

Anders Bredenberg – 3/5/19

1<sup>st</sup> QTR Summary:

Notes that may require action:

No non-conformities were observed at the time of the audit.

Notes:

- 1) Observed ELucas Receiving Parts ID's 900614, 900303, and 900614. No obvious issues were present.
- 2) Observed MSegura putting away part ID's 401112, 500301, and 500908. No obvious issues were present.
- 3) Observed TIrvin QC'ing Part ID 107992. No obvious issues with regards to procedure were noticed, however, there is an issue with how close receiving, QC, and shipping are specially speaking. It's very easy to mix the processes / skip processes, or do them I the wrong order, intentionally, or unintentionally.
- 4) Observed TDalasta picking part ID 108663. No obvious issues were present.
- 5) Observed TBaltes assembling W/O 108042. Work instructions were up, and being utilized.
- 6) Observed DClark assembling W/O 108687. Work instructions were up, and being utilized. I requested he close them, and find them again. He was able to do this.
- 7) Observed RCarnes QA'ing W/O 108571. Work instructions were pulled up, and QA was logged into QA step. Required specifications were reviewed.
- 8) The latest Management review meeting was chaired by the appropriate parties.
- 9) Management reviews have been conducted a minimum of twice a year.

- 10) The most recent management review included all data related to the quality performance, as outlined in QM 4.1.
- 11) Quality objectives, and actual data are noted in the most recent management review.
- 12) Dee's Quality policy can be found in ECIS, on the home page.
- 13) Per QM 5.2, the Dee quality policy is to be found also on the Dee Electronics internet site, but I was unable to locate it.
- 14) The ECIS CAR system is used to identify and record any non-conformities, or problems relating to product, process and the Quality system, root cause of those non-conformities, and the verification of any implemented solutions.
- 15) When there are known issues with product, it is tagged for incoming inspection and is unable to be received before the integrity of the product is verified.
- 16) In order to determine trends of decreasing quality of In house assemblies, in-process measurements are recorded, and analyzed.

# Understanding the organization and its context

Quality Manual	4 – Context of the organization	
Section 4.1	Section Revision: A	Revision Date: 6/19/2017
<b>4.1 Understanding the organization and its context</b>		
Approved By: Dave Zirkelbach		Date: 6/19/2017

## GENERAL POLICY

The quality system described in this section of the Quality Manual conforms to the requirements of the standard: Element 4.1 ISO 9001:2015 Management Review.

Top management conducts periodical reviews of the quality system. The review evaluates the suitability and effectiveness of the system, identifies opportunities for improvement, and considers the need for changes to the quality policy and quality objectives. Results of the review are documented.

## PROCEDURAL POLICIES

### 1. General

1.1 The purpose of management reviews is to:

- 1. Evaluate the suitability, adequacy and effectiveness of the quality system;

*Consider changes to the quality management system and to the quality policy and quality objectives; and*

*Identify opportunities for improvement of the quality system, processes and products.*

2. 1.2 Management reviews are chaired by the President and are attended by the executive management team, representing all departments within the company.

3. 1.3 Management reviews are conducted at minimum twice per year. More frequent reviews are scheduled in periods when organizational changes, or other circumstances require increased attention and input from the top management.

## 2. Review input

4. 2.1 Input into the management reviews consists of information and data related to quality performance of the organization. At a minimum, this includes:

*Results of audits,*

*Customer feedback and complaints,*

*Process performance and product conformance data,*

*Status of preventive and corrective actions,*

*Changes that could affect the quality system,*

*Follow-up actions from earlier management reviews, and*

*Recommendations for improvement.*

## 3. Review output

5. 3.1 Management reviews are concluded with actions related to improvement of the quality management system, and improvement of processes and products to better meet customer requirements. The review also identifies resource needs to implement these actions.

3.2 Results of management reviews are documented in minutes of the review meeting. The minutes include improvement actions, and assign responsibilities and allocate resources for implementation of these actions.

## 4. External Content

4.1 We review during management review meetings external content in the forms of legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local. We will review and respond to any content from that come in to us on a situation by situation basis.

4.2 We review our clients social, legal, quality, and ethical policies.

1. Review MR minutes

2. "\_\_\_\_\_"

3. "\_\_\_\_\_"

4. "\_\_\_\_\_"

5. "\_\_\_\_\_"

## 4.2 Understanding the needs and expectations of interested parties

Quality Manual	4 – Context of the organization	
Section 4.2	Section Revision: B	Revision Date: 9/13/2017
<b>4.2 Understanding the needs and expectations of interested parties</b>		
Approved By: Dave Zirkelbach		Date: 6/19/2017

Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet DEE client and applicable statutory and regulatory requirements, DEE determines the parties and requirements of interested parties that are relevant to the quality management system, as well as monitor and review information about these via:

1. Identifies Tier 2 Suppliers that will be supplying material/components and assesses their ongoing performance
2. Identifies Client Critical to Quality (CTQ) elements/aspects of components or assemblies and translates these into a documented Inspection Plan, which
3. Can translate into requesting Certificates of Assurance from Tier 2 Suppliers to ensure quality aspects/needs/expectations of products are met,
4. Identifies risk level of components or assemblies and documents this risk scoring assessment, and the higher risk items trigger greater CTQ review and PFMEA Poka Yoke review,
5. Performs First Article Approval process for new components and assemblies to verify needs and expectations will be met,
6. Performs PFMEA Risk assessments within First Article Approval
7. Performs Management Review Meetings which review Employee, Supplier, and Client feedback, performance, and data,
8. Monitor Quality Performance of Tier 2 Supplier and DEE internal quality and performance with automated flag systems and reporting,
9. Review Client Purchase Orders and Contracts which specify requirements, needs, expectations, and regulatory requirements – and translate these into order requirements, work instructions

Dee Electronics defines the following as interested parties:

1. All clients
2. All internal team member
3. All Suppliers
4. External vendors which perform calibration on tools
5. All banks involved with day to day operations
6. All shipping carriers

7. Our client's customers

1. Where is this found?
2. What are these systems?

Revs  
2/2/19  
ATB

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

If this document is printed or copied, it is an uncontrolled document

Quality Manual	4 – Context of the organization	
Section 4.3	Section Revision: A	Revision Date: 6/19/2017
<b>4.3 – Determining the scope of the quality management system</b>		
Approved By: Dave Zirkelbach		Date: 6/19/2017

**DEE Electronics is a Distributor and Value-Added Integrator who performs Sales, Customer Service, Distribution, Manufacturing, Assembly, and other Value-Added functions with components and assemblies for its Original Equipment Manufacturer (OEM) Clients/Customers.**

Dee Electronics developed and implemented a quality management system to demonstrate its ability to provide consistently, product that meets customer and applicable regulatory requirements, and to address customer satisfaction through the effective application of the system, including continual improvement and the prevention of nonconformity. Dee Electronics believes that determining, implementing of, and continued improvement of processes and systems (process approach) drives desired outcomes.

The quality system complies with the international standard ISO 9001:2015.

The manual is divided into seven sections modeled on the sectional organization of the ISO 9001:2015 standard. Sections are further subdivided into several subsections representing main quality system elements or activities. Each subsection starts with a general policy statement expressing the commitment to implement the basic principles of the pertinent quality system element or activity. The general policy statement is followed by more specific procedural policies outlining how the general policy is implemented, and referencing applicable operational procedures.

The purpose of this manual is to define and describe the quality system, to define authorities and responsibilities of the management personnel involved in the operation of the system, and to provide general procedures for all activities comprising the quality system.

Another purpose of this manual is to present the quality system to our customers and other external interested parties, and to inform them what specific controls are implemented at Dee Electronics, Inc. to assure quality.

The quality management system shall be relevant to the nature of our organization and products, and to customer and regulatory requirements. For this reason, those requirements of ISO 9001:2015 that do not apply are excluded from the scope of our quality system.

## PROCEDURAL POLICIES

The following rules and criteria are used for excluding irrelevant requirements:

1. An ISO 9001:2015 requirement may be excluded only when both of the following conditions are met:

*a) The requirement must be within ISO 9001:2015 Clause 4.3*

*b) The exclusion may not affect our ability, nor absolve us from the responsibility, to provide product that meets customer and applicable regulatory requirements.*

2. The President is responsible for identifying those requirements of ISO 9001:2015 that do not apply to our organization or products, and to propose exclusions of such requirements from the scope of the quality system.

3. Top executive management has the responsibility and authority for evaluating whether the proposed exclusions are appropriate, and for approving them. Evaluation and approval of exclusions are conducted within the framework of management reviews of the quality system.

4. Any exclusions taken are documented in this section of the quality manual. The excluded requirements are precisely identified with reference to specific clauses and/or statements in the standard. There is also a brief justification why the exclusion is taken and why it is appropriate.

## EXCLUSIONS

1. **Exclusion:** ISO 9001:2015 Section 8.3, Design and Development of products and services, including all subsections

**Justification:** Dee Electronics, Inc. does not design or develop products. All principal product characteristics are specified by the customers or their consultants. Dee Electronics is a Distributor and Contract Manufacturer which buys, assembles, and resells products designed by other companies.

2. **Exclusion:** ISO 9001:2015 Section 8.5.1 Control of production and service provision(subsection "f")

**Justification:** Dee Electronics, Inc. does not require Validation of Processes because we have no Special Processes.

# QOP-43-01 Determining the scope of the quality management system

If this document is printed or copied, it is an uncontrolled document

<b>QMS Operational Procedure</b>	QOP-43-01	
Section 4.3	Section Revision: A	Revision Date: 6/19/2017
<b>Determining the scope of the quality management system</b>		
Approved By: Dave Zirkelbach		Date: 6/19/2017

## PURPOSE

The purpose of this procedure is to:

- a) Identify documents defining the quality management system, production processes, and products: and
- b) Assign responsibilities for establishing and maintaining the documentation.

## APPLICATION

Scope: This process pertains to all documents utilized in the Dee Electronics quality system.

## PROCEDURE

### 2. Quality manual

2.1 The purpose of the quality manual is to:

*State the company's principal quality policy as well as specific policies related to particular elements of the quality system;*

*Define and describe quality system processes, their sequence, and interrelation;*

*Define responsibility and authority of management personnel involved in the operation of the quality system; and*

*Outline general procedures for various activities comprising the quality system, and reference applicable Operational Procedures.*

2.2 The President and VP of Quality formulates the principal quality policy and approves the quality manual. The President and VP of Quality is responsible for maintaining the manual. The quality manual is authorized by the President and VP of Quality.

# 4.4 – Quality management system and its processes

If this document is printed or copied, it is an uncontrolled document

<b>Quality Manual</b>	4 – Context of the organization	
Section 4.4	Section Revision: A	Revision Date: 6/19/2017
<b>4.4 – Quality management system and its processes</b>		
Approved By: Dave Zirkelbach		Date: 6/19/2017

## GENERAL POLICY

The quality system described in this section of the Quality Manual conforms to the requirements of the standard: Element 4.4 Quality management system and its processes.

Dee Electronics Inc. is committed to determine, establish, document, implement and maintain a quality management system, and continually improve its effectiveness, in conformance with requirements of ISO9001:2015 International Standard.

## PROCEDURAL POLICIES

### 1. Quality system processes

1.1 Processes needed for the quality management system are determined in this quality manual and in associated operational procedures and work instructions. The documentation defines these quality system processes and their sequence and interaction, and instructs on how to implement and apply them throughout the organization.

1.2 Quality system documentation also defines criteria and methods needed to ensure that the operation and control of quality system processes are effective. This

usually includes assignment of responsibilities and allocation of resources for the process, instructions on how to carry out (or operate) the process, and definition of methods for monitoring and/or measuring the effectiveness of the process.

1.3 Dee/Company evaluates and addresses the risk and opportunities referenced in QM 6.1

1.4 Dee/Company evaluates, processes and implement changes to ensure the processes achieve their intended results, further referenced in QM 6.1

# QM 5.1 – Leadership and Commitment

If this document is printed or copied, it is an uncontrolled document

Quality Manual	5 – Leadership	
Section 5.1	Section Revision: A	Revision Date: 3/30/2017
<b>5.1 – Leadership and Commitment</b>		
Approved By: Dave Zirkelbach		Date: 3/30/2017

## GENERAL POLICY

The executive management is ultimately responsible for establishing, implementing, maintaining, and improving the quality system. Management commitment is demonstrated by communicating to the organization the importance of meeting requirements, establishing the quality policy and quality objectives, conducting management reviews of the quality system, and ensuring the availability of necessary resources.

## PROCEDURAL POLICIES

### 1. General

1.1 For the purpose of administrating the quality management system, executive management includes the President, CEO/Treasurer, Vice President-Sales, and Vice President-Operations, Vice President of Quality, Vice President of Manufacturing, and Vice President of Finance.

1.2 Dee management has put in place procedures and system to ensure the effectiveness of the quality system such as management review, internal quality auditing, various and many alert and flagging systems, in process quality inspection data entry. Proof of accountability is we put in systems to test the systems. We are committed to continuously improving effectiveness assessment systems.

1.3 Dee management committed to Six Sigma quality principals. With integration with six sigma into our processes, we utilize risk assessment via PFMEA, first article, etc. We promote process

orientation by process flow diagrams, flow charts, and other process oriented tools to manage our system.

1.4 Dee management engages, directs, and supports their employees to contribute to the effectiveness of the quality management system through various means such as various brainstorm meetings, the ability to request systematic and procedural updates, etc.

## 2. Customer Focus

2.1 Executive management is committed to communicate the importance of meeting customer as well as regulatory and legal requirements. The Management representative is responsible for implementing this commitment by promoting awareness of customer requirements throughout the organization.

# QM 5.2 Policy

If this document is printed or copied, it is an uncontrolled document

<b>Quality Manual</b>	5 – Leadership	
Section 5.2	Section Revision: A	Revision Date: 3/30/2017
<b>5.2 – Policy</b>		
Approved By: Dave Zirkelbach		Date: 3/30/2017

## GENERAL QUALITY POLICY

Dee Electronics is committed throughout to meeting our customer's requirements and expectations, as well as committed to continuous improvement.

### 1. Establishing the Quality Policy

The R&A for overall administration of Dee Electronics quality activities are shared by the President, the CEO, Treasurer, the Vice President-Sales, the Vice President – Operations, Vice President of Quality and IT, and the Vice President of Mfg. who make up the Executive Management Team.

Our Organizational Goals: – Complete Customer Satisfaction – Complete Employee Satisfaction – Complete Supplier Satisfaction – Profitability, through implemented efficiency, innovation, teamwork, integrity, quality output, and customer satisfaction.

All quality objectives are reviewed by the executive team every 6 months at a management review meeting.

### Quality Performance Objectives:

- a) Delivery Performance/late or early ' Objective set for delivery performance average of 97.0% or above for our Top 80% of our customers by \$
- b) Error-free Shipments ' Objective set for 99.7%+ lines to be delivered error-free to the customer

### Service quality objectives:

- a) RMA Turnaround Time ' Objective of 24 hour average turnaround or less for overall customer base

b) Improved New Product Introduction Service to Customers ' objective set to increase the level of New product introduction being done to customers as a service to improve our position with the customer. Evidence is increased new production information being sent out to salespeople, and sales people reflecting presentation in their call reports.

**Quality system objectives:**

- a) Reach Tier 1 Preferred supplier recognition status at 2 customers each 12 months.
- b) Receive feedback from 3 customers regarding the outstanding nature of our quality system each 12 months as compared to our peers.

**Continuous Improvement Objectives:**

- a) Constant and continuous improvement in quality and service visible in daily or weekly improvement (measurable by changes to systems and procedures)
- b) Continuous efficiency improvement and reduction of operating costs to enable us to be extremely competitive in the marketplaces we serve (measurable by growth in sales, increase in quoting activity, and lower operating costs as a % of net sales)
- c) Continuous creation of new and differentiated advantages and services for our Customers, Suppliers, and Employees, via continuous development and improvement in Quality System (measurable by new services and programs created)
- d) Intertwining of Quality System with our servicing and value-adding processes to achieve superior customer growth and retention (measurable by growth in sales, employee satisfaction and ability to perform for the customer, and new services and service levels created for customers)

**2. Communicating the Quality Policy**

2.1 The quality policy is posted throughout the company and held online for anyone to view.

2.2 The quality policy and its role is explained and discussed at the general orientation training provided to all employees.

2.3 The quality policy is also communicated to customers, vendors, and other interested parties. For this purpose, it is displayed in the reception area and posted on the company's internet site.

*Fanson  
EoS*

## 5.3 – Organizational roles, responsibilities and authorities

If this document is printed or copied, it is an uncontrolled document

Quality Manual	5 – Leadership	
Section 5.3	Section Revision: A	Revision Date: 6/19/2017
<b>5.3 – Organizational roles, responsibilities and authorities</b>		
Approved By: Dave Zirkelbach		Date: 6/19/2017

### **GENERAL POLICY**

Functions and their interrelation within the company are defined and communicated.

Executive management appoints a management representative of the Dee Electronics organization responsible for establishment and maintenance of the quality system, and for reporting to the executive management on the performance of the system.

Issues regarding the quality system are communicated internally through distribution of pertinent documents, meetings, training and awareness programs, and management reviews.

### **PROCEDURAL POLICIES**

The Responsibility and Authority for overall administration of Dee Electronics quality activities are shared by the Executive Management: the President and the CEO/Treasurer. The associates of Dee Electronics have the responsibility to carry out all quality activities in support of its quality policy, quality system documentation and customer requirements. Each associate has been granted appropriate authority in order to meet specified requirements.

Departments, groups and functions within the company, and their interrelations, are defined in the Dee Electronics Quality Manual, Quality Operations Procedures, and Organizational Chart.

## MANAGEMENT RESPONSIBILITY

1.1 Quality Policy – A company quality policy has been established by executive management identifying quality system goals, objectives and commitment to customer expectations. This policy has been communicated to all employees and is maintained as the highest priority within the company. Each associate understands his or her role.

1.2. Responsibility and Authority – The responsibility, authority and interrelation of personnel who manage, perform and verify work affecting quality has been defined and documented, particularly for personnel who need the organizational freedom and authority to:

- Call for a stop* • Initiate action to prevent nonconformities relating to product, process and quality system,
- CAR System* • Identify and record any problems relating to the product, process and quality system,
- IT* • Initiate, recommend or provide solutions through designated channels,
- CAR System* • Verify the implementation of solutions,
- INC, WP* • Control further processing or delivery of nonconforming product until the deficiency or unsatisfactory condition has been corrected.
- SPEC hand* • ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented

1.3. Resources – Resources required to complete quality system activities are identified during management review and adequate resources are provided, including assignment of trained personnel for management, performance of work and verification activities, including internal quality audits.

1. Training will ensure the availability of qualified people to perform management, distribution and verification activities.
2. Team Members with input to the adequacy of resources are invited to submit their suggestions and/or concerns to executive management by way of the Employee Concern Form posted on the Internet Site.

1.4. Management Review – The executive management team carries out scheduled Management Review meetings at defined intervals. These reviews determine the effectiveness and suitability of the implemented quality system requirements. Minutes of these review meetings are maintained as records.

## 2. INTERNAL COMMUNICATION

Internal communication regarding the quality system flows two ways:

WI  
2.1. The management communicates to the organization the quality policy and objectives; customer and regulatory requirements; product and process specifications; verification and validation requirements; and instructions on how to implement and use the quality system.

Clm before  
CARs  
2.2. The organization communicates to the management information and data regarding customer needs and expectations, customer satisfaction, quality performance, the effectiveness of the quality system, and opportunities for improvement.

The information is communicated through manuals, procedures, instructions, quality records, reports, etc.; and through training, on-the-job instruction, and meetings.

2.3. Management review meetings have a special role in ensuring proper communication between the top management and the organization. The meeting provides the framework for the organization to report on the status of quality-related issues and activities, and for the management to formulate policies and directives to change and/or improve the quality system.

2.4. The President has the overall responsibility for ensuring that all pertinent documents, reports and records are distributed to appropriate departments and functions, and that information and data about quality performance and the effectiveness of the quality system are reported to the top management.

## 3. Quality system planning

3.1 Quality system elements and processes are planned to ensure that the system is appropriate for its intended purpose, and that it is effective and efficient. The purpose of the quality system is:

*To achieve the quality policy;*

*To ensure and demonstrate our ability to provide consistently product and services that meets customer and regulatory requirements;*

*To ensure high level of customer satisfaction;*

*To facilitate continual improvement; and*

*To comply with requirements of ISO 9001:2015 standard.*

3.2 The output of quality system planning is documented in this quality manual, in associated operational procedures, and in other referenced documents. These documents identify and define all elements and processes of the quality system.

3.3 Changes to the quality system are planned within the framework of management reviews. These changes may be in response to changing circumstances, such as product, process, capacity, or other operational or organizational change; or to improve the effectiveness and efficiency of the quality system.

## **ASSOCIATED DOCUMENTS**

Organizational Chart

# 6.1 – Actions to address risks and opportunities

If this document is printed or copied, it is an uncontrolled document

Quality Manual	6 – Planning	
Section 6.1	Section Revision: A	Revision Date: 6/19/2017
<b>6.1 – Actions to address risks and opportunities</b>		
Approved By: Dave Zirkelbach		Date: 6/19/2017

## GENERAL POLICY

Quality objectives are established to support and implement the quality policy and continual improvement. Quality planning includes identification and determination of quality system processes (including any exclusions of ISO 9001:2015 requirements); priorities for continual improvement; and resources needed to achieve quality objectives and to maintain and improve the quality system. Quality plans are periodically reviewed and updated to maintain the integrity of the quality system during organizational and other changes.

## PROCEDURAL POLICIES

### 1. Quality system planning

1.1 Quality system elements and processes are planned to ensure that the system is appropriate for its intended purpose, and that it is effective and efficient. The purpose of the quality system is:

To achieve the quality policy;

*To ensure and demonstrate our ability to provide consistently product and services that meets customer and regulatory requirements;*

*To ensure high level of customer satisfaction;*

*To facilitate continual improvement; and*

*To comply with requirements of ISO 9001:2015 standard.*

1.2 The output of quality system planning is documented in this quality manual, in associated operational procedures, and in other referenced documents. These documents identify and define all elements and processes of the quality system.

1.3 Changes to the quality system are planned within the framework of management reviews. These changes may be in response to changing circumstances, such as product, process, capacity, or other operational or organizational change; or to improve the effectiveness and efficiency of the quality system.

## **2. CORRECTIVE AND PREVENTIVE ACTION**

### 2.1 Preventive versus corrective action

*In Pro meas*  
2.1.1 Preventive actions are requested and implemented when there are trends of decreasing quality capability and/or effectiveness of the quality system that create a risk for a potential nonconformity. Corrective actions are used when an actual nonconformity is identified.

2.1.2 Recognizing this difference, Dee Electronics has separate systems for identifying the need for corrective and preventive actions. However, once the need is identified, a common system is used to process both types of actions. Forms, logs and other documents and records for processing of corrective and preventive actions are the same.

2.1.3 Both corrective and preventative actions work to enhance all desirable effects on a case by case basis in all capacity.

### 2.2 Corrective actions

2.2.1 The need for corrective action is determined on the basis of identified actual nonconformities. Corrective action requests are typically triggered by such events as a failed inspection, customer complaint and/or product return, nonconforming delivery from a supplier, or a quality system audit finding.

### 2.3 Preventive actions

2.3.1 The need for preventive action is determined on the basis of information and data regarding capability and performance of processes, product nonconformity rates, post-order fulfillment

experience feedback, customer complaints, quality system audit findings, and management review ideas. Such information and data are collected and analyzed to detect unfavorable trends that, if not checked, will increase the risk of nonconformities. The system for collecting and analyzing quality performance information and data is defined in Section 8.4 of this manual.

## 2.4 Processing of corrective and preventive actions

2.4.1 Preventive and corrective actions are initiated, processed and followed up using a CAR or Internal Audit/Management Corrective/Preventive Action Form. The forms document the unsatisfactory condition and the corrective or preventive action to be taken, and is used to record the verification and closure of the action. Open CARs are reviewed regularly to ensure that the actions are implemented and followed up in a timely manner.

## 2.5 Continual improvement

2.5.1 Continual improvement actions are often defined as corrective and preventive actions. This is especially true for preventive actions.

## **2.6 Effectiveness of Corrective Action and Preventative Action**

2.6.1 The effectiveness of Corrective Action and Preventative Action taken is reviewed and records of this are maintained in the Corrective Action log and Management Review Meeting Minutes.

# QM 6.2 Quality objectives and planning to achieve them

If this document is printed or copied, it is an uncontrolled document

Quality Manual	6 – Planning	
Section 6.2	Section Revision: A	Revision Date: 3/30/2017
6.2 – Quality objectives and planning to achieve them		
Approved By: Dave Zirkelbach		Date: 3/30/2017

## GENERAL POLICY

Quality objectives are established to support and implement the quality policy and continual improvement. Quality planning includes identification and determination of quality system processes (including any exclusions of ISO 9001:2015 requirements); priorities for continual improvement; and resources needed to achieve quality objectives and to maintain and improve the quality system. Quality plans are periodically reviewed and updated to maintain the integrity of the quality system during organizational and other changes.

## PROCEDURAL POLICIES

### 1. Quality objectives

1.1 Quality objectives are established throughout the organization to implement the quality policy, to meet requirements for products and processes, and to improve quality system and quality performance.

1.2 Quality objectives define the direction and priorities for continual improvement.

1.3 Quality objectives are classified into the following four categories:

*Policy objectives:*

*These are principal, strategic objectives that apply to the whole organization (Continuous Improvement Objectives). They are typically included in the Quality Policy itself, or may be communicated in memoranda from the top management. Policy objectives are authorized by the President.*

*Quality performance objectives:*

*These objectives set specific, measurable targets for improving operational performance to ensure customer satisfaction (examples are: improvement of on-time delivery performance, improvement in delivery of un-damaged product, etc...). They apply to departments and functions having direct responsibility for activities that require improvement. Performance objectives are established, documented, and monitored within the framework of management reviews of the quality system.*

*Service quality objectives:*

*These objectives pertain to improvement of services (examples are improved packaging techniques, improvement in Packing Slips, improvement customer alerts, etc...). Service objectives are established by the President and top executive managers responsible for marketing and product/service development. They can be documented in product briefs, memoranda, or minutes of meetings; and apply to functions responsible for development of services.*

*Quality system objectives:*

*These objectives pertain to improvement of quality system processes and performance (examples are: Customer Recognition Awards, expansion of ISO9001:2015 Certification to other facilities, etc...). Quality system objectives are established, documented, and monitored within the framework of management reviews of the quality system.*

# QM 6.3 Planning of changes

If this document is printed or copied, it is an uncontrolled document

Quality Manual	6 – Planning	
Section 6.3	Section Revision: A	Revision Date: 3/30/2017
<b>6.3 – Planning of changes</b>		
Approved By: Dave Zirkelbach		Date: 3/30/2017

## GENERAL POLICY

Quality objectives are established to support and implement the quality policy and continual improvement. Quality planning includes identification and determination of quality system processes (including any exclusions of ISO 9001:2015 requirements); priorities for continual improvement; and resources needed to achieve quality objectives and to maintain and improve the quality system. Quality plans are periodically reviewed and updated to maintain the integrity of the quality system during organizational and other changes.

## PROCEDURAL POLICIES

### 1. Quality system planning

1.1 Quality system elements and processes are planned to ensure that the system is appropriate for its intended purpose, and that it is effective and efficient. The purpose of the quality system is:

To achieve the quality policy;

*To ensure and demonstrate our ability to provide consistent product and services that meets customer and regulatory requirements;*

*To ensure high level of customer satisfaction;*

*To facilitate continual improvement; and*

*To comply with requirements of ISO 9001:2015 standard.*

1.2 The output of quality system planning is documented in this quality manual, in associated operational procedures, and in other referenced documents. These documents identify and define all elements and processes of the quality system.

1.3 Changes to the quality system are planned within the framework of management reviews. These changes may be in response to changing circumstances, such as product, process, capacity, or other operational or organizational change; or to improve the effectiveness and efficiency of the quality system.

1.4 Top level management reviews changes to the integrity of the quality system. IQA's validate the integrity of the system. We also do control tests on smaller scales when deemed necessary.

1.5 Dee reviews the availability of resources and allocation / re-allocation of resources by acquiring and analyzing data for tact time data for assembly, manufacturing, distribution, corrective actions, etc. Since we know how long everything takes, we can calculate what the planned changes impacts will be.