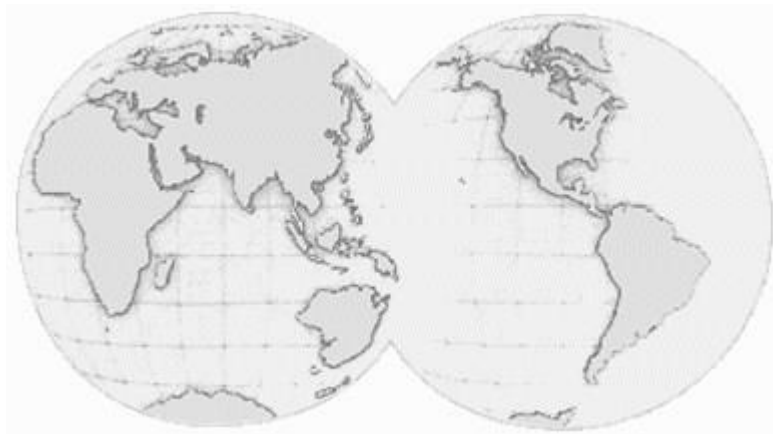




# Global Quality Manual

Lasting relationships. Global success.

 Creating Quality for Life



## Who We Are

Kimball Electronics is a global, multifaceted manufacturing solutions provider recognized for its reputation of excellence. We are committed to a high-performance culture that values personal and organizational commitment to quality, reliability, value, speed, and ethical behavior.

## What We Do

Kimball Electronics provides end-to-end engineering, design and manufacturing solutions, including contract Electronics Manufacturing Services (EMS) and Diversified Contract Manufacturing Services (DCMS) to customers in the automotive, medical, and industrial end markets. We deliver award-winning service through our highly integrated global footprint, stringent quality systems, customer relationship management model, and supply chain support.

### CONTROLLED DOCUMENT

This manual is a controlled document in electronic version only. Printed copies are considered uncontrolled and will not be updated. Revision can be verified through the Kimball Electronics on-line Documentation Center.

This manual and the information it contains are the property of Kimball Electronics. It cannot be reproduced in whole or part without prior written consent from Kimball Electronics.

Revision: [N](#)

Rev Date: [06/07/2024](#)

DC: [430557](#) SAP QSD: 10000020088

## Approvals

Approval / Release Date: 06/07/2024

### Title

Chief Executive Officer (CEO)  
[Chief Operations Officer](#)  
VP Global Human Resources  
Chief Legal & Compliance Officer and Secretary  
VP New Platforms  
[Chief Commercial Officer](#)  
Chief Financial Officer  
Chief Information Officer  
KEJ  
    General Manager  
    Quality Manager  
KEMX  
    General Manager  
    Quality Manager  
KETA  
    General Manager  
    Quality Manager  
KEIND  
    General Manager  
    Quality & Regulatory Affairs Manager  
KEPS  
    General Manager  
    Quality & Infrastructure Manager  
KERO  
    General Manager  
    Quality Manager  
KETL  
    General Manager  
    Quality Manager  
KECN  
    General Manager  
    Quality Manager  
[Business Systems Analyst for Quality](#)  
Global Quality Systems Representative

# **1 - Table of Contents**

<b>Section</b>	<b>Page Number</b>
1 - Table of Contents	3
2 - Introduction to Kimball Electronics	4
3 - Scope and Application	4
4 - Context of Kimball Electronics	5
4.1 - Understanding KE and its context	5
4.2 - Interested parties	5
4.3 - Scope of the QMS	6
4.4 - QMS Processes	8
5 - Leadership	9
5.1 - Leadership and commitment	9
5.2 - Quality Policy	11
5.3 - Organizational roles, responsibilities and authorities	11
6 - Planning	11
6.1 - Actions to address risk and opportunities	11
6.2 - Quality objectives	12
6.3 - Planning of changes	12
7 - Support	12
7.1 - Resources	12
7.2 - Competence	15
7.3 - Awareness	16
7.4 - Communication	16
7.5 – Documented information	16
8 - Operation	17
8.1 - Operational planning and control	17
8.2 - Requirements for products and services	18
8.3 - Design and development of manufacturing processes	19
8.4 - Control of externally provided process, products and services	20
8.5 - Production and service provision	21
8.6 - Release of products and services	24
8.7 - Control of nonconforming outputs	24
9 - Performance evaluation	25
9.1 - Monitoring, measurement, analysis and evaluation	25
9.2 - Internal audit	26
9.3 - Management review	26
10 - Improvement	27
10.1 - General	27
10.2 - Nonconformity and corrective action	27
10.3 - Continual improvement	28
11 - Addendum GQM-1 (controlled separately from GQM)	28

## **2 - Introduction to Kimball Electronics**

Kimball Electronics was established in 1961 as the Jasper Electronics Manufacturing Company to build electronic organs for our then parent company, Jasper Corporation. Jasper Corporation later became Kimball International. During the late 1960's, contract manufacturing began with the first Industrial contract from General Electric Appliances of Louisville, KY. As the electronics industry evolved, and Kimball expanded, Kimball Electronics did as well.

During the 1980's we became focused solely on contract electronic manufacturing services and expanded into the Automotive, Medical and Public Safety markets and eventually became known as Kimball Electronics Group. Since that time, it has been our mission to be a worldwide Electronics Manufacturing Service Industry leader in providing superior services and technology while growing profitably. On October 31, 2014, Kimball Electronics was spun-off from parent company Kimball International and became a publicly traded company on the NASDAQ Global Select stock exchange under the Kimball Electronics name and symbol KE.

Today, Kimball Electronics is a leading contract manufacturer of durable goods electronics serving a variety of industries on a global scale. Kimball Electronics (KE) continues to make the customer the focus of everything we do and will continue to provide the highest industry quality through continual improvement.

[Kimball Electronics Global Facilities](#) are determined to continually improve quality through use of our quality management systems.

## **3 - Scope and Application**

This Global Quality Manual is published to document the formal Quality Management System in use by all KE facilities. Addendums to this Global Quality Manual or other site-specific manuals may be used to define facility specific requirements. The facility specific addendum can be used to reference procedures, define the facility and customer specific requirements, and address exceptions and items that are not applicable.

The Quality Management System has been developed and organized to ensure that all KE processes comply with a minimum of ISO 9001 and any other applicable QMS standards. Refer to the KE [Certification Registration Status Matrix](#) for details of current certifications and registrations. KE management endorses this manual to assure the required level of product quality and reliability for our customers.

This Global Quality Manual summarizes the basic policies and processes for the KE Quality Management System which assures compliance with customer product requirements.

## **4 - Context of Kimball Electronics**

### **4.1 - Understanding Kimball Electronics and its context**

**Our Vision Statement** sets the strategic direction of our company.

To be the world's most preferred multifaceted manufacturing solutions provider and to set the industry standard for Quality, Reliability and Service.

For non-EMS business units within Kimball Electronics, refer to the site-specific Global Quality Manual Addendum for applicable Vision Statement.

**Our Mission Statement** defines how we plan to meet our vision.

To attract, develop, and maintain long-term successful relationships with all the stakeholders of our business: our customers, employees, suppliers, communities, and share owners and to keep our promise to help achieve success with those relationships wherever we go in the world.

**Our Guiding Principles** identify critical aspects of our business, including our Customers, our People, and our Citizenship.

**Our Purpose:**  Creating Quality for Life.

Relevant external and internal issues are determined, monitored, and reviewed as applicable. Such as:

- Customer specific requirements
- Industry and regulatory requirements
- Technology and climate changes
- Business values, cultures, and strategies

### **4.2 - Interested parties**

Kimball Electronics has determined the following interested parties as being relevant to our Quality Management System (QMS):

- Our customers
- Regulatory agencies
- Our suppliers
- Our employees
- Our shareholders

Requirements from our customers and regulatory agencies are included in our QMS and are flowed down to our suppliers as required.

Information and requirements from these interested parties are monitored and reviewed using the following:

- Customer feedback and scorecards
- Customer, internal and 3<sup>rd</sup> party audits
- Regulatory inspections, if applicable
- Supplier performance
- Employee feedback and surveys
- Profits

### 4.3 - Scope of the QMS

Kimball Electronics' (KE's) Quality Management System (QMS) directs business activities for meeting or exceeding customers' expectations, requirements and internal needs. The QMS is reviewed and monitored through Corporate and Facility management reviews to continually improve its effectiveness.

The QMS identifies the processes needed within the organization. The application, sequence, interaction, operation and control of these processes have been determined and are monitored for effectiveness by using Operational Excellence and facility specific metrics.

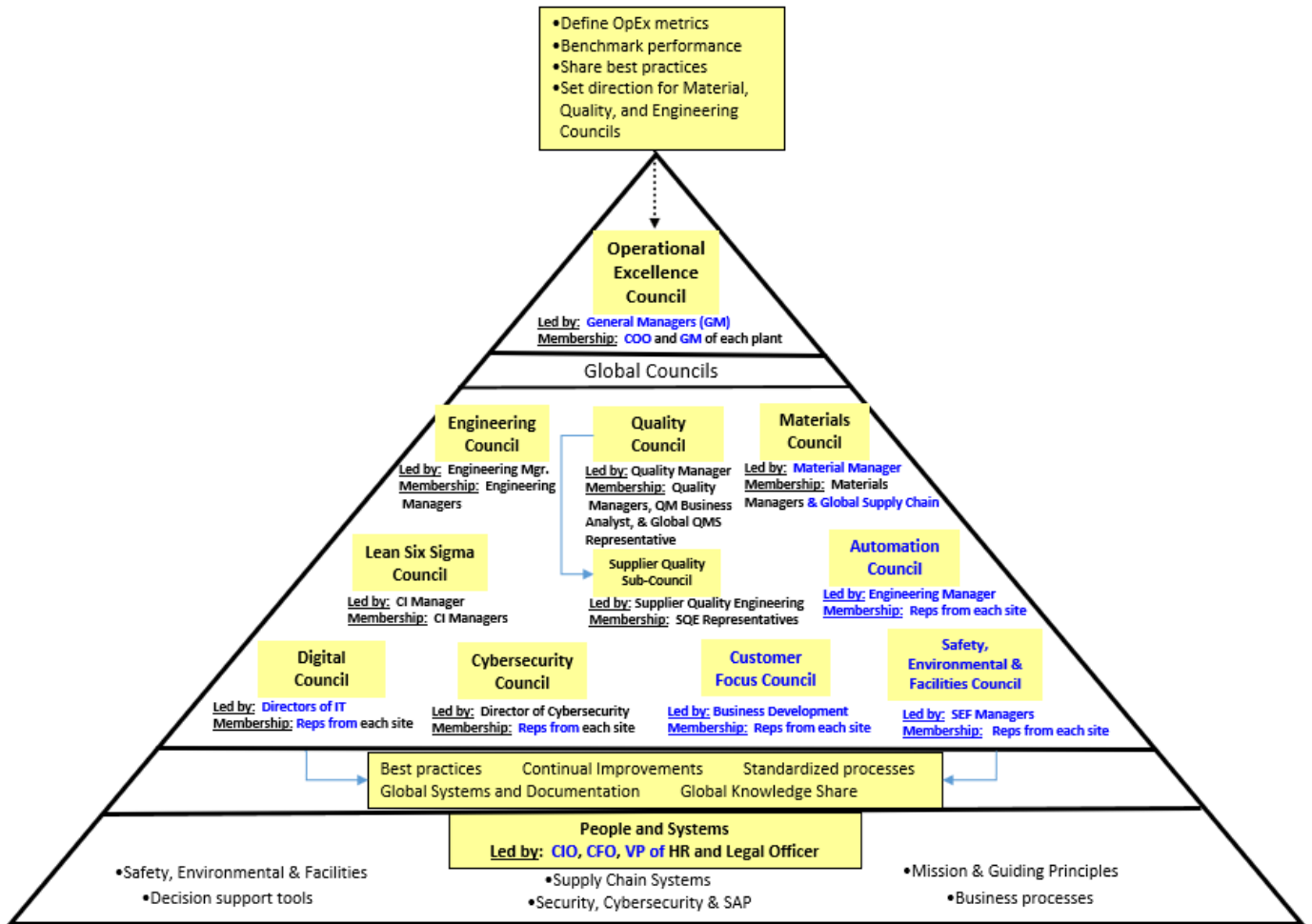
The KE Headquarters, located at 1205 Kimball Boulevard, Jasper, Indiana USA is a “remote support site” to the KE manufacturing facilities, and is referred to as Global Shared Services.

The KE Headquarters is included in the Kimball Electronics - Jasper location's applicable QMS certification(s) scope. Therefore, internal and certification body QMS audits are conducted at Jasper on the processes performed by Global Shared Services and the other KE facilities use these results to support their facility's QMS certification(s). Refer to the [GQM Addendum #1](#) for additional details.

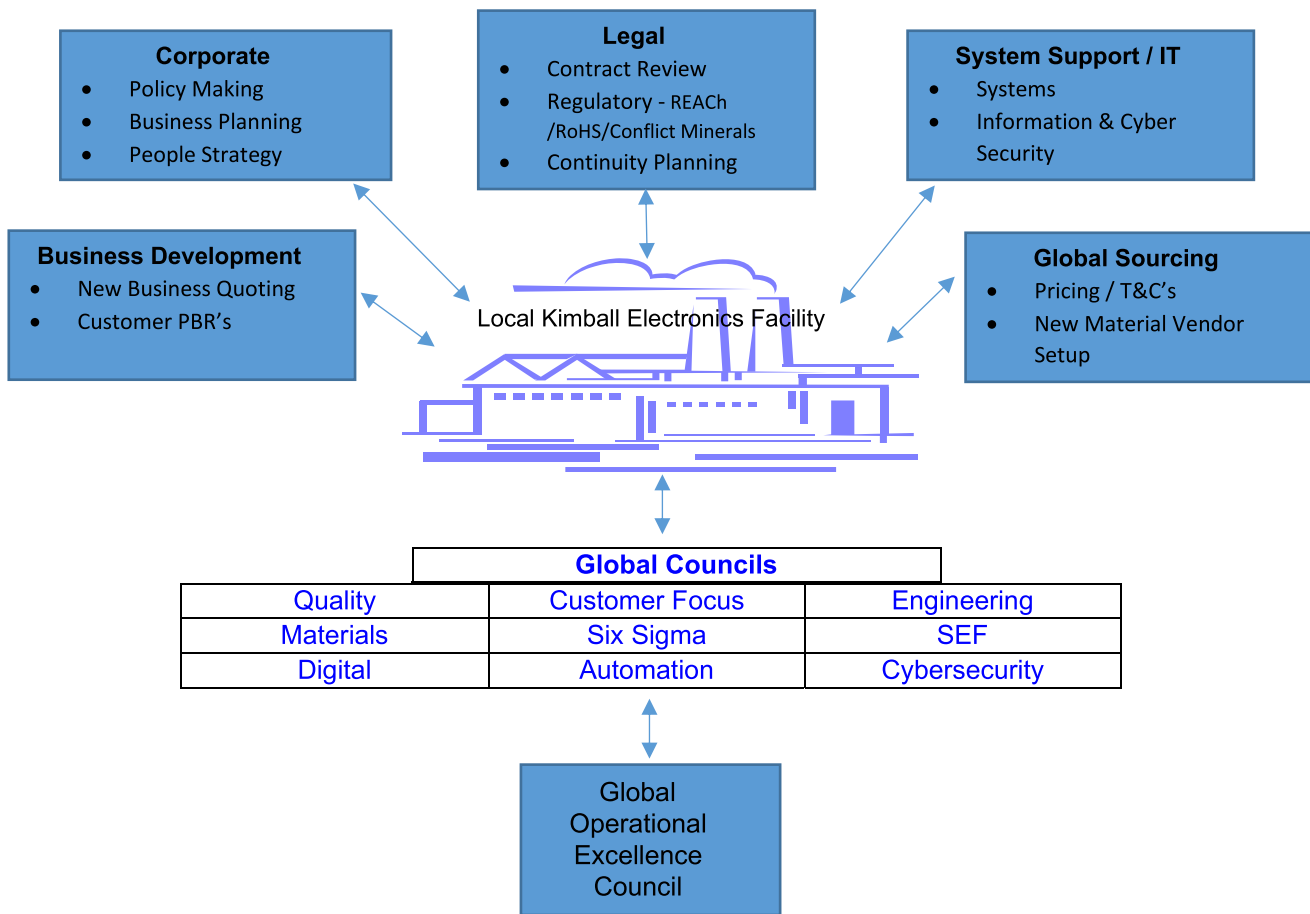
Any inputs or outputs performed at the manufacturing facilities in support of the Global Shared Services processes will be incorporated into that site's QMS audits and certification(s) scope, as required.

The interrelations of Global Shared Services processes with facility specific processes are documented within the applicable QMS procedures. KE's Global Councils also support the interrelations of processes.

The following diagrams depict the structure of the various Global Councils and Shared Services, along with some of their primary roles in supporting KE as a Global organization and their interaction with the manufacturing site.



Interrelation of Global Shared Services processes and supporting Global Councils is depicted below.



#### 4.4 - QMS Processes

The interaction of various KE QMS processes are defined in the facility specific addendums.

Resources and information are available to support, monitor, measure, analyze, evaluate and continually improve our processes. This includes in part:

- Systems, databases, reports, etc.
- Global Operational Excellence metrics
- Local facility metrics
- Continual improvement methodology

When processes are outsourced, KE identifies and ensures control over these processes that affect product conformity with requirements, as specified. KE accepts responsibility for quality and conformity of outsourced products and processes.

KE has determined the processes and documentation needed to ensure the effective planning, operation and control of its processes. This documentation includes, but is not limited to:



- Statement of Quality Policy and Quality Objectives
- Quality Manual and supporting Addendums
- Procedures
- Instructions
- Records
- Additional documents as needed

#### **4.4.1 - Quality Manual**

The scope of the Quality Management System for each facility is defined using this manual and facility specific addendums.

Where a KE facility is not product design responsible, the requirements of the ISO Quality Management System standards sections related to product design are not applicable. Justification for this is based on the customer owning the design and it cannot be changed by KE without the customer's approval.

KE is responsible for manufacturing process design.

#### **4.4.2 - Control of Documents and Records**

KE has established a document control system using a documentation change system to ensure the integrity of all types of documents and records that affect our products and processes. The Enterprise Resource Planning (ERP) system is used as the primary configuration management tool for document storage and retrieval.

KE follows a defined process for the review, distribution and implementation of all engineering specifications and changes. KE ensures that implementation of the engineering changes meet the customer's and regulatory requirements.

Records are established and maintained to provide evidence of conformance to the QMS and its effectiveness. KE meets internal, customer and regulatory requirements for retention of records.

### **5 - Leadership**

#### **5.1 - Leadership and commitment**

##### **5.1.1 - General**

KE's top management is committed to the development and implementation of our QMS and works to continually improve its effectiveness. This is accomplished through:

- Establishing our Quality Policy and Quality Objectives and assuring their compatibility with KE's Vision, Mission and Guiding Principles, and the strategic direction of the Company

- Incorporation of QMS requirements into the established processes
- Communicating the importance of effective quality management and compliance to the QMS requirements to all KE employees
- Risk and opportunity management
- Ensuring the effectiveness and efficiency of processes and their ability to achieve intended results
- Promoting and sustaining a culture of improvement and effectiveness
- Ensuring adequate resources are available
- Supporting management roles on all levels of the organization in the area of leadership

### 5.1.2 - Customer Focus

KE top management ensures that applicable customer, statutory and regulatory requirements are determined, understood and consistently met, with the goal of **assuring and** increasing customer satisfaction.

This is accomplished through various processes that interface directly with the customer, such as:

- Quoting
- Contract Review / Supply Agreement
- Supply Chain Management
- New Product Introduction (NPI)
  - **Includes Transfer of Work (TOW)**
- Customer Supplied Product and Tooling
- Return Material Authorization (RMA)
- Corrective and Preventive Action
- Customer Satisfaction and Feedback
- Business Continuity / Contingency Planning
- Delivery and Export

Process description documents and procedures are used to define the processes which interface with the customer. This includes the following detail, as applicable:

- Related Processes
- Inputs / Outputs
- Performance Metrics
- References to QMS Documentation
- QMS Standard References
- Customer Specific Requirements
- Product Conformity Risks and Opportunities

## 5.2 - Quality Policy

### Kimball Electronics' Quality Policy:

- Our first priority is customer satisfaction; obtained through superior quality, customer service and continual improvement.
- Our Quality Management System will define the requirements for meeting our business needs, complying with regulatory requirements and the tools to be used for establishing, reviewing and measuring our quality objectives.
- We are all personally responsible for commitment and compliance to our Quality Management System, for ensuring its suitability, and continually improving its effectiveness, in order to enhance our customers' satisfaction.

## 5.3 - Organizational roles, responsibilities and authorities

KE organizational structure exists on a global level as well as on the manufacturing sites' level. The assignment of the roles within the organization are defined in and communicated through the relevant Organization Charts and supporting documents.

KE utilizes Roles and Responsibilities (R&R's), and procedures to communicate responsibilities and authorities throughout the organization.

Employees on all shifts are responsible for product quality and are empowered to stop production to ensure a quality issue is corrected. Each KE facility has established a quality data system to promptly notify managers and responsible personnel of product and process non-conformities.

KE's top management has designated overall responsibility and authority to the Business Manager / Program Managers for addressing our customers' requirements. These customer requirements include, but are not limited to:

- Selection of special characteristics
- Setting quality objectives
- Related training
- Corrective and preventive actions

## 6 - Planning

### 6.1 - Actions to address risk and opportunities

The QMS has taken into consideration the context of KE along with the needs and expectations of our interested parties. Risk and opportunities are taken in account as defined in the QMS processes for achieving intended results, understanding and responding to effects, and improvement of the QMS.

Actions taken for risks and opportunities will be implemented into the QMS and effectiveness will be evaluated. KE has developed and deployed the tools used for supporting risk management.

When required by our customers, actions will not be taken without their approval.

## **6.2 - Quality objectives**

KE's top management assures that Quality Objectives are established and communicated at relevant functions and levels within KE and are included in the KE Business Plan. The Quality Objectives are consistent with the Quality Policy, monitored, measurable, address applicable requirements, and are relevant to the business.

### Kimball Electronics' Quality Objectives:

Our Quality Objectives are to focus on our customers' expectations and satisfaction by measuring and improving:

- Customer Quality
- On Time Delivery
- Operational performance
- Compliance to our Quality Management System

KE uses defined Operational Excellence Metrics to monitor and measure those processes that are most critical to the success of our business.

## **6.3 - Planning of changes**

Changes made to the QMS are planned and documented. Consideration is given to the purpose of the change, potential consequences, and integrity of the QMS, resources and responsibilities.

This is achieved through the use of a document change system which provides for analysis and approval by effected KE functions. Changes are communicated appropriately.

## **7 - Support**

### **7.1 Resources**

#### **7.1.1 – General**

KE determines and provides the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system. Resources are reviewed and determined during the New Product Introduction (NPI) process.

KE considers:

- The capabilities of, and constraints on, existing internal resources
- What needs to be obtained from external providers.

Based on these considerations, the processes for hiring additional employees, purchasing equipment, etc. may be implemented.

## **7.1.2 - People**

KE determines and provides the persons necessary for the effective implementation of the quality management system and for the operation and control of processes. KE develops our people as defined in the Guiding Principles by fostering an organizational structure, information systems and development of personal skills that maximize flexibility to respond to the customers

This includes resources for continually improving the effectiveness of the QMS and enhancing customer satisfaction by meeting or exceeding our customers' requirements.

## **7.1.3 - Infrastructure**

KE determines, provides and maintains the appropriate infrastructure (buildings, workspace, utilities, process equipment, transportation, technology and supporting services needed for the infrastructure) for the operation of its processes and to achieve conformity of products. Business planning is used to identify these needs and plan annual business requirements.

A multidisciplinary approach is used to develop and monitor the effectiveness of facility and equipment plans. Facility layouts optimize material travel, handling and value-added use of floor space, and facilitate material flow. This is supported through the NPI process and may include tools such as Lean / Six Sigma and Kaizen.

Each KE facility maintains an individualized contingency plan specific to their processes and personnel in order to satisfy customer requirements in the event of an emergency.

## **7.1.4 - Environment for the operation of processes**

KE determines, provides and maintains the environment necessary for the operation of its processes and to achieve conformity of products, which includes personnel safety and cleanliness requirements. All employees are responsible for safety, with assigned personnel having responsibility for measuring and improving safety.

## **7.1.5 - Monitoring and measuring resources**

### **7.1.5.1 - General**

KE determines and provides the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products to requirements.

KE ensures that the resources provided:

- Are suitable for the specific type of monitoring and measurement activities being undertaken
- Are maintained to ensure their continuing fitness for their purpose

KE retains appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

KE is responsible to identify, develop, verify, validate, or calibrate, and implement and maintain measuring and monitoring devices. These devices are used to ensure product quality and customer satisfaction. The calibration system controls these devices and is used to:

- Verify prior to use, when required
- Re-verify or validate at specified intervals
- Adjust as necessary
- Protect from unauthorized adjustments
- Identify calibration status
- Protect from damage and deterioration
- Address out of calibration conditions, such as:
  - Assessment of effects
  - Customer notification
  - Product containment
  - Corrective action
- Maintain records of the calibration and verification results.

KE uses measurement system analysis to validate measurement and test devices and systems, when required.

When required, KE will ensure the adequacy, competency, capability and record retention of any laboratory facilities used throughout the product realization process. When required, external laboratories will be accepted by the customer or accredited to ISO/IEC 17025 or equivalent or have evidence that the laboratory meets the requirements for internal laboratories.

#### **7.1.5.2 - Measurement traceability**

When measurement traceability is a requirement, or is considered by KE to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be:

- Calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification is retained as documented information
- Identified in order to determine their status
- Safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results

KE determines if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose and takes appropriate action as necessary.

### 7.1.6 - Organizational knowledge

KE determines the knowledge necessary for the operation of its processes and to achieve conformity of products.

This knowledge is maintained and is made available through the following:

- Procedures, instructions and training materials
- Guidelines and standards
- Continuous Improvement [KIM-CI database](#)
- Global Corrective Action [Intalex database](#)
- Lessons Learned

When addressing changing needs and trends, KE considers its current knowledge and determines how to acquire or access any necessary additional knowledge and required updates. Organizational knowledge is shared among KE facilities through the Global Councils and the Councils promote consistency within and throughout all KE business units.

### 7.2 - Competence

KE determines the necessary competence of person(s) under its control that affects the performance and effectiveness of the quality management system. KE ensures that these persons are competent based on appropriate education, training, skills and experience; where applicable, takes actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken, and retains appropriate documented information as evidence of competence.

Each KE facility determines and records the necessary competence and training information for personnel performing work that affects product quality. Each facility:

- Determines and assesses the necessary competence
- Selects and trains personnel performing work affecting product quality
- Assesses the effectiveness of training
- Ensures employees are aware of the relevance and importance of activities and how they contribute to achieving the Quality Objectives
- Retains records of training, education, experience, and skills

Training requirements can include, but are not limited to:

- On-the-job training (OJT)
- Classroom training
- Applicable certifications

Each KE facility determines the processes used to motivate employees for achieving Quality Objectives, for making continual improvements and promoting innovation.

### **7.3 - Awareness**

KE ensures that persons doing work under KE's control are aware of:

- The quality policy
- Relevant quality objectives
- Their contribution to the effectiveness of the quality management system, including the benefits of improved performance
- The implications of not conforming with the quality management system requirements

### **7.4 - Communication**

KE's 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. KE determines the internal and external communications relevant to the quality management system.

KE internal and external communication tools include, but are not limited to:

- Operational Excellence Metrics
- Corporate and Facility Management Reviews
- KE Operation / Town Hall Reviews
- Customer Periodic Business Reviews (PBR) and Scorecards
- Supplier PBR and Scorecards

### **7.5 - Documented information**

#### **7.5.1- General**

KE has determined the documentation needed to ensure the effective planning, operation and control of its processes. KE's quality management system includes, but is not limited to:

- Statement of Quality Policy and Quality Objectives
- Quality Manual
- Procedures
- Instructions
- Records
- Additional documented information required by the standards and documented information determined by the organization as being necessary for the effectiveness of the quality management system.

#### **7.5.2 - Creating and updating documented information**

When creating and updating documented information, KE ensures appropriate identification, description, format, media, review and approval for suitability and adequacy.

KE has established a document control system with interface to the ERP system to ensure the integrity of all types of documents and records that affect our products and processes. Documented information required by the quality management system is controlled to ensure



it is available and suitable for use, where and when it is needed, and it is adequately protected (e.g. from loss of confidentiality or improper use).

### **7.5.3 - Control of documented information**

KE follows a defined process for the review, distribution, access, retrieval, use, storage, preservation (including legibility), retention, disposition and implementation of all documented information, engineering specifications and changes. KE ensures that implementation of the engineering changes meet the customer's and regulatory requirements.

Documented information of external origin determined by KE to be necessary for the planning and operation of the quality management system is identified as appropriate and controlled.

Documented information retained as evidence of conformity is protected from unintended alterations.

Records are established and maintained to provide evidence of conformance to the QMS and its effectiveness. KE meets internal, customer and regulatory requirements for retention of records.

## **8 - Operation**

Note: Services provided by KE to our customers include processes such as, product delivery, handling of claims, change management, etc. Service processes will be addressed at the local plant level.

### **8.1 - Operational planning and control**

KE plans, implements, and controls the processes (see Quality management system and its processes) needed to meet the requirements for the provisions of products, and to implement the actions determined in planning by:

- Determining the requirements for the products
- Establishing criteria for the processes and the acceptance of products
- Determining the resources needed to achieve conformity to the product requirements
- Implementing control of the processes in accordance with the criteria
- Determining, maintaining and retaining documented information to the extent necessary to have confidence that the processes have been carried out as planned and to demonstrate the conformity of products to their requirements

The output of this planning is suitable for KE's operations. KE controls planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary. [If used](#), KE ensures that outsourced processes are controlled.

New Product Introduction (NPI) processes are used for the successful implementation of product realization. Product realization at KE begins with the customer's "Request for Quote" and, upon acceptance, may include tasks and activities dealing with Product and/or Manufacturing Process Design and Development, Advanced Product Quality Planning (APQP) and Program Management. Customer requirements, technical specification references, acceptance criteria and risk management may also be included in the planning of product realization.

Each KE facility will have its own plant level NPI procedure. These procedures, at a minimum, shall have two toll gates related to a concept feasibility review and a production readiness / documentation review. Additional tollgate reviews may be utilized as required within the local processes.

KE has a process to control and react to changes that impact product realization. Changes that apply to product and manufacturing processes are assessed and verified to ensure compliance with regulatory, statutory and customer requirements, including supplier caused changes. Changes are validated before implementation, when required.

## **8.2 - Requirements for products and services**

### **8.2.1 - Customer communication**

Communication with customers includes:

- Providing information relating to products
- Handling enquiries, contracts or orders, including changes
- Obtaining customer feedback relating to products, including customer complaints
- Handling or controlling customer property
- Establishing specific requirements for contingency actions, when relevant

The Business Managers and Program Managers are the primary communication path between KE and our customers.

### **8.2.2 - Determining the requirements for products and services**

The appropriate Business Manager / Program Manager is responsible for obtaining all requirements as they relate to the product during the New Product Introduction process. These requirements include, but are not limited to:

- Customer specified
- Statutory and regulatory
- Safety and environmental
- Handling and storage
- Those considered necessary by KE

KE ensures it can meet the claims for the products it offers by following the NPI process.

### **8.2.3 - Review of the requirements for products and services**

KE ensures it has the ability to meet the requirements for products to be offered to customers. KE conducts a review before committing to supply products to a customer, which includes:

- Requirements specified by the customer, including the requirements for delivery activities
- Requirements not stated by the customer, but necessary for the specified or intended use, when known
- Requirements specified by KE
- Statutory and regulatory requirements applicable to the products
- Contract or order requirements differing from those previously expressed

KE ensures contract or order requirements differing from those previously defined are resolved. The customer's requirements are confirmed by KE before acceptance, when the customer does not provide a documented statement of their requirements.

Conformity to customer requirements for designation, documentation and control of special characteristics is initiated during the NPI process, is documented in control plans, FMEAs, etc. and demonstrated within the manufacture of product. KE retains documented information, as applicable, on the results of the review and on any new requirements for the products.

It is KE's policy, and management's commitment, to comply with all applicable government, safety, and environmental regulations.

#### **8.2.4 - Changes to requirements for products and services**

KE ensures relevant documented information is revised, and that relevant parties are made aware of the changed requirements, when the requirements for products are changed.

### **8.3 - Design and development of Manufacturing Processes**

KE design and development efforts focus on error prevention rather than detection. KE establishes, implements, and maintains a design and development process to ensure that the manufacturing processes are appropriate to the products being manufactured.

The process will define the required steps, responsibilities, and interactions necessary for successful design and development of manufacturing processes.

### **8.4 - Control of externally provided processes, products, and services**

#### **8.4.1- General**

KE recognizes the importance of supplied materials to the quality of products and meeting customers' expectations, and ensures that externally provided processes, products and

services conform to requirements. KE determines the controls to be applied to externally provided processes, products, and services when:

- a) Products and services from external providers are intended for incorporation into the products
- b) Products and services are provided directly to the customer(s) by external providers on behalf of KE
- c) A process, or part of the process, is provided by an external provider as a result of a decision by KE

The extent of controls placed on suppliers and their products is based on effects to the final product. These processes and controls are used to ensure supplied components meet all specifications and requirements

KE determines and applies criteria for the evaluation, selection, monitoring of performance and re-evaluation of external providers.

Documented information is retained of these activities and any necessary actions arising from the evaluations.

The [KE Global Supplier Quality Manual](#) details the requirements and expectations for all KE suppliers. Additionally, it defines KE supplier quality management system requirements.

KE purchases products, materials, and services from approved sources. The use of customer-designated sources does not absolve KE of the responsibility for ensuring the quality of purchased products.

#### **8.4.2 - Type and extent of control**

KE ensures that externally provided processes, products and services do not adversely affect KE's ability to consistently deliver conforming products and services to its customers by:

- a) Ensuring that externally provided processes remain within the control of its quality management system
- b) Defining both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output
- c) Taking into consideration:
  - The potential impact of the externally provided processes, products, and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements
  - The effectiveness of the controls applied by the external provider
- d) Determining the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements

Each KE facility is responsible for methods to ensure that purchased product and suppliers meet requirements, such as:

- Receiving inspection
- Monitoring process fall out

- Supplier metrics (quality, delivery, and service)
- Certificates of Compliance, Certificates of Analysis, etc.
- Third party verification

### **8.4.3 - Information for external providers**

Each KE facility is responsible for ensuring that purchasing information fully describes the processes, product, and services to be purchased. Each KE facility also ensures the adequacy of specified purchase requirements prior to their communication to the supplier.

Communication of requirements to suppliers includes the following, as applicable:

- Approval of products, services, methods, processes, equipment and release of products or services
- Competence and qualification of persons
- Interaction and communication with KE
- Control and monitoring of performance
- Verification or validation to be performed at the supplier's site

## **8.5 - Production and service provision**

### **8.5.1 - Control of production and service provision**

KE utilizes methods to control manufacturing processes to ensure customer satisfaction. These methods include, but are not limited to:

- Process flows
- Process FMEAs
- Control plans
- Operator control instructions
- Job set up verifications
- Preventive and predictive maintenance
- Management of production tooling
- Production scheduling
- Feedback from failure analysis and returns
- Error proofing
- Validation

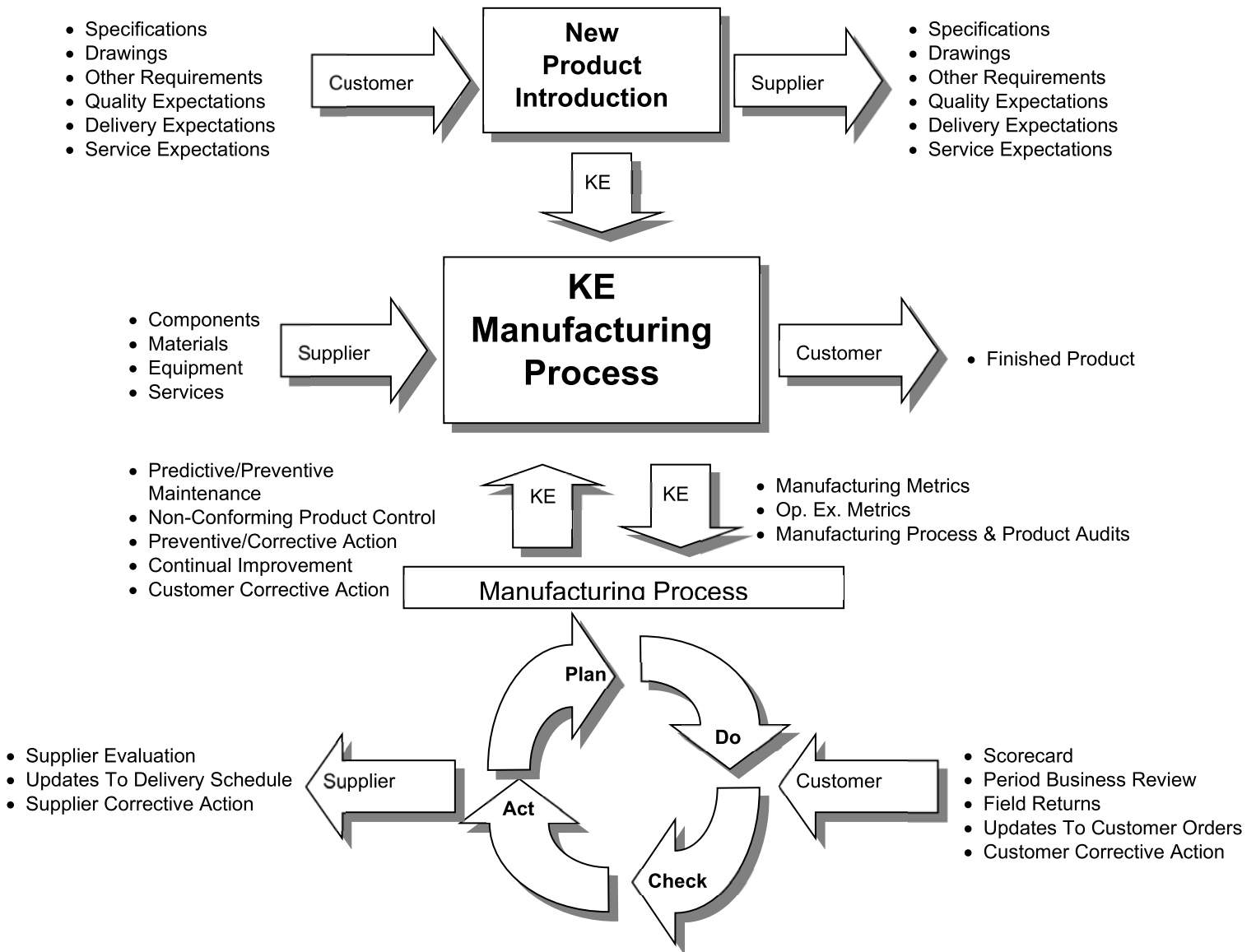
#### Validation of processes for production provision

KE uses validation processes during New Product Introduction, as required, to validate processes and measurement systems throughout manufacturing. The validation processes may include the following tools:

- Identification of critical to quality elements
- Establishment and validation of measurement systems
- Process capability studies
- Monitoring of quality performance

- Rolled through-put metrics
- Shipping defects
- Customer failures

The actual processes used to manufacture products for our customers are developed at the plant level and are specialized to our customers' needs. The following diagram depicts the major inputs to and outputs from the overall KE manufacturing process.



### 8.5.2 - Identification and traceability

KE identifies materials and products by suitable means throughout product realization, including the products' status.

Minimum traceability requirements are defined by the customer. KE will meet these requirements and may exceed them if needed to ensure product quality. KE retains the documented information necessary to enable traceability.

### **8.5.3 - Property belonging to customer or external providers**

KE is responsible to exercise care with property belonging to customers or external providers. KE identifies, verifies, protects and safeguards its customers' or external providers' property under KE's control or being used by KE. Customer property can include, but is not limited to:

- Tooling
- Equipment
- Returnable packaging
- Intellectual property
- Material

If any customer or externally provided property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the owner and records maintained.

KE utilizes an intellectual property strategy to ensure that sensitive customer and external provider's data is protected and access to such data is restricted. The confidentiality of company specific data is also ensured through the use of non-disclosure agreements.

### **8.5.4 - Preservation**

KE is responsible for product preservation, including identification, handling, contamination control, packaging, storage and protection of product through the internal manufacturing process and delivery to the customer. This includes, but is not limited to:

- Assessment of stock
- Inventory management
- First-In-First-Out (FIFO)
- Monitoring of shelf life
- Control of obsolete product
- ESD and MSD controls, as applicable

### **8.5.5 - Post-delivery activities**

Post-delivery activities are limited to specific agreements with the customer, such as product warranties and customer specific requirements for the local KE site.

### **8.5.6 - Control of changes**

KE reviews and controls changes for production through the document change system. The review and approval process are used to ensure continuing conformity with requirements.

Records are retained of the change process including the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

## **8.6 - Release of products and services**

KE verifies that the product requirements have been met. The release of products to the customer does not proceed until the planned arrangements have been met, unless otherwise approved by a relevant authority and, as applicable, by the customer.

KE retains records on the release of products to evidence conformity and traceability to release authority.

## **8.7 - Control of nonconforming outputs**

To ensure product integrity and quality, KE identifies and controls non-conforming outputs. KE facilities are responsible to create, implement and manage this process.

KE takes appropriate action based on the nature of the nonconformity and its effect on the conformity of products. This also applies to nonconforming products detected after delivery of products.

KE recognizes its responsibility to promptly notify customers in the event that non-conforming material or products are shipped. Additionally, KE will not intentionally ship non-conforming material without customer consent and approval. When regulatory requirements apply, non-conforming product cannot be accepted by concession unless the regulatory requirements have been met.

KE deals with nonconforming outputs in one or more of the following ways:

- a) Correction
- b) Segregation, containment, return or suspension of provision of products
- c) Informing the customer
- d) Obtaining authorization for acceptance under concession

Conformity to the requirements is verified when nonconforming outputs are corrected. This may include re-inspection or re-testing of products.

KE retains documented information describing the nonconformity, actions taken, concessions obtained, and the authority deciding the action taken.



## **9 - Performance evaluation**

### **9.1 - Monitoring, measurement, analysis and evaluation**

#### **9.1.1 - General**

KE has established a system to provide monitoring, measuring, analysis and evaluation of key QMS process data to:

- Ensure product quality and customer satisfaction
- Ensure effectiveness and efficiency of the quality management system
- Drive continual improvement throughout the organization

To accomplish these goals, KE uses many tools, such as:

- Operational Excellence Metrics
- Operational Excellence Benchmarking
- Customer Scorecards
- Process Metrics
- Quality System audits
- Lean / Six Sigma techniques
- Statistical Process Control
- Process Capability Studies
- Verification / Validation Processes

KE monitors and measures appropriate processes and product characteristics utilizing tools such as:

- Process capability studies
- Statistical Process Control
- Operational Excellence Metrics
- Quality Management System audits

The results of these analyses are used to drive activities such as:

- Process improvement projects
- Continual improvements
- Corrective actions
- Preventative actions
- Reaction plans

KE provides the required training throughout the organization to allow these tools to be used effectively.

### **9.1.2 - Customer satisfaction**

KE's first priority is customer satisfaction. To measure, analyze, evaluate and improve our performance, KE uses tools such as:

- Customer Scorecards
- Periodic Business Reviews
- Operational Excellence Metrics
- Customer Surveys
- Individual Facility Metrics
- Business Manager relationship with the customer

### **9.1.3 - Analysis and evaluation**

The analysis and evaluation of the gathered data is performed on various levels of the organization, depending on the tool and metric used, as detailed in section 9.1.1.

## **9.2 - Internal audit**

KE conducts internal audits according to an established audit program to ensure the integrity and conformity of the Quality Management System and its processes to the relevant internal, customer and normative requirements. These audits may include:

- Quality Management System audits
- Manufacturing process audits
- Product audits

To ensure the proper performance of audit process, KE utilizes:

- Internal audit programs
- Defined audit criteria and scope
- Qualified and objective auditors
- Reporting of audit results to relevant management
- Correction and Corrective Actions
- Evidence of audit program implementation

## **9.3 - Management review**

Top management utilizes periodic Corporate and Facility Management Reviews to assess the status of the QMS, including its suitability, adequacy, effectiveness and compatibility with the KE strategic direction. Elements of the KE Corporate and/or Facility Management Reviews include as a minimum:

- Review of the Quality Policy and Quality Objectives
- Results related to quality objectives
- Customer satisfaction and any other external feedback
- Process performance and product conformity
- Cost of poor quality and field failures (as required)
- Status of preventive and corrective actions

- Results of audits
- Supplier performance
- Opportunities for continual improvement
- Adequacy of resources
- Internal and external changes that could affect the quality management system (including technology and climate changes)
- Effectiveness of actions related to risk and opportunity management
- Follow-up actions from previous management reviews
- New or revised regulatory requirements (if applicable)

Records from the Corporate and Facility Management Reviews include decisions and action item assignments to address improvement and resource needs as well as required changes or adjustments of the QMS. These records are used to evidence achievement of the Quality Objectives and customer satisfaction with products provided.

## **10 - Improvement**

### **10.1 - General**

KE utilizes a continual improvement program based on the Lean / Six Sigma methodology and a global corrective action system using the eight disciplines of problem solving (8-D), or a recognized methodology, or the customer's required system. These tools are used to drive improvements and to correct and prevent issues.

Additionally, KE uses on-going process monitoring and customer feedback to continually improve our processes and our customers' satisfaction.

### **10.2 - Nonconformity and corrective action**

KE will take appropriate actions when nonconformities occur. This includes:

- Containing, controlling and correcting the issue
- Evaluating the need for correction or corrective action
- Implementing the action(s) needed
- Reviewing the effectiveness of action(s) taken
- Evaluating risks and opportunities
- Changing the QMS, if needed

When appropriate, KE utilizes the Global Corrective Action [Intalex](#) system to track and record nonconformities and actions taken. Records of nonconformities, actions taken, and corrective action results will be maintained.

To ensure product integrity and quality, KE identifies and controls non-conforming materials and products. KE facilities are responsible to create, implement and manage this process.

KE recognizes its responsibility to promptly notify customers in the event that nonconforming material or products are shipped. Additionally, KE will not intentionally ship non-conforming

material without customer consent and approval. When regulatory requirements apply, non-conforming product cannot be accepted by concession unless the regulatory requirements have been met.

### **10.3 - Continual Improvement**

KE is committed to continual improvement of the QMS and our business processes. Various improvement processes and tools are used, such as:

- Corrective Action
- Preventive Action
- Lean / Six Sigma projects
- Error proofing

There are many data sources that result in the use of these processes and tools, including:

- Internal audit results
- Failure analysis from field and customer returns
- Statistical process control
- Process FMEA
- Customer complaints
- Internal corrective and preventive action requests
- Management reviews (corporate and facility level)

### **11 - Addendum GQM-1**

This [Addendum to the KE Global Quality Manual](#) is specific for business units having IATF 16949 certification.

**- END OF DOCUMENT -**