESOURCES	14
7.1.1	<i>General.....</i>	14
7.1.2	<i>People.....</i>	14
7.1.3	<i>Infrastructure</i>	14
7.1.4	<i>Environment for the Operation of Processes.....</i>	14
7.1.5	<i>Monitoring and Measuring Resources</i>	15
7.1.6	<i>Organizational Knowledge</i>	16
7.2	COMPETENCE	16
7.3	AWARENESS	16
7.5	DOCUMENTED INFORMATION.....	17
7.5.1	<i>General.....</i>	17
7.5.2	<i>Creating and Updating</i>	17
7.5.3	<i>Control of Documented Information</i>	17
8.	OPERATION	18

UNCONTROLLED IF PRINTED

Title Multilayer Prototypes Quality Manual		
Document Identification QM	Revision 008	Page 3 of 41

8.1 OPERATIONAL PLANNING AND CONTROL.....	18
8.1.1 <i>Operational Risk Management</i>	19
8.1.2 <i>Configuration Management</i>	20
8.1.3 <i>Product Safety</i>	20
8.1.4 <i>Prevention of Counterfeit Parts</i>	20
8.2 REQUIREMENTS FOR PRODUCTS AND SERVICES.....	20
8.2.1 <i>Customer Communication</i>	20
8.2.2 <i>Determining the Requirements for Products and Services</i>	21
8.2.3 <i>Review of the Requirements for Products and Services</i>	21
8.2.4 <i>Changes to Requirements for Products and Services</i>	22
8.3 DESIGN AND DEVELOPMENT OF PRODUCTS AND SERVICES – NON-APPLICABLE (EXCLUDED).....	22
8.4 CONTROL OF EXTERNALLY PROVIDED PROCESSES, PRODUCTS, AND SERVICES	22
8.4.1 <i>General</i>	22
8.4.2 <i>Type and Extent of Control</i>	23
8.4.3 <i>Information for External Providers</i>	24
8.5 PRODUCTION AND SERVICE PROVISION	25
8.5.1 <i>Control of Production and Service Provision</i>	25
8.5.2 <i>Identification and Traceability</i>	27
8.5.3 <i>Property Belonging to Customers or External Providers</i>	28
8.5.4 <i>Preservation</i>	28
8.5.5 <i>Post-Delivery Activities</i>	29
8.5.6 <i>Control of Changes</i>	29
8.6 RELEASE OF PRODUCTS AND SERVICES	29
8.7 CONTROL OF NONCONFORMING OUTPUTS.....	30
9. PERFORMANCE EVALUATION.....	31
9.1 MONITORING, MEASUREMENT, ANALYSIS, AND EVALUATION	31
9.1.1 <i>General</i>	31
9.1.2 <i>Customer Satisfaction</i>	32
9.1.3 <i>Analysis and Evaluation</i>	32
9.2 INTERNAL AUDIT	32
9.3 MANAGEMENT REVIEW.....	33
9.3.1 <i>General</i>	33
9.3.2 <i>Management Review Inputs</i>	33
9.3.3 <i>Management Review Outputs</i>	34
10. IMPROVEMENT	34
10.1 GENERAL	34
10.2 NONCONFORMITY AND CORRECTIVE ACTION	34
10.3 CONTINUAL IMPROVEMENT	35
ATTACHMENT A.....	36
<i>PROCESS MAP</i>	36
ATTACHMENT B	38
<i>DOCUMENTED INFORMATION</i>	38

UNCONTROLLED IF PRINTED

Title Multilayer Prototypes Quality Manual		
Document Identification QM	Revision 008	Page 4 of 41

ATTACHMENT C **39**
LIST OF PROCEDURES 39

ATTACHMENT D **40**
ORGANIZATIONAL CHART 40

ATTACHMENT E **41**
INTERESTED PARTIES 41

ATTACHMENT F **42**
 REVISION TABLE 42

UNCONTROLLED IF PRINTED

Title Multilayer Prototypes Quality Manual		
Document Identification QM	Revision 008	Page 5 of 41

1.0 INTRODUCTION AND SCOPE

1.1 Scope:

This Quality Manual describes the policies and organization-wide control system of Multilayer Prototypes' Quality Management System ("QMS"). The QMS meets the requirements of ISO 9001;2015/AS9100 Rev D as defined by the International Organization for Standardization and the American National Standards Institute.

The scope of this QMS includes processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements.

Refer to section 4.3 for Multilayer Prototypes' Scope Statement and List of Non-Applicable Clauses.

1.2 Multilayer Prototypes Overview:

The name of this organization is Multilayer Prototypes, Inc. It is located at 2513 Teller Rd, Newbury Park, CA 91320.

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.

1.3 Mission:

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

1.4 Corporate Quality Policy:

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

Quality Policy Statement

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

Title Multilayer Prototypes Quality Manual		
Document Identification QM	Revision 008	Page 6 of 41

2.0 REFERENCES

- 2.1 ANSI/ASQ 9001-2015, Quality Management Systems – Requirements.
- 2.2 AS 9100 Revision D, Quality Management Systems – Requirements.

3.0 DEFINITIONS

- 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 Multilayer Prototypes, which have high risk to being achieved, thus requiring their inclusion in the risk management process.

UNCONTROLLED IF PRINTED

Title Multilayer Prototypes Quality Manual		
Document Identification QM	Revision 008	Page 7 of 41

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 Multilayer Prototypes 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 Multilayer Prototypes needs for its quality management system and which Multilayer Prototypes chooses to have performed by an external party.

4.0 CONTEXT OF THE ORGANIZATION

4.1 Understanding the Organization and Its Context

Multilayer Prototypes determines external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system.

Multilayer Prototypes monitors and reviews information about these external and internal issues.

4.2 Understanding the Needs and Expectations of Interested Parties

Due to their effect or potential effect on Multilayer Prototypes' ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, Multilayer Prototypes determines:

- a. the interested parties that are relevant to the quality management system;
- b. the requirements of these interested parties that are relevant to the quality management system.

Multilayer Prototypes monitors and reviews information about these interested parties and their relevant requirements.

UNCONTROLLED IF PRINTED

Title Multilayer Prototypes Quality Manual		
Document Identification QM	Revision 008	Page 8 of 41

4.3 Determining the Scope of the Quality Management System

Multilayer Prototypes has determined the boundaries (processes as defined in Attachment A) and applicability of the quality management system to establish its scope. When determining this scope, Multilayer Prototypes considers:

- a. the external and internal issues referred to in 4.1;
- b. the requirements of relevant interested parties referred to in 4.2;
- c. the products and services of Multilayer Prototypes.

Multilayer Prototypes applies all the requirements of ISO 9001:2015 and AS9100 Rev D if they are applicable within the determined scope of its quality management system.

Scope Statement: Manufacturing company specializing in quick-turn prototype PCB Fabrication. The scope and boundaries of this QMS includes processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements. Not-applicable to the scope of this manual and the QMS is “Design and Development”, as Multilayer Prototypes does not design products.

Non-Applicable Clauses at Multilayer Prototypes Include:

- Section 8.3 Design and Development of Products and Services

4.4 Quality Management System and Its Processes

4.4.1 Multilayer Prototypes establishes, implements, maintains, and continually improves a quality management system, including the processes needed and their interactions (see attachment A).

Multilayer Prototypes' quality management system also addresses customer and applicable statutory and regulatory quality management system requirements.

Multilayer Prototypes determines the processes needed for the quality management system and their application throughout Multilayer Prototypes, and:

- a. determines the inputs required and the outputs expected from these processes;
- b. determines the sequence and interaction of these processes;
- c. determines and applies the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;

UNCONTROLLED IF PRINTED

Title Multilayer Prototypes Quality Manual		
Document Identification QM	Revision 008	Page 9 of 41

- d. determines the resources needed for these processes and ensures their availability;
- e. assigns the responsibilities and authorities for these processes;
- f. Addresses the risks and opportunities as determined in accordance with the requirements of 6.1 ;
- g. evaluates these processes and implements any changes needed to ensure that these processes achieve their intended results;
- h. improves the processes and the quality management system.

4.4.2 To the extent necessary, Multilayer Prototypes:

- a. maintains documented information to support the operation of its processes;
- b. retains documented information to have confidence that the processes are being carried out as planned.

Multilayer Prototypes establishes and maintains documented information that includes:

- A general description of relevant interested parties (see 4.2 a); the scope of the quality management system, including boundaries and applicability (see 4.3);
- A description of the processes needed for the quality management system and their application throughout Multilayer Prototypes; The sequence and interaction of these processes; Assignment of the responsibilities and authorities for these processes.

5. LEADERSHIP

5.1 Leadership and Commitment

5.1.1 General

Top management demonstrate leadership and commitment with respect to the quality management system by:

- a. taking accountability for the effectiveness of the quality management system;
- b. ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of Multilayer Prototypes;
- c. ensuring the integration of the quality management system requirements

UNCONTROLLED IF PRINTED

Title Multilayer Prototypes Quality Manual		
Document Identification QM	Revision 008	Page 10 of 41

into Multilayer Prototypes' business processes;

- d. promoting the use of the process approach and risk-based thinking;
- e. ensuring that the resources needed for the quality management system are available;
- f. communicating the importance of effective quality management and of conforming to the quality management system requirements;
- g. ensuring that the quality management system achieves its intended results;
- h. engaging, directing, and supporting persons to contribute to the effectiveness of the quality management system; promoting improvement;
- j. supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

5.1.2 Customer Focus

Top management demonstrates leadership and commitment with respect to customer focus by ensuring that:

- a. customer and applicable statutory and regulatory requirements are determined, understood, and consistently met;
- b. the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;
- c. the focus on enhancing customer satisfaction is maintained; product and service conformity and on-time delivery performance are measured and appropriate action is taken if planned results are not, or will not be, achieved

5.1.3 Customer Agreements

Multilayer Prototype shall only accept agreements and instructions in writing (e.g., PO's, Change Orders, etc.). Verbal agreements and instructions will not be construed as approval or authorization.

UNCONTROLLED IF PRINTED

Title Multilayer Prototypes Quality Manual		
Document Identification QM	Revision 008	Page 11 of 41

5.2 Policy

5.2.1 Establishing the Quality Policy

Top management has established, implemented, and maintained a quality policy that:

- a. is appropriate to the purpose and context of Multilayer Prototypes and supports its strategic direction;
- b. provides a framework for setting quality objectives;
- c. includes a commitment to satisfy applicable requirements;
- d. includes a commitment to continual improvement of the quality management system.

Refer to Section 1.4 of this Quality Manual for Multilayer Prototypes' Quality Policy Statement

5.2.2 Communicating the Quality Policy

The quality policy is:

- a. available and maintained as documented information;
- b. communicated, understood, and applied within Multilayer Prototypes;
be available to relevant interested parties, as appropriate.

5.3 Organizational Roles, Responsibilities, and Authorities

Top management ensures that the responsibilities and authorities for relevant roles are assigned, communicated, and understood within Multilayer Prototypes.

Top management has assigned the responsibility and authority for.

- a. ensuring that the quality management system conforms to the requirements of ISO 9001:2015 and AS9100 Rev D.
- b. ensuring that the processes are delivering their intended outputs;
- c. reporting on the performance of the quality management system and on opportunities for improvement;

UNCONTROLLED IF PRINTED

Title Multilayer Prototypes Quality Manual		
Document Identification QM	Revision 008	Page 12 of 41

- d. ensuring the promotion of customer focus throughout Multilayer Prototypes;
- e. ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

Top management has appointed a specific member of Multilayer Prototypes 's management, identified as the management representative, who has the responsibility and authority for oversight of the above requirements.

The management representative has organizational freedom and unrestricted access to top management to resolve quality management issues.

6. PLANNING

6.1 Actions to Address Risks and Opportunities

6.1.1 When planning for the quality management system, Multilayer Prototypes considers the issues referred to in 4.1 and the requirements referred to in 4.2 and determines the risks and opportunities that need to be addressed to:

- a. give assurance that the quality management system can achieve its intended result(s);
- b. enhance desirable effects;
- c. prevent, or reduce, undesired effects;
- d. achieve improvement.

6.1.2 Multilayer Prototypes plans:

- a. actions to address these risks and opportunities;
- b. plans how to:
 - integrate and implement the actions into its quality management system processes (see 4.4);
 - evaluate the effectiveness of these actions.

Actions taken to address risks and opportunities are proportionate to the potential impact on the conformity of products and services.

UNCONTROLLED IF PRINTED

Title Multilayer Prototypes Quality Manual		
Document Identification QM	Revision 008	Page 13 of 41

6.2 Quality Objectives and Planning to Achieve Them

6.2.1 Multilayer Prototypes establishes quality objectives at relevant functions, levels, and processes needed for the quality management system.

The quality objectives are:

- a. consistent with the quality policy;
- b. measurable;
- c. considering applicable requirements;
- d. relevant to conformity of products and services and to enhancement of customer satisfaction;
- e. monitored;
- f. communicated;
- g. updated, as appropriate.

Multilayer Prototypes maintains documented information on the quality objectives;

The Multilayer Prototypes Quality Objectives Are:

- On-time Delivery
- Product Quality
- External Provider On-time Delivery
- External Provider Product Quality
- Customer Satisfaction

6.2.2 When planning how to achieve its quality objectives, Multilayer Prototypes determines:

- a. what will be done;
- b. what resources will be required;
- c. who will be responsible;
- d. when it will be completed;
- e. how the results will be evaluated.

UNCONTROLLED IF PRINTED

Title Multilayer Prototypes Quality Manual		
Document Identification QM	Revision 008	Page 14 of 41

6.3 Planning of Changes

When the Multilayer Prototypes determines the need for changes to the quality management system, the changes are carried out in a planned manner (see 4.4).

Multilayer Prototypes considers:

- a. the purpose of the changes and their potential consequences;
- b. the integrity of the quality management system;
- c. the availability of resources;
- d. the allocation or reallocation of responsibilities and authorities.

7. SUPPORT

7.1 Resources

7.1.1 General

Multilayer Prototypes determines and provides the resources needed for the establishment, implementation, maintenance, and continual improvement of the quality management system.

Multilayer Prototypes considers:

- a. the capabilities of, and constraints on, existing internal resources;
- b. what needs to be obtained from external providers.

7.1.2 People

Multilayer Prototypes determines and provides the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.

7.1.3 Infrastructure

Multilayer Prototypes determines, provides, and maintains the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.

7.1.4 Environment for the Operation of Processes

UNCONTROLLED IF PRINTED

Title Multilayer Prototypes Quality Manual		
Document Identification QM	Revision 008	Page 15 of 41

Multilayer Prototypes determines, provides, and maintains the environment necessary for the operation of its processes and to achieve conformity of products and services.

7.1.5 Monitoring and Measuring Resources

7.1.5.1 General

Multilayer Prototypes determines and provides the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.

Multilayer Prototypes ensures that the resources provided:

- a. are suitable for the specific type of monitoring and measurement activities being undertaken;
- b. are maintained to ensure their continuing fitness for their purpose.

Multilayer Prototypes retains appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

7.1.5.2 Measurement Traceability

When measurement traceability is a requirement, or is considered by Multilayer Prototypes to be an essential part of providing confidence in the validity of measurement results, measuring equipment is:

- a. calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification is retained as documented information;
- b. identified in order to determine their status;
- c. safeguarded from adjustments, damage, or deterioration that would invalidate the calibration status and subsequent measurement results.

Multilayer Prototypes establishes, implements, and maintains a process for the recall of monitoring and measuring equipment requiring calibration or verification

Multilayer Prototypes maintains a register of the monitoring and measuring equipment. The register includes the equipment type, unique identification, location, and the calibration or verification method, frequency, and acceptance criteria.

Calibration or verification of monitoring and measuring equipment is carried out under suitable environmental conditions (see 7.1.4).

UNCONTROLLED IF PRINTED

Title Multilayer Prototypes Quality Manual		
Document Identification QM	Revision 008	Page 16 of 41

Multilayer Prototypes determines if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and takes appropriate action as necessary.

7.1.6 Organizational Knowledge

Multilayer Prototypes determines the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

This knowledge is maintained and be made available to the extent necessary.

When addressing changing needs and trends, Multilayer Prototypes considers its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.

7.2 Competence

Multilayer Prototypes:

- a. determines the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;
- b. ensures that these persons are competent on the basis of appropriate education, training, or experience;
- c. where applicable, takes actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;
- d. retains appropriate documented information as evidence of competence.

7.3 Awareness

Multilayer Prototypes ensures that persons doing work under Multilayer Prototypes's control are aware of:

- a. the quality policy;
- b. relevant quality objectives;
- c. their contribution to the effectiveness of the quality management system, including the benefits of improved performance;
- d. the implications of not conforming with the quality management system requirements;
- e. relevant quality management system documented information and changes thereto;

UNCONTROLLED IF PRINTED

Title Multilayer Prototypes Quality Manual		
Document Identification QM	Revision 008	Page 17 of 41

- f. their contribution to product or service conformity;
- g. their contribution to product safety;
- h. the importance of ethical behavior,

Multilayer Prototypes determines the internal and external communications relevant to the quality management system, including:

- a. on what it will communicate;
- b. when to communicate;
- c. with whom to communicate;
- d. how to communicate;
- e. who communicates.

7.5 Documented Information

7.5.1 General

Multilayer Prototypes's quality management system includes:

- a. documented information required by this International Standard;
- b. documented information determined by Multilayer Prototypes as being necessary for the effectiveness of the quality management system.

7.5.2 Creating and Updating

When creating, and updating documented information, Multilayer Prototypes ensures appropriate:

- a. identification and description (e.g., a title, date, author, or reference number);
- b. format (e.g., language, software version, graphics) and media (e.g., paper, electronic);
- c. review and approval for suitability and adequacy.

7.5.3 Control of Documented Information

7.5.3.1 Documented information required by the quality management system and by ISO 9001:2015 and AS9100 Rev D is controlled to ensure:

- a. it is available and suitable for use, where and when it is needed;

UNCONTROLLED IF PRINTED

Title Multilayer Prototypes Quality Manual		
Document Identification QM	Revision 008	Page 18 of 41

- b. it is adequately protected (e.g., from loss of confidentiality, improper user or loss of integrity).

7.5.3.2 For the control of documented information, Multilayer Prototypes addresses the following activities, as applicable:

- a. distribution, access, retrieval. and use;
- b. storage and preservation, including preservation of legibility;
- c. control of changes (e.g., version control);
- d. retention and disposition;
- e. prevention of the unintended use of obsolete documented information by removal or by application of suitable identification or controls if kept for any purpose.

Documented information of external origin determined by Multilayer Prototypes to be necessary for the planning and operation of the quality management system is identified as appropriate, and be controlled.

Documented information retained as evidence of conformity is protected from unintended alterations.

When documented information is managed electronically, data protection processes is defined (e.g., protection from loss, unauthorized changes, unintended alteration, corruption, physical damage).

8. OPERATION

8.1 Operational Planning and Control

Multilayer Prototypes plans, implements, and controls the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in clause 6, by:

- a. determining the requirements for the products and services;
- b. Establishing criteria for:
 - 1. The processes;
 - 2. The acceptance of products and services;
- c. Determining the resources needed to achieve conformity to the product and service requirements and to meet on-time delivery of product and services;
- d. Implementing control of the processes in accordance with the criteria;

UNCONTROLLED IF PRINTED

Title Multilayer Prototypes Quality Manual		
Document Identification QM	Revision 008	Page 19 of 41

- e. Determining, maintaining, and retaining documented information to the extent necessary:
 - 1. To have confidence that the processes have been carried out as planned;
 - 2. To demonstrate the conformity of products and services to their requirements;
- f. Determining the processes and controls needed to manage critical items, including production process controls when key characteristics have been identified;
- g. Engaging representatives of affected organization functions for operational planning and control;
- h. Determining the process and resources to support the use and maintenance of the products and services;
- i. Determining the products and services to be obtained from external providers;
- j. Establishing the controls needed to prevent the delivery of nonconforming products and services to the customer.

As appropriate to Multilayer Prototypes, customer requirements, and products and services, Multilayer Prototypes plans and manages product and service provision in a structured and controlled manner including scheduled events performed in a planned sequence to meet requirements at acceptable risk, within resource and schedule constraints.

Multilayer Prototypes controls planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

Multilayer Prototypes ensures that outsourced processes are controlled (see 8.4).

Multilayer Prototypes establishes, implements, and maintains a process to plan and control the temporary or permanent transfer of work, to ensure the continuing conformity of the work to requirements. The process ensures that work transfer impacts and risks are managed.

8.1.1 Operational Risk Management

Multilayer Prototypes plans, implements, and controls a process for managing operational risks to the achievement of applicable requirements, which includes as appropriate to Multilayer Prototypes and the products and services:

- a. assignment of responsibilities for operational risk management;

UNCONTROLLED IF PRINTED

Title Multilayer Prototypes Quality Manual		
Document Identification QM	Revision 008	Page 20 of 41

- b. definition of risk assessment criteria (e.g., likelihood, consequences, risk acceptance);
- c. identification, assessment, and communication of risks throughout operations;
- d. identification, implementation, and management of actions to mitigate risks that exceed the defined risk acceptance criteria;
- e. acceptance of risks remaining after implementation of mitigating actions.

8.1.2 Configuration Management

Multilayer Prototypes plans, implements, and controls a process for configuration management as appropriate to Multilayer Prototypes and its products and services in order to ensure the identification and control of physical and functional attributes throughout the product lifecycle. This process includes:

- a. control of product identity and traceability to requirements, including the implementation of identified changes;
- b. assurance that the documented information (e.g., requirements, design, verification, validation and acceptance documentation) is consistent with the actual attributes of the products and services.

8.1.3 Product Safety

Multilayer Prototypes plans, implements, and controls the processes needed to assure product safety during the entire product life cycle, as appropriate to Multilayer Prototypes and the product.

8.1.4 Prevention of Counterfeit Parts

Multilayer Prototypes plans, implements, and controls processes, appropriate to Multilayer Prototypes and the product, for the prevention of counterfeit or suspect counterfeit part use and their inclusion in product(s) delivered to the customer.

8.2 Requirements for Products and Services

8.2.1 Customer Communication

Communication with customers includes:

- a. providing information relating to products and services;
- b. handling enquiries, contracts, or orders, including changes;

UNCONTROLLED IF PRINTED

Title Multilayer Prototypes Quality Manual		
Document Identification QM	Revision 008	Page 21 of 41

- c. obtaining customer feedback relating to products and services, including customer complaints;
- d. handling or controlling customer property;
- e. establishing specific requirements for contingency actions, when relevant.
- f. notifying customers if 100% of the manufacturing process of an order will be performed by an external provider.

8.2.2 Determining the Requirements for Products and Services

When determining the requirements for the products and services to be offered to customers, Multilayer Prototypes ensures that:

- a. the requirements for the products and services are defined including:
 - 1. any applicable statutory and regulatory requirements;
 - 2. those considered necessary by Multilayer Prototypes;
- b. Multilayer Prototypes can meet the claims for the products and services it offers;
- c. special requirements of the products and services are determined;
- d. operational risks (e.g., new technology, ability and capacity to provide, short delivery time frame) have been identified.

8.2.3 Review of the Requirements for Products and Services

8.2.3.1 Multilayer Prototypes ensures that it has the ability to meet the requirements for products and services to be offered to customers. Multilayer Prototypes conducts a review before committing to supply products and services to the customer, which includes:

- a. requirements specified by the customer, including the requirements for delivery and post-delivery activities;
- b. requirements not stated by the customer, but necessary for the specified or intended use, when known;
- c. requirements specified by Multilayer Prototypes;
- d. statutory and regulatory requirements applicable to the products and services;
- e. contract or order requirements differing from those previously expressed.

This review is coordinated with applicable functions of Multilayer Prototypes.

UNCONTROLLED IF PRINTED

Title Multilayer Prototypes Quality Manual		
Document Identification QM	Revision 008	Page 22 of 41

If upon review Multilayer Prototypes determines that some customer requirements cannot be met or can only partially be met, Multilayer Prototypes negotiates a mutually acceptable requirement with the customer.

Multilayer Prototypes ensures that contract or order requirements differing from those previously defined are resolved.

The customer requirements are confirmed by Multilayer Prototypes before acceptance, when the customer does not provide a documented statement of their requirements.

8.2.3.2 Multilayer Prototypes retains documented information, as applicable:

- a. on the results of the review;
- b. on any new requirements for the products and services.

8.2.4 Changes to Requirements for Products and Services

Multilayer Prototypes ensures that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

8.3 Design and Development of Products and Services – Non-applicable (excluded)

8.4 Control of Externally Provided Processes, Products, and Services

8.4.1 General

Multilayer Prototypes ensures that externally provided processes, products, and services conform to requirements.

Multilayer Prototypes is responsible for the conformity of all externally provided processes, products, and services, including from sources defined by the customer.

Multilayer Prototypes ensures, when required, that customer-designated or approved external providers, including process sources (e.g., special processes), are used, Multilayer Prototypes identifies and manages the risks associated with the external provision of processes, products, and services, as well as the selection and use of external providers,

Multilayer Prototypes requires that external providers apply appropriate controls to their direct and sub-tier external providers, to ensure that requirements are met.

UNCONTROLLED IF PRINTED

Title Multilayer Prototypes Quality Manual		
Document Identification QM	Revision 008	Page 23 of 41

Multilayer Prototypes determines the controls to be applied to externally provided processes, products, and services when:

- a. products and services from external providers are intended for incorporation into Multilayer Prototypes's own products and services;
- b. products and services are provided directly to the customer(s) by external providers on behalf of Multilayer Prototypes;
- c. a process, or part of a process, is provided by an external provider as a result of a decision by Multilayer Prototypes.

Multilayer Prototypes determines and applies criteria for the evaluation, selection, monitoring of performance, and reevaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. Multilayer Prototypes retains documented information of these activities and any necessary actions arising from the evaluations.

8.4.1.1 Multilayer Prototypes:

- a. defines the process, responsibilities, and authority for the approval status decision, changes of the approval status, and conditions for a controlled use of external providers depending on their approval status;
- b. maintains a register of its external providers that includes approval status (e.g., approved, conditional, disapproved) and the scope of the approval (e.g., product type, process family);
- c. periodically reviews external provider performance including process, product and service conformity, and on-time delivery performance;
- d. defines the necessary actions to take when dealing with external providers that do not meet requirements;
- e. defines the requirements for controlling documented information created by and/or retained by external providers.

8.4.2 Type and Extent of Control

Multilayer Prototypes ensures that externally provided processes, products, and services do not adversely affect Multilayer Prototypes's ability to consistently deliver conforming products and services to its customers.

Multilayer Prototypes:

- a. ensures that externally provided processes remain within the control of its quality management system;
- b. defines both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;

UNCONTROLLED IF PRINTED

Title Multilayer Prototypes Quality Manual		
Document Identification QM	Revision 008	Page 24 of 41

- c. takes into consideration:
 - 1. the potential impact of the externally provided processes, products, and services on Multilayer Prototypes's ability to consistently meet customer and applicable statutory and regulatory requirements;
 - 2. the effectiveness of the controls applied by the external provider;
 - 3. the results of the periodic review of external provider performance;
- d. determines the verification, or other activities, necessary to ensure that the externally provided processes, products, and services meet requirements.

Verification activities of externally provided processes, products, and services are performed according to the risks identified by Multilayer Prototypes. These include inspection or periodic testing, as applicable, when there is high risk of nonconformities including counterfeit parts

When externally provided, product is released for production use pending completion of all required verification activities, it is identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.

When Multilayer Prototypes delegates verification activities to the external provider, the scope and requirements for delegation are defined and a register of delegations are maintained.

Multilayer Prototypes periodically monitors the external provider's delegated verification activities.

When external provider test reports are utilized to verify externally provided products, Multilayer Prototypes implements a process to evaluate the data in the test reports to confirm that the product meets requirements. When a customer or organization has identified raw material as a significant operational risk (e.g., critical items), Multilayer Prototypes implements a process to validate the accuracy of test reports.

8.4.3 Information for External Providers

Multilayer Prototypes ensures the adequacy of requirements prior to their communication to the external provider.

Multilayer Prototypes communicates to external providers its requirements for:

- a. the processes, products, and services to be provided including the identification of relevant technical data (e.g., specifications, drawings, process requirements, work instructions);
- b. the approval of:
 - 1. products and services;
 - 2. methods, processes, and equipment;
 - 3. the release of products and services;

UNCONTROLLED IF PRINTED

Title Multilayer Prototypes Quality Manual		
Document Identification QM	Revision 008	Page 25 of 41

- c. competence, including any required qualification of persons;
- d. the external providers' interactions with Multilayer Prototypes;
- e. control and monitoring of the external providers' performance to be applied by Multilayer Prototypes;
- f. verification or validation activities that Multilayer Prototypes, or its customer, intends to perform at the external provider's premises;
- g. design and development control;
- h. special requirements, critical items, or key characteristics;
- i. test, inspection, and verification (including production process verification);
- j. the use of statistical techniques for product acceptance and related instructions for acceptance by Multilayer Prototypes;
- k. the need to:
 - implement a quality management system;
 - use customer-designated or approved external providers, including sources (e.g., special processes);
 - notify Multilayer Prototypes of nonconforming processes, products, or services and obtain approval for their disposition; prevent the use of counterfeit parts (see 8.1.4);
 - notify Multilayer Prototypes of changes to processes, products, or services, including changes of their external providers or location of manufacture, and obtain Multilayer Prototypes's approval; flow down to external providers applicable requirements including customer requirements; provide test specimens for design approval, inspection/verification, investigation, or auditing; retain documented information, including retention periods and disposition requirements;
- l. the right of access by Multilayer Prototypes, their customer, and regulatory authorities to the applicable areas of facilities and to applicable documented information, at any level of the supply chain;
- m. ensuring that persons are aware of:
 - their contribution to product or service conformity;
 - their contribution to product safety;
 - the importance of ethical behavior.

8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision

Multilayer Prototypes implements production and service provisions under controlled conditions.

Controlled conditions include, as applicable:

- a. the availability of documented information that defines:
 - 1. the characteristics of the products to be produced, the services to

UNCONTROLLED IF PRINTED

Title		
Multilayer Prototypes Quality Manual		
Document Identification	Revision	Page
QM	008	26 of 41

- be provided, or the activities to be performed;
 - 2. the results to be achieved;
 - b. the availability and use of suitable monitoring and measuring resources;
 - c. the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;
 - 1. ensuring that documented information for monitoring and measurement activity for product acceptance includes:
 - criteria for acceptance and rejection; where in the sequence verification operations are to be performed; measurement results to be retained (at a minimum an indication of acceptance or rejection);
 - any specific monitoring and measurement equipment required and instructions associated with their use;
 - 2. ensuring that when sampling is used as a means of product acceptance, the sampling plan is justified on the basis of recognized statistical principles and appropriate for use (i.e., matching the sampling plan to the criticality of the product and to the process capability).
 - d. the use of suitable infrastructure and environment for the operation of processes;
 - e. the appointment of competent persons, including any required qualification;
 - f. the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;
 - g. the implementation of actions to prevent human error;
 - h. the implementation of release, delivery. and post-delivery activities;
 - i. the establishment of criteria for workmanship (e.g., written standards, representative samples, illustrations);
 - j. the accountability for all products during production (e.g., parts quantities, split orders, nonconforming product);
 - k. the control and monitoring of identified critical items, including key characteristics, in accordance with established processes;
 - l. the determination of methods to measure variable data (e.g., tooling, on-machine probing, inspection equipment);
 - m. the identification of in-process inspection/verification points when adequate verification of conformity cannot be performed at later stages;
 - n. the availability of evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized;
 - o. the provision for the prevention, detection, and removal of foreign objects;
 - p. the control and monitoring of utilities and supplies (e.g., water, compressed air, electricity, chemical products) to the extent they affect conformity to product requirements (see 7.1.3);
 - q. the identification and recording of products released for subsequent production

UNCONTROLLED IF PRINTED

Title Multilayer Prototypes Quality Manual		
Document Identification QM	Revision 008	Page 27 of 41

use pending completion of all required measuring and monitoring activities, to allow recall and replacement if it is later found that the product does not meet requirements.

8.5.1.1 Control of Equipment, Tools, and Software Programs

Equipment, tools, and software programs used to automate, control, monitor, or measure production processes are validated prior to final release for production and are maintained.

Storage requirements are defined for production equipment or tooling in storage including any necessary periodic preservation or condition checks.

8.5.1.2 Validation and Control of Special Processes

For processes where the resulting output cannot be verified by subsequent monitoring or measurement, Multilayer Prototypes establishes arrangements for these processes including, as applicable:

- a. definition of criteria for the review and approval of the processes;
- b. determination of conditions to maintain the approval;
- c. approval of facilities and equipment;
- d. qualifications of persons;
- e. use of specific methods and procedures for implementation and monitoring the processes;
- f. requirements for documented information to be retained.

8.5.1.3 Production Process Verification

Multilayer Prototypes implements production process verification activities to ensure the production process can produce products that meet requirements.

Multilayer Prototypes uses a representative item from the first production run of a new part or assembly to verify that the production processes, production documentation, and tooling are able to produce parts and assemblies that meet requirements. This activity is repeated when changes occur that invalidate the original results (e.g., engineering changes, production process changes, tooling changes).

Multilayer Prototypes retains documented information on the results of production process verification.

8.5.2 Identification and Traceability

UNCONTROLLED IF PRINTED

Title Multilayer Prototypes Quality Manual		
Document Identification QM	Revision 008	Page 28 of 41

Multilayer Prototypes uses suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

Multilayer Prototypes maintains the identification of the configuration of the products and services in order to identify any differences between the actual configuration and the required configuration.

Multilayer Prototypes identifies the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), Multilayer Prototypes establishes controls for the media.

Multilayer Prototypes controls the unique identification of the outputs when traceability is a requirement, and retains the documented information necessary to enable traceability.

8.5.3 Property Belonging to Customers or External Providers

Multilayer Prototypes exercises care with property belonging to customers or external providers while it is under Multilayer Prototypes's control or being used by Multilayer Prototypes.

Multilayer Prototypes identifies, verifies, protects, and safeguards customers' or external providers' property provided for use or incorporation into the products and services.

When the property of a customer or external provider is lost, damaged, or otherwise found to be unsuitable for use, Multilayer Prototypes reports this to the customer or external provider and retain documented information on what has occurred.

8.5.4 Preservation

Multilayer Prototypes preserves the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

Preservation of outputs include, when applicable in accordance with specifications and applicable statutory and regulatory requirements, provisions for:

- a. cleaning;
- b. prevention, detection, and removal of foreign objects;
- c. special handling and storage for sensitive products;
- d. marking and labeling, including safety warnings and cautions;
- e. shelf life control and stock rotation;
- f. special handling and storage for hazardous materials.

UNCONTROLLED IF PRINTED

Title Multilayer Prototypes Quality Manual		
Document Identification QM	Revision 008	Page 29 of 41

8.5.5 Post-Delivery Activities

Multilayer Prototypes meets requirements for post-delivery activities associated with the products and services.

In determining the extent of post-delivery activities that are required, Multilayer Prototypes considers:

- a. statutory and regulatory requirements;
- b. the potential undesired consequences associated with its products and services;
- c. the nature, use, and intended lifetime of its products and services;
- d. customer requirements;
- e. customer feedback;
- f. collection and analysis of in-service data (e.g., performance, reliability, lessons learned);
- g. control, updating, and provision of technical documentation relating to product use, maintenance, repair, and overhaul;
- h. controls required for work undertaken external to Multilayer Prototypes (e.g., off-site work);
- i. product/customer support (e.g., queries, training, warranties, maintenance, replacement parts, resources, obsolescence).

When problems are detected after delivery, Multilayer Prototypes takes appropriate action including investigation and reporting.

8.5.6 Control of Changes

Multilayer Prototypes reviews and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.

Persons authorized to approve production or service provision changes are identified.

Multilayer Prototypes retains documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

8.6 Release of Products and Services

Multilayer Prototypes implements planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.

The release of products and services to the customer do not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a

UNCONTROLLED IF PRINTED

Title Multilayer Prototypes Quality Manual		
Document Identification QM	Revision 008	Page 30 of 41

relevant authority and, as applicable, by the customer.

Multilayer Prototypes retains documented information on the release of products and services. The documented information includes:

- a. evidence of conformity with the acceptance criteria;
- b. traceability to the person(s) authorizing the release.

When required to demonstrate product qualification, Multilayer Prototypes ensures that retained documented information provides evidence that the products and services meet the defined requirements.

Multilayer Prototypes ensures that all documented information required to accompany the products and services are present at delivery.

8.7 Control of Nonconforming Outputs

8.7.1 Multilayer Prototypes ensures that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

Multilayer Prototypes takes appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This also applies to nonconforming products and services detected after delivery of products. during or after the provision of services.

Multilayer Prototypes's nonconformity control process is maintained as documented information including the provisions for:

- Defining the responsibility and authority for the review and disposition of nonconforming outputs and the process for approving persons making these decisions;
- Taking actions necessary to contain the effect of the nonconformity on other processes, products or services;
- Timely reporting of nonconformities affecting delivered products and services to the customer and to relevant interested parties;
- Defining corrective actions for nonconforming products and services detected after delivery, as appropriate to their impacts.

Multilayer Prototypes deals with nonconforming outputs in one or more of the following ways:

- a. correction;
- b. segregation, containment, return, or suspension of provision of products and services;
- c. informing the customer;
- d. obtaining authorization for acceptance under concession by a relevant authority

UNCONTROLLED IF PRINTED

Title Multilayer Prototypes Quality Manual		
Document Identification QM	Revision 008	Page 31 of 41

and, when applicable, by the customer.

Dispositions of use-as-is or repair for the acceptance of nonconforming products is only implemented:

- After approval by an authorized representative of Multilayer Prototypes responsible for design or by persons having delegated authority from the design organization;
- After authorization by the customer, if the nonconformity results in a departure from the contract requirements.

Product dispositioned for scrap are conspicuously and permanently marked, or positively controlled, until physically rendered unusable.

Counterfeit, or suspect counterfeit, parts are controlled to prevent reentry into the supply chain.

Conformity to the requirements are verified when nonconforming outputs are corrected

8.7.2 Multilayer Prototypes retains documented information that:

- a. describes the nonconformity;
- b. describes the actions taken;
- c. describes any concessions obtained;
- d. identifies the authority deciding the action in respect of the nonconformity.

9. PERFORMANCE EVALUATION

9.1 Monitoring, Measurement, Analysis, and Evaluation

9.1.1 General

Multilayer Prototypes determines:

- a. what needs to be monitored and measured;
- b. the methods for monitoring, measurement, analysis, and evaluation needed to ensure valid results;
- c. when the monitoring and measuring is performed;
- d. when the results from monitoring and measurement are analyzed and evaluated.

Multilayer Prototypes evaluates the performance and the effectiveness of the quality management system.

UNCONTROLLED IF PRINTED

Title Multilayer Prototypes Quality Manual		
Document Identification QM	Revision 008	Page 32 of 41

Multilayer Prototypes retains appropriate documented information as evidence of the results.

9.1.2 Customer Satisfaction

Multilayer Prototypes monitors customers' perceptions of the degree to which their needs and expectations have been fulfilled. Multilayer Prototypes determines the methods for obtaining, monitoring, and reviewing this information.

Information to be monitored and used for the evaluation of customer satisfaction includes, but is not limited to, product and service conformity, on-time delivery performance, customer complaints, and corrective action requests. Multilayer Prototypes develops and implements plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results.

9.1.3 Analysis and Evaluation

Multilayer Prototypes analyzes and evaluates appropriate data and information arising from monitoring and measurement.

The results of analysis are used to evaluate:

- a. conformity of products and services;
- b. the degree of customer satisfaction;
- c. the performance and effectiveness of the quality management system;
- d. if planning has been implemented effectively;
- e. the effectiveness of actions taken to address risks and opportunities; the performance of external providers;
- f. the need for improvements to the quality management system.

9.2 Internal Audit

9.2.1 Multilayer Prototypes conducts internal audits at planned intervals to provide information on whether the quality management system;

- a. Conforms to:
 1. Multilayer Prototypes's own requirements for its quality management system;
 2. The requirements of this International Standard.
- b. Is effectively implemented and maintained.

9.2.2 Multilayer Prototypes:

UNCONTROLLED IF PRINTED

Title Multilayer Prototypes Quality Manual		
Document Identification QM	Revision 008	Page 33 of 41

- a. plans, establishes, implements, and maintains an audit program(s) including the frequency, methods, responsibilities, planning requirements, and reporting, taking into consideration the importance of the processes concerned, changes affecting Multilayer Prototypes, and the results of previous audits;
- b. defines the audit criteria and scope for each audit;
- c. selects auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
- d. ensures that the results of the audits are reported to relevant management;
- e. takes appropriate correction and corrective actions without undue delay;
- f. retains documented information as evidence of the implementation of the audit program and the audit results.

9.3 Management Review

9.3.1 General

Top management reviews Multilayer Prototypes's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness, and alignment with the strategic direction of Multilayer Prototypes.

9.3.2 Management Review Inputs

The management review is planned and carried out takes into consideration:

- a. the status of actions from previous management reviews;
- b. changes in external and internal issues that are relevant to the quality management system;
- c. information on the performance and effectiveness of the quality management system, including trends in:
 - 1. Customer satisfaction and feedback from relevant interested parties;
 - 2. The extent to which quality objectives have been met;
 - 3. Process performance and conformity of products and services;
 - 4. Nonconformities and corrective actions;
 - 5. Monitoring and measurement results;
 - 6. Audit results;
 - 7. The performance of external providers;
 - 8. On-time delivery performance;
- d. the adequacy of resources;
- e. the effectiveness of actions taken to address risks and opportunities (see 6.1);
- f. opportunities for improvement.

UNCONTROLLED IF PRINTED

Title Multilayer Prototypes Quality Manual		
Document Identification QM	Revision 008	Page 34 of 41

9.3.3 Management Review Outputs

The outputs of the management review include decisions and actions related to:

- a. opportunities for improvement;
- b. any need for changes to the quality management system;
- c. resource needs;
- d. risks identified.

Multilayer Prototypes retains documented information as evidence of the results of management reviews.

10. IMPROVEMENT

10.1 General

Multilayer Prototypes determines and selects opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction.

These include:

- a. improving products and services to meet requirements as well as to address future needs and expectations;
- b. correcting, preventing, or reducing undesired effects;
- c. improving the performance and effectiveness of the quality management system.

10.2 Nonconformity and Corrective Action

10.2.1 When a nonconformity occurs, including any arising from complaints, Multilayer Prototypes:

- a. react to the nonconformity and, as applicable:
 1. Take action to control and correct it;
 2. Deal with the consequences;
- b. evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
 1. Reviewing and analyzing the nonconformity;
 2. Determining the causes of the nonconformity, including, as applicable, those related to human factors;
 3. Determining if similar nonconformance's exist, or could potentially occur;

UNCONTROLLED IF PRINTED

Title Multilayer Prototypes Quality Manual		
Document Identification QM	Revision 008	Page 35 of 41

- c. implement any action needed;
- d. review the effectiveness of any corrective action taken;
- e. update risks and opportunities determined during planning, if necessary;
- f. make changes to the quality management system, if necessary;
- g. flow down corrective action requirements to an external provider when it is determined that the external provider is responsible for the nonconformity;
- h. take specific actions when timely and effective corrective actions are not achieved.

Corrective actions are appropriate to the effects of the nonconformities encountered. Multilayer Prototypes maintains documented information that defines the nonconformity and corrective action management processes.

10.2.2 Multilayer Prototypes retains documented information as evidence of:

- a. the nature of the nonconformities and any subsequent actions taken;
- b. the results of any corrective action.

10.3 Continual Improvement

Multilayer Prototypes continually improves the suitability, adequacy, and effectiveness of the quality management system.

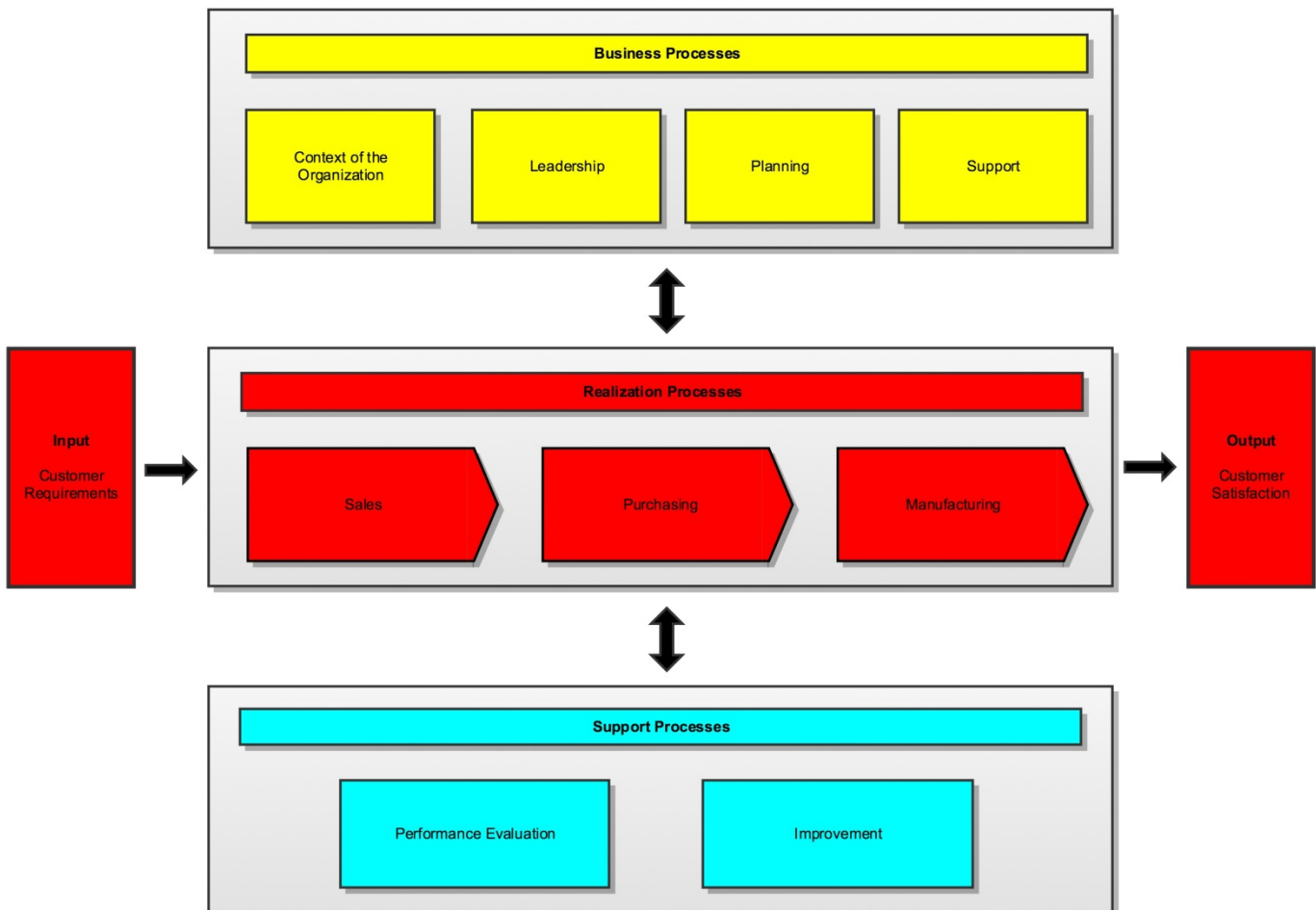
Multilayer Prototypes considers the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that need to be addressed as part of continual improvement.

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

Title Multilayer Prototypes Quality Manual		
Document Identification QM	Revision 008	Page 36 of 41

Attachment A

Process Map



*See Key Processes Matrix Below:

UNCONTROLLED IF PRINTED

Title Multilayer Prototypes Quality Manual		
Document Identification QM	Revision 008	Page 37 of 41

Annex A	Key Processes Matrix					
Process:	Input:	Criteria & Methods:	Resources:	Outputs:	Metrics:	Responsibility & Authority:
Sales	-Customer Requirements -Sales Literature -Pricing	-Provide Specifications -Prepare Quotes -Answer Customer Inquires -Take Orders -Review Orders -Send to Purchasing / Manufacturing	-MRP/ERP Software -Telephone Communication -Company Website -Marketing Support	-Customer Orders -Clearly Defined Requirements	-On-time delivery -Product Quality	Dara
Purchasing	-Requirements from all functions -Pricing Information -Historical Supplier Performance	-Qualify Suppliers -Monitor Supplier Performance -Process Purchase Orders -Maintain Approved Supplier List -Improve Supplier Performance	-ERP Software -Internet for Supplier Research -Approved Supplier List -Supplier Performance Data	-Purchased Product -Data on Supplier Performance	-Supplier On-time Delivery -Supplier Product Quality	Dara
Manufacturing	-Product Specifications -Purchased Suppliers & Materials	-Machining -Assembly -Finishing (If applicable) -Inspection and testing	-Travelers/Work Order -Personnel -QC Devices -Machines	-Final Product -Test Data	-Product Quality	Dara

UNCONTROLLED IF PRINTED

Title Multilayer Prototypes Quality Manual		
Document Identification QM	Revision 008	Page 38 of 41

Attachment B

Documented Information

<u>AS9100 Rev D Section</u>	<u>Description</u>	<u>Documented Information</u>
4.3	Quality Management System Scope	Quality Manual
4.4.2	Description of Interested Parties	Quality Manual
5.2.2	Quality Policy	Quality Manual
6.2.1	Quality Objectives	QM & Mgmt Review
7.1.5.1/2	Calibration	QP-7.5.1.2
7.2	Job Descriptions and Performance Review	H. R. Documents
7.5.3.1	Document Control including External Docs.	QP-7.5.3
7.5.3.2	Control of Records	QP-7.5.3
8.1	Planning and Control	Work Orders/Travelers
8.2.3.2	Contract Review	QP-8.3.3.2
8.4	Evaluation and Control of External Providers	QP-8.4.1
8.5.1	Control of Production & Service Provision	Prints, Work orders, travelers
8.5.2	Identification and Traceability	Q.M.
8.5.3	Customer Property	Q.M.
8.6	Release of Products/Services	Work Orders, Travelers, C of C
8.7.1	Nonconformity Control Process	QP-8.7.1
9.2.2	Internal Audit	QP-9.2.2
9.3.3	Management Review Meeting	QP-9.3, Meeting Minutes
10.2.2	Nonconformity and Corrective Action	QP-10.2.1, CAPA Log

UNCONTROLLED IF PRINTED

Title Multilayer Prototypes Quality Manual		
Document Identification QM	Revision 008	Page 39 of 41

Attachment C

List of Procedures

QP-4.4.1 Risk Management

QP-7.3 Competence, Awareness and Training

QP-7.5.1.2 Control of Monitoring and Measuring Devices and Production Equipment

QP-7.5.3 Document and Record Control

QP-8.1.4 Fraudulent Counterfeit Parts Control Plan

QP-8.3.3.2 Review of Requirements Related to Product

QP-8.4.1 Purchasing Process and Information

QP-8.7.1 Control of Nonconforming Product

QP-9.1.2 Customer Satisfaction

QP-9.2.2 Internal Audit

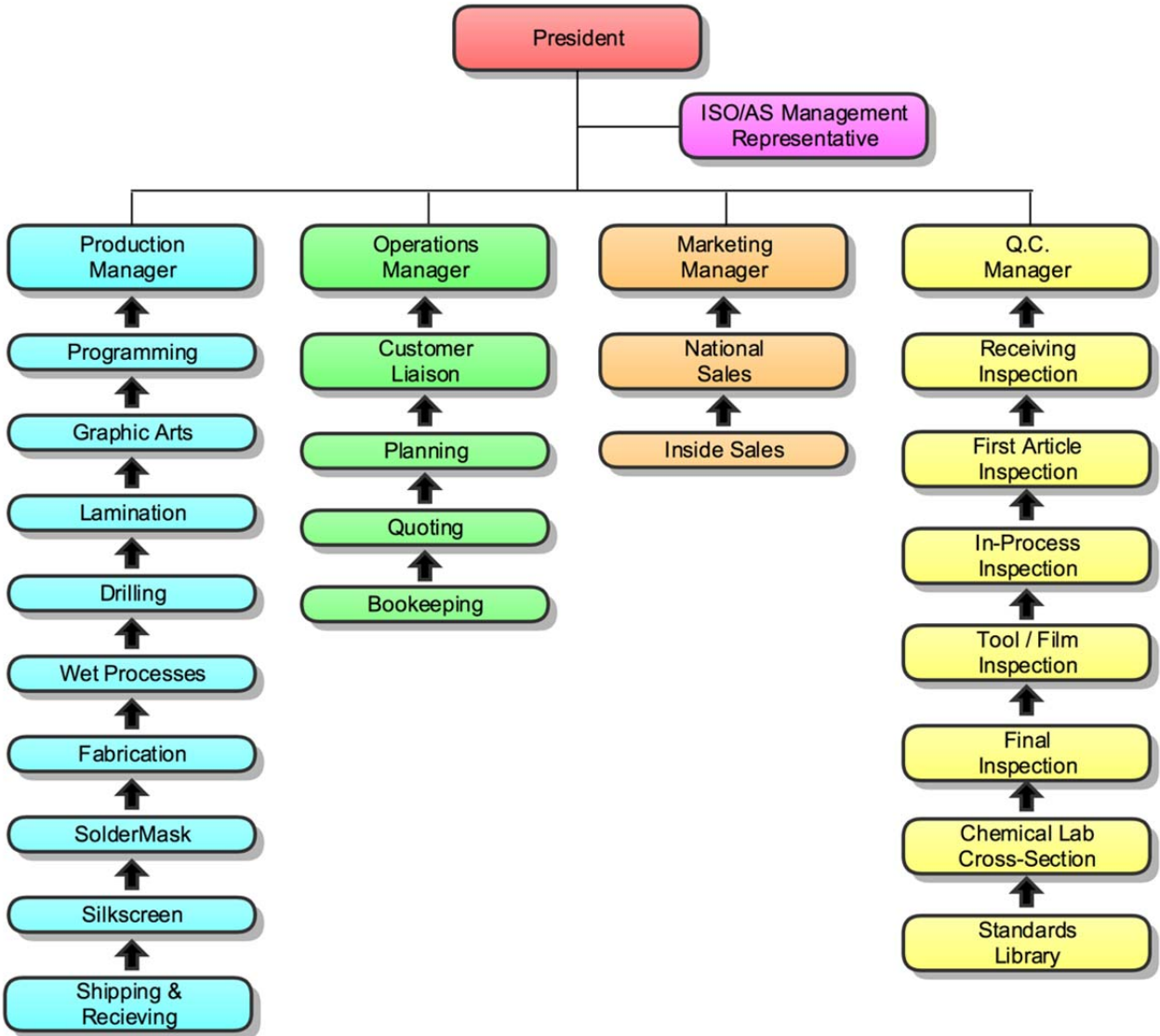
QP-9.3 Management Review Meeting

QP-10.2.1 Corrective Action

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Attachment D

Organizational Chart



UNCONTROLLED IF PRINTED

Title Multilayer Prototypes Quality Manual		
Document Identification QM	Revision 008	Page 41 of 41

Attachment E

Interested Parties

Interested Party:	Requirements:	QMS Processes
Customers	- Orders accurately taken	- Sales and customer service

UNCONTROLLED IF PRINTED

Title Multilayer Prototypes Quality Manual		
Document Identification QM	Revision 008	Page 42 of 41

	- Products arrive on time - All product specifications met	process - Shipping - Purchasing
Suppliers	- Accurate purchase orders - On-time Delivery - Timely payment of invoices	- Purchasing Process - Receiving
Employees	- Clear instructions and training - Paychecks accurate and on time - Proper work environment - Awareness of QMS	- Human Resources Process
Managers	- Current information for decision making - Availability of resources	- Management Review Process - Reporting on Quality Objectives
Regulatory Bodies	- Regulatory Compliance	- Knowledge of applicable regulations - Regulatory Compliance
Law Enforcement	- Compliance with all laws - Reporting of illegal activities - Ethical Business Practices	- Human Resources Process - Management Practices
Emergency Responders	- Reporting of dangerous substances - Planned approach to emergencies	- Emergency Response - Evacuation Plans

Attachment F

Revision Table

Revision Level	Revision Date	Revised By	Summary of Changes	Approved By	Approval Date
007	10/25/17	WEB	Initial Release Conforming to AS9100 Rev D	D.G.	10/25/17
008	08/02/18	DG	Added verbage per customer request page 20	D.G.	08/02/18

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