Anders Bredenberg – 3/29/17

1st QTR Summary:

Findings that require action:

1) QOP 42-03, Item 3. This is mostly accurate, but needs tweaked. For example, not every server is backed up daily, some are weekly. Also, we also send snapshots to DM from CR and vice versa now.
2) QOP 71-01. Dave Z currently is not involved in Dee DM's PFEMA process. This needs to be updated to the quality coordinator reviews and quality manager has final sign off.
3) Sue Klug seems to begrudge the filing process, as she has several large stacks of papers that need to be filed sitting behind her desk. When I asked why they are there, she said "I would have to go all the way back to the filing cabinets to do that. They are also getting full."

Notes:

1) All employees have access to the parts of the Quality manual that relates to their position, however, most do not know where to find the full manual.
2) Currently, the only work instructions in use are for DBA assemblies. No other procedural work instructions exist.
3) I asked Rose Carter and Gene Engstrom to close their current work instructions, and locate them again. They were both able to do so.
4) All customer drawings/specifications are found on the K: drive. They are never linked on work instructions.
5) I reviewed the control plan for DBA 101187. No non-conformances.
6) The quality manual, and supporting documents are split into 4 different levels.
   a) The first tier consists of the quality system documentation structure. This covers all requirements of the standard.
   b) The second tier consists of our documented procedures.
   c) The third consists of our work instructions
   d) The fourth consists of records, forms, tags, and other documentation.
7) The quality manual change request form is found in the ECIS Access app>Quality Control>Document Change Request.
8) All changes are also documented here.
9) The most recent change made to the Dee DM quality manual was an addition to QM 6.4 regarding the 5s champion.
10) All changes made are highlighted in bold when viewing the quality manual.
11) Dee DM has 7 CARs currently open.
    a) Four stemming from CR.

b) Most are just waiting for credit to be issued from the vendor.
c) The oldest CAR currently open was entered on 3/8/17.

12) Chris Winslow creates all control plans for Dee DM.
13) Brenda was having an issue with a supplier that sends them a C of C certifying that the parts all conform to their given print/CTQ elements, however they continue to receive parts that are non-conforming and cannot be used.
14) Dee DM's calibration log is worked on a weekly basis. Brenda prints the list of tools that need calibration out, gives it to QA, and they will typically return the completed list the following Monday.

QM 4.1 – General Requirements

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Quality Manual	4 – Quality Management System	
Section 4.1	Section Revision: **C**	Revision Date: **9/16/2014**
4.1 – General Requirements		
Approved By: Todd Gifford		Date: 7/12/2010

GENERAL POLICY

The quality system described in this section of the Quality Manual conforms to the requirements of the standard: Element 4.1 General Requirements.

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 ISO9001:2008 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 Operational Procedure QOP-42-01, Quality System Documentation, explains in more detail how quality system processes are defined and documented.

2. Resources and information

2.1 President is responsible for determining resource and information requirements necessary to support the operation and monitoring of quality system processes, and for communicating these requirements to the top management. The top executive management is responsible for ensuring the availability of necessary resources and information. Section 6.1 of this quality manual, Provision of Resources, explains in more detail how resource requirements are identified and satisfied.

3. Monitoring and measurement

3.1 The performance of quality system processes is systematically monitored and/or measured (where applicable). This is to ensure their effectiveness and identify opportunities for improvement.

3.2 The performance of product realization processes is usually monitored by measuring process parameters and/or product characteristics resulting from the process; and through the program of inspections and tests applied to the product. The performance of processes required for quality management is usually monitored through internal quality audits. The overall performance of the quality system is monitored by measuring customer satisfaction.

3.3 Monitoring and measuring activities are defined in Sections 8.1 and 8.2 of this quality manual, and in the corresponding operational procedures.

4. Conformance and continual improvement

4.1 Quality management system processes are regularly reviewed by the top management to identify any possible failures or breakdowns, as well as opportunities for improvement. Actions necessary to address actual or potential problems and to improve the quality system are implemented through corrective and preventive actions and management improvement projects. Sections 5.6 and 8.5 of this quality manual and the corresponding operational procedures define how management reviews and

corrective/preventive actions are used to ensure conformance and improvement.

5. Outsourced processes

5.1 Dee Electronics currently does outsourcing for a select group of items / situations.

5.2 When processes that affect product conformity are outsourced (performed by an external party), special controls are implemented to ensure that these processes meet specified requirements. Such controls may include, as appropriate: evaluation and pre-qualification of suppliers; assessment of supplier realization processes and quality system; monitoring of supplier quality performance; requirements for inspection, testing or other records demonstrating product conformity; or containment and verification of the supplied product. Section 7.4 of this quality manual and the corresponding operational procedures define such purchasing control system.

ASSOCIATED DOCUMENTS

Quality Manual: All sections

Operational Procedure QOP-42-01: Quality System Documentation

QM 4.2 – Documentation and Records

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Quality Manual	4 – Quality Management System	
Section 4.2	Section Revision: A	Revision Date: 7/12/2010
4.2 – Documentation and Records		
Approved By: Todd Gifford		Date: 7/12/2010

GENERAL POLICY

The quality system described in this section of the Quality Manual conforms to the requirements of the standard: Element 4.2 Documentation Requirements.

Scope of the quality system documentation is defined. Establishment and revision of documents, and their distribution, are controlled. New documents and revisions are reviewed and approved prior to issue; and are identified with respect to their revision level. Appropriate documents are available at locations where they are used. Obsolete documents are removed from points of use. Documents of external origin are identified and their distribution is controlled.

Quality records are identified and indexed to facilitate their retrieval, and are stored in a suitable environment to minimize deterioration. Quality records are retained for a period of time at least equivalent to the lifetime of the product.

PROCEDURAL POLICIES

1. Scope

1.1 Dee Electronics, Inc. quality system documentation comprises the following types of documents and records:

Quality manual (including a documented quality policy); Documented statements of quality objectives; Operational procedures; Work instructions; Product realization and control plans.

The documentation structure that is used in this quality system consists of four tiers:

- The first tier of the quality system documentation structure is the quality manual (including documented Quality Policy), which covers all requirements of the standard, makes reference to quality system procedures, outlines the documentation structure and illustrates Dee Electronics' positive commitment to fulfill these requirements.
- The second tier consists of documented procedures, which are specified methods for managing activities. These procedures are consistent with the requirements of the standard and DEE's quality policy, and are to be implemented effectively.
- The third tier is work instructions, which are highly specific ways to perform activities.
- The fourth tier consists of records, forms, tags and other documentation.

A single document may include the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.

Purpose, scope, and responsibility for controlling various types of documents are defined in Operational Procedure QOP-42-01, Quality System Documentation.

2. Quality Manual

2.1 The top level document defining the overall quality management system is the Quality Manual. It includes:

The scope of the quality system, including details of and justification for any exclusions (refer to Section 0.3);

Description of quality system processes, their sequence, and interrelation; and

References to documented procedures.

3. Document control

3.1 Dee Electronics has established and maintains documented procedures to control all documents and data that relate to requirements of the ISO 9001:2008 standard, including, to the extent applicable, documents of external origin (those

determined by the organization to be necessary for the planning and operation of the quality management system).

3.2 Document and Data Approval and Issue – The documents and data are reviewed and approved for adequacy by authorized personnel prior to use. An electronic document control procedure identifying the current revision status of documents is readily available to prevent the use of invalid and/or obsolete documents.

3.3 The authorized functions and the rules governing the issue of documents are defined in procedures QOP-42-01, Quality System Documentation, and QOP-42-02, Control of Documents. All documents are reviewed and approved prior to issue.

3.4 The pertinent issues of appropriate documents are available electronically at all locations where operations essential to the effective functioning of the quality system are performed. Invalid and/or obsolete documents are promptly removed from electronic access, or otherwise assured against unintended use. Any obsolete documents retained for legal and/or knowledge purposes are suitably identified.

3.5 Changes to documents and data are reviewed and approved by the same functions that performed the original review and approval, unless specifically designated otherwise. The designated functions or organizations have access to pertinent background information upon which to base their review and approval. Where practicable, the nature of the change is identified in the document or the appropriate attachments.

4. Control of quality records

4.1 Dee Electronics has established and maintains documented procedures to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records. Records maintained are legible, identifiable, and retrievable.

4.2 Quality records are established and maintained to provide evidence that: There has been conformance to specified requirements, and the quality system is operated in accordance with documented procedures and that it is effective.

4.3. All quality records are legible, and are stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times of quality records have been established and recorded. Where agreed contractually, quality records are made available for evaluation by the customer or the customer's representative for an agreed period.

ASSOCIATED DOCUMENTS

Operational Procedure QOP-42-01: Quality System Documentation

Operational Procedure QOP-42-02: Control of Documents

Operational Procedure QOP-42-03: Control of Quality Records

QOP-42-01 – Quality System Documentation

Brenda B.
Rose C.
Gene E.

7. DBA 10/18/T

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QMS Operational Procedure	QOP-42-01	
Section 4.2	Section Revision: **B**	Revision Date: **8/14/2014**
Quality System Documentation		
Approved By: Todd Gifford		Date: 7/12/2010

PURPOSE

The purpose of this procedure is to:

a) Identify documents defining the quality management system, production processes, and products: and

1. 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

1. General

1.1 The scope and extent of quality system documentation is determined on the basis of the complexity and interaction of processes, elements, and activities; and

on competence of personnel. The documentation is sufficient to ensure the effective planning, operation and control of the quality system, processes, and products.

2. 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 formulates the principal quality policy and approves the quality manual. The President is responsible for maintaining the manual. The quality manual is authorized by the President.

3. Operational procedures

3.1 The purpose of operational procedures is to define systems, assign responsibilities and authorities, and provide instructions for carrying out activities comprising the quality system. Operational procedures explain the what, when, who and how for each activity; identify interfaces for the activity; and instruct who should be informed and how the results of the activity should be recorded.

3.2 Operational procedures are code numbered QOP-SS-NN. QOP stands for *Quality Operational Procedure*, SS is the section in the quality manual to which the procedure pertains, and NN is the consecutive number of a procedure for the section.

4. Work instructions

3. 4.1 The purpose of work instructions is to guide personnel in performing specific tasks, such as carrying out and controlling processes (process operator instructions), handling products, conducting tests or inspections, and so forth.

4. 4.2 Work instructions are documented electronically, generally, on the forms in which the personnel performing the task are using.

5. Customer engineering documents

5. 5.1 This category includes customer drawings, specifications and other documents defining the customer's requirements. These can be product documentation, testing procedures, acceptance criteria, and so forth.

6. 5.2 Customer's documents are not used directly in our processes. They are re-interpreted and re-issued as Dee Electronics's own documents/work instructions/records.

6. Product realization and control plans

6.1 Documents under this category are the output of product realization and verification planning, as defined in Section 7.1 of the quality manual.

6.2 The purpose of product realization plans is to sequence, coordinate, and schedule operations; and reference electronic forms used. Process flowcharts and electronic order input forms are examples of documents defining plans.

6.3 Control plans identify process control scope and methods, define the inspection/testing points and methods, and reference specific process control and inspection instructions, and acceptance criteria.

6.4 These types of documents are usually issued by the **Facility Ops Manager** or Quality Assurance.

ASSOCIATED DOCUMENTS

Operational Procedure QOP-42-02: Control of Documents

1. Define what these are?
2. Ask 3 employees where the quality manual is located.
3. Where are these located? do they only cover assemblies?
4. Ask 3 employees to locate a work instruction relevant to them.
5. Where are these located?
6. Are these Specs/Prints linked on work instruction?
7. Control Plan example.

QOP-42-02 – Control of Docu

Dave

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QMS Operational Procedure	QOP-42-02	
Section 4.2	Section Revision: **B**	Revision Date: **8/14/2014**
Control of Documents		
Approved By: Todd Gifford		Date: 7/12/2010

General

Purpose:The intent of this procedure is to describe the process at Dee Electronics for Document and Data Control, Section 4.2.3 of ISO 9001:2008.

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

Definitions

1. QM- Quality Manual.
2. QOP- Quality Operations Procedure.
3. QF- Quality Form.

Responsibilities

1. The overall R&A for activities relating to this element of the standard have been assigned to the President and the MR. Team Members are charged with the responsibility to implement the procedure as written, and have been granted appropriate freedom and authority to do so.

Procedure

1. Dee Electronics makes every effort to create a paperless environment for quality documentation. Controls are in place to ensure accessibility and security.
2. The quality system documentation at Dee Electronics consists of four levels, as described in QM 4.2 of the Quality Manual.
1. 3. Level I through Level IV documentation, and a corresponding Master List, is located on our Intranet website on our Network, and is accessible by all employees.
4. Documentation on the Intranet website is maintained in a read-only format. Only the President **and Quality Manager are** permitted to alter the format or content of our Quality System documentation.
2. 5. Requests for changes to quality documents are submitted to the MR or President by way of an electronic Document Change Request, Form QF-42-02-01, identifying the originator of the change, the approval of the change by the original approval authority, and background information explaining the reason(s) for the change. The Document Change Request is associated electronically with the revised document so that the change history is always available.
6. Quality document change requests are reviewed and approved by the the President **or Quality Manager,** verbally or via electronic mail for entry into controlled documents.
3. 7. Quality Manual and Procedure last changes will be highlighted in bold type.
8. Dee Electronics conforms to the PRO-3 Registration Mark Procedure concerning the use of the Registration Mark and the Accreditation Marks.
9. Dee Electronics can control external documents if it has need to do so.

Related Documentation

QF-42-02-01 Quality Form: Document Change Request Form

QOP-42-01 Operational Procedure

1. Where is this located?

2. "_____"

3. Example

Dave

Dave

QOP-42-03 – Control of Recc

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QMS Operational Procedure	QOP-42-03	
Section 4.2	Section Revision: **B**	Revision Date: **8/14/2014**
Control of Records		
Approved By: Todd Gifford		Date: 7/12/2010

General

Purpose: The intent of this procedure is to describe the process at Dee Electronics for the

Control of Quality Records, Section 4.24 of ISO 9001:2008.

1.2 Scope: This procedure pertains to all company and vendor-related quality records that are utilized in the Dee Electronics quality system documentation plan and are required by ISO 9001:2008.

Definitions: none

Responsibilities
The overall R&A for this element of the standard have been assigned to the President and the MR. Team Members are charged with the responsibility to implement the procedure as written, and have been granted appropriate freedom and authority to do so.

Procedure

1. As Retention R&A for specific categories of quality records, the President and the MR ensure that identified electronic quality records are retained and stored using methods that guarantee their preservation, legibility and accessibility to authorized persons.
2. The President or MR makes hard copy quality records available to customers when contractually agreed.
3. The President **and Quality Manager** maintain, revises, and safeguards required electronic quality records, including off-site storage of backed-up records. Backups are done nightly, which is a snapshot of every virtual server. 10 restore points (10 days worth of backup) is kept on the server. A monthly backup is created the first Saturday of every month to an external hard drive. This hard drive is stored in a fire proof safe when not full in the IT Director's office, and when it is full, it is given to the President to be retained in his home.

Associated Documents

QF-42-01 Quality Form – Quality Records List / Retention Matrix

QOP-42-01 Operational Procedure – Quality System Documentation

QOP-42-02 Operational Procedure – Control of Documents

QM 5.2 – Customer Focus

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Brenda

Oldest 3/8/17
CARs Open 7/4 CR

Quality Manual	5 – Management Responsibility	
Section 5.2	Section Revision: A	Revision Date:
5.2 – Customer Focus		
Approved By: Todd Gifford		Date: 7/12/2010

GENERAL POLICY

The principal objective of the quality management system is to focus our organization on the customer, and in particular, on customer satisfaction. The key to achieving high customer satisfaction is a good understanding of customer requirements and a capability to consistently fulfill these requirements.

PROCEDURAL POLICIES

1. Determining customer requirements

1.1 Customer requirements are understood broadly to include all aspects of product requirements and associated services, that are relevant to customer satisfaction. When appropriate, this may also include customer needs and expectations. Specialized ongoing Customer requirements and attributes are also understood and documented.

1.2 Customer order requirements are determined and verified through the process of order review. This process is defined in this manual in Section 7.2, Customer-related Processes, and in operational procedures QOP-72-01 Order Processing.

2. Meeting customer requirements

2.1 Nearly all processes and elements of the quality system are designed and implemented specifically to ensure that customer requirements are met. This starts

with provision of required training, and adequate infrastructure and suitable work environment (Section 6, Resource Management). Next follows planning and implementation of reliable and effective product realization processes (Section 7, Product Realization). And finally, activities related to product and process monitoring and verification (Section 8, Measurement, Analysis and Improvement).

2.2 Meeting of customer requirements is monitored and/or verified by variety of methods defined in Section 8.2, Monitoring and Measurement, and in associated operational procedures. Results of these verification activities are recorded to provide evidence of product conformity, as defined in Section 4.2, Documentation and Records.

3. Customer satisfaction

3.1 Focusing on customer requirements and on meeting these requirements should result in enhancing customer satisfaction. In fact, the level of customer satisfaction is used as a measure of the effectiveness of the whole quality system.

3.2 Specific methods for determining customer satisfaction are defined in quality manual Section 8.2 and in the associated operational procedure QOP-82-01, Customer Satisfaction. This valuable information is reported and used as described in Section 5.6, Management Review.

ASSOCIATED DOCUMENTS

QOP-72-01 Operational Procedure: Order Processing

QOP-72-02 Operational Procedure: Customer Feedback and Complaints

QOP-82-01 Operational Procedure: Customer Satisfaction

QOP-56-01 Operational Procedure: Management Review

QM 7.1 – Planning of Product Realization

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Quality Manual	7 – Product Realization	
Section 7.1	Section Revision: A	Revision Date: 7/12/2010
7.1 – Planning of Product Realization		
Approved By: Todd Gifford		Date: 7/12/2010

GENERAL POLICY

Planning of product realization processes includes determination of requirements and quality objectives for products and services applicable to a product distribution-only environment; and establishment of processes, and documents, and to provide resources specific to the product. The plan also defines requirements for records necessary to demonstrate process and product conformity.

PROCEDURAL POLICIES

1. Product requirements and quality objectives

1.1 Product requirements and quality objectives (if applicable) for product are defined and communicated in customer orders submitted to Dee Electronics.

1.2 Section 7.2 of this manual explains in more detail how customer and product requirements are determined and reviewed.

2. Product realization planning

2.1 Product realization planning includes, as applicable:

Development of adequate and capable processes,

Identification of special processes and consideration of associated risks and consequences,

Establishment and implementation of appropriate process control measures,

Development of instructions, documents, and training for process operators, and

Requirements for records necessary to demonstrate process conformity.

2.2 Product realization plans are established in collaboration between the President, CEO/Treasurer, Vice President of Operations, Operations staff, and Quality Assurance. The plans are defined in various types of documents, such as process flowcharts, work instructions, work orders, control plans, operator instructions, process validation reports, etc.

2.3 Operational procedures related to Section 7.5, Production and Service/Operations, explain how outputs of product realization planning are used.

3. Product verification and validation planning

3.1 Product verification, validation, monitoring, measurement, and inspection plans determine the inspection program (if applicable) for a product or service. This includes:

Any applicable Identification of inspection points,

Any applicable Inspection scope, frequency, and method,

Any applicable Acceptance criteria, and

Any applicable Requirements for records necessary to demonstrate product conformity.

3.2 The President, Vice President of Operations, Vice President of Sales, Quality Assurance, Production Supervisor, and Distribution Supervisor are responsible for development of any applicable product verification plans. The plans are defined in various types of documents, such as specifications, special handling instructions, work orders, purchasing documents, inspection procedures, and so forth. Documents defining the inspection program for a product (if applicable) are collectively referred to as control plans.

3.3 Operational Procedures QOP-74-03, Verification of Purchased Product; QOP-82-04, In-process Inspections; and QOP-82-05, Final Inspection, explain how outputs of product verification and validation planning are used.

ASSOCIATED DOCUMENTS

QOP-72-01 Operational Procedure: Order Processing

QOP-74-03 Operational Procedure: Verification of Purchased Product

QOP-82-04 Operational Procedure: In-process Inspections

QOP-82-05 Operational Procedure: Final Inspection

QOP-71-01 Control Plan Dev

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Dave
Brenda

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QMS Operational Procedure	QOP-71-01	
Section 7.1	Section Revision: B	Re
Control Plan Development		
Approved By: Todd Gifford		Date: 11/15/14

I PURPOSE

The purpose of this procedure is to provide for a system and instructions, and to assign responsibilities for creating assembly Control Plans.

II APPLICATION

This procedure applies to all assemblies. This procedure concerns Assembly and Quality Assurance departments.

III PROCEDURE

1. 1. DEE creates a Control Plan for each assembly or applicable assembly family that includes a PFD Process Flow Diagram, PFMEA, Control Plan, Work Instructions, and linked or relevant specifications and client requirements. Training for developing Control Plans is identified in the Training Matrix.

2. The PFMEA is created and identifies higher risk processes or components or CTQ Critical to Quality aspects of assembly. Client CTQ Critical to Quality issues or aspects for assembly are requested by DEE and included in PFMEA/Control Plan where applicable. Where there is a high risk process or component identified in the PFMEA, the following steps are taken:

2.1 High risk process – identify poke yoke/error proofing methods to eliminate risk, which could be systems or jigs, etc…

2. 2.2 High risk component – request a Certificate of Analysis for CTQ aspect of component from supplier or request a PFMEA/Control plan from supplier or identify specific incoming inspection criteria and utilize for incoming inspection.

3. 2.3 High risk process involving a tool or device with calibration requirements – identify a proactive assessment process to ensure proper calibration. An example would implementation of an in-process quality inspection or measurement which proactively assesses proper calibration.

4. **2.4 Quality Manager will sign off PFMEA of all control plans**

3. Control Plan is linked in System to Assembly Part # and only the most current version of the Control Plan is available to users.

ASSOCIATED DOCUMENTS

QM 7.1 Planning of Product Realization

1. Control Plan Champion?
2. How often is this done? Example?
3. Calibration Log.
4. Dave Sign off?