



Luminus Devices, Inc
Quality Management Systems Manual
ISO 9001:2008

Quality Management Systems Manual

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Owner Title:	Quality Manager		

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INTRODUCTION

0.1 General

This Quality Management System Manual specifies requirements for Luminus Devices used to address customer satisfaction, to meet customer and applicable regulatory requirements and to meet ISO9001:2008 requirements, and is supported by additional procedures.

0.2 Process Approach

This Manual has adopted the process approach to quality management. Figure 1, is a conceptual illustration of the process approach at Luminus Devices.

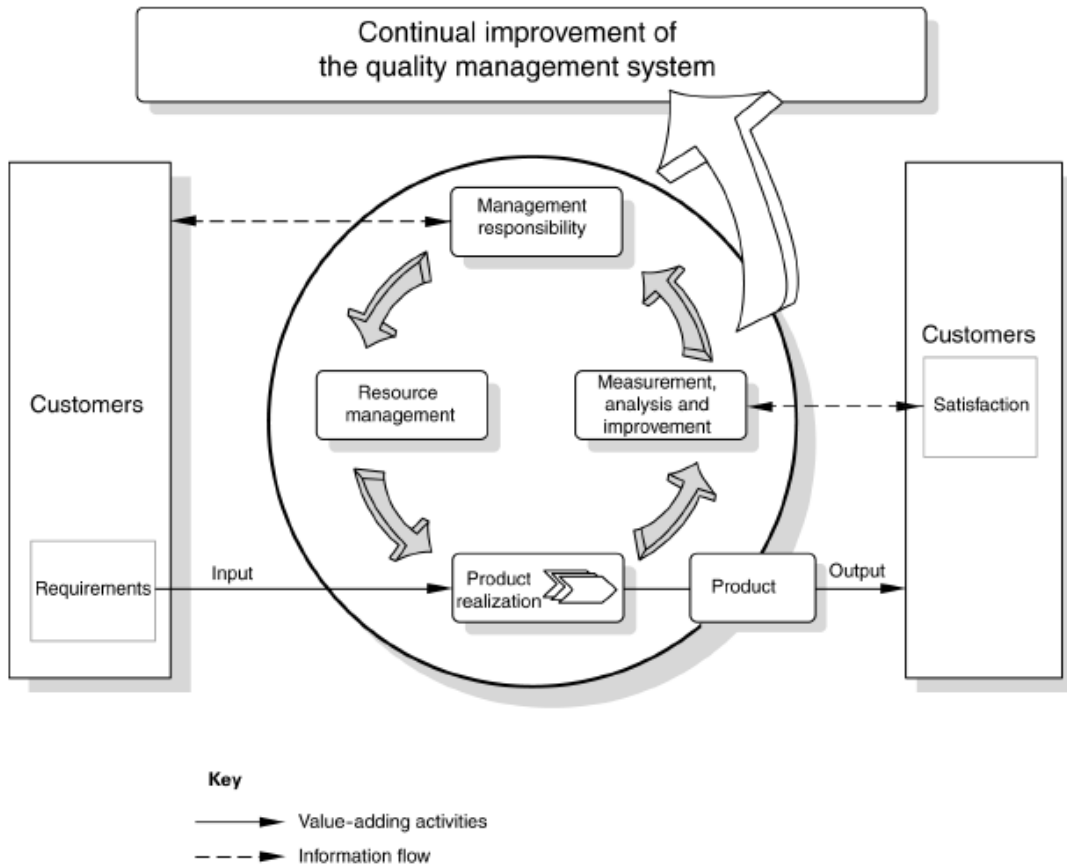


Figure 1 — Model of a process-based quality management system

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1.0 SCOPE

1.1 General

This document specifies requirements for a quality management system in which Luminus Devices:

- a) demonstrates its ability to consistently produce product that meets customer and applicable statutory and regulatory requirements,
- b) aim to enhance customer satisfaction through the effective application of the quality system, including processes for continual improvement and the assurance of conformity to customer and applicable statutory and regulatory requirements

1.2 Permissible Exclusions

Luminus Devices does not provide post-delivery activities at customer locations per section 7.5.1 F of the ISO9001:2008 standard.

1.3 Quality Management Scope

The scope of the quality management system, at Luminus Devices is to **Design, Manufacture and Deliver LED Products**

Locations include:

Luminus Devices, Inc.

175 New Boston St
Woburn, MA 01801

2.0 REFERENCE DOCUMENTS

ISO9000:2005 Quality Management Systems –fundamentals and Vocabulary
ISO9001:2008 Quality Management Systems -Requirements

Luminus Document Master List (Luminus Intranet/Quality/Documentation)

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3.0 TERMS AND DEFINITIONS

QMS Quality Management System

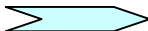
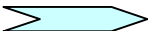
Term “**Product**” only applies to:

- a) a product intended for or required by the customer;
- b) any intended output resulting from the product realization processes section 7.0 herein
- c) wherever the term “product” occurs, it can also mean “service”

Term “**Work Environment**” relates to those conditions under which work is performed including physical, environmental and other factors (such as noise, temperature, and humidity, lighting or weather)

Statutory and **Regulatory** requirements can be expressed as legal requirements.

Term “**Documented Procedure**” appears herein, 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: The terms used in this Manual are to describe the supply-chain as follows:
SUPPLIER  ORGANIZATION  CUSTOMER

4.0 QUALITY MANAGEMENT SYSTEM

4.1 General Requirements

Luminus Devices establishes, documents, implements, maintains and continually improves its quality management system in accordance with the requirements of ISO9001:2008.

To implement the quality management system, Luminus Devices:

- a) determine the processes needed for the quality management system,
- b) determines the sequence and interaction of these processes,
- c) determines criteria and methods required to ensure the effective operation and control of these processes,
- d) ensures the availability of resources and information necessary to support the operation and monitoring of these processes,
- e) monitor, measure where applicable and analyzes these processes, and implements action necessary to achieve planned results and continual improvement,

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- f) implement action necessary to achieve planned results and continual improvement of these processes.

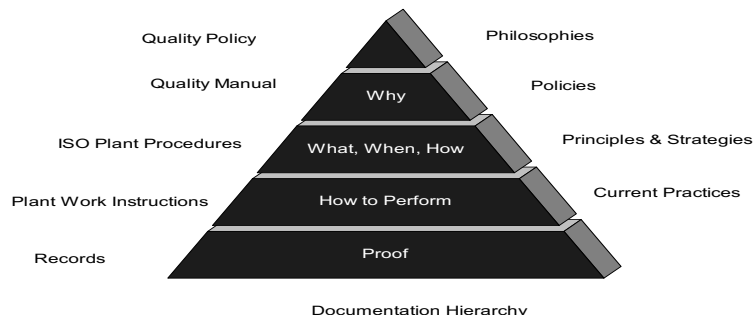
When any process is outsourced Luminus ensures product conforms to the required statutory, regulatory and customer requirements. How Luminus ensures control over those outsourced processes as defined and managed as specified in the Supplier Management Procedure, QAP-000305 and QSP-000022, Product or Process Transfer to Contract Manufacturing. This may include but is not limited to assembly, test and wafer fab processing. Refer to Appendix 1.

4.2 Documentation Requirements

4.2.1 General:

The quality management system documentation includes:

- a) documented statements of a quality policy and quality objectives
- b) a quality manual
- c) procedures and records required per ISO9001:2008;
- d) documents , including records required by Luminus Devices to ensure the effective planning, operation and control of its processes;
- e) requirements imposed by the applicable regulatory authorities



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4.2.2 Quality Manual

This quality manual has been established and maintained to include:

- a) refer to section 1.3 for the scope of the quality management system,
- b) reference to the documented procedures established for this Quality Management System,
- c) a description of the sequence and interaction of the processes included in the quality management system see appendix 1.

4.2.3 Control of Documents

Documents required for the quality management system are controlled through QSP-000002, Document and Data Control. The Engineering Change Order, Procedure DCP-000103 defines 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 identify the current revision status of documents and changes,
- d) to ensure that relevant versions of applicable documents are available at points of use,
- e) to ensure that documents remain legible, readily identifiable and retrievable,
- f) to ensure that documents of external origin determined by Luminus to be necessary for the planning and operation of the QMS are identified and their distribution controlled,
- g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

4.2.4 Control of Quality Records

Records are established to provide evidence of conformance to the requirements and the effective operation of the QMS. Luminus defines the controls needed for the identification, storage, protection, retrieval, retention and disposition of records in procedure QSP-000006, Control of Records.

Records shall be available for review by customers and regulatory authorities in accordance with contract or regulatory requirements.

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5.0 MANAGEMENT RESPONSIBILITY

5.1 Management Commitment

Management personnel provide evidence of its commitment to the development and improvement of the quality management system by:

- a) communicating to the organization the importance of meeting customer as well as regulatory and legal requirements,
- b) establishing the quality policy and quality objectives,
- c) conducting management reviews, and
- d) ensuring the availability of necessary resources

5.2 Customer Focus

Management ensures that customer needs and expectations are defined per procedure QSP-000009, New Product Introduction, SMP-000116, Contract Review, converted into requirements and fulfilled with the aim of achieving customer satisfaction.

5.3 Quality Policy

The Executive team has defined the Company's quality policy. This policy:

- a) is appropriate to the purpose of Luminus Devices,
- b) includes a commitment to meet requirements and to continually improve the Quality Management System,
- c) provides a framework for defining, establishing, documenting and reviewing quality objectives,
- d) is communicated and understood at appropriate levels within the company; and
- e) is reviewed for continuing suitability during Management review

The Quality Policy for Luminus is:

Luminus delivers value to its customers by enabling them with industry leading LED products and excellence in customer support. Our employees are personally committed to continually improve the effectiveness of our management system.

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5.4 Planning

5.4.1 Quality Objectives

The CEO together with the Executive Management Team ensures that the company sets objectives and updates them annually. These objectives are measurable and consistent with the quality policy and designed to help meet customer requirements for the products and ensure the success of the business. The objectives are communicated to all levels of the Luminus organization and progress is reviewed periodically.

5.4.2 Quality Management System Planning

Managers ensure that the resources needed to achieve the quality objectives are identified and planned. The quality plan is documented and kept according to procedure QSP-000019, Quality Planning and Product Realization. The Management Representative ensures that change is conducted in a controlled manner and that the integrity of the quality management system is maintained during this change.

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

Top Management shall identify functions and their interrelations within Luminus Devices through organization charts, procedures, flowcharts and job descriptions.

5.5.2 Management Representative

The Luminus CEO has appointed the Quality Manager as the management representative who, irrespective of other responsibilities, has the responsibility and authority for:

- a) ensuring that processes of the quality management system are established, implemented and maintained;
- b) reporting to top management on the performance of the quality management system, including needs for improvement;
- c) promoting awareness of customer requirements throughout Luminus Devices;
- d) liaison with external parties on matters relating to the quality management system;
- e) organizational freedom to resolve quality matters;

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5.5.3 Internal Communication

Luminus Devices has created appropriate processes to ensure communication among its various levels and functions regarding the processes of the quality management system and their effectiveness. This is documented in procedure QSP-000020, Communication.

5.6 Management Review

5.6.1 General

The Luminus Devices Executive management team reviews the quality management system at least twice per year to ensure its continuing suitability, adequacy and effectiveness. This review evaluates any need for changes to Luminus Devices' Quality Management System, including its quality policy and quality objectives.

5.6.2 Review Input

Input to management review includes current performance and improvement opportunities related to the following:

- a) internal quality audit results;
- b) feedback from internal and external customers;
- c) process performance and product conformance;
- d) status of preventive and corrective actions;
- e) follow-up actions from earlier management reviews;
- f) changes that could affect the quality management system;
- g) recommendations for improvement;

5.6.3 Review Objectives

The Management Review will include actions related to:

- a) improvement of the quality management system and its processes;
- b) improvement of product related to customer requirements;
- c) resource needs;

Results of management reviews are recorded and maintained according to Procedure QSP-000015, Management Review of the Quality System.

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6.0 RESOURCE MANAGEMENT

6.1 Provision of Resources

The CEO working with his staff reviews resource needs, as required.

Luminus Devices shall determine and provide the resources needed to implement and maintain the quality management system and continually improve its effectiveness, and to enhance customer satisfaction by meeting customer requirements.

6.2 Human Resources

6.2.1 General

Luminus Devices personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience.

6.2.2 Competency, Training and Awareness

Training is documented in Procedure QSP-000011. Luminus Devices management:

- a) utilizes job descriptions to identify competency requirements for personnel performing work affecting conformity to product requirements,
- b) where applicable, provide training or take other actions to achieve the necessary competence,
- c) evaluates the effectiveness of the action taken,
- d) ensures that its employees are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and
- e) maintain appropriate records of education, experience, training and skills.

6.3 Facilities

Luminus Devices provides and maintains its facilities to achieve the conformity of product, including:

- a) workspace and associated facilities,
- b) equipment, hardware and software, and
- c) supporting services (such as transport, communication or information systems)

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6.4 Work Environment

Luminus Devices maintains its facilities to identify and manage the human and physical factors of the work environment needed to achieve product conformity, as appropriate. The list may include but not limited to:

- SOP-000117, Operational Area Guidelines
- SOP-000346, ESD Program
- SOP-000985, Environmental Controls

7.0 PRODUCT REALIZATION

7.1 Planning of Realization Processes

The sequence of processes and sub-processes required to achieve the product defines product realization. Planning of product realization processes shall be consistent with the other requirements of Luminus Devices' quality management system and is documented in forms suitable for Luminus Devices' method and areas of operation. In planning the processes for realization of product Luminus Devices has determined the following, as appropriate:

- a) quality objectives for the product, project or contract,
- b) the need to establish processes and documents, and to provide resources specific to the product,
- c) verification, validation, monitoring, measurement, inspection and test activities specific to the product, and the criteria for product acceptance,
- d) records are necessary to provide confidence of conformity of the processes and resulting product, and
- e) identification of resources to support operation and maintenance of the product

Documentation that describes how the processes of the quality management system are applied for a specific product, project or contract can be referred to as a quality plan.

7.2 Customer-Related Processes

7.2.1 Identification of Customer Requirements

Luminus Devices determines customer requirements including:

- a) product requirements specified by the customer, including the requirements for delivery and post delivery support (includes warranty and contract obligations when applicable),
- b) product requirements not specified by the customer but necessary for intended or specified use,

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- c) statutory and regulatory requirements applicable to the product, and
- d) any additional requirements considered necessary by Luminus

7.2.2 Review of Product Requirements

Luminus Devices reviews the identified customer requirements together with any additional requirements determined as specified in SMP-000116, Customer Purchase Order Processing and SMP-001562, Quote Generation Process. Contract review is conducted prior to the commitment to supply a product to the customer (e.g. submission of a tender, acceptance of a contract or order) and ensures that:

- a) product requirements are defined,
- b) contract or order requirements differing from those previously expressed (e.g. in a tender or quotation) are resolved,
- c) Luminus Devices has the ability to meet defined requirements, and
- d) risk has been evaluated during the engineering reviews under the New Product Introduction Process.

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

The results of the review and subsequent follow-up actions are recorded. Where product requirements are changed, Luminus Devices ensures that relevant documentation is amended following QSP-000002 Document and Data Control Process using Omnify PLM System. Luminus Devices communicates any changes to relevant personnel to ensure they are made aware of the changed requirements. Records of changes are maintained per QSP-000006.

7.2.3 Customer Communication

Luminus Devices arranges communication as appropriate, with customers relating to, but not limited to:

- a) product information,
- b) inquiries, contracts or order handling, including amendments,
- c) Customer feedback includes but not limited to:
 - SMP-000892, Customer Complaint Procedure
 - QAP-000121, Processing Customer Returns

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7.3 Design and/or Development

Luminus Devices does perform Design & Development of Products. The Design & Development Process is discussed in detail in QSP-000009.

7.3.1 Design & Development Planning

Luminus Devices plans and controls the Design & Development of products and process. During the concept and feasibility phase, Luminus Devices shall determine:

- a) design and development stages,
- b) review, verification and validations that are appropriate to each stage, and
- c) responsibilities and authorities for design and development

Luminus Devices manages the interfaces between different groups involved in Design & Development process to ensure effective communication and clear assignment of responsibility and authority.

The planning records shall be updated, as appropriate, as the design and development planning progresses.

Note: Design and development review, verification and validation have distinct purposes as outlined in QSP-000009, Design Control/New Product Introduction Procedure. They may be conducted and reported separately or in any combination, as suitable for the product and Luminus.

7.3.2 Design & Development Inputs

Inputs relating to product requirements are determined and records are maintained. Inputs include, but are not limited to:

- a) functional and performance requirements,
- b) applicable statutory and regulatory requirements,
- c) information derived from previous similar designs, and
- d) other essential requirements

The inputs are reviewed for adequacy, with requirements being completed, unambiguous and not in conflict with each other.

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7.3.3 Design & Development Outputs

The outputs of Design & Development are provided in a form that enables verification against the Design & Development inputs and are reviewed and approved before release. This is supported through Luminus Intuitive Enterprise Business System (ERP) and Omnify (PLM) Product Lifecycle Management software.

Luminus Devices' Design & Development outputs:

- a) meet the input requirements for design and development,,
- b) provide appropriate information for purchasing and production,,
Note: information may include preservation of product,
- 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) identify appropriate key characteristics

All pertinent data required to allow the product to be identified, manufactured, inspection, used and maintained is maintained in the Intuitive Enterprise Business System (ERP) software.

7.3.4 Design & Development Review

Luminus Devices at suitable stages performs systematic reviews of Design and Development under planned arrangements as specified in QSP-000009, Design Control/New Product Introduction Procedure;

- a) to evaluate the designs to meet requirements, and
- b) identify any problems and propose necessary actions

Reviews shall involve representatives from all functions within Luminus Devices that are concerned with the applicable design and development stage being reviewed. Records of the results of the reviews and any necessary action are maintained as specified in QSP-000006, Control of Records.

7.3.5 Design & Development Verification

Verification is performed in accordance with planned arrangements to ensure that the Design & Development outputs have met the Design & Development input requirements. Records of the result of the verification and any necessary actions are maintained.

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7.3.6 Design & Development Validation

Design & Development validation are performed in accordance with planned arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use. Wherever practical, validation will be completed prior to the delivery or commercial introduction of the product. Records of the result of validation results and any necessary actions are maintained as specified in QSP-000006, Control of Records.

7.3.7 Control of Design & Development Changes

Design & Development changes are identified and records maintained through the Engineering Change Order Procedure, DCP-000103. The changes are reviewed, verified and validated, as appropriate and approved before implementation.. The review of Design & Development changes includes evaluation of the effects of the changes on constituent parts and product already delivered, as appropriate.

Records of the results of the review of changes and any necessary actions are maintained through the Omnify (PLM) Product Lifecycle Management System.

7.4 Purchasing

7.4.1 Purchasing Process

Luminus Devices has a process to ensure that purchased product conforms to specified purchase requirements. The type and extent of control to be exercised depends upon the type of product, the impact of purchased product on the quality of final product, and previously demonstrated capability and performance of Suppliers as specified in QSP-000008 Purchasing, and QSP-000022 Product Transfer to Contract Manufacturer.

Luminus Devices:

- a) evaluates and selects its suppliers based on their ability to supply product in accordance with its requirements,
- b) establishes and maintains a list of acceptable Suppliers,
- c) selection criteria for initial and ongoing evaluation and re-evaluation shall be established, and
- d) records of the results and any necessary actions shall be maintained

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7.4.2 Purchasing Information

Purchasing documents contain information describing the product to be purchased, including where appropriate:

- a) requirements for approval of:
 - product,
 - procedures,
 - processes,
 - equipment
- b) requirements for qualification of personnel;
- c) quality management system requirements;

Purchasing or their designee ensures the adequacy of specified requirements contained in the purchasing documents prior to their release per QSP-000008.

7.4.3 Verification of Purchased Products

Luminus Devices identifies and implements the activities necessary for verification of purchased product. Where Luminus Devices or its customer proposes to perform verification activities at the supplier's premises, Luminus Devices may specify the intended verification arrangements and method of product release in the purchasing information.

Verification may include:

- a) obtaining objective evidence of the quality of the product from suppliers;
- b) inspection and auditing at supplier's premises;

Where specified by contract, the customer, or regulatory representatives shall be afforded the right to verify at the supplier's premises and Luminus Devices' premises that subcontracted product conform to requirements. This information is stated in the Purchase Order.

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

Luminus Devices controls production and service operations through:

- a) the availability of information that specifies the characteristics of the product,
- b) the availability of work instructions that accurately reflect the require work where necessary
- c) the use and maintenance of suitable equipment for production,

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- d) the availability and use of measuring and monitoring equipment,
- e) the implementation of monitoring and measuring activities, and
- f) the implementation of product release, delivery and applicable post-delivery activities

7.5.2 Validation of Processes

Validation demonstrates the ability of the processes to achieve planned results. Luminus Devices validates any production processes where the resulting output cannot be verified by subsequent measurement or monitoring. This includes any processes where deficiencies may become apparent only after the product is in use or has been delivered.

Luminus Devices has defined arrangements for validation that include the following, as applicable:

- a) defined criteria for review and approval of the processes,
- b) approval of equipment and personnel,
- c) use of defined methodologies and procedures,
- d) requirements for records, and
- e) re-validation;

Procedures include but limited to:

-
- SOP-001108 Equipment Qualification Procedure
-

7.5.3 Identification & Traceability

Luminus Devices identifies, the product, where appropriate, by suitable means throughout product realization.

Product status is identified with respect to measurement and monitoring requirements throughout the product realization.

Luminus Devices controls and records the unique identification of the product where traceability is a requirement and records are maintained.

7.5.4 Customer Property

Care will be exercised while customer property is under control or being used by Luminus Devices. Luminus will identify, verify, protect and maintain customer property (including intellectual property and

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personal data given in confidence) provided for use or incorporation into the product.

In the event of any customer property that is lost, damaged or otherwise found to be unsuitable for use it will be recorded in accordance with QSP-000003, Non-conforming Product and reported to the customer as required. Records of such activity are maintained.

7.5.5 Preservation of Product

Luminus Devices preserves product conformity to customer requirements during internal processing and delivery to the intended destination in order to maintain conformity to requirements. This includes identification, handling, packaging, storage and protection and applies to the constituent parts of a product. This is documented in QSP-000014, Handling, Storage, Packaging, and Preservation..

7.6 Control of Monitoring and Measuring Equipment

Luminus Devices identifies the measurements to be made as well as the measuring and monitoring equipment required to assure product conformity to specified requirements. This is documented in QSP-000007. Control of Monitoring and Measuring Equipment used, are controlled to ensure that measurement capability is consistent with the measurement requirements. Where applicable, measuring and monitoring equipment shall:

- a) be calibrated, verified or both and adjusted periodically or prior to use, against devices traceable to international or national standards; where no such standards exist, the basis used for calibration is recorded;
- b) be adjusted or re-adjusted as necessary;
- c) have identification in order to determine its calibration status;
- d) be safeguarded from adjustments that would invalidate the calibration;
- e) be protected from damage and deterioration during handling, maintenance and storage;

Luminus has the validity of previous results re-assessed if they are subsequently found to be out of calibration. When deemed necessary, Corrective Action is taken; on the equipment and any product affected.

Non-commercial or customized software used for measuring and monitoring of specified requirements is validated prior to use.

Note: Software used is verified to ensure it is suitable for use for the intended application.

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Luminus Devices shall maintain a register of monitoring and measuring equipment, and define the process employed for their calibration including details of equipment type, unique identification, location, frequency of checks; check method, acceptance criteria, and that environmental condition are suitable for the calibrations, inspections, measurements and tests being carried out.

Records of the results of calibration and verification are maintained.

8.0 MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 General

Luminus Devices defines plans and implements the measurement and monitoring activities needed to assure conformity of the product requirements and QMS and to achieve continuous improvement. This includes the determination of the need for, and use of, applicable methodologies including statistical techniques.

8.2 Measurement and Monitoring

8.2.1 Customer Satisfaction

Luminus Devices monitors information on customer satisfaction as one of the measurements of performance of the quality management system. How Luminus monitors the customer perception may include but not limited to:

-
-
- Processing Customer Returns as specified in QAP-000121.

8.2.2 Internal Audit

Luminus Devices conducts internal audits at planned intervals to determine whether the quality management system conforms to the requirements of ISO9001:2008 and has been effectively implemented and maintained.

Luminus Devices plans the audit program annually, taking into consideration the status and importance of the activities and areas to be audited as well as the results of previous audits. The audit scope, frequency and methodologies are to be re-defined at that time.

Audits are conducted by personnel other than those who perform the activity being audited.

Procedure QSP-000005, Internal Audit System, defines

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- the responsibilities and requirements for planning and conducting audits,
- ensures audits are conducted by personnel other than those who perform the activity being audited to ensure objectivity and impartiality of the audit process,
- audit records and results to be maintained, and
- reporting of results to management.

Management responsible for the area being audited takes timely corrective action on deficiencies found during the audit. Results of audits are recorded and maintained. Follow-up actions include the verification of the implementation of corrective action, and the reporting of verification results.

8.2.3 Measurement and Monitoring of Processes

Luminus Devices applies suitable methods for measurement and monitoring of those realization processes necessary to meet conformity to product requirements and on the effectiveness of the quality management system. These methods confirm the continuing ability of each process to satisfy its intended purpose. When planned results are not achieved, appropriate Corrective Action is taken.

8.2.4 Measurement and Monitoring of Product

Luminus Devices measures and monitors the characteristics of the product to verify that requirements for the product are met. This is carried out at appropriate stages of the product realization process. Evidence of conformity with the acceptance criteria is documented and maintained on the applicable process traveler. Records will indicate the authority responsible for the release of the product for delivery to the customer.

Acceptance of product and service for delivery to the customer will not proceed until all the specified activities have been satisfactorily completed, unless otherwise approved by the customer.

8.3 Control of Nonconforming Product

Luminus Devices ensures that product which does not conform to requirements is identified and controlled to prevent unintended use or delivery and takes appropriate action to eliminate the detected nonconformity. QSP-000003, Nonconforming Product defines the controls and related responsibilities and authorities for dealing with nonconforming product/. material. Luminus Devices deals with Nonconforming product by one or more of the following ways

- a) by taking action to eliminate the detected nonconformity;

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- b) by correcting and subjecting to re-verification after correction to demonstrate conformity,
- c) by authorizing its use, release or acceptance under concession by a body of designated Luminus employees and where applicable by the customer,
- d) by taking action to preclude its original intended use or applications,
- e) by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started,

Records of the nature of the nonconformities and any subsequent action taken including concessions obtained through the Material Review Board (MRB) shall be maintained.

8.4 Analysis of Data

Luminus Devices collects and analyzes appropriate data to determine the suitability and effectiveness of the quality management system and to identify improvements that can be made. This includes data generated by measuring and monitoring activities and other relevant sources. Procedure QSP-000017 documents this process.

Luminus Devices analyzes this data to provide information on:

- a) customer satisfaction and/or dissatisfaction,
- b) conformance to customer requirements,
- c) characteristics of processes, product and their trends, and
- d) suppliers

8.5 Improvement

8.5.1 Planning for Continual Improvement

Luminus Devices plans and manages the processes necessary for the continual improvement of the quality management system. Luminus Devices facilitates the continual improvement of the quality management system through the use of the quality policy, objectives, audit results, analysis of data, corrective and preventive action and management review.

8.5.2 Corrective Action

Luminus Devices takes corrective action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective action is to be appropriate to the impact of the problems encountered.

The documented procedure for corrective action is QSP-000004, and defines requirements for:

- a) identifying nonconformities (including customer complaints),
- b) determining the causes of nonconformity,
- c) evaluating the need for actions to ensure that nonconformities do not recur,
- d) determining and implementing the corrective action needed,

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- e) recording results of action taken,
- f) reviewing the effectiveness of the corrective action taken

8.5.3 Preventive Action

Luminus Devices identifies preventive action to eliminate the causes of potential nonconformities to prevent occurrence. Preventive actions taken are appropriate to the impact of the potential problems.

The documented procedure for preventive action, QSP-000004, defines requirements for:

- a) identifying potential nonconformities and their causes,
- b) determining and ensuring the implementation of preventive action needed,
- c) recording results of action taken, and
- d) reviewing the effectiveness of the preventive action taken.

Please direct all comments, concerns, and recommendations to the

Quality Manager
Luminus Devices, Inc.

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Woburn, MA 01801

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Appendix 1: Interaction of Processes

