Challenge Electronics

QUALITY MANAGEMENT SYSTEMS MANUAL

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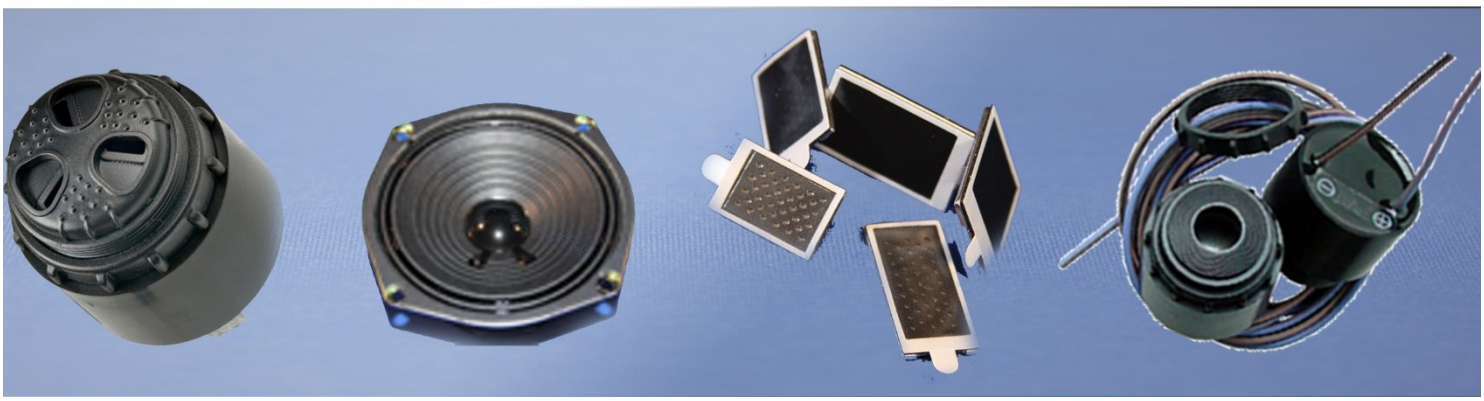

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INTRODUCTION

1.1. Purpose

1.1.1. This document has been prepared to describe the Quality management system in place at Challenge Electronics. It provides policy and guidelines for all processes related to product provided by Challenge Electronics to its customers.

1.1.2. This "Quality Management System Manual" is the top level of a multi-tiered structure, and is organized along the lines of ISO 9001:2008. While this Quality Management Systems Manual is referred to as the "Quality Management System Manual", the details for implementation of policies and guidelines are provided in lower tiered documents such as procedures and work instructions.

1.1.2.1. Ensuring quality is a multi-functional effort covering many aspects of Challenge Electronics' operations. It is a continuous process involving:

- The identification and documentation of customer needs;
- The development, manufacture and delivery of products and services to meet those needs consistently;
- Feedback from the customer to assess the company's performance;
- Action on the customer's feedback to improve the company's performance.

1.1.3. Developed and endorsed by company management, the Challenge Electronics Quality Management System is part of an integrated corporate management system, encompassing the requirements of numerous external standards and internal company requirements. Challenge Electronics' quality management system conforms, at minimum, to specified requirements of international standards, like ISO 9001. Product quality is maintained through work process and quality architecture standardization, and process control. Service quality covers all aspects of customer transactions and is ensured by the function that is providing the service. Both product and service quality characteristics are agreed upon by Challenge Electronics and the customer.

1.2. Scope

1.2.1. Introduction to Challenge Electronics

Established in 1988, **Challenge Electronics**, a division of Surge Components is a publicly held company with the financial resources to manage the dynamic growth within the electronics industry. Headquartered in New York, **Challenge Electronics** conducts business from its modern 25,000 square foot facility. Surge Components is listed on the Dow Jones Industrial under SPRS, and Company Unique Dun & Bradstreet ID #: 15-7725524.

Challenge Electronics is an excellent supplier of high performance Sounding Devices: Piezoelectric-Alarms, Piezoelectric-Buzzers, Piezoelectric-Transducers, Electromagnetic-Buzzers, Electromagnetic-Transducers, miniature and standard Speakers, and Microphone elements. These Sounding Devices are utilized and procured by original equipment manufacturers (OEMs) worldwide in the: Agriculture, Appliances, Automotive, Electronics Equipment, Gaming, Industrial Equipment, Marine, Medical Equipment, Recreation, Security, Telecommunications, and Wireless Applications Industries.

With outstanding product breadth and top-of-the-line technical staff, **Challenge Electronics** provides standard, custom, and hard to-find products at competitive prices with off-the-shelf availability. This is backed up by an infrastructure that includes **ISO 9001:2008, ISO- TS 16949-2009, ISO14001:2009** certified factory Partnership. This infrastructure ensures the **Challenge Electronics** PDQ service concept that addresses key aspects of Price, Delivery, Quality, and Service.

The Quality System Manual describes the **Challenge Electronics** Quality System. It provides the authorization and control of related activities and their associated documentation. Although, **Challenge Electronics** is not

ISO 9001:2008 Certified, **it follows the ISO Standard Procedures. All of Challenge Electronics Manufacturing Partners are ISO 9001:2008 Certified**.

In today's fast-paced business arena, you need a direct path to the right products, with immediate delivery, and unsurpassed quality. **Challenge Electronics** makes it happens' **PDQ**.

1.3. Challenge Electronics Quality Policy Mission

Quality Performance is a commitment to excellence by each Challenge Electronics employee. It is achieved by teamwork and a process of continuous improvement.
We are dedicated to being the leader in providing quality products and services which meet or exceed the expectations of our customers.

1.4. Challenge Electronics Values

We commit to meeting customer expectations to the best of our ability with integrity and recognition of quality, value, and service.

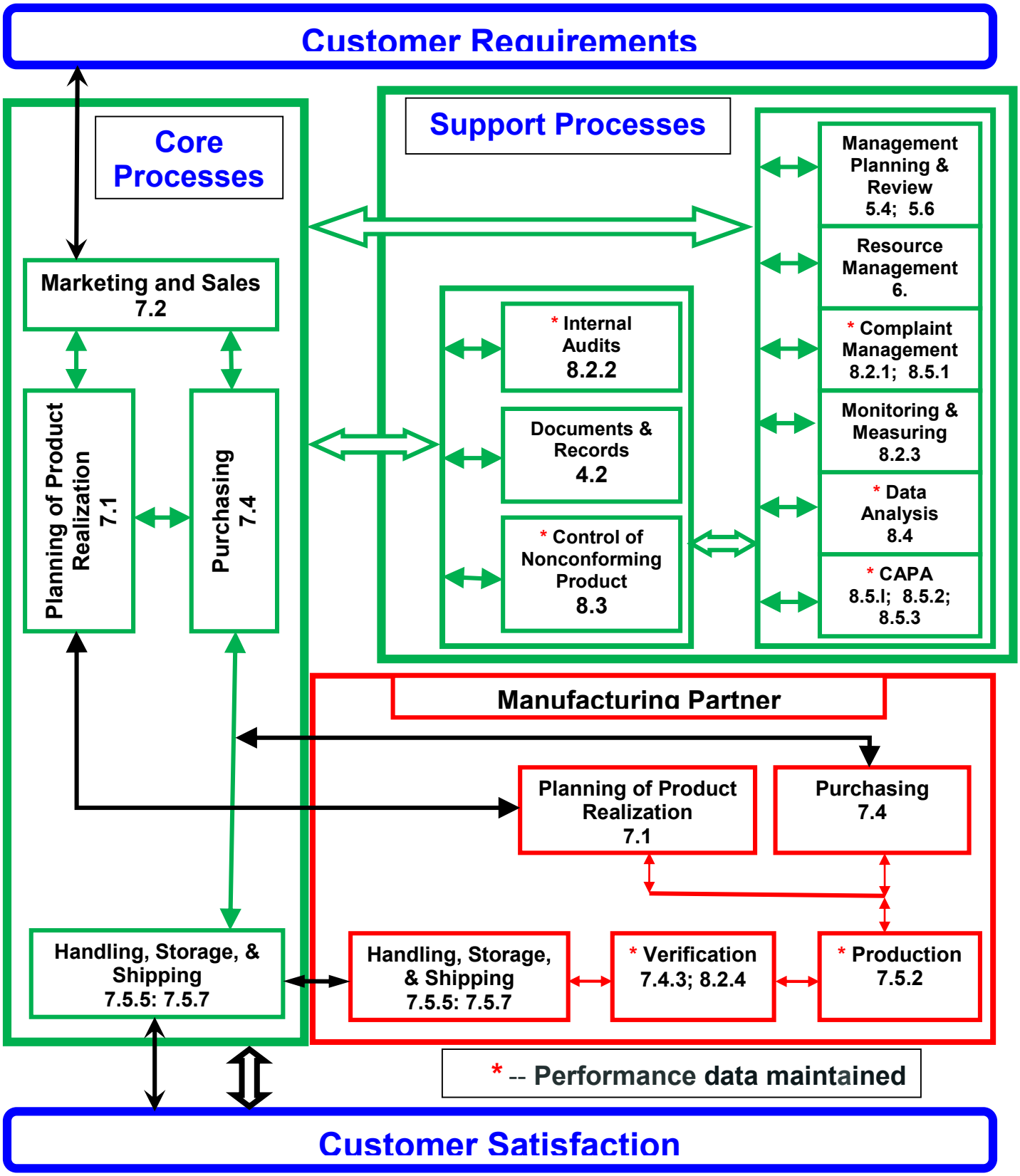
Key value points:

- **Intense collaboration**
- **Passionate customer focus**
- **Thoughtful, fast, disciplined execution**
- **Tenacious commitment to continuous improvement**

1.5. Applicability

This Quality Policy, established by the management of **Challenge Electronics**, communicates the company's organizational goals in pursuit of satisfying its customers' expectations. **Challenge Electronics and its Manufacturing Partners** Quality Policy is communicated to all employees through training to promote awareness. The quality policy goals are reviewed and measured during management review meetings. This review ensures that our quality policy and objectives for meeting our policy remain relevant to our organizational goals and the expectations and needs of our customers.

2. The Sequence and Interaction of the Quality Management System Processes Chart



3. Terms and definitions

3.1. Throughout the text of this Quality Manual, terms and definitions given in ISO 9001 apply.

3.2. Special Requirements: those requirements identified by the customer or determined by the organization to have high risks to being achieved. Such requirements are typically subject to the risk management process.

3.3. Critical items: Items that have a significant effect on the product realization and use of the product, including safety, performance, fit, function, produce ability, service life-all which may require specific actions to ensure they are adequately managed.

3.4. Key Characteristic: An attribute or feature whose variation has a significant effort on product fit, form, function, performance, service life or produce ability, that requires specific actions for the purpose of controlling variation.

3.5. Advisory Notice: A notice issued by the organization subsequent to the delivery of a medical device. An advisory notice provides information regarding the use or modification of the medical device, the return of the medical device to the organization, or the destruction of the medical device.

3.6. Responsible Engineering and Quality Director: Also known as the "Management Representative"

4. Quality Management System

4.1. **Challenge Electronics and its Manufacturing Partners** has established, documented, implemented, and continues to maintain a Quality management system (QMS). The effectiveness of the QMS is maintained in accordance with International Standards and other documents that are shown in the Scope section of this Quality Manual.

4.2. **Application and responsibility for OMS processes: The Director of Engineering and Quality is** responsible for overall implementation of the QMS at **Challenge Electronics**. Responsibilities of individual managers and their departments for implementing and supporting QMS processes are shown in Appendix A, QMS Support and Implementation

4.3. **Challenge Electronics and its Manufacturing Partners'** quality management system also addresses' customer and applicable regulatory quality management system requirements. **Challenge Electronics and its Manufacturing Partners Electronics** performs the following:

- **a.** Determines the processes needed for the quality management system and their application throughout the organization
- **b.** Determines the sequence and interaction of these processes as seen in Figure 1, The Sequence and Interaction of the Quality Management System Processes
- **c.** Determines criteria and methods needed to ensure that both the operation and control of these processes are effective
- **d.** Ensures the availability of resources and information necessary to support the operation and monitoring of these processes
- **e.** Monitors, measures and analyzes these processes
- **f.** Implements actions necessary to achieve planned results, continual improvement, and maintain the effectiveness of these processes
- **g.** When **Challenge Electronics and its Manufacturing Partners** chooses to outsource any process that affects product conformity to requirements , the organization ensures control over such processes
- **h.** The type and extent of control of outsourced processes are identified within the supplier management systems and contractual agreements

NOTE 1: Processes needed for the Quality management system referred to above include processes for management activities, provision of resources, product realization, measurement, analysis and improvement.

NOTE 2: An outsourced process is a process that the organization needs for its quality management system and which the organization chooses to have performed by an external party.

NOTE 3: Ensuring control over outsourced processes does not absolve **Challenge Electronics and its Manufacturing Partners** of the responsibility of conformity to all customer statutory and regulatory requirements. The type and extent of control applied to outsourced processes can be influenced by factors such as:

- **a.** The potential impact of the outsourced process on the organization's capability to provide product that conforms to requirements
- **b.** The degree to which the control for the processes is shared
- **c.** The capability of achieving the necessary control through the application of purchasing processes

4.4. Documentation Requirements

4.4.1. General

The **Challenge Electronics and its Manufacturing Partners** Quality Management System documentation include the following in compliance with ISO standard requirements:

- **a.** A documented Quality Policy
- **b.** This Quality Manual
- **c.** Documented Procedures
- **d.** Manufacturing Procedures (MP)
- **e.** Documents identified as needed for the effective planning, operation and control of our processes, and Records
- **f.** Forms and Tags

g. Records required by contract and regulatory authorities

Challenge Electronics ensures that personnel have access to quality management system documentation and are aware of relevant procedures. We also provide customers or regulatory authorities access to quality management system documentation.

4.4.2. Quality Manual:

This Quality Manual has been prepared to describe **Challenge Electronics OMS**. The scope and permissible exclusions of the OMS are described in section one of this manual. Each section of the manual references documented OMS procedures relating to the requirements outlined in that section. The Process Flow Diagram at the end of section 4 provides a description of the interaction between the processes of the OMS system.

4.4.3. Control of Documents:

Documents required by the quality management system are controlled in the following manner:

- **a.** Approve documents for adequacy prior to issue
- **b.** Review, update, and as necessary, re-approve documents
- **c.** Ensure that changes and the current revision status of documents are identified
- **d.** Ensure that relevant versions of applicable documents are available at points of use and older versions are removed and placed in Obsolete Documents Folder (OBS)
- **e.** Ensure that documents remain legible and readily identifiable
- **f.** Ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled
- **g.** Identify and maintain status of controlled documents, to ensure that changes and the current revision status of documents are identified
- **h.** Remove ALL obsolete documents and store in Obsolete Documents Folder (OBS)
- **i.** Ensure that changes to documents are reviewed and approved either by the original approving function or another designated function which has access to pertinent background information upon which to base its decisions
- **j.** Personnel have access to **QMS** documentation and are aware of relevant procedures
- **k.** Customer and/or regulatory authority representatives have access to non-proprietary **OMS** documentation

NOTE: Records are a special type of document and are controlled in accordance with section **4.4.4.b.**

4.4.4. Control of Records:

Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system are controlled. A documented procedure defines the controls needed for the identification, storage, protection, retrieval, retention and disposition of records. Controls include:

- **a.** Records remain legible, readily identifiable and retrievable
- **b.** Records are retained for a period of time at least equivalent to the lifetime of the medical device as defined by **Challenge Electronics and its Manufacturing Partners**, but not less than two years from the date of product release by **Challenge Electronics and its Manufacturing Partners** or as specified by relevant regulatory requirements
- **c.** Records are available for review by customers and regulatory authorities in accordance with contract or regulatory requirements

5. Management Responsibility

5.1. Management Commitment

5.1.1. Top management provides evidence of its commitment to the development and implementation of the Quality management system and continually improving its effectiveness by:

- **a.** Communicating to **Challenge Electronics and its Manufacturing Partners** employees the importance of meeting customer as well as statutory and regulatory requirements
- **b.** Establishing the quality policy
- **c.** Establishing quality objectives
- **d.** Conducting management reviews
- **e.** Ensuring the availability of resources
- **f.** Ensuring that those responsible for verifying quality have sufficient authority, direct access to management, organizational freedom, and the access to work to perform their function

Note: In some cases, the "customer" may be referred to as the "marketing authorization holder and other bodies receiving the products".

5.1.2. A description of the functional organizations and their responsibilities are depicted in Appendix D.

5.2. Customer Focus

5.2.1. Top management ensures that customer requirements are determined and are met with a goal of enhancing customer satisfaction.

5.2.2. Top management ensures product conformity and on-time delivery performance are measured and that appropriate action is taken if planned results are not, or will not be achieved.

5.3. Quality Policy

5.3.1. **Challenge Electronics and its Manufacturing Partners** have an established Quality Policy. Top management ensures that the quality policy:

- ❖ Is appropriate to the purpose of **Challenge Electronics**
- ❖ Includes a commitment to comply with requirements
- ❖ Includes a commitment to continually improve and maintain the effectiveness of the quality management system
- ❖ Provides a framework for establishing and reviewing quality objectives
- ❖ Communicated and understood within Challenge Electronics
- ❖ Is reviewed for continuing suitability
- ❖ Is based on customer focus

5.3.2. The Challenge Electronics Quality Policy is as follows:

We are committed to total customer satisfaction through compliance to requirements, maintenance of the quality management system and continuous improvement of our processes, products and services.

5.4. Quality Planning and Evaluation

5.4.1. Quality Objectives: Top management ensures that quality objectives, including those needed to meet requirements for product, are established at relevant functions and levels within **Challenge Electronics**. The quality objectives are measurable and consistent with the quality policy.

5.4.2. Quality Management System Planning: Top management ensures that:

- Planning of the quality management system is carried out to meet the requirements of the quality objectives and the general requirements to establish, document and maintain the quality management system
- The integrity of the quality management system is maintained when changes to the quality management system are planned and implemented
- Actions are taken to implement improvements to the quality management system as soon as practical

5.5. Responsibility, Authority and Communication

5.5.1. Responsibility and Authority: Top management ensures that responsibilities and authorities are defined, documented and communicated within the organization.

5.5.1.1. Top management establishes the interrelation of all personnel who manage, perform and verify work affecting quality, and ensures the independence and authority necessary to perform these tasks.

5.5.2. Management representative: Top management appoints a member of the organization's management who, irrespective of other responsibilities has the responsibility and authority that includes:

a. Ensuring that processes needed for the quality management system are established implemented and maintained
b. Reporting to top management on the performance of the Quality management system and any need for improvement
c. Ensuring the promotion of awareness of regulatory and customer requirements throughout **Challenge Electronics and its Manufacturing Partners**
d. Promoting awareness among **Challenge Electronics and its Manufacturing Partners** employees of the Quality Policy and the requirement for customer focus in all activities
e. Has organizational freedom and unrestrictive access to top management to resolve matters pertaining to quality management
f. Serves as the **Challenge Electronics** point of contact when liaison with external parties on matters relating to the quality management system is required

5.5.3. Internal communication: Management ensures that appropriate communication processes are established. The organization ensures that communication takes place regarding the effectiveness of the quality management system by one or more of the following means:

a. Formal periodic reviews of the quality management system
b. Communication of quality objectives and the status of their implementation in distributed reports
c. Periodic all-employee meetings held by top management
d. Periodic meetings between department managers and the employees in their departments

5.6. Management Review

5.6.1. General: Top management reviews **Challenge Electronics and its Manufacturing Partners** quality management system in accordance with documented procedures. Management reviews:

a. Are performed at planned intervals to ensure its continuing suitability, adequacy and effectiveness
b. Assess opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives
c. Are documented in management review presentations and minutes, including actions to be taken

5.6.2. Review input to management review includes information from :

a. Results of audits,
b. Customer feedback
c. Process performance and product conformity
d. Status of preventive and corrective actions
e. Follow-up actions from previous management reviews
f. Changes that could affect the quality management system
g. Recommendations for improvement
h. New or revised regulatory requirements

5.6.3. Review output from the management review includes any decision and actions related to:

- **a.** Improvements needed to maintain the effectiveness of the quality management system and its processes
- **b.** Improvement of product related to customer requirements
- **c.** Resource needs

6. Resource Management

6.1. Provision of Resources

6.1.1. Management determines and provides the resources needed:

- **a.** To implement tl1e Quality management system and to continually improve and maintain its effectiveness
- **b.** To meet regulatory and customer requirements
- **c.** To achieve **Challenge Electronics** business and quality objectives
- **d.** To enhance customer satisfaction by meeting or exceeding customer expectations

6.2. Human Resources

6.2.1. General: Personnel who perform work affecting conformity to product requirements are competent on the basis of appropriate education, training, skills and experience.

NOTE: Conformity to product requirements can be affected directly or indirectly by personnel performing any task within the quality management system.

6.2.2. Competence, Training and Awareness. The organization:

- **a.** Determines the necessary competence for personnel performing work affecting conformity to product quality
- **b.** Where applicable, assesses the competence of employees and provides training or other takes other actions to achieve the necessary competence
- **c.** Evaluates the effectiveness of the actions taken to establish and maintain employee competence
- **d.** Ensures that personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives
- **e.** Generates and maintains appropriate records of education, training, skills and experience
- **f.** Establishes documented procedures for identifying training needs based on regional or national regulations if required

6.2.3. **Challenge Electronics and its Manufacturing Partners** ensure that all employees receive initial and periodic training in quality management system procedures applicable to their job function.

6.3. Infrastructure

6.3.1. **Challenge Electronics and its Manufacturing Partners** determines, provides, and maintains the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable:

- **a.** Buildings, workspace and associated utilities
- **b.** Process equipment (both hardware and software)
- **c.** Supporting services (such as transport, communication or information systems)
- **d.** Pest control (such as insects or rodents) is provided on an as-needed basis in manufacturing and administrative areas

6.3.2. Documented procedures outline requirements for maintenance activities, including their frequency, when such activities or lack thereof can affect product quality.

6.3.3. Hardware and software suitable for minimizing variation while ensuring product conformity is provided and maintained. A preventive maintenance program is implemented to assure that equipment performs reliably within design parameters. Software quality assurance procedures ensure that software is protected from modification without proper authorization and testing.

6.3.4. Records of maintenance activities and results are maintained.

6.4. Work Environment

6.4.1. **Challenge Electronics and its Manufacturing Partners** determine the requirements for, and manages the work environment needed to achieve conformity to product requirements.

6.4.2. **Challenge Electronics and its Manufacturing Partners** maintain a safe and efficient work environment for its employees. The following requirements apply:

- **a.** Documented requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could adversely affect the quality of the product
- **b.** Where the work environment conditions can have an adverse effect on product quality, **Challenge Electronics and its Manufacturing Partners** have established documented requirements for the work environment conditions and documented procedures or work instructions to monitor and control these work environment conditions. Factors to be considered include temperature, humidity, lighting, cleanliness, protection from electrostatic discharge, etc.
- **c.** All personnel who are required to work temporarily under special environmental conditions within the work environment are appropriately trained or supervised by a trained person
- **d.** If appropriate, special arrangements are established and documented for the control of contaminated or potentially contaminated product in order to prevent contamination of other product, the work environment, or personnel
- **e.** All necessary actions are taken to minimize the use and generation of hazardous materials and to ensure full compliance with applicable environmental regulations

NOTE: The term "work environment" relates to those conditions under which work is performed including physical, environmental and other factors such as noise, temperature, humidity, lighting or weather.

6.4.3. Safety Program. **Challenge Electronics and its Manufacturing Partners** has made appropriate provisions for the safety of its employees through:

- **a.** Actively managing the work environment in order to provide a safe, efficient work place that maximizes employee effectiveness
- **b.** A plant-wide safety program that focuses on such factors as safety guarding, fire hazards, trip hazards, and electrical safety has been established. When required, special safety programs (e.g., overhead lifting safety and forklift safety) are implemented and managed

7. Product Realization

7.1. Planning of Product Realization

Challenge Electronics and its Manufacturing Partners plans and develops the processes needed for the manufacture of product in accordance with documented procedures. Planning of product realization is consistent with the requirements of the other processes of the quality management system. The organization determines as appropriate:

a. Quality objectives and requirements for the product (see Note 1)
b. The need to establish processes, documents, and provide resources specific to the product
c. Required verification , validation, monitoring , inspection and test activities specific to the product and the criteria for product acceptance
d. Records needed to provide evidence that the realization processes and resulting product meet requirements
e. Configuration management appropriate to the product
f. Resources to support the use and maintenance of the product (as applicable)
g. Cleanliness to specified levels and the removal of process agents, and
h. Regulatory requirements for the product (as applicable)

NOTE 1: Quality objectives and requirements for the product include consideration of aspects such as:

- Product and personnel safety
- Reliability, availability and maintainability
- Produce ability and inspect ability
- Suitability of parts and materials used in the product
- Selection and development of embedded software
- Recycling or final disposal of the product at the end of its life

NOTE 2: A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract can be referred to as a "quality plan."

7.1.1. Project Management:

As appropriate to the organization and the product, **Challenge Electronics and its Manufacturing Partners** plans and manages product realization in a structured and controlled manner to meet requirements at acceptable risk. This is accomplished within known resource and schedule constraints.

7.1.2. Risk Management:

Challenge Electronics and its Manufacturing Partners have established processes for managing risk to the achievement of applicable requirements. Risk management includes:

a. Assignment of responsibilities for risk management
b. Definition of risk criteria (e.g. , likelihood, consequences, risk acceptance)
c. Identification , assessment and communication of risks throughout product realization
d. Identification , implementation and management of actions to mitigate risks that exceed the defined risk acceptance criteria
e. Acceptance of risks remaining after implementation of mitigating actions
f. Additional assessments when requirements change
g. Documentation of assessments

NOTE: Documented risk analyses are performed for product as required by International Standards or specific customer requirements.

7.1.3. The output of planning for product realization are in a form suitable for **Challenge Electronics and its Manufacturing Partners**' method of operations, as applicable:

a. Sequence of manufacturing operations (traveler)
b. A Bill Of Material **(BOM)**
c. The establishment of process controls and development of control plans where key characteristics have been identified by the customer
d. The identification of in-process verification points when adequate verification of conformance cannot be performed at a later stage of realization

e. The provision for tooling and measuring equipment so that variable measurements can be taken whenever possible, (particularly for key characteristics identified by the customer)
f. Identification of special processes and related qualification requirements
g. A means to record completion of manufacturing operations, and to collect data
h. Requirements for product certification

7.2. Customer-Related Processes

7.2.1. Determination of requirements related to the product:

Challenge Electronics and its Manufacturing Partners reviews the requirements related to the product in accordance with documented procedures. These reviews are conducted prior to the commitment to supply a product to the customer, including:

a. Requirements specified by the customer, including product requirements and the requirements for delivery, and post-delivery activities
b. Requirements not stated by the customer but necessary for specified or intended use (where known)
c. Statutory and regulatory requirements applicable to the product
d. Any additional requirements considered necessary
e. Internally-generated requirements are determined and can be met

NOTE: Post-delivery activities include actions under warranty provisions or contractual obligations.

7.2.2. Review of requirements related to the product:

Challenge Electronics performs reviews prior to the commitment to supply a product to the customer (e.g. acceptance of contracts or orders, acceptance of changes to contracts or orders) and ensures that **(Review of Contract Requirements Special Product Order Processing; Operating Procedure SA 050)**:

a. Product requirements are defined and documented
b. Contract or order requirements differing from those previously expressed are resolved
c. The organization has the ability to meet the defined requirements
d. Special requirements of the product are determined
e. Risks (e.g., new technology, short delivery time scale) have been identified and evaluated

7.2.3.

Where the customer provides no documented statement of requirement, the customer requirements are confirmed by **Challenge Electronics** before acceptance.

7.2.4.

Where product requirements are changed, **Challenge Electronics and its Manufacturing Partners** ensures that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

- Records of the results of the review and actions arising from the review are documented and maintained.

NOTE: In some situations such as Internet sales, a formal review is impractical for each order. The review may cover relevant product information such as catalogs or advertising material.

7.2.5. Customer Communication and Satisfaction:

Challenge Electronics determines and implements effective arrangements for communicating with customers. These activities include:

a. Product information
b. Inquiries, contracts or order handling, including amendments
c. Customer feedback, including customer complaints
d. Advisory Notices via Engineering Change Notice **(ECN)** of any (Supplier Change, Material Change, Process Change, etc…)

7.2.6.

As one of the measurements of the performance of the Quality management system, the organization monitors and reports information relating to customer perception as to whether **Challenge Electronics** has met customer requirements, and has taken appropriate actions.

7.3. Design and Development

The Design and Development, Verification, Validation, and Improvements of Product are combined and shared between Challenge Electronics and its Manufacturing Partners. All of the ISO Procedures are followed by Challenge Electronics and its Manufacturing Partners.

7.3.1. Design and Development Planning:

The Engineering Department plans design and development and process for controlling the design. The design plan includes:

a. Design and development stages including organization, task sequence, mandatory steps, significant stages and method of configuration control

b. Required design reviews, verification appropriate to each design stage

c. Responsibilities and authorities for design and development

d. Where appropriate, due to complexity, the organization gives consideration to the following activities:

- Structuring the design effort into significant elements
- For each element, analyzing the tasks and the necessary resources for its design and development. This analysis considers an identified responsible person, design content, input data, planning constraints, and performance conditions. The input data specific to each element is reviewed to ensure consistency with requirements

e. Verification methods appropriate to each design and development stage

f. Responsibilities and authorities for design and development

g. Identification of the technical interfaces required for the project

h. Updating of the design plan as the project progresses

i. The different design and development tasks to be carried out, defined according to specified safety or functional objectives of the product in accordance with customer or regulatory authority requirements

7.3.2. Design and Development Inputs:

a. Functional and performance requirements

b. Applicable statutory and regulatory requirements

c. Where applicable, information derived from previous similar designs

d. Other requirements essential for design and development

7.3.3. Design and Development Outputs:

Outputs of design and development are documented. They are documented in a format that enables verification against the inputs, and are approved prior to release. Outputs:

a. Meet the input requirements

b. Provide appropriate information for purchasing and production provision

c. Contain or reference product acceptance criteria

d. Specify the characteristics of the product that are essential for its safe and proper use.

e. Identify key characteristics in accordance with design or contract requirements

All pertinent data required to allow the product to be identified, manufactured, inspected, used and maintained is defined by the organizations.

7.3.4. Design and Development Review:

The design plan specifies suitable stages of the project to conduct design and development review. Reviews take place according to the design and development procedure; results of design review are signed off on the checklist plan, final design and overall schedule which are maintained as a quality record. Design reviews:

a. Evaluate the results of design and development activities and determine if they fulfill requirements

b. Identify any problems and propose necessary actions

c. Include representatives of functions concerned with the design and development stage being reviewed to authorize progression to the next stage.

7.3.5. Design and Development Verification:

Design verification is planned and performed to ensure that the design and development outputs have satisfied the design and development input requirements. Records of the results of the verification and any necessary actions are maintained.

7.3.6. Design and Development Validation:

Design and development validation is performed according to the design plan to ensure that the resulting product is capable of fulfilling the requirements for the specified or known intended use or application. Validation is completed prior to delivery whenever practicable. Records of the validation activities are maintained according to the design and development procedure.

7.3.6.1. Documentation of Design and/or Development Verification and Validation:

At the completion of design and/or development, the organization ensures that reports, calculations, test results, etc., demonstrate that the product definition meets the specification requirements for all identified operational conditions.

7.3.6.2. Design and/or Development Verification and Validation Testing:

Where tests are necessary for verification and validation, these tests are planned, controlled, reviewed, and documented to ensure and prove the following:

- **a.** Test plans or specifications identify the product being tested and the resources being used, define test objectives and conditions, parameters to be recorded, and relevant acceptance criteria
- **b.** Test procedures describe the method of operation, the performance of the test, and the recording of the results
- **c.** The correct configuration standard of the product is submitted for the test
- **d.** The requirements of the test plan and the test procedures are observed
- **e.** The acceptance criteria are met

7.3.7. Control of Design and Development Changes:

The design and development procedure defines a process for identifying, recording, verifying, validating and approving design changes. The review of design and development changes includes an evaluation of the effect of the changes on constituent parts and delivered product. Records are maintained to show the results of the review and any necessary actions identified during the review. This procedure provides for customer or regulatory authority approval of changes, when required by contract or regulatory requirement.

7.4. Purchasing

7.4.1. Purchasing process:

Challenge Electronics and its Manufacturing Partners has established documented procedures to ensure that purchased product conform to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product is dependent upon the effect of the purchased product on subsequent product realization or the final product. Supplier controls include:

- **a.** Evaluation and selection of suppliers in accordance with their ability to supply product or meet requirements. In some cases, suppliers must meet specific quality management system requirements
- **b.** Criteria for selection, evaluation and re-evaluation of suppliers is established in documented procedures
- **c.** The maintenance of an Approved Supplier List **(ASL)** that includes approval status and the scope of the approval (typically by commodity or service)
- **d.** The periodic review of supplier performance. The results of these reviews are used as a basis for establishing the levels of control needed to ensure conformity to product or service requirements
- **e.** Necessary actions to be taken when dealing with suppliers who do not meet requirements is defined
- **f.** When required, **Challenge Electronics and its Manufacturing Partners** use customer approved special process sources
- **g.** The process, responsibilities and authority for supplier evaluation and approval, changes of approval, and the status and conditions for controlled use of suppliers is defined
- **h.** The risk and mitigation actions for use of suppliers are determined
- **i.** Records of the results of supplier selection and evaluation are documented as well as any necessary actions arising from the evaluations

NOTE 1: Challenge Electronics and its Manufacturing Partners is responsible for the conformity of all products purchased from suppliers, including product from sources directed by the customer.

NOTE 2: One factor that can be used during supplier selection and evaluation is supplier quality data obtained from objective and reliable external sources (such as an accredited quality management system, certification bodies or government or customer approvals).

Use of this data represents one component of **Challenge Electronics and its Manufacturing Partners** supplier control process. The organization remains responsible for the verification of purchased product to ensure that it meets specified purchase requirements

7.4.2. Purchasing information:

Purchasing information describes the product or service to be purchased, including where appropriate:

- **a.** Requirements for approval of product, procedures, processes and equipment
- **b.** Requirements for qualification of personnel
- **c.** Quality management system requirements
- **d.** The identification and revision status of specifications, drawings, process requirements, inspection/verification instructions and other relevant data
- **e.** Requirements for test, inspection, verification (including production process verification)
- **f.** Use of statistical techniques for product acceptance, related instructions for acceptance by the organization and applicable critical items including key characteristics
- **g.** Requirements for test specimens for inspection/verification, investigation or auditing
- **h.** Requirements for the need of the supplier to:
  - Notify **Challenge Electronics and its Manufacturing Partners** of nonconforming product,
  - Obtain approval of nonconforming product disposition
  - Notify **Challenge Electronics and its Manufacturing Partners** of organizational changes such as product/process changes, changes of suppliers, changes of manufacturing facility move
  - Flow down to the supply chain applicable requirements including customer requirements,
- **i.** Record retention requirements
- **j.** The right of access by **Challenge Electronics and its Manufacturing Partners**, its customers and regulatory agencies to applicable areas of all facilities, at any level of the supply chain involved in the order and to all applicable records

7.4.3. Verification of purchased product:

Challenge Electronics and its Manufacturing Partners has established and implemented systems for inspection and/or other activities necessary to ensure that product meets specified requirements. These systems include as applicable

a. Obtaining objective evidence of the quality of the material from suppliers (e.g. accompanying documentation, certification of conformity, test reports, statistical records , process control data),
b. Inspection and/or audit at supplier's premises
c. Review of the required documentation
d. Inspection of materials upon receipt (Small Quantity and Special Products do 100% inspection)
e. Delegation of verification to the supplier, or supplier certification
f. Purchased material is not used or processed until it has been verified as conforming to specified requirements unless it is conditionally released under positive recall procedures
g. Where **Challenge Electronics and its Manufacturing Partners** utilizes test reports to verify purchased material, the data in those reports is acceptable per applicable specifications. **Challenge Electronics and its Manufacturing Partners** periodically validates test reports for raw material
h. Where **Challenge Electronics and its Manufacturing Partners** delegates verification activities to a supplier, the requirements for delegation are defined and a register of delegations maintained
i. Where **Challenge Electronics and its Manufacturing Partners** or its customer intends to perform verification at the supplier's premises, **Challenge Electronics and its Manufacturing Partners** states the intended verification arrangements and method of product release in the purchasing information
j. Where specified in the contract, the customer or the customer's representative is afforded the right to verify at the supplier's premises and **Challenge Electronics and its Manufacturing Partners**' premises that subcontracted product conforms to specified requirements
k. Verification by the customer is not used by **Challenge Electronics and its Manufacturing Partners** as evidence of effective control of quality by the supplier and does not absolve **Challenge Electronics and its Manufacturing Partners** or the supplier of the responsibility to provide acceptable product, nor does it preclude subsequent rejection by the customer
l. Where purchased product is released for production use pending completion of all required verification activities, the product is identified and recorded to allow recall and replacement if the product is later found nonconforming
m. Records of all verification activities are maintained

7.4.4. Specified Purchase Requirements

Challenge Electronics ensures the adequacy of specified purchase requirements prior to their communication to the supplier.

7.4.5. Traceability

To the extent required for traceability, **Challenge Electronics** maintains relevant purchasing information and records.

7.4.6. Warehouse, Receiving

Document the procedure for the receiving of incoming products. Ensure that products are received against a valid purchase order and are those shown on the shipping documents. Ensure that additional required documents are attached to shipping documents, that containers or packaging are not damaged and that products received are identified for pending inspection. Receiving includes Incoming products and materials from suppliers. Product returned from customers.

A. Material received against PO are inspected and verified for:

A.1. The shipments container or boxes are not damaged and matching the number on carrier receipt and packing slip prior to signing carrier receipt.
A.2. In case of damaged or missing container or boxes warehouse clerk to follow process listed in point 2.4.
A.3. Opens box and visually inspect for damage parts.
A.4. Matches the PO information to packing slip
A.5. Record the receiving date on packing slip
A.6. If packing slip does not include Date code/lot code and serial numbers, Receiving clerk marks them on packing slip
A.7. If date codes/lot codes or serial numbers are out of order, they are packaged separately for easy identification.
A.8. Insures that all required documentations listed in PO are included in the boxes.
A.9. Makes duplicate copies of all documentation and packing slip.
A.10. Place Original documents in the received shipment.
A.11. Send shipment to Incoming Inspection for shipment acceptance.
A.12. Send documentations to Purchasing Manager.
A.13. Place received shipment on shelf in warehouse. If same parts are in inventory, place new parts behind old inventory to insure FIFO

B. Receiving Samples

B.1. The shipments container or boxes are not damaged and matching the number on carrier receipt and packing slip prior to signing carrier receipt.
B.2. In case of damaged or missing container or boxes warehouse clerk to follow process listed in point 2.4.
B.3. Opens box and visually inspect for damage parts.
B.4. Record the receiving date on packing slip
B.5. Send box with packing slip to Purchasing Manager

C. Electrostatic sensitive device (ESD) Receiving / inspection

Receiving personal must insure:

C.1. Purchasing should insist in Purchase Order Instruction that all ESDS items be packaged in a shielded package.
C.2. Receiving station should be ESD safe
C.3. Remove all non-ESD packaging from area: Standard bubble wraps, packing peanuts, plastic bags, Styrofoam.
C.4. Inspect packaging and content for conformal to ESD standards.
C.5. Use of ESD labels / tape
C.6. ESD Markings alert handlers of contents. Important if sending sensitive components through uncontrolled areas.
C.6.a. Products:
C.6.b. Bags: antistatic poly, shielding bags, bubble wrap, ESD tape, mat / wrist strap or heel grounders.

D. Receiving MRA:

D.1. The shipments container or boxes are not damaged and matching the number on carrier receipt and packing slip prior to signing carrier receipt.
D.2. In case of damaged or missing container or boxes warehouse clerk to follow process listed in point 2.4.
D.3. Opens box and visually inspect for damage parts.
D.4. Record the receiving date on packing slip
D.5. Record the Returned PN
D.6. Record the quantity received
D.7. Notify the Account Sales Manager
D.8. Send box with packing slip to Purchasing Manager

E. As applicable, any damaged boxes and/or discrepancies are communicated to the Purchasing Manager or Sales Manager who will decide on how to proceed. Any discrepancies or irregularities are recorded on the Bill of Lading before signing for receipt of the product.

F. Transporting Receiving Material

F.1. Movement of carts and other wheeled equipment through the facility can also generate static charges that can transfer to products being transported
F.2. Transporting ESDS from workstation to workstation
F.3. Covered totes
F.4. Racks / carts grounded to ESD floor. ESD safe cart covers can keep dust off without generating charge.
F.5. Personnel should be grounded
F.6. Workstation should be ESD safe
F.7. Products to use:

- ESD safe carts:
- Drag chains (don't get as dirty as dissipative wheels)
- Make sure all shelves are grounded.
- Covers
- Tote boxes
- In plant handlers

G. Storage

G.1. Open parts bins, dissipative storage boxes
G.2. Grounded shelving areas with conductive paint, shelf liner,
G.3. Items to use: bins / storage boxes
G.4. Take Precautions to prevent ESD damage in transporting and storing ESD materials.
G.4.a. Shelving should be grounded and operators should be grounded while stocking or

picking items.

G.4.b. Products to use:

- Dissipative bins, storage boxes
- Shelving: shelf liner, conductive paint
- Heel grounders / ESD floor

7.4.7. Warehouse, Shipping

E. Responsibility:

E.1. **Challenge Electronics'** Management Responsibilities:

- Maintain a Quality System
- Maintain an acceptable performance level that assures **Challenge Electronics'** remains eligible for Self-Release.
- Respond to any Honeywell corrective action requests by the required due date using Root Cause Corrective Action process **(8D-CAR).**
- Perform and Document all training that Self-Release Representatives require to enable them to successfully accomplish their responsibilities.
- Assure that all inspection personnel have received eye exams that meet Customer requirements.
- Inspect Inventory to verify products is storage are still within the shelve life of the product
- Provide refresher training to all inspection personnel when Customer requirements are changed and as necessary to ensure compliance with contract and Self-Release requirements.
- Provide Honeywell representatives access to supplier's facilities and documentation to conduct periodic Self-Release audits.

F. Shipping Process

F.1. Daily, pending orders are followed-up in **Challenge Electronics'** computer sales accounting system and are released to shipping department

F.2. Shipping **SRR** pulls inventory from wheelhouse for shipping based on **FIFO**

F.3. Inspect Inventory to verify products is storage are still within the shelve life of the product

F.4. Products are packaged to protect from damage and corrosion in storage and during transport

F.5. **SRR** reviews that shipping instructions are followed

F.6. When required, Special labels are added to the packaging

F.7. Shipping Box is checked that all required documentations are included (**C of C, C of O,** etc)

F.8. Prior to closing the shipment **ASM/SRR** is asked to inspect the shipment.

- PN, Part Number
- Revision Number
- PO
- Line Item
- Signature of Inspector
- Date
- Number of shipping boxes
- Shipping Method
- Tracking Number

G. Billing Process

After shipment is made

G.1. Shipping documents are sent to accounting department

G.2. Invoice is prepared per customer instructions

- Billing address
- PO
- Customer PN
- Description
- Quantity
- Shipping date
- Shipping method
- Packing slip number
- Number of invoices required

7.5. Production

7.5.1. Production Control:

H. Challenge Electronics and its Manufacturing Partners Control of:

H.1. Manufacturing Process Changes are handled as follows:

H.1.a. The organization identifies and obtains acceptance of changes that require customer and/or regulatory authority approval in accordance with contract or regulatory requirements

H.1.b. Changes affecting: Processes, Manufacturing-Equipment, Tools, and Programs are Documented. Procedures are available to control their implementation

H.1.c. Persons authorized to approve changes to manufacturing processes are identified

H.1.d. The results of changes to manufacturing processes are assessed to confirm that the desired effect has been achieved without adverse effects to product quality

H.2. Control of manufacturing equipment, tools and computer programs: is handled as follows:

H.2.a. Manufacturing equipment, tools and programs is safeguarded from deterioration at all times, validated prior to use, and maintained and inspected periodically according to documented procedures

H.2.b. Validation prior to manufacturing use includes verification of the First Article Inspection **(FAI)** produced to the design data/specification

H.3. Control of Production-specific requirements for cleanliness and contamination control establishes documented requirements for cleanliness of product if:

H.3.a. Product is cleaned by the organization prior to its use

H.3.b. Contaminated Process are to be removed from product during manufacture

H.4. Control and Monitor of Special Processes

H.4.a. Inspection verification of Special Processes (Plating, Welding, Molding, Painting) by manufacturer or subcontractor

7.5.2. Identification and Traceability:

As appropriate, **Challenge Electronics and its Manufacturing Partners** identify product status by suitable methods throughout product realization. The organization has established procedures for product identification that includes:

A. Travelers, tags or other documents are maintained to ensure product status through manufacture, inspection and other measuring and monitoring activities

B. Status identification of product is maintained throughout product realization and storage of the product to ensure that only product that has passed the required inspections and test (or released under an authorized concession) is dispatched and used

C. Controls for the identification is maintained throughout the product life

D. The establishment of documented procedures to ensure that medical devices and other products returned to Challenge Electronics and its Manufacturing Partners are identified and distinguished from Conforming Product

E. The establishment of documented procedures for traceability. Such procedures define the extent of product traceability and the records required

F. For a given product, a sequential record of its manufacturing is retrievable

G. For an assembly, the identity of its components and those of the next higher assembly to be traced

H. Provisions for the recording of the unique identification of the product including heat lot and other lot numbers

I. Identify the amount manufactured and approved for distribution or sale

NOTE: Configuration management at **Challenge Electronics and its Manufacturing Partners** is a means by which identification and traceability can be maintained.

7.5.3. Customer property:

Challenge Electronics and its Manufacturing Partners exercises care with customers' property while it is under the organization's control or being used by the organization. **Challenge Electronics and its Manufacturing Partners**:

A. Identifies, verifies, protects and safeguards customer property provided for use or incorporation into the product

B. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization reports the conditions to the customer, and records are maintained

NOTE: Customer property can include intellectual property and personal data.

7.5.4. Preservation of product:

Challenge Electronics and its Manufacturing Partners has controls in place to ensure that product is preserved during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation includes:

- Identification, cleaning, handling, packaging, storage and protection. Preservation also applies to other constituent parts of a product
- Controls for the prevention, detection and removal of foreign objects
- Special handling of sensitive products
- Marking and labeling including safety warnings
- Shipping Containers must be labeled with a minimum of the following:
    - Customer Part Number (when Requested)
    - Customer Purchase Order number
    - Quantity
    - Shipping Container Gross Weight
    - Supplier name
    - Country of Origin
- Documented procedures or documented work instructions for the control of product with a limited shelf life or requiring special storage conditions. Such special storage conditions also include stock rotation
- Where applicable, special handling for sensitive products and hazardous materials
- Where applicable, special handling tools and equipment (e .g. lifting equipment) are utilized and controlled where necessary to ensure safe and adequate handling. This tooling and equipment is inspected and tested periodically or prior to use as necessary to ensure satisfactory performance

7.6. Control of Monitoring and Measuring Devices

7.6.1. **Challenge Electronics and its Manufacturing Partners** determines the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements.

7.6.2. **Documented procedures establish controls for monitoring and measurement to ensure that such activities are carried out in a manner that is consistent with the monitoring and measurement requirements.**

7.6.3. **Where necessary** to ensure valid results, measuring equipment is:

- Calibrated or verified (or both) at specific intervals, whenever the accuracy of the equipment is suspect, or prior to use against measurement standards traceable to international or national measurement standards. Where no such standards exist, the basis used for calibration or verification is recorded
- Adjusted or re-adjusted as necessary
- has unique identification in order to determine its calibration status
- Is safeguarded from adjustments that would invalidate the measurement result
- Protected from damage and deterioration during handling, maintenance and storage
- Registered in a system for controlling monitoring and measurement devices
- Has assigned specific requirements for calibration, including details of equipment type, unique identification , location, frequency of checks, check method and acceptance criteria

7.6.4. **Challenge Electronics and its Manufacturing Partners** assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization takes appropriate action for the equipment and any product affected.

7.6.5. A **documented** process is in place for the recall of monitoring and measuring equipment requiring calibration or verification.

7.6.6. **When** used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application is confirmed. This is undertaken prior to initial use and reconfirmed as necessary.

NOTE: Confirmation of the ability of computer software to satisfy the intended application typically includes its verification and configuration management to maintain its suitability for use.

7.6.7. **Records** of the results of calibration and verification are maintained.

8. MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1. General:

Challenge Electronics and its Manufacturing Partners plans and implements the monitoring, measurement, analysis and improvement processes needed to:

- Demonstrate conformity to product requirements
- Ensure conformity of the quality management system
- Initial Preproduction Part Approval Process **(PPAP)** system
- Continually improve the effectiveness of the quality management system and processes (both product and administrative)

8.1.1. Methods to be used, including statistical techniques and the extent of their use, are prescribed where applicable.

8.1.2. According to the nature of the product and depending on specified requirements, statistical techniques can be used to support:

- Quality Plans or Control Plans for Parts and Assemblies (most recent plan only)
- Design of experiment
- Design and Process Failure Modes and Effects Analysis
- Flow Chart
- Process Control
- Production and Process Failure Modes and Effects Analysis
- Measurement Systems Analysis Data
- **Gage R&R** Analysis
- Capability and **SPC** Data
- Selection of inspection of key characteristics
- Process capability measurements
- Inspection
- Dimensions, Functional and Performance Test Data
- Initial Sample Inspection Report **(ISIR)**
- Statistical process control
- Heat Treatment Processing Data
- Destructive and Non-Destructive Testing Data
- Appearance and Evaluation Report
- Production Part Approval Warrant **(PAW)** Documents Major Process Change Data
- Quality System Internal Assessments
- Production Lot Control Data
- Employee Training Records (kept for term of employment)
- Gage Calibration and Maintenance Records
- Scrap, Reclaim, and Deviation Records
- Quality Rejections and Disposition Records
- Corrective Action Requests and Responses
- Engineering Change Notice
- Preventive Change Notice

8.2. Monitoring and Measurement

8.2.1. Customer satisfaction and feedback:

As one of the measurements of the performance of the quality management system, **Challenge Electronics** monitors information relating to whether it has met customer requirements. **Challenge Electronics** has implemented a documented procedure for a feedback system and to provide early warning of quality problems. The process also provides for input into the corrective and preventive action systems as applicable.

- Monitoring customer perception includes obtaining input from customers from sources such as:
- Customer satisfaction surveys
- Customer performance data for product quality and on-time delivery
- Customer complaints and claims
- Corrective action requests

- Opinion surveys
- Compliments
- Lost business analysis

NOTE: Customer satisfaction may also be determined based on the perceptions of **Challenge Electronics** employees who are in contact with customers on a regular basis.

- Plans are developed and implemented for customer satisfaction improvement that addresses deficiencies noted in evaluations and perceptions. The effectiveness of the results is assessed.

NOTE: If national or regional regulations require the organization to gain experience from the post-production phase, the review of this experience is part of the feedback system.

8.2.2. Internal Audit:

Internal audits are conducted at planned intervals to determine whether the quality management system is effectively implemented and maintained and meets the requirements of the International Standards, and regulatory requirements cited in the Scope of this Quality Manual.

- The internal audit program is documented and planned, taking into consideration:
- The status and importance of the processes and areas to be audited
- Results of previous audits
- Plans for audit criteria, scope, frequency and methods
- The selection of auditors and the conduct of audits to ensure objectivity and impartiality (auditors do not audit their own work)
- A documented procedure to define the responsibilities and requirements for planning and conducting audits
- Establishing records
- Reporting audit results
- Responsibility for necessary corrections and corrective actions to be taken without undue delay to eliminate detected nonconformities and their causes
- Follow up activities that include the verification of actions taken and the reporting of verification results
- The need for the maintenance of records of audits and their results

NOTE: Planned arrangements include customer contractual requirements.

8.2.3. Monitoring and measurement of processes:

Challenge Electronics and its Manufacturing Partners monitors and measures the characteristics of the quality management system processes. These methods demonstrate the ability of the processes to achieve planned results.

- Consideration is given to the type and extent of monitoring and measurement in relationship to its impact on the conformity to product requirements and on the overall effectiveness of the quality management system.
- Managers responsible for specific quality management system processes apply suitable methods for monitoring and, where applicable, measurement of those processes. These methods demonstrate the ability of the processes to achieve planned results.
- When planned results are not achieved, remedial and Corrective-Action are taken, as appropriate.
- In the event of a process nonconformity, the following occurs:
  - Appropriate actions are taken to address the nonconforming process
  - An evaluation is performed to determine if the process nonconformity has resulted in product nonconformity
  - An evaluation is performed to determine if the process nonconformity is limited to a specific case or whether it could have affected other processes or product
  - Identify and control of any nonconforming product is maintained

8.2.4. Monitoring and measurement of product:

Challenge Electronics and its Manufacturing Partners monitors and measures the characteristics of the product to verify that product requirements have been met. Documented procedures for monitoring and measurement of product include:

- Planning and work instructions ensure that monitoring and measurement are carried out at appropriate stages of the product realization process and are completed before the product is released for shipment
- The release of product to the customer does not proceed until the planned arrangements have been satisfactorily completed
- Product shipped to customers conforms to the customer's requirements
- Records of actions taken to confirm conformity with the acceptance criteria are maintained

- When key characteristics have been identified by the customer, they are monitored and controlled ,
- When sampling inspection is used as a means of product acceptance, the plan is statistically valid and appropriate for use. If required, the plan is submitted for customer approval. When specifically required by contract, the plan precludes the acceptance of lots whose samples have known nonconformities
- Evidence of conformity with the acceptance criteria is maintained
- Test records show actual inspection/test data when required by specification of acceptance test plan
- Only qualified persons perform inspection for acceptance
- Records indicate the person(s) authorizing the release of product for delivery to the customer
- Records of the identity of personnel who perform inspection and testing is maintained
- All documents required to accompany the product are present at delivery

8.3. Control of Nonconforming Product

8.3.1. **Challenge Electronics** has measures in place to ensure that product that does not conform to product requirements is identified and controlled to prevent its unintended use or delivery.

8.3.2. The controls and related responsibilities and authorities for dealing with nonconforming product, and also with nonconforming material received from vendors is documented, implemented and maintained. These controls include:

- Taking action to eliminate the detected nonconformity
- By authorizing its use, re lease or acceptance under concession by a relevant authority or customer,
- Taking action to preclude its original intended use or application, and
- Taking actions appropriate to the effects, or potential effects of the nonconforming product detected after delivery or use.

8.3.3. Nonconforming material is separated from conforming material physically and/or by clear marking or labeling to ensure that no confusion is possible regarding the status of the material.

8.3.4. Nonconforming product is accepted by concession only if customer or regulatory requirements are met. The identity of the person(s) authorizing the concession is maintained as quality records.

8.3.5. When nonconforming product is corrected, it is subject to Re verification to demonstrate conformity with requirements.

8.3.6. Rework plans are determined and prepared by authorized personnel.

8.3.7. Any adverse effects of rework is documented and appropriately disposition.

8.3.8. When nonconforming product is detected after delivery or use has started, Challenge Electronics takes action appropriate to the effects, or potential effects of the nonconformity.

8.3.9. Notifications include a clear description of the nonconformity, which includes, as necessary, parts affected, customer and/or Challenge Electronics part numbers, quantity, and dates(s) delivered.

8.3.10. Parties requiring notification of nonconforming product include, but are not limited to suppliers, internal departments, customers, distributors, and regulatory authorities.

8.3.11. Records of nonconformance and associated actions, including on cessions, are maintained in accordance with documented procedures.

8.4. Analysis of Data

8.4.1. Management determines data to be collected to demonstrate the suitability and effectiveness of the quality management system, and to evaluate where continual improvement of its effectiveness can be made. This includes data generated as a result of monitoring and measurement and from other relevant sources. This data is made available for ongoing review and analysis and provides information relating to:

- Customer feedback and satisfaction
- Conformity to product requirements
- Characteristics and trends of processes and products including opportunities for preventive action
- Performance and reliability of suppliers

8.4.2. Records of data analysis are maintained in accordance with documented procedures.

8.5. Improvements

8.5.1. Continuous improvement:

Challenge Electronics continually improves the effectiveness of the quality management system through the implementation of the Quality Policy and Quality Objectives, audit results, collection and analysis of performance data (internal and external), corrective and preventive action, and actions resulting from management review of the data.

- Actions directed by management are augmented and supported by an ongoing program of corrective and preventive actions, initiated and executed at all levels of the company.
- The implementation of improvement activities and the evaluation of the effectiveness of the results are monitored.
- Continual improvement opportunities can result from lessons learned, problem resolutions and evaluations of the effectiveness of the results.
- Challenge Electronics establishes documented procedures for the issue and implementation of advisory notices. These procedures are capable of being implemented at any time.
- Customer complaints are documented in a database and investigated in a timely manner to ensure the validity of the complaint.
- If investigation indicates that activities outside of the organization contributed to the customer complaint, relevant information is exchanged between all organizations involved.
- Customer complaints that are not followed by corrective or preventive actions are justified by authorized personnel.
- When national or regional regulations require notification of adverse events, corrective action procedures are employed for notification to those agencies.
- Records of customer complaints are maintained in a complaint database or in corrective/preventive action files.

8.5.2. Corrective Action Report (8D-CAR):

Challenge Electronics and its Manufacturing Partners Management and employees take systematic action to eliminate the cause of deficiencies in product and processes in order to prevent recurrence. **8D-CAR** are appropriate to the effects of the deficiencies encountered. Procedures regarding corrective actions are documented and cover:

- Reviewing nonconformities (including customer complaints)
- Containing Work In Process and Finish Goods of the Product
- Determining the Root Causes of nonconformities
- Evaluating the need for action to ensure that non conformities do not recur
- Determining and implementing action needed, including, if appropriate, updating documentation
- Recording the results of any investigation and action taken
- Verifying corrective action taken and its effectiveness
- Flowing **8D-CAR** requirements to a supplier, when supplier is responsible for the Root-Cause
- Validating corrective action taken its effectiveness
- Taking specific actions where timely and/or effective corrective actions are not achieved
- Determining if other product exists based on the causes of the non-conformities and taking further action when required

8.5.3. Preventive Action:

Challenge Electronics takes action to eliminate the cause of potential nonconformities in order to prevent their occurrence. Preventive actions are appropriate to the effects of the potential problem. Documented procedures include the requirements for:

a. Determining potential nonconformities and their causes

b. Evaluating the need for action to prevent occurrence of nonconformities
c. Determining and implementing action needed
d. Records of resulting investigations and actions taken
e. Reviewing the effectiveness of the preventive action taken

- The foundation of the preventive action program is the combination of systems for document control: process qualification and control; manufacturing control; training, configuration control; infrastructure management (including preventive maintenance); monitoring and measurement; and corrective actions.
- Sources of information that may be used to identify additional opportunities for preventive action include:
  - Nonconformance reports
  - Customer claims (complaints)
  - Trend analysis
  - Failure mode effects, analysis studies
  - Process capability data
- Preventive actions are appropriate to the effects of the potential problems. When it has been determined that preventive action is required, a plan for accomplishment of specific actions is developed.
- Organization maintains a system for recording preventive actions, and tracking the progress and closeout of preventive action plans. These items are reviewed periodically as part of the management review process.
- Programs that help to eliminate sources of problems include process qualifications, process control, configuration control, training and preventive maintenance.
- Records of preventive actions are in accordance with documented procedures.

9. QUALITY MANAGEMENT SYSTEM MANUAL RECORDS

9.1. REVISION HISTORY

Rev.	Description	Date
A	Initial Release	7/11/2008
B	Modified CAR and PPAP Reports	9/12/2009
C	Updated Organization Chart and Contact List	8/2/2011
D	Revised entire manual	1/16/2014
E	Modified Company profile	1/26/2015
F	Modify the Contact List and revised RoHS and REACH Compliance Declaration	7/26/2016
G	Added information to sections 7.1. 7.2. & 7.4.	8/23/2016

9.2. QUALITY MANAGEMENT SYSTEM MANUAL APPROVAL

The release/change document, "Document Change Request," that is maintained in Document Control provides the approval signatures of: CEO/President, CFO, and management representatives from: Business Units, Sales, Engineering Services, Purchasing, Accounting, and Operations and Quality Assurance.

QUALITY MANAGEMETNT SYSTEM MANUAL APPROVAL

We, department managers, approve this **QUALITY MANAGEMETNT SYSTEM MANUAL,** Revision G, and will do our best to follow and inforce our department to comply with it.

Name	Title	Date	Signature
Steve Lubman	President	8/24/2016	
Ira Levy	Vice President	8/24/2016	
Lori Mongelli	Accounting & Human Resource Manager	8/24/2016	
Craig Schroeder	Director of Sales & Marketing	8/24/2016	
Walt Sargent	Information Technology Manager	8/24/2016	
Christina Maratto	Scheduling & Purchasing Manager	8/24/2016	
Mike Trace	Shipping Manager	8/24/2016	
Josh Klyman	Engineer Manager	8/24/2016	
Ely Zofan	Director of Engineering & Quality	8/24/2016	

10. Appendix Table of Contents

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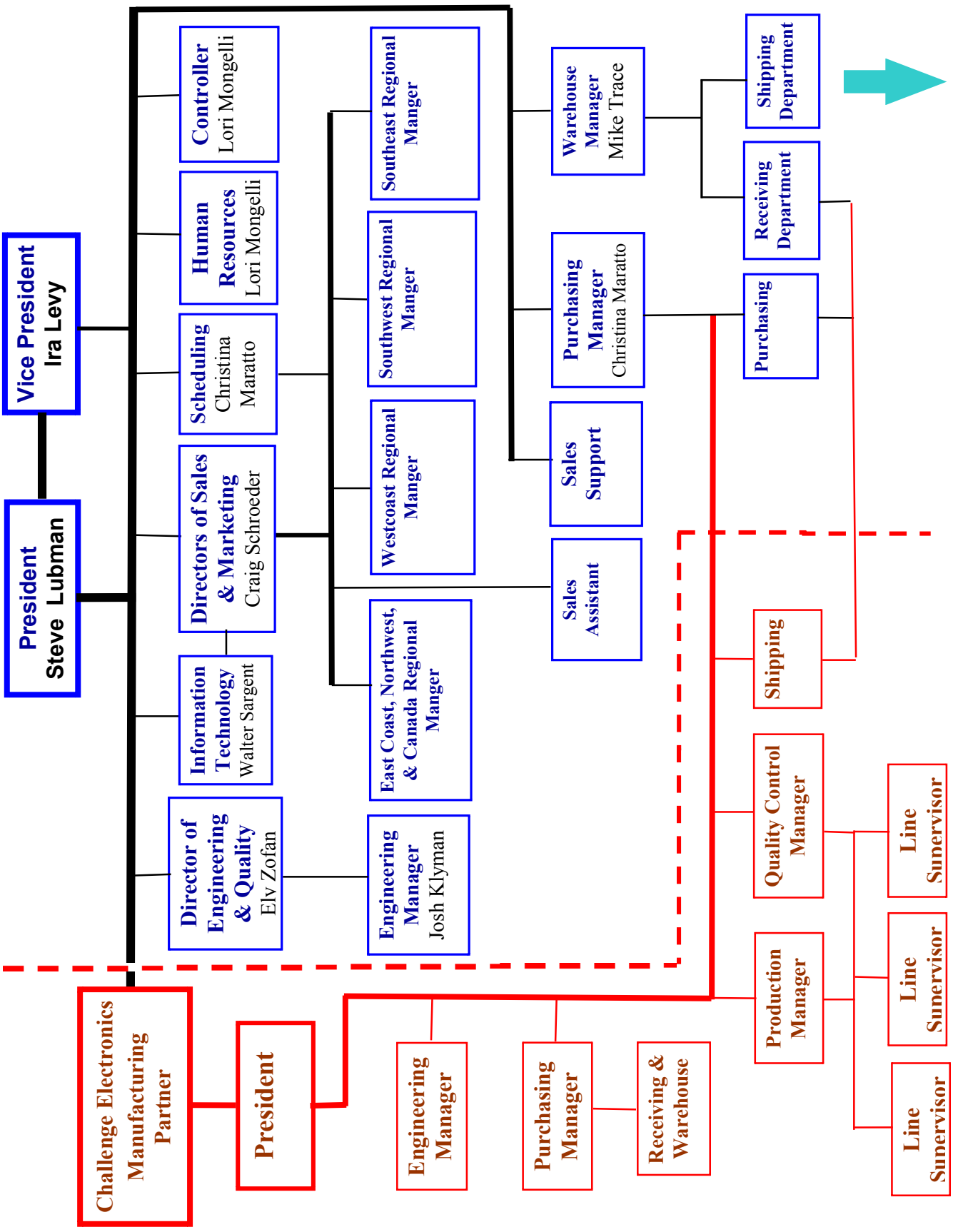
Appendix A

Definitions

Terms and Definitions; Terms and definitions contained in this manual and unique to our organization or business are listed below. Customer definitions will take precedence over all other definitions.

Term	Definition
ASL	Approved Supplier List
AVL	Approved Vendor List
BOM	Bill of Material
CAR	Corrective Action Report
ECN	Engineering Change Notice
FAI	First Article Inspection
HRO	Human Resources Manager
IQC	Incoming Quality Check
IQL	Incoming Quality Level
OI	Standard Operating Instructions
MRP	Material Requirement Planning
NIST	National Institute of Standards and Technology
OEM	Original Equipment Manufacturer.
OP	Standard Operating Procedure
PCN	Process Change Notice
PDQ	Price, Delivery, Quality
PM	Preventive Maintenance
PPAP	Pre-Production Approval Process
QAI	Quality Assurance Instructions
QMS	Quality Management System
QSM	Quality System Manual
RMA	Return Material Authorization
SPL	Sound Pressure Level

Appendix B ORGANIZATIONAL CHART



Appendix C — CONTACT DIRECTORY

Tel: 800-722-8197 or 631-595-2217 Fax: 631-940-2633

Name	Title	Ext.	Cell	FAX
Olivia Branigan	Sale Support	1000		631-667-5484
			olivia@challelec.com	
Priscilla Gibbons	Sale Support	1032		631-586-5899
Josh Klyman	Engineer Manager	1030	201-310-4184	631-667-5484
			jklyman@challelec.com	
Ira Levy	Vice President	1119		631-595-1283
Steve Lubman	President	1013	631-831-8311	631-940-2633
			steve@challelec.com	
Christina Maratto	Scheduling & Purchasing Manager	1006		631-667-5484
			christina@challelec.com	
Donna Bencivenga	Regional Sales Manager	1003		631-586-5899
			DBencivenga@challelec.com	
Lori Mongelli	Accounting & Human Resource Manager	1004		631-243-4322
			lori@challelec.com	
Walt Sargent	Information Technology Manager	1031		631-667-5484
			walt@challelec.com	
Craig Schroeder	Director of Sales & Marketing	1008	516-297-6065	631-586-5899
			craig@challelec.com	
Peter Sedlak	Westcoast Regional Sales Manager		408-906-9041	
			psedlak@challelec.com	
Mike Trace	Shipping Manager	1011		631-667-5484
			mike@challelec.com	
Ely Zofan	Director of Engineering & Quality	1009	614-325-5567	631-667-5484
			ezofan@challelec.com	

Appendix D List of Products

1. ALARMS & BUZZERS

- Piezoelectric Industrial Panel Alarms

Variety of Sounds:	♦ Continuous ♦ Interrupted	♦ Chime ♦ Warble	♦ Siren ♦ Hoops	♦ Staccato
Multi Sound Alarms:	♦ Continuous with Interrupted ♦ Continuous with Chime	♦ Continuous with Warble		
Multiple Sound Levels:	♦ Soft	♦ Medium Loud	♦ Loud	♦ Extra Loud ♦ Ultra Loud
Terminations:	♦ Quick Connect Terminals ♦ Terminals with Screw	♦ PC Pins	♦ Wire Leaded ♦ Connectors	

- Electromagnetic Buzzers
- Piezoelectric Buzzers
- Mechanical Buzzers
- Backup Alarms

2. SOUND TRANSDUCERS

- Electromagnetic Sound Transducers
- Piezoelectric Sound Transducers
- Options: SMD, Pins for PCB, and Panel Mounts

3. SPEAKER

- Oval Speakers
- Round Speakers
- Square Speakers
- Ultra Mini Speakers
- P.C.B. Mountable Speakers

Options:	♦ Shielded Speakers ♦ Water Proof Speakers	Terminations	♦ Terminals ♦ Wire Leads ♦ Blades ♦ Connectors

4. ELECTRET CONDENSER MICROPHONES

- UNI Directional Microphones
- OMNI Directional Microphones
- Bi-Directional Microphones
- Noise Cancelling Directional
- Standard, PCB, and SMD Microphones
- Digital Microphones

5. BATTERY ACCESSORIES

- Battery Snap – P.C.B. Leads
- Battery Contacts
- Battery Snap –Wire Leads
- Coin Cell Holders
- Cylindrical Terminals Rivet
- "D" Size Battery Holders
- "C" Size Battery Holders
- "AA" Size Battery Holders
- "AAA" Size Battery Holders
- "N" Size Battery Holders

6. Value Added

7. Custom Engineered Products

PRODUCT COMPLY All Challenge Electronics products comply with

- RoHS, Lead Free
- Substance of Very High Concern (REACH)

Appendix E CE-0151.005P RoHS and REACH Compliance Declaration

RoHS and REACH Compliance Declaration

For Sounding Devices Articles

With Exemptions for Piezoelectric Alarms, Buzzers, and Sound Transducers

7/14/2016

Dear Customer,

By means of this letter, we confirm to you we are well aware of the obligations deriving from the EC Regulation 1907/2006 (called "**REACH**"). Thus, we inform you that **Challenge Electronics** has duly analyzed the impact that this Regulation may have on **Challenge Electronics** both in its role as a Supplier and as a Customer. Therefore, **this document certifies that, to the best of our knowledge, Challenge Electronics Sounding Devices Articles are in RoHS Compliance**:

A. **The Challenge Electronics Sound Devices Articles manufactured under the Lead Free Program and complies with European Union Directive 2011/65/EU (RoHS Directive) of the European Parliament**
B. **In addition, of the Council of 8 June 2011 and all subsequent amendments, on the restriction of the use of certain hazardous substances in electrical and electronics equipment (RoHS Directive) in accordance with the definitions set forth in the directives and its exemptions.**
C. **The Piezoelectric-Ceramic-Disc article CONTAINS more than 0.1% (w/w) of REACH. Candidate List SVHC Lead-Zirconium-Titanium-Oxide (CAS 12626-81-2)**, which is a key ingredient of the Piezoelectric-Ceramic-Disc in **Challenge Electronics Piezoelectric Alarms, Piezoelectric buzzers, Piezoelectric Sound Transducers, Ultrasonic Sensor and Transmitter** operation.

RoHS COMPLIANCE DECLARATION

The ANNEX III of the Directive Applications exempted from the restriction in Article 4(1):

- **6(c)-- Copper alloy** containing up to 4% Lead by weight
- **7(a)-- Lead in high melting temperature** type solders (i.e. Lead- based alloys containing 85 % by weight or more Lead)
- **7(c)-I--** Electrical and electronic components containing lead in a glass or ceramic other than dielectric ceramic in capacitors, e.g. **Piezoelectronic devices**, or in a glass or ceramic matrix compound.
  Piezoelectric is also known as Lead Zirconate Titanate (PZT) ceramics. Piezoelectric Ceramic disc, (PZT), Lead as high covalent compound in the ceramic matrix to achieve good ferroelectric properties in a wide temperature range. The best-known performances can be reached with PZT ceramics, which are a mixture of PbTiO3 and PbZrO3. The Lead content, homogeneous material compound is between 58% and 68% by weight depending on the proportion of Zirconium (Zr) and Titanium (Ti).
- **30--** Cadmium alloys as electrical/mechanical solder joints to electrical conductors located directly on the voice-coil in transducers used in high-powered loudspeakers with sound pressure levels of 100 dB (A) and more

With the exception of the Piezoelectric Articles, Challenge Electronics Sound Devices Articles are in RoHS Compliant and do not exceed the maximum limit for the following 10 designated substances. See Product Line List on page # 2

Restricted Substance	Maximum Threshold Limit	Product Results
Lead (Pb) / Lead Compounds	≤1,000 ppm	**≤ 10,000 ppm (*)**
Mercury (Hg) / Mercury Compounds	≤1,000 ppm	**In compliance**
Cadmium (Cd) / Cadmium Compounds	≤ 100 ppm	**In compliance**
Hexavalent Chromium (Cr_{VI})	≤1,000 ppm	**In compliance**
Poly Brominated Diphenyl Ethers (PBDE)	≤1,000 ppm	**In compliance**
Bis (2-Ethylhexyl) Phthalate (DEHP)	≤1,000 ppm	**In compliance**
Butyl Benzyl Phthalate (BBP)	≤1,000 ppm	**In compliance**
Dibutyl Phthalate (DBP)	≤1,000 ppm	**In compliance**

(*) In compliance for all Sounding Devices **except Piezoelectric Alarms, Buzzers, and Sound Transducers**
European Union Directive 2011/65/EU (RoHS Directive) of the European Parliament. And of the Council of 8 June 2011 and all subsequent amendments, The ANNEX III of the Directive Applications exempted from the restriction in Article 4(1): 7(c)-I, Electrical and electronic components containing Lead in ceramic matrix compound Piezoelectric is also known as Lead Zirconate Titanate (PZT) ceramics. Lead content, homogeneous material compound is between 58% and 68% by weight depending on the proportion of Zirconium (Zr) and Titanium (Ti)

REACH COMPLIANCE DECLARATION

In Compliance with REACH Directives which is the European Community Regulation on chemicals and their safe use (EC Regulation No. 1907/2006), Challenge Electronics assures its customers that all **Challenge Electronics Sound Devices** Articles, See Product Line List below, meet the following requirements pertaining to the 168 SVHCs (Substances of Very High Concern).

The Candidate list is also published at: http://echa.europa.eu/web/guest/candidate-list-table

1) According to the REACH terminology, Challenge Electronics acknowledge being Producers, Importers and Marketer of **Sound Devices Articles**, which do not contain **Substances of Very High Concern (SVHC's)** to be intentionally released.

2) Challenge Electronics hereby declares, to the best of our knowledge and based on our China Manufacturers and Fabricators information, that, all **Challenge Electronics Sound Devices Articles** are chemically safe, and should not harm any human, animals, or the environment.

3) **It should be noted that SVHC items are not banned from inclusion, but are Reportable per current REACH regulations**

- **a)** **With the exception of The Piezoelectric-Ceramic-Disc article that CONTAINS more than 0.1% (w/w) of REACH Candidate List SVHC Lead-Zirconium-Titanium-Oxide (CAS 12626-81-2), which is a key ingredient of the Piezoelectric-Ceramic-Disc in the Alarm operation.** See also the RoHS Compliance ANNEX III of the Directive Applications exempted from the restriction in Article 4(1)
- **b)** **Some SMD and Dip type Capacitors CONTAINS one of the following Lead Oxides published in the ECHA SVHC Candidate List at or greater than 0.1% of total weight: Lead monoxide (CAS 1317-36-8), Lead titanium zirconium oxide (CAS 12626-81-2)**

4) In all cases, the lead substance is chemically combined in Capacitors and presents no hazard to humans or the environment under normal handling and use. In addition, **Challenge Electronics** complies with the restrictions stated in Annex XVII of REACH.

5) In **Challenge Electronics** role as Supplier, we have taken the necessary steps towards our China Manufacturing in order to get a written confirmation about their knowledge of the Regulation and their analysis of the impact on their company.

Challenge Electronics Product Line List

Product Line	REACH Complaint	Exception for
Electromagnetic Sound Transducers	**YES**	
Electromagnetic Buzzers	**YES**	
Mechanical Buzzers	**YES**	
Piezoelectric Alarms	**Yes with Exception**	**Piezoelectric is also known as Lead Zirconate Titanate (PZT) Ceramics**
Piezoelectric Buzzers	**Yes with Exception**	**Piezoelectric is also known as Lead Zirconate Titanate (PZT) Ceramics**
Piezoelectric Sound Transducers	**Yes with Exception**	**Piezoelectric is also known as Lead Zirconate Titanate (PZT) Ceramics**
Piezoelectric Sound Elements	**Yes with Exception**	**Piezoelectric is also known as Lead Zirconate Titanate (PZT) Ceramics**
Speakers (Excluding Piezoelectric Speakers)	**YES**	
Piezoelectric Speakers	**Yes with Exception**	**Piezoelectric is also known as Lead Zirconate Titanate (PZT) Ceramics**
Microphones (Excluding Piezoelectric Microphones)	**YES**	
Piezoelectric Microphones	**Yes with Exception**	**Piezoelectric is also known as Lead Zirconate Titanate (PZT) Ceramics**
Ultrasonic Sensors (Transmitters and Receivers)	**Yes with Exception**	**Piezoelectric is also known as Lead Zirconate Titanate (PZT) Ceramics**
Battery Accessories	**YES**	

IMDS Information for Piezoelectric

Automotive Industry Interpretation Guide for ELV Annex II (2016/774/EU) with IMDS Information added by the IMDS Steering Committee

- **Interpretation Guide for ELV Annex II (2016/774/EC) Version 3.0**
- **Definition/interpretation of -Exemption (10a)**

10(a). Electrical and electronic components, which contain lead in a glass or ceramic, in a glass or ceramic matrix compound, in a glass-ceramic material, or in a glass-ceramic matrix compound. This exemption does not cover the use of lead in: • glass in bulbs and glaze of spark plugs, • dielectric ceramic materials of components listed under 10(b), 10(c) and 10(d)
DUE DATE: none
IMDS APPLICATION CODE:

10(a). Electrical and electronic components, which contain lead in a glass or ceramic, in a glass or ceramic matrix compound, in a glass-ceramic material, or in a glass-ceramic matrix compound. This exemption does not cover the use of lead in:

- glass in bulbs and glaze of spark plugs,
- dielectric ceramic materials of components

Listed under 10(b), 10(c) and 10(d).

This exemption is related to electrical/ electronic applications in general, which are not covered by 10b -d). Exemptions 10b-d subsume specific applications of lead in glass and ceramic of electric and electronic components.

- To better understand what is meant here and what is in scope, the single elements of this exemption are defined separately.
- For definitions on electrical and Electronic Components, please see guide section for entry 8a.

2) Examples for components covered by 10 a)

a) Piezoceramics

Piezoceramics are characterized through their ability to transform mechanical energy in electrical energy and reciprocal. They fulfil technical functions as actuators, sensors, generators and motors. They are used for instance in Actuators for diesel and gasoline injection valves, knock sensors, resonator and filter, actuators, bending actuators for pneumatic valves, tire Pressure Sensors, ceramic sensors (like ABS, air bag, pressure, car navigation sensors), **Piezoelectric Alarms, Piezoelectric buzzers, Piezoelectric Sound Transducers, Ultrasonic Sensor and Transmitter**. The lead content in the Piezoceramics ceramics is around 50 to 70% by weight, depending on the content of dopants, required functional properties and on the proportion of Zirconium (Zr) and Titanium (Ti).

➢ The statements in this letter regarding RoHS Compliance and lead content do not extend to, or apply to any product subjected to unintended contamination, misuse, neglect, accident, improper installation, or to use in violation of instructions furnished by **Challenge Electronics**

❖ **No Ozone Depleting Substance (ODS),** covered by the Montreal Protocol, are used in the manufacturing process of Challenge Electronics Audio Devices

The above statements fulfill the communication requirements stated in REACH, Article 33. All enquiries related to RoHS, REACH and SVHCs could be sent to our REACH Coordinator, Ely Zofan, by e-mail ezofan@challelec.com

Sincerely,

Authorized signatures for **Challenge Electronics**:

Name: **Ely S. Zofan** Position: **Director of Engineering and Quality**

Signature: Ely Zofan Date: **7/14/2016**

The information contained in this letter is being provided for informational purposes only and to clarify certain information concerning **Challenge Electronics** products. Nothing provided in this letter is:

(i) a representation, warranty or agreement to indemnification by **Challenge Electronics**

(ii) a statement which may form the basis of reliance by **Challenge Electronics**

a modification of any of the terms and conditions of sale agreed to in writing between **Challenge Electronics** and its customers with respect to any **Challenge Electronics** products, whether previously sold or to be sold in the future

Revisions to SVHC Candidate List, which have been reviewed in preparation of this statement:

Regulation (EC) 440/2008 of 30 May 2008	Regulation (EC) 987/2008 of 8 October 2008	Regulation (EC) 134/2009 of 16 February 2009
Regulation (EC) 552/2009 of 22 June 2009	Regulation (EC) 761/2009 of 23 July 2009	Regulation (EU) 276/2010 of 31 March 2010
Regulation (EU) 453/2010 of 20 May 2010	Regulation (EU) 1152/2010 of 8 December 2010	Regulation (EU) 143/2011 of 17 February 2011
Regulation (EU) 207/2011 of 2 March 2011	Regulation (EU) 252/2011 of 15 March 2011	Regulation (EU) 253/2011 of 15 March 2011
Regulation (EU) 366/2011 of 14 April 2011	Regulation (EU) 494/2011 of 20 May 2011	Regulation (EU) 109/2012 of 9 February 2012
Regulation (EU) 125/2012 of 14 February 2012	Regulation (EU) 412/2012 of 15 May 2012	Regulation (EU) 640/2012 of 6 July 2012
Regulation (EU) 835/2012 of 18 September 2012	Regulation (EU) 836/2012 of 18 September 2012	Regulation (EU) 847/2012 of 19 September 2012
Regulation (EU) 848/2012 of 19 September 2012	Regulation (EU) 126/2013 of 13 February 2013	Regulation (EU) 254/2013 of 20 march 2013
Regulation (EU) 348/2013 of 17 April 2013	Regulation (EU) 1272/2013 of 6 December 2013	Regulation (EU) 260/2014 of 24 January 2014
Regulation (EU) 301/2014 of 25 March 2014	Regulation (EU) 317/2014 of 27 March 2014	Regulation (EU) 474/2014 of 8 May 2014
Regulation (EU) 900/2014 of 15 July 2014	Regulation (EU) 895/2014 of 14 August 2014	Regulation (EU) 2015/282 of 20 February 2015
Regulation (EU) 2015/326 of 2 March 2015	Regulation (EU) 2015/628 of 22 April 2015	Regulation (EU) 2015/830 of 28 May 2015
Regulation (EU) 2015/1494 of 4 September 2015	Regulation (EU) 2016/266 of 7 December 2015	Regulation (EU) 2016/9 of 5 January 2016
Regulation (EU) 2016/26 of 13 January 2016	Regulation (EU) 2016/217 of 16 February 2016	Regulation (EU) 2016/863 of 31 May 2016

Appendix F: OP-SA-04-5100.001 Challenge Electronics Product Warranty

Product Warranty

Challenge Electronics warrants its Sounding Devices for a period of one (1) year from the date of manufacture that will, when used under **Normal Operating Conditions**, Conform to the company's then-current Product Information (Specifications) published at the time of product purchase, and Be free of defects in materials and workmanship. Seller's sole and exclusive obligation under this warranty, provided Non-Conformity or Defect product found, upon Seller's Engineering examination of returned , to have failed to conform to relevant Product Information (Specifications) or to have malfunctioned due to faulty materials or workmanship during the warranty period, will be to repaired or replaced the Non-Conformity or Defect product at no charge, at Seller's discretion, which shall be the Purchaser's sole and exclusive resolution, provided return of Non-Conformity or Defect product is made prepaid to Seller or its designated representative with the following information: (i) Date of shipment of such goods to Purchaser; (ii) Date such goods are determined to be Non-Conforming or Defective; and (iii) Specifying the apparent Non-Conformity or Defect. Seller shall not be liable, under any legal or equitable theory of recovery, for special, incidental or consequential damages, regardless of the circumstances. This warranty will become void with respect to products that have been subjected to: misuse, Abused, Alteration. Used out of Specified Operating Conditions, Unusual use or exposed abnormal environmental conditions, or Unauthorized Repairs. "Normal Operating Conditions" are defined in Seller's General Product Information (Operating and Environmental Specifications) in effect at the time of product purchase, and can be obtained from the company's website or upon request from Seller.

Except for the express Warranty set forth above, all other warranties, whether expressed, implied, statutory, or warranty of merchantability and fitness for any particular purpose, except of Title. Seller assumes no liability for any special, indirect, consequential, incidental or other damages of any type (including, but not limited to, damages related to lost sales and profits, excessive or increased costs and expenses, field recall and retrofit, costs and expenses, downtime costs and claims of customers or purchaser for such damages) resulting from non-conforming or defective condition of any goods sold by seller to purchaser hereunder, and purchaser assumes all liability for all consequences arising out of its use or sales of such goods. The aforesaid remedy of purchaser is exclusive and this limitation of liability provision shall apply to any and all claims or suits based upon negligence, breach of contract, breach of warranty, strict liability, or any other legal theory upon which liability may be asserted against seller by purchaser of others.

This warranty is effective for purchases of Product on or after the effective date set for at the time of Product shipment date. Seller reserves the right to modify this warranty from time to time. Any modification of this warranty shall be effective for all orders placed with Seller on or after the effective date of such revised warranty

Appendix G: Customer Special Product Process Handling

7.2.1. Contract Review Requirements of Special Product Order Processing Operating Procedure SA 050H

7.2.1.1. Determination of requirements related to the product:

Challenge Electronics and its Manufacturing Partners reviews the requirements related to the product in accordance with documented procedures. These reviews are conducted prior to the commitment to supply a product to the customer, including:

(a) Requirements specified by the customer, including product requirements and the requirements for delivery, and post-delivery activities
(b) Requirements not stated by the customer but necessary for specified or intended use (where known)
(c) Statutory and regulatory requirements applicable to the product
(d) Any additional requirements considered necessary
(e) Internally-generated requirements are determined and can be met

NOTE: Post-delivery activities include actions under warranty provisions or contractual obligations.

7.2.1.2. Review of requirements related to the product:

Challenge Electronics performs reviews prior to the commitment to supply a product to the customer (e.g. acceptance of contracts or orders, acceptance of changes to contracts or orders) and ensures that **(Review of Contract Requirements Special Product Order Processing; Operating Procedure SA 050)**:

(a) Product requirements are defined and documented
(b) Contract or order requirements differing from those previously expressed are resolved
(c) The organization has the ability to meet the defined requirements
(d) Special requirements of the product are determined
(e) Verify that the manufacture have procedures to comply with customer requirements of inspection/test and documentation of Airworthiness/Product Safety (AW/PS) material
(f) Risks (e.g., new technology, short delivery time scale) have been identified and evaluated

7.2.1.3. Where the customer provides no documented statement of requirement, the customer requirements are confirmed by **Challenge Electronics** before acceptance.

7.2.1.4. Where product requirements are changed, **Challenge Electronics and its Manufacturing Partners** ensures that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

- Records of the results of the review and actions arising from the review are documented and maintained.

NOTE: In some situations such as Internet sales, a formal review is impractical for each order. The review may cover relevant product information such as catalogs or advertising material.

7.2.1.5. Procedure

Account Sales Manager

(a) RFQ (Request for Quotation) Process

- Account Sales Manager receives, **ASM**, the **RFQ** from Honeywell buyer/planner
- **ASM** verify each individual item with Honeywell buyer/planner
- Part Number and description
- Quantity
- Request delivery
- Insure that the Revision level is current
- Is a **FAI** (First Article Inspection) needed (**F2** code)? Make sure to review the current **INF-1448 Revision 32** on HW website.
- Is it an **AWP** (Air Worthy Product)? Any special documents requested from **HW**?

(b) ASM inquire with vendor:

- Pricing breakdown
- Delivery Time
- Product status EOL (End Of Life)
- Any Changes or Modification done to product
- Insure that supplier will provide required documentation (**C of C, C of O, RoHS**)
- **ASM** conducts a Contract Review with the President to generate a Quote.

(c) ASM generate a quote and submit to customer, quote to include:

- Where applies, Name of Sale Representative Organization and contact information
- Part Number
- Description

- Price at different levels
- Minimum shipments
- Freight Original Point
- Payment Terms
- Statement of Non Cancelation of Purchase Order and Non Return Terms
- Any other information required by customer.

(d) **ASM** attaches the part specifications to the quote.
(e) **ASM** .fills records Quote information in the Quote Log in the computer in the E drive.
(f) **ASM** contact the customer buyer/planner to follow up on the quote status

7.4.1. Purchase order Process

7.4.1.1. Purchase Orders are received through ESIS Internet Format

7.4.1.2. When Purchase Orders is received **ASM** must verify that

- Part Number and Revision are correct
- Description
- Component approved source is confirmed
- All conditions on **PO** are the same as on quote sent to customer
- The Header and Clauses are confirmed (**F2 code INF'**s etc.) Make sure to review the current **INF-1448 Revision 32** on HW website.
- The in house receiving date can be met
- Shipping Date is entered into the system to allow the time for shipment to meet customer in house requirements
- Customer shipping instructions are reviewed and entered into the system
- A Sales Order is entered into the Challenge Electronics VAMSQL computer system
- ASM enter a SO into the **Challenge Electronics'** computer sales accounting system.

7.4.1.3. Placing PO with Supplier Process

After customer PO is approved and entered into Challenge Electronics system a PO is generated and sent to supplier.

A. **PO** should include very clear instruction as to:

- Part Number and Revision
- Description
- Quantity
- Unit Cost
- Shipping date
- Shipping Instructions
- Payment Instructions
- Documentations required with shipping

B. Order is sent via email to supplier

- Within 24 hours after sending out **PO** to supplier, verify receiving confirmation from supplier and check that all information is per issued **PO**.
- Send **PO** acknowledgment to **HW** Buyer/Planner through **ESIS** system, after confirming that supplier confirmation is per **PO** instructions.

7.4.1.4. Expediting Process

- Once a week verify and/or expedite **PO** with the supplier
- If supplier informs of any delays, information is immediately related to **HW** Buyer/Planner
- If customer, **HW**, makes any changes to delivery requirements, make sure to update information with supplier prior to acknowledging changes.

7.4.6. Receiving Process

Receiving clerk:

7.4.6.1. Receives the shipment from carrier
7.4.6.2. Visually inspect shipping box for any damage prior to signing carrier receipt
7.4.6.3. Opens box and visually inspect for damage parts.
7.4.6.4. Matches the **PO** information to packing slip
7.4.6.5. If packing slip does not include Date code/lot code and serial numbers, Receiving clerk marks them on packing slip
7.4.6.6. If date codes/lot codes or serial numbers are out of order, they are packaged separately for easy identification.
7.4.6.7. Insures that all required documentations are supplied.
7.4.6.8. Makes duplicate copies of all documentation and packing slip.
7.4.6.9. **SRR** completes ***Form SA-05 Honeywell Air Receiving Log***

7.4.6.10. Places original documentation in the box and sends the copied documents to **ASM** to file.

7.4.7. Warehouse, Shipping

Operating Procedure SA 052H, Honeywell Air Sample SR Procedure

A. Training of Self-Release Representatives ("SRR"):

A.1. The following guidelines shall be utilized by **Challenge Electronics'** Management to train prospective Honeywell **SRR** personnel on the requirements of performing product acceptance on behalf of Honeywell Engines, Systems and Services.

A.2. **Challenge Electronics'** Management shall perform periodic audits of Honeywell Self-Release activities to ensure continuous compliance to Honeywell requirements. At a minimum these audits will be conducted upon Honeywell flow-down change to ensure that all documentation and training is current.

A.3. **SRR**s shall be trained on the following criteria, (as a minimum).

- Supplemental Purchase Order Conditions (**SPOC**s) Section 1.0 thru 3.0 of the **SPOC** Manual and **SPOC**s 100, 106, 124, 127, 128, 129, 130, 140, 142, 149, 154, 165, 200, 239, 267, 354, 418, 419 and all others that apply.
- Be familiar with the **SPOC** Manual in order to locate and understand additional **SPOC**s that may be included on the purchase order.
- Have knowledge as to where in **Challenge Electronics'** system the **SPOC** requirements are addressed.
- Be capable of working to SRR work Instructions provided in this document.
- Products are packaged to protect from damage and corrosion in storage and during transport

B. Responsibility:

B.1. **Challenge Electronics'** Management Responsibilities:

- Maintain a Quality System
- Maintain an acceptable performance level that assures **Challenge Electronics'** remains eligible for Self-Release.
- Respond to any Honeywell corrective action requests by the required due date using Root Cause Corrective Action process **(8D-CAR).**
- Perform and Document all training that Self-Release Representatives require to enable them to successfully accomplish their responsibilities.
- Assure that all inspection/**SRR** personnel have received eye exams that meet **Honeywell SPOC** manual requirements.
- Inspect Inventory to verify products is storage are still within the shelve life of the product
- Provide refresher training to all inspection/**SRR** personnel when Honeywell requirements are changed and as necessary to ensure compliance with contract and Self-Release requirements.
- Provide Honeywell representatives access to supplier's facilities and documentation to conduct periodic Self-Release audits.

B.2. **SRR Responsibilities**

- Self Release Representatives shall be knowledgeable with **HW SPOC** Manual requirements.
- Fully review **HW** purchase order and **SPOC** requirements.
- Review drawings and other required specifications and documents.
- Review the production router/traveler for completion of all operations.
- Perform the following product/documentation review:
- Verify certifications are per **SPOC140** to assure that all required processes were performed to correct specifications and revisions.
- Assure Honeywell approved **FAIR** is on file to the applicable **PO**/contract requirement and Honeywell Quality has approved it.
- Verify a detailed Inspection plan exists for compliance to **SPOC 128.**
- Verify Fixed and/or Flight Safety Approval is on file and current.
- Visually inspect parts for damage and correct park marking per blueprint and **SPOC 200**.
- If parts are on **MRB** acceptance forms, ensure proper compliance to **SPOC 100.**
- Assure copies of Statistical Process Control data is included with the shipment per **SPOC 154** requirements.
- Assure copies of required traceability forms and bar codes labels are included with the shipment.
- Verify Functional Test data sheets are included with the shipment as per **SPOC 129.**
- Verify packaging conforms to **SPOC 239**.

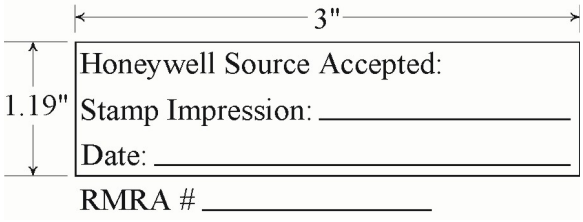
C. Procedure:

Challenge's Quality personnel whom are authorized to conduct Honeywell Self Release activities are listed on **Challenge Electronics'** Form **SA-052-SR PERSONAL**.

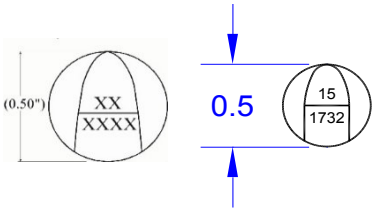
C.1. **After** Challenge's Final Inspection is completed Honeywell Form **TAS-HIA-028**, the Product Release Checklist is used to document the Honeywell Self Release for each product and/or lot and serves as documented objective evidence of compliance.
After completing the Product Release Checklist and all applicable items are noted as acceptable the **Honeywell Self Release Log**, **Challenge Electronics'** Form **SA-052-SR LOG** is to be completed by the individual that completed the **Honeywell Product Release Checklist** documenting the Self Release.

- Products are packaged to protect from damage and corrosion in storage and during transport
- Honeywell Self Release Log shall contain the following data:
- **PN,** Part Number
- Revision Number
- **PO**
- **Line Item**
- **Name of Self-Release Representative**
- **Signature of Inspector**
- **Da**te

C.2. Upon acceptance the authorized Self Release Representative will apply the following stamp on the Packing Slip (Honeywell Source Accepted) then sign/stamp and date



C.3. The following Honeywell "A" stamp is applied to all other documents including **C of C**'s Serialization Lists, test/supporting documentation, etc…., which is required per the **PO**. Below is an example of the "A" stamp. Supplier Code No **151732**. The Supplier Code/Vendor Code is to be placed where X's are shown. Leading zeros are not to be used. The supplier code is usually 5 or 6 digits not counting the leading zeros. If you do not know our Honeywell supplier codes please refer to the Honeywell purchase orders. They are listed adjacent to our company name on the face of the **PO**.
CAUTION - If we are shipping to more than one Honeywell site we may need more than one "A" stamp. Verify the stamp being used for the self release has the supplier code which matches the applicable **PO**.



D. Shipping Process

D.1. Daily, pending orders are followed-up in **Challenge Electronics'** computer sales accounting system and are released to shipping department
D.2. Shipping **SRR** pulls inventory from wheelhouse for shipping based on **FIFO**
D.3. Inspect Inventory to verify products is storage are still within the shelve life of the product
D.4. Products are packaged to protect from damage and corrosion in storage and during transport
D.5. **SRR** reviews that shipping instructions are followed
D.6. Special **HW** labels are added to the packaging
D.7. Shipping Box is checked that all required documentations are included (**C of C, C of O,** etc)
D.8. Prior to closing the shipment **ASM/SRR** is asked to inspect the shipment.
D.9. Master carton is labeled with **HW PO** number, Manufacture PN, Honeywell **PN / R**, and Quantity
D.10. **SRR** Stamps the Box with:
D.11. Honeywell Source Accepted Stamp
D.12. A Stamp
D.13. **SRR** Signs and date the lines inside the Honeywell Source Stamp.

D.14. Orders shipped UPS Ground or FedEx Standard Overnight per **HW** instructions.

D.15. **SRR** completes ***Form SA-052-SR LOG***.

D.16. **ASM** notifies **HW** buyer/planer of the shipment and sends the following information:

- **HW PO**
- **HW PN**
- Quantity
- Number of shipping boxes
- Shipping Method
- Tracking Number

E. Billing Process

After shipment is made

E.1. Shipping documents are sent to accounting department

E.2. Invoice is prepared per customer instructions

- Billing address
- **PO**
- **HW PN**
- Description
- Quantity
- Shipping date
- Shipping method
- Packing slip number
- Number of invoices required