



QUALITY MANUAL

D.L. MARTIN Co.

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A handwritten signature in blue ink, reading 'Michael A. White', is positioned above a horizontal line. Below the line, the name 'Michael A. White' and his title 'Director of QA & Engineering' are printed in a bold, black, sans-serif font.

Michael A. White
Director of QA & Engineering

QUALITY POLICY

The D.L. Martin Co. will provide products that consistently meet the quality expectations of our customers.



Todd M. Musso
President & CEO

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Section 1

Scope of Quality Management System (QMS)

1.1 General

This D.L. Martin Co. Quality Manual specifies the requirements for our quality management system, which is in compliance with the requirements of International Standard ISO 9001:2015 and implemented as a means to

- a) demonstrate our ability to consistently provide products that meet customer and applicable statutory and regulatory requirements, and
- b) enhance customer satisfaction through the effective application of our quality management system, including processes for the continual improvement of our system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

To facilitate cross-referencing, the sections of this D.L. Martin Co. Quality Manual are organized according to the clause structure of International Standard ISO 9001:2015. Each clause of ISO 9001:2015 is addressed in the corresponding section of this quality manual. A cross-reference matrix (see Appendix B) is provided to show the correspondence between the sections of this quality manual and the applicable documented procedures in our D.L. Martin Co. Operating Procedures Manual.

This quality manual and our operating procedures are reviewed, updated and controlled under the authority of the Director of QA & Engineering (see OP05-1).

1.2 Boundaries & Applicability

The D.L. Martin Co. Quality Management System (QMS), as described in this quality manual, applies to our manufacturing facility located in Mercersburg, PA and is designed to comply with all applicable requirements of ISO 9001:2015. Our organization is primarily a manufacturer of machined and fabricated metal components and assemblies meeting customer product specifications, but has the engineering capabilities necessary to design products or provide design assistance based on customer product design specifications. Services, as defined by ISO 9000:2015 (Ref. 3.7.7) do not apply to our operation. Our organization provides product warranties, but does not offer after-sales agreements to provide periodic servicing of products.

Section 2

Normative Reference

In establishing the D.L. Martin Co. Quality Management System described in this quality manual, consideration was given to the provisions of the following normative document:

ISO 9000:2015, Quality Management Systems — Fundamentals & Vocabulary

Section 3

Terms & Definitions

For the purposes of this D.L. Martin Co. Quality Manual, the terms and definitions given in Appendix A apply.

Section 4

Context of the Organization

4.1 Understanding the Organization & Its Context

Our organization has determined external and internal issues that are relevant to our purpose and strategic direction and that affect our ability to achieve the intended results of our quality management system.

Our organization monitors and reviews information about these external and internal issues.

4.2 Understanding the Needs & Expectations of Interested Parties

Due to their effect or potential effect on our organization's ability to consistently provide products that meet customer and applicable statutory and regulatory requirements, our organization determined

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

Our organization monitors and reviews information about these interested parties and their relevant requirements.

4.3 Determining the Scope of the QMS

Our organization has determined the boundaries and applicability (see 1.2) of our quality management system to establish its scope.

When determining this scope, our organization considered

- 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 of our organization.

Our organization applies all the requirements of ISO 9001:2015 if they are applicable within the determined scope of our quality management system.

The scope of our quality management system is documented in this quality manual (see Section 1) and the manual is available by accessing our organization's website. The scope states the types of products covered, and provides justification for any requirement of ISO 9001:2015 that our organization determined is not applicable to the scope of our quality management system.

Conformity to ISO 9001:2015 is being claimed considering the requirements determined as not being applicable do not affect our organization's ability or responsibility to ensure the conformity of our products and the enhancement of customer satisfaction.

4.4 Quality Management System & its Processes

4.4.1

Our organization established, implemented, maintains and continually improves our quality management system, including the processes needed and their interactions, in accordance with the requirements of ISO 9001:2015.

Our organization determines the processes needed for our quality management system and their application throughout our organization 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;
- 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 our quality management system.

4.4.2

To the extent necessary, our organization

- a) maintains documented information (see OP01-1 & OP02-1) to support the operation of our processes;
- b) retains documented information (see OP01-1, OP02-1, OP10-1, OP10-2, OP10-3 & OP20-1) to have confidence that our processes are being carried out as planned.

Section 5

Leadership

5.1 Leadership & Commitment

5.1.1 General

Our top management demonstrates leadership and commitment with respect to our quality management system by

- a) taking accountability for the effectiveness of our quality management system (see 9.3);
- b) ensuring our quality policy and quality objectives are established for our quality management system and compatible with the context and strategic direction of our organization (see 5.2);
- c) ensuring the integration of our quality management system requirements into our organization's business processes (see 4.4);
- d) promoting the use of the process approach and risk-based thinking (see 4.4 & 6.1);
- e) ensuring the resources needed for the quality management system are available (see 7.1);
- f) communicating the importance of effective quality management and of conforming to our quality management system requirements (see 7.3, 7.4 & 9.3);
- g) ensuring our quality management system achieves its intended results (see 9.3);
- h) engaging, directing and supporting employees to contribute to the effectiveness of our quality management system (see 7.3, 7.4 & 9.3);
- i) promoting continual improvement (see 7.3, 7.4 & 9.3);
- j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility (see 9.3).

5.1.2 Customer Focus

Our top management demonstrates leadership and commitment with respect to customer focus by ensuring

- a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met (see 8.2.2);
- b) risks and opportunities (see 6.1) that can affect conformity of products and the ability to enhance customer satisfaction (see 9.1.2) are determined and addressed;
- c) focus on enhancing customer satisfaction (see 9.1.2) is maintained.

5.2 Quality Policy

The following quality policy is established by the President & CEO of D.L. Martin Co. considering the purpose and context of our organization and is communicated, understood and applied throughout our organization:

*The D.L. Martin Co. will provide products
that consistently meet the quality expectations
of our customers.*

D.L. Martin Co. operates a quality management system meeting the requirements of ISO 9001:2015 as the means of moving our organization in the strategic direction defined by this quality policy. The policy provides a framework for setting quality objectives in order to continually improve our quality management system, improve our overall performance and enhance “Customer Satisfaction.”

Our mission is to deliver the highest quality products, on time, every time, at world market competitive prices. Our employees strive to identify and eliminate the source of non-value adding waste in our operation as a means of achieving “Continual Improvement in Quality, Cost & Delivery.”

Top management has the responsibility for developing and supporting our quality management system and ensuring it is implemented to meet customer as well as any statutory and regulatory requirements.

The top management of D.L. Martin Co. is committed to the quality management system described in this quality manual and communicates throughout our organization the importance of meeting the requirements specified herein. All of our employees are expected to comply with the requirements of our quality management system as they apply to their respective assignments.

This quality policy is available to interested parties by viewing this quality manual on our website.

5.3 Organizational Roles, Responsibilities & Authorities

Our top management ensures that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization.

The Director of QA & Engineering has the assigned responsibility and authority for

- a) ensuring our quality management system conforms to the requirements of ISO 9001:2015;
- b) ensuring our processes are delivering their intended outputs;
- c) reporting on the performance of our quality management system and on opportunities for improvement (see 10.1) to our top management;
- d) ensuring the promotion of customer focus throughout our organization;
- e) ensuring the integrity of our quality management system is maintained when changes to our quality management system are planned and implemented.

Section 6

Planning

6.1 Actions to Address Risks & Opportunities

6.1.1

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

- a) give assurance that our quality management system can achieve its intended results;
- b) enhance desirable effects;
- c) prevent or reduce undesired effects;
- d) achieve continual improvement.

6.1.2

Our organization plans

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

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

6.2 Quality Objectives & Planning to Achieve Them

6.2.1

Our organization establishes quality objectives at relevant functions, levels and processes needed for our quality management system.

Our quality objectives

- a) are consistent with our quality policy;
- b) are measurable;
- c) take into account applicable requirements;
- d) are relevant to conformity of products and to enhancement of customer satisfaction;
- e) are monitored;
- f) communicated;
- g) updated as appropriate.

Our organization maintains documented information (see OP01-1 & OP02-1) on our quality objectives.

6.2.2

When planning how to achieve our quality objectives, our organization 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.

6.3 Planning of Changes

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

Our organization considers

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

Section 7 **Support**

7.1 Resources

7.1.1 General

Our organization determines and provides the resources needed for the establishment, implementation, maintenance and continual improvement of our quality management system.

Our organization considers

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

7.1.2 People

Our organization determines and provides the people necessary for the effective implementation of our quality management system and for the operation and control of its processes.

7.1.3 Infrastructure

Our organization determines, provides and maintains the infrastructure necessary for the operation of our processes and to achieve conformity of products. Our infrastructure includes, as applicable,

- a) buildings and associated utilities;
- b) equipment, including hardware and software;
- c) transportation resources;
- d) information and communication technology.

7.1.4 Environment for the Operation of Processes

Our organization determines, provides and maintains the environment necessary for the operation of our processes and to achieve conformity of products.

7.1.5 Monitoring & Measuring Resources

7.1.5.1 General

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

Our organization ensures the resources provided

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

Our organization retains appropriate documented information (see OP11-1) as evidence of fitness for purpose of monitoring and measurement resources.

7.1.5.2 Measurement Traceability

When measurement traceability is a requirement, or is considered 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 (see OP11-1);
- b) identified in order to determine its status;
- c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

Our organization 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

Our organization determines the knowledge necessary for the operation of our processes and to achieve conformity of products.

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

When addressing changing needs and trends, our organization considers its current knowledge and determines how to acquire or access any necessary additional knowledge and required updates.

7.2 Competence

Our organization

- a) determines the necessary competence of persons doing work under our control that affects the performance and effectiveness of our quality management system;
- b) ensures those persons are competent on the basis of appropriate education, training and/or experience;
- c) takes appropriate action to acquire the necessary competence and evaluates the effectiveness of the actions taken, where applicable;
- d) retains appropriate documented information (see OP18-1) as evidence of competence.

7.3 Awareness

Our organization ensures that persons doing work under our control are aware of

- a) our quality policy;
- b) relevant quality objectives;
- c) their contribution to the effectiveness of our quality management system, including the benefits of improved performance;
- d) the implications of not conforming with our quality management system requirements.

7.4 Communication

Our organization determines the internal and external communications relevant to our quality management system, including

- a) what to 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

Our organization's quality management system includes

- a) documented information required by ISO 9001:2015 (see 4.3, 4.4.2, 5.2, 6.2.1, 7.1.5.1, 7.1.5.2, 7.2, 7.5.3.2, 8.1, 8.2.3.1, 8.2.3.2, 8.2.4, 8.3.2, 8.3.3, 8.3.4, 8.3.5, 8.3.6, 8.4.1, 8.5.1, 8.5.2, 8.5.3, 8.5.6, 8.6, 8.7.2, 9.1.1, 9.2.2, 9.3.3 & 10.2.2);
- b) documented information determined by our organization as being necessary for the effectiveness of our quality management system (e.g., procedures, work instructions & forms).

The extent of our quality management system documentation depends on

- the type of activities, processes and/or products;
- the complexity of processes and their interactions;
- the competence of personnel.

7.5.2 Creating & Updating

When creating and updating documented information, our organization ensures appropriate

- a) identification and description (e.g., 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 our quality management system and by ISO 9001:2015 (see 7.5.1) is controlled to ensure that it is

- a) available and suitable for use, where and when it is needed;
- b) adequately protected (e.g., from loss of confidentiality, improper use or loss of integrity).

7.5.3.2

For the control of documented information, our organization addresses the following activities, as applicable:

- distribution, access, retrieval and use;
- storage and preservation, including preservation of legibility;
- control of changes (e.g., revision control);
- retention and disposition.

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

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

Section 8 **Operation**

8.1 Operational Planning & Control

Our organization plans, implements and controls the processes (see 4.4) needed to meet the requirements for the provision of products and to implement the actions determined in 6.1-6.3 by

- a) determining the requirements for products;
- b) establishing criteria for
 - 1) the processes;
 - 2) the acceptance of products;
- c) determining the resources needed to achieve conformity to product requirements;
- d) implementing control of processes in accordance with the criteria;
- e) determining, maintaining and retaining documented information (see OP02-1, OP10-1, OP10-2 & OP10-3) to the extent necessary
 - 1) to have confidence that processes have been carried out as planned;
 - 2) to demonstrate conformity of products to their requirements.

The output of this planning is suitable for our organization's operations.

Our organization controls planned changes and reviews the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

Our organization ensures outsourced processes are controlled (see 8.4).

8.2 Requirements for Products

8.2.1 Customer Communication

Communication with customers includes

- a) providing information relating to products;
- b) handling inquiries, contracts or orders, including changes;
- c) obtaining customer feedback relating to products, including customer complaints;
- d) handling or controlling customer property;
- e) establishing specific requirements for contingency actions, when relevant.

8.2.2 Determining the Requirements for Products

When determining requirements for products offered to customers, our organization ensures

- a) the requirements for the products are defined, including
 - 1) any applicable statutory and regulatory requirements;
 - 2) those considered necessary by our organization;
- b) our organization can meet the claims for the products offered.

8.2.3 Review of the Requirements for Products

8.2.3.1

Our organization ensures it has the ability to meet requirements for products offered to customers and conducts a review before committing to supply those products, which includes

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

Contract or order requirements differing from those previously defined are resolved.

Customer requirements are confirmed before acceptance when the customer does not provide a documented statement of their requirements.

8.2.3.2

Our organization retains documented information (see OP03-1), as applicable

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

8.2.4 Changes to Requirements for Products

Our organization ensures relevant documented information is amended, and that relevant persons are made aware of changed requirements, when requirements for products are changed.

8.3 Design & Development of Products

8.3.1 General

Our organization established, implemented and maintains a design and development process that is appropriate to ensure the subsequent provision of products.

8.3.2 Design & Development Planning

In determining the stages and controls for design and development, our organization considers

- a) the nature, duration and complexity of the design and development activities;
- b) the required process stages, including applicable design and development reviews;
- c) the required design and development verification and validation activities;
- d) the responsibilities and authorities involved in the design and development process;
- e) the internal and external resource needs for the design and development of products;
- f) the need to control interfaces between persons involved in the design and development process;
- g) the need for involvement of customers and users in the design and development process;
- h) the requirements for subsequent provision of products;
- i) the level of control expected for the design and development process by customers and other relevant interested parties;
- j) the documented information needed to demonstrate design and development requirements have been met.

8.3.3 Design & Development Inputs

Our organization determines the requirements essential for the specific types of products to be designed and developed and considers

- a) functional and performance requirements;
- b) information derived from previous similar design and development activities;
- c) statutory and regulatory requirements;
- d) standards or codes of practice that our organization has committed to implement;
- e) potential consequences of failure due to the nature of the products.

Inputs are adequate for design and development purposes, complete and unambiguous.

Conflicting design and development inputs are resolved.

Our organization retains documented information (see OP04-1) on design and development inputs.

8.3.4 Design & Development Controls

Our organization applies controls to the design and development process to ensure

- a) the results to be achieved are defined;
- b) reviews are conducted to evaluate the ability of design and development results to meet requirements;
- c) verification activities are conducted to ensure design and development outputs meet input requirements;
- d) validation activities are conducted to ensure the resulting products meet requirements for the specified application or intended use;
- e) any necessary actions are taken on problems determined during the reviews or verification and validation activities;
- f) documented information of these activities is retained (see OP04-1).

8.3.5 Design & Development Outputs

Our organization ensures design and development outputs

- a) meet input requirements;
- b) are adequate for subsequent processes for provision of products;
- c) include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;
- d) specify characteristics of the products that are essential for their intended purpose and their safe and proper provision.

Our organization retains documented information (see OP04-1) on design and development outputs.

8.3.6 Design & Development Changes

Our organization identifies, reviews and controls changes made during, or subsequent to, the design and development of products, to the extent necessary to ensure there are no adverse impacts on conformity to requirements.

Our organization retains documented information (see OP04-1) on

- a) design and development changes;
- b) results of reviews;
- c) authorization of changes;
- d) actions taken to prevent adverse impacts.

8.4 Control of Externally Provided Processes & Products

8.4.1 General

Our organization ensures externally provided processes and products conform to requirements.

Our organization identifies controls to be applied to externally provided processes and products when

- a) products from external providers are intended for incorporation into our organization's own products;
- b) products are provided directly to customers by external providers on our behalf;
- c) a process is provided by an external provider as a result of a decision by our organization.

Our organization 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 in accordance with requirements. Our organization retains documented information (see OP06-1) of these activities and any necessary actions arising from the evaluations.

8.4.2 Type & Extent of Control

Our organization ensures externally provided processes and products do not adversely affect our ability to consistently deliver conforming products to our customers.

Our organization

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

- c) takes into consideration
 - 1) the potential impact of externally provided processes and products on our ability to consistently meet customer and applicable statutory and regulatory requirements;
 - 2) the effectiveness of controls applied by external providers;
- d) determines the verification, or other activities, necessary to ensure externally provided processes and products meet requirements.

8.4.3 Information for External Providers

Our organization ensures the adequacy of requirements prior to their communication to external providers.

Our organization communicates to external providers our requirements for

- a) the processes and products to be provided;
- b) the approval of
 - 1) products;
 - 2) methods, processes and equipment;
 - 3) the release of products;
- c) competence, including any required qualification of persons;
- d) the external providers' interactions with our organization;
- e) control and monitoring of the external providers' performance to be applied by our organization;
- f) verification or validation activities that our organization, or our customer, intends to perform at the external providers' premises.

8.5 Production Provision

8.5.1 Control of Production Provision

Our organization implements production provision 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 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 criteria for control of processes or outputs, and acceptance criteria for products, have been met;
- 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 processes for production provision, where 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.

8.5.2 Identification & Traceability

Our organization uses suitable means to identify outputs when it is necessary to ensure conformity of products.

Our organization identifies the status of outputs with respect to monitoring and measurement requirements throughout production provision.

Our organization controls the unique identification of outputs when traceability is a requirement and retains the documented information (see OP08-1) necessary to enable traceability.

8.5.3 Property Belonging to Customers or External Providers

Our organization exercises care with property belonging to customers or external providers while it is under our control or being used by our organization.

Our organization identifies, verifies, protects and safeguards customer or external provider property provided for use or incorporation into products.

When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, our organization reports this to the customer or external provider and retains documented information (see OP13-1) on what has occurred.

8.5.4 Preservation

Our organization preserves outputs during production provision to the extent necessary to ensure conformity to requirements.

8.5.5 Post-Delivery Activities

Our organization meets requirements for post-delivery activities associated with products.

In determining the extent of post-delivery activities required, our organization considers

- a) statutory and regulatory requirements;
- b) the potential undesired consequences associated with products;
- c) the nature, use and intended lifetime of products;
- d) customer requirements;
- e) customer feedback.

8.5.6 Control of Changes

Our organization reviews and controls changes for production provision to the extent necessary to ensure continuing conformity with requirements.

Our organization retains documented information (see OP02-1) describing the results of the review of changes, the persons authorizing the changes, and any necessary actions arising from the review.

8.6 Release of Products

Our organization implements planned arrangements at appropriate stages to verify product requirements have been met.

Release of products to the customer does not proceed until planned arrangements have been satisfactorily completed unless otherwise approved by a relevant authority and, as applicable, by the customer.

Our organization retains documented information (see OP10-1 & OP10-3) on the release of products including

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

8.7 Control of Nonconforming Outputs

8.7.1

Our organization ensures outputs that do not conform to requirements are identified and controlled to prevent unintended use or delivery.

Our organization takes appropriate action based on the nature of the nonconformity and its effect on the conformity of products. This also applies to nonconforming products detected after delivery of products.

Our organization deals with nonconforming outputs in one or more of the following ways:

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

Conformity to requirements is verified when nonconforming outputs are corrected.

8.7.2

Our organization retains documented information (see OP13-1) that

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

Section 9

Performance Evaluation

9.1 Monitoring, Measurement, Analysis & Evaluation

9.1.1 General

Our organization 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 monitoring and measuring is performed;
- d) when results from monitoring and measurement is analyzed and evaluated.

Our organization evaluates the performance and effectiveness of our quality management system.

Our organization retains appropriate documented information (see OP01-1, OP10-1, OP10-2, OP10-3, OP20-1 & OP20-2) as evidence of the results.

9.1.2 Customer Satisfaction

Our organization monitors customer perception of the degree to which their needs and expectations have been fulfilled and determines the methods for obtaining, monitoring and reviewing this information.

9.1.3 Analysis & Evaluation

Our organization analyzes and evaluates appropriate data and information arising from monitoring and measurement activities.

Results of analysis are used to evaluate

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

9.2 Internal Audits

9.2.1

Our organization conducts internal audits at planned intervals to provide information on whether the quality management system

- a) conforms to
 - 1) our organization's requirements for our quality management system;
 - 2) the requirements of ISO 9001:2015;
- b) is effectively implemented and maintained.

9.2.2

Our organization

- a) plans, establishes, implements and maintains an internal audit program including the frequency, methods, responsibilities, planning requirements and reporting which takes into consideration the importance of the processes concerned, changes affecting our organization and results of previous audits;
- b) defines the audit criteria and scope for each audit;
- c) selects auditors and conducts audits to ensure objectivity and impartiality of the audit process;
- d) ensures results of audits are reported to relevant management;
- e) takes appropriate corrective action without undue delay;
- f) retains documented information (see OP17-1) as evidence of the implementation of our audit program and the audit results.

9.3 Management Review

9.3.1 General

Our top management reviews our quality management system at planned intervals to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of our organization.

9.3.2 Management Review Inputs

Management reviews are planned and carried out taking into consideration

- a) the status of actions from previous management reviews;
- b) changes in external and internal issues relevant to our quality management system;
- c) information on quality management system performance and effectiveness, 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;
 - 4) nonconformities and corrective action;
 - 5) monitoring and measurement results;
 - 6) audit results;
 - 7) the performance of external providers;
- d) the adequacy of resources;
- e) the effectiveness of actions taken to address risks and opportunities (see 6.1);
- f) opportunities for improvement.

9.3.3 Management Review Outputs

Outputs of management reviews include decisions and actions related to

- a) opportunities for improvement;
- b) any need for changes to our quality management system;
- c) resource needs.

Our organization retains documented information (see OP01-1) as evidence of the results of management reviews.

Section 10

Improvement

10.1 General

Our organization determines and selects opportunities for improvement and implements any necessary actions to meet customer requirements and enhance customer satisfaction.

These include

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

10.2 Nonconformity & Corrective Action

10.2.1

When a nonconformity occurs, including any arising from complaints, our organization

- a) reacts to the nonconformity and, as applicable
 - 1) takes action to control and correct it;
 - 2) deals with the consequences;
- b) evaluates the need for action to eliminate the causes 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;
 - 3) determining if similar nonconformities exist or could potentially occur;
- c) implements any action needed;
- d) reviews the effectiveness of any corrective action taken;
- e) updates risks and opportunities determined during planning, if necessary;
- f) makes changes to our quality management system, if necessary.

Corrective actions are appropriate to the effects of nonconformities encountered.

10.2.2

Our organization retains documented information (see OP13-1 & OP14-1) as evidence of

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

10.3 Continual Improvement

Our organization continually improves the suitability, adequacy and effectiveness of our quality management system to enhance performance.

Our organization considers the results of analysis and evaluation, and outputs from management reviews, to determine if there are needs or opportunities to be addressed as part of continual improvement.

Appendix A

Terms & Definitions

Context of the Organization - Combination of internal and external issues that can have an effect on an organization's approach to developing and achieving its quality objectives.

Concession - Permission to use or release products that do not conform to specified requirements.

Continual Improvement - Recurring activity to enhance performance.

Customer Satisfaction - Customer's perception of the degree to which their expectations have been fulfilled.

Documented Information - Information (i.e., documents & records) required to be controlled and maintained by an organization and the medium on which it is contained.

Infrastructure - System of facilities, equipment and services needed for the operation of an organization.

Interested Party - Person or group that can affect or be affected by an organization's decisions or activities related to quality (e.g., customers, suppliers, regulators & employees).

Process - Set of interrelated or interacting activities which transforms inputs into outputs.

Quality - Degree to which a set of inherent characteristics fulfills requirements.

Quality Management System (QMS) - Management system used to manage quality.

Quality Manual - Document specifying requirements of the quality management system of an organization.

Quality Objective - Objective set by an organization consistent with its quality policy.

Quality Policy - Overall intentions and direction of an organization related to quality as formally expressed by the organization's top management.

Release - Permission to proceed to the next stage of a process or the next process.

Requirement - Need or expectation relating to quality that is stated, generally implied or obligatory. Such a need or expectation may be an internally-generated, customer-based or regulatory requirement.

Traceability - Ability to trace the history, application or location of that which is under consideration (e.g., origin of materials and parts, processing history, and distribution and location of products after delivery).

Validation - Confirmation through the provision of objective evidence that requirements for a specific intended use or application have been fulfilled. The term "validated" is used to designate the corresponding status.

Verification - Confirmation through the provision of objective evidence that specified requirements have been fulfilled. The term "verified" is used to designate the corresponding status.

Risk - Effect of uncertainty.

Risks & Opportunities - Potential adverse effects (threats) and potential beneficial effects (opportunities).

Appendix B

Cross-Reference Matrix

QUALITY MANUAL / ISO 9001:2015		OPERATING PROCEDURES
1	Scope of Quality Management System (QMS)	
2	Normative Reference	
3	Terms & Definitions	
4	Context of the Organization	
4.1	Understanding the Organization & Its Context	OP01-1
4.2	Understanding the Needs & Expectations of Interested Parties	OP01-1
4.3	Determining the Scope of the QMS	
4.4	Quality Management System & Its Processes	OP01-1, OP02-1, OP10-1, OP10-2, OP10-3 & OP20-1
5	Leadership	
5.1	Leadership & Commitment	
5.1.1	General	QM00 (4.4, 5.2, 6.1, 7.1, 7.3, 7.4 & 9.3) & OP01-1
5.1.2	Customer Focus	QM00 (6.1, 8.2.2 & 9.1.2) & OP01-1
5.2	Quality Policy	OP01-1
5.3	Organizational Roles, Responsibilities & Authorities	OP01-1
6	Planning	
6.1	Actions to Address Risks & Opportunities	OP01-1, OP02-1, OP06-1, OP13-1, OP14-1 & OP20-1
6.2	Quality Objectives & Planning to Achieve Them	OP01-1 & OP02-1
6.3	Planning of Changes	OP01-1 & OP02-1
7	Support	
7.1	Resources	
7.1.1	General	OP01-1
7.1.2	People	OP01-1
7.1.3	Infrastructure	OP09-1
7.1.4	Environment for the Operation of Processes	OP09-1
7.1.5	Monitoring & Measuring Resources	OP11-1
7.1.6	Organizational Knowledge	OP01-1, OP02-1 & OP09-1
7.2	Competence	OP01-1 & OP18-1
7.3	Awareness	OP01-1 & OP18-1
7.4	Communication	OP01-1
7.5	Documented Information	
7.5.1	General	OP02-1
7.5.2	Creating & Updating	OP05-1, OP05-2, OP05-3 & OP16-1
7.5.3	Control of Documented Information	OP05-1, OP05-2, OP05-3 & OP16-1
8	Operation	
8.1	Operational Planning & Control	OP02-1, OP10-1, OP10-2 & OP10-3
8.2	Requirements for Products	
8.2.1	Customer Communication	OP01-1, OP03-1 & OP14-1
8.2.2	Determining the Requirements for Products	OP03-1 & OP04-1
8.2.3	Review of the Requirements for Products	OP03-1
8.2.4	Changes to Requirements for Products	OP03-1
8.3	Design & Development of Products	
8.3.1	General	OP04-1
8.3.2	Design & Development Planning	OP04-1
8.3.3	Design & Development Inputs	OP04-1
8.3.4	Design & Development Controls	OP04-1
8.3.5	Design & Development Outputs	OP04-1
8.3.6	Design & Development Changes	OP04-1

Appendix B

Cross-Reference Matrix

QUALITY MANUAL / ISO 9001:2015		OPERATING PROCEDURES
8.4	Control of Externally Provided Processes & Products	
8.4.1	General	OP06-1
8.4.2	Type & Extent of Control	OP06-1 & OP10-1
8.4.3	Information for External Providers	OP06-1
8.5	Production Provision	
8.5.1	Control of Production Provision	OP09-1, OP15-1 & OP19-1
8.5.2	Identification & Traceability	OP08-1, OP10-1, OP10-2, OP10-3 & OP12-1
8.5.3	Property Belonging to Customers or External Providers	OP07-1 & OP13-1
8.5.4	Preservation	OP15-1
8.5.5	Post-Delivery Activities	OP01-1 & OP19-1
8.5.6	Control of Changes	OP02-1
8.6	Release of Products	OP10-1, OP10-2, OP10-3, OP20-1 & OP20-2
8.7	Control of Nonconforming Outputs	OP13-1
9	Performance Evaluation	
9.1	Monitoring, Measurement, Analysis & Evaluation	
9.1.1	General	OP01-1, OP10-1, OP10-2, OP10-3, OP20-1 & OP20-2
9.1.2	Customer Satisfaction	OP01-1
9.1.3	Analysis & Evaluation	OP01-1 & OP20-1
9.2	Internal Audits	OP17-1
9.3	Management Review	
9.3.1	General	OP01-1
9.3.2	Management Review Inputs	OP01-1
9.3.3	Management Review Outputs	OP01-1
10	Improvement	
10.1	General	OP01-1
10.2	Nonconformity & Corrective Action	OP13-1, OP14-1 & OP17-1
10.3	Continual Improvement	OP01-1, OP14-1 & OP17-1