1st QTR Audit Summary:

1) The majority of my audit was with Brenda. She is the QC for this site and the audit was specific to Quality Management.
2) The DM office has made huge strides to get everything up and running in the short time they have been at the new site. A lot of improvements were done in the 3 months since I was last there.
3) Brenda is the main person that Des Moines uses and utilizes for all repairs or needs. She is the go to person to get things done and fixed.
    a. There should be something documenting this for employees. Especially new employees besides word of mouth.
    b. There should also be a back up to this process in the event Brenda is out of the office. This should also be documented.
4) To assist in Quality in production, each employee is assigned a locker with a padlock. All production and warehouse employees are also assigned a cup with a locking lid.
    a. This is to ensure that no one is taking or damaging company or personal property.
5) Confidential paper is shredded. The company is called Shred-It.
    a. They supply 4 bins. 3 with locks and 1 open larger bin.
    b. Any and all paper goes into one of the 4 bins depending on what the paper is and what it was used for.
6) Brenda uses an excel file for monitoring and measuring quality Des Moines site wide.
    a. I have advised before for this to be done in ECIS.
    b. This time the excel file was not on just her computer. It has been put in a place where DM and also CR personnel can get to it if needed.
    c. The4 excel file goes back to 2013 and a query can be done to find multiple instances in part, vendor, manufacture, or employee.
7) Chris Winslow looks at the reports for Quality Management for the Des Moines office.
8) There is a Prietto chart that has the corrective action log.
    a. There is also Defective Raw Materials in this log.
    b. You can attach a person or reason to any portion of the log.
    c. Part DM00753
        i. This part is supposed to be cut into 15” length and was actually being cut into a shorter length of 12” at 500 pieces.
        ii. Brenda talked to employees to find out what happened.
        iii. Terry retrained on work instruction pads.
            1. The employees did not realize that they had to physically X out or shut down the previous work instructions to get the new ones up or it will stay on the original work instructions.
        iv. Brenda documented in the employees training log that they were retrained on this.
9) Any and all employees will come directly to Brenda to with needs or wants pertaining to the documentation for quality.
10) All employees have access to the Quality Manual.

    a. I am unsure as to how many know how and where to find it.
11) The majority of QA in the Des Moines office is done by Brenda, per Brenda. The RMA/Quality information is available to Brenda, Chris Winslow, Brian, etc.
12) Tools are job specific and organized as such.
    a. The tools are organized per work station with pictures of what tools are at that work station on the table or bench. When the employee comes in and leaves, such tools should all be accounted for.
    b. This not only helps with Quality but also 5S.
13) Todd approves and formulates the Quality Manual.
14) Brenda stated all work instructions are on the tablet and every employee knows how to access them.
    a. This includes all drawings and control plans. They are also all in one spot and on each work order as they are pulled up.
    b. While walking through the production area, all the employees had the work instructions up and were working off of them.
15) There is no Emergancy Manual for Des Moines.
    a. They use the same procedures as Cedar Rapids.
    b. This is something that Brenda, Dave Z, and I talked about in the quality meeting and we will be working together to make new and updated ones that are site specific.
16) All documented instructions, quality manual, operation procedures, control plans, and product realization are available on the intranet.
17) Dave handles the documentation of the four tiers. He makes any changes per the direction of Todd and management meetings.
18) Todd and Dave also handle updating any and all changes to the quality manual.
19) Data control specifically for the Des Moines office is done by Chris Winslow.
    a. This includes the work instructions.
20) There is a permanent paper file for active parts and quotes.
    a. When the Des Moines office moved to the new location in 2015, they did get rid of a lot of the previous year's documents.
    b. The electronic records are deleted or moved at some point depending on the documents per Dave Z.
21) Quality Audits, Quality Folders, and Corrective Actions are all on the R Drive.
    a. Any tablets belonging to the quality auditors or management have access to the R Drive from the tablets.

TT Brenda
Dimas one person (Brenda) that receives all repairs and is the go to person to get things done fixed.

TT- Brenda
Each employee is assigned lockers w/padlocks + also assigned cups w/lids.

Confidential Paper - Shred-It 1/3 bins. 3 w/locks 1 General.

Des Moines Quality Management System

ISO9001:2008 Standard

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

Pareto Chart
Corrective action log-
Defective raw material
attach person or reason

DM00753 15" length
12"
w/o was for longer work order 15"
500 pcs
QA + Brenda talked to employees
NA cause
Retrain on work instruction pads

Access employee file to notate training.

Employees didn't realize that they had to physically X out or shut down previous work instructions to get new ones up, or it will stay on original instruction.
Terry retrained on working the work instructions on the pads/tablet.

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

Des Moines Quality Management System

ISO9001:2008 Standard

TT Brenda + briefly to Terry

QOP-42-01 – Quality System Documentation

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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

b) Assign responsibilities for establishing and maintaining the documentation.

Terry: Orangone employee talks to Brenda. Brenda makes documentation.

APPLICATION

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

PROCEDURE

1. General

All employees have access to the QM. I am unsure as to how many know how and where to find it.

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.

The majority of QA in DM is done by Brenda, per Brenda. The RMA/ Quality Info is available to Brenda, Chris, Brian, etc.

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;

Tools are job specific. Organized w/pictures of what tools are at that station. (Visual) This not only help w/Quality but also 5S.

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.

This is done by Todd.

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

TT Brenda

We are on tablets. Each production person has access to them.

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.

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

All of the work instructions, drawings, and control plans are all in one spot accessible to every employee.

5. Customer engineering documents

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.

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

Des Moines Quality Management System

ISO9001:2008 Standard

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

QM left in Excel spreadsheet Runs query Started in 2013

1. Scope

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

This is part of the QM. There is NO real emergency manual. This is something that Brenda Dave, and I all talked about and will be making and it will be site specific.

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.

Dave

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

Todd + Dave do this.

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.

Per Brenda

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).

Data control is done by QA (work instruction)

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.

On tablets

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.

← Checking w/ Dave at meeting

There is a permanent paper file for active parts & quotes. (Get rid of a lot when they moved.

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.

These records are deleted or moved at some point or are deleted or moved depending on the document. Per Dave

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.

Same as previous page per date

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.

Orientation QA Dual Folders Corrective Actions are on Rdrive Drawings

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

Des Moines Quality Management System

ISO9001:2008 Standard

QOP-42-02 – Control of Documents

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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.

Per meeting w/ Dave + Brenda, this is done by Dave + Todd.

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.
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.
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.
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.

Alterations to manual are done by Dave by Todd's advise and directions.

Related Documentation

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

QOP-42-01 Operational Procedure

Des Moines Quality Management System

ISO9001:2008 Standard

QOP-42-03 – Control of Records

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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