Sensors and Specialist Components

Quality Manual

QM01
ISO 9001:2015
Quality Management System

RELEASED
DATE: 3/23/2022
Document Control

CORPORATE HEADQUARTERS:

OPTEK Technology
2900 E. Plano Parkway, Suite 200
Plano TX 75074

MANUFACTURING:

Optron de Mexico
Avenue Rio Bravo #1551-A
Parque Industrial Rio Bravo
Cd. Juarez, Chihuahua 32557

Table of Contents

About this Manual

This manual was developed for a quality management system aimed primarily at achieving customer satisfaction by meeting customer requirements through the application of the system, the continual improvement of the system and the prevention of nonconformity. The quality management system developed by this manual was based on & demonstrates throughout its wording good quality principles such as leadership, customer focus, continual improvement, involvement of the employees, mutually beneficial supplier relationships, process focus, management by a system of processes and ultimately decisions that are based on good sound data.

Optek's Management maintains this manual for the Quality Management System and for Optek employees' use. The online version incorporates links (in blue) to other pertinent procedures, process maps, and documents making it use easier than a printed version.

Requests for changes should be submitted to Management. Updates of the manual are issued as required. The online version of this quality manual is available to all employees via computers. The online version is to be considered the most current and takes precedence over any printed copy.

It is the responsibility of the Department Heads to ensure that employees are familiar with the manual's content related to their work and responsibilities, and that they are kept informed of any changes and updates.

Effective date of this quality manual: May 3, 2004

RELEASED
DATE: 3/23/2022
Document Control

Approvals:

Juan Gonzalez	Stewart Partridge
Mgmt. Representative Date	Vice President & General Manager Sensors and Specialist Components Date

Overview of TT Electronics / OPTEK

TT Electronics / OPTEK Technology, hereafter called **OPTEK,** is headquartered at 2900 E. Plano Parkway, Suite 200, Plano, Texas 75074 with manufacturing facilities at Optron de Mexico, Avenue Rio Bravo #1551-A Park Industrial Rio Bravo, Cd. Juarez, Chihuahua Mexico 32557. OPTEK's business activities are the design, manufacturing, and sale of electronic sensors. OPTEK provides sensor technologies such as optical (IR, visible, UV & VCSEL), magnetic (Hall-effect) and fiber optic (LED & VCSEL to 2.5G). OPTEK sensors are found in office equipment, industrial applications, encoders, military & Hi-Rel applications, medical diagnostic equipment, automotive engine and door controls and ignition security and fiber optic

data communication applications. Sensors can be standard product or custom made to customer's specification.
This quality manual describes the Quality Management System of OPTEK**.** Its purpose is:

- **for internal use,** to communicate to employees the company's Quality Policy and quality objectives, to make the employees familiar with the method of compliance with **ISO 9001** requirements, to facilitate the implementation and maintenance of the Quality Management System and to ensure its continuity and required updates during changing circumstances, to provide effective communication and control of quality related activities and a documented base for quality system audits.

- **for external use,** to inform OPTEK's customers and other interested external partners about OPTEK's Quality Policy, OPTEK's implemented Quality Management System, and measures of compliance with the requirements of **ISO 9001**.

Scope

This Quality Management System described hereafter complies with all the requirements of **ISO 9001**, is focused on the enhancement of customer satisfaction through continual improvement of processes and products and demonstrates compliance with customer and regulatory requirements.

The scope of the Quality Management System covers the design and manufacturing of sensor systems, the manufacture of custom-made piece parts and final products as well as the construction of dies and fixtures at either OPTEK's location at 2900 E. Plano Parkway, Suite 200, Plano, Texas 75074 or Optron de Mexico, Juarez manufacturing site.

Customer specific requirements are evaluated and included per **ISO 9001** guidelines.

OPTEK's Quality Management System meets all requirements of **ISO 9001.**

Exclusions / Justifications:
Exclusions as applied to the Optron de Mexico manufacturing site are all those as related to the Product Design Functions, such functions are based at Optek Technology Plano Texas site where the company headquarters are located. The processes about New Product Introduction are initiated and controlled from OPTEK's Plano Texas facility. Appropriate communication channels exist between the Design site and the Manufacturing site for product documentation, product validation and product change approvals. Ultimate approval of product changes remains at the Design Product Engineering Function out of Plano Texas.

Applicable Standards

The content and application of this quality manual makes reference to the following publications and related documents:

- **ISO 9001:2015**
- **ISO/IEC 80079-34**

The quality manual includes the scope of the Quality Management System and makes reference to applicable operating procedures and other pertinent documents. Process Map#057 is a description of the Quality Management System interaction of processes. **Referenced specific procedures or MAP's may vary from site to site.**

Management Structure

The management at Optek Technology, Inc. is led by the Sensors and Specialist Components Division leadership which consist of VP Operations and General Manager. Reporting directly to the VP/GM are VP Engineering, Global Sales Director, VP Quality, Strategic Sourcing Director, and Site Directors. Reporting dotted line to VP/GM are VP Human Resources and VP Finance.

Corporate Responsibility

TT Electronics maintains corporate responsibility policies and periodically communicates to management.

- TT Electronics Statement of Values and Business Ethics Code
- Anti-Bribery & Corruption (ABC)
- TT Bribery Act Group Policy

Process Owners

Process owners are responsible for management of the organization processes and related outputs, process owners understand their roles and are competent to perform those roles. Process owners are assigned to functional department heads for Manufacturing, Production Control, Purchasing, Process Engineering, Human Resources, Finance, Quality, Product Engineering, Sales, and Customer Service.

Context of the Organization

Optek determines, reviews and monitors information on external and internal issues, positive and negative conditions, that are relevant to its purpose and strategic direction and that affect its ability to achieve the intended results of its quality management system through opportunities for improvement identified by (SWOT) Strengths Weaknesses Opportunities and Threats analysis.

1 Management Processes

1.1 Quality Management System Implementation & Maintenance

It is the responsibility of Management

- to continually improve the effectiveness of the Quality Management System

1.1.1 QMS General Requirements

a) Operational and administrative activities affecting quality of the departments Engineering, Manufacturing, Quality Assurance, Purchasing, Warehouse, Toolroom, Sales and Customer Service and Quality Management System Administration are in compliance with **ISO 9001.** It is the responsibility of the Management Representative and Department Heads to ensure that the activities/processes included in the scope of this Quality Management System are identified and are performed in compliance with **ISO 9001.**

b) It is the responsibility of the Management and Department Heads to ensure that the sequence and interaction of processes or activities of this Quality Management System are determined in a suitable manner, utilizing tools such as process maps, quality plans, flow charts, operating procedures, etc. Process Map #040

c) It is the responsibility of the Management and Department Heads to apply the necessary techniques and criteria in order to verify that established processes/activities and their implemented controls are effective.

d) It is the responsibility of the division EVP, Management, and the Department Heads to ensure that the necessary human and material resources, as well as the necessary information, are available to ensure the effective operation and control of the processes of the Quality Management System.

e) Compliance of product with IECEx Certificate of Conformity # IECEx BAS 11.0123u

f) It is the responsibility of the Management and Department Heads to ensure that the processes / activities which are part of the Quality Management System are monitored, measured, and analyzed regarding their achievement of planned results.

g) As required, the Management and Department Heads ensure that action is taken to obtain expected results of processes/activities, as well as the continual improvement of these processes/activities.

h) In the event that processes, which affect product conformity, are outsourced, Purchasing via Supplier Quality establishes and implements the necessary controls for approval processes to ensure conformance to specified requirements. These implemented controls however do not absolve OPTEK from the responsibility of supplying products that meet customer requirements.

i) QMS Documentation requirements

As a minimum, the documentation of OPTEK's Quality Management System includes

- a Quality Policy and objectives
- this quality manual
- other documents needed by OPTEK for the effective planning, operation and control of processes of the Quality Management System

The document structure of OPTEK's Quality Management System consists of two levels:

1) The Quality Manual, describing the Quality Management System of OPTEK and its compliance with **ISO 9001**

2) Operating procedures, work instructions, forms, master lists, operating instructions, quality plans, control plans and other documents needed by OPTEK for the effective and efficient operation of the Quality Management System.

In addition, records are created as required by **ISO 9001**, as well as records necessary to meet other internal and external requirements.
It is the responsibility of Management to ensure the availability of corporate documents of the Quality Management System**.**

It is the responsibility of the Department Heads to ensure the development and availability of documented procedures, work instructions, operating instructions and any other documents related to their departments, that are necessary to ensure the effective implementation, control and functioning of the Quality Management System and its processes.

1.1.2 Management Commitment

The management of OPTEK is committed to the development, implementation and optimum functioning of the Quality Management System and the continual improvement of its effectiveness. In order to provide this evidence, the division EVP ensures that:

- A corporate Quality Policy is established
- Quality objectives are established by selected departments based on the company business plan
- The importance of meeting customer requirements and statutory and regulatory requirements is part of the training of each employee (245-0015-M01)
- Resources for the implementation and maintenance of the Quality Management System and its processes are provided in a timely manner
- At a minimum, yearly management reviews are conducted to verify the effectiveness, efficiency, and proper functioning of the Quality Management System, including product realization processes and support processes.

1.1.3 Customer Focus

The division EVP ensures that procedures for determining, and meeting customer requirements are established and implemented. The effectiveness of these procedures is measured through customer satisfaction data, which are part of Management Reviews (see 2.1.1 & 1.2.4).

1.1.4 Quality Policy

The management of OPTEK has developed a Corporate Quality Policy, which meets the needs of OPTEK and its customers.

Corporate Quality Policy

TT Electronics is committed to being Trustworthy and Responsible, delivering defect-free and competitive products on time while meeting all customer requirements and striving to continually improve customer satisfaction.

Stewart Partridge
Vice President / General Manager

It is the responsibility of OPTEK's management to implement and maintain this Quality Policy. The Quality Policy includes OPTEK's commitment for continual improvement, for meeting internal requirements and customer requirements, and provides a basis for the establishment and review of quality objectives. The Quality Policy is made known within the organization and understood and adhered to by employees. During management reviews, the Quality Policy is reviewed for its continuing suitability.

1.1.5 Quality Management System Planning

In the first quarter of the year, Management calls for a meeting of the Department Heads with the purpose to review, coordinate and plan the efficiency and effectiveness of the Quality Management System and the realization of established quality objectives of the departments, as well the coordination of improvement opportunities.

The output of these planning activities includes the identification of required resources. As appropriate, results from audits of the Quality Management System are considered. Planning activities are documented and are consistent with other requirements of the Quality Management System.

It is the responsibility of Management to ensure that resulting organizational changes and their consequences are identified and defined, that changes resulting from planning activities are coordinated and implemented in a controlled manner, that changes to the Quality Management System are documented, implemented, and approved, and that the Quality Management System is properly maintained during these changes.

Note: The Quality Planning Team under the responsibility of the Manufacturing Department performs Quality planning for manufacturing process activities.

Each Department Head develops and maintains a process map, flow chart, quality plan or operating procedure, etc. as required for his/her department, showing the workflow of the department as well as evidence of compliance with the requirements of the quality system.

Planning of the quality system includes the risks and opportunities that need to be addressed to:

a) Give assurance that the quality management system can achieve the intended results.
b) Enhance desirable effects.
c) Prevent or reduce un-desirable effects.
d) Achieve improvements.
e) Integrate and implement actions into the quality management system processes.
f) Evaluate the effectiveness of the actions.

Planning for changes

Changes to the quality system are carried out in a planned manner considering:

a) The purpose of the change and its potential consequences.
b) The integrity of the quality management system.
c) The availability of resources.
d) The allocation or reallocation of responsibilities and authorities.

Risk analysis

Risk analysis includes lessons learned from product recalls, product audits, filed returns and repairs, complaints, scrap and rework as applicable.

Customer Specific Requirements

Where applicable customer specific requirements are addressed thru new product introduction and maintained as changes occur.

1.1.6 Responsibility and Authority

It is the responsibility of the site HR to develop and maintain an organization chart of OPTEK. Updated charts are distributed to Department Heads and are available to employees on a need-to-know basis.

1.1.6.1 Responsibility for Quality

It is the responsibility of personnel in Quality Assurance, or personnel in Production and Warehouse, to inform the responsible Department Head of any nonconformity of products or processes. Corrective action is taken as appropriate, including action for the review and improvement of processes. Documents are updated as required.

If necessary, the Department Head can transfer the nonconformity to the Quality Planning Team for review and action.

In the event of nonconformity in production, all personnel are responsible for product quality and have the authority to stop production in order to correct any quality problems. It is ensured that an employee responsible for quality is present at all times during production.

Quality Management ensures that non-conforming product is not shipped to customers and that potential non-conforming products are identified and contained.

Management ensures that production operations on all shifts are staffed with personnel in charge of or, delegated responsibility for insuring conformity to product requirements.

1.1.6.2 Departmental Responsibility for Quality

The responsibility for quality in each department rests with the Department Head. The Department Head is responsible for the development and approval of the department's procedures and work instructions. The Department Heads ensure that the department staff understands and follows the applicable policies and guidelines outlined in the Quality Manual, that the department's personnel adhere to all applicable procedures and work instructions and participates, as appropriate, in the quality improvement process.

In addition, employees are made aware of the importance to meet customer requirements and expectations. It is the responsibility of the Department Heads to ensure that customer requirements and customer expectations, which relate to activities under the department's responsibility, are identified, defined, documented, and met.

Department Heads ensure that the responsibility of employees or functions whose activities affect quality, are defined in procedures and job descriptions. In yearly performance reviews, or when required, these responsibilities for quality, together with other responsibilities of the function, are reviewed and discussed between the Department Head and the employee and are assessed and re-defined as necessary.

1.1.6.3 Individual Responsibility

All employees follow the policies and guidelines outlined in the quality manual and in established procedures. It is the duty of each employee to inform the Department Head or Quality Management when performed activities do not match the established procedures, or when established procedures and work instructions are unclear or ambiguous. The Department Head is notified of any identified nonconformity or deficiency where the correction or prevention of such nonconformity or deficiency is out of the employee's scope of responsibility.

1.1.7 Management Representative

The management of OPTEK appoints a Management Representative who, irrespective of other duties and responsibilities, has the defined authority and responsibility for

a) Ensuring that the processes are delivering their intended outputs.
b) Reporting on the performance of the quality management system and on opportunities for improvement, particularly to top management.
c) Ensuring the promotion of customer focus throughout the organization.
d) Ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

The Management Representative is responsible for the overall coordination, implementation, and administration of the Quality Management System.

1.1.7.1 Customer Representative

The management of OPTEK has assigned the inter-departmental coordination of customer requirements to the manager of the Sales Department, and the direct responsibility of addressing customer requirements to the Department Heads of Sales, Engineering and Manufacturing.

Responsibilities related to customer requirements include:

Sales:

- Coordination of issues related to customer requirements
- Recommendations for corporate quality objectives, including quality objectives for other departments
- Conveyance of temporary deviations to customers
- Analysis of feedback from customers regarding nonconformities
- Follow-up on corrective actions
- Provides information relating to products and services
- Handling enquiries, contracts, or orders including changes
- Handling or controlling customer property
- Establishing specific requirements for contingency actions when relevant

Engineering:

- Recommendations for corporate quality objectives, including quality objectives for other departments
- Quality planning activities
- Product design and development
- Communication with customers on technical issues
- Customer prototype support
- Selection of Special Characteristics

Manufacturing:

- Recommendations for corporate quality objectives, including quality objectives for other departments
- Special training requirements for production and warehouse
- Production planning
- Issues related to customer supplied products (in coordination with Purchasing and/or

Supplier Quality Engineering

- Delivery requirements - shipping inspection

Quality:

- Ensures customer requirements are met.
- Recommendations for corporate quality objectives, including quality objectives for other departments
- Quality planning activities
- Communication with customers on corrective actions
- Corrective and preventive action
- Customer score cards
- Customer portals
- Authority to stop shipments and stop production to correct quality problems

Process Engineering:

- Recommendations for corporate quality objectives, including quality objectives for other departments
- Quality planning activities
- Communication with customers on technical issues
- Customer prototype support
- Selection of Special Characteristics
- Capacity analysis

Human Resources:

- Provides training needed to achieve quality objectives

Production Control:

- Logistics information (outgoing)

Purchasing:

- Logistics information (incoming)

The Sales Department is informed of corrective actions taken by the responsible department regarding the compliance with customer requirements.

1.1.8 Provision of Resources

Management ensures that approved material and human resources, which have been identified by the Department Heads during budget planning and quality planning, are available in a timely manner. This refers to resources required for the implementation, maintenance, and continual improvement of the processes of the Quality Management System, for meeting customer requirements and achieving customer satisfaction. Also included are resource requirements for new projects and other quality related activities. Related expenses are included in the company's financial budget. (Process Map#058).

Consideration is given to capability and constraints of internal resources and what needs to be obtained from external providers.

1.1.9 Human Resources - General

It is the responsibility of the Department Heads to identify qualification requirements of functions or personnel assigned to defined activities that affect quality of product. Qualification requirements include education, training, skills, and experience as appropriate. In the department's budget are provisions for the employment and assignment of qualified and trained personnel.

1.1.9.1 Competence, Awareness and Training

Department Heads ensure that the qualification requirements (such as education, skills, training, experience) for each job are identified, determined, and documented in job descriptions. Training is provided to employees (245-0015-M01) (Process Map#058) or other actions are taken in order to meet defined qualification requirements. The effectiveness of provided training or of related actions is evaluated, actions are taken where applicable.

Employees are made aware of the importance and the impact of their work in relation to product quality, the quality policy, to the achievement of quality objectives and customer satisfaction and how their contribution affects the performance and effectiveness of the quality system and the benefits of improved performance, and the implications of not conforming to the quality management system requirements. Records of employees' education, experience and other qualifications are maintained.

Employees receive Communication internal and external as relevant to the quality system during induction presentations, tier meetings, periodic all hands meetings and other communication activities from sources such as internal and external ppm performance, internal and external ppm events, and customer feedback as applicable.

Organizational knowledge is maintained throughout. Documented procedures, specifications, people experience, education and training support maintenance of organizational knowledge. When needs change and trends change, the available knowledge is validated and/or needs identified for additional requirements.

1.1.9.2 Product Design Skills

It is the responsibility of Engineering to ensure that personnel with responsibility of product design are qualified for the job and have the necessary skills and experience as specified in the applicable job description.

1.1.9.3 Training

Management establishes and maintains the documented procedure (245-0015-M01) for identifying training needs and for providing required training to employees who are performing activities affecting product quality. The procedure includes training for the fulfillment of specific customer requirements. The HR Representative provides training for safety and the handling of hazardous materials. HR prepares annual training plans thru prioritization and according to budget to address training needs as identified by department heads including awareness and achieving competence of all personnel performing activities affecting conformity to product and process requirements.

1.1.9.4 Training on the Job

Department Heads ensure that personnel, assigned to new or modified responsibilities affecting product quality, are trained on-the job. Including customer, internal regulatory or legislative requirements training where applicable, including contracted personnel. Personnel performing activities that can affect quality are informed of potential consequences to the customer in the event that defined requirements will not be met (245-0015-M01).

1.1.9.5 Employee Motivation and Empowerment

Performance reviews conducted by the Department Heads include and document the degree of employee's awareness regarding the importance of their work and their contribution in achieving quality objectives.
Employees throughout the whole organization are continuously motivated and empowered to achieve quality objectives, to make continual improvements and promote innovation.

1.1.10 Planning of Product Realization

The Engineering Department is responsible for the quality planning (Process Map #065) of the production processes of new products and for changes of existing products. Planning activities are consistent with other requirements of the Quality Management System. Prior and during the planning process, quality objectives and quality requirements for product related to the planning project are established by the quality planning team.

As appropriate, the planning process covers provision of resources necessary, manufacturing processes and documents, required verification, validation, monitoring, inspection and test activities, and criteria for product acceptance

Records for providing evidence that manufacturing processes, and manufactured product meet requirements are defined and specified.

1.1.10.1 Planning of Product Realization - Supplemental

Customer requirements and references to technical specifications are included in the quality plan.

1.1.10.2 Acceptance Criteria

Acceptance criteria are defined in the planning process and as required, approved by the customer. Acceptance for attribute data sampling is zero defects (Process Map #065).

1.1.10.3 Confidentiality

Confidentiality of information and data about customer-contracted products/projects is ensured (Process Map #065).

1.1.10.4 Change Control

Changes to production processes (Process Map #065), including changes to products/materials from suppliers, are assessed, validated, and approved by Engineering prior to use and implementation. For proprietary designs, the impact of changes is reviewed with the customer. If requested by the customer, additional verification/identification requirements are met.

1.2 Management Review

1.2.1 General - Quality Management System Performance (Mgmt. Review)

At planned intervals, management have a formal meeting to discuss and review (Process Map #057) the continuing effectiveness and adequacy of the Quality Management System. The review includes the evaluation of the need for changes to the Quality Management System, the Quality Policy and quality objectives, as well as the assessment of improvement opportunities based on the review and analysis of performance trends, achievement of quality objectives, customer satisfaction, the cost of poor quality, and improvement opportunities identified by (SWOT) Strengths Weaknesses Opportunities and Threats analysis.

The frequency of management review is increased based on risk of compliance with customer requirements resulting from internal or external changes impacting the quality management system and performance related issues.

The management review ensures the continuing suitability, adequacy, effectiveness, and alignment with the strategic direction of the organization.

This review covers all clauses of the Quality Management System. As required, Department Heads and employees are invited to attend the meeting when issues of his/her area of responsibility are discussed. The person(s) responsible for the ATEX/IECEx quality systems, as defined in 99-00726-088, shall participate in the review.

Management prepares the agenda of upcoming meetings, ensures that the required data and documents are available for management review, writes the minutes of the meeting, and informs results to the Department Heads and individuals concerned and follows-up on required actions resulting from these meetings. Management is kept informed on the status of follow-up activities. Records of management reviews are maintained.

1.2.1.1 Review Input

As a minimum, the following inputs are to be considered for at least one meeting during the year:

- **a)** The status of actions from previous management reviews.
- **b)** Changes in external and internal issues that are relevant to the quality management system.
- **c)** Information on the performance and effectiveness of the quality management system including trends in:
  1) Customer satisfaction and feedback from relevant parties.
  2) The extent to which quality objectives have been met.
  3) Process performance and conformity of products and services.
  4) Nonconformities and corrective actions.
  5) Monitoring and measurement results.
  6) Audit results.
  7) The performance of external providers.
- **d)** The adequacy of resources.
- **e)** The effectiveness of actions taken to address risks and opportunities.
- **f)** Opportunities for improvement.
- **g)** Cost of poor quality (cost of internal and external nonconformance).
- **h)** Measures of process effectiveness.
- **i)** Measures of process efficiency.
- **j)** Product conformance.
- **k)** Assessments of manufacturing feasibility made for changes to existing operations and for new facilities or new product.
- **l)** Customer satisfaction.
- **m)** Review of performance against maintenance objectives.
- **n)** Warranty performance (where applicable).
- **o)** Review of customer score cards (where applicable).
- **p)** Identification of potential filed failures identified thru risk analysis (such as FMEA).
- **q)** Actual field failures and their impact on safety or the environment.
- **r)** **ISO/IEC 80079-34** standards for “Equipment for use in explosive atmospheres”
- **s)** Review of internal audit, and overall processes & external (authorized product line engineer must attend meeting).
- **t)** Improvement opportunities from SWOT analysis.
- **u)** Internal and External interested parties needs and expectations.
- **v)** Improvement opportunities from risk analysis in process maps.

1.2.1.2 Review Output

Results of the assessment and conclusions of management reviews include the following output:

a) Opportunities for improvement.
b) Any need for change to the quality management system.
c) Resource needed.
d) Action plan when customer performance targets are not met.

1.2.2 Quality Objectives

Each year, management defines Corporate Quality Initiatives in the Business Plan. Yearly quality objectives and measurements are established by Department Heads for their departments based on these Quality Initiatives. Management approves these departmental quality objectives. Internal and external Interested parties and their relevant requirements, needs and expectations are considered when the objectives are established

Established quality objectives are consistent with the Quality Policy, are measurable, take into account applicable requirements, be relevant to conformity of products and services, enhance customer satisfaction, are monitored, are communicated, are updated as appropriate include - as appropriate - objectives to meet product-customer requirements (see 1.1.10), and are defined in such a way that their degree of achievement and results can be measured.

Determination is made about what will are done, what resources are required, who is responsible, when will they be completed, how the results will be evaluated.

Quality objectives for Manufacturing and Quality Assurance are related to the performance of product.

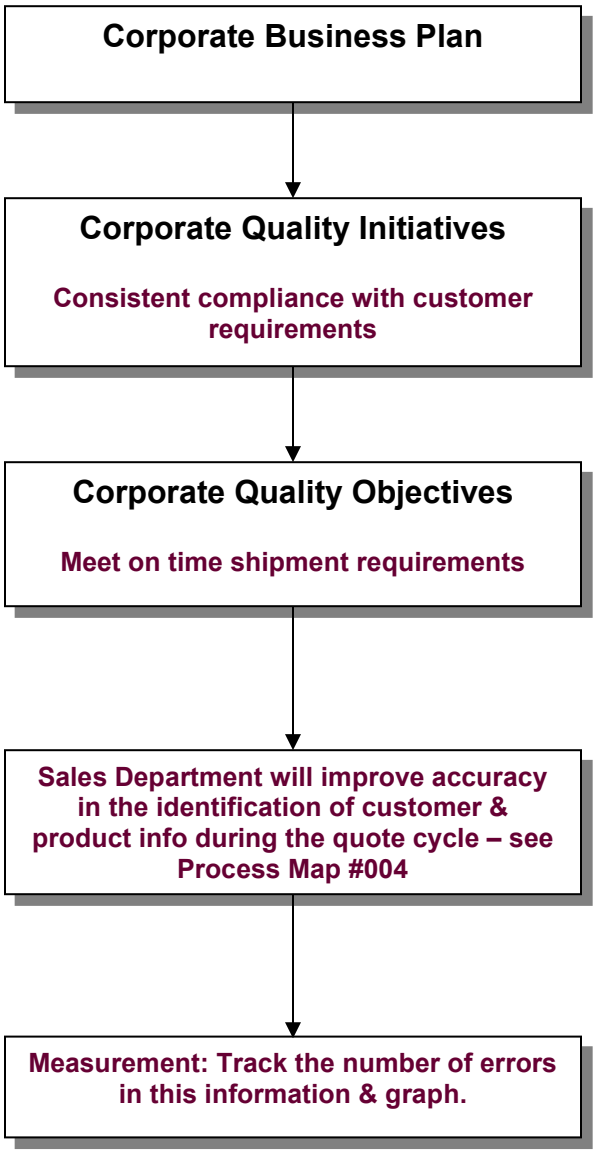
The completion and achievement of yearly quality objectives included in the business plan and departmental quality objectives are reviewed during management review regarding their level of achievement.

Corporate Quality Initiatives
Based on the corporate Quality Policy, the management of OPTEK has established the following corporate quality initiatives based on one premise – that of **Exceeding the Customer's Expectations**. These quality initiatives will be reviewed each year to ensure alignment with the business plan.

- Provide Exemplary Customer Satisfaction
- Be a leader in Advanced Technology Development
- Eliminate waste wherever it exists
- Be the industry benchmark for manufacturing capability

- Provide a work environment that promotes competency, teamwork, empowerment, and accountability
- Deliver exceptional financial performance over time

The translation from a Corporate Quality Initiative to a measurable index for demonstrating results and continual improvement is demonstrated in the following example:



Established by top management to set the direction for the business

Deployment strategies are Optek's Quality Objectives

Objectives are deployed to the function or department with specific goals defined

Specific measurements are tracked to demonstrate results with continual improvement

The end result of this process is to clearly tie the business plan into operational terms that have meaning to front line personnel at all levels within the organization. Our business objectives are our Quality Objectives.

Based on internal and external audit results and statistics issued by Management (Process Map #069), these quality initiatives are reviewed during management reviews regarding their continuing suitability.

Departmental Quality Objectives
Each year, the Department Heads of Administration, Sales, Engineering, Manufacturing, Warehouse, Toolroom and Quality Assurance establish quality objectives for his/her department. These quality objectives are in accordance with the corporate Quality Policy and are focused on the improvement of departmental processes/activities (see process maps). The departmental quality objectives for the coming year are submitted to management for review and approval. A summary of the achievement of the department's quality objectives of the past year is documented by the applicable Department Head and submitted to management.

1.2.3 Measurement Analysis & Improvement - General

In order to demonstrate the conformity of manufactured product, the conformity of the Quality Management System and its continual improvement, Management develops and distributes frequent statistics (Process Map #069). These statistics are analyzed by Department Heads and corrective and preventive action for the continual improvement of the Quality Management System is taken as appropriate.

Key metrics are defined from such subjects as Safety, Quality, Delivery, Cost, and Inventory. Tier meetings are set for continual monitoring of performance to key metrics, and the identification of actions where appropriate thru the PDCA cycle.

1.2.3.1 Identification of Statistical Tools

During product quality planning (Process Map #065), appropriate statistical tools are determined for each process and are included in the control plan. This includes statistical methods for product development (variation analysis, dependability analysis, etc.), for product verification (process capability, variation analysis, control charts, etc.), and other processes.

New processes are evaluated thru process capability studies on key special characteristics to verify process capability and provide additional input to process control.

Process flows or product routings, PFMEA's and control plans are implemented by product or by product families as applicable. Significant process events such as tool change or machine repair are recorded.

1.2.3.2 Knowledge of Basic Statistical Concepts

Department Heads, ensure that personnel are trained in the use and application of basic statistical concepts defined by quality planning and used in their respective departments.

Statistical concepts such as variation, control, process capability and the consequences of over adjustment are understood by employees involved in the collection, analysis, and management of statistical data. Training records are maintained (245-0015-M01)

1.2.4 Customer Satisfaction

Periodic monitors of customer perceptions of the degree of which their needs and expectations are being fulfilled thru customer meetings, delivery parts quality performance, customer satisfaction data, which include customer complaints and feedback, customers' business disruptions (245-0011-M01) customer returns of nonconforming product (field, recalls, warranty) (217-0027-001) and delivery performance, premium freight, customer notifications related to quality or delivery issues, including special status are analyzed and evaluated. As required, management takes corrective or preventive action. Management monitors the effectiveness of these corrective or preventive actions.

1.2.5 Analysis and Use of Data

Management issues statistics regarding the performance of the Quality Management System thru the analysis and use of data. Ratings on supplier performance are issued by Purchasing (Process Map# 060). The statistics are analyzed by Management regarding the effectiveness, suitability and opportunities for improvement of the processes of the Quality Management System, and by Department Heads regarding the performance and suitability of activities and processes under their responsibility. This includes the analysis of customer complaints 245-0011-M01 and customer returns (Process Map# 069).

A summary report is issued by Management, providing information on customer satisfaction or dissatisfaction, product quality, characteristics and trends of processes and products including opportunities for preventive action, and supplier performance.

Management controls and coordinates the implementation of required corrective or preventive actions. Analysis results of statistics and actions are reported by the Department Heads to Management who monitors the progress and results of these actions.

In addition, trends in quality and operational performance are compared with progress toward objectives and lead to action to support: the development of priorities to resolve customer-related problems, to determine customer related trends and correlation for status review, decision making and longer-term planning, and an information system for reporting of product information related to usage.

Improvement

It is the responsibility of Management to form and implement a Quality Planning Team for the handling of assigned activities related to the Quality Management System. Members should be from Quality Assurance, Manufacturing, Engineering, Sales, Purchasing and any other additional members deemed necessary.

The purpose of the Quality Planning Team is to review, analyze and make final decisions on Corrective Action Requests (245-0024-M01) and Quality Improvement Proposals, to make recommendations for preventive actions and quality improvements, to coordinate and implement preventive actions and quality improvement projects, monitor results, and to provide a forum for any quality issue which requires a cross-functional approach. Nonconformities and deficiencies are analyzed, root causes are determined and required action is taken or recommended as appropriate.

As required and/or decided by management, selected *Quality Improvement Proposals* are referred to the Quality Planning Team for review regarding their feasibility and benefits.

1.2.6 Continual Improvement

The planning, coordination and control of activities for continual improvement (Process Map# 069) or (245-0029-M01) is the responsibility of Management and the Quality Team. Continual improvement activities include - but are not limited to - the following:

- activities of the Quality Team under the responsibility of Management
- actions on results from analysis of data
- evaluation of suppliers (213-0115-001); (Process Map# 060)
- achievement of departmental quality objectives
- results from internal quality audits
- quality improvement proposals (QIP)
- corrective actions and preventive actions (CAR)
- periodic review of controlled documents (Process Map #027)

The objectives of the corporate Quality Policy are taken into consideration for planning of improvement. During Management Reviews, its outputs and the effectiveness of continual improvement for the suitability, adequacy and effectiveness of the quality management system is reviewed and opportunities for improvement are identified.

Manufacturing process improvement
It is the responsibility of personnel in Manufacturing to continually monitor the performance of manufacturing processes regarding conformity with product characteristics and process parameters. In monthly meetings with the production staff, process performances of production areas are analyzed, and opportunities for improvement are identified and implemented (QS11) or (245-0029-M01).

1.3 Communication

1.3.1 Internal Communication

Effective internal communication is essential for the proper functioning of the Quality Management System. Management, with the assistance of the Department Heads, ensures that required communication and information between departments and

functions is defined in documented procedures, memos, forms and/or documents, and staff meetings.

Any communication problem regarding the Quality Management System is reported to Management for corrective action.

1.3.2 Customer Communication

In order to meet customer requirements and to ensure the proper and effective communication between the various departments within OPTEK and the customer, Sales establishes a list with some main contacts within OPTEK regarding customer inquiries. This list is updated as required, is distributed to functions concerned and is attached to the main directory available at the front lobby.

Internal and external communication related to the planning of products and processes (Process Map #065) is defined by Engineering and/or Sales and/or the quality planning team, as applicable.

It is the responsibility of Engineering, with the assistance of the IS-department, to install and use electronic communication and design systems (such as CAD) that are compatible with the customers' systems, in order to effectively communicate and interchange information with the customers.

It is the responsibility of Sales, with the assistance of the IS-department, to develop, implement and maintain a computerized system (such as EDI) for the receipt of planning information of customer orders, shipping schedules and shipping information.

Written and verbal communications are made in the language agreed with the customer.

1.4 Internal Auditing

1.4.1 Internal Audit of the Quality Management System

Following the established documented Process Map #057 Internal Quality Audits, Management is responsible for internal audits. Internal audits are planned and scheduled in such a way that all applicable clauses of **ISO 9001** and other additional quality system requirements are audited regarding compliance with this implemented Quality Management System and **ISO/IEC 80079-34**. Audits do also verify if the Quality Management System is effectively implemented and maintained, and that it meets the requirements of OPTEK, including planned actions, objectives, and results.
Internal audits take into consideration the importance of the processes concerned, changes affecting the organization and the results of previous audits.
Internal audits are prioritized based on risk, internal and external performance trends, and criticality of the processes. Where applicable, software development capability assessments are included in the internal audit program.

Management selects the auditors and ensures that they have required experience and knowledge to perform auditing activities.

Audits are scheduled based on the importance of the activity to be audited. Audit activities are assigned to personnel not responsible for the area or activity to be audited. Frequency of audits is reviewed, and where appropriate adjusted based on occurrence of process changes, internal or external nonconformities, and/or customer complaints. The effectiveness of the audit program is reviewed as part of management review.

Audit results are recorded, and corrective action is taken as required. Where applicable, follow-up audits are conducted to ensure that corrective action was implemented and is effective.

Records of internal audits are maintained. As appropriate, management is informed of the results of audits and follow-up audits and takes additional corrective action. Management ensures that audit results are part of Management Review.

1.4.2 Internal Audit Plans

Internal audits cover the entire Quality Management System and its processes, including all shifts of these processes, and are scheduled according to a yearly auditing plan and schedule prepared by Management (245-0037-M01). Due to special circumstances, such as nonconformities and customer complaints, the auditing frequency is increased as appropriate.

The entire quality system processes are audited on a three-year calendar period according to an annual program using the process approach. Integrated to these audits are samples of customer specific quality management system requirements for effective implementation.

1.4.3 Internal Auditor Qualification

It is the responsibility of Management to ensure that internal auditors of the Quality Management System have the necessary experience and qualification for performing internal quality audits (245-0037-M01). Training needs are identified, and training is provided as required (245-0015-M01). Internal auditors conduct audits ensuring objectivity and impartially of the audited process.

Internal auditors are competent and take into account customer requirements. Quality system auditors, manufacturing process auditors and product auditors have competence on:

a) Understanding of the automotive process approach for auditing, including risk-based thinking
b) Understanding applicable customer specific requirements
c) Understanding of applicable **ISO 9001** requirements.as related to the scope of the audit
d) Understanding of applicable core tool requirements as related to the scope of the audit

e) Understanding how to plan, conduct, report, and close audit findings

Additionally manufacturing process auditors have technical understanding of the manufacturing process they audit including PFMEA and control plan. Product auditors understand product requirements and relevant test and inspection equipment to verify product conformance.

Second party audits (where applicable) are conducted by competent, qualified internal Quality System auditors.

1.4.4 Manufacturing Process Audit

In addition to the normal internal audits of the Quality Management System, Management coordinates with the Manufacturing department the auditing of all manufacturing processes. Audits of manufacturing processes are performed on a three-year calendar period including the effective implementation of process risk analysis thru PFMEAs, control plans and manufacturing instructions. Responsible personnel in Manufacturing take required corrective actions. A summary of audit results of the manufacturing processes is prepared and included in Management Reviews.

1.4.5 Product Audit

During the auditing of process in Manufacturing and the Warehouse, inspection, and test results of product in process and finished product are audited to verify conformity to specified requirements. Incoming product, product in inventory and product ready for shipping is audited regarding compliance with packaging and labeling requirements. As appropriate, physical product can be inspected and tested by the auditor to confirm the product's conformance to requirements and proper functionality.(Process Map#057)

1.5 Corrective & Preventive Action

1.5.1 Corrective Action

It is the responsibility of Management to implement and maintain the documented procedure (245-0024-M01) corrective action that defines a corporate approach for corrective action.

Following the established procedure for corrective action (245-0024-M01), nonconformities are identified, root causes are determined, corrective action is evaluated and defined, recurrence of the nonconformity is prevented, corrective actions and their results are recorded, and the effectiveness of corrective action taken is reviewed. Corrective actions are appropriate to the importance and impact of the addressed nonconformity.

It is the responsibility of the Department Heads to inform the Sales/Service department of all customer complaints (Process Map#072) and related corrective actions.

It is the responsibility of the Department Heads to establish and maintain records of corrective actions and their results.

1.5.1.1 Problem Solving

To determine the root cause of a problem or deficiency, and to establish required corrective action, a disciplined problem solving method as outlined in the work instruction (245-0030-M01) or any other suitable method, is used as appropriate.

Customer specific prescribed processes, tools and systems for problem solving will be applied where applicable and specifically required by customers.

1.5.1.2 Error-Proofing

As appropriate, error-proofing methods are applied in the corrective action process to prevent recurrence of the problem. And as part of the preventive action process thru FMEAS. Challenge parts are identified, controlled, and verified.

1.5.1.3 Corrective Action Impact

As applicable, the Team applies lessons learned implemented corrective action to other similar processes or products in order to correct nonconformity, or potential nonconformity.

1.5.1.4 Rejected Product Test / Analysis

Product returned from customers is analyzed by Quality Assurance in order to initiate appropriate corrective action and to prevent recurrence (Process Map #72)

1.5.2 Preventive Action

It is the responsibility of Management to implement and maintain the documented procedure (245-0024-M01) Preventive Action that defines a corporate approach for preventive action to prevent the occurrence of potential non-conformities, deficiencies or problems. Any employee can suggest a preventive action to the responsible Department Head (245-0024-M01). Preventive actions eliminate causes of potential nonconformities in order to prevent their occurrence and are appropriate to the severity of the potential issue.
Processes are established to lessen the impact of negative effects of risk including:

a) Determination of potential non-conformances and their causes
b) Evaluation of the need for action to prevent occurrence of non-conformities
c) Determination and implementing the action needed
d) Documentation of the action taken
e) Review of effectiveness of the preventive action
f) Utilization of lessons learned to prevent recurrence in similar processes

Department Heads analyze and evaluate data of statistics and perform periodic reviews of procedures (Process Map #061) in order to detect deficiencies and problems and to take preventive action as required.

PFMEA's are used as a tool for preventive actions, daily monitors of the Manufacturing factors allow for identification of conditions that may potentially create a non-conformity.

It is the responsibility of the Department Heads to establish and maintain records of preventive actions and their results. Management ensures that relevant information on preventive action is on the agenda of management reviews.

2 Realization Processes:

2.1 Requirements Determination & Review

2.1.1 Determination of requirements related to product

It is the responsibility of the Sales department to ensure that customer requirements related to product are identified and defined. Requirements include recycling, environmental impact and other characteristics identified as a result of the organization knowledge of the product and manufacturing processes.

Potential new or modification to standard products will be reviewed per the New or Modified Standard Product Selection Procedure (99-00726-086) prior to the design and implementation into manufacturing.

Potential new or modification to existing **ISO/IEC 80079-34** products will be reviewed per specification 99-00726-087 prior to the design and implementation into manufacturing.

It is the responsibility of Engineering, represented by the Quality Planning Team, to identify and determine requirements not specified by the customer but necessary for the proper and intended use of the product or service, as well as other requirements identified during product development and quality planning (Process Map #065), including regulatory and statutory requirements (Process Map #065). Once these requirements are determined, they are used as input for product development and quality planning, and other functions concerned are informed as appropriate.

In addition to customer requirements included in design, development, and quality planning (Process Map #065), Department Heads ensure that other requirements specified by customers, as well as customer needs and expectations are identified, determined and documented by the responsible department, and that these requirements are met as appropriate. The Sales department or responsible Department Head also ensures that during set-up and maintenance of new customer files (217-0020-001), order taking and processing (217-0014-001, 217-0011-001), customer returns (217-0027-001) and shipping of products, customer requirements are identified and documented, and understood by all functions concerned.

Based on sales forecast and/or other special requirements documented by the Sales department, Manufacturing prepares production schedules and material requirement reports to ensure availability of product for the fulfillment of customer orders.

Optek has established an International Traffic in Arms Regulations (ITAR) compliance Manual (89-00015-179) that addresses legal and ethical compliance and more specifically, compliance with International Trade Regulations.

Customer-designated special characteristics
It is the responsibility of Engineering, the quality planning team and Manufacturing to apply, document and control special characteristics designated by the customer, with focus on processes affecting safety, compliance with regulatory requirements, the fit or function of a product, or any other requirement of importance. Symbols to be used for these special characteristics are those designated by the customer or other commonly used symbols used in the industry.

2.1.2 Review of Requirements Related to Product, Manufacturing Feasibility

The Sales department is responsible for the review of product specifications and customer requirements (Process Map# 072, 217-0020-001) SDQA. Prior to the submission of a quotation to the customer, or the acceptance or confirmation of an order from a customer, the order or quotation is reviewed to ensure that

- the product and customer requirements are clearly defined and documented
- OPTEK has the capability to meet the requirements of the quotation or order
- requirements of verbal orders are recorded and confirmed prior to acceptance
- any differences between the customer's order and OPTEK's quotation are clarified and resolved.

Waiving the requirement for a formal review requires customer approval. Manufacturing feasibility is analyzed, and a risk analysis is performed, confirmed, and documented (217-0020-001). The results of reviews and required actions are documented.

In the event of changes to product requirements, or other changes to a quotation or order, it is ensured that relevant documents and data are updated and that other functions concerned are notified. Records of contract reviews are maintained.

2.2 Design & Development

2.2.1 Design and Development

If there is a need for the design and/or development of a new custom product or for a change of the design or manufacturing process of a custom product, the originating department submits a Redfolder (217-0020-001) request to Engineering.

If there is a need for a design and /or development of a new standard product or for a change of the design or manufacturing process of a new standard product, the New or Modified Standard Product Selection Procedure (99-00726-086) will be followed.

Design and development activities focus on error prevention rather than error detection.

2.2.2 Design and Development Planning

The planning and control of design and development of product is the responsibility of Engineering (Process Map #065). During the planning process (Design Control Handbook), the project team determines the stages of the design and development project, defines the review, verification and validation of each design and development stage as appropriate, and assigns responsibilities of required tasks and actions.

It is the responsibility of the Project Team Leader to ensure the effective communication and distribution of information between the team members and other functions participating in the planning process.

As the planning process develops, planning output is updated as appropriate, and thru the gate review process of New Product Introduction.

2.2.3 Multidisciplinary Approach

Organizational and technical interfaces, including customer communication, are defined in the Project Plan and Schedule (Design Control Handbook) and are reviewed during each meeting of the team. As required, other functions are consulted within their areas of expertise. A multidisciplinary approach is also used for the development and monitoring of special characteristics, and the development and review of FMEAs and control plans.

2.2.4 Design and Development Input

The originator of the Greenfolder (217-0010-001) identifies and documents the input requirements, which are reviewed by Engineering. Input for product design and development includes functional and performance requirements, statutory and regulatory requirements, customer requirements, product quality and performance objectives, and any other identified requirements. Input for the development of manufacturing processes includes product design output data, targets for productivity, capability, cost, and customer requirements, as applicable (Design Control Handbook).

Any past experience or information from similar projects is applied as appropriate. Ambiguous, missing, or conflicting information is clarified and resolved with the originator of the request before proceeding with the project. Records of design input are maintained.

2.2.5 Special Characteristics

Special characteristics for product and processes, and which are specified by the customer or by OPTEK, are identified and included in control plans, FMEAs and applicable documents in order to ensure proper identification of special requirements of product and processes (Process Map #065).

2.2.6 Design and Development Output

The Project Team produces design output, which is documented, is expressed in terms that can be verified and validated against design input requirements, meets design input requirements, contains, or makes reference to acceptance criteria and includes critical and crucial characteristics for safety and functionality of the product or process. As applicable, design and development output provide data and information for product design, manufacturing process design. Additional outputs for product design include FMEAs, special characteristics, product definitions, design reviews and other defined output results. Additional outputs for process design include drawings, FMEAs, control plans, process performance and other information and data to ensure that manufacturing processes meet requirements (Design Control Handbook).

Design outputs are reviewed prior to release.

2.2.7 Design and Development Review, Monitoring

The Project Team performs formal design reviews to identify any potential problems in meeting requirements and design goals. Problems are identified and appropriate action is taken.

Progress and end results of design and development planning (such as effectiveness, costs, lead time) are recorded at defined stages of the planning and are submitted to Management for input to management reviews.

Records of design reviews and resulting actions are maintained.

RELEASED
DATE: 3/23/2022
Document Control

2.2.8 Design and Development Verification

The Project Team performs periodic design verifications to verify that design and development outputs meet the design and development input requirements. Results of design verifications and resulting actions are recorded and maintained.

2.2.9 Design and Development Validation

The Project Team performs design validation to ensure that the designed product meets defined customer/user needs and requirements. Validation is according to customer requirements and includes program timing. If possible, this validation should be performed prior to production. However, if required, partial validation is acceptable. Results of validations and necessary actions are recorded and maintained.

2.2.10 Prototype Program

If required by the customer, the product development includes the development of a control plan and a prototype (Process Map #065). Processes, equipment, and materials used for the prototype should be the same as those used for final production runs. Testing activities are monitored regarding timely completion and compliance with requirements. In the event that services for prototype development are outsourced, it is understood that OPTEK is still responsible for the quality and performance of the prototype. As required, OPTEK provides technical assistance and support to contractors/suppliers.

2.2.11 Product Approval Process

Sample submission of production parts for consequent customer approval is the responsibility of Quality Assurance. Methods and guidelines specified by the customer are followed. Production part approval is requested for production parts, engineering change of production part, manufacturing location, material suppliers and production process environment. Any change to these conditions requires customer notification and possible re-submission of production parts for approval. OPTEK is responsible for contracted materials and services. (Process Map#062).

As appropriate, production part approval is extended for engineering approval of purchased products.

The Quality Planning Team properly validates engineering changes.

2.2.12 Control of Design and Development Changes

Requests for design and development changes, including proposed changes from suppliers, are documented (217-0010-001, Design Control Handbook). Requests are reviewed and approved by Engineering. Results and necessary actions are documented, and records are maintained.

2.2.13 Product Safety

Product safety considerations:

a) Identification of statutory and regulatory product safety requirements
b) Customer notification of requirements per a) above
c) Special approval for design FMEA
d) Identification of product safety characteristics
e) Identification and controls of safety related characteristics of product and at the point of manufacturing
f) Special approval of control plans and process FMEA's
g) Reaction plans
h) Defined responsibilities, definition of escalation process and flow of information, including top management and customer notification
i) Training identified by the organization or the customer for personnel involved in product safety related products and associated manufacturing processes
j) Changes of products or process shall be approved prior to implementation, including evaluation of potential effects on product safety from process and product changes
k) Transfer of requirements regarding product safety throughout the supply chain, including customer-designated sources
l) Product traceability by manufacturing lot (at a minimum) throughout the supply chain
m) Lessons learned for new product introduction

2.2.14 Software Embedded Product

Product software development assessments and verifications are carried on such products where applicable to ensure the quality of the product.

2.3 Purchasing

2.3.1 Purchasing Process

The Purchasing department is responsible for the effective and efficient operation of purchasing functions and activities (Process Map# 059).

Depending on the effect of the purchased product on the final product or production processes, the type of control applied to the supplier and the method used for verification of purchased product are identified and established by Engineering and/or Quality Assurance.

Production materials, products and services are only purchased from approved suppliers. Suppliers are evaluated and selected according to defined selection criteria and their ability to supply product that meets specified requirements. Records of evaluation and selection of suppliers as well as related actions are maintained by Supplier Quality Engineering (SQE) and/or Supplier Quality Development (SQD).

Supplier performance is monitored per the Supplier *Quality Requirements* paragraph 4 page 12 through the evaluation of product quality, problems reported by manufacturing involving supplied product, delivery performance to acknowledged date and continual improvement.

2.3.2 Regulatory Conformity

Supplier Quality Engineering verifies that incoming purchased products and materials are in compliance with applicable regulatory requirements (245-0009-M01)

2.3.3 Supplier Quality Management System Development

The Purchasing staff encourages suppliers to prepare for and/or implement the necessary procedures in order to meet the requirements of **ISO 9001** and to become certified. All suppliers have access to the manual TT Electronics/OPTEK Supplier *Quality Requirements* as an initial step for getting familiar with quality system requirements. As required, the assistance of Management is requested. Purchasing &/or Supplier Development follows up on the suppliers' progress with the implementation of **ISO 9001** or an acceptable quality management system Process Map# 060.

2.3.4 Customer-Approved Sources

Where according to customer contract, a product or material is to be purchased from a customer-designated supplier, it is the responsibility of the Purchasing department to ensure that these materials, products, or services are only purchased from the customer-designated supplier. The customer must approve alternate suppliers for this product, material, or service. Materials supplied by customer-designated suppliers are subject to

receiving inspection by Quality Assurance (245-0009-M01). For the supply of materials for other applications, the customer-approved supplier must be approved according to OPTEK's approval criteria. Supplier *Quality Requirements*

2.3.5 Purchasing Information

For products and services purchased, including customer supplied product, Purchasing, SQE and/or SQD ensures that required records are set up and maintained. The data describe and clearly identify the product to be ordered, requirements for the approval of product, procedures, processes and equipment, statutory and regulatory requirements, requirements for qualification of personnel, and Quality Management System requirements, as applicable. As appropriate, standards or other documents are referenced. The adequacy of specified purchase requirements is ensured prior to submission to the supplier.

2.3.6 Verification of Purchased Product and Incoming Product Quality

The extent of quality control exercised over a supplier or over the supplied product is determined by Supplier Quality Assurance and depends on the importance of the product or product class, the initial evaluation of the supplier, and/or type and extent of inspection performed by the supplier, and/or the results of ongoing performance ratings of the supplier. Incoming purchased product is submitted to an incoming inspection (245-0009-M01) performed and recorded by Supplier Quality Assurance when supplier product is non-certified.

In the event that OPTEK or one of OPTEK's customers wants to verify purchased product at the supplier's premises, these verification requirements and/or the method of product release are requested and defined by either Engineering, Quality Assurance or Sales, and are specified either in the purchase order and/or part specification. Verification activities at the supplier's premises are coordinated through the Purchasing and/or Quality department. Verification at supplier's site does not exclude subsequent rejection after receipt at OPTEK or OPTEK's customer.

2.3.7 Supplier Monitoring

Supplier performance is monitored through evaluation of product quality, cost competitiveness, continuous improvement efforts, problems reported by manufacturing involving supplied product, delivery performance, and customer feedback.

Purchasing/Supplier Quality develops periodic performance ratings (Supplier Quality Requirements) of approved active suppliers and distributes on a regular basis to the top suppliers, others on request or at OPTEK's discretion. Suppliers are informed of their rating and corrective action is taken as required. Records of supplier performance ratings are maintained.

2.4 Facilities & Equipment Management

2.4.1 Infrastructure

The required infrastructure and resources for manufacturing activities are identified during quality planning (Process Map #065). As applicable, this includes building facilities, necessary workspace and utilities as well as needed equipment and services such as maintenance, warehousing and transportation, information and communication technologies.

Management ensures the timely availability of identified and approved resources.

2.4.1.1 Plant, Facility and Equipment Planning

Plant, facility and equipment planning of the effectiveness of existing equipment and facilities are the responsibility of a multidisciplinary approach and involves departments and functions concerned, plant, facilities and equipment plans in designing plant lay outs are aimed at optimization of material flow, material handling and value-added use of floor space including control of non-conforming product and to facilitate synchronous material flow. The productivity and effectiveness of existing operations is reviewed, monitored and evaluated considering (Process Map#039).

- Human factors
- Operator and line balance
- Availability of supplies
- Use of automation
- Work plans
- Capacity planning
- Lean manufacturing

RELEASED
DATE: 3/23/2022
Document Control

Records of planning activities are maintained as per applicable master list of records.

2.4.1.2 Contingency Plans

The Management team, with participation from Manufacturing, Engineering and Sales, develops contingency plans to meet customer requirements in the event of a production halt or labor shortage. Contingency plans are reviewed in the first quarter of each year regarding their validity. New plans are developed as required.

2.4.2 Work Environment

2.4.2.1 Work Environment

The quality planning team defines special conditions of the work environment that are necessary for the processes to meet defined requirements of product quality and regulatory requirements (Process Map #065). These special conditions are included in the quality plan, manufacturing plan, process sheet or other documents. It is the responsibility of the Department Head to implement these requirements.

Environment factors such as social (i.e., non-discriminatory), psychological (i.e., stress reducing) and physical (i.e., hygiene) are provided and maintained.

2.4.2.2 Personnel Safety to Achieve Product Quality

It is the responsibility of the Department Heads to ensure the safety of employees and to minimize risk of injuries when performing their duties. Accidents at the workplace are recorded, (240-0055-M01), (Process Map# 058). and sent to the HR Representative who keeps a master list of accidents for corrective or preventive actions.

The HR Representative forms the Health and Safety Committee that includes representatives of applicable areas. Any issues or concerns regarding health and safety of processes are reported to the departmental representative.

Product safety is addressed during the design and development process under the responsibility of Engineering.

2.4.2.3 Cleanliness of Premises

It is the responsibility of management to ensure that the premises of OPTEK are kept clean and in a good state of order. It is the responsibility of Manufacturing and Warehouse to ensure that production facilities and the warehouse are kept clean and in good order. As required, housekeeping procedures are developed and implemented by individual Department Heads.

RELEASED
DATE: 3/23/2022
Document Control

2.4.3 Customer Property

2.4.3.1 Customer Property

Customer owned product supplied for production is inspected by Supplier Quality Assurance according to defined inspection requirements.

The responsible Department Head ensures that customer owned product is identified, stored, used, handled, and shipped in an appropriate manner in order to ensure its suitable condition for use.

During periodic cycle counts conducted by designated personnel in Manufacturing or Warehousing, a visual inspection of products, including customer owned product, is performed to verify the product's condition and proper identification. Any loss, damage or deterioration of customer-supplied product is recorded, and the customer is notified.

2.4.3.2 Customer Owned Production Tooling

It is the responsibility of the Toolroom & Manufacturing under direction of finance to ensure that customer owned tooling and fixtures are clearly identified with a metal plate or permanent marking method showing the ownership of the equipment.

2.4.4 Control of Monitoring & Measurement Devices

2.4.4.1 Control of Monitoring and Measuring Devices

To ensure accurate and reliable monitoring and inspection results, Quality Assurance, Manufacturing, Toolroom and Engineering ensure that monitoring and measuring equipment and devices are controlled, calibrated, and maintained.
Resources are provided to ensure valid and reliable results are achieved when monitoring or measuring devices are used to verify conformity of products and services to requirements.

The type of monitoring and measuring equipment/device/software to be used in Manufacturing, by Quality Assurance and Toolroom, and the required accuracy of these monitoring and measurement activities are defined during quality planning and specified in the manufacturing plan (Process Map #065), process traveler and/or inspection reports (245-0009-M01).

It is the responsibility of the applicable department to ensure that monitoring and measuring processes are capable for their intended purpose and are performed in a manner that is consistent with requirements.

To ensure valid results, measuring equipment is

- Calibrated and/or checked in defined intervals or prior to use, and according to a recognized standard; where no recognized standard is used, the basis applied for the calibration is documented
- Adjusted and re-adjusted as necessary to ensure required accuracy
- Identified with a unique identification number and the current calibration status
- Kept in a secure and restricted location to prevent misuse and improper adjustments that could invalidate calibration settings
- Protected from damage and deterioration during handling, maintenance, and storage

In the event that monitoring and measuring devices are found out of calibration, previous measuring results are reviewed regarding their validity. Corrective action on the measuring device or product affected is taken, including recall of nonconforming product, if required.

Prior to the use of computer software for monitoring and measuring activities, it is verified and confirmed that the software produces defined results. Records of these verifications are maintained

2.4.4.2 Measurement System Analysis

It is the responsibility of Equipment Maintenance Engineering to ensure that Measurement System Analysis (as minimum Repeatability and Reproducibility study) is conducted (245-0012-M01) for each measuring device referenced in control plans with prioritization to those sued for critical or special product or process

characteristics. Records of these studies provide evidence of the variations present in the results of each type of measuring device and are taken into consideration when inspection reports are developed.

2.4.4.3 Calibration / Verification Records

The department performing the calibration of monitoring and measuring devices is responsible for the record keeping of calibration activities. These records include the identification of the equipment and the calibration standard, revisions due to engineering changes, and calibration results such as out-of-specification/conformity to specifications. (Process Map#063).

When monitoring and inspection equipment is found out-of-specifications, the impact on products previously measured with this equipment is reviewed and validated and an *Out-Of-Calibration Report* is initiated as appropriate. If suspect product/material has been shipped, the customers are informed, and the product is recalled as required.

Verification that monitoring and inspection equipment is in specification shall be confirmed by a current calibration certification sticker on the equipment. In the event that the calibration certificate is found to have expired and has not been used in the production and testing of product the equipment shall be removed from the lab and scheduled for the next calibration cycle.

2.4.4.4 Laboratory Requirements

2.4.4.4.1 Internal Laboratory

It is the responsibility of the Maintenance function to define and document the scope of the capability of tests and inspection activities, which can be performed by the in-house laboratory facility which has specified and implemented technical requirements for the

- Suitability of implemented procedures
- Competency of personnel
- Testing of product
- Capability to perform these services correctly and according to pertinent process standards,
- The review of related records

2.4.4.4.2 External Laboratory

As required, qualified laboratories are used for inspection, test and calibration, and other contract services. Only laboratories are used which include in their defined laboratory scope the required service to be performed, and which are either capable based on business history and/or previous services provided, or laboratories that are accredited to ISO/IEC 17025 or another equivalent national standard. If a specific calibration service cannot be performed by an external

laboratory, or in the absence of such a laboratory, the original equipment manufacturer or their accredited representative can provide this service.

2.5 Company Control Specifics

2.5.1 Document Control

2.5.1.1 Control of Documents and Engineering Specifications

Documents required by the Quality Management System are controlled documents.

It is the responsibility of the Department Heads to implement and maintain the documented procedure (Process Maps #057) Control of Documents, which defines the responsibilities for the development of controlled documents, their approval for adequacy, changes and re-approval, revision status, document formats, identification, and distribution.

Following the documented procedure (224-0001-001) (245-0020-M01) Document and Data Control, the Engineering Department is responsible for the identification, control and distribution of technical engineering documents, including documents and data of external origin such as standards and customer drawings. Engineering documents developed by Engineering or engineering documents from the customer, including the distribution of these documents, are recorded. Incoming customer engineering standards and specifications, including changes, are reviewed as soon as possible, not to exceed two weeks, by Engineering, and are then distributed and implemented as required. Records of implementation dates in production are maintained.

It is the responsibility of the applicable Department Head to ensure that current revisions of controlled documents are legible, readily available where needed, that obsolete copies are replaced and destroyed or invalidated, and that obsolete documents retained for any purpose are clearly identified.

As required, it is the responsibility of the IS Department to establish a schedule for producing back-ups of defined computer data. These back-ups on tape or CD-ROM are kept in a secure place. Schedules for backup responsibilities and compliance are documented.

RELEASED
DATE: 3/23/2022
Document Control

2.5.2 Records Control

2.5.2.1 Control and Retention of Records

Records are maintained to provide evidence of activities and their results, of conformance to requirements and of the effective operation of the Quality Management System. Department Heads are responsible for the proper identification, storage, retrieval, protection, retention time and disposition of records according to the established documented procedure QS12 (245-0021-M01).

2.5.3 Control of Production Provision

2.5.3.1 Control of Production

Manufacturing processes activities are performed under controlled conditions. Based on the output from quality planning (Process Map #065), Manufacturing and Document Control ensure that the necessary documents, data and operating instructions for the performance of manufacturing processes are developed and available to personnel. These documents or data describe in sufficient detail the product characteristics, production processes, the equipment to be used, as well as the activities for monitoring and measuring of these processes. Included are procedures for release, delivery, and post-delivery activities.

The Manufacturing department ensures that operating instructions, including instructions for special processes, are available at the workstation, that production activities, verification results and SPC records are recorded, and that activities for the monitoring and measurement of production processes are implemented and followed.

It is also the responsibility of the Manufacturing department to ensure that the work environment is appropriate for the work being performed and meets statutory requirements. The HR Representative is responsible for compliance with regulatory requirements.

2.5.3.2 Control Plan

Control plans are developed during quality planning (Process Map #065) and define the development of prototypes, pre-launch, and production processes, as applicable. Control plans are available for all production stages of products or parts, including assembly. Pre-Launch control plans heed the outputs of DFMEAs and PFMEAs.

As applicable, control plans specify

- The required controls for manufacturing processes
- The methods used for monitoring applied controls over special characteristics (customer/OPTEK)
- Customer-required information
- The reaction plan to be initiated when the process becomes unstable or not capable

With changes of product specifications, or any changes affecting the product, manufacturing processes, inspection activities, logistics, supply sources or FMEAs, control plans are updated by the quality planning team (Process Map #065). If required, customer approval is obtained for the change.

2.5.3.3 Work Instructions

It is the responsibility of the Department Heads to develop and maintain documented work instructions and operating instructions that are necessary for the performance of processes and activities affecting quality of products. These documents are made

accessible to personnel at the workplace. Work instructions and operating instructions are derived from the output data from quality planning, such as the quality plan or control plan. (Process Map#061).

2.5.3.4 Verification of job set-ups

Manufacturing is responsible for proper set-ups of production equipment. Quality Assurance performs a last-off comparison, as appropriate. First-Offs are approved by Quality Assurance. As applicable, statistical verification methods are used. Set ups are documented thru manufacturing instructions, records are retained as applicable. Product compliance to be verified after prolonged line shutdowns.

2.5.3.5 Preventive and Predictive Maintenance

A master list of machinery and equipment that requires preventive maintenance to ensure continuous process capability is developed and maintained by Manufacturing. Preventive maintenance objectives are established and documented in the first quarter of each year. These objectives are evaluated at least yearly regarding their achievement and opportunities for improvement.

Designated staff in Manufacturing performs required preventive maintenance. The actual maintenance status of each piece of equipment is identified. The maintenance system includes a MIN/MAX - inventory system of frequently used replacement parts and a predictive maintenance analysis that assists in the review of preventive maintenance cycles, maintenance methods and inventory of replacement parts. Equipment and tooling and gauging that are kept in Manufacturing are packaged and preserved according to manufacturer's guidelines and recommendations. (Process Map #061)

2.5.3.6 Management of Production Tooling

As applicable, the departments of Manufacturing, Engineering, Toolroom and Quality Assurance are responsible for the design, construction, review and approval of production tooling and fixtures. (Process Map #064)

- The Toolroom is responsible for the construction of tooling and fixtures. Established controls are followed to effectively coordinate all activities, including a full dimensional inspection of the tooling and the monitoring of timely completion.
- The status or availability of tooling and fixtures is clearly identified.
- The Mexico Toolroom is responsible for preventive maintenance, repair, storage, and recovery of production tooling.
- The set-up of tooling and equipment is the responsibility of Manufacturing.
- Manufacturing establishes programs for changes of perishable tools in production.
- The Engineering department is responsible for design changes of tooling and fixtures, including engineering change level. As required, these changes are passed on to the Toolroom for implementation.

- Tool modification and revision to documentation are coordinated between Engineering and the Toolroom.
- As required, the Quality Planning Team is involved in the planning of changes to tooling and fixtures.

In the event that design, or construction is contracted to outside sources, a tracking and follow-up system is put in place by Engineering or Manufacturing.

Customer-supplied tooling is inspected and approved by Manufacturing, Toolroom and Quality Assurance.

2.5.3.7 Production Scheduling

Manufacturing is responsible for production scheduling. The production scheduling of custom-made parts is forecasted.

Quarterly, the inventory turnover rate is calculated, and corrective action is taken in case that the turnover rate is below the established minimum.

2.5.3.8 Feedback of Information

Based on customer feedback provided by Sales, Management issues quarterly statistics which are analyzed by the heads of Engineering, Sales, Manufacturing and Quality Assurance. Corrective or preventive action is taken as required.

2.5.4 Validation of Processes

Validation of processes for production

Where the resulting process output cannot be verified through monitoring or measurement, the Quality Planning Team validates production processes with the assistance of Manufacturing and Engineering, regarding their ability to achieve planned results.

The quality planning team establishes procedures for the review, approval and requirements of these processes, including - as applicable: criteria for review and approval, approval of equipment and qualified personnel, the use of methods and procedures, required records, and re-validation in case that expected results are not achieved.

Attention is given to special processes where the results cannot be verified through measurement or testing, where deficiencies become apparent when the product is already in use.

2.5.5 Identification of Traceability

Identification and traceability

Designated personnel in Supplier Quality Assurance, Manufacturing and Warehouse identify incoming product and material, product and material during production, and

product and material in storage with the product identification and inspection status (241-0032-M01).

Using the implemented computerized system in Manufacturing, sensors manufactured by OPTEK are traceable by date codes.

2.5.6 Preservation

2.5.6.1 Preservation of Product

It is the responsibility of Manufacturing and the Warehouse to ensure the proper identification, handling, packaging, storage and protection of product and materials during receiving, handling and storage, shipping, and production. This includes constituent parts of a product.

Temperature sensitive products and materials are stored in the temperature-controlled room.

2.5.6.2 Storage and Inventory

During periodic cycle counts, the condition of materials and products in the warehouse is verified to ensure that any deterioration or damage is detected and recorded, and that required corrective action is taken.

The MRP-system in Manufacturing is used to ensure optimized inventory turns over time, minimum inventory levels and appropriate stock rotation (FIFO) of product and raw materials. Manufacturing is responsible for keeping established inventory levels of finished product, using the computerized production scheduling system.

The inventory turnover rate is periodically reviewed, and corrective action is taken in the event that the turnover rate is below the established minimum.

When processing shipping orders (217-0014-001), the staff in Warehousing ensures that FIFO is applied.

2.5.7 Monitoring & Measuring of Processes

2.5.7.1 Monitoring and Measurement of Processes

During Quality Management System Planning and based on statistics of operational performance and the achievement of quality objectives, the processes of the Quality Management System are analyzed by Management and responsible Department Heads regarding their effectiveness. As required, corrective action is implemented to achieve planned results and product conformity, to correct nonconformities or to improve the operational effectiveness and efficiency of the processes of the Quality Management System.

2.5.7.2 Monitoring and Measurement of Manufacturing Processes

To verify process capability and provide additional input for process control, the quality planning team arranges for the monitoring of new and modified manufacturing processes (Process Map #065). Results are documented and include instructions for production processes, verification, and maintenance as well as objectives for manufacturing process capability, reliability, maintainability, and availability.

Manufacturing ensures that processes are implemented according to control plans and other applicable procedures or documents in order to ensure that process capability and process performance is maintained according to customer part approval process requirements.

Control plans and process flow diagrams are implemented, including adherence to specified measurement techniques, sampling plans, acceptance criteria and reaction plans.

It is the responsibility of Manufacturing to monitor process capability and to ensure that process capability and performance is according to applicable control plans. In case of nonconformity of processes, defined reaction plans are followed.

Important events that are occurring during production, such as down times are recorded.

If identified characteristics on the control plan become unstable or non-capable, the applicable reaction plan is followed. If appropriate, these reaction plans include containment of produced parts or products and 100% inspection. Corrective action is taken as per established procedure (245-0024-M01) in order to restore required process capability and product quality. If required, these corrective action plans are reviewed with and approved by the customer.

Effective dates of process changes are documented by Manufacturing.

2.5.8 Monitoring & Measuring of Product

2.5.8.1 Monitoring and Measurement of Product

It is the responsibility of Quality Assurance to establish and maintain procedures and inspection reports for receiving inspection, in-process inspection and final inspection of product and materials.

Product is not released until all specified requirements have been met, unless otherwise approved by an authorized function - and where applicable by the customer.

The warehouse staff performs a visual inspection of outgoing product to ensure that the product and packaging is in good condition and that marking and labeling requirements are met.

In the event that purchased product is released for urgent production prior to inspection and acceptance by Quality Assurance, the product is recorded and controlled in order to permit recall and replacement in case of nonconformity of the product.

Product that does not meet specified requirements is rejected and quarantined per established documented procedure.

As required, Quality Assurance selects accredited laboratories for certain inspection or testing activities. Records of these inspection results are verified, reviewed and maintained.

Inspection results are recorded, and records are maintained. These inspection records document acceptance criteria, inspection results, whether the product was accepted or rejected and the inspection authority responsible for the product release.

2.5.8.2 Dimensional Inspection and Functional Testing

At least once every twelve months, or as otherwise specified by the customer, Quality Assurance performs a dimensional inspection and functional verification for each product specified in control plans. Results are available to the customer upon request. This applies to Automotive products only.

2.5.9 Control of Nonconforming Product

2.5.9.1 Control of Nonconforming Product and Reworked Product

Nonconforming product and product without proper identification is quarantined and controlled according to the documented procedure (245-0040-M01)(Process Map #062). The nonconformity of the product is verified and confirmed by Quality Assurance and verification results and recommended disposition or action are recorded. Functions concerned are notified.

Quality Assurance, Manufacturing, Engineering or Sales review and authorizes the release of quarantined product for its final disposition, according to the following options:

- Rework to meet specified requirements
- Accept with or without repair by concession
- Re-grade for alternative applications
- Reject or scrap

RELEASED
DATE: 3/23/2022
Document Control

If the acceptance with or without repair requires the concession of the customer or the approval or permit of a regulatory body or other authority, Manufacturing ensures that the required concession is received prior to initiation of the repair.

Qualified personnel in manufacturing process rework orders. Detailed instructions for required rework are available to operators in work instructions.

Reworked product is re-inspected by Quality Assurance.

As appropriate and required, the customer is notified by Sales of the proposed use or repair of nonconforming product. Where applicable, Manufacturing ensures that the reworked product is identified with the actual condition of the product, including the customer's release authorization.

Records of nonconforming product, including the type of nonconformity, actions taken, and concessions obtained are maintained in First Time Quality reports.

In the event that nonconforming product is detected after the product was shipped to the customer, or after its use in production or service, the Engineering department with Manufacturing & Quality Assurance and Sales department analyze the impact of the nonconformity and take appropriate action. As required, the customer is informed, and the nonconforming product is recalled.

Nonconforming purchased product and material is returned to the supplier with a Supplier Corrective Action Request (Process Map: #057) issued by Supplier Quality Assurance. Supplier *Quality Requirements*

2.5.9.2 Customer Waiver

In the event that manufactured product, or purchased product, or manufacturing processes are different from the product or process approved by the customer, or that temporary change to product and processes is required, the request for temporary change or deviation is submitted to Engineering for approval (Process Map #065). As required, customer production part approval is obtained.

Concessions outside of original design are not permitted by **ISO/IEC 80079-34**

Manufacturing keeps records of expiration dates and quantities of authorized deviations and ensures that normal production activities are re-instated after expiration of engineering deviations.

Products manufactured and shipped on customer authorization are identified as such on each packaging unit or container.

RELEASED
DATE: 3/23/2022
Document Control

Approvals & Revision History

OPTEK Quality Manual - revision control

Page No.	Reference	Revision	Date	Description of Change	Initials
All (1-45)	1st issue	0	2004/Mar/11	No change - first issue	
35, 44	051689	A	2007/May/3	Added prototype process maps #015, #016 to section 2.5.1.1 .	M.T.
6, 10	052767	B	2009/March/18	Change Jerry Gallagher to Bob Taber. Delete Magnetoresistive and add UV.	L.T.
26, 27	052939	C	2009/July/10	Update sections 2.1.1 (under Requirements Determination & Review), 2.2.1 (Design and Development)	L.T.
1, 7, 10, 26	053405	D	2010/ Feb/23	Updated ref. to ISO/TS 16949 to 2009 rev & ISO9001 to 2008 rev. Updated Corporate Quality Policy – added ITAR Compliance Manual hyperlink in para 2.1.1. Adding numeric revision to all process maps.	R.B.
7, 8, 17, 23, 26, 43, 46	053950	E	2011/June 16	Updated to include IECEx/EN13980 Baseefa references. Update 003, 005, 006, 007, 012 & 013 Process Maps from HP to SAP.	L.T.
9, 47	054425	F	2012/August 17	Updated IECEx Certificate of Conformity	L.T.
All	054919	G	2014/March/28	Change Bob's title from President/CEO to Vice President/General Manager. Update Process Maps 003, 004, 010, 011 & 012 and operating procedure QS07. Update the TT Electronics logo.	L.T.
Process Maps 003 & 011	055002	H	2014/July/8	Updated process maps #003 to rev 5 and #011 to rev 3	L.T.
Process Maps 003 & 011	055157	I	2015/January/ 28	Updated process maps #003 to rev 6 and #011 to rev 4	L.T.
Process Map 010	055179	J	2015/April/13	Updated process map #010 to rev 3, only first page of process map changed.	L.T.
26, 43	055229	K	2015/April/23	Clarify process map #s under section 1.5.1.4 change (Process Map – Process Flow) to (Process Map 010) and under section 2.5.9.1 (Process Map: SCAR Process) to (Process Map 009).	L.T.
5, 7, 18, 24, 27, 44, 47	055317	L	2015/July/27	Replace all references to EN13980/IECEcOD005 to ISO/IEC 80079-34.	L.T.
16	055319	M	2015/July/31	Add the maximum interval between management reviews to section 1.2.1.	L.T.
6, 10 36	055487 055489	N	2016/Feb/23 2016/Feb/25	Replace Bob Taber with Tim Roberts and update the Corporate Quality Policy. Add paragraph to section 2.4.4.3	L.T.

RELEASED
DATE: 3/23/2022
Document Control

Approvals & Revision History

OPTEK Quality Manual - revision control

Page No.	Reference	Revision	Date	Description of Change	Initials
8-12, 14-16, 20-22, 31-37, 39-41 & 43	055534	O	2016/April/6	Updated the following 1) Optron address 2) Management Structure 3) removed references to “President/CEO” replace with “division EVP” 4) Delete all of the references to non-existent operating procedures 5) References to Management Representative Updated sections 1.1.5, 1.1.6, 1.1.9.5, 1.2.2 thru 1.2.5, 2.3.2, 2.3.6, 2.4.1.2, 2.4.3.1, 2.4.3.2, 2.4.4.2, 2.5.5, 2.5.8.2 6) Corrected typos 7) Section 2.5.1.1	L.T.
1, 6 & 8	055750	P	2017/Feb/10	Remove “make possible” from the TT logo. Replace Sensing and Control with Industrial Sensing and Control and Passives and remove Optek logo. Update management structure. Replace Jeff Beatty with Ismael Rodarte as management representative. Replace Tim Roberts with Tim Wallaert on approval page.	L.T.
16	055784	Q	2017/Feb/24	Add “The person(s) responsible for the ATEX/IECEx quality system, as defined in 99-00726-088, shall participate in the review.” to section 1.2.1.	L.T.
1, 4,6-22, 24-31, 33-49, 53-54	056236	R	2018/June/28	Replace ISO/TS 16949:2009 with IATF 16949:2016 / ISO 9001:2015, Replace Industrial Sensing and Control and Passives with Sensors and Specialist Components. Added section for Product Safety, Exclusions / Justifications, Corporate Responsibility, Process Owners, Planning for changes, Risk Analysis and Customer Specific Requirements. Removed most references to Management Representative. Replace Ismael Rodarte with Hilda Bejarano. Updated Quality Manual to the revised standards ISO 9001:2015 and IATF 16949:2016.	L.T.
1, 6-12, 14, 15, 18, 24, 26, 27 & 41	056979	T	2022/January/31	Eliminated IATF 16949:2016 references. Replaced management representative with Juan Gonzalez and VP & General Manager with Stewart Partridge. Replaced Carrollton address with Plano. Updated process map #s.	L.T.
8, 18-20	057013	U	2022/March/23	Added “Context of the organization” section. Updated Management Review section 1.2.1. Added t thru v to Review Input section 1.2.1.1. Updated Quality Objectives section 1.2.2.	L.T.

RELEASED
DATE: 3/23/2022
Document Control

Appendix A: Cross Reference to this Manual

Description	OPTEK Quality Manual Paragraph
Quality Management System	
QMS General Requirements	1.1.1
QMS General Requirements	1.1.1
Quality Manual	About this Manual
Scope	Scope
Document Control	2.5.1
Engineering Specifications	2.5.1.1
Records Control	2.5.2
Records Retention	2.5.2.1
Management Responsibility	
Management Commitment	1.1.2
Process efficiency	1.1.2
Customer Focus	1.1.3
Quality Policy	1.1.4
Quality Objectives	1.2.2
Quality Objectives - Supplemental	1.2.2
QMS Planning	1.1.5
Responsibility, Authority & Communication	1.1.6
Responsibility for Quality	1.1.6
Management Representative	1.1.7
Customer Representative	1.1.7
Internal Communication	1.3.1
Management Review	1.2.1
Corporate Responsibility	About this manual
Process Owners	About this manual
Resource Management	
Provision of Resources	1.1.8
Human Resources	1.1.9
Competence, awareness & training	1.1.9.1
Product design skills	1.1.9.2
Training	1.1.9.3
Training on the job	1.1.9.4
Employee motivation & empowerment	1.1.9.5
Infrastructure	2.4.1
Plant, facility & equipment planning	2.4.1.1
Contingency plans	2.4.1.2
Work Environment	2.4.2.1
Personnel safety to achieve product quality	2.4.2.2
Cleanliness of premises	2.4.2.3

Product Realization	
Planning of Product Realization	1.1.10
Planning of product realization - supplemental	1.1.10.1
Acceptance criteria	1.1.10.2
Confidentiality	1.1.10.3
Change Control	1.1.10.4
Determination of Requirements	2.1.1
Customer designated special characteristics	2.1.1
Review of Requirements related to the product	2.1.2
Review of Requirements related to the product - Suppl.	2.1.2
Organization manufacturing feasibility	2.1.2
Customer Communication	1.3.2
Design & Development	2.2.1
Product Safety	2.2.13
Purchasing	2.3.1
Control of Production Provision	2.5.3
Validation of Processes	2.5.4
Identification & Traceability	2.5.5
Customer Property	2.4.3
Preservation	2.5.6
Control of Monitoring & Measurement Devices	2.4.4
Measurement, Analysis & Improvement	
Measurement Analysis & Improvement: General	1.2.3
Customer Satisfaction	1.2.4
Internal Auditing	1.4.1
Monitoring & Measuring of Processes	2.5.7
Monitoring & Measuring of Product	2.5.8
Control of Nonconforming Product	2.5.9
Analysis of Data	1.2.5
Continual Improvement	1.2.6
Corrective Action	1.5.1
Preventive Action	1.5.2

New Product Requirements	2.1.1	27
Customer Waivers	2.5.9.2	44

RELEASED
DATE: 3/23/2022
Document Control

Appendix B: ISO/IEC 80079-34 ATEX Certification References

QMS Description	QMS Section	QMS Page #
QMS Table of Contents	Table of Contents	5
Applicable Standards	Applicable Standards	7
Management Processes – QMS General Requirements	1.1.1	9
Records Control	2.5.2	37
Records Retention	2.5.2.1	37
Management Commitment	1.2.1.1	18
Responsibility, Authority & Communication	1.1.6	12
Management Review Input	1.2.1.1	18
Internal Auditing	1.4.1	24