Moline 1st QTR Audit 3/6/2019

Brenda Bayles

Kevin Garrand - using ECIS; as he was beginning to enter an order into ECIS; he had indicated he is getting along okay with ECIS system; but is self-teaching himself and is learning something different with each order he enters.

Brenda Baker – Brenda shared that Production does not seem to be following process when they need to communicate with picking / i.e. shortages; damaged parts etc. She couldn't give a specific occurrence, but it seems she wishes to be informed so it can be determined if an error if any had occurred.

Julie Harkarts – her input consisted of the following; shortages from picking; seem to happen often; the assembly dash board doesn't appear to always be current; QTY's not matching the build QTY – she wasn't able to offer any examples of what may be occurring with the exception of what was being seen in connection to the J/O 588486

Rick Hardeman - regarding the usage of the MRBA vs CAR he indicated that MRBA it is to be used internally only; to determine error in production he indicated that it is difficult to identify the "who" on PCB level builds. They do have Control Plans and work instructions will be updated if required. When asked who is responsible for the control documents it was indicated that Lisa Bennett-Colley / Quality Inspector is responsible for document control along with training. Lisa was not available the day of the audit, but Rick did indicate that occasionally Lisa will speak to a production worker; but that o training is documented in connection to any production errors on an individual assembler.

Rick was unfamiliar with the CTQ' terminology and how it could be useful in identifying components which have been troublesome i.e. inserted backwards in items which may not be tested;

Rick was unaware how to proceed when he had IT projects

Brandon Foley – Asked serval questions of Brandon; such as where is the Quality Manual located; who completes any orientation with a new employee; have you read the quality manual; are you aware of Dee's Mission and Purpose; most every question was answered with no; he indicated he gets involved in cycle counts and purchasing

Penny Worthington – It was asked how she could get more training on DEI's and how to process them. Suggested she get with Lisa Pfranger; Lisa did send me an e-mail indicating that Penny did reach out to her regarding DEI's and Lisa was working with her

Julie Olsen – Julie is requesting more training with the Quality Group; possibly shadow QCC in both locations. She indicated she has weekly meetings on Thursday with Anders on CAR's but is frustrated as she feels as if she doesn't know what she is doing. The following 704; 630 which were cycle counts were reviewed. Along with the 720;721 –

Tooling Log –

Moline isn't using a tooling log for tool maintenance and calibration schedules,

In the Testing Area when fixtures are being used; there was a cabinet where customer supplier test fixtures are kept. Per Kevin / Cater they do not provide any routine maintenance or inspection unless it is warranted. Carter briefly walked me through a process where he was repairing a component (capacitor) on a test fixture; asked if they informed the customer that repairs had been required and it was indicated as no.

The document sheet used in the test lab Test Department Sheet being used has no reference what has tested or inspected – no part number is listed been documented; example attached

Upon arrival there was some system issue involving J/O 588486; it seemed that there were numerous duplication of the parts across the board; several individuals had commented on the error; by the time I reached Rick Hardeman when it was brought up to him he indicated he was aware it was a system issue and he had since gotten it worked out with DZ

Observations:

The area considered "informative" employee rights etc. area; has out dated and duplicated Employee Rights Documents still posted; some of the posting date back to 2011

A Beverage Container Policy may wish to be reviewed; there were several easily spill able glasses /cups in the PCB stuffing area. Some were on an upper shelf and some were next to product being completed

There was a general feeling that there seems to be little consistency in processes; they feel as if things are change frequently. This feeling was shared; by Brenda Baker; Christina Calussen, Brandon Foley and Rick Hardeman

The scale in the ware house scale model 171552 which is used for picking was scheduled for calibration on 3/14/19 and is calibrated every 6 months; The calibration date was listed under the plate on the scale. It was suggested that whoever does the calibration request them to put their label on the front so it can be easily visible for future reference. It was also suggested that all old calibration labels be removed.

There is no specific process of where product goes when product is being returned on a CAR/RMA; parts sometimes get delivered to Rick or Julie or even Brandon

No 5's coordinator has been assigned

Suggestions:

Rick Hardeman would like to see the Moline payroll system get worked out since they are paid weekly, he indicated it does not seem to be consistent and is difficult to manage

Sheet from testing Lab

HSI Test Department Historical PCB Problems Sheet

Description:
Part Number:

Symptom:	Problem Found:	Tally
Red LED comes on at close	P1 had solder shorts under part	
No LEDS	U18 Backwards	
Error Code 110 110	Q3 Shorted	
	U9 Bad	
Will not close in Run position		
No Leds come ON	D3 Bad, BACKWARDS	
Fail Code 116	U15 bad	
Red on Fail code 110	Q2 - Q5 bad	
Fails self test. No rotation of motor. PWM from U1 pin 4 less than a 1 vp-p. Should be 5 V P-P.	U12 Shorted to VCC. U12 Bad	
Fuse Blows	U17 Backwards	
U5 Runs hot. 12 Volts low.	Bridges on C37 and C11	
Low [redacted] torque in close direction	Pin 1 of U17 socket bent under.	
During Nudge Test when fixture switch in closed position motor turns in open direction	Found wire lodged under [redacted] C17, C19, C47 positive leads. Shorting them together. UUT read as Fixtures Open Close and Nudge were all on simultaniously.	

HARRINGTON QUALITY MANUAL

ISO9001:2015 Standard (If this document is printed or copied, it is an uncontrolled document)

3-5-19 BB

orientation or training not conducted or documented

QP7301 AWARENESS PROCESSES

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

1. Company-wide training and awareness programs

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

there appears to be no plan or procedure with respect to orientation and quality training per Brandon and Rick

Harrington 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.

1.3 **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.

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

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

2. 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. per Rick - there is no process for evaluations

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.

Revision History:

Revision	Date	Description of Changes	Approved By
0.0	07/03/17	Initial Release	Jim Theesfeld
1.0	8/17/18	Digitized version, procedure changes to work with new management structure	Todd Gifford

HARRINGTON QUALITY MANUAL

ISO9001:2015 Standard (If this document is printed or copied, it is an uncontrolled document)

3.5-9 BB

8.1 OPERATIONAL PLANNING AND CONTROL

GENERAL POLICY

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

PROCEDURAL POLICIES

1. Product requirements and quality objectives

1.1 Product requirements, CTQ's (Critical to Quality) Elements, and quality objectives (if applicable) for product are defined and communicated in customer orders and specifications submitted to Harrington.

per Rick

the CTQ terminology was a new phrase for Harrington

2. Product realization planning

2.1 Product realization planning includes, as applicable:

Development of adequate and capable processes,

Identification of special processes and consideration of associated risks and consequences, per Rick - there have been no guideline laid out per customer CTQ requirements

Establishment and implementation of appropriate process control measures,

Development of instructions, documents, and training for process operators, and Revised work instructions for P/N D020-1042-100 Rev Q, 23 pages with photos. These are printed off in file for assembler

Requirements for records necessary to demonstrate process conformity.

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

3. Product verification and validation planning

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

Any applicable Identification of inspection points,

Any applicable Inspection scope, frequency, and method,

Any applicable Acceptance criteria, and

Any applicable Requirements for records necessary to demonstrate product conformity.

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

Referenced Procedure

QP1140 Manufacturing Control - visited with Kevin/Carter in testing area - asked how problems are documented and a sheet was shown to me - (See attached) regarding defects through testing lab - not all items go through this process - it is up to customer.

Revision History:

Revision	Date	Description of Changes	Approved By
0.0	07/03/17	Initial Release	Jim Theesfeld
1.0	8/17/18	Digitized version	Todd Gifford

HARRINGTON QUALITY MANUAL

ISO9001:2015 Standard (If this document is printed or copied, it is an uncontrolled document)

3-5-19 BB

9.3 MANAGEMENT REVIEW

GENERAL POLICY

Brandon, Rick, nor Julie - where aware of where the quality manual was located or had read policy

The quality system described in this section of the Quality Manual conforms to the requirements of the standard: Element 5.6 ISO 9001:2015 Management Review.

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

PROCEDURAL POLICIES

1. General

1.1 The purpose of management reviews is to:

Evaluate the suitability, adequacy and effectiveness of the quality system;

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

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

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

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

2. Management Review input

Rick indicated he speaks to Todd daily but has not been involved in mgment mgt -

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

Results of audits,

Customer feedback and complaints,

Process performance and product conformance data,

Status of preventive and corrective actions, rarely are non conformities or errors discussed with any assembler

Changes that could affect the quality system,

Follow-up actions from earlier management reviews, and

Recommendations for improvement.

3. Management Review output

3.1 Management reviews are concluded with actions related to improvement of the quality management system, and improvement of processes and products to

better meet customer requirements. The review also identifies resource needs to implement these actions.

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

Reference Documents

Management Review Minutes

External Audits

Reference Procedures

3-5-19 reviewed these notes - Moline is now to this process - not much documented

QP9301 Management Review – General

QP9302 Management review input

QP9303 Management review output

Revision History:

Revision	Date	Description of Changes	Approved By
0.0	07/03/17	Initial Release	Jim Theesfeld
1.0	8/17/18	Digitized version, updated procedures	Todd Gifford

HARRINGTON QUALITY MANUAL

ISO9001:2015 Standard (If this document is printed or copied, it is an uncontrolled document)

3-5-19 BB

Moline. Rick, nor Brandon have participate in a management review

QP9301 MANAGEMENT REVIEW – GENERAL

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, Vice President of Manufacturing, Vice President of Quality, 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.

Associated Documents

Management Review Minutes

Revision History:

Revision	Date	Description of Changes	Approved By
0.0	07/03/17	Initial Release	Jim Theesfeld
1.0	8/17/18	Digitized version, procedure changes related to new management structure	Todd Gifford

HARRINGTON QUALITY MANUAL

ISO9001:2015 Standard (If this document is printed or copied, it is an uncontrolled document)

3-5-19
BB

Reviews are set up via management VP Quality / President

QP9302 MANAGEMENT REVIEW INPUT

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 - does not have 5's coordinator assigned

IT Systems Projects Completed and Future Review - Rick unsure how to request IT project

Six Sigma Initiatives - Rick not familiar

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. this data would be gathered from CAR/MRBA info

Customer satisfaction:

Review of customer satisfaction data and trends.

Vendor Performance:

Review of significant vendor quality performance issues.

Training: training programs have yet to be established

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. training is not being entered on regular basis

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.

Associated Documents

Management Review Minutes

Revision History:

Revision	Date	Description of Changes	Approved By
0.0	07/03/17	Initial Release	Jim Theesfeld
1.0	8/17/18	Digitized version and procedure changes for new management structure	Todd Gifford

HARRINGTON QUALITY MANUAL

ISO9001:2015 Standard (If this document is printed or copied, it is an uncontrolled document)

3-5-19
BB

QP1020 INTERNAL AUDITS

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 **VP of Quality** 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 **VP of Quality** schedules dates and assigns audit teams for all auditable sections.

1.3 The internal audit plan is generally, but not always, synchronized with management reviews of the quality system, 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 Coordinators that conducts the audits. Activities that are the responsibility of Quality Coordinators 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.

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 significant/major nonconformity is noted, it is brought to the attention of, and discussed with, the VP Quality. 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

VP, Quality or President who uses the rest of the from 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 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 CAR/RMA/MRBA Form for documenting findings that require Corrective Action.

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

Don't understand CAR/MRBA - are they acting as separate systems

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 meetings.

Reference Documents:

QP1020-1 Internal Audit Program / Schedule ✓ Reviewed 3-5-19 BB

Internal Audit Document 8/31/18 ✓

Internal Audit Document 9/17/17 ✓

Revision History:

Revision	Date	Description of Changes	Approved By
0.0	07/03/17	Initial Release	Jim Theesfeld
1.0	8/17/18	Digitized version, procedure changes to simplify	Todd Gifford

Moline is not similar with external personnelle conducting internal audits - and unsure why at this time. But seem to not be considering any audit as an invasion as the previous 2 audits

HARRINGTON QUALITY MANUAL

ISO9001:2015 Standard (If this document is printed or copied, it is an uncontrolled document)

Read 3-5-19 BB

Production – no one was aware of policy and had not read policy

7.3 AWARENESS

Personnel are kept aware of the quality policy, quality objectives, and their contribution to the effectiveness of the quality management system, including non-conformances, through regular production meetings, individual corrective action communications, company newsletter, or quality training.

Reference Procedure:

QP7301 – Awareness Processes

Revision History:

Revision	Date	Description of Changes	Approved By
0.0	07/03/17	Initial Release	Jim Theesfeld
1.0	8/17/18	Digitized version	Todd Gifford

HARRINGTON QUALITY MANUAL

ISO9001:2015 Standard (If this document is printed or copied, it is an uncontrolled document)

3-5-19 BB

10.2 NONCONFORMITY AND CORRECTIVE ACTION

The Vice President of Quality is responsible for managing the Corrective Action Program. As defined in the Corrective Action Procedures, all personnel are responsible for taking action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

The Corrective Action Procedure defines requirements for:

- Reacting to the nonconformity and, as applicable:
  - taking action to control and correct it;
  - dealing with the consequences;
- Evaluating the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
  - reviewing and analyzing the nonconformity;
  - determining the causes of the nonconformity;
  - determining if similar nonconformities exist, or could potentially occur;
  - implementing any action needed;
  - reviewing the effectiveness of any corrective action taken;
  - updating risks and opportunities determined during planning, if necessary;
  - making changes to the quality management system, if necessary.

Referenced Procedures

QP1040 Nonconformity Corrective Action ✓

QOP-10-02 Nonconformity and corrective action ✓BB

Revision History:

Revision	Date	Description of Changes	Approved By
0.0	07/03/17	Initial Release	Jim Theesfeld
1.0	8/17/18	Digitized version	Todd Gifford

The car system is new to Julie and is just now up and going.
Julie is requesting more training on the CAR process noted that there seems to be crossover using CAR / MRBA example 7076 seemed to be a training issue but was not documented in CAR but in the MRBA, no follow up training had been documented. also noted initials vs using names -

Quality Management System
ISO9001:2015 Standard
Index

QOP-10-02 Nonconformity and corrective action

3-5-19 BB

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

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. 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. Utiliztion 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.

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 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.

With CAR | MRBA both being used it appears there is little communication between the 2 systems

Can see the MRBA is focused on production errors, observed little or few corrective action for errors, nor trend of employee errors

HARRINGTON QUALITY MANUAL

ISO9001:2015 Standard (If this document is printed or copied, it is an uncontrolled document)

3-5-19 BB

QP1140 MANUFACTURING CONTROL

Policy:	Harrington Signal Inc. shall develop, implement, and maintain product realization processes under controlled conditions which produce goods/services that conform to requirements.
Purpose:	To describe processes followed in the manufacture, inspection, and packaging of product for the customer's use.
Scope:	This procedure applies to all personnel involved in the manufacture and handling of Harrington Signal Inc. products and their components.
Responsibilities:	The Manufacturing Manager is responsible for managing Harrington Signal Inc.'s manufacturing processes, ensuring that all personnel, materials, and equipment needed to create and maintain the manufacturing schedule are available and able to function as expected. The Manufacturing Manager is also responsible for ensuring that Manufacturing personnel receive adequate training to perform their assigned duties and that they have complete, accurate, and up-to-date manufacturing documentation. The Manufacturing and Quality Managers are responsible for producing Harrington Signal Inc.'s end product(s) in a manner that ensures quality and meets statutory/regulatory and customer requirements.

Brenda shared that production does not seem to follow process when extra parts are required

Stockroom Personnel are responsible for picking product components and sending them to Manufacturing.

The Inspection & Test Departments are responsible for monitoring and measuring manufacturing (i.e., product realization) processes, to ensure Harrington Signal Inc. products conform to requirements.

Christina | picking observed picking of several parts on 5860024 - P/N 891554-002 - Qty 250 was difficult to count by hand but was done -

Enterprise Resource Planning (ERP) – Information system or process that coordinates manufacturing resources (e.g., production scheduling, parts purchasing, inventory handling, external provider interaction, customer service, and order tracking).

Definitions:

Has a good handle on cycle counts and when they should be sent

Key characteristic – Special feature of a material, part, or process, variation of which will significantly influence a product's fit, performance, service life, or manufacturability. Key characteristics are essential to meeting product goals are identified so that the Company's resources can be focused on those items.

Product realization – Act of bringing a product or service into existence (aka, "manufacturing the product"). "Realization" is a broader term than "manufacturing" or "production", so its use is increasing as services make up a larger share of the economy.

Procedure:

1.0 Manufacturing control

1.1 Harrington Signal Inc. shall apply suitable methods for monitoring and, where applicable, measurement of manufacturing processes in accordance with QP1180 PROCESS MONITORING-MEASUREMENT. These methods shall demonstrate the processes' ability to produce results that conform to internal and external requirements.

1.2 When planned results are not achieved, correction and corrective action, as appropriate, shall be taken in accordance with QP1040 CORRECTIVE ACTION.

1.3 Methods of production control include:

- Kitting work orders
- Production scheduling

2.0 Product REALIZATION

2.1 The Manufacturing Manager shall assign the work order for the first operation on the Routing (build instructions) to competent persons, including any required qualification.

2.2 The Lead/Operator shall prepare the work area by verifying that:

Observed Julie Hacket set up for W/O 590844

- Appropriate documented information (production plans, work instructions, layouts, diagrams, control plans, inspection sheets, labeling, etc.) is in place and *key characteristics* are understood.
- Required tooling, measuring resources, personal protective equipment, and or storage containers are available.
- Equipment setup is completed, the work area is clean, and production equipment is ready (good working order).

3.3 Inspection and test instructions are to include references to any special equipment, materials or forms to be used and are to be reviewed, approved and distributed in accordance with Documented Information Control Procedures.

3.4 The Automated Optical Inspection Scanner (AOI) is being used by inspection and test personnel to inspect boards that have come through the SMT line or through the Wave machine. The SMT operators also are trained to run boards through AOI. This would include first piece as well as production runs. The data collected is used by the Post Wave operators to repair boards as needed.

3.5 The inspector/tester shall initial or stamp the status tag, indicating whether the part passed or failed inspection/tests.

3.6 Non conformances identified during an inspection or test shall be tagged, documented and processed in accordance with QP1030 CONTROL OF NONCONFORMING OUTPUTS. there was a shelf for items that were not testing so disposition could be made

3.7 The status tag shall accompany the product through packaging and labeling, final verification, and final release.

they both

4.0 Packaging and Labeling - Did observe this area with Brenda

4.1 The Packaging operator shall apply required labels to product packaging in accordance with QP1150 IDENTIFICATION AND TRACEABILITY. nothing was in process

4.2 The operator shall package finished products according to work instructions for the product. Kayla Briggs walked me through process but did not observe

4.3 The operator shall apply box labels to the packaged product in accordance with work instructions and stage the product for release in the appropriate area.

4.5 If the product is a component to be used in a subsequent operation, the operator shall place the product in an appropriate container and attach a tag,

indicating the component name/ID and work order number on the tag. The operator shall include a shop router, as needed.

5.0 Final VERIFICATION AND Release

5.1 Packaging personnel shall verify that the product, as packaged, conforms to requirements.

5.2 Packaging personnel shall review all documentation in the work order packet to verify that it is complete.

5.3 Inspection and Test personnel shall verify that all inspections and testing have been performed and that the product has passed all required inspections and tests. If reworked nonconforming parts, materials, etc., have been included in the product to be released, the Quality Inspection shall verify that reworked product inspections have been performed and that the reworked product has passed all inspections.

6.0 Manufacturing CHANGE CONTROL

6.1 The Manufacturing Manager shall ensure continuing conformity with requirements by verifying that all changes to production or service provisions:

per Rick no documented process for engineering changes

- Are properly documented;
- That the documented information contains the person(s) authorizing the change; and
- That the documented information contains any necessary actions arising from the review.

Effectiveness Criteria:

- Product completed by due date
- Meeting due dates consistently
- Low/falling reject and waste disposal rates
- Elimination of quality/safety defects
- Amount of nonconforming product released to (or found by) customer
- Reduction, elimination, or prevention of product recalls

Revision History:

Revision	Date	Description of Changes	Approved By
0.0	07/03/17	Initial Release	Jim Theesfeld
1.0	8/17/18	Digitized version	Todd Gifford