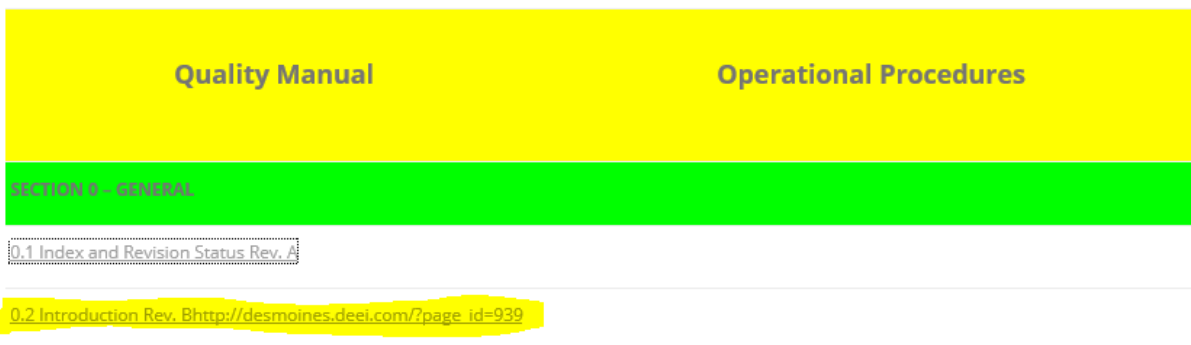


ISO 9001:2015 Standard comparison to our QMs.

QM 0.1 – It looks like this QM (The navigation page) hasn't been updated to the new standard, as it's last REV date is 7/12/2010. It only shows this when you click on 0.1 link though.

QM 0.2 – This QM says "The manual is divided into four sections modeled on the sectional organization of the ISO 9001:2015 standard." I think the new standard has more than 4 sections, though I may be misunderstanding.

This navigation page for the quality manual seems to have links to both new and old links listed.



QM 0.3 – This one doesn't seem to exist on the new navigation page, but it is listed above, linking to the old QM.

QM 0.1 INDEX	QM 0.2	QM 0.3	QM 0.4
QM 5.5	QM 6.1	QM 6.2	QM 6.3
QM 8.2	QM 8.3	QM 8.4	QM 8.5

[0.1 Index and Revision Status Rev. A](#)

[0.2 Introduction Rev. Bhttp://desmoines.deei.com/?page_id=939](#)

[0.4 Registration Mark/Logo Rev. A](#)

[0.5 Description of Sequence and Interaction of Processes Rev. A](#)

QM 4.1 – Looks to be accurate.

QM 4.2 - Looks to be accurate.

QM 4.3 – It looks like the latter half of this QM should be in QM 0.3 in addition to being here as well.

The Standard says, “f) address the risks and opportunities as determined in accordance with the requirements of 6.1;” and “g) evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results;” However, other than these phrases being copy pasted into this QM, there are no other expositions about them in this QM. Not sure if this meets the standard.

QM 4.4 - Looks to be accurate.

QM 5.1 – The standard says, “Top management shall demonstrate leadership and commitment with respect to the quality management system by: h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;” However, I do not see this mentioned in this QM.

The standard says, “Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that: b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed; c) the focus on enhancing customer satisfaction is maintained.” However, I do not see evidence of this in the QM.

QM 5.2 - Looks to be accurate.

QM 5.3 - Looks to be accurate.

QM 6.1 – The Standard says, “... determine the risks and opportunities that need to be addressed to: b) enhance desirable effects;” I do not see obvious evidence of this.

QM 6.2 – This QM mentions QOP-85-01, which is incorrect.

QM 6.3 – Looks to be accurate.

QM 7.1 – I would change point 2.1 so that it specifically mentions people as it relates to what is said in the standard “The organization shall determine and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.”

In point 4.3.1 and .2, this QM says, “Reviews are sent to Production Manager to review workstations for potential 5s improvements.”

Health and safety" Firstly, is point 1 accurate? Secondly, I'm not sure how point 2 relates to the preceding wording.

QM 7.2 – Looks to be accurate.

QM 7.3 – This QM mentions QOP-62-01, which is incorrect.

QM 7.4 – I think the general policy mentioned in this QM should be the same from all other QM 7 documents.

QM 7.5 – Looks to be accurate.

QM 8.1 – This QM mentions QM 7.2, which is incorrect.

The standard says, "The output of this planning shall be suitable for the organization's operations. The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary. The organization shall ensure that outsourced processes are controlled" I do not see evidence of these.

QM 8.2 – Looks to be accurate.

QM 8.4 – The standard says, "The organization shall:

- a) ensure that externally provided processes remain within the control of its quality management system;
- b) define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;
- c) take into consideration:
 - 1) the potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements;
 - 2) the effectiveness of the controls applied by the external provider;" Even though this can be inferred from our QM, it's not as clear as it could be.

The standard says, "The organization shall ensure the adequacy of requirements prior to their communication to the external provider.

The organization shall communicate to external providers its requirements for:

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

j) external providers' premises." I do not see evidence of this.

QM 8.5 – This QM mentions QOP-76-01, which is incorrect.

The Standard says, "The organization shall implement production and service provision under controlled conditions.

Controlled conditions shall include, as applicable:

e) the appointment of competent persons, including any required qualification;" I do not see evidence of this.

QM 8.6 – This QM mentions QOP-74-03, QOP-82-04, and QOP-82-05, which look to be incorrect.

QM 8.7 – The standard says, "The organization shall retain documented information that:

a) describes the nonconformity;

b) describes the actions taken;

c) describes any concessions obtained;

d) identifies the authority deciding the action in respect of the nonconformity." Where this is implied, it is not listed specifically.

QM 9.1 – This QM mentions QM 8.2, which is incorrect.

The standard says, "The results of analysis shall be used to evaluate:

d) if planning has been implemented effectively;

e) the effectiveness of actions taken to address risks and opportunities;

g) the need for improvements to the quality management system." I see no evidence of these.

QM 9.2 – Looks to be accurate.

QM 9.3 – The standard says, "The outputs of the management review shall include decisions and actions related to:

b) any need for changes to the quality management system;" I see no evidence of this.

QM 10.1 – Looks to be accurate.

QM 10.2 – The standard says, "When a nonconformity occurs, including any arising from complaints, the organization shall: a) react to the nonconformity and, as applicable:

1) take action to control and correct it;

2) deal with the consequences;

b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:

1) reviewing and analysing the nonconformity;

2) determining the causes of the nonconformity;

3) determining if similar nonconformities exist, or could potentially occur;

c) implement any action needed;

d) review the effectiveness of any corrective action taken;

e) update risks and opportunities determined during planning, if necessary;

f) make changes to the quality management system, if necessary.

Corrective actions shall be appropriate to the effects of the nonconformities encountered.

10.2.2 The organization shall retain documented information as evidence of:

a) the nature of the nonconformities and any subsequent actions taken;
b) the results of any corrective action.” I feel this QM can be further fleshed out, as more of the things listed above are not specifically mentioned.

QM 10.3 – The standard says, “The organization shall continually improve the suitability, adequacy and effectiveness of the quality management system. The organization shall consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.” I feel as though this QM can be pared back to be more concise, and does not need to mention the corrective, or preventive actions, as it is mentioned elsewhere.

QOP Audit

NEW – QOP-43-01 Determining the scope of the quality management system

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QMS Operational Procedure	QOP-43-01	
Section 4.3	Section Revision: A	Revision Date: 6/19/2017
Determining the scope of the quality management system		
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 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.

- Looks to be accurate.

NEW – QOP 71-01 Competence

- The QOP-72-01 link on the navigation page leads to QOP-71-01

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QMS Operational Procedure	QOP-72-01
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Section 7.2	Section Revision: A	Revision Date: 6/19/2017
Competence		
Approved By: Dave Zirkelbach		Date: 6/19/2017

I PURPOSE

The purpose of this procedure is to provide for a system and instructions, and to assign responsibilities for determining training needs and providing the required training where applicable, for establishing awareness programs, and for maintaining training records.

II APPLICATION

This procedure applies to training and awareness provided by Dee Electronics. This procedure concerns Human Resources and all departments that provide training for their employees who affect quality and conformity to product requirements.

The Responsibility and Authority for activities relating to this element of the standard have been assigned to the President, CEO/Treasurer, Vice President of Operations, and Vice President, Sales. Team members are charged with the responsibility to implement the procedure as written, and have been granted appropriate freedom and authority to do so.

III PROCEDURE

1. Training and awareness needs

1.1 The objective of Dee Electronics training program is to ensure that employees are familiar with relevant requirements of the quality system pertaining to their job functions; and that they possess the required knowledge and skills for performing their jobs. - Are employees shown the QMs / QOPs that are relevant to them at time of hire? Employees are trained on their job function, not where to find information about their job function in the Quality Manual. They would only be trained on work instructions and special processes which would be the only relevant requirements.

1.2 Awareness programs focus on understanding the importance of customer requirements, and on the relevance of individual contributions to meeting these requirements and achieving the quality policy and objectives. – What is an example of these programs? Anything pertaining to TK and stuff we do to their quality manual (24 hour turnaround time on containment for an example).

1.3 The President, CEO/Treasurer, Vice President of Operations, and Vice President, Sales have defined the knowledge and skills (competencies) required for each appropriate job category. These competencies constitute the training needs for the organization, and the training needs have been recorded on a Training Needs Matrix, Form QF-62-02.

1.4 Each individual is assessed against the Training Needs Matrix and provided any training that is absent or deficient.

1.5 Dee Electronics provides training and awareness from internal and external sources.

1.6 Employees who have been trained on the job prior to ISO Certification have been grandfathered into the Quality System and their qualifications are documented.

1.7 On the job training subsequent to ISO Certification is documented in the training record, including the content of the training, the completion date and signatures of the trainee and the appropriate Manager. – Given our ECIS training log, I do not believe the signature aspect to be accurate any longer.

1.8 The MR maintains records of employee qualifications to perform quality-related tasks on the basis of education, training, and experience.

2. Company-wide training and awareness programs

2.1 General orientation and quality system training: The President, Human Resources, CEO/Treasurer, and Vice President, Sales provides employee orientation training to all new and existing employees. This training familiarizes employees with administrative rules, employee programs and benefits, etc.; and explains what Dee Electronics does, who our customers/suppliers are, and the quality system. At a minimum, the overview and quality system training comprises:

Dee Electronics Mission and Purpose;

Presentation of the company's quality system;

Discussion of quality policy; and

Explanation of how individual employees can contribute to maintaining and improving the quality system.

2.3 Use of company-wide systems: Employees are trained in the use of interdepartmental systems, such as part and material coding/numbering system, bar-code system, retrieval and creation of electronic (computer) documents and records, and so forth.

2.4 External training: External Training is evaluated on a case-by-case basis, and approved by Executive Management.

2.5 Self-study: Dee Electronics encourages personnel on all levels to read professional reports, magazines, and books.

3. Training effectiveness evaluation

The following methods and approaches are used for evaluating the effectiveness of training provided:

Performance evaluation of trained employees, via annual performance assessments.

Review of the overall performance in areas relevant to particular training programs.

Consideration of competency and training when investigating causes of quality system failures and product or process nonconformities.

A global review of all training and awareness programs, conducted within the framework of management reviews of the quality system.

ASSOCIATED DOCUMENTS

QF-62-01-01 Quality Form: Training Records

[QF-62-02 Quality Form: Training Requirements Matrix](#)

QOP-75-02 Operational procedure: Work Instructions

NEW-QOP 73-01 Awareness

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QMS Operational Procedure	QOP-73-01	
Section 7.3	Section Revision: A	Revision Date: 6/19/2017
Awareness		
Approved By: Dave Zirkelbach		Date: 6/19/2017

I PURPOSE

The purpose of this procedure is to provide for a system and instructions, and to assign responsibilities for determining training needs and providing the required training where applicable, for establishing awareness programs, and for maintaining training records.

II APPLICATION

This procedure applies to training and awareness provided by Dee Electronics. This procedure concerns Human Resources and all departments that provide training for their employees who affect quality and conformity to product requirements.

The Responsibility and Authority for activities relating to this element of the standard have been assigned to the Top Management. Team members are charged with the responsibility to implement the procedure as written, and have been granted appropriate freedom and authority to do so.

III PROCEDURE

2. Company-wide training and awareness programs

2.1 General orientation and quality system training: The President, Human Resources, CEO/Treasurer, and Vice President, Sales provides employee orientation training to all new and existing employees. This training familiarizes employees with administrative rules, employee programs and benefits, etc.; and explains what Dee Electronics does, who our customers/suppliers are, and the quality system. At a minimum, the overview and quality system training comprises:

Dee Electronics Mission and Purpose;

Presentation of the company's quality system;

Discussion of quality policy; and

Explanation of how individual employees can contribute to maintaining and improving the quality system.

2.3 Use of company-wide systems: Employees are trained in the use of interdepartmental systems, such as part and material coding/numbering system, bar-code system, retrieval and creation of electronic (computer) documents and records, and so forth.

2.4 External training: External Training is evaluated on a case-by-case basis, and approved by Executive Management.

2.5 Self-study: Dee Electronics encourages personnel on all levels to read professional reports, magazines, and books.

3. Training effectiveness evaluation

The following methods and approaches are used for evaluating the effectiveness of training provided:

Performance evaluation of trained employees, via annual performance assessments.

Review of the overall performance in areas relevant to particular training programs.

Consideration of competency and training when investigating causes of quality system failures and product or process nonconformities.

A global review of all training and awareness programs, conducted within the framework of management reviews of the quality system.

- This QOP looks to be mostly the same as the previous one. I feel it either needs to be differentiated, or removed.

NEW-QOP-75-01 General

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QMS Operational Procedure	QOP-75-01	
Section 7.5	Section Revision: A	Revision Date: 6/20/2017
General		
Approved By: Dave Zirkelbach		Date: 6/20/2017

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

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.

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."**

-Looks to be accurate.

QOP-75-02 Creating and Updating

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QMS Operational Procedure	QOP-75-02	
Section 7.5	Section Revision: A	Revision Date: 6/20/2017
Creating and Updating		
Approved By: Dave Zirkelbach		Date: 6/20/2017

General

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

1. Definitions

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

2. Responsibilities

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

3. 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 7.5 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 is permitted to alter the format or content of our Quality System documentation.
5. Requests for changes to quality documents are submitted to the President or VP of Quality by way of an electronic Document Change Request, 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, verbally or via electronic mail for entry into controlled documents.
7. Quality Manual and Procedure last changes will be highlighted in bold type. – Is there ever a point where a section we become un-bolded? Or will all changed, whether done in the last year, or last 10 years all be in bold? Always stay bolded, expect for when Dee made a brand new manual, then it starts from scratch. The bold indicates a change has been made from the creation date of the file.
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. Example of an external document and the control thereof: All our drawings from clients / PPAP's / control plans

QOP-75-03

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QMS Operational Procedure	QOP-75-03	
Section 7.5	Section Revision: A	Revision Date: 6/20/2017
Control of documented Information		
Approved By: Dave Zirkelbach		Date: 6/20/2017

Procedure

As Retention R&A for specific categories of quality records, the President and the VP of Quality ensure that identified electronic quality records are retained and stored using methods that guarantee their preservation, legibility and accessibility to authorized persons.

The President or VP of Quality makes hard copy quality records available to customers when contractually agreed.

The President maintains, 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. These virtual snapshots are synchronized between two locations, Cedar Rapids to Des Moines and Des Moines to Cedar Rapids. Weekly snapshots are also taken.

NEW – QOP 81-01 Operational planning and control

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QMS Operational Procedure		QOP-81-01	
Section 8.1	Section Revision: A	Revision Date: 6/21/2017	
Operational planning and control			
Approved By: Dave Zirkelbch			Date: 6/21/2017

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. 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. **- I do not see this training 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 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.

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.

2.4 Quality 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. – **Currently, Quality does not sign off on Dee DM's control plans.**

NEW – QOP 82-01 Customer Communication

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QMS Operational Procedure	QOP-80-01	
Section 8.2	Section Revision: A	Revision Date: 6/21/2017
Customer communication		
Approved By: Dave Zirkelbach		Date: 6/21/2017

I PURPOSE

The purpose of this procedure is to provide for a system and instructions, and to assign responsibilities for receiving and processing customer feedback and complaints.

II APPLICATION

This procedure applies to all material customer feedback and complaints. This procedure concerns Inside Sales/Customer Service, Field Sales, Sales Management, and Quality Assurance.

III PROCEDURE

1. Receiving and logging customer feedback and complaints

1.1 All after-sale customer communication, whether written or verbal, are forwarded to the Sales/Customer Service department. Verbal communication by phone is documented in a [Call Report Form QF-72-02-01](#), established during, or immediately following, the conversation with the customer.

2. Processing customer feedback and complaints

2.1 When customer feedback or complaints are noted in Call Reports, the President and Vice President of Sales reviews the customer feedback/complaint information, and determines what type of response is appropriate. Complaints regarding product nonconformity are handled via a Corrective Action/Return Material Authorization (CAR/RMA) process via Inside Sales/Customer Service.

- This could be updated to include what DM does, since they do not have sales people and Dee CR is their only customer. Complaints are routed to their QCC.

NEW – QOP 82-02 Determination of requirements for products and services

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QMS Operational Procedure	QOP-82-02	
Section 8.2.2	Section Revision: A	Revision Date: 6/21/2017
Determination of requirements for products and services		
Approved By: Dave Zirkelbach		Date: 6/21/2017

I PURPOSE

The purpose of this procedure is to provide for a system and instructions, and to assign responsibilities for processing and review of customer orders.

II APPLICATION

This procedure applies to all customer orders. This procedure concerns Sales, Warehouse, and Quality Assurance departments.

III PROCEDURE

1. Dee Electronics' sales activities generates interest in new orders and products.
2. Sales contacts receive customer inquiries by phone, fax, mail, or electronic mail.
3. Sales and Operations management review the inquiries and product requirements and prepare a quote.
4. After reviewing material availability, costing, delivery dates and all other customer requirements, the President, CEO/Treasurer, or Vice President of Sales sign off on the quotation. The quotation is then communicated to the customer either verbally or in writing.

5. When the customer responds there may be changes to the quotation. Sales will resolve any such differences with appropriate parties prior to accepting an order.

6. Received orders are verified to the quotation for cost, quantity, and any special requirements and entered using DBA system. – Cedar Rapids does not use the DBA system, unless I'm confusing it with something else.

- If a PPAP or 1st Article Approval is required, the [PPAP/1st Article Procedure/flowchart](#) is followed in conjunction with all other applicable procedures

7. Sales contacts verify that requirements not specified by the customer, but necessary for intended or specified use, and requirements dictated by laws and regulations are known.

8. Changes to orders are received and authorized by Sales, Sales management, or the President, CEO/Treasurer as necessary. Authorized changes to the orders are updated to reflect the changes.

9. The completed quotation, order, and sales invoice are quality records. See QOP-42-03 for retention details.

- This QOP is only relevant to Cedar Rapids.

NEW – QOP-84-01 General

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QMS Operational Procedure	QOP-84-01	
Section 8.4	Section Revision: A	Revision Date: 6/21/2017
General		
Approved By: Dave Zirkelbach		Date: 6/21/2017

I PURPOSE

The purpose of this procedure is to provide for a system and instructions, and to assign responsibilities for evaluation and monitoring of suppliers.

II APPLICATION

This procedure applies to evaluation and monitoring of vendors supplying parts that are resold to customers. This procedure concerns Purchasing and Quality Assurance.

III PROCEDURE

1. Supplier Evaluation

1.1 Cedar Rapids location Purchasing Manager maintains a record of acceptable vendors for products and services that affect quality, as well as records of any vendors utilized under emergency procedures. Emergency purchases may take place when:

1. Product is not available from approved vendors.
2. Product is identical to that available from approved vendors.
3. Emergency purchase is approved by Purchasing Manager.

1.2 Suppliers utilized under emergency procedures are considered for approved status when the transaction proves to be satisfactory to Dee Electronics and Dee

Electronics' customer, and after the prospective supplier has undergone the vendor approval process.

1.3 Manufacturers or Distributors of parts/components requested by manufacturer part number are approved as acceptable vendors, provided they are approved by President, CEO/Treasurer, or Purchasing Manager to be added as an approved Vendor. They are subject to monitoring for quality and delivery.

1.4 Vendors providing quality products or services prior to the initiation date of our quality system are grandfathered into the Acceptable Vendor/Supplier List without being subject to the vendor evaluation process. The vendor approval process consists of one or more of the following:

1. Financial and Qualitative Review/approval done by CEO/Treasurer, President, or Purchasing Manager 2. Customer-specified Vendor 3. Evidence of ISO9001:2015 Certification 4. Part Sample or Drawing verification

2. Quality Performance Monitoring

2.1 After approval, an acceptable vendors is continuously monitored for on-time delivery and conforming product. Records are kept electronically, accessible from ECIS (Cedar Rapids) and DBA (Des Moines).

2.2 Product determined to be nonconforming upon receipt is reported to the Quality Control Coordinator via the Corrective Action (CAR/RMA) Form in DBA. Subcontractor corrective action, if necessary, is documented in the subcontractor's performance record and followed-up.

3. Approved Vendor List

Purchasing in Cedar Rapids location is responsible for maintaining a list of acceptable suppliers in the Vendor Master Listing. The list is updated and authorized by Purchasing, and the CEO/Treasurer or President.

- Looks to be accurate.

NEW – QOP-84-02 Type and Extent of Control

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QMS Operational Procedure	QOP-84-02	
Section 8.4	Section Revision: A	Revision Date: 6/21/2017
Type and Extent of Control		
Approved By: Dave Zirkelbach		Date: 6/21/2017

I PURPOSE

The purpose of this procedure is to provide for a system and instructions, and to assign responsibilities for evaluation and monitoring of suppliers.

II APPLICATION

This procedure applies to evaluation and monitoring of vendors supplying parts that are resold to customers. This procedure concerns Purchasing and Quality Assurance.

III PROCEDURE

1. Verification methods

1.1 Following methods and approaches are used for verification and acceptance of purchased product:

- *Receiving inspection,*
- *Additional Inspection,*
- *Source inspection,*
- *Supplied evidence of product conformity (this may be in the form of inspection, testing, or process control records, or certificates supplied with the product);*

- *Confidence in supplier's quality system and product verification program (this may be based on supplier's quality system certification, supplier audits, and satisfactory quality performance history).*

1.2 The President, CEO/Treasurer, Vice President of Operations, and Quality Assurance is responsible for selecting appropriate verification and acceptance methods for specific products. The selection is based on:

Criticality and importance of the product;

Availability of product verification records or certificates from the supplier or an independent third party;

Knowledge of, and/or confidence with the supplier's quality management system and product verification program.

1.3 Product verification and acceptance methods to be applied are specified in purchasing documents, Additional Inspection Master Database, procedures, or supplier files. This information is communicated to Receiving prior to the arrival of purchased product.

1.4 Receiving inspection is applied to all purchased components.

1.5 Additional Inspection is applied to components with previous corrective action issues deemed significant, critical components, and shipments of a new parts added to our system. When Additional Inspection is required, the 2 X 1 Dee Incoming Product Label will reflect an "X", as well as this part is noted in our Additional Inspection Required database. – I do not think this applies to our new receiving system, but if it does, I'm not sure what it's referring to.

2. Receiving inspection

2.1 Upon unloading of deliveries, receiving clerk counts the number of delivered units, checks marking and identification of packages, and inspects all packages for any signs of tampering or damage. If all these checks and inspections are satisfactory, he or she signs the delivery receipt. If not, any shortages or damages are noted on all copies of the delivery receipts.

2.2 Next, the received packages are moved to the designated receiving area, a copy of the relevant purchase order is retrieved from the pending orders file, and the packing slips (if any) are removed from packages. The goods are counted, their part numbers are verified against the purchase order and the packing slip, and the goods are examined visually for any signs of damage. – This point seems to need updating.

The term “pending orders file”, can probably be changed to something more similar to what we do now where we enter the PO number to find the associated order in our system.

2.3 If no other product verification activities are required, the goods are moved to appropriate material putaway staging areas, and then are putaway in designated inventory storage areas.

2.4 If Additional Inspection is required but not done immediately, the goods are segregated in a HOLD Area or on a Cart, requiring additional inspection.

2.5 If a nonconforming product is identified, the receiving person moves the product to a HOLD area, and initiates a nonconformity report in accordance with Procedure QOP-83-01, Control of Nonconforming Product. The product is labeled with a CAR/RMA label, the CAR/RMA number is marked on the sticker. Quality Control Coordinator is notified. – This one mentions QOP 83 01, which is incorrect.

3. Additional Inspection

3.1 As applicable, receiving additional inspection comprises:

Review of packaging/part markings, material certificates, source inspection records, compliance certificates, or other such documentation delivered with the product;

Visual inspection to detect any damage or other visible problems;

Taking measurements and testing as required; and

3.2 When products pass the inspection, they are moved to appropriate putaway staging areas, and then putaway in a designated storage area. Quality records established during the receiving inspection are entered. – I’ve noticed that many times when someone receives something that requires an additional inspection, though it might pass the inspection, the only notes the receiver enters is their initials. Where this is not a non-conformance, it could be an area of improvement to capture better detailed notes of the receiving inspection, should we need to go back at some point.

3.3 If products fail the additional inspection, a nonconformity report in accordance with Procedure QOP-83-01, Control of Nonconforming Product. The product is moved to a designated HOLD area. Quality Control Coordinator is notified. – This one mentions QOP 83 01, which is incorrect.

4. Source inspection

4.1 Where purchased product verification is to be performed or witnessed at the supplier's location, this should be specified in purchasing documents. This also applies to cases where source inspections are performed or witnessed by customers.

5.1 Where product is sent to have a process completed, Dee Electronics marks said part for incoming inspection and places product specific inspection notes on each product. The following processes Dee has outsourced on a part specific basis:

- 1) Powder coating – visual inspection
- 2) Printed Circuit Board Assembly – visual inspection
- 3) Braising / Soldeing – visual inspection
- 4) Milling – visual inspection
- 5) Cut conduit – measured inspection

NEW-QOP-84-03 Information for external providers

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QMS Operational Procedure	QOP-84-03	
Section 8.4	Section Revision: A	Revision Date: 6/21/2017
Information for external providers		
Approved By: Dave Zirkelbach		Date: 6/21/2017

I PURPOSE

The purpose of this procedure is to provide for a system and instructions, and to assign responsibilities for the establishment of purchasing documents.

II APPLICATION

This procedure applies to purchase orders for materials and parts that are resold to customers. This procedure directly concerns Purchasing, and is relevant to Quality Assurance and Inside Sales/Account Administration.

III PROCEDURE

Dee Electronics purchases parts and components to fill orders already received or to stock inventory on behalf of customers future requirements.

Purchasing sorts parts and components listed on Orders into vendor-specific Requisitions, sometimes ordering additional inventory to achieve a quantity-based price reduction.

Purchasing creates Purchase Orders from Requisitions, adds necessary detail, checks for accuracy and completeness, signs-off and forwards the PO to an acceptable vendor.

Purchasing may only create a Requisition/Purchase Order with a Vendor that is Approved.

1. Verification methods

1.1 Following methods and approaches are used for verification and acceptance of purchased product:

- *Receiving inspection,*
- *Additional Inspection,*
- *Source inspection,*
- *Supplied evidence of product conformity (this may be in the form of inspection, testing, or process control records, or certificates supplied with the product);*
- *Confidence in supplier's quality system and product verification program (this may be based on supplier's quality system certification, supplier audits, and satisfactory quality performance history).*

1.2 The President, CEO/Treasurer, Vice President of Operations, and Quality Assurance is responsible for selecting appropriate verification and acceptance methods for specific products. The selection is based on:

Criticality and importance of the product;

Availability of product verification records or certificates from the supplier or an independent third party;

Knowledge of, and/or confidence with the supplier's quality management system and product verification program.

1.3 Product verification and acceptance methods to be applied are specified in purchasing documents, Additional Inspection Master Database, procedures, or supplier files. This information is communicated to Receiving prior to the arrival of purchased product.

1.4 Receiving inspection is applied to all purchased components.

1.5 Additional Inspection is applied to components with previous corrective action issues deemed significant, critical components, and shipments of a new parts added to our system. When Additional Inspection is required, the 2 X 1 Dee Incoming Product Label will reflect an "X", as well as this part is noted in our Additional Inspection Required database. *- I do not think this applies to our new receiving system, but if it does, I'm not sure what it's referring to.*

2. Receiving inspection

2.1 Upon unloading of deliveries, receiving clerk counts the number of delivered units, checks marking and identification of packages, and inspects all packages for any signs of tampering or damage. If all these checks and inspections are satisfactory, he or she signs the delivery receipt. If not, any shortages or damages are noted on all copies of the delivery receipts.

2.2 Next, the received packages are moved to the designated receiving area, a copy of the relevant purchase order is retrieved from the pending orders file, and the packing slips (if any) are removed from packages. The goods are counted, their part numbers are verified against the purchase order and the packing slip, and the goods are examined visually for any signs of damage. – This point seems to need updating. The term “pending orders file”, can probably be changed to something more similar to what we do now where we enter the PO number to find the associated order in our system.

2.3 If no other product verification activities are required, the goods are moved to appropriate material putaway staging areas, and then are putaway in designated inventory storage areas.

2.4 If Additional Inspection is required but not done immediately, the goods are segregated in a HOLD Area or on a Cart, requiring additional inspection.

2.5 If a nonconforming product is identified, the receiving person moves the product to a HOLD area, and initiates a nonconformity report. The product is labeled with a CAR/RMA label, the CAR/RMA number is marked on the sticker. Quality Control Coordinator is notified.

3. Additional Inspection

3.1 As applicable, receiving additional inspection comprises:

Review of packaging/part markings, material certificates, source inspection records, compliance certificates, or other such documentation delivered with the product;

Visual inspection to detect any damage or other visible problems;

Taking measurements and testing as required; and

3.2 When products pass the inspection, they are moved to appropriate putaway staging areas, and then putaway in a designated storage area. Quality records established during the receiving inspection are entered.

3.3 If products fail the additional inspection, a nonconformity report is generated. The product is moved to a designated HOLD area. Quality Control Coordinator is notified.

4. Source inspection

4.1 Where purchased product verification is to be performed or witnessed at the supplier's location, this should be specified in purchasing documents. This also applies to cases where source inspections are performed or witnessed by customers.

5.1 Where product is sent to have a process completed, Dee Electronics marks said part for incoming inspection and places product specific inspection notes on each product. The following processes Dee has outsourced on a part specific basis:

- 1) Powder coating – visual inspection
- 2) Printed Circuit Board Assembly – visual inspection
- 3) Braising / Soldering – visual inspection
- 4) Milling – visual inspection
- 5) Cut conduit – measured inspection

NEW-QOP-85-01 Control of production and service provision

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QMS Operational Procedure	QOP 8.5.1	
Section 8.5.1	Section Revision: A	Revision Date: 7/11/2017
Control of production and service provision		
Approved By: Dave Zirkelbach		Date: 7/11/2017

I PURPOSE

The purpose of this procedure is to provide for a system and instructions, and to assign responsibilities for production and service provision.

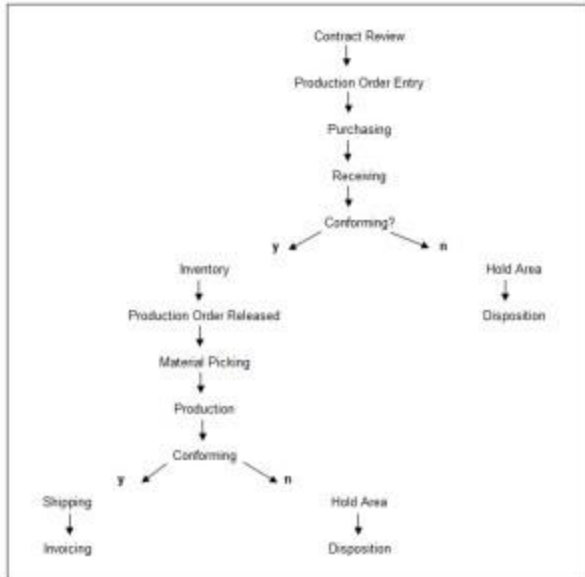
II APPLICATION

This procedure applies to customer orders for parts. The order fulfillment process at Dee Electronics begins with the receipt of customer order and ends when product is shipped in accordance with customer requirements.

The overall Responsibility and Authority for activities related to this element of the standard have been assigned to the President. Team members are charged with the responsibility to implement the procedure as written, and have been granted appropriate freedom and authority to do so.

III PROCEDURE

1. The servicing method of Dee Electronics is identified on the following Process Flow Chart.



1.1. Modifications of the Process Flow Chart may be suggested via the Team Member Concern Form and are handled per procedures for Corrective and Preventive Action.

1.2. Appropriate equipment provisions (e.g., information systems, scanning equipment, and scales) are selected by the President to meet process flow requirements and ensure that customer requirements are adequately defined and fulfilled. Such equipment is utilized and maintained per Dee Electronics and manufacturer's instructions, as applicable.

1.3. New equipment additions may be suggested via the Team Member Concern Form and are handled per procedures for Corrective and Preventive Action.

1.4. The President, Vice President of Operations, and Vice President, Sales ensures that all personnel implicated on the Process Flow Chart maintain a suitable, safe, organized, and clean work environment.

1.5. The President ensures that all personnel implicated in the process flow follow documented procedures and customer specified packaging requirements.

1.6. The process flow is monitored and evaluated for continued effectiveness via statistical data compiled and analyzed per procedures for Statistical Techniques.

1.7. Personnel implicated in the process flow are adequately trained to meet specified servicing requirements per procedures for Training.

2. Validation of processes for production service provision

2.1 The need for work instructions and workmanship standards for a given process is determined on the basis of the following considerations:

Importance of the process

: Work instructions are desirable for processes that are critical to our operation.

Complexity of the process

: Work instructions are desirable for more complex processes.

History of quality problems: *Work instructions may be developed for processes that have a history of quality problems, especially when these problems can be associated with the lack of adequate instructions.*

2.2 The need for work instructions for other than order fulfillment processes is determined on the basis of the importance and complexity of the process or task; the level of education, experience and training of personnel; and the degree and depth of the instructions already provided in the quality manual and operational procedures.

3. Issue and authorization

3.1 Work instructions are normally issued by the President, Vice President of Operations, or Vice President of Sales. However, Quality Assurance or Production Supervisor may issue work instructions and workmanship standards, regardless of where they are used.

4. Format, control and distribution

4.1 Work instructions can be in the form of electronic procedures.

4.2 Irrespective of their format, work instructions are electronic and located with the electronic user forms they are associated with.

-Looks to be accurate.

NEW-QOP-85-02 Identification and Traceability

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QMS Operational Procedure	QOP-85-02	
Section 8.5	Section Revision: A	Revision Date: 7/11/2017
Identification and Traceability		
Approved By: Dave Zirkelbach		Date: 7/11/2017

I General

1.1 Purpose: The intent of this procedure is to describe the process for Product Identification and Traceability at Dee Electronics

1.2 Scope: This procedure pertains to all products purchased, stored and distributed by Dee Electronics.

II Responsibilities

1. The overall Responsibility and Authority for activities related to this element of the standard have been assigned to the President. Team members are charged with the responsibility to implement the procedure as written, and have been granted appropriate freedom and authority to do so.

III Procedure

1. Identification at Dee Electronics is accomplished by a unique numerical identifier on a 2" X 1" Product Label affixed to each package of product upon receipt.
2. With the exception of products that were purchased prior to the labeling system being put into place, and product returned from customer that is not traceable to Dee Purchase Order, the Product Label also bears the Dee Electronics Purchase Order number.

3. Where traceability is a contractual requirement, the product is traceable to the original purchase order if the product is specific / unique to a finished good and specific quantity to that finished good.
4. Inspection status – All inspections are recorded in an electronic database. Inspection instructions are communicated to relevant personnel via computer database information.
5. Received goods are verified against PO/packing slips and are checked for visual damage. Additional inspection requirements are indicated and defined by the inspection database. Nonconforming products are routed to the HOLD area and await **disposition per procedures for the “Control of Nonconforming Product.”**
6. In-process inspections are conducted by inventory personnel at the time orders are released to production. This includes quantity counts and visual inspections. Nonconforming items are routed to the HOLD area.
7. **Final inspections include verification of packaging requirements. Final inspection authority is held by shipping personnel and recorded via authorization identification. By virtue of the controls implicit in the process flow, final inspectors are ensured that previous inspections are completed when appropriate paperwork is received. Nonconforming products are routed to the HOLD area. Nonconforming orders are repackaged, recounted, and/or rescanned, as applicable.**

- Looks to be accurate.

NEW-QOP-85-04 Preservation

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QMS Operational Procedure	QOP-85-04	
Section 8.5	Section Revision: A	Revision Date: 7/11/2017
Preservation		
Approved By: Dave Zirkelbach		Date: 7/11/2017

I PURPOSE

The purpose of this procedure is to provide for a system and instructions, and to assign responsibilities for product handling and preservation activities.

II APPLICATION

This procedure applies to all products involved with Dee Electronics' processes.

This procedure concerns Receiving/Putaway, Picking, Packaging, and Shipping departments.

III PROCEDURE

Responsibilities

The Responsibility and Authority for this element of the standard has been assigned to the Vice President of Operations and the Warehouse Supervisor. Team members are charged with the responsibility to implement the procedure as written, and have been granted appropriate freedom and authority to do so.

Product Handling

1. Warehouse Personnel check product condition upon receipt.

2. Segregate nonconforming product.
3. Place conforming product in appropriate warehouse areas.
4. Place nonconforming product in an area clearly marked HOLD AREA.
5. When necessary, utilize ESD (ElectroStatic Discharge) precautions to safeguard components that could be damaged by electrostatic discharge.
6. **When handling printed circuit board, if one is dropped, it shall be moved to the hold shelf for appropriate disposition with the assumption of internal damage.**

Preservation

1. Date-sensitive materials are stored and rotated from stock using FIFO methods to prevent degrading or deterioration.
2. Products with shelf-life issues or "use-by" dates are utilized prior to expiration or scrapped. During cycle counting, date sensitive products will be evaluated and scrapped if beyond date expiration. -How would we know if a product expires?
Example? There are a few products, such as a battery we sell to TK, (5 year shelf life) or Loctite products that have expiration dates, but we either use them before the expiration, or our cycle count system gets rid of them before they expire. Simply put, we don't typically carry a part longer than 1, or 2 years, depending on customer's orders. This could probably be removed.
3. Condition of product is checked during inventory.

NEW-QOP-86-01 Release of products and services

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QMS Operational Procedure	QOP-82-04	
Section 8.2	Section Revision: A	Revision Date: 7/11/2017
Release of products and services		
Approved By: Dave Zirkelbach		Date: 7/11/2017

I PURPOSE

The purpose of this procedure is to provide for a system and instructions, and to assign responsibilities for performing and recording in-process inspections.

II APPLICATION

This procedure applies to products throughout the order fulfillment cycle. This procedure concerns Picking and Quality Assurance.

III PROCEDURE

1. Scope and responsibilities

In-process inspections include operator self-inspections throughout the production process. Also, additional in process verifications are performed as required by the Work Instructions.

2. First-Time-Buy Part and Production Assembly inspection

[1st Article Procedure Flow Chart](#)

In an effort to reduce risk for the client, Dee Electronics will perform a 1st article inspection on all new parts when the part is assessed as a high risk part, regardless if the client requires one or not. **“Part”** is identified as any new finished good added to the Dee system and includes component off the shelf parts, custom parts, and Dee assembled / manufactured parts. The following ways are used to flag a part as high risk; therefore, requiring 1st article inspection:

1. Each part is scored upon entry into the Dee system based upon cost, product category, and customization.
2. When Dee mgmt. deems the part warrants a 1st Article Inspection
3. When the client requires a 1st Article Inspection
4. All Dee assemblies require 1st Article Inspection

The elements of each 1st Article Inspection will vary from part to part, but each and every 1st Article will have the following steps performed:

1. Sales and Quality will work together to identify the quantity of the first purchase / build
2. Verify measured elements of part from the print (if a print is supplied)
3. Identify CTQ elements of said part. Below are a few ways to identify CTQ elements:
 1. Sales will identify if the client has any CTQ elements
 2. If assembly, Production and Quality will perform a PFMEA Risk Analysis of the build
 3. Quality will study the print to identify any CTQ elements
 4. Quality will physically assess the part in house to identify any CTQ elements
 5. Quality will use historical corrective actions for similar parts for CTQ elements

When a new part is identified as not high risk; therefore, not requiring 1st Article Inspection, the following steps are still performed by the warehouse during the first incoming inspection:

1. Ensure the part received matches the part number on the packing slip and PO.
2. Inspect for visual damage on the outer box, and inside the box
3. **Attempt to verify the part is the correct part by reading Dee’s internal description of the part.**
4. If there is a print or picture, then the print / picture is verified against the part received.

When the 1st Article Inspection is completed, the results will be filed and uploaded to the Inventory Card. The elements identified to pose risk will then be translated into Incoming Inspection by one of two means:

1. When a CTQ element is identified, Dee will ask the mfg to supply a C of A for the specific element of the CTQ. Incoming Inspection will require the C of A to be shipped with the product, and a warehouse personnel will find the C of A and confirm it was sent. If no C of A was sent, **then the Warehouse will follow Dee’s Control of Non-Conforming Product (QOP-83-01)**. The C of A could ask for any of the following as examples (or anything else, below are just a few examples):
 1. Verify measurements
 2. Verify for damage
 3. Verify unit powers
1. If the C of A will not be provided by the Mfg, then Dee will attempt to perform risk reduction methods of said CTQ element in house during Incoming Inspection. Incoming Inspection will identify who, and what, will be performed before the part can **be received into Dee’s system**. **If the part does not pass inspection, then Dee’s Control of Non-Conforming Product** will be followed.

3. Picking Process

- 1.

- Personnel picking parts verify each item associated to the work instructions is correct as picked.
 - Personnel also visually inspect parts as they are picked as appropriate and feasible.
4. All in-process inspections required during the assembly process are noted in the assembly work instructions. Appropriate records of assembly in-process inspections are kept.

5. Quality Check Process

As product is moved throughout the production process any in-process quality inspection is verified as required by the work instructions. Any required in-process check is then documented / recorded and stored per production order.

Quality Audit is a Final Inspection process that is performed based upon the documented requirements in the Work Instructions.

6. Release of product

Completed product is routed to the Quality Assurance queuing area where the Quality Assurance inspector verifies the product is conforming to the work instructions and requirements. If conforming, the product is released to ship and documented electronically.

7. Nonconforming product

If a product is found to be non-conforming, Quality Assurance is notified and moves the product to a HOLD area.

8. Design, Material, Plant, or Process changes

DEE works to proactively identify historical and future Plant / Part / Material / Process / Design changes.

Each month an automated email is sent to Suppliers asking for any historical or future Plant Changes or Part Design Changes. Whenever the supplier answers Yes to any of the questions, then the Sr. VP of Sales and VP of Quality are notified of the entry via automated email. Immediately following the receipt of information, the following action items occur:

1. The system will automatically tag the part as High Alert which stops any further quoting, order entry, and picking of the part without approval from upper mgmt.
2. DEE, upon learning of a potential or historical change, will immediately and formally notify our client.

At this time, Sales and Quality will work together to identify the following:

1. If the change already occurred, then the following will happen:
 1. Quality will analyze historical corrective actions for trending data.
 2. Sales will analyze the information and identify if the client needs to be notified

1. If the change has not occurred yet, then the following will happen:
1. Quality will assess risk of the part. If part is identified as a high risk part, then the part will be tagged requiring 1st Article Inspection, and the procedure for 1st Article Inspection will be performed.
2. Sales will analyze the information and identify if the client needs to be notified.
3. Quality will update the card with appropriate notes from the review.
4. A change of plant, material, design, or process will trigger a revalidation or a new 1st Article approval process, verified with the client

- Looks to be accurate.

NEW-QOP-87-01 Control of nonconforming outputs

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QMS Operational Procedure	QOP-87-01	
Section 8.7	Section Revision: A	Revision Date: 7/11/2017
Control of Nonconforming Product		
Approved By: Dave Zirkelbach		Date: 7/11/2017

I PURPOSE

The intent of this procedure is to describe the process at Dee Electronics for the Control of Nonconforming Product (Section 8.7 of ISO 9001:2015).

The overall Responsibility and Authority for activities related to this element of the standard have been assigned to the President. Team members are charged with the responsibility to implement the procedure as written, and have been granted appropriate freedom and authority to do so.

II APPLICATION

This procedure pertains to actions taken when product fails to pass any inspection and/or test.

III PROCEDURE

1. Upon receipt, if products are nonconforming (damaged, part number wrong, count wrong, etc.), Purchasing, Quality Assurance Coordinator, and Sales, when appropriate, are notified. The Quality Control Coordinator or Receiving Personnel records the nonconformance if nonconformance is traceable to

supplier error. Product is labeled with Non-Conforming label and then moved to a HOLD AREA.

2. If product is found to be nonconforming after being received, it is labeled with Non-Conforming label, and then moved to a HOLD AREA to await disposition. Corrective Action Report (CAR)/RMA document identification is noted on labeling when the document record has been created.
3. The Quality Control Coordinator determines the disposition of nonconforming product (disposition may also be delegated to the Warehouse Supervisor).
4. Disposition alternatives include:
 1. Shipping to customer after receiving customer concession,
 2. Returning to supplier,
 3. Stocking in inventory for future sale,
 4. Scrapping
5. When customers accept the order by concession without repair, Sales records the acceptance on the original order in the ECIS database. Details of the concession include identification of the customer representative, the date of the concession and a description of the order as accepted. The record of concession without repair is a retained quality record.
6. Returned goods are given an RMA # approval by Quality Control Coordinator or Purchasing and recorded in the ECIS database. Quality Control Coordinator dispositions customer-returned goods as stated above in paragraph 4.
7. Product nonconformances are investigated for root causes, analyzed for trends, and discussed in Management Review.
8. Nonconforming orders (e.g., improper scanning, inappropriate product numbers, or inaccurate counts) are refilled, recounted, and rescanned by warehouse personnel.
9. PRODUCT RETURNS: If a product nonconformity is detected by the customer after delivery or use has started, the customer is instructed to return the product, and a Return Authorization/Corrective Action (RMA/CAR) is issued by Inside Sales (Customer Service), approved by Quality Control Coordinator.

- Looks to be accurate.

NEW-QOP-91-02 Customer satisfaction

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QMS Operational Procedure	QOP-91-02	
Section 9.1	Section Revision: A	Revision Date: 7/11/2017
Customer Satisfaction		
Approved By: Dave Zirkelbach		Date: 7/11/2017

I PURPOSE

The purpose of this procedure is to provide for a system and instructions, and to assign responsibilities for determining and reporting customer satisfaction.

II APPLICATION

This procedure applies to products, delivery, servicing, and other activities bearing on customer satisfaction. This procedure directly concerns Sales, Marketing, and Customer Service.

III PROCEDURE

1. Sources of information

1.1 Information and data on customer satisfaction are acquired from customer feedback and by analyzing customer behavior, to include:

Customer Feedback, compliments, and developmental suggestions,

Dee Team Member Feedback,

Customers' Dee Electronics Performance Reports,

Product returns and rejections,

New Key Customer Growth, and

Existing Customer Sales Growth and Market share.

Customer Surveys.

1.2 The general scope, methods, and program for collecting customer satisfaction data and information are defined in this procedure. However, the program may be periodically adjusted.

2. Customer feedback and complaints

2.1 Customer complaints, spontaneous expressions of satisfaction, and other unsolicited customer feedback are collected and processed by Customer Service/Inside Salespeople, Field Salespeople, and Sales Management.

2.2 The resulting data is periodically compiled and analyzed by the President, and is presented and discussed at management review meetings.

3. Customer Performance Reports, Recognition/Awards

3.1 Dee Electronics encourages customers to rate its performance, and seeks to participate in customer's award and recognition programs. As such recognitions and ratings are a direct expression of customer satisfaction or dissatisfaction, they are considered as one of the most important inputs into determining customer satisfaction. Dee Electronics can also produce delivery performance data by customer, in absence of the customer providing it to Dee. This is used if customer does not provide Dee with performance data.

3.2 Awards and recognitions, as well as failures to achieve them, are used in determining customer satisfaction. Executive Management analyses which aspects of products and/or services are most responsible for achievement of the recognition, and determines how this should be used in determining overall customer satisfaction for these aspects. The results are presented at management reviews. Customer ratings are analyzed and used in the same way as other customer feedback.

4. Product returns and rejections

4.1 Customer Service/Inside Sales handles product return authorization requests. The reason for each return request or claim is recorded in our CAR/RMA (Corrective Action/Return Material Authorization) Form.

4.2 Product return CAR/RMA records are periodically compiled and analyzed at the management review meetings.

5. New Key Customer Growth

5.1 Sales records are periodically analyzed to identify trending of new key customers. The trending of these new customers sales is one of the most important indicators of new key customer satisfaction.

5.2 Statistics on new key customers trends are presented and discussed at management reviews.

6. Existing Customer Market share

6.1 Sales Management is responsible for collecting and analyzing data regarding existing customer market share. This data is periodically analyzed and presented at management review meetings.

7. Customer Surveys

7.1 Surveys, when and where appropriate at the discretion of the President, are selectively done to gain additional feedback from clients. These can range from 1 question to ten questions typically.

8. Analysis and presentation of results

8.1 Sales Management assembles, and analyses all customer satisfaction data collected from various sources and pertaining to different aspects of company's products and services, and presents this information at Management Review meetings.

8.2. Executive Managers participating in the meeting discuss the reasons for successes or failures in reaching customer satisfaction objectives, and provide input for setting new objectives for the coming year.

- Looks to be accurate, but mostly only applies to CR.

NEW-QOP-92-01 Internal audit

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QMS Operational Procedure	QOP-92-01	
Section 9.2	Section Revision: A	Revision Date: 7/11/2017
Internal Audit		
Approved By: Dave Zirkelbach		Date: 7/11/2017

I PURPOSE

The purpose of this procedure is to provide for a system and instructions, and to assign responsibilities for conducting internal quality audits.

II APPLICATION

This procedure applies to all activities comprising the quality system. This procedure directly concerns Quality Assurance and the executive management, and is indirectly relevant to all departments.

III PROCEDURE

1. Internal quality audit plan

1.1 The President is responsible for planning and scheduling internal quality audits. Each section is audited at least once a year. In addition to the annually scheduled audits, certain sections may be selected for more frequent auditing, depending on their status, importance, and past compliance history.

1.2 The President schedules dates and assigns audit teams for all auditable sections.

1.3 The **internal audit plan** is synchronized with management reviews of the quality system, so that results of an auditing cycle are available for the management review meeting. – I did not see an updated version of the internal audit plan. This should be created, and linked to this page.

2. Audit team

2.1 Personnel assigned to carry out internal audits are independent of those having direct responsibility for the audited activity. If there is no conflict of interest, it is usually Quality Assurance that conducts the audits. Activities that are the responsibility of Quality Assurance are usually audited by trained IQA individuals from other departments.

2.2 Internal auditors are trained by in-house IQA-certified Trainers or professional IQA Trainers. Quality Assurance maintains a copy of the ISO9001:2015 standard on the company Intranet. IQA Training, whether done in-house or by professionals, is recorded in the Training Records. – I do not see a copy of the Standard on the intranet.

3. Preparing for audit

3.1 Auditors prepare for an audit by familiarizing themselves with the ISO 9001 standard, refreshing their knowledge of the quality manual and relevant operational procedures, reviewing corrective actions files, and reviewing the IQA checklist.

4. Conducting and reporting the audit

While conducting the audit, auditors seek objective evidence demonstrating whether the audited activities conform with the requirements of the documented quality system, and whether the system is effectively implemented and maintained. When a nonconformity is noted, it is brought to the attention of, and discussed with, the President. Before the end of an audit each noted nonconformity is documented using the Internal Audit/Management Corrective Action and Preventive Action system. Auditors fill out only part of the form, describing the noted nonconformity. The form is then handed over to the President who uses the rest of the form to propose a corrective action and follow through to close out the corrective action.

5. Corrective action and follow up

5.1 Once a nonconformity is identified and documented, further processing of the nonconformity report is similar to the corrective action requests. Upon receiving the report, the President and appropriate managers investigate the cause of the problem noted as a nonconformity, proposes a corrective action to be taken, and indicates the date by which the corrective action will be fully implemented.

5.2 When there is objective evidence that the corrective action is implemented and effective, the nonconformity report is closed out. If more work is needed to fully implement the action, a new follow-up date is set.

6. Documentation and record

6.1 Internal audits and implementation of resulting corrective actions are documented using Internal Audit Checklist Form for documenting the Audits, and the Internal Audit/Management Corrective and Preventive Action Form for documenting findings that require Corrective Action.

6.2 The Internal Audit Checklist Form contains the results and documentation of the Audit. The Internal Audit/Management Corrective and Preventive Action Form contains a description of any nonconforming condition found during the Audit, the proposal for a corrective action, and corrective action implementation information.

6.3 At the end of an auditing cycle, all nonconformity reports established during the cycle are compiled and analyzed, and are presented at the management review meeting.

NEW-QOP-93-01 General

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QMS Operational Procedure	QOP-93-01	
Section 9.3	Section Revision: A	Revision Date: 7/11/2017
General		
Approved By: Dave Zirkelbach		Date: 7/11/2017

I. PURPOSE

The purpose of this procedure is to provide for a system and instructions, and to assign responsibilities for scheduling, conducting, and recording management reviews of the quality management system.

II. APPLICATION

This procedure applies to all activities comprising the quality system, and in particular those named in ISO 9001:2015 Standard 9.3, Management Review General.

This procedure directly concerns the top executive management.

III. PROCEDURE

1. Frequency and Scheduling

Quality performance and the quality management system are reviewed by the executive management twice per year, at minimum. The President determines the actual date for the review, coordinating with participating managers.

2. Attendance

Attendance required to qualify as a Management Review meeting includes, at a minimum: Three out of the following people: President, CEO/Treasurer, Vice President-Sales, Vice President of Operations, and Chairman of the Board of Directors.

3. Agenda

3.1 The agenda for management review meetings is prepared by the President. It is distributed to the participating managers at the meeting, or shortly before the meeting. At a minimum, the agenda covers all items listed in Clause 4 of this procedure, Review input.

4. Quality policy and quality objectives

4.1 An important role of management reviews is to determine progress toward fulfilling the quality policy and achieving quality objectives.

4.2 Quality objectives established through the review period are systematically evaluated to assess progress. Objectives that have been achieved may either be upgraded to a higher performance level, or be closed out to free resources for improvement in another area.

4.3 When objectives are not achieved on time, the review investigates and determines causes for the failure to achieve the objectives. Depending on the nature of the objective and causes for failure to achieve it, the top management may decide to drop the objective, reduce its scope or level, reassign responsibilities and/or allocate additional resources, or extend the due date for achieving the objective. Any decisions regarding quality objectives are recorded in the minutes of the review.

4.4 New objectives are established where it is necessary to improve performance or quality system to fulfill the quality policy or other organizational goals or aspirations. New objectives are documented in the minutes of the review.

4.5 The principal quality policy is also reviewed to ensure its continuing relevance. The policy is changed when the goals expressed in the policy have been achieved, or when changes within or outside the company render the policy inadequate or inappropriate.

5. Record

5.1 Minutes of management review meetings are prepared by the President in electronic form, and are distributed to the attending and, if any, absent managers. The minutes and other documents associated with the review are confidential.

- Looks to be accurate.

**NEW-QOP-93-02 Management review
input**

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QMS Operational Procedure	QOP-93-02	
Section 5.6	Section Revision: A	Revision Date: 7/11/2017
Management Review Input		
Approved By: Dave Zirkelbach		Date: 7/11/2017

I. PURPOSE

The purpose of this procedure is to provide for a system and instructions, and to assign responsibilities for scheduling, conducting, and recording management reviews of the quality management system.

II. APPLICATION

This procedure applies to all activities comprising the quality system, and in particular those named in ISO 9001:2015 Standard 9.3.2, Review input.

This procedure directly concerns the top executive management.

III. PROCEDURE

1. Review input

1.1 At a minimum, following information and data are presented for review:

Action items from last meeting:

Status of action items from previous meeting. Items which are not completed are carried on as continuing actions, and are recorded as such in the minutes of the meeting.

Resources:

Review of adequacy and allocation of resources, including capital equipment needs, staffing levels.

Resource Requirements Review

Measurement Systems Analysis Review (MSA)

5S Systems Review

IT Systems Projects Completed and Future Review

Process performance and product conformance:

Review of quality performance data. These include rates or process and product nonconformities, on-time delivery performance, supplier quality performance, and productivity data.

Internal quality audits:

Review of results of internal quality system audits. This includes summaries of results for the cycle, frequencies of audit findings against particular elements of the quality system, and discussion of particularly important findings.

Corrective and preventive actions:

Review of most important corrective and preventive actions implemented through the period, and the status of pending actions.

Customer feedback and complaints:

Review of customer feedback and complaints, including analysis of trends for particular categories.

Customer satisfaction:

Review of customer satisfaction data and trends.

Vendor Performance:

Review of significant vendor quality performance issues.

Training:

Review status of training programs and the effectiveness of training provided. This includes correlation of training with quality and productivity performance trends in corresponding areas.

Continual improvement:

Review of data demonstrating progress toward achieving continual improvement goals, and reviews current and completed improvement projects.

Changes that could affect the quality system:

Review/discussion of any process, capacity, or other operational or organizational changes that affect the quality system; and proposes specific actions to update or modify the system in response to these changing circumstances.

1.2 In addition to the topics listed above, management review may also consider such issues as cost of quality and non-quality; integration of the quality system with other operations and activities; market and customer response to the quality effort; and any other such issues related to the quality management system.

- Looks to be accurate.

NEW-QOP-93-03 Management review output

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QMS Operational Procedure	QOP-93-03	
Section 9.3	Section Revision: A	Revision Date: 7/11/2017
Management Review Output		
Approved By: Dave Zirkelbach		Date: 7/11/2017

I. PURPOSE

The purpose of this procedure is to provide for a system and instructions, and to assign responsibilities for scheduling, conducting, and recording management reviews of the quality management system.

II. APPLICATION

This procedure applies to all activities comprising the quality system, and in particular those named in ISO 9001:2015 Standard 9.3.3, Review output.

This procedure directly concerns the top executive management.

III. PROCEDURE

1. Review output

1.1 Management reviews are concluded with actions related to:

Improvement of the quality management system,

Improvement of quality performance, and

Improvement of products and/or services to better meet customer requirements and increase customer satisfaction.

1.2 These improvement actions are often formulated as quality objectives with specific measurable targets, due dates, assignments of responsibilities, and allocation of resources for their implementation.

1.3 Management review output is documented in the minutes of the review meeting. Action items are highlighted or are placed under a special heading to ensure that they are easily identifiable. Whenever applicable, action items include assignment of responsibility, timeframe, and allocation of resources for implementation of the action.

- Looks to be accurate.

NEW-QOP-10-02 Nonconformity and corrective action

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QMS Operational Procedure	QOP-10-02	
Section 10.2	Section Revision: A	Revision Date: 7/11/2017
Nonconformity and corrective action		
Approved By: Dave Zirkelbach		Date: 7/11/2017

PURPOSE

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

APPLICATION

This process pertains to all aspects of the quality system at Dee Electronic; it is not restricted to product-related concerns or nonconformities. Process and system nonconformities are also provided for.

PROCEDURE

1. The Corrective Action database of ECIS is utilized by team members universally to collect information for improving the effectiveness of the Quality System, such as:
 1. Customer concerns
 2. Inspection and testing results and trends
 3. Internal audit Nonconformances
 4. External audit Nonconformances
 5. Team member concerns
2. Preventive Actions may be taken by management as a result of successful Corrective Action. When Corrective Action is applied to other Dee Electronics products, processes or locations, it is preventive action. Additional sources for Preventive Action include:
 1.
 1. Team member concerns
 2. Management Review ideas
 3. Industry and non-industry Best Practices
 4. Internal and external audit Observations

3. If there is observable evidence that the problem already exists (Corrective Action called for):
 1.
 1. Team Members in the affected area devise a Corrective Action Plan.
 2. Team Members are trained as appropriate.
 3. Team Members implement Corrective Action Plan. Utilization of the following tools is conducted when determining root cause: 5 Why's and Cause/Effect (Fish Bone) Diagrams.
 4. Quality Control Coordinator and President follow up and determine the effectiveness of the CA.
 5. President revises documentation as necessary, maintains records and reports to management in Management Review.
4. If there is no observable problem but there is a potential that one may exist in the near future (Preventive Action called for):
 1.
 1. President and affected Team Members brainstorm preventative solution(s).
 2. President proposes Preventive Action in Management Review moves ahead with implementation as appropriate.
 3. Quality practices, documented procedures, processes and forms are revised as needed.
 4. President revises and reissues quality system documentation, as necessary.
 5. Management provides necessary resources.
 6. Team Members are trained as appropriate.
 7. Team Members implement Preventive Action.
 8. President determines effectiveness of Preventive Action and reports during Management Review or prior if appropriate.
 9. President maintains records of Preventive Action in Internal Audit/Management Corrective/Preventive Action Form.
5. Corrective and Preventive Actions are continuously assessed by:
 1.
 1. Internal quality audits.
 2. External quality audits.
 3. Feedback from Team Members.
 4. Feedback from Customers.
6. The President and Vice President of Quality maintain electronic records (ECIS) related to Corrective and Preventive Action.
7. Continual Improvement – Continual improvement actions are often defined as corrective and preventive actions. This is especially true for preventive actions. Operational Procedure, Continual Improvement, and Management Review, explain how the corrective and preventive action system is used for facilitating continual improvement.
8. The effectiveness of Corrective Action and Preventative Action taken is reviewed by ongoing statistical analysis (prompting for review of effectiveness of Corrective Actions and Preventative Actions) as well as reviewed in Management Review Meetings by reviewing Corrective Action and Preventative Action trending.

- Looks to be accurate.

NEW-QOP-10-03 Continual Improvement

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QMS Operational Procedure	QOP-10-03	
Section 10.3	Section Revision: A	Revision Date: 7/11/2017
Continual Improvement		
Approved By: Dave Zirkelbach		Date: 7/11/2017

I PURPOSE

The purpose of this procedure is to provide for a system and instructions, and to assign responsibilities for facilitating continual improvement of the quality management system.

II APPLICATION

This procedure applies to all activities comprising the quality management system. This procedure concerns all departments.

III PROCEDURE

1. General

1.1 Dee Electronics deploys continual improvement philosophy throughout the entire organization. The quality system itself is designed to incorporate all elements necessary to identify opportunities for improvement and to implement improvement projects.

1.2 Everyone in the organization is encouraged to come forward with ideas for improving products, processes, systems, productivity, and working environment. Improvement suggestions are evaluated and prioritized by the executive management team.

2. Identification of improvement opportunities

2.1 Opportunities for improvement are identified from such sources as:

Data of process and product characteristics and their trends;

Records of product nonconformities;

Customer satisfaction, dissatisfaction and other customer feedback;

Market research and analysis of competitive services;

Feedback from employees, suppliers, manufacturer representatives and other interested parties; and

Internal and external audits of the quality system.

2.2 In addition to the above-listed systems for continual performance monitoring, special assessment projects may be initiated to identify opportunities for improvement in other areas. Examples are:

Non value-added use of floor space,

Waste of labor and materials,

Excessive cost of non-quality, and

Excessive handling and storage.

2.3 Opportunities for improvement of operations and systems are identified on two levels: continuously, by the management team and supervisors, based on daily feedback from operations and other activities; and periodically, by the management review, based on analysis of longer-term data and trends. Opportunities for improvement of services are identified mainly by Sales/Marketing Management.

3. Evaluation of improvement opportunities

3.1 Those opportunities for improvement based on daily feedback from operations are evaluated by executive management and, when appropriate, are implemented through the system of corrective and preventive action. Typically, they would be triggered by such events as identification of a

nonconforming process or product, customer complaint, internal audit finding, and other such specific events.

3.2 Opportunities of improvement based on longer-term data and trends are evaluated by the management review. They are prioritized with respect to their relevance for reaching the quality policy and quality objectives. When new important opportunities for improvement are not adequately supported by the current policy and objectives, the management review may change the policy and/or establish new quality objectives.

3.3 Opportunities for improvement of services are evaluated by the President and Vice President, Sales.

4. Implementation of improvement projects

4.1 Improvements required to address daily feedback from operations and other activities are usually implemented through corrective and preventive actions.

4.2 Longer-term improvement projects to fulfill the quality policy, attain quality objectives, or correct unfavorable trends are implemented through special management actions defined by the management review. These actions may be documented in management review minutes, or be issued as directives, memoranda, policy statements, etc. The corrective and preventive action system may also be used for this purpose.

4.3 Service improvement projects are usually implemented via projects guided by the President.

- Looks to be accurate.