

# QUALITY MANAGEMENT SYSTEM MANUAL

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QM 7.5.1-001

## DEL Corporation

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## QUALITY MANAGEMENT SYSTEM - SCOPE

This quality management system document is intended to identify the manner in which the organization, DEL Corporation, addresses and fulfills the specific quality management system requirements of:

- ISO 9001:2015 – Quality Management System – Requirements

This document serves as an organizational guidance document for the integration of a process approach for developing, implementing, and improving the effectiveness of the quality management system. The goal of this document is to provide, at a minimum, the requirements for the development of a quality management system that makes provision for:

- Continual improvement of quality management system processes to consistently provide products and services that meet customer and applicable statutory and regulatory requirements
- Continual improvement of products and/or services offered by the organization and/or required by the customer
- Continual improvement of the product realization (business) processes to improve organizational efficiency and enhance customer satisfaction
- Continual improvement of the product realization (business) process with an emphasis on defect prevention, reducing variation, and minimizing waste
- Demonstrating conformity to specified quality management system requirements

The purpose of the quality management system is to develop and maintain a process and risk based quality management system which promotes continual process, product and organizational improvement while focusing on:

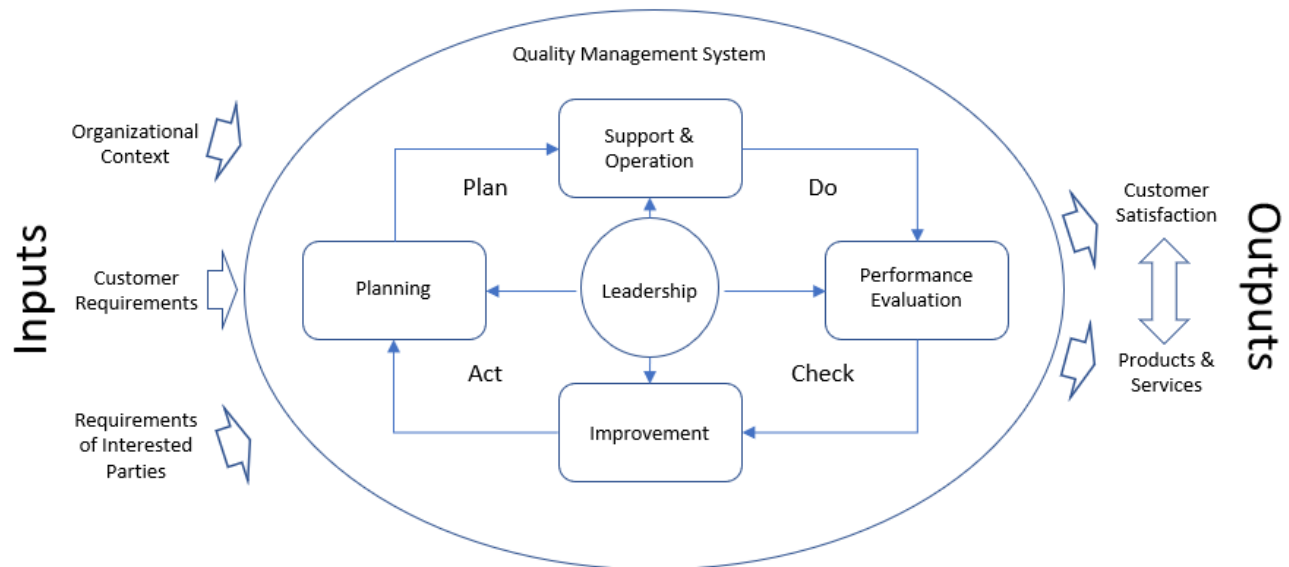
- Meeting customer requirements
- Creating a leadership structure that promotes continual improvement
- Engagement/ownership of the quality management system by organizational personnel
- Implementation and development of the process approach to business operations
- Risk based decision making
- Relationship management of internal and external interested parties

This document has been reviewed and approved by the organization's top management and the management representative with the approvals documented at the end of this manual and in the electronic quality management system.

**This document shall be treated as an uncontrolled document if printed with no documented evidence of approval or retrieved electronically from a location other than the QMS Document Management Module.**

### QUALITY MANAGEMENT SYSTEM – PROCESS APPROACH (PDCA)

The organization shall employ the process approach to quality management which incorporates the PDCA cycle. The PDCA (Plan – Do – Check – Act) cycle allows the organization to develop planned quality management system activities towards efficiently realizing product and enhancing customer satisfaction. The PDCA cycle is represented in the graphic below:



The development and implementation of a process approach-based quality management system is a strategic decision made by the organization's top management. The application of the process approach is to facilitate:

- A more consistent method of determining, understanding, and meeting requirements
- Consideration of quality management system processes in terms of adding value
- Improving the effectiveness of quality management system processes
- Determining process effectiveness based on analysis of data and information

## 4 CONTEXT OF THE ORGANIZATION

### 4.1 Understanding the organization and it's context

The organization has developed a quality management system that enables the it to manage internal and external issues while supporting its strategic direction and meet customer requirements in accordance with planned arrangements. In the context of the organization, the term **issues** refers to events and/or relationship interactions that **may** positively or negatively affect the quality management system. The organization defines internal and external issues as follows:

- Internal Issues: Issues from within the organization that may prevent or facilitate the organizations ability in meeting strategic goals or producing product in accordance with planned quality management system arrangements. Such internal issues include, but may not be limited to, workforce/resource availability, adequate infrastructure, personnel competency, etc.
- External Issues: Issues from outside the organization that may prevent or facilitate the organizations ability in meeting strategic goals or producing product in accordance with planned quality management system arrangements. Such external issues include, but may not be limited to, limited supplier base, shortage based on an increased demand for product/materials, customer change in product requirements or terms of delivery, etc.

The organization monitors, and reviews internal and external issues continually and formally addresses them in the annual management review (QMF 9.3.1-001 Management Review) and report to management (QMF 9.3.3-001 Report to Management).

### 4.2 Determining the needs and expectations of interested parties

The organization has determined that interested parties are people or organizations that have a direct or indirect influence on, may be influenced by, or perceive to be influenced by any activity associated with the quality management system. The organization has determined that interested parties include, but may not be limited to, the following:

- DEL Corporation
- DEL Corporation personnel
- Vendor organizations - product
- Vendor organizations - service
- Customer organizations

The organization monitors, and reviews meeting the needs of interested parties continually and formally addresses them in the annual management review (QMF 9.3.1-001 Management Review) and report to management (QMF 9.3.3-001 Report to Management).

#### **4.3 Determining the scope of the quality management system**

DEL Corporation, referred to as the organization, has implemented a quality management system that considers the following within the scope of the quality management system:

- Internal and external issues
- Requirements of relevant interested parties
- Products and services offered by the organization

The organizations quality management system incorporates the following components:

- Quality Management System Manual
- Quality Management System Procedures (QMSP)
- Quality Management System Documents ( forms, matrices, drawings, etc.)
- Electronic Quality management system components (referenced in this document and respective procedures)

The scope of the organizations quality management system supports the realization of dewatering, solids control, bulk material handling, and custom manufactured/fabricated equipment, as well as service to such equipment as required by customer organization(s).

The organization claims no exemptions from the requirements of ISO 9001:2015.

#### 4.4 QUALITY MANAGEMENT SYSTEM AND ITS PROCESSES

##### 4.4.1

The organization has developed, implemented, and maintains a quality management system that conforms to the requirements set forth in the ISO 9001:2015 quality management system standard. Additionally, the organization continually tries to improve the quality management system and its processes to more effectively meet customer requirements and to ensure best business practices are considered and implemented as appropriate. The organization uses the following tools, at a minimum, to ensure continual improvement of the quality management system, its processes, and organizational interactions:

- Internal audit
- Organizational planning meetings
- Management review, including the report to management
- Corrective action
- Preventive Action
- Quality objectives
- Quality policy

This manual, procedures, documents, and the electronic quality management system components identify the required processes needed to describe, manage, facilitate, and document the quality management system. The sequence and interaction of these processes are shown in PI 4.1.4-001 Process Interaction Chart. The organization obtains quantifiable data in key performance areas (kpi) of the quality management system, as outlined in QO 6.2-001 Quality Objectives. Information obtained shall be analyzed, presented in the management review and used as indicators for the suitability and effectiveness of the quality management system. This manual and the procedures encompassing the quality management system include criteria and methods necessary to insure the effective operation and control of the quality management system processes.

The internal audit program is the primary tool for ensuring the quality management system conforms to planned arrangements, ISO 9001:2015, and to the quality management system requirements set forth in this manual and quality management system procedures. Effectiveness of the quality management system and an evaluation of the conformance to planned arrangements shall be evaluated and verified, at a minimum, through the internal audit program.

#### 4.4.1 Continued

Through the development of this quality management system manual and the supporting documented information the organization has developed a quality system capable of:

- Determining/defining the required quality management system inputs and the outputs expected from the planned arrangements/processes
- Determining/defining the sequence and interaction of quality management system processes
- Determining/defining and applying the criteria and methods needed to ensure the effectiveness of the quality management system
- Determining/defining and ensuring the availability of the resources necessary for the effective operation of the quality management system
- Determining and assigning the responsibilities and authorities for the quality management system processes
- Assessing and addressing risk and improvement opportunities
- Objectively evaluating quality management system process and effectively manage changes needed to ensure continued conformance to requirements
- Improving quality management system processes, products, and relationships with relevant interested parties

#### 4.4.2

The organization shall maintain documented information/records to support the operation of all quality management system requirements and to provide objective evidence that quality management system processes are being carried out in accordance with planned arrangements.

## 5 LEADERSHIP

### 5.1 Leadership and Commitment

#### 5.1.1 General

Top management is committed to the development, implementation, and continual improvement of the quality management system. Top management demonstrates its commitment to the quality management system by:

- Taking accountability for the effectiveness of the quality management system by reviewing and approving the quality management system manual, as well as, participating in the annual management review and report to management
- Reviewing and approving the quality policy and quality objectives and ensuring they are compatible with the context and scope of the quality management system
- Ensuring product realization processes (business processes) align with quality management system principles
- Promoting the process approach to product realization and ensuring decisions are made after considering risk to the quality management system requirements
- Communicating quality management system requirements in organizational planning meetings and the importance of conformance to requirements in meeting customer expectations
- Participating in the management review and the report to management which incorporates the results of the annual quality management system internal audit
- Supporting organizational management and promoting ownership of product realization processes
- Promoting continual improvement of the quality management system, products and services, and relationships with relevant interested parties
- Endorsing an organizational structure that promotes process ownership of product realization activities and quality management system principles. OC 4.2.2-001 Organizational Chart and JD 4.2.2-XXX documents define the structure and roles for personnel operating under the guidance of the quality management system

#### **5.1.1 General cont.**

Top management demonstrates continued commitment to the effectiveness of the quality management system by appointing a management representative. The Quality Manager is currently appointed as the management representative and has the responsibility and authority for:

- Ensuring quality management system processes are established, implemented, and maintained
- Reporting to top management on the performance of the quality management system and any opportunities for improvement
- Ensuring actions are planned and carried out, to minimize the likelihood of nonconformance occurrence(s)
- Scheduling/conducting internal audits
- Serving as the point of contact for external parties on matters relating to quality

#### **5.1.2 Customer focus**

Top management is committed to meeting customer requirements by ensuring:

- Customer product and/or service requirements are clearly defined, understood by the organization, and are met with each project the organization enters into contract or agreement
- The organization provides products and/or services that meet applicable statutory and regulatory requirements as applicable to the type of equipment and/or service provided
- Potential risk that may negatively affect the organizations ability to provide product and/or services that conform to specified requirements are assessed, addressed, and mitigated
- Customer perception is evaluated and customer satisfaction enhanced

### **5.2 POLICY**

#### **5.2.1 Establishing the quality policy**

Top management has established, implemented, and maintains a quality policy, QP 5.2-001, that:

- Is appropriate to the context of the organizations quality management system and strategic direction
- Provides and includes the use of quality objectives for organizational continual improvement
- Includes the organizations commitment to enhancing customer satisfaction and meeting requirements
- Includes the organizations commitment to the continual improvement of the quality management system

### 5.2.2 Communicating the quality policy

QP 5.2-001 Quality Policy has been developed and maintained as an affirmation of the organizations commitment to continual improvement. The quality policy:

- Is approved by top management and is made available via the electronic quality management system
- Is communicated throughout the organizations personnel and engrained in the organizations quality management system
- Is a training topic for personnel to ensure understanding (records of training are maintained)
- Is available to relevant interested parties, as appropriate

### 5.3 Organizational roles, responsibilities, and authorities

Top management has created an organizational structure that facilitates effective realization of product in conformance with quality management system requirements. The organizational structure is documented on OC 5.3-001 Organization Chart. JD 4.2.2-XXX (job descriptions) series documents provide specific information on personnel roles in the context of the quality management system.

The Del Corporation Quality Manager has been designated by top management as the organization's Management Representative. The Management Representative, irrespective of other responsibilities, has the responsibilities and authority that include the following:

- Ensuring the processes needed for the effective operation of the quality management system are established, implemented, and maintained
- Ensuring the quality management system conforms to the requirements of ISO 9001:2015
- Monitoring and measuring the quality management system to insure processes meet intended outputs
- Reporting to top management on the performance of the quality management system and any recognized opportunities for improvement
- Ensuring the promotion of organizational awareness of meeting customer requirements
- Ensuring the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented
- Responsible for ensuring internal audits are accomplished annually
- Serves as the point of contact for interested parties on matters relating to quality

## **6 PLANNING**

### **6.1 Actions to address risks and opportunities**

#### **6.1.1**

Quality management system planning shall be accomplished to ensure all elements, requirements, and provisions that make up the quality management system consider meeting customer requirements and ensure product conformity. The organization shall identify and plan the processes, resources, and documents required for the effective operation of the quality management system. Product realization planning shall be consistent with quality management system requirements.

Planning shall be accomplished with consideration for the following:

- Ensuring the quality management system can achieve planned organizational results as intended
- Ensuring the quality management system facilitates meeting goals and can enhance desired effects
- Preventing or minimizing any undesired effects
- Facilitates continual improvement
- Required resources and work environment
- Product and/or customer specified requirements
- Legal and other applicable requirements
- Product conformity
- Customer satisfaction
- Management of change opportunities

#### **6.1.2**

The organization considers risk and opportunities for improvement in planning. Consideration is made for the potential negative effects of such risks and opportunities on planned arrangements. Actions taken to mitigate risk and/or to evaluate opportunities for improvement are generally accomplished in planning/production meetings. Such meetings facilitate the solicitation of information, from each potentially impacted department, regarding the potential impact identified risk has on departments responsible for the realization of product. Quality management system documents are revised to incorporate and implement additional requirements needed as a result of recognized risks and opportunities for improvement. Revision of quality management system documents or change in organizational processes are evaluated to ensure effectiveness. Effectiveness is measured by the potential risk scenario not coming to fruition and/or opportunities for improvement positively affected planned arrangements and resulted in positive outcome(s).

## 6.2 Quality objectives and planning to achieve them

### 6.2.1

Top management has developed quality objectives to provide quantifiable goals for key performance indicators within the organization. Quality objectives are documented on QO 6.2-001 Quality Objectives and are included in the annual management review. Quality objectives consider the following and represent a comprehensive cross section of the organization:

- Department/Function
- Objective
- Method of measurement
- Action plan

Quality objectives for the organization are:

- Consistent with the organizations quality policy
- Quantifiable and provide accurate data for improvement initiatives
- Consistent with applicable requirements (quality management system, customer)
- Developed around conformity of products and services
- Centered around enhancing customer satisfaction
- Monitored and included in the analysis of data (Report to Management) and the Management Review
- Made available to all personnel through the electronic quality management system
- Updated as appropriate to the organizations ability to meet objectives
- Maintained as documented evidence, included in the Report to Management and are a line item for the annual Management Review

### 6.2.2

QO 6.2-001 makes provision for:

- Creating and developing an action plan for each quality objective
- Any resource required to facilitate meeting quality objectives
- Identifying the relevant department/function responsible for each quality objective
- Timeframe associated with completing/measuring quality objectives
- Method of measurement and a quantifiable objective for each indicator

### 6.3 Planning of changes

#### 6.2.1

The organization utilizes several quality management system components to plan activities associated with a change opportunity. Change opportunity shall be processed in accordance with planned arrangements and consider the effects of risk on the integrity of the quality management system. The controls required to appropriately manage change shall be relative to the potential risk to the quality management system. While all change requires varying degrees of management to process effectively, the controls required shall be relative to the potential effect(s) on the quality management system. The organization uses the following components in planning change:

- Project management software: used for planning and managing change for individual projects
- Management of change module: may be used to manage change alone or in conjunction with other quality management system components
- Business Overview Board: used to process specific tasks relating to change opportunities
- Preventive Action Module: used to manage change for recognized opportunities for improvement
- Vault: used to control potential changes to design elements

Each of the quality management system tools listed above make consideration for the following regarding change:

- The reason for change and the potential consequences of enacting change
- Managed under controlled conditions to preserve the integrity of the quality management system
- Resource allocation to effectively manage change
- Allocation or reallocation of personnel responsible for approving, processing, or managing change

The organization shall use the appropriate quality management system components to plan and process change opportunities for any of the following that may impact the quality management system.

- Changes in organizational structure
- Changes in key/essential personnel
- Changes in critical suppliers
- Changes to quality management system documented information (procedures, drawings, forms, etc.)

## **7 SUPPORT**

### **7.1 Resources**

#### **7.1.1 General**

Top management has the responsibility and authority to determine and provide resources required for the effective operation of the quality management system. Determination, allocation, and effectiveness of allocated resources are continually evaluated and considered a focus item in the annual management review. When evaluating adequacy of resources, top management with input from departmental management, shall consider:

- Capabilities and/or limitations of existing internal resources
- Requirement for resources from external providers

The evaluation of resources is accomplished at several stages throughout the product realization process to include purchase order acceptance, production meetings, and at a minimum the annual management review. Consideration of resources is made for, but not limited to the following:

- Human resources
- Workforce/personnel
- Supplier base
- Information and communication systems
- Infrastructure
- Real property
- Work environment
- Training availability
- Financial resources

#### **7.1.2 People**

Top management, with input from departmental resources, is responsible for evaluating and maintaining an adequate workforce to ensure the effective realization of product and the effective operation of the quality management system.

### 7.1.3 Infrastructure

Infrastructure is continually evaluated, with input from departmental resources, by top management to determine adequacy of existing infrastructure. Top management is also responsible for evaluating recommendations for improvement to existing infrastructure and/or procuring additional infrastructure resources that may affect the quality management system and/or the product realization process. Infrastructure includes, but may not be limited to:

- Building, real-property, and associated utilities
- Equipment used in the realization of product
- Transportation resources
- Information and communication technology, including hardware and software

### 7.1.4 Environment for the operation of processes

The organization shall maintain an adequate work environment for achieving product conformance and for the effective operation of the quality management system. The organization's work environment shall be continually evaluated by top management, with input from departmental management, to ensure adequacy. Consideration of environmental factors includes health and safety of all personnel, safeguarding of resources, influence on meeting customer requirements, product conformance, and the effectiveness of the quality management system. Top management encourages all DEL Corporation personnel to offer recommendation for opportunities for improvement regarding the work environment.

It is the DEL Corporation policy to maintain a work environment that is:

- Non-discriminatory, non-confrontational, and promotes cooperation
- Aware of the potential for negative psychological influences due the external pressures associated in an ever-evolving work environment. Top management is committed to creating a safe work environment where the negative impacts are reduced or eliminated
- Aware of the potential negative effects on personnel based on the physical environment due to extreme temperatures and climate. Top management is committed to creating a safe work environment and/or limiting exposure to potential negative impacts of the physical environment

### 7.1.5 Monitoring and measuring resources

#### 7.1.5.1 General

QMSP 7.1.5-001 Control of Monitoring and Measuring Resources has been developed and is maintained to make provision for monitoring and measuring activities and associated equipment used by the organization. This procedure, as well as the calibration module in the electronic quality management system , provides details and controls required to ensure valid measurement result.

The calibration module is an electronic quality management system component used by the organization to maintain measurement records. It also provides an accessible matrix of equipment/devices used by the organization, to include the following information.

- Type of equipment
- Unique identification
- Manufacturer
- Model (as appropriate)
- Location of equipment (as appropriate)
- Status
- Calibration dates (accomplished/due)
- Availability
- Frequency of calibration
- Methods of calibration/verification
- Acceptance criteria
- Records

The organization shall determine monitoring and measuring activities to be used and the equipment required to provide evidence of conformance.

#### 7.1.5.2 Measurement traceability

The organization requires measuring devices to calibrated or verified to traceable international/national measurement standards. The organization requires vendors measure, verify, and/or calibrate equipment to NIST (National Institute of Standards and Technology) standards. Calibration records are maintained in accordance with QMSP 7.5.3-001 Control of Records.

Calibration status is documented in the Calibration Module of the electronic quality management system. Additionally, stickers or some other means of identification denote calibration due date. This allows the user to easily identify calibration status.

#### **7.1.5.2 Measurement traceability cont.**

The organization shall assess and record the validity of previous measurement results when equipment is found not to be in tolerance. The organization shall take appropriate action(s) on equipment and affected product when equipment is found to be out of tolerance. In such cases, customers shall be notified with records maintained if out of tolerance equipment was used to verify product and it is discovered after delivery to customer. When used for monitoring and measurement, the ability of computer software to satisfy the intended application shall be verified.

#### **7.1.6 Organizational knowledge**

The organization defines the minimum knowledge requirements on JD 4.2.2-XXX series documents (job descriptions) to ensure personnel have the appropriate skill set(s) to ensure conformity of products and services. On-the-Job training is the primary method of conveying relevant knowledge throughout the organization. Employee appraisals consider individual employees' ability to retain/convey organizational knowledge. Electronic job folders contain historical data which is accessible by all personnel with access to a work station. Organizational meetings such as production meetings, initial project meetings, and purchase order acceptance meetings (as required), are also used to convey organizational knowledge. These types of meetings also consider the existing knowledge base and any actions required when change opportunities are presented.

### **7.2 Competence**

The organization makes provision for personnel competence in QMSP 7.2-001 Competence. This quality management system document:

- Outlines the criteria for personnel competence, for those personnel performing any activity that may affect the effectiveness of the quality management system, on JD 4.2.2-XXX series documents (job descriptions)
- Provides a minimum criteria for competence based on appropriate education, training, and/or experience
- Makes provision for ensuring continued competence through performance evaluation
- Makes provision for maintaining records supporting competence

QMSP 7.2-001 also makes provision for identifying training needs, providing training for personnel performing activities within the scope of the quality management system, and awareness of the importance each position holds within the scope of the quality management system.

## 7.2 Competence cont.

Emphasis for training is placed on the awareness, relevance, and importance of personnel roles within the scope of the quality management system, as well as job related, customer specified, and/or customer provided training. The organization shall ensure:

- All personnel performing work potentially affecting product conformity receive quality management system and appropriate job/position training as applicable
- Personnel, as required, receive customer specified and/or customer provided training
- Frequency and content of training is identified
- Personnel performing work affecting conformity to product requirements are aware of the relevance and importance of their activities and how they contribute to the achievement of established quality objectives
- Training is effective
- Records or documented information are maintained

Note: Where the organization requires third party providers to be competent to meet internal quality management system requirements, qualifications must be verified prior to accepting any product and/or service.

## 7.3 Awareness

The organization shall ensure personnel accomplishing any activity under the scope of the quality management system are:

- Trained and aware of the importance of the quality policy
- Trained and aware of the importance of established quality objectives
- Trained and aware of their individual roles in fulfilling quality management system requirements
- Trained and aware of negative ramifications for not conforming to quality management system requirements

## 7.4 Communication

The organization has made provision for effective internal and external communication regarding the quality management system. The organization maintains adequate resources and infrastructure to ensure effective internal and external communication. Provision for effective communication has been made to address:

- What will be communicated
- When communication is required
- With whom communication shall be maintained
- What methods of communication shall be used
- Responsibilities for communication

Top management has ensured that appropriate communication processes have been established and implemented within the organization and that communication takes place regarding the effectiveness of the quality management system.

Provision for effective internal communication is accomplished through the following:

- Management communication of the quality policy, quality objectives, customer and/or regulatory requirements, product and process specifications, verification and validation requirements, training opportunities, and the relevance and importance of the quality management system
- Communication of data regarding meeting customer requirements and expectations, customer satisfaction, quality management system performance, and opportunities for improvement
- Quality management system requirements are communicated through this manual, procedures, instructions, quality records, formalized training, and the components of the electronic quality management system
- Management reviews are significant in ensuring communication is effective. The review process provides a framework for the organization to report quality related issues and activities, and for management of change opportunities to improve the effectiveness of the quality management system

Top management has ensured that appropriate communication processes have been established and implemented within the organization for communication with external organization in matters regarding product realization, product conformance, and the quality management system.

#### **7.4 Communication cont.**

Provision for external communication includes, but may not be limited to the following:

- Quotes resulting from customer inquiries
- Contracts/purchase orders processing and acceptance
- Suitable means of addressing nonconforming product and negative customer feedback
- Product realization quality plans
- Supporting product realization documents when required by contract
- Customer supplied documentation

#### **7.5 Documented information**

##### **7.5.1 General**

The organizations quality management system includes the following components:

- Quality Manual (QM 7.5.1-001)
- Quality policy (QP 5.2-001)
- Quality objectives (QO 6.2-001)
- Documented information (required procedures, records) required by ISO 9001:2015
- Documented information not required by ISO 9001:2015 but need by the organization to meet quality management system requirements

##### **7.5.2 Creating and updating**

Organizational quality management system documents are:

- Uniquely identified and contain a either a description of the intent of the document, or instruction on the use of the document
- Formatted in such a manner that they are easily identifiable as quality management system documents
- Reviewed and approved prior to release

### 7.5.3 Control of documented information

#### 7.5.3.1

The organization has made provision for the control of documented information with implementation of the following quality management system procedures:

- QMSP 7.5.3-001 Control of Documents
- QMSP 7.5.3-002 Control of Drawings
- QMSP 7.5.3-003 Control of Records
- QDM 7.5.3-001 Master List of External Documents

QMSP 7.5.3-001 is the documented procedure that makes provision for the control of quality management system documents for the organization. QMSP 7.5.3-001 makes provision for:

- The control of documents required by the quality management system
- Approval activities of quality management system documents prior to release
- Identifying and managing changes to quality management system documents
- Identifying revision status and revision history of quality management system documents
- Ensuring relevant versions of quality management system documents are made available at points of use
- Review, update, approval, and re-release activities for quality management system documents
- Ensuring documents remain legible and readily identifiable
- Ensuring that documents of external origin are identified, distribution controlled, and relevant versions are available for use
- Preventing the unintended use of obsolete documents
- Applying suitable means of identification for obsolete external documents

QMSP 7.5.3-002 is the documented procedure that defines and establishes the controls required for the identification, distribution, control, and management of drawings used by the organization for concept and/or realization of product activities.

### 7.5.3.2

QDM 7.5.3-001 is the quality management system document that makes provision for the identification and control of documents of external origin required for the product realization process. Documents of external origin include, but may not be limited to, published industry standards, recommended practices, vendor quality documentation, and nationally/internationally recognized quality management system standards. Documents of external origin may be maintained in hard copy and/or electronically.

QMSP 7.5.3-003 Control of Records has been established and defines the controls required for the identification, distribution, and control of records. Records maintained by the organization ensure and provide evidence of conformity to requirements, and the effective operation of the quality management system. This document provides the controls for the following:

- Ensuring quality records are legible, readily identifiable, protected from alteration, and retrievable
- Provides a frame work for the identification, storage, protection, retrieval, retention period, and disposition
- Identifies the function responsible for collection and maintenance of records
- Types of records maintained by the organization
- Location of records
- Media type

Note: The organization has determined that quality records shall be maintained a minimum of 5 years, however the must be retained in accordance with QMSP 7.5.3-003 should the retention time exceed 5 years or otherwise noted.

## **8 OPERATION**

### **8.1 Operational planning and control**

QMSP 8.1-001 is the quality management system document that makes provision for the control of production and servicing activities accomplished by the organization. This documented quality management system procedure addresses the following actions for the realization of product(s) and/or service(s):

- Determining the inputs required and the availability of information to realize product(s) and/or provide service(s) in accordance with customer requirements
- Establishing the processes required to realize product(s) and/or provide service(s) in accordance with customer requirements
- Establishing activities required for the acceptance criteria of products and services
- Determine and ensure the organization has adequate resources to achieve product conformance and effectively meet customer requirements
- Establish the controls needed to ensure product conformance and meet customer requirements
- Determining, maintaining, and retaining documented information required to carry out planned arrangements
- Determining, maintaining, and retaining document information that demonstrate conformance of product(s) and/or service(s)

Outputs developed for use in the realization of product(s) and for providing required service(s) shall be suitable for the organization's operations. The organization shall also control required changes by mitigating risks associated with change.

The organization shall ensure outsourced processes are controlled to the extent necessary for conformance of product(s) and/or service(s) and to meet the organization's quality management system requirements.

### **8.2 Requirements for products and services**

#### **8.2.1 Customer communication**

Top management shall ensure that appropriate communication processes are established and implemented within the organization for communicating with external interested parties in matters regarding product conformance and the quality management system. Provision for external communication includes, but may not be limited to the following:

### 8.2.1 Customer communication cont.

- Providing information to customer organizations relating to products and services prior to entering into contract, while the product is being realized or services rendered, and after delivery of product or services to the customer organization
- Activities relating to the quote process, including changes to documented information as required
- Activities relating to the contract or order handling process, including changes to document information as required
- Obtaining customer perception feedback for products and services provided by the organization
- Management of customer property, including notification to the customer organization should customer property be lost or damaged
- Communication to customer organization in the event contingency actions are required
- Suitable means of addressing nonconforming product, negative customer feedback, or recalls/notification for nonconforming product identified after delivery to a customer organization

### 8.2.2 Determining the requirements for products and services

QMSP 8.2.-001 Requirements for Products and Services is the organizations documented procedure that makes provision for establishing the process used in determining requirements for products and services. The organization shall determine customer requirements and assess the organizations capability of meeting those requirements **prior** to entering into contract with or accepting a purchase order for products and services. The organization shall consider and determine:

- Product and/or service requirements, including statutory and regulatory requirements, are defined
- Requirements not stated by the customer but determined and considered necessary by the organization are defined
- Products and services offered by the organization can meet customer requirements and fulfill expected performance outputs

### 8.2.3 Review of the requirements for products and services

QMSP 8.2.-001 Requirements for Products and Services is the organizations documented procedure that makes provision for the review of requirement for products and services.

#### 8.2.3.1

A review of requirements shall be accomplished by the organization to affirm its ability to meet customer requirements for products and services. The organization shall consider, identify, and determine the following:

- Nature of the product and/or service requirements specified by the customer organization to include delivery and post-delivery activities
- Requirements not stated by the customer organization, but considered by the organization as necessary for the specified product and/or service
- Requirements specified by the organization as relevant to the realization of product and/or service provided
- Any statutory and regulatory requirements
- Changes in contract or order requirements are identified and resolved as applicable

The organization's ability to provide products and/or services shall be confirmed by the organization **prior** to acceptance. Where the customer does not provide a documented statement of requirements, the organization shall affirm its understanding of customer requirements and its ability to provide products and services.

#### 8.2.3

The organization shall maintain documented information (records) of:

- Results of reviews for products and/or services
- Any new requirements for the products and/or services

#### 8.2.4 Changes to requirements of products and services

The organization shall ensure that changes in orders/contracts are documented, communicated to relevant organizational personnel, and documented information maintained.

### **8.3 Design and development of products and services**

#### **8.3.1 General**

QMSP 8.3-001 is the quality management system document that makes provision for establishing, implementing, and maintaining a design and development process that is appropriate to the scope of the organizations quality management system and conformance of products and/or services.

#### **8.3.2 Design and development planning**

QMSP 8.3-001 is the organizations documented procedure that makes provision for planning and control of design activities. The procedure makes provision and/or considers the following regarding design and development planning:

- The type of equipment, with consideration for the complexity of the activities required in the design and development process
- Consideration for the time required to provide adequate design outputs
- Identification of the required design and development stages, to include design reviews
- Identification of design verification and validation activities
- Identification and assignment of responsibilities and authorities for personnel included in the design and development process
- Identification of external resources needed for design and development activities
- Controls for the required interfaces for design and development activities
- Controls for customer input/involvement for design and development activities
- Identification and provision for additional resources for design and development activities
- Controls required for customer and/or relevant interested parties' involvement with design and development activities
- Requirements for documented information showing objective evidence that design and development requirements have been met

#### **8.3.3 Design and development inputs**

The organization shall determine the essential inputs required for design and development activities relative to the type of product and/or service being designed.

### 8.3.3 Design and development inputs cont

When developing inputs for design and development activities the organization shall consider:

- Functional and performance requirements
- Historical data from previously approved similar designs
- Applicable statutory and regulatory requirements
- External documents that influence the quality of realized product
- Assessed risk and the potential consequences of failure based on the nature of the products and/or services being designed and developed

The organization shall ensure inputs are adequate, complete, and unambiguous for design and development activities. Design and development inputs that are conflicting shall be resolved before design and development outputs are released.

The organization shall retain documented information of design and development inputs.

### 8.3.4 Design and development controls

The controls outlined in QSMP 8.3-001 are designed to ensure that the organization:

- Defines the intended results of design and development activities
- Conducts reviews, at planned intervals within the design and development process, to evaluate the ability of the outputs to meet product and/or service requirements
- Defines and conducts necessary verification activities to ensure design outputs meet input requirements
- Defines and conducts necessary validation activities to ensure designed product and/or services meet the requirements for the specified product and/or service application or intended use
- Takes necessary actions on issues discovered during reviews, verification, and validation activities to ensure they do not preclude the product and/or service intended application or use
- Maintains appropriate documented information of review, verification, and/or validation activities

Note: Reviews, verification, and validation activities each address a distinct function within the design and development process. Each may be conducted separately or combined relative to the nature of the product and/or service being rendered.

#### **8.3.5 Design and development outputs**

The organization shall establish and implement the required controls for design and development outputs to ensure:

- Design and development outputs are capable of meeting design and development inputs
- Design and development outputs are adequate for the realization of product and rendering of services
- Design and development included required monitoring and measuring activities to confirm conformance
- Design and development outputs accurately describe products and/or services and include characteristics that are essential for safe, proper, and intended application
- Documented information of design and development outputs are maintained

#### **8.3.6 Design and development changes**

Design and development changes shall be identified, reviewed, controlled, and managed by the organization to ensure that there are no negative impacts on product and/or service conformance to requirements. Documented information shall be maintained for the following:

- Design and development changes
- Results of design and development reviews resulting from change opportunities
- Personnel authorizing design and development changes
- Any actions taken to minimize or prevent the possibility of adverse impacts or product nonconformity to requirements

## **8.4 Control of externally provided processes, products, and services**

### **8.4.1 General**

The organization maintains QMSP 8.4-001 to define the required controls to ensure any externally provided process, product, and/or service conforms to the requirements of the organization's quality management system. Control shall be applied to processes, products, and/or services for the following:

- Products and/or services from external providers are intended for incorporation into the organization's products, services, and/or products
- Products and/or services are provided directly to customer organizations on behalf of the organization
- A process, whole or in part, is provided by an external provider because of an established need by the organization

QMSP 8.4-001 makes provision for the selection, evaluation, monitoring, and subsequent re-evaluation of providers of processes, services, and/or products for their ability to meet the organizations requirements. Documented information of supplier selection, evaluation, monitoring, and re-evaluation activities and any actions resulting from vendor evaluation shall maintained.

### **8.4.2 Type and extent of control**

QMSP 8.4-001 defines the controls needed to ensure that externally provided processes, products, and services conform to the organizations quality management system requirements and do not adversely affect the organizations ability to consistently provide products and/or services. QMSP 8.4-001 defines the controls required to:

- Ensure externally provided processes conform to the organizations quality management system requirements
- Define the controls required for initial evaluation, continued evaluation, and any re-evaluation activities of external provider(s)
- Define the controls required for acceptance of processes, products, and/or services provided
- Assess the criticality and potential impact externally provided processes, products, and services has on the organizations ability to consistently meet customer requirements and any applicable statutory and regulatory requirements
- Assess the effectiveness of the controls placed on external providers
- Determine verification activities to ensure processes, products, and/or services meet quality management system requirements

#### 8.4.3 Information for external providers

Information provided by the organization to external providers shall be documented and communicated via organization issued purchase orders. Purchase orders must be specific in nature and communicate the organization's requirements and acceptance criteria for the following:

- The processes, products, and/or services required by the organization
- Approval/acceptance criteria of:
  - › Products and services
  - › Methods, processes, and/or equipment needed to ensure conformance and valid results
  - › Release activities for products and services
- Qualifications or competency of personnel
- Required interactions between the supplier and the organization
- Control and monitoring of supplier performance (inclusion on the active vendors list)
- Verification or validation activities to be accomplished at supplier location(s)

### 8.5 Production and service provision

#### 8.5.1 Control of production and service provision

QMSP 8.5-001 is the organization's documented procedure that makes provision for the control of production and servicing activities. Controlled conditions include the following, as applicable:

- The availability of documented information that defines the characteristics of the product being realized, the services to be provided, or the activities to be performed towards conformance
- The availability of documented information that defines the results to be achieved
- Availability and use of suitable production, testing, monitoring, and measurement equipment
- The identification and implementation of monitoring and measurement activities in accordance with planned arrangements to ensure conformance to requirements
- Providing an adequate infrastructure and suitable work environment for the product realization process
- Defining competency requirements of personnel performing work under the scope of the quality management system to include any required additional qualification.

#### **8.5.1 Control of production and service provision cont.**

- The evaluation of processes that require validation, to include re-validation, for outputs that cannot be verified by monitoring and measuring activities and their ability to meet planned arrangements
- The implementation and processing of Preventive Actions/Opportunities for improvement to prevent nonconformance based on human error
- The implementation of release, delivery, and post-delivery activities and management of supporting documented information

#### **8.5.2 Identification and traceability**

QMSP 8.5.2-001 is the documented procedure implemented by the organization to make provision for identification and traceability requirements. The documented procedure addresses identification and traceability requirements for the product realization process, delivery, and post-delivery activities as required by the quality management system, customer requirements, and/or applicable product specifications. QMSP 8.5.2-001 makes provision for, at a minimum, the following:

- Product identification
- Identification of materials used in the product realization process
- Status of product
- Management of documented information as it relates to identification and traceability

#### **8.5.3 Property belonging to customers or external providers**

Provision for customer supplied or externally provided property maintained or used by the organization is made in QMSP 8.5.3-001 Customer or External Provider Property. The procedure makes provision for the following control activities:

- Identification and management of customer or external provider property
- Verification of customer or external provider property when incorporated with manufactured product
- Provision for protection and safeguarding of customer or external provider property while under the organizations control
- Provision for customer or external provider notification should property be lost, damaged, or deemed otherwise unsuitable for its intended use
- Management of documented information regarding customer or external provider property

Note: property may include materials, components, tools, equipment, premises, intellectual property, and personal data

#### **8.5.4 Preservation**

The organization shall make all necessary provision for ensuring product conformance, to include constituent parts, throughout the product realization process, delivery, and post delivery activities. The organization shall ensure the necessary resources are available to maintain product conformance.

Preservation may include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.

#### **8.5.5 Post-delivery activities**

The organization shall determine and meet the requirements for post-delivery activities associated with products and/or services provided by the organization. When determining product and/or service requirements the organization should consider the following:

- Statutory and regulatory requirements
- Potential undesired consequences associated with products and/or services
- The nature, use, and anticipated lifetime of the type of product and/service provided by the organization
- Customer requirements for post-delivery activities
- Addition, revision, and/or improvement of post-delivery practices based on customer feedback

Note: Post-delivery activities may include warranty actions, contract requirements, scheduled/routine maintenance agreement, and supplementary services such as environmental considerations or disposal.

#### **8.5.6 Control of changes**

Change opportunities required during the product realization process or service provision shall be reviewed to ensure continuing conformance with requirements. The organization shall retain documented information for the following, at a minimum:

- Details of the required change
- Results from the review of the change
- Personnel responsible for authorizing the change
- Any actions needed to implement change

## 8.6 Release of products and services

The organization shall implement inspection and/or testing activities at appropriate stages throughout the product realization process to ensure planned arrangements and requirements are met. Release of products and/or services to customer organizations may not proceed until verification that all planned arrangements have been satisfactorily completed.

Records of release activities shall be maintained. Documented information to shall include the following:

- Evidence of product and/or service conformance with requirements, to include acceptance criteria
- Traceability to the relevant authority responsible for release

## 8.7 Control of nonconforming outputs

### 8.7.1

QMSP 8.7-001 is the documented procedure that makes provision for controls and tools used by the organization for identifying, processing, and managing product that does not conform to requirements to prevent their unintended use or delivery. This documented procedure identifies the required controls, as well as, the related responsibilities and authorities for addressing and processing nonconforming product. Provision for control of nonconforming product discovered during the product realization process includes the following:

- Identification of product deemed to be nonconforming
- Preventing the unintended use or delivery of nonconforming product
- Processing and managing nonconforming product
- Determining and developing the root cause of nonconformance to minimize the possibility of recurrence
- Authorizing acceptance, release, and/or use of nonconforming product under concession

QMSP 8.7-001 also includes the following provisions for nonconforming product identified after delivery to customer:

- Identifying, documenting, and reporting nonconformities or product failures
- Determining the root cause of nonconformities should sufficient information regarding the failure is available
- Actions taken are appropriate to the effects, or potential effects, of the nonconformity when discovered after product has been released to the customer or discovered while in use for its intended application

**8.7.1 Cont.**

Nonconforming product shall be classified (disposition) and processed in one or more of the following ways:

- Correction, repair, or rework. Verification activities may be required to confirm conformance
- Rejection, scrap, segregation, containment, return to supplier
- Regrade for alternative applications
- Customer notification/request for concession
- Release under concession
- Repair by replacement
- Return to supplier
- Process change
- Us As Is
- Retrain

**8.7.2**

The organization shall maintain records (documented information) regarding the nature of nonconformities and any action(s) implemented towards resolution. Documented information shall include the following:

- Description of the nonconformity
- Any actions taken to manage the occurrence
- Concessions obtained
- Authority for actions towards resolution and final disposition

## **9 PERFORMANCE EVALUATION**

### **9.1 Monitoring, measurement, analysis, and evaluation**

#### **9.1.1 General**

The organization monitors, measures, analyzes, and evaluates the following quality management system tools and components to quantify key performance indicators and to ensure adequate performance of the quality management system. QMSP 9.1-001 is the organizations documented procedure that makes provision for organizational performance monitoring, measurement, analysis, and evaluation. This quality management system document provides guidance and outlines the controls required to determining:

- What needs to be monitored and measured
- The methods required for monitoring, measurement, analysis, and evaluation required to ensure valid results
- When monitoring and measuring activities shall be accomplished
- When monitoring and measuring data shall be analyzed and evaluated
- Required documented information of monitoring and measurement activities

QMSP 9.1-001 also makes provision for evaluating the performance and effectiveness of the quality management system, as well as determining the appropriate documented information to be maintained as objective evidence of the results of such evaluation activities.

### 9.1.2 Customer satisfaction

QMSP 9.1.2-001 is the organizations documented procedure that makes provision for measuring customer satisfaction.

The procedure addresses:

- Frequency of measurement
- Methods for obtaining customer perception data
- Identifying key performance indicators

Monitoring customer perception may include, but may not be limited to, input from the following:

- Surveys (electronic and/or hardcopy)
- Customer feedback
- Formally and/or informally acquired data

Customer satisfaction data shall be obtained, documented, and evaluated. Data collected shall be used to improve the overall effectiveness of the quality management system.

### 9.1.3 Analysis and evaluation

Analysis and evaluation of data shall be accomplished in accordance with QMSP 9.1.3 Analysis and Evaluation of Data.

This quality management system procedures makes provision for the identification, collection, and analysis of data to demonstrate the effectiveness of the quality management system. Data analysis shall include:

- Customer satisfaction/perception
- Product conformance to requirements
- Effectiveness and opportunities for improvement of the quality management system
- Planning effectiveness to include characteristics and trends of processes and products
- Opportunities for improvement as noted in the corrective/preventive action processes
- Supplier performance
- Quality objectives

Information derived from analysis shall be included in the annual report to management and used to evaluate the status of the quality management system and recognize opportunities for improvement.

## **9.2 Internal Audit**

### **9.2.1**

QMSP 9.2-001 is the documented procedure that makes provision for the organizations quality management system internal audit program. Internal audits shall be accomplished to evaluate the organizations ability to satisfy the quality management system requirements as prescribed in ISO 9001:2015 quality management system specification, as well as the organizations own quality management system requirements. This documented procedure makes provision for planning, conducting, and documenting internal audits. Internal audit(s) encompass the entire quality management system and shall be accomplished within a period not to exceed 12 months. Consideration shall be made for results of past audits and the criticality of the processes being audited. Outsourced activities impacting product quality shall be included in the internal audit process when outsourced activities are accomplished at the DEL Corporation facility. Records of internal audits shall be maintained as documented evidence that the internal audit program is effectively implemented and maintained.

### **9.2.2**

QMSP 9.2-001 makes provision for the following internal audit activities:

- Establishing, planning, implementing, and maintaining an audit program
- Identify the frequency, methods, responsibilities, and reporting of internal audits
- Defining the scope and criteria of the internal audit
- Criteria for auditor selection
- Inputs for the Management Review and Report to Management
- Provision for processing correction and corrective measures
- Records management and disposition

## **9.3 Management review**

### **9.3.1**

The organization, in conjunction with the annual internal audit, conducts a management review, at a minimum, every 12 months. The management review is a presented to inform top management, as well as organizational/departmental management of the suitability, adequacy, and effectiveness of the quality management system. Annual management review content is documented on QMF 9.3.1-001 Management Review.

### 9.3.2 Management review inputs

The annual management review shall consider the following (included in the management review agenda):

- Introduction/opening commentary
- Overview: defines the scope of the management review and line items to be presented
- Quality policy: review of the organizations quality policy
- Results of audits: internal and external audit results included as applicable
- Customer feedback: summary of customer perception
- Adequacy of resources: infrastructure, personnel, etc.
- Product conformance: evaluation of overall product conformance
- Process performance: evaluation of the effectiveness of quality management system processes
- Supplier performance: overall assessment of active supplier base
- Status of corrective/preventive actions
- Quality objectives: evaluation of the organization's performance regarding established objectives
- Risk assessment and opportunities for improvement
- Follow-up actions from previous management reviews
- Internal or external changes that may impact the quality management system
- Effectiveness of the quality management system: overall assessment
- Recommendations for improvement

### 9.3. Management review outputs

The Report to Management, accomplished within the context of the management review, is the documented assessment of the information presented in the management review. The Report to Management (QMF 9.3.3-001) includes data, decisions, and actions related to the following:

- Quantified data as outlined in the management review
- Recognized opportunities for improvement
- Recognized potential changes needed for the effectiveness of the quality management system
- Resources required

Records of the management review and report to management shall be maintained as objective evidence of the results of the management review (inputs and outputs).

## **10 IMPROVEMENT**

### **10.1 Monitoring, measurement, analysis, and evaluation**

The organization employs the following quality management system components to ensure continual improvement of the quality management system/business processes, products and services, and to enhance customer satisfaction.

Additionally; continual improvement initiatives promote correcting, preventing, and/or reducing outcomes contrary to planned arrangements:

- Quality policy
- Quality objectives
- Internal and external audit results
- Data analysis (customer perception, product conformity, nonconformance trend, supplier performance)
- Corrective actions (to include intermediate correction measures)
- Preventive actions
- Management review

### **10.1 Nonconformity and corrective action**

#### **10.2.1**

The organization shall take appropriate action when a nonconformance, including customer complaints, occurs or is reported to the organization. The organizations response to nonconformance reports shall be commensurate with the severity of the occurrence. The organization shall:

- Take intermediate steps to control and correct the nonconformance occurrence
- Ensure corrective measures are developed to minimize the possibility of recurrence

The organization shall evaluate each occurrence to determine the root cause of the nonconformance. To ensure the risk of recurrence or occurrence elsewhere is mitigated, the organization shall:

- Review and analyze the occurrence and similar previous (trend) occurrences
- Determine the root cause of the nonconformance
- Determine if there is a trend or potential for a trend

**10.2.1 cont.**

The organization shall also:

- Implement any correction and corrective measures need
- Review and determine the effectiveness of the corrective measures
- Evaluate the risk of potential occurrence for subsequent products and/or services
- Make any changes to the quality management system to ensure the possibility of recurrence if minimized

**10.2.2**

The organization shall maintain documented information regarding details of nonconformance occurrence. Records shall include information about:

- The nature of the nonconformance occurrence and subsequent corrective measures taken
- The results and the effectiveness of corrective measures implemented

**10.3 Continual Improvement**

The organization shall take all necessary actions to create, maintain, and continually improve the suitability, adequacy, and the effectiveness of the quality management system.