Esterline
Control & Communication Systems

46902 Rev D
December 5, 2016

QUALITY MANUAL

FOR

KORRY ELECTRONICS CO.

Prepared by:
Esterline Control Systems - Korry Electronics Co.
11910 Beverly Park Road
Everett, WA 98204
http://www.korry.com
CAGE 81590

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It does not contain technical data as defined in 15 CFR 772 or 22 CFR 120.10.
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RECORD OF REVIEW AND HISTORY

REV	DESCRIPTION	APPROVED	
		DATE	BY
-	New Release. Supersedes Korry Electronics Company's AS9100 Quality Manual, PO910000 Rev. 12/19/2012. Per ECO0118315.	2013-03-25	JHL
A	Updated sections 2.3, 6.2.2, 7.5.1.4, 7.5.5 to reference current documentation numbers. Figure 1 and 2 were updated. Per ECO0120039.	2014-01-29	JHL
B	Updated sections 1.2, 2.3, 3.5 and 7. Reference ECO0129027	2015-01-15	JHL
C	Updated section 5.6.2. Per ECO0131576.	2015-03-04	JHL
D	Updated section 1.2, 2.3, 5.1, 5.3, 7.4.3. Per ECO0140521.	2016-12-05	JHL

See separate ECO for revision approvals.

Initiated by Lada Hekala, Lead Auditor Quality Assurance 2013-01-11

See separate release record for release approvals.

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1. INTRODUCTION

1.1 Scope

This Quality Manual meets the requirements of the Aerospace Standard (AS) AS9100C, "Quality Management Systems – Requirements for Aviation, Space and Defense Organizations". This manual is a top level document. Korry's QMS supports the Design, Manufacture, and Repair of Electro-Optical, Control and Display Systems and Components for the Aerospace/Defense Markets.

1.2 Organization

Korry's Organizational Chart is shown on Figure 1 below.

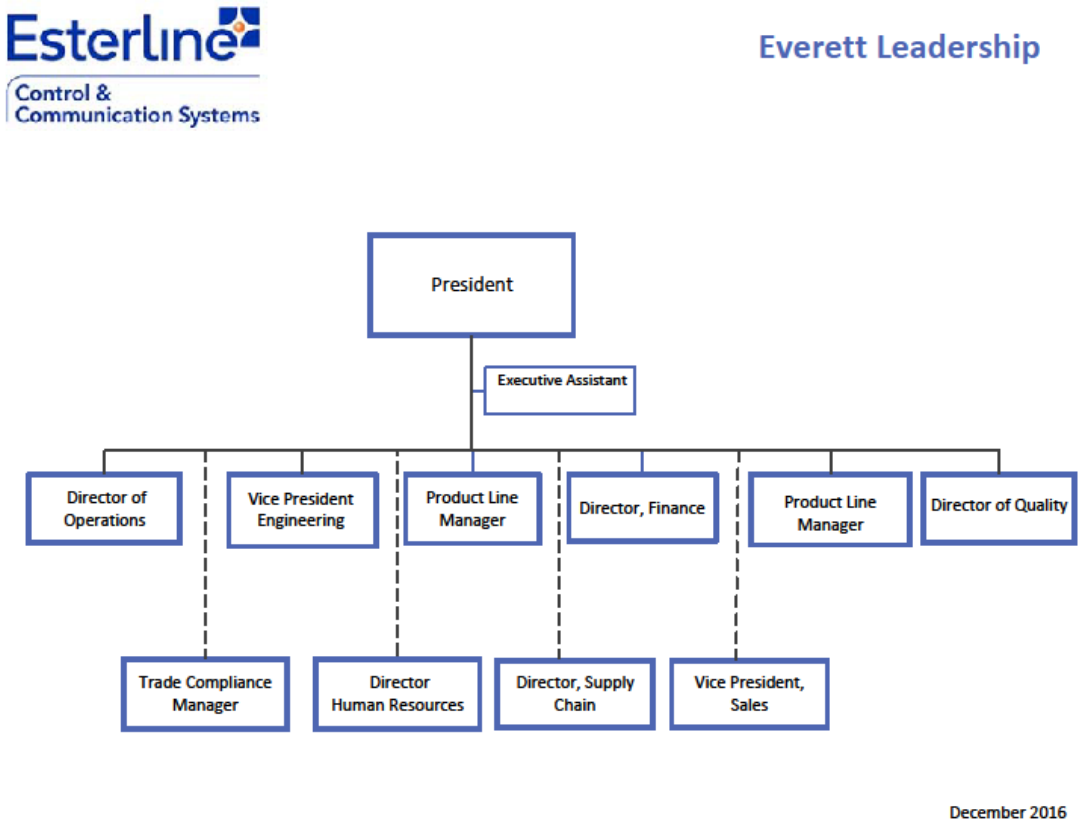

Figure 1 Korry Electronics Organization Structure

1.3 Responsibilities

The Quality Director or designee maintains this Quality Manual and is responsible for the implementation of the requirements of this document.

2. APPLICABLE DOCUMENTS

2.1 Government Documents

14 CFR Part 21	Certification Procedure for Product and Parts
14 CFR Part 45	Identification and Registration Marking
MIL-STD-973	Configuration Management
MIL-STD-480	Configuration Control – Engineering Changes, Deviations, and Waivers
MIL-PRF-22885	Performance Specification: Switches, Push Button, Illuminated, General Specification For
FAA Order 8110.42A	Parts Manufacturer Approval Procedures
FAA 8150.1B	Technical Standard Order Program

2.2 Non-Government Documents

The following documents form a part of this document to the extent specified herein.

INTERNATIONAL STANDARDIZATION AGREEMENTS

AS9100C	Quality Management Systems - Requirements for Aviation, Space and Defense Organizations
AS9115:2010	Requirements for Aviation, Space and Defense Organizations – Deliverable Software.
AS9102B	(R) Aerospace First Article Inspection Requirement
EIA-649-B	Configuration Management Standard
ISO 10007	Guidelines for Configuration Management
ISO 19011	Guidelines for Auditing Management Systems

2.3 Other Documents, Drawings, and Publications

KORRY ELECTRONICS CO.

-	Safety Policies and Plan
-	Chemical Hazard Communication Plan
33524-001	Subcontractor Assembly Facility Requirements Flow-Down per Electronic Component Management Plan
33924	Standard Configuration Management Plan
35524	Electronic Component Management Plan (ECMP)
38396	Standard Software Configuration Management Plan (SCMP)

41247	Lead Free Control Plan (LFCP)
47041	Red Label Process (RL)
48054	Obsolescence Management Plan (OMP)
48055	Counterfeit Parts Control Plan (CPCP)
49620	Enterprise Change Order (ECO) Process
49628	Record Control Plan
49629	Non Conforming Material Procedure
49631	Corrective Action Procedure
49632	Preventive Action Procedure
49640	Continuous Improvement Plan
49682	Audits Procedure
49705	Configuration Information Notice (CIN) Process
KWS03	Korry Workmanship Standard - Electronic Assembly and Soldering
49926	Foreign Object Debris (FOD) Prevention
MP151	Manufacturing Process - Welding
MP237	Manufacturing Process - Laser Welding
49887	FAA Repair Station Manual
49901	European Aviation Safety Agency (EASA) Supplemental Reference to FAA FAR-145
49817	FAA Repair Station Training Program
50274	ESD Handling Procedure
50350	Receiving Inspection procedure
51166	Product Development Process
51759	Work Transfer Process For Buy To Buy Transfers
51760	Training Process
PO700001	PMA and TSO Quality Manual

2.4 Order of Precedence

In the event of a conflict between this document and the references cited herein, this document takes precedence.

3. TERMS AND DEFINITIONS

For the purposes of this Quality Manual, the terms and definitions given in ISO 9000 apply.

Throughout the text of this Quality Manual, wherever the term “product” occurs, it can also mean “service”.

3.1 Risk

An undesirable situation or circumstance that has both a likelihood of occurring and a potentially negative consequence.

3.2 Special Requirements

Those requirements identified by the customer, or determined by the organization, which have high risks to being achieved, thus requiring their inclusion in the risk management process. Factors used in the determination of special requirements include product or process complexity, past experience and product or process maturity. Examples of special requirements include performance requirements imposed by the customer that are at the limit of the industry’s capability, or requirements determined by the organization to be at the limit of its technical or process capabilities.

3.3 Critical Items

Those items (e.g., functions, parts, software, characteristics, processes) having significant effect on the product realization and use of the product; including safety, performance, form, fit, function, producibility, service life, etc.; that require specific actions to ensure they are adequately managed. Examples of critical items include safety critical items, fracture critical items, mission critical items, key characteristics, etc.

3.4 Key Characteristic

An attribute or feature whose variation has a significant effect on product fit, form, function, performance, service life or producibility, that requires specific actions for the purpose of controlling variation.

NOTE: Special requirements and critical items are new terms and, along with key characteristics, are interrelated. Special requirements are identified when determining and reviewing requirements related to the product (see 7.2.1 and 7.2.2). Special requirements can require the identification of critical items. Design output (see 7.3.3) can include identification of critical items that require specific actions to ensure they are adequately managed. Some critical items will be further classified as key characteristics because their variation needs to be controlled.

3.5 Product Lifecycle Management (PLM)

Korry's PLM tool is ARAS Innovator which is used to manage the entire lifecycle of a product from its conception, through design and manufacture, to service and disposal. PLM integrates people, data, processes and business systems and provides a product information backbone for company and Korry's extended enterprise.

4. QUALITY MANAGEMENT SYSTEM

4.1 General Requirements

Korry Electronics Co. (Korry further through this document) established, documented, implemented, and maintains a Quality Management System, and continually improves its effectiveness in accordance with the requirements of AS9100C.

Korry:

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 identified in the Korry Quality Model, Figure 2.
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 where applicable, and analyzes these processes, and
f) implements actions necessary to achieve planned results and continual improvement of these processes.

These processes are managed by Korry in accordance with the requirements of AS9100C.

Figure 2 Korry Quality Model

Note: Figure 2 is only the sample. Actual Quality Model located on Korry's intranet webpage.

Korry notifies customers and regulatory agencies about any significant process changes that could impact product quality or production schedule. These changes include, but are not limited to: facility changes, major changes to supply strategy including subcontracting, or significant change to the Quality Management System. Customers are notified three months in advance of the plan to make major process changes unless it is beyond the control of Korry.

Where Korry chooses to outsource any process that affects product conformity with requirements, Korry ensures control over such processes. The type and extend of

control to be applied to these outsourced processes is defined within the Quality Management System. Korry's only outsourced process is Calibration by SIMCO.

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 Korry needs for its Quality Management System and which Korry chooses to have performed by an external party.

NOTE 3: Ensuring control over outsourced processes does not absolve Korry of the responsibility of conformity to all customer, statutory, and regulatory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such as:

a) the potential impact of the outsourced process on Korry's capability to provide product that conforms to requirements,
b) the degree to which the control for the process is shared,
c) the capability of achieving the necessary control through the application of 7.4.

4.2 Documentation Requirements

4.2.1 General

The Quality Management System documentation includes:

a) documented statements of quality policy and quality objectives,
b) a quality manual,
c) documented procedures and records required by AS9100C,
d) documents, including records, determined by Korry to be necessary to ensure the effective planning, operation, and control of its processes.

Korry ensures that personnel have access to Quality Management System documentation and are aware of relevant Quality Management System documentation and changes. Korry's QMS is on-line. All departments have computer terminals that provide all personnel access. Customers and/or regulatory authorities may also access Korry Quality Management System documentation.

NOTE 1: Where the term "document procedure" appears within this Quality Manual, this means that the procedure is established, documented, implemented, and maintained. A single document may address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.

NOTE 2: The documentation can be in any form or type of medium.

4.2.2 Quality Manual

The Korry Quality Model shows the interactions between processes. Korry established and maintains a quality manual that includes:

a) the scope of the Quality Management System with no exclusions to Section 7,
b) the documented procedures established for the Quality Management System, and
c) a description of the interaction between the processes of the Quality Management System.

Korry's Quality Manual and Record Control Plan is located and controlled with the PLM system.

4.2.3 Control of Documents

Documents required by the Quality Management System are controlled. Records are a special type of document and are controlled according to the requirements given in 4.2.4.

The Korry Standard Configuration Management Plan 33924 is a documented procedure established to define the controls needed

a) to approve documents for adequacy prior to issue,
b) to review and update as necessary and re-approve documents,
c) to ensure that changes and the current revision status of documents are identified,
d) to ensure that relevant versions of applicable documents are available at points of use,
e) to ensure that documents remain legible and readily identifiable,
f) to ensure that documents of external origin determined by Korry to be necessary for the planning and operation of the Quality Management System are identified and their distribution controlled, and
g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

Korry coordinates document changes with customers and/or regulatory authorities in accordance with contract, regulatory and statutory requirements.

4.2.4 Control of Records

Records established to provide evidence of conformity to requirements and of the effective operation of the Quality Management System are controlled.

The Record Control Plan 49628 is a documented procedure established to define the controls needed for the identification, storage, protection, retrieval, retention time, and disposition of records. The plan ensures records remains legible, readily identifiable and retrievable. This documented procedure also defines the method for controlling records that are created by and/or retained by suppliers.

Records are available for review by customers and regulatory authorities in accordance with contract, regulatory and statutory requirements.

5. MANAGEMENT RESPONSIBILITY

5.1 Management Commitment

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 the organization the importance of meeting customer as well as statutory and regulatory requirements,

Korry's top management communicates to the organization through support and compliance to the Quality Management System documentation, training and company correspondence and meetings.

b) Establishing the quality policy,

Korry's Quality Policy is established and documented in this Quality Manual, section 5.3.

c) Ensuring that quality objectives are established,

Top management ensures the quality objectives are established annually through Korry's internal Macro Plan. Korry's Quality Objectives are established per fiscal year and are cascaded to each department and employees. Quality Objectives are measured through charts by each department and the progress is posted in the work centers.

d) Conducting management reviews,

Top management conducts at least annually Quality Management System review meetings per section 5.6 of this Quality Manual.

e) And ensuring the availability of resources.

Management ensures the availability of resources during the budget process and makes changes throughout the year as business demands change. Korry's management team evaluates resource needs and initiates resource planning to maintain and continually improve the Quality Management System effectiveness. This is done annually during budget planning and when needed throughout the fiscal year as customer, business, and forecast demands change. The Human Resource department maintains Korry's staffing report.

Evidence of Management commitment can be found throughout the company. Specific department goals and progress is posted in the work centers. The company wide Macro Plan goals and results are presented at monthly management business review meetings. Continuous improvement and Lean project results can be observed throughout the company and Quality Management System improvements are in the revision history records.

5.2 Customer Focus

Top management ensures that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1). Customer related processes are reviewed prior to contract acceptance.

Korry measures and monitors customer satisfaction through customer score cards, surveys, audit results, and corrective actions. Top management ensures that product conformity and on-time delivery performance is measured and that appropriate action is taken if planned results are not, or will not, be achieved.

5.3 Quality Policy

Korry Quality Policy:

"It is our goal as one Esterline team to meet our customer and regulatory requirements, to continuously improve our effectiveness for delivering on time in full while never compromising on the quality of our goods and services.".

Top management ensures that the Quality Policy:

a) is appropriate to the purpose of the organization,
b) includes a commitment to comply with requirements and continually improve the effectiveness of the Quality Management System,
c) provides a framework for establishing and reviewing quality objectives,
d) is communicated and understood within the organization,
e) and is reviewed for continuing suitability.

The Quality Policy is posted in prominent locations within the facility and on the company intranet. The Policy is reviewed during new hire QMS overview training and is reviewed annually by the Director of Quality for continuing suitability.

5.4 Planning

5.4.1 Quality Objectives

Top management ensures that quality objectives, including those needed to meet requirements for product (see 7.1 a), are established at relevant functions and levels within the organization. The quality objectives are measurable and consistent with the quality policy.

Top Management establishes the quality objectives through the Macro Plan strategic planning process annually. Product quality is measured by Defective Parts per Million (DPPM) and On-Time Delivery (OTD) by the operations department and is reported during monthly management business review meetings.

5.4.2 Quality Management System Planning

Top management ensures that:

a) the planning of the Quality Management System is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and
b) the integrity of the Quality Management System is maintained when changes to the Quality Management System are planned and implemented.

5.5 Responsibility, Authority, and Communication

5.5.1 Responsibility and Authority

Top management ensures that responsibilities and authorities are defined and communicated within the organization. Korry's Organization Chart in Section 1.2 identifies the responsibility and authority.

5.5.2 Management Representative

Top management has appointed a Director of Quality as the Management Representative; who, irrespective of other responsibilities, has 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 customer requirements throughout the organization, and
d) the organizational freedom and unrestricted access to top management to resolve quality management issues.

NOTE: The responsibility of a management representative can include liaison with external parties on matters relating to the Quality Management System.

Director of Quality and appointed quality staff has the organizational freedom and encourages all employees to identify and to resolve matters pertaining to quality.

5.5.3 Internal Communication

Top management ensures that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the Quality Management System.

5.6 Management Review

5.6.1 General

Top management reviews the Korry's Quality Management System at least annually to ensure its continuing suitability, adequacy, and effectiveness. This review includes assessing opportunities for improvement and the need for changes to the Quality Management System, including the quality policy and quality objectives.

Records from management reviews are maintained (see 4.2.4).

Quality Management System Review (QMSR) meeting records (agenda, power point presentation, minutes) are kept on file.

5.6.2 Review Input

The input to management review includes information on

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, and
g) recommendations for improvement including special consideration of In Service Agreements.

5.6.3 Review Output

The output from the management review includes any decisions and actions related to

a) improvement of the effectiveness of the Quality Management System and its processes,
b) improvement of product related to customer requirements, and
c) resource needs.

6. RESOURCE MANAGEMENT

6.1 Provision of Resources

Korry determines and provides the resources needed

a) to implement and maintain the Quality Management System and continually improve its effectiveness, and
b) to enhance customer satisfaction by meeting customer requirements.

Korry's management team evaluates resource needs and initiates resource planning to maintain and continually improve the QMS effectiveness. This is done annually during budget planning and when needed throughout the year as customer, business, and forecast demands change. The Human Resource department maintains Korry's staffing report.

6.2 Human Resources

6.2.1 General

Personnel performing work affecting conformity to product requirements is competent on the basis of appropriate education, training, skills, and experience.

Korry's hiring requisition form provides the requirements of the experience and/or education required for the position being filled.

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

Korry does

a) determine the necessary competence for personnel performing work affecting conformity to product requirements,

   Jobs affecting product quality are determined and based on the job responsibility, regulations, customer requirements and company training policies.

b) where applicable, provide training or take other actions to achieve the necessary competence,

   Needed training is provided by Korry supervisors, process owners, manufacturing engineers, customers, or accredited training experts depending on the job function to be performed and the required training for the specific tasks.

c) evaluate the effectiveness of the actions taken,

   The effectiveness of the training done can be evaluated by observation and mentoring of work done by the trainer, manager or supervisor or designee.

When required, a written or verbal test can be given. Annual employee performance evaluation is performed by manager or supervisor.

d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives,

All employees performing work that affects product quality is scheduled for Quality Management System training within the first 90 days of hire.

e) maintain appropriate records of education, training, skills and experience (see 4.2.4).

Records and training schedules are kept in Human Resources Information System (HRIS) database per D51760 Training Process.

FAA Repair Station Training Program 49817defines the provisions made within Korry to determine training responsibilities, identify training requirements, and provide training to all personnel performing work that affects quality in accordance with the Korry Electronics Repair Station operations under the Korry Electronics Repair Station certificate #KE7R393J.

6.3 Infrastructure

Korry 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), and
c) supporting services (such as transport, communication or information systems).

6.4 Work Environment

Korry determines and manages the work environment needed to achieve conformity to product requirements.
Korry uses 5S process thru the organization for the continual improvement.

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).

7. PRODUCT REALIZATION

The essential steps in product realization from planning through design and development are shown in Figure 3.

Figure 3 Product Realization Process

Depending on the scope of a product's development, individual project plans may be created to that vary in scope or complexity. Section 7.3.1 of this Quality Manual provides more detail.

7.1 Planning of Product Realization

Korry plans and develops the processes needed for product realization. Planning of product realization is consistent with the requirements of the other processes of the Quality Management System (see 4.1).

Korry maintains standard plans and processes for product realization in its Product Development Process (PDP). These may be tailored for individual programs provided that the plans remain consistent with this Quality Management System. Standard methods for product realization include full-scale development, which utilizes the PDP process, and configured products (configurables), which utilize the Engineering Service Request (ESR) process.

In planning product realization, Korry determines the following, as appropriate:

a) quality objectives and requirement for the product,

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

- product and personal safety
- reliability, availability and maintainability,
- producibility and inspectability,
- suitability of parts and materials used in the product,
- selection and development of embedded software, and
- recycling or final disposal of the product at the end of its life.

b) the need to establish processes and documents, and to provide resources specific to the product,

c) required verification, validation, monitoring, measurement, 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 (see 4.2.4);
e) configuration management appropriate to the product;
f) resources to support the use and maintenance of the product.

The output of this planning is in a form suitable for Korry's method of operations.

NOTE: 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.

NOTE: Korry may also apply the requirements given in 7.3 to the development of product realization processes.

7.1.1 Project Management

Korry plans and manages product realization in a structured and controlled manner to meet requirements at acceptable risk, within resource and schedule constraints.

Program Management is responsible for the planning and execution of new development programs and works closely with the teams to ensure all program milestones are scheduled and documented as appropriate to the project.

Template documents for standard plans are maintained within the PDP for full-scale developments. For configurable products the standards and plans are maintained within the ESR process. Product realizations plans are maintained as defined by their respective development process (full-scale vs configurable)

7.1.2 Risk Management

Korry maintains a process for managing risk to the achievement of applicable requirements, that includes as appropriate to the organization and the product

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, and
e) acceptance of risks remaining after implementation of mitigating actions.

Risk to the achievement of applicable requirements are managed throughout the product realization. These activities are documented as defined products respective development process (full-scale vs configurable).

7.1.3 Configuration Management

Korry maintains a configuration management process that includes, as appropriate to the product

a) configuration management planning,
b) configuration identification,
c) change control,
d) configuration status accounting, and
e) configuration audit.

Korry's Configuration Management processes are detailed within Korry's standard configuration plans:

- Configuration Management Plan (CMP) 33924.
- Standard Software Configuration Management Plan (SCMP) 38396,
- Configuration Information Notice (CIN) Process 49705
- Enterprise Change Order Process 49620
- When applicable the Red Label Process 47041.

If required project-specific configuration management plans are maybe used for programs involving DO-178B software development, DO-254 programmable hardware development, or ARP4754 system/equipment development.

NOTE: Guidance on configuration management is given in ISO 10007 Quality Management – Guidelines for Configuration Management.

Electronic component management is detailed within Korry standard electrical component plans:

- Electronic Component Management Plan (ECMP) 35524.
- Obsolescence Management Plan (OMP) 48054.
- Lead Free Control Plan (LFCP) 41247,
- Counterfeit Parts Control Plan (CPCP) 48055.

7.1.4 Control of Work Transfers

Korry maintains a process to plan and control the temporary or permanent transfer of work (e.g., from one organization facility to another, from the organization to a supplier,

from one supplier to another supplier) and verifies the conformity of the work to requirements.

Temporary or permanent work transfers between facilities, suppliers, or between suppliers are planned and controlled by processes implemented and maintained in concert with Supply Chain Management, Material Planning and Engineering per 51759 Work Transfer Process For Buy To Buy Transfers.

7.2 Customer Related Processes

7.2.1 Determination of Requirements Related to Product

Korry determines:

a) requirements specified by the customer, including 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 related to the product, and
d) any additional requirements determined by the organization.

NOTE: Requirements related to the product can include special requirements.

NOTE: Post-delivery activities include, for example, actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

7.2.2 Review of Requirements Related to Product

Korry reviews the requirements related to the product. This review is conducted prior to Korry's commitment to supply a product to the customer (e.g., submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and ensures that:

a) product requirements are defined,
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, and
e) risks (e.g., new technology, short delivery time frame) have been identified (see 7.1.2).

Records of the results of the review and actions arising from the review are maintained (see 4.2.4).

Product requirements are reviewed and document per the individual product respective development process (full-scale vs configurable).

Contracts and Customer Purchase Orders are reviewed using Korry standard processes.

- Contract Review Process
- Terms and Conditions Review Guidelines
- CustomerPurchase Orders are accepted per Korry's Booking Guidelines. and documented using the PO/Contract Checklist and/or the Terms Review Matrix.
- A Configuration Information Notice is created to document and flow down contract requirements.

Requirements affecting departments per the Terms and Conditions Guideline Matrix, Purchase Order Checklist, and/or Returns Checklist are disseminated for review. Sales Order Acknowledgement is created and forwarded to customers.

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

Where product requirements are changed, Korry ensures that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

NOTE: In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.

7.2.3 Customer Communication

Korry maintains effective communication with customers in relation to:

a) product information,
b) inquiries, contracts or order handling, including amendments, and
c) customer feedback, including customer complaints.

7.3 Design and Development

7.3.1 Design and Development Planning

Korry plans and controls the design and development of product per 51166 Product Development Process. During design and development planning or design team determines:

a. The design and development stages,
b. The review, verification, and validation, appropriate to each design and development stage.
c. The responsibilities and authorities for design and development.

Where appropriate, Korry divides the design and development effort into distinct activities and, for each activity, defines the tasks, necessary resources, responsibilities, design content, input and output data and planning constraints.

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

Design and development planning shall consider the ability to produce, inspect, test and maintain the product.

Korry manages the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output is updated, as appropriate, as the design and development progresses.

NOTE: Design and development review, verification and validation have distinct purposes. They can be conducted and recorded separately or in combination as suitable for the product and the organization.

Design and development tasks are based on the safety and functional objectives for the product in accordance with the customer, statutory, and regulatory requirements. Planning and development considers the ability to produce, inspect, test, and maintain the product. Development plans are maintained and updated as needed throughout the design and development process.

Where appropriate, due to complexity, planning gives consideration to the following activities:

a) Structuring the design effort into significant elements; and
b) For each element, analyzing the tasks and the necessary resources for design and development. This analysis does consider 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.

Interfaces between different groups are managed through design team staffing plan. For full-scale development, project engineers have authority to assign responsibility within the project team. For configurables, responsibilities are systematized and documented in the team's procedures.

Planning output is updated by the project team or project team leadership, as appropriate, as the design and development progresses. This is seldom necessary for configurables.

7.3.2 Design and Development Inputs

Inputs relating to product requirements are determined and records maintained (see 4.2.4). These inputs includes:

a) functional and performance requirements,
b) applicable statutory and regulatory requirements,
c) where applicable, information derived from previous similar designs, and
d) other requirements essential for design and development.

These inputs are reviewed for adequacy. Requirements are complete, unambiguous, and not in conflict with each other. In some cases a trade-off study may be a planned task.

Template documents supporting requirements capture are defined in the PDP.. For full-scale development requirements are captured as defined in the PDP. For configurables, captured requirements are documented per work cell procedures.

7.3.3 Design and Development Outputs

The outputs of design and development are provided in a form suitable for verification against the design and development input and are approved prior to release.

Design and development outputs:

a) meet the input requirements for design and development,
b) provide appropriate information for purchasing, production and for service provision,
c) contain or reference product acceptance criteria,
d) specify the characteristics of the product that are essential for its safe and proper use, and
e) specify, as applicable, any critical items, including key characteristics, and specific actions to be taken for these items.

Korry defines the data required to allow the product to be identified, manufactured, inspected, used, and maintained; including:

a) the drawings, parts lists and specifications necessary to define the configuration and design features of the product, and
b) the material, processes, manufacturing and assembly data needed to ensure conformity of the product.

The PDP defines common design outputs for Korry programs. For configurables, design outputs are standardized and described in work cell procedures.

NOTE: Information for production and service provision can include details for the preservation of product.

7.3.4 Design and Development Review

At suitable stages, systematic reviews of design and development are performed in accordance with planned arrangements (see 7.3.1)

a) to evaluate the ability of the results of design and development to meet requirements,
b) to identify any problems and propose necessary actions, and
c) to authorize progression to the next stage.

Participants in such reviews include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions are maintained (see 4.2.4) in project folders, project data vault, or project server, depending on the need of the program; or per work cell procedures.

7.3.5 Design and Development Verification

Verification is performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions are maintained (see 4.2.4).

Verification records are created and maintained as defined per the PDP.

7.3.6 Design and Development Validation

Design and development validation is performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation is completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions are maintained (see 4.2.4).

Verification records are created and maintained as defined per the PDP.

7.3.6.1 Design and 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 products 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 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.

Verification and validation test plans and procedures are created and maintained as defined per the PDP..

7.3.6.2 Design and Development Verification Documentation

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

Verification and validation documentation is created and maintained as defined per the PDP..

7.3.7 Control of Design and Development Changes

Design and development changes are identified and records maintained. The changes are reviewed, verified and validated, as appropriate and approved before implementation. The review of design and development changes includes evaluation of the effect of the changes on the constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions are maintained (see 4.2.4).

Design and development changes are controlled in accordance with the configuration management process (see 7.1.3).

7.4 Purchasing

7.4.1 Purchasing Process

Korry ensures that purchased product conforms 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.

Korry is responsible for the conformity of all products purchased from suppliers, including product from sources defined by the customer.

Korry evaluates and selects suppliers based on their ability to supply product in accordance with Korry's requirements. Criteria for selection, evaluation, and re-evaluation are established. Records of the results of evaluations and any necessary actions arising from the evaluation are maintained (see 4.2.4).

NOTE: One factor that can be used during supplier selection and evaluation is supplier quality data from objective and reliable external sources, as evaluated by the organization (e.g., information from accredited Quality Management System or process certification bodies, organization approvals form government

authorities). Use of such data would be only one component of Korry's supplier control process and Korry remains responsible for verifying that purchased product meets specified purchase requirements.

Korry:

a) maintains a register of its suppliers that includes approval status (e.g., approved, conditional, disapproved) and the scope of the approval (e.g., product type, process family);

Supplier Quality Engineering (SQE) approves and maintains the Approved Supplier List (ASL). Suppliers are evaluated based on their technical expertise needed and the commodity type of product the supplier may provide Korry. Supplier Quality Engineering uses the supplier audit process for determining supplier capability and designates the scope of commodity approval a supplier may receive. Once a supplier is approved the designated approval type is coded and updated in e-CADR. In addition to the ASL, the buyers use ERP System to review the current Approval Code for each potential source.

b) periodically reviews supplier performance; the results of these reviews are used as a basis for establishing the levels of controls to be implemented;

Supplier Quality Engineering reviews supplier performance periodically. Korry tracks supplier performance through the supplier report cards database. The Suppliers are also evaluated through periodic audits as scheduled or as needed to evaluate performance issues.

c) defines the necessary actions to take when dealing with suppliers that do not meet requirements;

The SQE may issue Notifications, Corrective Actions or perform an On-Site Audit for non-performing suppliers.

d) ensures where required that both Korry and all suppliers use customer-approved special process sources;

The Bill of Materials (BOM) and item master, generated by Engineering and maintained by Document Control defines all required "source controlled processes" and "source controlled suppliers". The Buyer uses this information when identifying source of supply. Q-notes are added to each order indicating any specially identified requirements.

e) defines the process, responsibilities and authority for the approval status decision, changes of the approval status and conditions for a controlled use of suppliers depending on the supplier's approval status, and

The SQE has the authority to disapprove a supplier.

f) determines and manages the risk when selecting and using suppliers (see 7.1.2).

7.4.2 Purchasing Information

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

a) requirements for approval of product, procedures, processes and equipment,

Current configuration of product is defined through part Item Masters for each item. The part item master lists all the required parts and documents i.e. drawing, work instructions, test procedures and parts or material specifications. The purchase order (PO) lists the current part configuration as defined in the ERP system at the time of its creation. When required by changes in configuration, the part revision on the PO is updated and communicated to the supplier. Quality attachments are added to the PO for any special quality requirements such as First Article Inspections, Source Inspections, test data etc.

b) requirements for qualification of personnel,

Within a parts configuration would be any specifics related to special processes, supplier controls, or special equipment. These would be confirmed as part of the Buyer/SQE reviews prior to PO placement.

c) Quality Management System requirements,

Each production PO contains paragraph Q1, requiring maintenance of the supplier's approved quality system.

d) the identification and revision status of specifications, drawings, process requirements, inspection/verification instructions and other relevant technical data,

Suppliers receive all the required specifications with the item's design package depending on the commodity type of product being purchased. Each item is identified using an Item Master within the PLM system. The Item Master may include a Bill of Material required to manufacture the part, if not, the requirements are indicated in the items documentation. The Item Master also contains all drawings, specifications, and any relevant technical information needed to manufacture the item. If required, the item drawing defines all required "source controlled processes" and/or "source controlled suppliers".

e) requirements for design, test, inspection, verification (including production process verification), use of statistical techniques for product acceptance, and related instructions for acceptance by Korry, and as applicable critical items including key characteristics,

Suppliers are provided a configuration controlled design package, the package includes the Item Master, BOM, and Documents defined by the Item Master of the item. The design package contains any required acceptance test procedures

(ATP) or test plans. Additional specific quality requirements are added to the PO with Q notes when required and dependent of the commodity type. The Buyer confirms the item revision on the PO and the SQE reviews and approves the completeness of the PO prior to issuance to the supplier.

f) requirements for test specimens (e.g., production method, number, storage condition) for design approval, inspection/verification, investigation or auditing,

The Buyer confirms the BOM revision on the PO and the SQE reviews and approves the completeness of the PO prior to issuance to the supplier.

g) requirements regarding the need for the supplier to
- notify Korry of nonconforming product,
- obtain Korry approval for nonconforming product disposition,
- notify Korry of changes in product and/or process, changes of suppliers, changes of manufacturing facility location and, where required, obtain Korry approval, and
- flow down to the supply chain the applicable requirements including customer requirements,

Each PO includes quality attachments with paragraph Q2, Report of Discrepancy being required for all Production Purchase Orders. Korry uses Korry's standard MRB review system for review and disposition of nonconforming materials. Nonconforming material is managed and arranged per Korry's Non Conforming Material Procedure 49629 and Corrective Action Procedure 49631.

h) records retention requirements, and

Korry's terms and conditions, (PO Terms and Conditions), which are required for all Purchase Orders to notify the buyer and obtain written approval, prior to any changes in materials. Each PO includes quality attachments with paragraph Q1, Control of Quality being required for all Production Purchase Orders.

Korry considers any deviation to be a nonconformance which is managed per Non Conforming Material Procedure 49629.

i) right of access by Korry, their customer, and regulatory authorities to the applicable areas of all facilities, at any level of the supply chain, involved in the order and to all applicable records.

Each PO includes quality attachments with paragraph Q10 Right of Entry, being required for all Production Purchase Orders.

ECMP requirements flowed down per 33524-001 Subcontractor Assembly Facility Requirements Flow-Down per Electronic Component Management Plan.

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

7.4.3 Verification of Purchased Product

Korry establishes and implements the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements per D50350 Receiving Inspection.

Receiving Inspection inspects the parts/material to specifications identified on the PO, Item Master, BOM, item documentation, supplier C of C, required test data, etc. and verifies the current revision. If the item is compliant it receives a QC accept tag and is moved to its next location. If the item is not compliant, the part/material deficiency is documented on a Discrepancy Report and processes per Non Conforming Material Procedure 49629.
Some suppliers are eligible to become dock to stock (DTS) suppliers based on performance. DTS suppliers are issued source inspection QC stamps from Korry for Korry product. The suppliers perform the inspection per the inspection and test requirements provided in the design package. They stamp off the paperwork and add an accept tag or label to the parts prior to shipment.

NOTE: Customer verification activities performed at any level of the supply chain should not be used by the organization or the supplier as evidence of effective control of quality and does not absolve the organization of its responsibility to provide acceptance product and comply with all requirements.

NOTE: Verification activities can include:

a) obtaining objective evidence of the conformity of the product from supplier (e.g., accompanying documentation, certificate of conformity, test records, statistical records, process control records),

   Receiving Inspection, Inspects supplier records per the PO requirements, the supplier test data, FAI records, applicable Q notes the commodity type and the specific material specifications. When compliant the part receives an accept tag and is moved to stores. If not compliant, the part is moved to MRB for review.

b) inspection and audit at supplier's premises,

   Quality Engineering determines upon review of the PO whether source inspection is required (PO Review Process). If it is determined that source inspection is required, the QE imposes Source Inspection at Suppliers by adding it on the Purchase Order. The QE also has a planned audit schedule for suppliers.

c) review of the required documentation,

   Buyers review the Contract T's & C's, Quality requirement, FAIs, source inspections, quantities, product revision, material type, schedules and cost, Approved Supplier List, export and purchasing law requirements. Receiving

Inspection reviews the items documentation for acceptance during incoming inspection.

If not compliant, part/material deficiency is documented on a Discrepancy Report per section 8.3.

d) inspection of products upon receipt, and

e) delegation of verification to the supplier, or supplier certification.

Where purchased product is released for production use pending completion of all required verification activities, it shall be identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.

Where Korry delegates verification activities to the supplier, the requirements for delegation are defined and register of delegations maintained.

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

Korry plans and carries out production and service provision under controlled conditions. Controlled conditions do include, as applicable

a) the availability of information that describes the characteristics of the product,

The information that describes the characteristics of the product is provided through the Job Orders (JO). The JO package includes the customer order information, customer specific special instructions, the quantity and schedule, routing and a job Bill of Material (BOM). Supporting product definition information such as documents and instructions including the product drawing, Manufacturing Processes (MP), Assembly Instructions/Inspection record (AIR), General Test Procedure (GTP) or Acceptance Test Procedure (ATP) is accessed from the PLM system.

NOTE: This information can include drawings, parts lists, materials and process specifications.

b) the availability of work instructions, as necessary,

Work Instructions are provided in detailed documented procedures that include but are not limited to the Process routing, Manufacturing Processes (MP), Assembly Inspection Records (AIR) and Acceptance Test Procedures (ATP).

NOTE: Work instructions can include process flow charts, production documents (e.g., manufacturing plans, travelers, routers, work orders, process cards) and inspection documents.

c) the use of suitable equipment,

The required equipment is identified in the various work instructions such as routings, Manufacturing Processes (MP), Assembly Inspection Records (AIR) and Acceptance Test Procedures (ATP).

NOTE: Suitable equipment can include product specific tools (e.g., jigs, fixtures, molds) and software programs.

d) the availability and use of monitoring and measuring equipment,

The monitoring and measuring equipment are listed in the Acceptance Test Procedure (ATP).

e) the implementation of monitoring and measurement,

Monitoring and measuring are maintained through General Calibration Procedure for Measurement and Test Equipment 3.300.

f) the implementation of product release, delivery and post-delivery activities,

Job Orders are statused in stages by routing operation and inspection step completion. Evidence of Operation step completion is identified by Operator sign off and date. Evidence of QC acceptance and status is identified with a QC acceptance stamp impression placed on the job order next to the inspection step. Post Delivery is supported per section 7.5.1.4.

g) accountability for all product during production (e.g., parts quantities, split orders, nonconforming product),

Each item made or purchased is identified by a part number and a supporting order number. The order number is determined by the type of order. Types of orders are the job order, sales order and line item, purchase order and line item and/or a receiver number.

The order number is the unique lot number for the product or material and quantity on order. The configuration of the product on order is verified and listed on the order. All material/product is identified with a specific lot number, quantity, date code and part configuration which is all listed on the job order. Quality Acceptance is recorded on the job order and on the QC accept tags. Inventory transactions and procedures maintain the lot traceability throughout manufacturing. Any Nonconforming conditions are processed and recorded per Non Conforming Material Procedure 49629 and is recorded on the order and on a Rework or Discrepancy Report form which is also recorded on the job order. Job Order status is maintained in the material planning operating system by electronic transactions.

h) evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized,

Evidence is recorded on the Job Orders, routing step operation sign off and inspection step QC stamp buy-off. Also see 7.5.1 f)

i) provision for the prevention, detection, and removal of foreign objects,

Foreign Object Debris (FOD) Prevention 49926 procedure details the prevention, detection and the removal of foreign objects which all employees are trained to. Specific processes, such as the Cleanroom are also supported by MP248.

j) monitoring and control of utilities and supplies (e.g., water, compressed air, electricity and chemical products) to the extent they affect conformity to product requirements, and

Generally machines and equipment costing more than $2,000 are evaluated for preventive maintenance needs. Pieces requiring preventive maintenance are scheduled for cleaning, inspection, and routine servicing as required. Operators may perform minor maintenance tasks, Maintenance Technicians perform major tasks. All major tasks are documented in the Preventive Maintenance database. Specific Manufacturing Processes provide environmental and or utility instructions when needed.

k) criteria for workmanship, specified in the clearest practical way (e.g., written standards, representative samples, illustrations).

Korry Workmanship Standards (KWS), Manufacturing Processes (MP), Assembly Inspection Records (AIR), General Test Procedures GTP, and Acceptance Test Procedures (ATP) all provide the criteria for workmanship.

Planning does consider as appropriate,

- establishing, implementing and maintaining appropriate processes to manage critical items, including process controls where key characteristics have been identified,

The control of production and service provision is documented during the design & development of new program & design development phases.

Where possible, established processes are used. Process Control instructions are developed by Manufacturing Engineering or designee and are validated and approved for release. Once they are approved they are added to the applicable BOM or Department Process instructions and are revision and configuration controlled. Manufacturing Engineering uses different methods for creating process instructions:

Manufacturing Processes (MP) are written to support a specific process or special process instructions. If needed they can be referenced on an Item Master, on a Routing or in an Assembly Inspection / Instruction record (AIR) to provide process controls and specific controlled instructions that support the product build plan.

Assembly Inspection/Instruction Records (AIR) are created to provide specific step by step instructions to clearly show how to build a final or sub

assembly in easy to follow steps. The AIR defines the equipment and can include specified customer instructions and process verification steps. AIRs are referenced on the Item Master of the product. The AIR is the process instructions that are performed when an Assembly step is listed on a job order routing.

Key Characteristics can be flowed down from the customer or Engineering and can be set up and implemented by Manufacturing or Quality Engineering. When a Key Characteristic is required by the Customer or Korry Engineering it is added on the drawing with a key flag and is supported by a Key Characteristics Control Plan (KCCP). When it is implemented by ME or QE it may not be listed on the drawing but will have a supporting KCCP. When specified, Statistical Process Control (SPC) processes are developed to support the requirements.

- designing, manufacturing and using tooling to measure variable data,

The instructions list the tools and equipment to be used for the specific process. Equipment used to measure Key Characteristics is calibrated per General Calibration Procedure for Measurement and Test Equipment 3.300**.** Korry's Key Characteristics' plans are developed per Variation Reduction / Statistical Process Control (SPC) / Key Characteristic Control Plan (KCCP).

- identifying in-process inspection/verification points when adequate verification of conformance cannot be performed at a later stage of realization, and

The identification of in-process verification points can be instructed and accomplished using a few methods. A step may be listed on the routing as a Reduced Inspection Operation Step. The inspector checks the SPC charts and verifies the data is current and the process is stable and capable showing no evidence of the process being beyond the established control limits and uses a QC or CPK stamp to record the verification on the job order next to the operation step.

A step can be added to the AIR or MP giving operators specific process verification checks, using the operator operation sign or stamp next to the assembly step on the routing process to validate the operator completed the task and that the AIR/MP steps were accomplished as planned. Alternatively an actual Inspection operation step can be added to the routing and requires the buy off from an authorized inspector.

- special processes (see 7.5.2).

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Korry Special Processes	
Process	Validation Method
Laser Welding	MP237

Welding	MP151
J-STD Soldering	Korry Workmanship Standard (KWS) 03 (KWS03)
ESD Handling	Korry Document 50274 (ESD Handling Procedure)
Painting	MP287 KWS09-1: Cosmetic Inspection of Paint Class 1 KWS09-2: Cosmetic Inspection of Paint Class 2 KWS09-3: Cosmetic Inspection of Paint Class 3

Any new process or changed process is revalidated through process verification tests which is not limited to but can include First Article Inspections (FAI) and engineering process validation tests as applicable.

7.5.1.1 Production Process Verification

Korry uses a representative item from the first production run of a new part or assembly to verify that the production processes, production documentation and tooling are capable of producing parts and assemblies that meet requirements. This process is repeated when changes occur that invalidate the original results (e.g., engineering changes, manufacturing process changes, tooling changes)

NOTE: This activity is often referred to as first article inspection.

7.5.1.2 Control of Production Process Changes

Personnel authorized to approve changes to production processes are Manufacturing Engineer (ME), Quality Engineer (QE) and Design Engineer.

Korry controls and documents the changes affecting processes, production equipment, tools or software programs.

Changes to Manufacturing Processes (MP) and Assembly Inspection Records (AIR), Routings affecting processes are controlled per the configuration management process (see 7.1.3)

Changes to Routings on released job orders for rework or change incorporation are documented in the Process Planner training manual instructions. The instructions define the required signatures for the specific type of change. Changes to item routings are controlled by ECO in the PLM. Records of changes are kept per section 4.2.4.

The results of changes to production processes are assessed to confirm that the desired effect has been achieved without adverse effects to product conformity.Manufacturing Engineering can use the design validation and verification methods and shall follow AS9102 FAI requirements when making changes to processes. Testing requirements for processes

are detailed in the specific Manufacturing Process (MP) to assure changes do not have an adverse effect on product or quality compliance requirements. Change implementation instructions include requirements for re-training, and re- certification, in addition to maintenance procedures, audits and records of compliance.

7.5.1.3 Control of Production Equipment, Tools, and Software Programs

Production equipment, tools, and software programs used to automate and control/monitor product realization processes are validated prior to release for production and are maintained.
Storage requirements, including periodic preservation/condition checks are defined for production equipment or tooling in storage.

Control of Production Equipment, Tools and Numerical Control (NC) Machine Programs: Production equipment, tools and programs are validated prior to use and maintained and inspected periodically. Validation prior to production use includes verification of the first article produced to the design data/specification.

7.5.1.4 Post-Delivery Support

Korry provides post-delivery support as applicable for the

a) collection and analysis of in-service data,
b) actions to be taken, including investigation and reporting, when problems are detected after delivery,
c) control and updating of technical documentation,
d) approval, control, and use of repair schemes, and
e) controls required for off-site work (e.g., Korry's work undertaken at the customer's facilities).

Return Merchandise Authorization (RMA): A customer may request an RMA before returning product or an RMA will be generated upon receipt of returned product.

Customer Communication: The Customer Returns Administrator follows section 7.2.

Teardown: Product is issued for Teardown and analyzed for warranty. If the product qualifies for warranty it is repaired, inspected, and returned to the customer. If the product does not qualify, a repair quote is sent.

Failure analysis: A failure analysis is performed when requested by the customer or at the discretion of the quality engineer (QE).

FAA Repair Station: All Federal Aviation Administration (FAA) Parts Manufacturer Approval (PMA) FAA-PMA or Technical Standard Order (TSO) products are processed per FAA requirements as defined in the Repair Station Manual 49887 or the European Aviation Safety Agency (EASA) Supplemental Reference to FAA FAR-14549901, and Operation Specifications as applicable.

Customer Returns Database: The results of each return are entered into the Customer Returns database.

A corrective action is issued for each warranty issue per the Corrective Action Procedure 49631.

7.5.2 Validation of Processes for Production and Service Provision

Korry validates any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.

NOTE: These processes are frequently referred to as special processes.

Validation demonstrates the ability of these processes to achieve planned results.

Korry establishes arrangements for these processes including, as applicable:

a) defined criteria for review and approval of the processes,
b) qualification and approval of special processes prior to use,
c) approval of equipment and qualification of personnel,
d) use of specific methods and procedures,
e) control of the significant operations and parameters of special processes in accordance with documented process specifications and changes thereto,
f) requirements for records (see 4.2.4), and
g) revalidation.

7.5.3 Identification and Traceability

Where appropriate, Korry identifies the product by suitable means throughout product realization.

Korry maintains the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration.

Korry identifies the product status with respect to monitoring and measurement requirements throughout product realization.

When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), Korry does establish and document controls for the media.

Where traceability is a requirement, Korry controls and records the unique identification of the product and maintain records (see 4.2.4).

a) NOTE: Traceability requirements can include identification to be maintained throughout the product life,
b) the ability to trace all products manufactured from the same batch of raw material, or from the same manufacturing batch, to the designation (delivery, scrap),

c) for an assembly, the ability to trace its components to the assembly and then to the next higher assembly, and
d) for a product, a sequential record of its production (manufacture, assembly, inspection/verification) to be retrievable.

NOTE: In some industry sectors, configuration management is a means by which identification and traceability are maintained (see 7.1.3).

All parts are issued with a lot number. Lot numbers are stored with incoming receipts. First In/First Out (FIFO) is adhered to for all parts except where noted.

7.5.4 Customer Property

Korry exercises care with customer property while it is under Korry's control or being used by Korry. Korry identifies verifies, protects, and safeguards customer property provided for use or incorporation into the product. If any customer property is lost, damaged, or otherwise found to be unsuitable for use, Korry reports this to the customer and maintains records (see 4.2.4).

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

7.5.5 Preservation of Product

Korry preserves the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation includes identification, handling, packaging, storage, and protection. Preservation also applies to the constituent parts of a product.

Preservation of product also includes, where applicable in accordance with product specifications and applicable statutory and regulatory requirements, provisions for

a) cleaning,
b) prevention, detection and removal of foreign objects. Foreign Object Debris (FOD) Prevention is defined in Korry document 49926.Which details the prevention, detection and the removal of foreign objects which all employees are trained to.
c) special handling for sensitive products, Korry created and maintains specific processes for the handling of sensitive products, such as the ESD Handling Procedure defined in Korry document 50274.
d) marking and labeling including safety warnings,
e) shelf life control and stock rotation, and
Shelf life material is assigned to the shelf life location. The expiration date of the material shall be clearly visible on the container either on the label or on the container itself. The Supervisor/Manager of each area where shelf life materials are used in the production, servicing, rework of a Korry product, assigns an employee under their supervision to function as a Shelf Life Monitor who is responsible for:

- monitoring shelf life material expiration dates in their assigned areas.
- materials are stored in a manner to ensure the oldest stock on hand is used first (i.e., first in/first out).

Supervisors shall ensure that all expired shelf life materials are immediately turned in to MRB along with a listing of the materials.

Production Operators responsible for:

- verifying that any shelf life material they are using has not exceeded shelf life.
- shelf life materials transferred from their original containers into applicators such as syringes shall remain at the point of use and shall be used within the manufacturer's prescribed time frame and shall be discarded within the work shift.
- turning in unused materials transferred into applicators to the shelf life monitor at the end of their work shift.

f) special handling for hazardous materials.
Hazardous chemical are handled per Korry's safety polices Chemical Hazard Communication Plan and Fire Prevention Plan. Korry also follows Federal and Washington State law requirements.

Korry ensures that documents required by the contract/order to accompany the product, are present at delivery and are protected against loss and deterioration.

Material Manager ensures that:

- Inventory is maintained and controlled for use in production.
- Parts are received from outside vendors, internal production, and inspection requiring special handling are identified and stored according to the special handling requirements in the Product Master file.
- All parts are cycle counted according to their ABC classification.
- Parts are issued upon receipt of required documentation.
- All parts are issued with a lot number. Lot numbers are stored with incoming receipts. First In/First Out (FIFO) is adhered to for all parts except where noted.
- Final product is shipped according to specifications.

7.6 Control of Monitoring and Measuring Devices

Korry determines the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.

Korry maintains a register of the monitoring and measuring equipment and define the process employed for calibration/verification including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria.

NOTE: Monitoring and measuring equipment includes, but is not limited to: test hardware, test software, automated test equipment (ATE) and plotters used to produce inspection data. It also includes personally owned and customer supplied equipment used to provide evidence of product conformity.

Korry establishes processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements (see General Calibration Procedure for Measurement and Test Equipment 3.300)

Korry ensures that environmental conditions are suitable for the calibration, inspection, measurement and testing being carried out.

Where necessary to ensure valid results, measuring equipment is

a) calibrated or verified, or both, at specified intervals, 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 (see 4.2.4);
b) adjusted or re-adjusted as necessary;
c) has identification in order to determine its calibration status;
d) safeguarded from adjustments that would invalidate the measurement result;
e) protected from damage and deterioration during handling, maintenance and storage.

Korry established, implemented and maintains a process for the recall of monitoring and measuring equipment requiring calibration or verification.

In addition, Korry assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. Korry takes appropriate action on the equipment and any product affected.

Records of the results of calibration and verification are maintained in CERDAAC database (see 4.2.4).

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 software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.

8. MEASUREMENT, ANALYSIS, AND IMPROVEMENT

8.1 General

Korry plans and implements the monitoring, measurement, analysis and improvement processes needed:

a) to demonstrate conformity of the product requirements,
b) to ensure conformity of the Quality Management System, and
c) to continually improve the effectiveness of the Quality Management System.

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

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

a) design verification (e.g., reliability, maintainability, safety),
b) process control,
   - selection and inspection of key characteristics,
   - process capability measurements,
   - statistical process control,
   - design of experiment,
c) inspection, and
d) failure mode, effect and criticality analysis.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

As one of the measurements of the performance of the Quality Management System, Korry monitors information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information are determined.

Information to be monitored and used for the evaluation of customer satisfaction includes, but is not limited to, product conformity, on-time delivery performance, customer complaints and corrective action requests. Korry develops and implements plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results.

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

8.2.2 Internal Audit

Korry conducts internal audits at planned intervals to determine whether the Quality Management System:

a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the Quality Management System requirements established by the organization, and

NOTE: Planned arrangements include customer contractual requirements.

b) is effectively implemented and maintained.

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

The Audits Procedure 49682 is the documented procedure established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.

Records of the audits and their results are maintained in Audit Master database (see 4.2.4).

The Management responsible for the area being audited ensures that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).

NOTE: See the ISO 19011 for guidance.

8.2.3 Monitoring and Measurement of Processes

Korry applies suitable methods for monitoring and, where applicable, measurement of the Quality Management System processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action are to be taken, as appropriate.

In the event of process nonconformity, Korry

a) takes appropriate action to correct the nonconforming process,
b) evaluates whether the process nonconformity has resulted in product nonconformity,
c) determines if the process nonconformity is limited to a specific case or whether it could have affected other processes or products, and
d) identifies and controls any nonconforming product (see 8.3).

8.2.4 Monitoring and Measurement of Product

Korry monitors and measures the characteristics of the product to verify that product requirements have been met. This is carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria is maintained.

Measurement requirements for product acceptance are documented (see 7.5.1) and include:

a) Criteria for acceptance and /or rejection,
b) Where in the sequence measurement and testing operations are to be performed,
c) Required records of the measurement results (at a minimum, indication of acceptance or rejection), and
d) Any specific measurement instruments required and any specific instructions associated with their use.

When critical items, including key characteristics have been identified, Korry ensures they are controlled and monitored in accordance with the established processes.

When Korry uses sampling inspection as a means of product acceptance, the sampling plan is justified on the basis of recognized statistical principles and appropriate for use (i.e., matching the sampling plan to the criticality of the product and to the process capability).

Where product is released for production use pending completion of all required measurement and monitoring activities, it is identified and recorded to allow recall and replacement if it is subsequently found that the product meets requirements.

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

Where required to demonstrate product qualification, Korry ensures that records provide evidence that the product meets the defined requirements.

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

Korry ensures that all documents required to accompany the product are present at delivery.

8.3 Control of Nonconforming Product

Korry ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The Non Conforming Material Procedure 49629 is documented procedure established to define the controls and related responsibilities and authorities for dealing with nonconforming product.

NOTE: The term “nonconforming product” includes nonconforming product returned by a customer.

Korry’s Non Conforming Material Procedure 49629 defines the responsibility and authority for the review and disposition of nonconforming product, and the process for approving personnel making these decisions.

Where applicable, Korry deals with nonconforming product by one or more of the following ways:

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

- Korry's nonconforming product control process provides for timely reporting of delivered nonconforming product;

NOTE: Parties requiring notification of nonconforming product can include suppliers, internal organizations, customers, distributes and regulatory authorities.

e) By taking actions necessary to contain the effect of the nonconformity on other processes or products.

Dispositions of use-as-is or repair are used after approval by an authorized representative of the organization responsible for design.

NOTE: Authorized representative includes personnel having delegated authority from the design organization.

Korry does not use dispositions of use-as-is or repair, unless specifically authorized by the customer, if the nonconformity results in a departure from the contract requirements.

Product dispositioned for scrap is conspicuously and permanently marked, or positively controlled, until physically rendered unusable.

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

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

8.4 Analysis of Data

Korry determines, collects, and analyzes appropriate data to demonstrate the suitability and effectiveness of the Quality Management System and to evaluate where continual improvement of the effectiveness of the Quality Management System can be made. This includes data generated as a result of monitoring and measurement and from other relevant sources.

Management reviews the data analysis results by monthly Management Business Reviews (MBR) and at least annual Quality Management System Review (QMSR) meetings.

The analysis of data provides information relating to:

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

8.5 Improvement

8.5.1 Continual Improvement

Korry continually improves the effectiveness of the Quality Management System through the use of the Quality Policy, Quality Objectives, audit results, analysis of data, corrective and preventive actions and management review.

Korry monitors the implementation of improvement activities and evaluates the effectiveness of the results.

NOTE: Continual improvement opportunities can result from lessons learned, problem resolutions and the benchmarking of best practices.

8.5.2 Corrective Action

Korry takes action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered.

The Corrective Action Procedure 49631 is documented procedure established to define requirements for

a) reviewing nonconformities (including customer complaints),
b) determining the causes of nonconformities,
c) evaluating the need for action to ensure that nonconformities do not recur,
d) determining and implementing action needed,
e) records of the results of action taken (see 4.2.4), and
f) reviewing the effectiveness of the corrective action taken,
g) flowing down corrective action requirements to a supplier, when it is determined that the supplier is responsible for the nonconformity,
h) specific actions where timely and/or effective corrective actions are not achieved, and
i) determining if additional nonconforming product exists based on the causes of the nonconformities and taking further action when required.

8.5.3 Preventive Action

Korry determines action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are appropriate to the effects of the potential problems.

The Preventive Action Procedure 49632 is documented procedure established to define requirements for

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

NOTE: Examples of preventive action opportunities include risk management, error proofing, failure mode and effect analysis (FMEA), and information on product problems reported by external sources.