Harrington 3rd QTR Audit 8/21/2019 Brenda Boyles

Observations:

The informative wall areas in the production have been cleaned up with posted data being current.

Dee Quality Policy had been posted in various areas of the building;

Mission Statement was not posted

Other postings were observed i.e. Intertek Audit certification

2nd QTR internal audit had not been uploaded into the system

Most people when asked were aware of Quality Policy that it located on ECIS and where access to the Quality Manual was located

For those asked it was indicated the help desk was working well; things are being completed in a timely fashion.

Julie has been cleaning/organizing the Quality Hold Shelf in the receiving area

7051 – was entered by Rick; assigned to Brandon Foley; worked by Quality; will there be a corrective action requested from the vendor who made the error?

7152 – entered in the CAR system?

7154 – owner is Julie Harket; what will her involvement be on 1 pc of a damaged PCB; no further activity

7150 – CAR on a machine repair; no tooling log is used in Moline

Noticed several CAR's on PCB's listing delamination as the cause of the defect; is there an inquiry with the supplier as to the cause of the delamination; i.e. humidity or other cause? CAR's 7030, 7033

8.4 – Control of externally provided process –

In speaking with Brandon; Rick and Julie; there is no set process to evaluate suppliers;

Brandon and Julie both indicted they are having a great deal of Quality issues on the part A2164E; there are several CAR's in the system and are having difficulty getting down to the root cause of the issue and how to correct.

QP1210 / QP1220 review for update; Quality procedures are documented that they are completed by purchasing and or purchasing manager; Most items are now being completed by the Quality Group

Noticed there were several stacks of packing slips stacked up on a file cabinet which hadn't been filed; Does Moline Receiving scan packing slips as the other locations do?

Brandon Foley

Brandon brought up the p/n A2164E; he indicated that they are continuing to have quality issues with the supplier and asked for suggestions to correct; made a few suggestions to him to get more details from the supplier about the pull test they are preforming; ask for photos of equipment; Also noticed that Brandon had made several receiving entries on this part; is he receiving the part after he completes the pull test.

UL came up in the conversation as Brandon indicated they would be getting a new UL inspector as the regular one they have had for years is retiring; Inquired about the UL label process and where those records were kept; he said we don't keep any records; we just print out the labels as we need them; Deeper exploration of the UL process would be suggested to avoid non-conformities discovered by a new auditor which could result in a fine

Penny Worthington

Commented on the # of reports that are received daily; 13/14?

She is learning to work them; also pointed out she does forward the on-hold components report to Brandon;

Rick Dibbern had a po 107265; he came to Penny's office questioning if the product going to be for an ARC PO; ARC completes a kitting/ bag process PO 102791 for reference; is the process being circumvented because the part received was for ARC? When it was asked of Rick what he was going to do with the materials; he said he would hold on to them until Penny got the PO complete and then they deliver them to ARC; when asked why he wasn't completing the receiving/put away process it was indicated it was easier for him to just hold on to the item

Penny also commented she had a performance review

Rick Dirrben

Came to purchase office asking purchasing about the PO 102745 as no packing slip had been received. Indicated he wanted to know what to do with the product. Penny indicted that DEI's would need to be completed which were completed by Julie #107022

With regards to shortages Rick indicated he will give a copy of the packing slip to Penny for her.

Rick Hardeman

The Brag Wall was a topic; it was indicated the Brag Wall did not seem appropriate to their culture; as they try to promote a team culture vs individual

Indicated that IT projects are being completed in more of a timely manner since the addition of the Help Desk and Jim.

Also indicated that for the first time in a long time he felt Moline was moving towards a positive proactive state vs reactive

Julie Olson

Settling into the Quality position;

Does not conduct any incoming inspections; leaves all inspections to Lisa /QA; both on raw materials and finished goods

When asked if she uses PIR's to flag or special receiving instructions; she indicated the PIR's are for purchasing; but she has used it once on p/n 5500412 which is a box.

Julie brought up the struggle and the numerous CAR's on the A2164E and the brick wall they seemed to have run into with the suppler; asked for suggestions; the following suggestions were made; involve the customer in the CAR process; inquire how parts are stored/ handled; inquire about the installation process; inquire when / where defects are being discovered;

HR Department

Most people have had no interaction with Vanessa in HR

Rick Hardeman; indicated he has enjoyed working with her as he gets involved with her frequently involving he time clock and employee hours worked; he indicated that the 2nd shift time sheets continue to be an issue for him which he indicated there was a project in place to correct; he has developed the it is what it is attitude on any pay period issues.

Julie Olson; has not had change to interact with her on anything to this point as Julie is the point of contact for any documented injuries which require investigation.

Suggestions

Julie feels that the CAR and MRBA are over lapping and individuals do not know what system to use; examples 7042 / 7047

Penny suggests that a "back up personnel" plan be created

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Audit completed 8/21/19 Brenda Bayless

5.1 LEADERSHIP AND COMMITMENT

5.1.1 General

Top Management at Harrington Signal Inc. shows its commitment to the quality management system through the development and implementation of this quality manual. Additionally, management commitment is demonstrated through Harrington Signal Inc.'s Quality Policy, the specific objectives that are set and reviewed during Management Review Meetings, and by providing the resources required to meet our objectives for continually improving the effectiveness of our operations and quality system.

The management team consisting of the President and all department managers is chartered with ensuring our products and services meet customer as well as statutory and regulatory requirements.

5.1.2 Customer focus

Top management ensures customer requirements are understood, the focus on improving customer satisfaction is maintained, and risks are properly determined by setting and reviewing objectives related to customer satisfaction periodically as necessary and at Management Review Meetings.

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

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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

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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

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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:

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.

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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

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6-15-19 BB

8.4 CONTROL OF EXTERNALLY PROVIDED PROCESSES, PRODUCTS AND SERVICES

8.4.1 General

The purchasing process is essential to Harrington Signal Inc.'s ability to provide our customers with products that meet their requirements. Harrington Signal Inc. ensures that purchased product conforms to specified purchase requirements. Harrington Signal Inc. accomplishes this by controlling our supplier base and inspecting purchased product as required. Obviously, the type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.

It is the responsibility of the Purchasing Manager and the Purchasing Department to evaluate and select suppliers based on their ability to supply product in accordance with specified requirements. Manufacturing may be called on to assist as required. Criteria for selection, evaluation and re-evaluation are defined in the Externally Provider Evaluation procedure.

8.4.2 Type and extent of control

Purchased items and materials are verified for correctness by the Receiving Department. If additional inspection is required, it is noted on the purchase order and the item is sent to Quality Inspection for further inspection.

8-15-19 BB

Should Harrington Signal Inc. or any of our customers decide to perform verification at the supplier's premises, the verification arrangements and method of product release shall be stated in the purchasing information.

8.4.3 Information for external providers

Harrington Signal Inc. uses purchase orders (PO's) to describe the product to be purchased, including where appropriate:

- Requirements for approval of product, procedures, processes and equipment
- Requirements for qualification of personnel
- Quality management system requirements
- The Purchasing Department is responsible for ensuring the adequacy of specified purchase requirements before their communication to the supplier. Processes have been established for the external providers' interactions with the organizations, control and monitoring of the external provider's performance, and the verification or validation activities that the organization, or its customer, intends to perform at the external providers premises.

Reference Procedures

QP1210 Receiving Inspection BB

QP1220 Purchasing BB

Revision History: 8-15-19 BB

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

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QP1210 RECEIVING AND INSPECTION

Policy:	Harrington Signal Inc. shall determine if products meet specified requirements prior to their use, if possible and practicable.
Purpose:	To define appropriate methods for receiving materials, components, parts, finished goods, etc., inspecting them when required, and determining their disposition.
Scope:	This procedure applies to receipt of all incoming items.
Responsibilities:	Receiving Personnel are responsible for receiving materials; inspecting for correct items, quantities, and possible damage/nonconformity; stocking items; and forwarding paperwork to Purchasing (issues with incoming product) or Accounting (paperwork).

BG - does currently A/R + clerical personnel - there is project in the works to automate

Accounts Payable is responsible for paying invoices.

The Purchasing Department is responsible for contacting vendors in case of damaged shipments or discrepancies.

Project in works to automated similar to CR/DSM

Quality is responsible for conducting *detailed* examinations of incoming materials when required; recommending acceptance or rejection of goods to the Purchasing Manager or designate.

8-15-19 BB

Certificate of Analysis (C of A) – External providers written statement, authorized by contract or purchase order, certifying that supplies or services comply with contract requirements based on quantitative instrumented physical or chemical analysis of representative samples taken from the shipment accompanying the certificate.

Certificate of Conformance (C of C) – External providers written statement, authorized by contract or purchase order, certifying that supplies or services comply with contract requirements, signed by a responsible individual, and displaying part number and version number, buyer's purchase order (PO) number, PO date, and PO revision number. Also called "Certificate of Compliance".

Definitions:

Direct-to-stock (DTS) – Parts/supplies placed directly into stock without inspection; done to reduce duplicate inspections *and* where a vendor has a history of providing satisfactory quality.

First article inspection (FAI) – Process monitoring of key characteristics to ensure that parts can be manufactured continually, inexpensively, in compliance with specifications, and with minimum variation.

Positive recall – Where incoming product is released for urgent production purposes prior to verification, it is positively identified and recorded in order to permit immediate recall and replacement in the event it is found not in conformance to specified requirements.

Procedure:

8-15-19 BB

1.0 RECEIVING AND STOCKING

1.1 Receiving shall review all incoming shipment documentation against purchasing expectations (see QP1220 PURCHASING) and communicate such discrepancies to the Purchasing Department.

1.2 Receiving shall visually inspect all incoming shipments for possible damage.

- If damage is apparent (e.g., packaging is dented or punctured, leakage is evident), Receiving should notify the Purchasing Department and move the suspect shipment to the appropriate holding area for determination of disposition, in accordance with QP1030 CONTROL OF NONCONFORMING OUTPUTS.
- Management shall determine if a damaged shipment may be conditionally accepted and damaged items returned or the entire shipment is to be rejected and returned. The Purchasing Department shall file claims against the shipper, where applicable.
- If the shipment shows no signs of damage:

Information on the packing slip shall be matched with the incoming shipment; and Item inventory shall be updated.

1.3 Where the vendor and Harrington Signal Inc. have a "direct-to-stock" agreement in place, Receiving shall move incoming items directly to their appropriate storage area(s).

1.4 For items that must undergo a detailed inspection to conform to contractual or other requirements, Receiving shall notify Quality and move the shipment to the appropriate holding area.

1.5 Receiving shall update the computer System with the appropriate information, move incoming items to their appropriate storage areas, and forward

the packing slip to Accounts payable for reconciliation with the related purchase invoice.

1.6 Receiving shall not place parts, components, supplies, etc., into inventory unless they are found to conform to specified requirements, unless they are released under *positive recall* or are DTS items.

8-15-19 BB

2.0 DETAILED INSPECTION

conducted by Lisa QA

2.1 A first article inspection (FAI) report may be required on some items (e.g., new parts, part revisions). If Harrington Signal Inc. requires an FAI report of the vendor, the Purchasing Manager shall verify that it addresses Harrington Signal Inc.'s requirements.

2.2 If multiple part numbers are included in a shipment, each part will be segregated and handled (e.g., inspected, put into stock) according to applicable requirements.

2.3 The Quality Inspector shall record found nonconformities (nonconforming red tag), review the event/situation and place those products "on hold" in accordance with QP1030 CONTROL OF NONCONFORMING OUTPUTS.

Regardless of that determination, the Quality Inspector shall maintain this record for vendor evaluation, in accordance with QP1120 EXTERNAL PROVIDER EVALUATION. The Purchasing Manager shall be notified of nonconforming product by the Quality Inspector.

2.4 The Quality Inspector shall stamp acceptable items and notify Receiving personnel to update inventory and place items into stock. Receiving label shall indicate part number (and other identifiers, if needed) and date of acceptance.

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3.0 ITEMS RECEIVED WITH CERTIFICATES (C of C or C of A)

3.1 Items in this category, while similar to DTS items in that they do not require inspection, must be accompanied by a "C of C" or a "C of A" when moved into inventory. The certificate shall be filed by the Quality Manager and reference to the certificate.

3.2 Receiving shall notify the Purchasing Department when a C of C or C of A shipment is not accompanied by the required certificate and move the shipment to the appropriate holding area, pending investigation and resolution of the problem by the Purchasing Manager.

4.0 RECEIVING/INSPECTION REVIEW

not done

4.1 The Purchasing Manager shall periodically review and analyze the ability of the receiving inspection process to ensure that externally provided process, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers.

4.2 The Purchasing Manager shall periodically review and analyze related reports for nonconformities and trends. If found nonconformities, trends, or occurrences suggest a need for corrective action, the Purchasing Manager shall ensure that any such action is taken in accordance with QP1040 NONCONFORMITY AND CORRECTIVE ACTION.

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4.2 The Purchasing Manager shall report to Top Management on the effectiveness of the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements and are communicated at Management Review meetings (accordance with QP1060 MANAGEMENT REVIEWS).

Effectiveness Criteria:

- Timely processing of incoming goods
- Timely inspection of received goods (cycle time)
- Material availability for production
- Production down time due to material shortage or poor quality is kept to the minimum possible

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

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QP1220 PURCHASING

Policy:	Harrington Signal Inc. shall ensure the adequacy of purchasing requirements prior to their communication to external providers.
Purpose:	To define appropriate methods to communicate requirements to external providers for materials, supplies, and services used to produce goods and/or services.
Scope:	This procedure applies to the purchase of all inventory items, supplies, materials, subcontracted services, and capital equipment affecting the quality of Harrington Signal Inc.'s products and services.
Responsibilities:	All Employees requiring products or services for production of Harrington Signal Inc.'s products must complete purchase requisitions specifying items for purchase and obtain required approvals. The Purchasing Manager or designate is responsible for evaluating suppliers, maintaining raw material inventories, placing orders with approved suppliers, and negotiating pricing with suppliers.

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The Purchasing Manager or designate is responsible for ensuring inspection requirements are included on Purchase Orders where needed.

Receiving Personnel are responsible for receiving and, where necessary, inspecting materials and forwarding all paperwork to Accounts Payable for external provider/shipper payment.

Accounts Payable is responsible for payment of invoices only after satisfactory completion or delivery of goods/services has been made.

Definitions:

Purchase – Acquire by financial transaction; "purchasing" can be taken to mean leasing and other ways of obtaining materials or services.

Procedure:

1.0 Order Determination and Requisition

1.1 The Purchasing Manager or designate shall determine reorder quantities of standard production inventory items/components by comparing available stock on hand with the requirements to satisfy the production plan.

1.2 For non-inventory production items, including supplies, engineering components, and services, the originating individual/department shall prepare a PURCHASE REQUISITION. Requisitions should be completed and approved with the following items and any additional supporting documentation, as appropriate:

- Complete description of part, model numbers, processes, products or service to be performed;

8-15-19 BB

- Product, process or service specifications;
- Quantity and costs required;
- Date required;
- Requirements for methods, processes or equipment;
- Requirements for competence or qualification of employees;
- Communication requirements for interactions;
- Requesting department and accounting code;
- Recommended external provider, if applicable;
- Customer, regulatory, Quality Management System, Harrington Signal Inc., and other requirements;
- Requirements for verification or validation activities that the organization, or its customer, intends to perform at the external providers premises.

- Special release or shipping requirements; and
- Special inspection requirements upon receipt.
- 1.3 External provider selection for inventory and non-inventory items and subcontracted services shall be conducted in accordance with QP1120 EXTERNAL PROVIDER EVALUATION.

2.0 Order Placement

2.1 The Purchasing Manager or designate shall analyze terms, external provider pricing, price/quantity breaks, etc., and order accordingly, taking care of Harrington Signal Inc.'s best interests while doing so. The Purchasing Manager or designate shall obtain – from the requestor – approval of any material variance prior to placing the order.

2.2 The Purchasing Manager or designate shall review specified purchase requirements with Manufacturing and Stockroom personnel to ensure adequacy of requirements prior to the Purchasing Manager communicating them to the external provider(s).

2.3 The Purchasing Manager or designate shall complete Purchase Order with all applicable information (see purchase requisition data above). The Purchasing Manager or designate should include arrangements and method of product release in the purchasing information.

8-15-19 BB

2.4 The Purchasing Manager or designate and the requesting party (when required) shall review the purchase order for accuracy and consistency, then indicate in the form that it was reviewed.

- 2.5 The Purchasing Manager or designate may place orders by telephone, fax, mail, or online (e-mail or web form). When placing orders by telephone, the Purchasing Manager or designate shall record the external provider contact and date of order on the purchase order and follow up the call by sending a "confirming copy" of the purchase order to the external provider.
- 2.6 The Purchasing Manager or designate shall follow up on shipping, delivery, expediting, and partial shipments of ordered items, to assist Manufacturing in maintaining consistent production flow and ensure other departments' operational requirements are also met. The Purchasing Manager or designate may telephone external providers, keeping an email record of follow-up activity with the Purchase Order when applicable.

3.0 Recordkeeping and Matching

3.1 Purchased items shall be received in accordance with QP1210 RECEIVING AND INSPECTION.

3.3 Receiving personnel shall match Receiving documentation with the open purchase order. If receiving and open PO can be reconciled, Receiving personnel shall forward the receiving documentation to Accounts Payable.

- 3.4 For partial shipments, receiving personnel shall forward receiving paperwork to Accounts Payable. The original purchase order shall be remain

open until all items have been received. When all units have been received the purchase order will be auto closed.

4.0 PURCHASING REVIEW

4.1 The Purchasing Manager should periodically review the PURCHASE ORDER LOG for variances, trends, etc.; the log should also be compared with receiving and inspection logs (see QP1210 RECEIVING AND INSPECTION) for discrepancies, trends, etc. The Purchasing Manager shall report results of such reviews to affected departments (e.g., Inventory Control, Production) and Top Management in accordance with QP1060 MANAGEMENT REVIEWS or as needed.

4.2 The Quality Manager shall periodically audit the purchasing process in accordance with QP1020 INTERNAL AUDITING to ensure its continuing suitability, adequacy, effectiveness, and conformance to various requirements.

Effectiveness Criteria:

- Raw Material Inventory (in days)
- Materials for manufacture of Harrington Signal Inc.'s goods/services is readily available
- No nonconformities traceable to purchased materials, supplies or services

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

8-9-19 BB

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9.2 INTERNAL AUDITS

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. INTERNAL AUDIT

QP-1020 schedule

1.1 Planning and scheduling

1.1.1 The Vice President of Quality establishes an internal audit plan and schedule. 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.

1.2 Audit team and preparation for audit

1.2.1 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.

1.2.2 Auditors prepare for audits by reviewing applicable standards and procedures, analyzing quality records, and establishing questionnaires and checklists. Harrington follows the ISO 9001:2015 standard

1.3 Conducting the audit

1.3.1 Conducting the audit, auditors seek objective evidence indicating whether the audited activities comply with the requirements of the documented quality system and ISO 9001:2015, and whether the quality system is effective. The evidence is collected by observing activities, interviewing personnel, and examining records.

1.3.2 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.

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

1.4 Corrective action and follow up

1.4.1 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 is used for monitoring and recording the implementation of the corrective actions.

1.5 Audit Records / Reporting

1.5.1 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.

Referenced Procedures

QP1020 Internal Audits ✓

QP1040 Nonconformity Corrective Action ✓

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

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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.

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

Internal Audit Document 3/6/2019 8-19-19 Reviewed 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

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8-19-19 BB

QP1040 NONCONFORMANITY AND CORRECTIVE ACTION

Policy: Harrington Signal Inc. shall take action whenever necessary to eliminate nonconformities (nonconformance) in its QMS and prevent their recurrence. Corrective actions shall be appropriate to the effects of nonconformities encountered.

Purpose: To outline the responsibilities and methods for identifying causes of nonconformities in the QMS, initiating corrective action(s), and performing follow-up to ensure that those corrective action(s) have been effective in eliminating the nonconformities.

Scope: This procedure applies to all QMS nonconformities, whether identified during Internal Quality Audits or Management Reviews, by way of customer feedback, or by Management in general.

Responsibilities:

The Quality Manager is responsible for ensuring that corrective actions are accurate, understood, and implemented effectively and for reporting on corrective actions taken at Management Review Meetings.

reviewed mgmt notes from 4/12/19

All Managers are responsible for completing and following up on corrective actions for their respective areas.

All Employees are responsible for investigating and recording the cause(s) of nonconforming conditions when those tasks are assigned to them and for implementing corrective actions determined by this process.

Definitions: CAR – Corrective action request (or report).

Conform – Be in agreement; act according to prevailing standards or customs.

Correction – Action taken to rectify/repair a known nonconformity.

Corrective Action – Act of eliminating the root cause of a known nonconformance, defect, or other undesirable situation to prevent its recurrence.

Nonconformity – output not conforming to a standard or specification; something that falls outside of defined critical limits; also known as "nonconformance" and includes complaints.

Root cause – Ultimate, or initiating, cause of an effect; usually identified through an exercise known as "root cause analysis".

Procedure:

1.0 DETERMINING THE NEED FOR Corrective Action

1. Variances between planned and actual performance of products or processes are easier to resolve if they're identified before they become serious. An *occasional* variance, or nonconformity, may or may not be cause for concern: it has to be analyzed in context to determine if it requires simply a correction *or* if corrective action is needed.
2. While actions may be taken to rectify or mitigate short-term problems, Quality Management (QM) and the affected Department Manager(s) shall give consideration to preventing their recurrence – or preventing similar potential

problems from occurring in other areas – by making systemic changes to processes (i.e., taking corrective action).

3. Put another way...many nonconformities are of a "lesser" nature. Harrington Signal Inc. *needs to know* they exist and *should note them* (see QP1030 CONTROL OF NONCONFORMING OUTPUTS), but it does not necessarily have to *act* on them beyond a correction. However, when analysis reveals a *pattern* or *trend* of nonconformities – or even a *potential* trend or non-random event – a *corrective action* is in order.

2.0 Initiating Corrective Action

2.1 Corrective actions are taken in response to *found* nonconformities. Requests for corrective action may result from:

- Internal Quality Audits
- Management Reviews
- Management, in general
- Customer complaints or returns
- Testing or inspection results
- Process reviews
- Nonconformance reviews

1. When it is determined that a corrective action is required, such action shall begin with entering a CAR/RMA. The Quality Manager or other Department Management may initiate such a request. Every CAR/RMA/MRBA shall include a description of the problem, observation, or nonconformance and indicate when and where it was observed.
2.
3.
4. The Department Manager shall assign an employee or employees to investigate the cause, deal with the consequences, and/or take the necessary action(s) to correct and eliminate the recurrence of the problem, assign a target completion date, and notify the Quality Manager of the assignment. The

Quality Manager shall update the corrective action report in the access database accordingly.

5. The Quality Manager or Department Manager shall maintain the status of the CAR on the access database.

3.0 Investigating the Cause

1. The Manager assigned to the CAR shall investigate the problem and attempt to determine the underlying (root) cause or causes and if similar nonconformities exist, or could potentially occur with other outputs. Depending on the nature and scope of the situation under investigation, the Manager should enlist the aid of other employees or departments and form a *team* to investigate and address the problem.
2. In investigating root cause, the investigator should keep in mind that the *apparent* cause is rarely the *root* cause. It is often of value to identify the *apparent* cause and the *contributing* causes.[1] Further analysis using this process can lead to the root cause of the problem. Utilization of the 5-Why method: asking the question "Why?" five times, each time following up on the previous answer will aid the investigation into root cause.
3. The investigator shall record any observations, measurements, and the results of the investigation on the CAR/RMA/MRBA.
4. The investigator shall note the identified root cause(s) and recommended corrective actions on the CAR/RMA/MRBA.

4.0 Taking Corrective Action

1. Following the investigation, the Quality Manager and the affected Department Manager (or an authorized delegate) shall review the results and consult with the appropriate employees to determine what corrective action(s) may be taken to eliminate the root cause of the problem.

2. The Department Manager shall assign the corrective action and a target date for its completion and ensure that the Quality Manager is notified of the assignment. The Quality Manager shall update CAR/RMA accordingly.
3.
4. The Quality Manager shall periodically (e.g., weekly) review the status of open corrective actions with Department Managers to help ensure actions are appropriate and are completed in a timely manner.
5. The person responsible for taking action shall update the risks and opportunities determined during planning, if necessary.

5.0 Verification and Closure

1. Quality Management shall ensure the integrity of the QMS during changes. The Quality Manager shall review the effectiveness of corrective actions taken and determine the appropriate follow-up or verification required.
2. NOTE: To accurately judge the effectiveness of some corrective actions, one should allow them to work for a suitable period of time. The Quality Manager may elect to leave some CARs open for a period of time *after* corrective actions are taken to evaluate their reoccurrence.
3.
4. If it is determined that the corrective actions taken were ineffective, a new CORRECTIVE ACTION REPORT shall be generated.
5. NOTE: Ineffective corrective actions can result from improper or inaccurate root cause analysis. If so, a *new* nonconformance report and/or corrective action should be opened to correct the *root cause analysis defect.*

Effectiveness Criteria:

- Closure of corrective actions in a timely manner
- The problem requiring corrective action does not recur

[1]One commonly used technique is known as "The Five Whys".

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)

8-19-19

10.1 GENERAL

GENERAL POLICY

Harrington 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.

The quality system described in this section of the Quality Manual conforms to the requirements of the ISO 9001:2015 standard: Element 10.2 – Nonconformity and Corrective Action and Element, 10.3 – Continual Improvement

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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 ✓

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

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QOP-10-02 Nonconformity and corrective action

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

PURPOSE

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

APPLICATION

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

PROCEDURE

1. The Corrective Action database of ECIS is utilized by team members universally to collect information for improving the effectiveness of the Quality System, such as:
    1. Customer concerns
    2. Inspection and testing results and trends
    3. Internal audit Nonconformances
    4. External audit Nonconformances
    5. Team member concerns

2. Preventive Actions may be taken by management as a result of successful Corrective Action. When Corrective Action is applied to other Dee Electronics products, processes or locations, it is preventive action. Additional sources for Preventive Action include:

    1. 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.