

## 8.1 General

The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed

- a) to demonstrate conformity to product requirements,
- b) to ensure conformity of the quality management system, and
- c) to continually improve the effectiveness of the quality management system.

This shall include determination of applicable methods, including statistical techniques, and the extent of their use.

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# Des Moines Quality Management System

ISO9001:2008 Standard

## QM 8.1 – Planning for Monitoring and Measurement

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**Quality Manual**      8 – Measurement, Analysis, and Improvement

Section 8.1      Section Revision: B      Revision Date: 2/3/2014

### 8.1 – General / Planning for Monitoring and Measurement

Approved By: Todd Gifford      Date: 7/12/2010

#### **GENERAL POLICY**

Measurement and monitoring activities required to assure conformity to product requirements, ensure conformity to the quality management system, and to continually

improve the effectiveness of the quality management system are planned and defined.

When applicable, statistical techniques are used for analyzing measurement data in addition to exception reporting and other types of reporting.

#### **PROCEDURAL POLICIES**

##### 1. Planning

1.1 Measurement and monitoring activities to assure conformity of the Quality Management System are defined in this manual in Section 8.2, Measurement and Monitoring, and in several operational procedures referenced at the end of this section.

1.2 The effectiveness of the quality system is monitored by internal audits and by measuring quality performance and customer satisfaction. Results of these activities are reported to the top management and are used to identify opportunities for improvement. Activities related to internal audits and to measuring customer satisfaction and quality performance are further defined in this manual in Sections 8.2.

## 2. Statistical techniques

Dee Electronics identifies the need for statistical techniques necessary for establishing, controlling and verifying process capability and product characteristics. Dee Electronics establishes and maintains documented procedures to implement and control the application of identified statistical techniques.

### 1. Dee Electronics gathers the following data from Corrective Action, Preventative Action, and Measurement Systems Analysis (MSA):

1. Internal and external audit results.
2. Customer Feedback.
3. Team member Feedback.
4. Corrective and preventive actions.
5. Quality performance of subcontractors.
6. Surveys.
7. Supplier Quality/Performance Measurement Reports provided by Customers.
8. Dee Performance Reporting on key customer satisfaction metrics as developed internally based on our data.
9. Customer Sales Growth/Decline Reporting
10. **Statistical studies (e.g. Gage R&R) are conducted where feasible to analyze the variation present in the results of each active category of measuring and test equipment.**

2. Data is compiled and analyzed for trends that might merit preventive action. Analysis includes, but is not limited to: Analysis of Root Cause Category Statistics and Trends, Customer Complaint Corrective Actions, Statistical analysis of Supplier Corrective Actions and causes, and Employee and Supplier complaints.
3. The President, CEO/Treasurer, Vice President of Sales and Vice President of Operations select data analysis methods and provide training in the use of specific analytical methods as necessary.
4. Analyses are presented in Management Review Meetings where the usefulness of the data and the appropriateness of the methods used are evaluated.

## ASSOCIATED DOCUMENTS

**QF-81-01-01 Measurement Systems Analysis Log**

**QOP-82-01 Operational Procedure: Customer Satisfaction**

**QOP-82-02 Operational Procedure: Internal Audit**

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

**QOP-82-05 Operational Procedure: Final Inspection**

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

Systems -

Brenda

How are quality trends identified?

Excel spreadsheet on the R. Area  
documented by QA personnel  
part #, WO# , Qty - by employee can be filtered

Do you ask your customers  
for feedback regarding performance?

Get it through the corrective  
action process

Checked  
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AT

## 8.2 Monitoring and measurement

### 8.2.1 Customer satisfaction

As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.

NOTE Monitoring customer perception can include obtaining input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims and dealer reports.

### 8.2.2 Internal audit

The organization shall conduct internal audits at planned intervals to determine whether the quality management system

- a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and
- b) is effectively implemented and maintained.

An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.

Records of the audits and their results shall be maintained (see 4.2.4).

The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes.

Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).

NOTE See ISO 19011 for guidance.

### 8.2.3 Monitoring and measurement of processes

The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate.

NOTE When determining suitable methods, it is advisable that the organization consider the type and extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to product requirements and on the effectiveness of the quality management system.

### 8.2.4 Monitoring and measurement of product

The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained.

Records shall indicate the person(s) authorizing release of product for delivery to the customer (see 4.2.4).

The release of product and delivery of service to the customer shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

# Des Moines Quality Management System

ISO9001:2008 Standard

## QM 8.2 – Monitoring and Measurement

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**Quality Manual**      8 – Measurement, Analysis, and Improvement

Section 8.2      Section Revision: A      Revision Date: 2/28/2003

### 8.2 – Monitoring and Measurement

Approved By: Todd Gifford      Date: 2/28/2003

#### GENERAL POLICY

Customer satisfaction is the principal objective of the quality system, and the level of customer satisfaction is the most important measure of the effectiveness of the system. Customer satisfaction is measured by collecting and analyzing direct customer feedback, and by measuring secondary indicators of customer satisfaction. Customer satisfaction data is used by the top management to identify opportunities and priorities for improvement.

✓ All activities and areas relevant to the quality system are audited at least once a year. Audits are scheduled on the basis of the status and importance of the activity. Internal auditors are independent of those having direct responsibility for the audited activity. Identified nonconforming conditions are brought to the attention of the responsible managers and corrective actions are implemented in response to audit findings.

Quality system processes are monitored to ensure that they achieve planned results. Relevant product characteristics are measured through inspections and product verification activities, as specified in control plans. Evidence of product conformity is recorded. Products

are released for delivery only after all specified activities have been satisfactorily completed and verified.

## PROCEDURAL POLICIES

### 1. CUSTOMER SATISFACTION

#### ✓ 1.1 General

✓ 1.1.1 Marketing is responsible for developing suitable indicators of customer satisfaction, and for defining methods for collecting and analyzing the pertinent information.

✓ 1.1.2 Information and data pertaining to customer satisfaction and perception are collected from several sources. Specifically, these are:

*Customer Surveys,*

*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.*

✓ 1.1.3 Operational Procedure QOP-82-01, Customer Satisfaction, defines the system for collecting and analyzing the pertinent information and data, and for reporting results to the top management.

#### ✓ 1.2 Customer feedback

✓ 1.2.1 Customer complaints, spontaneous expressions of satisfaction, and other unsolicited customer feedback are collected and processed by the sales department and management.



These activities are defined in Operational Procedure QOP-72-02, Customer Feedback and Complaints. The resulting data is periodically analyzed by the Vice President, Sales and President, and is presented and discussed at management review meetings.

1.2.2 Executive Management interacts with customers periodically to understand how we are performing and assess customer's satisfaction and concerns. Conclusions of interaction are documented in Electronic Call Report Forms, and presented and discussed at management review meetings.

### 1.3 Performance Reports, Recognition/Awards

1.3.1 Dee Electronics encourages its customers to rate its performance and present periodic performance reports to Dee Electronics. If customer does not have a performance reporting system, Dee Electronics usually offers to produce its own self performance report and provide this to the customer. Dee Electronics reviews periodic performance reports carefully, and considers this information as an important input in determining customer satisfaction. Dee Electronics seeks to participate in customer's vendor/supplier recognition programs. These recognitions and ratings are considered as an important input into determining customer satisfaction.

### 1.4 Product returns and rejections

1.4.1 Information about the rate of product returns and rejections is extracted from database records. Results and trends are reported and analyzed at management review meetings.

### 1.5 New Key Customer Growth

1.5.1 Sales records are periodically analyzed to identify new key focus customers and track their purchase growth. Statistics on new key customer growth are presented and discussed at management reviews.

### 1.6 Existing Customer Market share

1.6.1 Vice President, Sales and the President are responsible for analyzing trending of market share at existing customers. This data is periodically analyzed and presented at management review meetings.

## 2, INTERNAL AUDIT

## 2.1 Planning and scheduling

2.1.1 The President establishes an internal audit plan and schedule in accordance with Procedure QOP-82-02, Internal Quality Audits. Every activity and area is audited at least once a year. Selected activities are audited more frequently, depending on their importance and quality performance history.

## 2.2 Audit team and preparation for audit

2.2.1 Only personnel independent of the audited activities are assigned to conduct internal audits. Normally, Quality Assurance coordinator leads the audit team except when QA activities are being audited. Audits of QA activities are conducted by other trained Internal Quality Auditors from other departments.

2.2.2 Auditors prepare for audits by reviewing applicable standards and procedures, analyzing quality records, and establishing questionnaires and checklists. Selection of auditors and preparation for the audit are explained in Procedure QOP-82-02, Internal Quality Audits.

## 2.3 Conducting the audit

2.3.1 Conducting the audit, auditors seek objective evidence indicating whether the audited activities comply with the requirements of the documented quality system and ISO 9001, and whether the quality system is effective. The evidence is collected by observing activities, interviewing personnel, and examining records.

2.3.2 Nonconforming conditions are documented on the Internal Audit checklist, and then audit nonconformities are recorded in the Internal Audit/Management Corrective and Preventive Action Form QF-82-02-01. This form is described in Procedure QOP-82-02.

2.3.3 Audits are conducted in a way that minimizes disruption of the audited activities.

## 2.4 Corrective action and follow up

2.4.1 When nonconforming conditions are identified, the Corrective Action process is followed, developing a Corrective Action solution(s). Implementation and effectiveness of the action are verified by the Corrective Action process. The Internal Audit/Management Corrective and Preventive Action Form QF-82-02-01 is used for monitoring and recording the implementation of the corrective actions.

## 2.5 Audit Records / Reporting

2.5.1 Records of the audits are maintained per 4.2.4. When the auditing cycle is completed, all nonconformity/corrective action reports established during the cycle are compiled and analyzed, and key results/findings are presented and reviewed at the management review meeting. Top Management or the appropriate department manager will ensure that any necessary corrections and corrective actions are taken without delay to eliminate detected nonconformities and their causes.

## 3. MONITORING OF QUALITY SYSTEM PROCESSES

### 3.1 Process monitoring

3.1.1 Quality system processes are monitored by variety of approaches and techniques, as appropriate for a particular process and its importance. These include:

*Conducting internal audits of the quality system;*

*Monitoring trends in corrective and preventive action requests;*

*Analyzing product conformity and other quality performance data and trends;*

*Measuring and monitoring customer satisfaction;*

*Listening to Feedback from organization Team Members.*

### 3.2 Response actions

3.2.1 When a quality system process does not conform with requirements, the President may request the person responsible for the process to implement a corrective action, in accordance with Operational Procedure QOP-85-02, Corrective and Preventive Action.

## 4. MONITORING AND MEASUREMENT OF PRODUCT

### 4.1 Product verification

✓ 4.1.1 Inspection and testing program for a product is defined by customer orders, purchasing documents/orders, inspection and testing procedures, and so forth. Documents defining the inspection and testing program for products are collectively referred to as control plans. Section 7.1 of this manual defines the process for establishing control plans.

✓ 4.1.2 **Verification of purchased product:** All purchased products are subjected to a visual inspection by the receiving clerk, and then some designated products are subjected to a more detailed additional inspection. Operational Procedure QOP-74-03, Verification of Purchased Product, sets forward detailed rules for performing receiving and additional quality control inspections. Urgent release is not done.

✓ 4.1.3 **In-process inspections:** In-process inspections may be in the form of product verification by bar code scanning equipment, or human visual review documented electronically. Each subsequent process verifies that the previous process was completed correctly. The focus is on defect prevention rather than detection. In-process inspection activities are regulated by Operational Procedure QOP-82-04, In-process Inspections.

✓ 4.1.4 **Final inspection:** Customer orders are subjected to the final authorization inspection. The shipping department reviews the order against all customer special handling requirements. Only customer orders that pass the final inspection can be shipped. Procedure QOP-82-05, Final Inspection, regulates these activities.

✓ 4.2 Inspection, test and monitoring records

✓ 4.2.1 Results of inspections are recorded and evidence of conformity with the acceptance criteria is maintained. Instructions for establishing records for specific types of inspections are defined in Operational Procedures QOP-74-03, QOP-82-04, and QOP-82-05. Filing and maintenance of inspection records are regulated by Operational Procedure QOP-42-03, Control of Quality Records.

✓ 4.3 Product release

✓ 4.3.1 Products are released for delivery only after all specified activities have been satisfactorily completed and conformity of the product has been verified. Only personnel performing final authorization inspections have the authority to release products. The identity of the person authorizing product release is recorded in the Shipping Final Authorization process. Operational Procedure QOP-82-05, Final Inspection, defines specific methods for product release.

**ASSOCIATED DOCUMENTS**

QF-82-02-01 Form [Cedar Rapids Location]: Internal Audit/Management Corrective and Preventive Action Form

QOP-82-01 Operational Procedure: Customer Satisfaction

QOP-82-02 Operational Procedure: Internal Quality Audits

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

QOP-82-05 Operational Procedure: Final Inspection

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

# Des Moines Quality Management System

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## QOP-82-01 – Customer Satisfaction

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**QMS Operational Procedure**      QOP-82-01

Section 8.2

Section Revision: A

Revision Date: 7/12/2010

### **Customer Satisfaction**

Approved By: Todd Gifford

Date: 7/12/2010

### **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**

V

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.~~ These activities are defined in Operational Procedure QOP-72-02, Customer Feedback and Complaints.

✓ 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.

3.3 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, in accordance with Clause 2 of this procedure and Operational Procedure QOP-72-02, Customer Feedback and Complaints.

#### 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.~~

#### 7. Existing Customer Market share

7.1 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.

#### 8. Customer Surveys

8.1 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.



9. Analysis and presentation of results

9.1 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.

9.2. 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.

**ASSOCIATED DOCUMENTS**

QOP-56-01 Operational Procedure: Management Review

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

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## QOP-82-02 – Internal Audits

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**QMS Operational Procedure**      QOP-82-02

Section 8.2

Section Revision: C

Revision Date: 5/20/2014

### **Internal Quality Audits**

Approved By: Todd Gifford

Date: 7/12/2010

### **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 (refer to Procedure QOP-56-01, Management Review), so that results of an auditing cycle are available for the management review meeting.

## 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 ISO9001:2008 standard on the company Intranet. **IQA Training, whether done in-house or by professionals, is recorded in the Training Records.**

## 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 Form QF-82-02-01. 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 (Procedure QOP-85-02, Corrective and Preventive Action). 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 QF-82-02-02 for documenting the Audits, and the Internal Audit/Management Corrective and Preventive Action Form QF-82-02-01 for documenting findings that require Corrective Action.

6.2 The Internal Audit Checklist Form QF-82-02-02 contains the results and documentation of the Audit. The Internal Audit/Management Corrective and Preventive Action Form QF-82-02-01 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.

## **ASSOCIATED DOCUMENTS**

QF-82-02-02 Quality Form: Internal Quality Audit Checklist Form and Archived IQA Records

QF-82-02-01 Quality Form [Cedar Rapids Location]: Internal Audit/Management Corrective and Preventive Action Form

QF-82-02-03 Quality Form: Internal Audit Plan

Operational Procedure QOP-85-02: Corrective and Preventive Actions



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## QOP-82-04 – In-Process Inspections

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**QMS Operational Procedure**      QOP-82-04

Section 8.2

Section Revision: A

Revision Date: 7/12/2010

### **In-Process Inspections**

Approved By: Todd Gifford

Date: 7/12/2010

### **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

X 2.1 When buying a part for the first time, Quality Assurance performs a second visual inspection in addition to the verification of purchased parts process.

Y 2.2 First-time-buy part additional inspections are called out on the 2 x 1 Incoming Bar-code label that Receiving puts on every product that is received.

X 2.3 First-time-buy parts are subjected to the additional inspection by Receiving, and may include QA and Product Management. When the result of the inspection is satisfactory, the inspector signs off the inspection record in the system (QF-74-03-02 Additional Inspection database form). The sign-off constitutes the record of the additional inspection, identifies the inspector, identifies the inspection status of the product, and authorizes the part to move to the next process.

Y 2.4 Quality Assurance and/or Operations may subject First-Time-Builds to additional inspection. If conforming, sign off is documented in the audit database. The sign-off documents the record of additional inspection, identifies the inspector, and the inspection status, and releases the product to the next process.

## 3. Picking Process

- X
- 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.
- 

Y 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

Y 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.

#### **ASSOCIATED DOCUMENTS**

QF-82-04-01 Quality Form (*DBA Form # WO-D*): Picking Form

QF-82-04-03 Quality Form: Instruction/Inspection Log Form

QF-82-05-02 Quality Form: Quality Assurance Audit Form

~~QOP-82-05 Operational Procedure: Final Inspection~~

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

QOP-83-01 Operational Procedure: Control of Nonconforming Product



# Des Moines Quality Management System

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## QOP-82-05 – Final Inspection

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**QMS Operational Procedure**      QOP-82-05

Section 8.2

Section Revision: A

Revision Date: 7/12/2010

### Final Inspection

Approved By: Todd Gifford

Date: 7/12/2010

### I PURPOSE



The purpose of this procedure is to provide for a system and instructions, and to assign responsibilities for performing the final inspection.

### II APPLICATION



This procedure applies to all products being shipped to customers. This procedure concerns Shipping and Quality Assurance departments.

### III PROCEDURE



#### 1. General

All finished products/orders are subjected to final authorization before they released to ship. Quality Assurance and/or Management is responsible for the final inspection and authorization.

It is the policy of Dee Electronics to concentrate resources and attention to defect prevention rather than defect detection. The verification effort is therefore focused on process control and in-process inspections. The purpose of final inspection is to all work instruction requirements have been met.

## 2. Scope

✓ At a minimum the scope of final authorization inspection comprises of reviewing the final product to the work instructions and meets any customer special requirements.

## 3. Carrying out the inspection

✓ Access to the work instructions are provided to appropriate personnel

✓ Products that pass all in-process and final inspections per the work instructions are identified as approved and moved to a shipping staging area.

## 4. Nonconforming product

✓ When a nonconforming product is identified by Quality Assurance or Management the nonconformity is first determined if it can be resolved. If it cannot be resolved the product is moved to the HOLD area for corrective action.

## 5. Release of product

✓ Only Quality Assurance Inspector or Management has the authority to release finished product for shipment.

## 6. Inspection record

✓ Final inspection documentation is stored in an electronic database (QF-82-05-02). The inspection documentation includes the production order number, the inspector name, the date inspected, and the quantity inspected.

## **ASSOCIATED DOCUMENTS**

QF-82-05-02 Quality Form: Quality Assurance Audit Form

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

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

QOP-83-01 Operational Procedure: Control of Nonconforming Product

# Systems-

Brenda-

- Where is product conformity recorded?

Excel RMA Log

date RMA # open date closed date Qty

where is the information regarding rate of returns and trends stored?

Excel RMA Log

- How is customer purchasing trends tracked?

Not needed as work orders constantly change

Sensata switches can be ordered in bulk  
Pick, production, inspection, packing, invoice and ship

- If a product is found to be non-conforming where is it put? who is alerted?

Label is made and put on lot 3 hold shelves

~~- When a product is inspected where are the nonconformities recorded?~~

Included in the internal

Quality chart

Order entry, purchasing and receipt

When a new product is purchased how is it noted for inspection?

Brenda - incoming inspection is noted once item cannot be received until updated

### 8.3 Control of nonconforming product

The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.

Where applicable, the organization shall deal with nonconforming product by one or more of the following ways:

- a) by taking action to eliminate the detected nonconformity;
- b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;
- c) by taking action to preclude its original intended use or application;
- d) by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.

When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).

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## QM 8.3 – Control of Nonconforming Product

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**Quality Manual** 8 – Measurement, Analysis, and Improvement

Section 8.3 Section Revision: A Revision Date: 7/12/2010

### 8.3 – Control of Nonconforming Product

✓ Approved By: Todd Gifford Date: 7/12/2010

#### GENERAL POLICY

Nonconforming product is identified, documented, evaluated, and prevented from being used or shipped. Appropriate actions are taken when product nonconformity is identified after delivery. When appropriate, corrective and preventive actions are implemented to prevent recurrence of identified nonconformities.

The quality system described in this section of the Quality Manual conforms to the requirements of the ISO 9001:2008 standard: Element 8.3 – Control of Nonconforming Product.

#### 1. RESPONSIBILITY AND AUTHORITY (R&A)

✓ The R&A for carrying out quality system activities related to this element have been assigned to the President. All associates have the responsibility to carry out their work assignments in accordance with the quality policy and quality system documentation. The

associates have been granted appropriate authority to complete the activities assigned in order to meet specified requirements.

## 2. CONTROL OF NONCONFORMING PRODUCT

✓ Dee Electronics has established and maintains documented procedures to ensure that nonconforming product is prevented from unintended use or installation. This control provides for identification, documentation, evaluation, segregation, disposition of nonconforming product, and notification to the functions concerned.

2.1 Review and Disposition of Nonconforming Product – Dee Electronics has defined the responsibility for review and authority for the disposition of nonconforming product.

✓ Nonconforming product is reviewed in accordance with documented procedures. Where applicable, it may be reworked to meet the specified requirements, accepted without repair by concession, rejected/returned, or scrapped. Dee Electronics does not do Repair. When nonconforming product is corrected, it is subject to re-verification to demonstrate conformity to the requirements. Records of the nonconformities and actions taken, including concessions obtained, are maintained per 4.2.4.

✓ 2.2 Where required by contract, the proposed use of product which does not conform to specified requirements is reported for concession to the customer or customer's representative. The description of the nonconformity that has been accepted is recorded to denote the actual condition. Reworked product is reinspected in accordance with documented procedures.

## 3. PRODUCT RETURNS

✓ 3.1 When 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).

✓ 3.2 When product nonconformity is detected internally after delivery or use has started, customers are informed and instructed what to do with the product via RMA/CAR.

## ASSOCIATED DOCUMENTS

QOP-83-01 Operational Procedure: Control of Nonconforming Product

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

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

**QOP-82-05 Operational Procedure: Final Inspection**



# Des Moines Quality Management System

ISO9001:2008 Standard

## QOP-83-01 – Control of Nonconforming Product

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**QMS Operational Procedure**      QOP-83-01

Section 8.3

Section Revision: A

Revision Date: 7/12/2010

### Control of Nonconforming Product

Approved By: Todd Gifford

Date: 7/12/2010

#### **I PURPOSE**

The intent of this procedure is to describe the process at Dee Electronics for the Control of Nonconforming Product (Section 8.3 of ISO 9001:2008).

✓ 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. See Procedure QOP-42-03, Control of Quality Records, for retention details.
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.
10. When product nonconformity is detected internally after delivery or use has started, customers are informed and instructed what to do with the product via RMA/CAR.

**ASSOCIATED DOCUMENTS**

QF-85-02-01 Quality Form: Corrective Action Report CAR/RMA Form

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

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

QOP-82-05 Operational Procedure: Final Inspection

QOP-85-02 Operational Procedure: Corrective and Preventive Action

## SYSTEMS

Brand

What is your time frame for issuing an RMA?

Within 24 hours for RMA  
within 30 days close

How do you determine to scrap or return?  
cost, what it is, if it's needed

Who writes out non-conforming labels?  
the person who finds the defect

order entry, purchasing and receipt process

When a product is scrapped is it immediate  
thrown away?

depends on what it is  
there is a recycle process

Pick production inspection, packing, invoicing and ship

How do you know if something is nonconforming  
before shipping?

## 8.4 Analysis of data

The organization shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data shall provide information relating to

- a) customer satisfaction (see 8.2.1),
- b) conformity to product requirements (see 8.2.4),
- c) characteristics and trends of processes and products, including opportunities for preventive action (see 8.2.3 and 8.2.4), and
- d) suppliers (see 7.4).

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12/16/11

# Des Moines Quality Management System

ISO9001:2008 Standard

## QM 8.4 – Analysis of Data

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**Quality Manual**      8 – Measurement, Analysis, and Improvement

Section 8.4              Section Revision: A              Revision Date: 7/12/2010

### 8.4 – Analysis of Data

Approved By: Todd Gifford                      Date: 7/12/2010

#### **GENERAL POLICY**

X

Dee Electronics collects, compiles and analyzes information and data required for evaluating the suitability and effectiveness of the quality system and for identifying opportunities for continual improvement.

#### **PROCEDURAL POLICIES**

##### 1. General

X

1.1 Data and information recorded in quality records are compiled and analyzed periodically to determine trends in the performance and effectiveness of the quality system and to identify opportunities for improvement.

1.2 The President is responsible for coordinating these activities, and for reporting conclusions and trends to the executive management team. This is usually done within the framework of management reviews of the quality system, in accordance with Operational Procedure QOP-56-01, Management Review.

2. Scope

Following categories of information and data are recorded, compiled and analyzed:

2.1 Conformity to product and customer requirements:

*On-time delivery performance – recorded in delivery performance reports*

2.2 Suppliers:

*Supplier quality performance – recorded in subcontractor/vendor quality performance files (Procedure QOP-74-01)*

2.3 Customers:

*Customer satisfaction levels – recorded in Management Review minutes (Procedure QOP-82-01) and evaluated for trends by executive management.*

*Customer complaints – recorded in Internal Audit/Management Corrective and Preventive Action Form (Form QF-82-02-01) and evaluated for trends by executive management.*

2.4 Quality System:

*Effectiveness of training – recorded in training evaluation reports (Procedure QOP-62-01) and evaluated for trends by executive management.*

*Effectiveness of quality system – recorded in internal audit reports (Procedure QOP-82-02) and evaluated for trends by executive management.*

**ASSOCIATED DOCUMENTS**

QOP-56-01 Operational Procedure: Management Review

QOP-85-01 Operational Procedure: Continual Improvement



Systems -

Brenda

How is effectiveness of training evaluated?

- if an issue arises it is addressed as needed

- 2 month email

- visit by the employee.

## 8.5 Improvement

### 8.5.1 Continual improvement

The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

### 8.5.2 Corrective action

The organization shall take action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

A documented procedure shall be established to define requirements for

- a) reviewing nonconformities (including customer complaints),
- b) determining the causes of nonconformities,
- c) evaluating the need for action to ensure that nonconformities do not recur,
- d) determining and implementing action needed,
- e) records of the results of action taken (see 4.2.4), and
- f) reviewing the effectiveness of the corrective action taken.

### 8.5.3 Preventive action

The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

A documented procedure shall be established to define requirements for

- a) determining potential nonconformities and their causes,
- b) evaluating the need for action to prevent occurrence of nonconformities,
- c) determining and implementing action needed,
- d) records of results of action taken (see 4.2.4), and
- e) reviewing the effectiveness of the preventive action taken.

OK  
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12/17/14

# Des Moines Quality Management System

ISO9001:2008 Standard

## QM 8.5 – Improvement

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**Quality Manual**      8 – Measurement, Analysis, and Improvement

Section 8.5      Section Revision: A      Revision Date: 7/12/2010

### 8.5 – Improvement

Approved By: Todd Gifford      Date: 7/12/2010

#### GENERAL POLICY

Dee Electronics deploys a continual improvement philosophy throughout the entire organization. The improvement effort is driven by goals defined in the quality policy and quality objectives. Improvement opportunities are identified by analyzing quality performance data and information. Improvement projects are defined and implemented through the system of corrective and preventive actions and management review actions.

Causes of identified nonconformities are investigated and, where appropriate, corrective actions are implemented to ensure that nonconformities do not recur. Preventive actions are implemented to eliminate the causes of potential nonconformities. Corrective and preventive actions taken are recorded and are followed up to ensure that they have been properly implemented and that they are effective.

#### PROCEDURAL POLICIES

##### 1. CONTINUAL IMPROVEMENT

### 1.1 Opportunities for improvement

✓ 1.1.1 Opportunities and priorities for improvement are identified by comparing present quality performance to objectives defined in the quality policy and quality objectives.

✓ 1.1.2 Quality performance is determined by analyzing information about customer satisfaction, records of product and process nonconformity, results of internal audits, and other data and information relevant to quality performance. Section 8.4, Analysis of Data, defines the scope and system for collecting and analyzing such information.

✓ 1.1.3 Quality performance is evaluated by management reviews of the quality system. Where quality performance falls short of a defined objective, the management review identifies specific improvement actions to reach the objective. When a quality objective is reached, the management review may set a new, higher objective in this area and specify new improvement actions for reaching it.

✓ 1.1.4 This process of facilitating continual improvement through the use of quality policy, objectives, and analysis of data, is defined in Operational Procedures QOP-85-01, Continual Improvement, and QOP-56-01, Management Review.

✓ 1.1.5 In addition to management reviews, departmental supervisors/managers identify improvement opportunities continually, based on daily feedback from their operations and other activities. Employees are also encouraged to come forward with ideas for improving products, processes, systems, productivity, and working environment. These improvement opportunities are evaluated and prioritized by the President and, where appropriate, are implemented through the system of corrective and preventive actions.

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### ✓ 1.2 Implementation of improvement projects

✓ 1.2.1 Improvement projects are usually implemented through management review actions and through corrective and preventive actions. Where appropriate, improvement projects may be also initiated by management directives, such as policy statements, announcements, memoranda, and so forth.

## 2. CORRECTIVE AND PREVENTIVE ACTION

### ✓ 2.1 Preventive versus corrective action

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

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

## 2.2 Corrective actions

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

## 2.3 Preventive actions

2.3.1 The need for preventive action is determined on the basis of information and data regarding capability and performance of processes, product nonconformity rates, post-order fulfillment experience feedback, customer complaints, quality system audit findings, and management review ideas. Such information and data are collected and analyzed to detect unfavorable trends that, if not checked, will increase the risk of nonconformities. The system for collecting and analyzing quality performance information and data is defined in Section 8.4 of this manual.

## 2.4 Processing of corrective and preventive actions

2.4.1 Preventive and corrective actions are initiated, processed and followed up using a CAR (Corrective Action Request)/RMA form (QF-85-02-01) or Internal Audit/Management Corrective/Preventive Action Form (QF-82-02-01). The forms document the unsatisfactory condition and the corrective or preventive action to be taken, and is used to record the verification and closure of the action. Open CARs are reviewed regularly to ensure that the actions are implemented and followed up in a timely manner. Procedure QOP-85-02, Corrective and Preventive Action, explains how to use the CAR system.

## 2.5 Continual improvement

2.5.1 Continual improvement actions are often defined as corrective and preventive actions. This is especially true for preventive actions. Operational Procedures QOP-85-01, Continual Improvement, and QOP-56-01, Management Review, explain how the corrective and preventive action system is used for facilitating continual improvement.

## 2.6 Effectiveness of Corrective Action and Preventative Action

2.6.1 The effectiveness of Corrective Action and Preventative Action taken is reviewed and records of this are maintained in QF-85-02-01 and Management Review Meeting Minutes.

### ASSOCIATED SECTIONS AND DOCUMENTS

QF-85-02-01 Form: Corrective Action Report CAR/RMA Form

QF-82-02-01 Form [Cedar Rapids Location/Shared between CR and DM]: Internal Audit/Management Corrective/Preventive Action Form

QOP-85-01 Operational Procedure: Continual Improvement

QOP-85-02 Operational Procedure: Corrective and Preventive Action

QOP-56-01 Operational Procedure: Management Review

# Des Moines Quality Management System

ISO9001:2008 Standard

## QOP-85-01 – Continual Improvement

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**QMS Operational Procedure**      QOP-85-01

Section 8.5

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### **Continual Improvement**


Approved By: Todd Gifford

Date: 7/12/2010

### **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. This evaluation and prioritizing process is defined in Operational Procedure QOP-56-01, Management Review.

✓ 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. Operational Procedure QOP-85-02, Corrective and Preventive Action, defines the process.

✓ 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.



**ASSOCIATED DOCUMENTS**

QF-85-01-01 Quality Form: Employee Idea, Feedback, Concern Form

QOP-56-01 Operational Procedure: Management Review

QOP-85-02 Operational Procedure: Corrective and Preventive Action

# Des Moines Quality Management System

ISO9001:2008 Standard

## QOP-85-02 – Corrective and Preventive Action

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**QMS Operational Procedure** QOP-85-02

Section 8.5

Section Revision: A

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### **Corrective and Preventive Action**

Approved By: Todd Gifford

Date: 7/12/2010

### **PURPOSE**

The intent of this procedure is to describe the process at Dee Electronics for Corrective and Preventive Action (Section 8.5.2 and 8.5.3 of ISO 9001:2008).

X 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. 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. 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. 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 QF-82-02-01.

5. Corrective and Preventive Actions are continuously assessed by:

1. Internal quality audits.
2. External quality audits.
3. Feedback from Team Members.
4. Feedback from Customers.

6. The President and MR maintain electronic records (ECIS) related to Corrective and Preventive Action. See QOP-42-03, Control of Records, for retention details.

7. Continual Improvement – Continual improvement actions are often defined as corrective and preventive actions. This is especially true for preventive actions. Operational Procedure QOP-85-01, Continual Improvement, and QOP-56-01, 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. Records of these reviews are maintained in QF-85-02-01 and in the Management Review Meeting minutes.

### **ASSOCIATED DOCUMENTS**

QF-56-01-01 Quality Form: Management Review Minutes

QF-85-01-01 Quality Form: Online Employee Feedback/Concern Form

~~QF-72-02-02 Quality Form: Online Customer Concern/Complaint/Feedback Form~~

QF-85-02-01 Quality Form: Corrective Action CAR/RMA Form

QF-82-02-01 Quality Form: Internal Audit/Management Corrective/Preventive Action Form

QOP-83-01 Operational Procedure: Control of Nonconforming Product

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

QOP-85-01 Operational Procedure: Continual Improvement



Systems -

Brenda

no formal cycle count process

How do you identify areas that may need improvement?

How often do you identify preventative actions

How are preventative actions logged?

work instructions are updated as needed

---

Employee brought  
box issue to  
Brenda to work  
through solution  
was found