Setra Systems, Inc.

Quality Management System

Setra Systems

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Setra's Quality Policy

"Setra will exceed customer expectations through technical innovation and superior delivery of high quality, value-added sensing products, sensing illumination, and services."

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Document Change Record

REVISION	REV DATE	BRIEF DESCRIPTION OF CHANGES	ECO #
A	2017-04-10	Initial Release	12072
B	2018-26-01	Correct Section heading errors (7.1 thru 7.5); add Customer Notification (5.1.2); modify Management Review to reflect QMS elements that are tracked and reviewed during monthly PD (9.3)	12266
C	2018-24-08	Insert Control of Records Table (Section 7.5.3)	12452
D	2019-04-10	Update Customer Satisfaction (Section 9.1.2)	12808
E	2020-21-09	Remove references to IEC 80079-43 and ISO 17025 (Sections affected in revision D to revision E are: 1., 2., 3., 5.1.1, 5.3, 5.3.1, 5.3.2, 7.5.4, 7.5.4, 8.2.3.4, 8.4.4, 8.5.1, 8.7.1, 9.2.1, 9.3.4, 10.2 and 11.) Add Documentation Control sections7.5.2.1 through 7.5.2.6.	13065
F	2021-25-10	Update new product development	13336

1. Scope

The purpose of this manual is to document the Quality Management System (QMS) for Setra Systems, Inc. which is registered to, and in compliance with the current revision of the ISO 9001 standard.

Setra Systems, Inc. designs, manufactures, and services sensors, weighing systems, low pressure calibrators, monitoring instruments and provides calibration and repair services.

This manual is our primary reference document for all quality related activities and is used to communicate our commitment to quality as well as the effectiveness of our QMS.

Setra's QMS follows the elements of ISO 9001 and references other key documents used in the QMS. Details, where required, are provided by way of procedures which, in some cases, may be associated with approved work instructions.

All activities performed at Setra Systems, Inc. are considered to be within the scope of the QMS and ISO 9001:2015. Our QMS includes all elements of ISO-9001:2015. We have made no exclusions.

This document is issued under the authority of Setra's Senior Staff and Quality Manager.

1.1 Setra's Quality Policy

"Setra will exceed customer expectations through technical innovation and superior delivery of high quality, value-added, sensing products, sensing illumination, and services."

2. Normative references

The following documents were reviewed and/or referenced in the development of this manual. For Reference only:

Document Name	**Title**
ISO 9001:2015	Quality Management Systems - Requirements
International vocabulary of metrology – Basic and general concepts and associated terms (VIM)	
Doc#: 3C0028.doc	Guidelines for Marked-Up Drawings
	Fortive Standards of Conduct

3. Terms and definitions

Audit: Examination and evaluation of objective evidence, that applicable elements of the quality system are appropriate, have been developed, and effectively implemented in accordance and in conjunction with specified requirements.

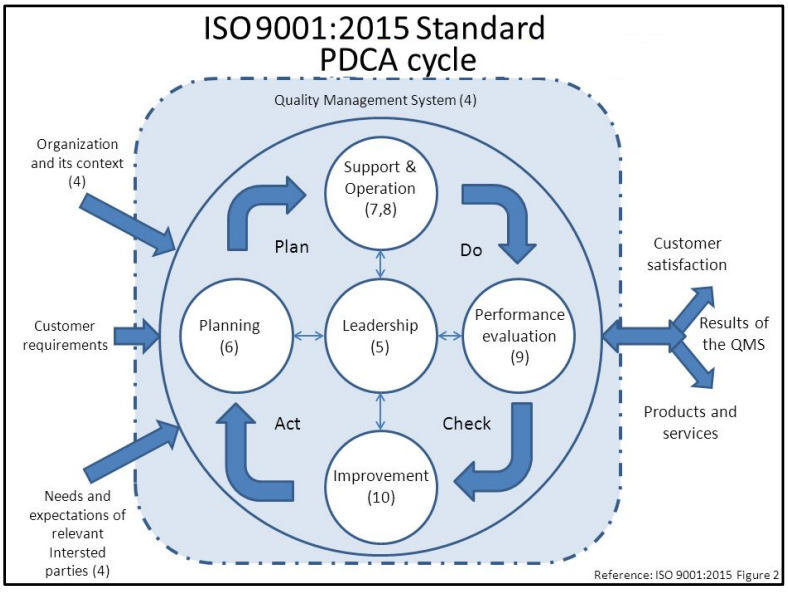
Auditee: The organization/department to be audited. Typically the Supervisor or Manager with direct responsibility for the activity audited.
Auditor: Individual or team of individuals who carry out the audit.
Audit Finding: A significant noncompliance or deficiency substantiated by objective evidence.
Audit Observation: A minor deficiency substantiated by objective evidence.
Client: The person or organization requesting the audit. Typically upper management.
Customer: The organization or person that receives a product or service.
Customer Satisfaction: The customer's perception of the degree to which the customer's requirements have been fulfilled.
Document: Information and its supporting medium.
Calibration Technician: A Calibration Technician who is approved to perform calibrations.
Manufacturing Cell (Measurement Facility): Work cell that calibrates or performs acceptance measurements on the products listed in Appendix A. Measurement facilities include Final Test Stations and equivalent test stations as required to meet product objectives.
Noncompliance: The nonfulfillment of specified requirements.
Objective Evidence: Qualitative or Quantitative information, records or statements of fact pertaining to the quality of an item or service or to the existence and implementation of a quality system element, which is based on observation, measurement, or test and which can be verified.

Organization: A group of people and facilities with an arrangement of responsibilities, authorities, and relationships.
Quality: The degree to which a set of inherent characteristics fulfils requirements.
Quality Assurance Program: Quality system specific to Setra.
Quality Audit: A systematic examination of products and systems in order to independently verify compliance to the requirements of the quality system.
Quality System: The collective plans, activities, and events that are provided to ensure that a product, process, or service will satisfy given needs.
Quality System Audit: A documented activity performed to verify, by examination and evaluation of objective evidence, that applicable elements of the quality system are appropriate, have been developed, and effectively implemented in accordance and in conjunction with specified requirements.
Record: Document stating results achieved or providing evidence of activities performed.
Requirement: A need or requirement that is stated, generally implied, or obligatory.
Service Cell (Measurement Facility): Work cell that provides after sales service on a warranty and non-warranty basis, as well as recalibration service to the customers bi-annual or annual calibration cycle requirement. The Service Technician provides repair service and / or re-calibration performing acceptance measurements on the products listed in Appendix A. Measurement facilities include Final Test Stations and equivalent test stations as required to meet product objectives.
Standards Room (Primary Laboratory): Calibration laboratory at Setra responsible for maintaining primary reference standards for a particular measurement discipline.

4. Context of the Organization

Setra's Quality Management System (QMS) follows the "Plan-Do-Check-Act" (PDCA) methodology.

Plan: Determine customer requirements, establish organizational policies, develop objectives and processes.
Do: Implement processes.
Check: Monitor and measure processes and product against pre-determined requirements and objectives.
Act: Take actions to continually improve process performance.



Plan Do Check Act cycle
Figure 1

4.1. Understanding the organization and its context

Setra determines the external and internal issues that are relevant to its purpose and strategic direction and affect its ability to achieve the intended results of its QMS. This is accomplished through, but not limited to the following, Setra tools and processes:

- Strategic planning (Strat Plan)
- Product development (Growth Board, LPM, APD, etc.)
- Daily management (DM)
- Internal and external audits
- Customer data
- Metrics (SQDIP, CVD, KPI, etc.)
- Management review
- etc.

4.2. Understanding the needs and expectations of interested parties

To ensure the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, Setra determines the interested parties that are relevant to the QMS and the requirements of those interested parties that are relevant to the QMS. Tools such as: VOC, trade show attendance, etc. are used to determine those requirements. Setra monitors and reviews information about these interested parties and their relevant requirements through tools such as: PD, strategic planning, associate survey, etc.

4.3. Determining the scope of the quality management system

Setra determines the boundaries and applicability of the QMS in establishing its scope. Setra considers external and internal issues referred to in section 4.1, the requirements of relevant interested parties referred to in section 4.2 and the products and services it provides to those interested parties.

Setra maintains the scope of the QMS in this document, which covers all products and services provided by Setra.

4.4. Quality management system and its processes

Setra has established, implemented, maintained and continually improves its QMS which insures the following:

a) The inputs required and the outputs from these processes have been determined,
b) The sequence and interaction of these processes have been determined,
c) Criteria and methods are determined to ensure the effective operation and control of these processes,
d) Ensure that the resources necessary to support the operation and monitoring of the processes are available,
e) Assign the responsibilities and authorities for these processes,
f) Address the risks and opportunities as determined in accordance with the requirements of section 6.1,
g) Evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results,
h) Improve the processes and the QMS.

To the extent necessary, Setra shall maintain documented information to support the operation of its process and shall retain documented information to have confidence that the processes are being carried out as planned.

5. Leadership

5.1 Leadership and commitment

5.1.1 General

Top management's leadership and commitment to the development, implementation, and improvement of the QMS is indicated in our quality policy / mission statement and our quality objectives.

a) Taking accountability for the effectiveness of the QMS,

b) Ensuring that the Quality Policy and Quality Objectives are established for the QMS and are compatible with the context and strategic direction of the organization,
c) Ensuring the integration of the QMS requirements into the organization's business processes,
d) Promoting the use of the process approach and risk-based thinking,
e) Ensuring that the resources needed for the QMS are available,
f) Communicating the importance of effective quality managements and of conforming to the QMS requirements,
g) Ensuring that the QMS achieves its intended purpose,
h) Engaging, directing and supporting persons to contribute to the effectiveness of the QMS,
i) Promoting improvement,
j) Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

5.1.2 Customer Focus

Top management demonstrates leadership and commitment with respect to customer focus by ensuring that:

a) Customer and applicable statutory and regulatory requirements are determined, understood and consistently met,
b) The risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed,
c) The focus on enhancing customer satisfaction is maintained.

Setra will provide advanced notification to customers of changes to items such as company name, facility location, company ownership etc. via the Setra website (www.setra.com).

Setra reserves the right to effect changes to the design and manufacture of Setra products without notification, unless a specific written agreement exists between Setra and the customer purchasing the product.

5.2 Policy

Setra's Quality Policy has been developed by top management and is displayed throughout the facility, demonstrating our commitment to quality. This policy ensures our commitment to meeting our customer and applicable regulatory and statutory requirements.

The policy is communicated throughout the organization to insure its understanding by all associates. All associates are responsible for understanding and practicing the quality policy.

Top management will insure that the quality policy remains appropriate to the organization and that it provides a solid framework to meet our objectives. The quality policy will be reviewed yearly during the management review process to ensure that it is still relevant and applicable to the organization.

"Setra will exceed customer expectations through technical innovation and superior delivery of high quality, value-added sensing products, sensing illumination, and services."

5.2.1 Establishing the Quality Policy

Top management has established, implemented and maintains a Quality Policy that:

a) Is appropriate to the purpose and context of the organization and supports its strategic direction,
b) Provides a framework for setting quality objectives,
c) Includes a commitment to satisfy applicable requirements,
d) Includes a commitment to continual improvement of the QMS.

5.2.2 Communicating the Quality Policy

Setra's Quality Policy is:

a) Available and maintained as documented information,
b) Communicated, understood and applied within the organization,
c) Available to relevant interested parties, as appropriate.

Internal communications have been established, which include:

- All Associates Meeting
- Departmental Meetings
- Management Walk Throughs
- Bulletin Boards (visual management boards)
- E-mail Communications
- Employee Surveys and Suggestions
- Training Programs
- Internal audit communications
- Key Performance Indicators
- Quality Meetings

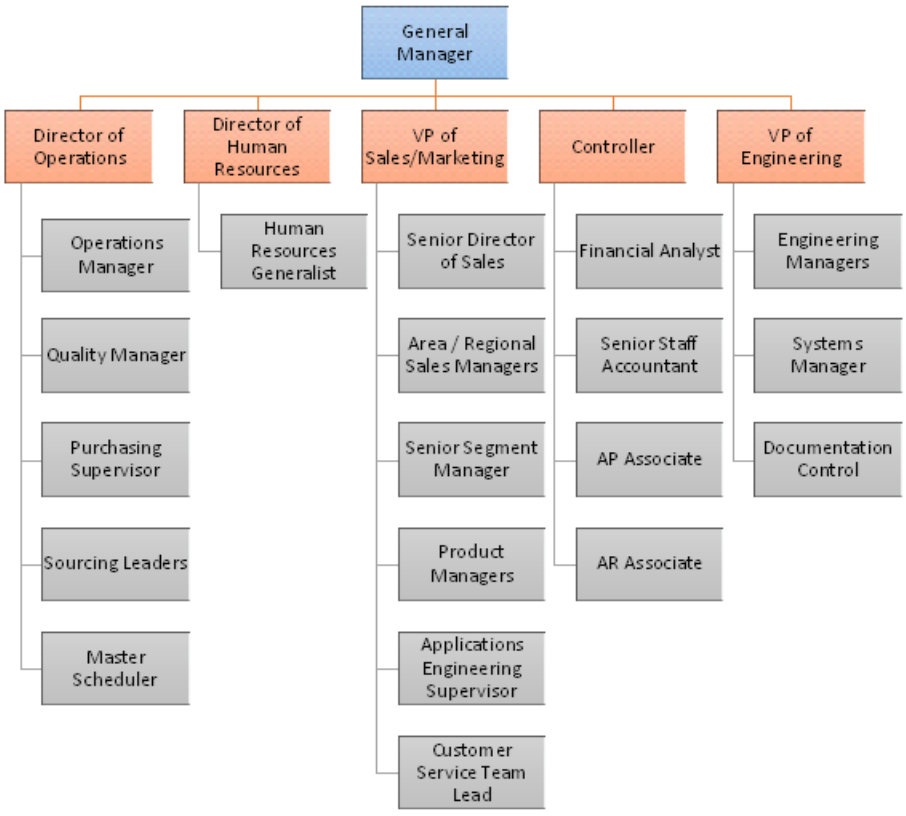
5.3 Organizational Roles, Responsibilities and Authority

Top management ensures that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization.

Top management has assigned responsibility and authority for:

a) Ensuring that the QMS conforms to the requirements of the current revision of the ISO 9001 Standard,
b) Ensuring that the process are delivering their intended outputs,
c) Reporting on the performance of the QMS and on opportunities for improvement, as indicated in section 10.1, in particular to top management,
d) Ensuring the promotion of customer focus throughout the organization,
e) Ensuring that the integrity of the QMS is maintained when changes to the QMS are planned and implemented.

The following chart provides a depiction of the organizational structure of key Setra personnel who are involved in developing, implementing, communicating, and maintaining the QMS.



Note: Subject to change without notice, contact HR to verify

Figure 2

The following list provides an overview of the roles and quality responsibilities of top management:

President / General Manager

- Makes final decision of the company's matters and direction of growth
- Formulates the quality policy
- Initiates and supervises the quality system
- Provides resources necessary to maintain the system
- Identifies and generates new strategic directions for the company
- Reviews the QMS at planned intervals

Sales & Marketing

- Assists customers with application-specific needs
- Conducts market research and analysis to establish the desired quality characteristics of products
- Establishes functional specifications of products and associated services (product briefs)
- Advertises and promotes company's products emphasizing their quality aspects
- Monitors the quality of competitors
- Carries out contract and order reviews
- Provides customer liaison and service
- Handles customer complaints

Engineering

- Benchmarks competitors' products
- Develops new technology
- Prepares functional product specifications from market research or customer-specified requirements
- Designs new products, processes and manufacturing equipment
- Initiates design reviews
- Verifies and tests the designs using design qualification tests
- Monitors and reviews the Engineering and Manufacturing pilot runs
- Assists manufacturing engineering and production as necessary

Documentation Control

- Prepares formal documentation and control drawings for the manufacturing process
- Maintains a controlled access system of master documentation
- Coordinates an ECR driven system that permits changes to documentation under approval guidelines

Manufacturing Engineering & Production

- Determines production personnel and equipment requirements
- Controls and monitors processes
- Maintains production equipment
- Administers storage areas
- Prepares production plans
- Dispositions discrepant material

Purchasing, Receiving and Inspection

- Selects qualified sub-suppliers and sub-contractors unless otherwise specified by Engineering (for no sub-parts)
- Prepares and approves purchasing documents
- Monitors and assesses sub-supplier performance
- Handles non-conforming sub-supplier parts
- Maintains inspection records

Finance

- Coordinates financial activities
- Generates and maintains financial information for the company

Quality

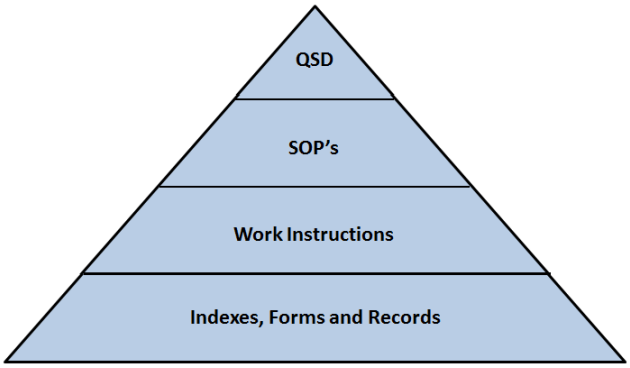
- Establishes and maintains the quality management system/plans

- Audits implementation of the quality system
- Initiates requests for and follows up on corrective actions
- Maintains and calibrates measuring and test equipment
- Carries out sub-supplier quality surveys and audits
- Performs inspections and testing of sub-supplier parts in accordance with the quality plans
- Processes orders for customer repairs and re-certification
- Collects product field reliability data
- Performs servicing
- Drives Quality Improvement
- Trains organization on quality improvement tools

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

Top management communicates to the organization the importance of meeting customer requirements as well as statutory and regulatory requirements.

The structure of documentation of the management system supports the corporate structure and is defined as follows:



Documentation Structure
Figure 4

a) Level 1 QSD: The Level 1 document that establishes general ISO9001 requirements in order for Setra to comply with the requirements of the various standards;
b) SOP's: Standard Operating Procedures that describe how to comply with particular portions of the various standards;
c) Work Instructions: Documents that are related to a particular task associated with compliance to the various standards;
d) Indexes: Documents that describe the path to compliance documents for particular sections of the various standards.

6. Planning

6.1 Actions to address risks and opportunities

When planning for the QMS, the organization considers the issues referred to in section 4.1 and determines the risks and opportunities that need to be addressed to:

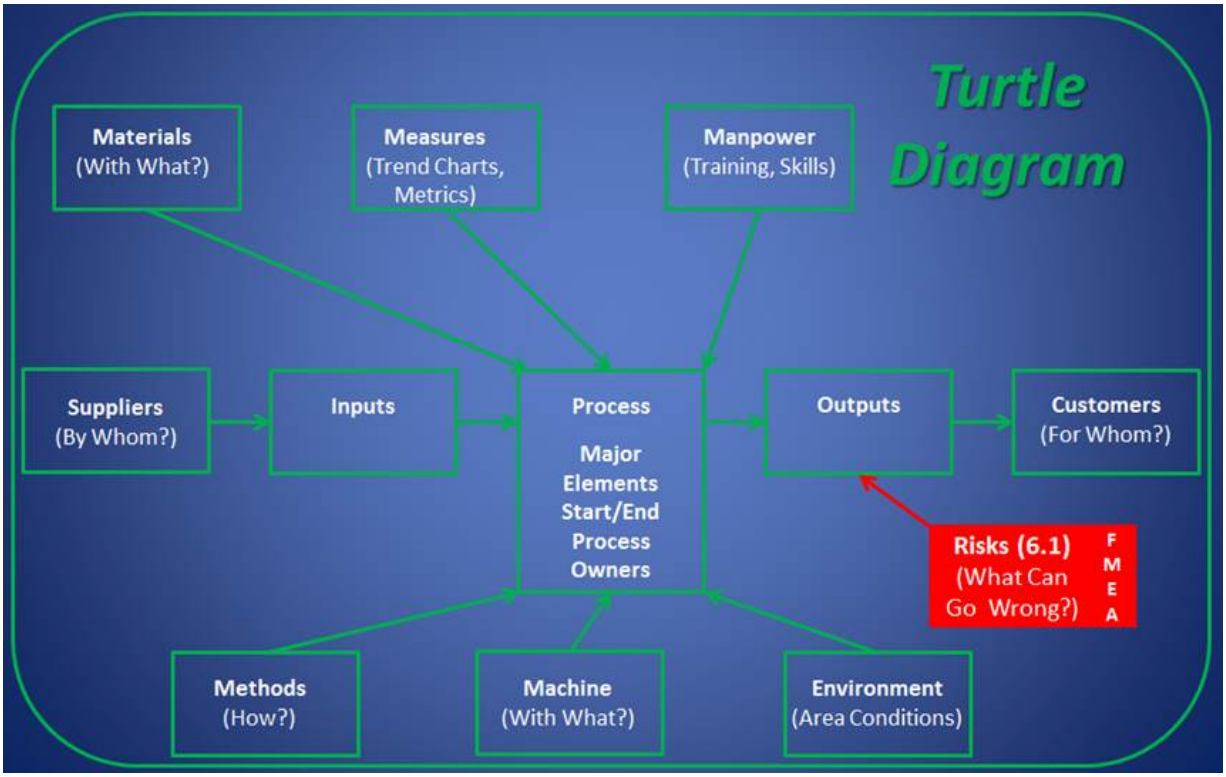
a) Give assurance that the QMS can achieve its intended results,
b) Enhance desirable effects,
c) Prevent, or reduce, undesired effects,
e) Achieve improvement.

The organization plans:

a) Actions to address these risks and opportunities,
b) How to:
   1) Integrate and implement the actions into the QMS processes (see section 4.4),

2) Evaluate the effectiveness of these actions.

Actions taken to address risks and opportunities are proportionate to the potential impact on the conformity of products and services.



Turtle Diagram
Figure 5

Note 1: Options to address risks can include avoiding risk, taking risk in order to pursue opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

Note 2: Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.

6.2 Quality objectives and planning to achieve them

The organization has established quality objectives at relevant functions, levels and processes for the QMS.

The quality objectives shall:

a) Be consistent with the Quality Policy,
b) Be measurable,
c) Take into account applicable requirements,
d) Be relevant to conformity of products and services and to the enhancement of customer satisfaction,
e) Be monitored,
f) Be communicated,
g) Be updated as appropriate.

The organization maintains documented information on the quality objectives.

When planning how to achieve its quality objectives, the organization determines:

a) What will be done,
b) What resources will be required,

c) Who will be responsible,
d) When it will be completed,
e) How the results will be evaluated.

6.3 Planning of changes

When the organization determines the need for changes to the QMS, the changes are carried out in a planned manner (see section 4.4).

The organization considers:
a) The purpose of the changes and their potential consequences,
b) The integrity of the QMS,
c) The availability of resources,
d) The allocation or reallocation of responsibilities and authorities.

7. Support

7.1 Resources

7.1.1 General

The organization determines and provides the resources needed for the establishment, implementation, maintenance and continual improvement of the QMS.

The organization considers:
a) The capabilities of, and constraints on, existing internal resources,
b) What needs to be obtained from external providers.

7.1.2 People

The organization determines and provides the persons necessary for the effective implementation of its QMS and for the operations and control of its processes.

7.1.3 Infrastructure

The organization determines, provides and maintains the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.

Note: Infrastructure can include:
a) Buildings and associated utilities,
b) Equipment, including hardware and software,
c) Transportation resources,
d) Information and communication technology.

Setra ensures that buildings and workspaces are clean, safe to work in, and that all equipment critical to the quality of the product we produce is identified, monitored, maintained, and stored appropriately.

Preventive maintenance will be scheduled and performed on key infrastructure and process equipment that effects product quality. Preventive maintenance cycles are based on, but are not limited to, manufacturer's recommendations, intended use of equipment, company experience/data, nonconforming material reports, or employee suggestion.

Records of preventive maintenance will be maintained either in hard copy or electronic format.

7.1.4 Environment for operation of processes

The organization determines, provides and maintains the environment necessary for the operation of its processes and to achieve conformity of products and services.

Note: A suitable environment can be a combination of human and physical factors, such as:
a) Social (e.g. non-discriminatory, clam, non-confrontational),
b) Psychological (e.g. stress-reducing, burnout prevention, emotionally protective),
c) Physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise).

7.1.5 Monitoring and measuring resources

7.1.5.1 General

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

The organization shall ensure that the resources provided:

a) Are suitable for the specific type of monitoring and measurement activities being undertaken,
b) Are maintained to ensure their continuing fitness for their purpose.

The organization retains appropriate documented information as evidence of fitness for purposes of monitoring and measurement resources.

7.1.5.2 Measurement traceability

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

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

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

7.1.5.2.1 Control, calibration, and maintenance of inspection, measuring, and test equipment

This section applies to all measuring and test equipment used within Setra. Associated documents include:

- ISO 17025 Standard
- InstNum.doc Assigning an Instrument Number (IN) for a Transducer Transfer Standard
- Outsideapproval.doc Approval of outside Calibration Sources
- M&TE Web Page

The Quality Manager shall be responsible for developing and maintaining a program for the calibration of all standards and M&TE used in the production of product, which is in compliance with the requirements of ISO-9001:2015.

Privately owned M&TE shall not be allowed for production usage unless it is under calibration control. Any rental equipment shall be verified to be under calibration control if used for production.

Supervisors shall be responsible to see that personnel in their area understand that "out of calibration" equipment, and references that do not have a valid tamper proof sticker, shall not to be used. Area supervisors shall also be responsible for maintaining a system than ensures that discrepant equipment is identified and submitted for repair or recalibration.

Any equipment that shows evidence of improper handling or use shall be reported to the Quality Manager or Area Supervisor for appropriate corrective action.

Area Supervisors and/or Engineers shall be responsible for ensuring that all new equipment requiring calibration (an Instrument ID Number) is delivered to the Test Equipment Technician. The Test Equipment Technician shall assign an Instrument Number, enter the unit into Setra's calibration system where appropriate, and ensure that the unit has a valid calibration if required.

Standards and M&TE used for calibration shall be a minimum of four times more accurate than the tolerances allowed for the unit being calibrated.

Any equipment that must be calibrated with a standard that is less than four times more accurate shall be documented. An “Exceptions List” shall be maintained by the Quality Department and shall include:

- Equipment Manufacturer
- Model Type
- Reason for reduced accuracy of standard
- Standard to be used
- Accuracy of standard to be used
- Date Authorized

Where traceability to an international or national standard is not available, Setra shall use any of the following methods:

- Participate in a suitable program of interlaboratory comparisons or proficiency testing
- Use an internationally accepted standard in the field concerned
- Refer to suitable reference materials
- Perform ratio or reciprocity-type measurements
- Use mutual consent standards, which are clearly specified and mutually agreed upon by all parties concerned

The measurement and the method chosen shall be documented in an "Exceptions List".

CALIBRATION INTERVALS AND RELIABILITY GOALS

The initial calibration interval shall be based on Instrument Calibration Categories and/or manufacturer's recommendation. New categories shall have calibration intervals based on the manufacturer's recommendations. The current categories and their initial calibration intervals are listed in this section.

Calibration intervals will be monitored quarterly, and may be adjusted as appropriate, by the Quality Manager. The overall goal is to achieve 95% reliability. The interpretation of this is that 95% of the equipment will be in tolerance when checked. The Quality Manager shall have the authority to deem M&TE Standards unreliable. They may specify that the equipment either be scrapped or given restricted usage status.

RECALL SYSTEM

A positive recall system shall be established to allow for the identification of any equipment due, or overdue for calibration. The recall system shall contain, at a minimum: equipment ID, equipment type, equipment location, calibration interval, calibration date, and calibration due date, and name of person performing calibration. The Quality Department shall use the recall system to periodically notify other departments when equipment is due for calibration.

CALIBRATION PROCEDURES

Calibration procedures shall be available for all measurement and test equipment, as well as standards used in production. Calibration procedures shall be located on the Setra Intranet from the M&TE Home Page and shall be identified by instrument category. Calibration procedures shall specify the following:

- Test equipment and standards to be used
- What is to be tested and how
- Acceptable limits
- Any special conditions of the test

Equipment manufacturer's instructions may be used without rewriting them.

At each calibration, the history of the equipment shall be reviewed for past problems, trends in wear, etc., that may suggest future problems with the equipment. If anything of concern is seen then the Calibration Technician should review it with the Quality Manager.

CALIBRATION RECORDS

The Quality Department shall maintain records for all calibrations performed. Calibration records shall include, as a minimum:

- Identity of any standards and equipment used
- Calibration Date
- Initials
- As-received data

- Final as-calibrated data
- Any corrective actions taken
- Record of any observed or reported failure symptoms
- As-received condition (working, not working, unreliable, etc.) of the unit

CALIBRATION CERTIFICATES

All calibration certificates and reports for Setra Systems M&TE shall contain the following information as a minimum:

- Identity of any standards and equipment used
- Date
- Identification of the person accepting responsibility for the content of the certificate or report
- As-received data
- Final as-calibrated data
- Corrective actions taken
- Record of any observed or reported failure symptoms
- As-received condition (working, not working, unreliable, etc.) of the unit
- Procedure used
- Printed copies of calibration data shall state “Do not reproduce the calibration report except in full”

OUT OF TOLERANCE CONDITIONS

Any equipment found out of tolerance in calibration shall have a "Failure Report" completed. A copy of the report shall be given to the Area Supervisor and to the Quality Manager. The Quality Manager shall decide the appropriate disposition. The disposition shall contain, at a minimum:

- Any change in calibration interval
- Determination of affected product, type and quantity. Equipment that is significantly out of tolerance (greater than 50% of tolerance) must include this item
- Disposition of affected product
- Corrective actions such as a change in the calibration interval

A final copy of this form shall be maintained in the calibration history record for the equipment.

CALIBRATION LABELS

Where possible, all M&TE and standards shall have a calibration status label attached. The calibration label shall contain, at a minimum:

- Date of calibration
- Due date of the next calibration
- Initials of the individual who performed the calibration

Where it is not convenient to label the actual instrument due to size or operational constraints, either the instrument case shall be labeled or the calibration sticker (with a reference to the instrument number) or a copy of the calibration certificate shall be held in the area where the equipment is used. In these instances, the item shall be uniquely identified so that it is traceable to its calibration label or certificate.

Any test, measuring, recording or other equipment in Manufacturing that does not require calibration will be labeled as such. Any operator accessible control or adjustment that can affect the calibration of a piece of equipment shall have a tamperproof seal on it. Any unit found with a damaged seal shall be immediately taken out of production usage, and not used until the calibration status has been verified and the seal fixed or replaced.

OUTSIDE CALIBRATION SOURCES

All outside calibration sources used by Setra shall be competent in their ability to test and/or calibrate specified equipment using standard, non-standard, or laboratory-developed methods. Upon return of the equipment, the Quality Department will review the information and initial and date the certificate or report if acceptable.

ENVIRONMENTAL CONTROLS

Most M&TE used within Setra is designed to be used within a standard building environment without extraordinary temperature or humidity controls.

Only the dead weight testers located within Setra's Standards Room require a controlled operating environment. These are operated at 70° +/- 5° F. This data is included in the calibration record of the pressure transfer standards calibrated on this equipment.

All other M&TE and standards will be stored and maintained per manufacturer's instructions or good industry practices. It is the responsibility of the Area Supervisor to assure proper training in the usage and storage of M&TE.

Instrument Categories and Initial Recalibration Intervals

Category Number	Category	Calibration Interval (years)
040	Accelerometer Secondary Standards	1
060	Calipers	1
080	Capacitance Meters	1
081	Gap Meter	1
100	Capacitance Standards	1.5
130	Countersink Gages	1
140	Counters	1
160	Current/Voltage Converters	1
180	Depth Gauges (see category 480)	NA
210	Dial Indicators	1
230	Dowel Gauges	NA
240	Electromagnetic Test Chambers	1
250	Error Boxes	1
260	Exciter Controller	2
300	Gauge Blocks	1
320	Hardness Testers	1
330	Laminar Flow Stations/Particle Counters	1
340	Calibrated Leaks	1
350	Illuminance Meter	1
360	Limit Gauges (Go/No-Go)	1
380	Hypot Tester	1
420	Manometers	1
480	Micrometers	1
490	Slides (Optical Length Standards)	2
510	Oscilloscopes	1
540	Ovens	1
580	Pressure Primary Standards	1
650	Pressure Secondary Standards	1/2
660	Pressure Transducers	1
670	Radius Gauges	NA
720	Scales	1
740	Strip Chart Recorders	NA
750	Temperature Gauges	1
765	Test Box	1
770	Torque Gages	1
780	Thread Gauges	2
800	Vacuum Gauges	1
810	Power Supplies	1
820	Voltage Calibrators	1
840	Voltage Standards	1

860	Voltmeters, Digital (formerly 760)	1
880	Multimeters	1
920	X-Y Recorders	1
930	Weight Set, Standards	1
940	Weight Sets, Pressure	1
960	Weight Sets, Scales	1
980	Wire Gauges	1
PC/CTS	Computer Test Stands	1

7.1.6 Organizational knowledge

The organization determines the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

This knowledge is maintained and made available to the extent necessary.

When addressing changing needs and trends, the organization considers its current knowledge and determines how to acquire or access any necessary additional knowledge and required updates.

Note 1: Organizational knowledge is knowledge specific to the organization; it is generally gained by experience. It is information that is used and shared to achieve the organization's objectives.

Note 2: Organizational knowledge can be based on:

a) Internal sources (e.g. intellectual property, knowledge gained from experience, lessons learned from failures and successful projects, capturing and sharing undocumented knowledge and experience, the results of improvements in processes, products and services),
b) External sources (e.g. standards, academia, conferences, gathering knowledge from customers or external providers).

7.2 Competence

The organization:

a) Determines the necessary competence of persons doing work under its control that affects the performance and effectiveness of the QMS,
b) Ensure that these are component on the basis appropriate education, training, or experience,
c) Where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken,
d) Retains appropriate documented information as evidence of competence.

Note: Applicable actions can include, for example, the provisions of training to, the mentoring of, or the reassignment of currently employed persons; or the hiring or contracting of competent persons.

All employees that perform tasks that affect product quality (e.g. management, production, and/or verification) shall be competent in their ability to perform those tasks. Competency is based on education, training, skills, and/or experience. This is the responsibility of the department managers, in cooperation with Human Resources and Quality.

7.3 Awareness

The organization ensures that persons doing work under the organization's control are aware of:

a) The Quality Policy,
b) Relevant quality objectives,
c) Their contribution to the effectiveness of the QMS, including the benefits of improved performance,
d) The implications of not conforming with the QMS requirements.

Human Resources has identified and documented required company-wide awareness training programs, including but not limited to:

- Company policies, expectations and benefits
- Setra Systems on-boarding orientation including QMS awareness
- Documentation of educational, external certifications and training records
- Identification of government and legal requirements

As required, the Quality Manager will provide training to all Associates on the basic requirements of ISO-9001:2015, Setra's QMS and Quality Policy.

Each functional group is responsible for establishing the following objectives and insuring that there is a sufficient level of resources available to implement and maintain the QMS:

- Position and job descriptions
- Identify and define the tasks necessary to conduct the assigned job or task
- Assess competency required
- Identify any applicable regulatory and customer requirements
- Insure that employees have the necessary education, training, skills, and experience for the tasks required
- Provide training or take other actions to achieve necessary competence
- Evaluate effectiveness of training
- Insure that employees are aware of the relevance and importance of their activities and how they contribute to the objectives of the organization
- Maintain records of employee education, qualifications, skills, experience, and training

7.4 Communication

The organization determines the internal and external communications relevant to the QMS, including:

a) On what it will communicate,
b) When to communicate,
c) With whom to communicate,
d) How to communicate,
e) Who communicates.

7.5 Documented Information

7.5.1 General

The organization's QMS includes:

a) Documented information required by ISO 9001:2015,
b) Documented information determined by the organization as being necessary for the effectiveness of the QMS.

Note: The extent of documented information for a QMS can differ from one organization to another due to:

- The size of the organization and its type of activities, processes, products and services
- The complexity of processes and their interactions
- The competence of persons

7.5.2 Creating and Updating

When the organization creates and updates documented information, it ensures appropriate:

a) Identification and description (e.g. a title, date, author, or reference number),
b) Format (e.g. language, software version, graphics) and media (e.g. paper, electronics),
c) Review and approval for suitability and adequacy.

All controlled documents shall be identified by a title, document number (optional for non-ECO controlled documents), and revision level. Document numbering shall be in accordance with requirements specified in DCN procedure. New documents, and document changes, may be initiated by anyone in the company, but shall be reviewed and approved by a designated authority before release. All controlled documents shall be legible and readily identifiable. All controlled documents shall identify the current revision status. Changes applicable to that revision shall be identified, which may be noted on the DCN or ECO. Controlled documents shall be reviewed and updated as necessary and re-approved. All documents shall be maintained and released through the Document Change control system.

7.5.2.1 DCN – Document Change Notice

DCN controlled documents shall consist of Level 2 quality policy and procedures as well as Level 3 departmental procedures and practices. New submissions, or changes to DCN controlled documents shall be made by authorized personnel or their designees. Authorized personnel initiating or changing documents

shall create a distribution list when submitting a document to the DCN. This list should contain representatives of any other departments affected by the change.

7.5.2.2 ECO – Engineering Change Order

ECO controlled documents shall consist of drawings and other technical level 3 documents that are used to manufacture products. Level 1 Quality policies and procedures require ECO approval and shall be submitted to Document Control using an ECO form. Document control shall determine appropriate authorization requirements and circulate the document for review and approval. See DCN procedure ECO Control Procedure.

Engineering Sign-Off documents shall include documents specified on the Quality System Documents, Overview Matrix. Authority for document review and approval shall be specified in individual level 3 procedure. See references listed at the end of this procedure. Copies of obsolete quality documents retained for legal and/or knowledge preservation purposes shall be maintained on the database. If the document is a revision a marked-up copy shall be saved for a period of at least 10 years.

7.5.2.3 Document Access

Documentation is available through FastLook or Setra's network file folders (accessible through Internet Explorer). Departments may determine individual web page content and structure. All Quality Documents and departmental procedures should be accessed using FastLook or Setra's network file folders (accessible through Internet Explorer). All printed copies of quality documents are considered "Uncontrolled". Employees should check the Intranet for the latest revisions, if copies are in question.

7.5.2.4 Data Control

Access to quality documents and data shall be controlled by restricting access and publication rights to the database. The IS Department and/or Database Programmer shall be responsible for assigning access and publication rights as instructed by department managers and supervisors. The IS Department shall be responsible for periodic back-up of quality documentation and maintaining back-up data and logs.

7.5.2.5 Obsolete Documents

All obsolete ECO controlled documents, as well as documents retained for legal and/or knowledge preservation purposes, shall be appropriately identified. Hard copies of original hand drawings only shall be archived on site and marked "Obsolete per the ECO number". Electronic documents shall be "obsolete per the ECO number" and moved into an Old Rev/OBSOLETE file directory. As space requires, files may be removed and archived to disk. As required, drawings shall be obsoleted through the ECO process. Drafting shall be responsible for archiving hard copy (for hand drawings only) and electronic originals. Drafting shall write "Obsolete" or "OBS" on the document with the date and number of the ECO and scan to appropriate Old Rev/Obs directory. Copies of obsolete drawings and technical documents shall be available on request from Engineering Services. Information concerning obsolete drawings shall be retained in the Fastlook Viewing Program for reference and shall be marked "Obsolete per the ECO number", but obsolete drawings will not be viewable. Drawings up-dated to the next revision level are removed from active drawing directory viewable through Fastlook and moved to Old Revs/Obs directory.

7.5.2.6 Documents of External Origin

Documents of external origin shall be controlled by the Quality and Engineering Departments. Document Control shall control external documents and standards (i.e. ISO-9001:2015). Document Control shall control all external documents pertaining to customer specifications, and product development and compliance. These documents shall be maintained using the Engineering Standards and Specifications database, which may be accessed through the Engineering Department web pages on the intranet.

7.5.3 Control of Documented Information

Documented information required by the QMS and the ISO 9001:2015 Standard is controlled to ensure:

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

For the control of documented information, the organization addresses the following activities, as applicable:

a) Distribution, access retrieval and use,
b) Storage and preservation, including preservation of legibility,

c) Control of changes (e.g. version control),
d) Retention and disposition.

Records Matrix	Indexing	Application / Storage Location	Responsible Department	Minimum Retention
Contract Review Records	SO Number	JDE	Customer Service	6 years
Corrective Action Request	CAR Number	CAWeb	Quality	5 years
Custom Business Opportunity	CBO Number	SFDC	Product Mgmt	5 years
Customer Repair Records	SR Number	JDE	Customer Service	5 years
Design Change Records	TG4, TG5	Network Drive	Engineering	5 years
Design Input Records	TG2	Network Drive	Engineering	5 years
Design Review Records	All TG	Network Drive	Engineering	5 years
Design Validation Records	TG5	Network Drive	Engineering	5 years
Design Verifications Records	TG4	Network Drive	Engineering	5 years
Document Change Notice	File Name	Network Drive	Engineering	5 years
Engineering Change Orders	ECO Number	Network Drive	Engineering	10 years
Final Inspection Records (Cal. Cert.)	Serial Number	GENTTS	Quality	5 years
Incoming Inspection Records	Part Number	Files	Quality	5 years
Internal Quality Audit Reports	Audit Number	Network Drive	Quality	3 years
Maintenance Records	Equipment ID	Simplicity	Facilities	1 years
Management Review Records	Date	Network Drive	Quality	3 years
M&TE Calibration Records	ID Number	Network/File	Quality	3 years
Policy Deployment (PD) Meeting	Date	Network Drive	FBSL Admin	3 years
Preventive Action Records (Kaizen)	DBS	Network Drive	FBSL Admin	5 years
Purchase Orders	P.O. Number	JDE	Sourcing	6 years
Purchase Order Receipt Records	Date	JDE	Sourcing	6 years
Supplier Corrective Action Request	SCAR Number	CAWeb	Quality	5 years
Supplier Qualification	Supplier	Network Drive	Sourcing	5 years
Temporary Deviation Notices	TDN Number	Network Drive	Engineering	10 years
Test Software Verification	Release Number	Network Drive	Engineering	2 years
Training Records	Product Cell	Network Drive	Departmental	5 years

All Records are Electronic, unless otherwise noted as "File".
On a case-by-case basis, longer retention periods may apply due to regulatory requirements.

Documented information of external origin determined by the organization to be necessary for the planning and operation of the QMS is identified as appropriate and controlled.

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

Note: Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.

8. Operations

8.1 Operational Planning and Control

The organization plans, implements and controls the processes needed to meet the requirements for the provision of products and services, and to implement the actions by:

a) Determining the requirements for the products and services,
b) Establishing criteria for:
   1) The processes,
   2) The acceptance of products and services,
c) Determining the resources needed to achieve conformity to the product and service requirements,
d) Implementing control of the processes in accordance with the criteria,
e) Determining, maintaining and retaining documented information to the extent necessary:
   1) To have confidence that the processes have been carried out as planned,

2) To demonstrate the conformity of products and services to their requirements,

The output of this planning is suitable for the organization's operations.

The organization controls planned changes and reviews the consequences of unintended changes, taking actions to mitigate and adverse effects, as necessary.

The organization ensures that outsourced processes are controlled (see section 8.4).

8.2 Requirements for Products and Services

8.2.1 Customer Communication

Communications with customers include:

a) Providing information relating to products and services,
b) Handling enquires, contracts or orders, including changes,
c) Obtaining customer feedback relating to products and services, including customer complaints,
d) Handling or controlling customer property,
d) Establishing specific requirements for contingency actions, when relevant.

8.2.2 Determining the Requirements for Products and Services

When determining the requirements for the products and services to be offered to customers, the organization ensures that:

a) The requirements for the products and services are defined, including,
    1) Any applicable statutory and regulatory requirements,
    2) Those considered necessary by the organization,
b) The organization can meet the claims for products and services it offers.

8.2.3 Review of the Requirements for Products and Services

The organization ensures that it has the ability to meet the requirements for products and services to be offered to customers. The organization conducts a review before committing to supply products and services to a customer, to include:

a) Requirements specified by the customer, including the requirements for delivery and post-delivery activities,
b) Requirements not stated by the customer, but necessary for the specified or intended use, when known,
c) Requirements specified by the organization,
d) Statutory and regulatory requirements applicable to the products and services,
e) Contract or order requirements differing from those previously expressed.

The organization ensures that contract or order requirements differing from those previously defined are resolved.

The customer's requirements shall be confirmed by the organization before acceptance, when the customer does not provide a documented statement of their requirements.

Note: In some situations, such as internet sales, a formal review is impractical for each order. Instead, the review can cover relevant product information, such as catalogs.

The organization retains documented information, as applicable:

a) On the results of the review,
b) On any new requirements for the products and services.

8.2.4 Changes to Requirements for Products and Services

The organization ensures relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

8.3 Design and Development of Products and Services

8.3.1 General

The organization established, implemented and maintains a design and development process that is appropriate to ensure the subsequent provision of products and service.

8.3.2 Design and Development Planning

In determining the stages and controls for design and development, the organization was considered:

a) The nature, duration and complexity of the design and development activities,
b) The required process stages, including applicable design and development reviews,
c) The required design and development verification and validation activities,
d) The responsibilities and authorities involved in design and development of products and services,
e) The internal and external resource needs for the design and development process,
f) The need to control interfaces between persons involved in the design and development process,
g) The need for involvement of customers and users in the design and development process,
h) The requirements for subsequent provisions of products and services,
i) The level of control expected for the design and development process by customers and other relevant interested parties,
j) The documented information needed to demonstrate that design and development requirements have been met.

8.3.3 Design and Development Inputs

The organization determines the requirements essential for the specific types of products and services to be designed and developed. The organization considers:

a) Functional and performance requirements,
b) Information derived from previous similar design and development activities,
c) Statutory and regulatory requirements,
d) Standards or codes of practice that the organization has committed to implement,
e) Potential consequences of failure due to the nature of the products and services.

Inputs are adequate for design and development purposes, complete and unambiguous.

Conflicting design and development inputs are resolved.

The organization retains documented information on design and development inputs.

8.3.4 Design and Development Controls

The organization applies controls to the design and development process to ensure that:

a) The results to be achieved are defined,
b) Reviews are conducted to evaluate the ability of the results of design and development to meet requirements,
c) Verification activities are conducted to ensure that the design and development outputs meet the input requirements,
d) Validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use,
e) Any necessary actions are determined during the reviews, or verification and validation activities,
e) Documented information of these activities is retained.

Note: Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in any combination, as is suitable for products and services of the organization.

8.3.5 Design and Developments Outputs

The organization ensures that design and development outputs:

a) Meet the input requirements,
b) Are adequate for the subsequent processes for the provision of products and services,
c) Verification activities are conducted to ensure that the design and development outputs meet the input requirements,

d) Include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria.

The organization retains documented information on design and development outputs.

8.3.6 Design and Development Changes

The organization identifies, reviews and controls changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.

The organization retains documented information on:

a) Meet the input requirements,
b) Are adequate for the subsequent processes for the provision of products and services,
c) Verification activities are conducted to ensure that the design and development outputs meet the input requirements,
d) Include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria.

8.3.7 Design and Development Process – Toll Gate Stages

DESIGN AND DEVELOPMENT PLANNING

Three categories of product design and development are identified as Engineering Change Order (ECO), Custom Business Opportunity (CBO) and New Product Development (NPD). The respective processes are utilized depending on the scope and nature of the product development activity.

a) ECO: When a change to an existing product is required due to manufacturing issues, errors in documentation, design improvements, etc., utilize the ECO process. ECO's could include:
   1) Specifications and/or drawings that are maintained and describe standard products based on proven and approved designs.
   2) Custom designs or design modifications that are maintained based on specified customer requirements and may include special features not required by other customers.
   3) When a CBO achieves sufficient sales or recurring sales as to become a standard defined product.
b) CBO: When an existing product is to be modified or changed to meet specific customer requirements, sales and/or marketing generates a request to enter a new product into the system using the CBO process. CBO products are intended to be special orders. When sufficient sales or recurring sales are observed, the CBO will be converted into a standard product configuration via the ECO process.
c) NPD: New product development consists of new designs or major design changes, and is controlled and documented using the Toll Gate (TG) process. The TG process is a multiple stage gate development process with defined deliverables and approvals by the Lean Portfolio Management (LPM) process required to proceed to the subsequent stage gates.

The level of product development and planning is according to the following process: Customer service refers all non-standard sales requests to the regional sales manager (RSM) or Applications Engineer (AE), who enters the information (if applicable) into the SFDC database. The RSM / apps engineer determines if the request is a CBO. If so a CBO is initiated. If not, the top opportunities or unmet needs are referred to the staff level at Growth Board or Lean Portfolio Management (LPM) meeting. At the Growth Board or LPM meeting the GM and his direct reporting staff decide if this opportunity is: a) a CBO, b) a TG new product development activity or, c) is not to be pursued further. If the opportunity is determined to be a TG project, it is referred to LPM for further action. LPM approves new products and is tracked in the LPM Dashboard. The LPM determines, based on the scope of the project, which projects go into the active Toll Gate process.

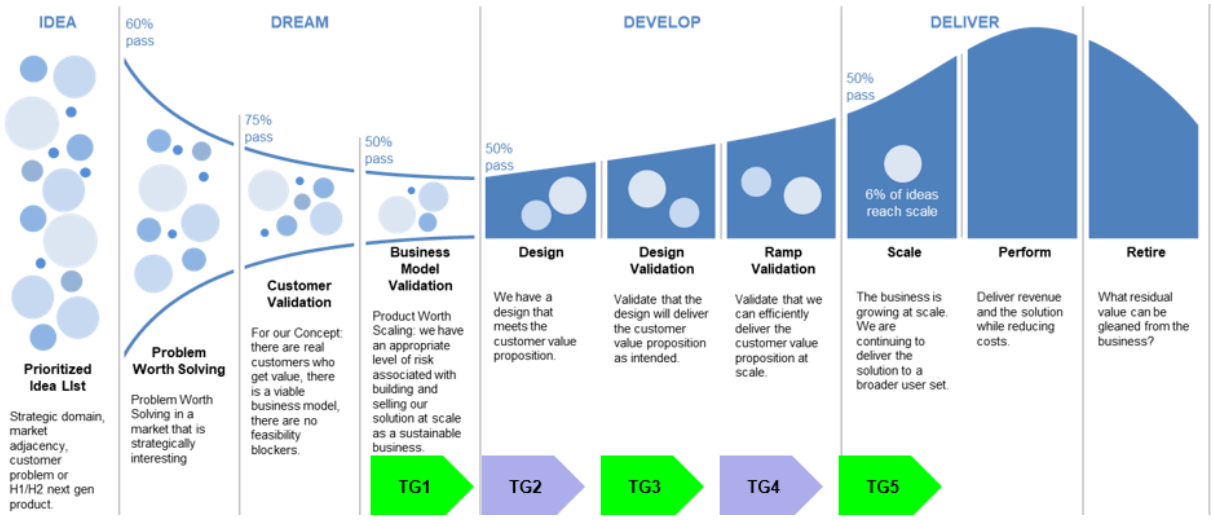
In addition to, and more commonly, a TG project is identified as a result of a broader ecosystem of development (see Figure 6). This is commonly referred to as the growth model and has three stages – Dream, Develop and Deliver. As defined by Fortive, the Dream stage is early work primarily lead by product marketing / product management to find customer and market problems that are worth solving. A new product or service is defined in the Dream stage including functional requirements, target pricing and related cost / margin and results in a qualified project culminating in Business Model Validation. Upon successful Business Model Validation by the General Manager and the L1 staff, the new product development process

begins in the Develop stage. At this point, the TG process is initiated at TG2 with a transfer of all pertinent information gathered from the Dream stage. The TG project is then managed and monitored in the monthly LPM meetings that are scheduled by the VP of Engineering.

As an alternative to the Dream stage, a new project can be initiated and brought to LPM for approval and assignment of resources through the L1 team. These types of projects may be limited in scope such as product line extensions, VAVE / cost reduction projects, etc. but still require the full diligence of the TG process. .

NEW PRODUCT DEVELOPMENT

The TG process consists of 5 phases. Each TG consists of a set of unique activities and goals related to the development process.



Toll Gate Process
Figure 6

The individual TGs are designed to ensure development is accomplished in a logical progression, so that the intermediate development results remain on target, the final design meets all product specifications and commercial objectives, the product and manufacturing process are in place to support the QDC targets and the commercialization plan is in place to meet post-launch sales. Specific deliverables are defined for each of the five phases of the TG process. The deliverables are intended to ensure that necessary development activities have been completed and to document the results. At the completion of each toll gate, a review meeting will be held with the LPM to determine if the project is still viable, ready to proceed to the next TG or if further work is required to receive LPM approval.

TOLL GATE DEFINITION & DELIVERABLES

Toll Gate 1- Project Approval: The purpose of TG1 is to provide the definition of an opportunity to meet the critical customer, market and product need in enough detail to identify possible technical concepts that the business opportunity. The expectation of this TG is to answer the question "Why would Setra go forward with this opportunity?" Upon approval of TG1, the cross functional product development team is identified and the program is active. TG1 specific deliverables include, but are not limited to*:

Tools / Tasks	Deliverables
Project Baseline	Financial Model
	Timeline
Opportunity	Project Description
	Project risks / issues
	Target Customers identified
	Window of Opportunity
VOC	Define unmet needs

	VOC plan & preliminary results
Initial Marketing Plan	Identify competition
	Key product features identified
	Target price by market channel
	Required Agency approvals
	Market analysis
Design Concept	Product concept

** Use latest revision of toll gate document as master for deliverables. These are subject to change without notice or update to this document.*

Projects that are a result of the Dream stage are not required to use TG1. Dream stage work has defined deliverables that are managed at the Growth Board and supervised by the Director of Marketing.

Toll Gate 2 – Product Specification: The purpose of TG2 is to provide performance specifications (design inputs) derived from market needs and accurate (transparent) financial analysis of the project. This phase will select the top product (or business) concept that meets the performance specifications and provide the first detailed analysis of the schedule, budget and risks within the project. The expectation of this TG is to answer the questions "What, exactly, is needed to fulfill the market / customer unmet need? What is the financial benefit of this opportunity to Setra?" TG2 specific deliverables include, but are not limited to*:

Tools / Tasks	**Deliverables**
Schedule	Gantt chart (excel or MS Project)
Detailed VOC	Customer requirements (from TG2 Kaizen)
	Identify target customers
	VOC Plan and results summarized
Specification Development	TG2 Kaizen (only if it is needed)
	Design concept
	Benchmark competitors – technical
	Benchmark competitors – commercial
	Gaps identified between functional marketing requirement spec and design spec
	Product Specification
	Identify key features required
	External process-at-a-glance – what does the customer do to our part upon receipt thru installation
	Develop test plan with inputs from target customers (what is their qualification test plan)
	Confirmation VOC from product spec / concept
Marketing Strategy – Value Prop	Competitive advantage
	Market share analysis
	Customer beta sites identified
	Estimate account breakdown in vol/yr
	Customer value statement
	Setra value statement
Mfg Concept	Initial Manufacturing Process
IP	IP Review
Export Compliance	ECCN number identified
	Licenses applied for
	Data secure
	Are all team members authorized to work on this project?

** Use latest revision of toll gate document as master for deliverables. These are subject to change without notice or update to this document.*

Toll Gate 3 – Product Concept: The purpose of TG3 is to provide frozen design specifications of the product that will be manufactured (i.e. software, hardware, user documentation requirements) and to provide

documented verification that the design specifications (design outputs) meet the performance specifications (design inputs). This TG will continue to provide detailed analysis of the schedule, budget and risks for the remainder of the project. The expectation of this TG is to answer the question "How, exactly, are we going to meet the product / service needs / requirements and will it perform to expectation?" TG3 specific deliverables include, but are not limited to*:

Tools / Tasks	Deliverables
Schedule	Gantt chart (excel or MS Project) updated
Product Design	POC or Alpha prototype – functional
	Concept design review
	Test high risk issues
	Finalize design concept
	Identify required component tooling
	Initial design specification sheet (DSS)
	Design 3P – if required
	Initial DFMEA
	BOM
Manufacturing Strategy	Preliminary process flow diagram
	Identify required equipment
	Manufacturing time and cost estimate
Finance	CAR approval for long lead items
Marketing	Update VOC
Sourcing	Identify any new suppliers for the project
	Identify & order necessary long lead items
IP	Update IP

** Use latest revision of toll gate document as master for deliverables. These are subject to change without notice or update to this document.*

Toll Gate 4 – Product Design: The purpose of TG4 is to build a working prototype that represents the product / service we intend to sell. In the event of a product, it is made using the final functionality and components and ideally the production processes – even if the cell is not complete. The prototype is used to verify that the product meets the design input requirements. Prototype units are also used for more extensive field testing, evaluation to test how well the product meets the customer needs and verification VOC. The expectation of this TG is to answer the question "Can we build it to specifications and will customers buy it?" TG4 specific deliverables include, but are not limited to*:

Tools / Tasks	Deliverables
Schedule	Gantt chart (excel or MS Project) updated
Design Development	Design Review
	BOM finalized
	Confirm product cost
	DFMEA with all high RPNs reduced
	Verification testing completed, countermeasure failures
	Submit ECO to release software / firmware
	Update DSS
	Packaging materials designed and approved
	Identify component CTQs including shelf life if applicable
	Agency compliance test plan and parts submitted
	Full product validation test plan
	Develop test equipment, procedures and pass/fail criteria for PCBA (functional and/or test points)
	Design finalized
	Build production intent prototypes
Manufacturing Process Development	Process 3P (if required)
	Order all new equipment
	Complete SW charter and schedule Kaizen

	Cell location and layout
	Critical equipment in-house and set-up
	PFMEA with high RPNs identified
	Design calibration / test stand software
	Critical fixtures designed
	Process validation and MSA plan
	Finalized Process Flow Map
	PAG (Process-at-a-Glance)
	Product service and repair plan
Finance	CAR approval for balance of capital purchasing
Materials Plan	All production suppliers selected
	All new suppliers are qualified and set up in JDE
	Contract in place for private label type product, if required
	BOM reviewed for Export Compliance
	Parts ordered for production pilot run
Sales & Marketing	Pre-release samples built
	List of target customers identified for pre-release samples
	Visit Beta customers with preliminary release package and complete configuration and P/N matrix
	Update VOC – documented feedback from sample / pre-release package from customer visits
	Identify lead time
	Label design complete
	Complete TG4 activities of Marketing Workbook (P/N, datasheet, operator manual, installation manual, etc.)
	Develop sales ramp up / ramp down for inventory control
	Forecast to Matls / Planner
IP	Update IP

** Use latest revision of toll gate document as master for deliverables. These are subject to change without notice or update to this document.*

Toll Gate 5 – Product Launch: The purpose of TG5 is to transfer the product from engineering to operations, develop and deliver a consistent and repeatable production and purchasing process and to begin the rollout of the commercialization plan. A pilot production run will be conducted with the product made using the tooled components from production sources and final processes staffed by trained cell associates. This tests the production processes, and provides the opportunity to make necessary corrections and adjustments. The pilot production parts will be used to obtain final compliance certificates, complete validation testing and to verify that market requirements have been met. The expectation of this TG is to answer the questions "Can we build it consistently? Will the financial targets originally established be realized?" TG5 specific deliverables include, but are not limited to:

Tools / Tasks	**Deliverables**
Cost Summary	Update TG Workbook to reflect final cost / margin
Manufacturing Readiness	Compete work cell set up
	Identify and set up required PM plan on all equipment, fixtures & tooling
	Associate and repair team trained
	Pilot Production Build
	Equipment validated
	Fixtures and tools in place and validated
	SW Kaizen complete
	Define product ID (e.g. serial number, date code) and traceability e.g. end product through raw material) requirements - if required
	Kanban and supermarket set up

	QSB 1Q complete and in place (CTQ, procedures, equipment set up, tools / fixtures P/N in place, PM)
	SQDIP and defect marketplace in the cell
	Product review with VS members / cell associates
	Manufacturing spec
	Failure modes in manufacturing database
	Verify >96% FPY
	PFMEA updated and high RPNs reduced
	Training needs plan
	Cell safety audit
Design Wrap-up	Validation testing complete
	PCBA test equipment, procedures and requirements transferred to production supplier
	Complete and release the DSS
	Final design ECO released
	IP submitted
	Compliance / agency approvals received
Materials	Inventory on hand to support lead times including labels and packaging
	FAI on 1st production units, CM nonconformances
	Supplier performance tracking in place
	Implement ramp up / ramp down plan
Sales Readiness	Promotion rollout defined
	Complete the Marketing Workbook action plan for TG5
IP	Update IP

** Use latest revision of toll gate document as master for deliverables. These are subject to change without notice or update to this document.*

Note: The L1 staff may provide approval to ship prior to TG5 sign off. In this case, Product shipping to customers prior to final signoff of TG5 should be fully documented via ECO and/or TDN processes to ensure traceability of the field population. At the discretion of the manufacturing engineer, the product serial number may be have PP prefix (denoting the product is pre-production or pre-TG5 sign off).

PROJECT SCOPING

It is important to realize that all projects that utilize the TG process may not require its full scope and deliverables. Such abridged projects may include product adjacencies that are more involved than CBO projects but already have a sufficient technical building block, market understanding, prior IP history, existing process capability / capacity to warrant less detail. In such a case, a reduced set of deliverables will be agreed to by the TG project manager at the beginning of each toll gate subsequent to TG1. Deliverables that are not required at the beginning of each TG will be clearly identified in the TG documents.

Lean Portfolio Management (LPM) AND TOLL GATE (TG) REVIEW / APPROVAL

At the initiation of all TG projects, the LPM determines and allocates teams, resources and leaders for the TG projects. The LPM shall insure that TGs are reviewed for adequacy and completeness and that any requirements that are incomplete, ambiguous, or conflicting are resolved before approving and signing off a new product development TG. The management team may approve a TG that has tasks not completed at their discretion provided those tasks are carried over into the subsequent TG stage or otherwise planned for. This will be noted on the TG checklist in the section adjacent to the approvals section to document these decisions.

The LPM consists of representatives from the following functional areas.

- General Manager
- VP of Sales
- VP of Engineering
- Director of Marketing

- Director of Operations
- Director of Finance

At least one representative from each functional area must be present at LPM meetings. A nominated alternate may be sent, in the event that the key person cannot attend. All active TG projects will report out top issues to the LPM and corresponding countermeasures.

TG review and approval meetings may be scheduled as separate meetings from LPM meeting and will review the program in detail to ensure compliance to all deliverables. It is the responsibility of the TG project manager to schedule these meetings at appropriate time in the product development cycle to ensure issues are raised and appropriate resources assigned to keep the project on time and meeting all targets.

Each TG will have a governing folder on the Setra network and all deliverables will be located in this master folder. Each TG stage will have a cover sheet which will be used as a signature approval sheet. A minimum set of documents will be required for any TG review:

- Project Workbook: Contains overall project charter, financial assessment of project and risk assessment, deliverables and timeline.
- Toll Gate documents: For each TG, there is a defined list of required documents when the project is reviewed. In addition there may be other workbooks required such as Marketing Workbook and Commercial Workbook as examples.

8.4 Control of Externally Provided Processes, Products and Service

8.4.1 General

The organization ensures that externally provided processes, products and services conform to requirements.

The organization determines the controls to be applied to externally provided processes, product and services when:

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

The organization determines and applies criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products or services in accordance with requirements. The organization retains documented information of these activities and any necessary actions arising from the evaluations.

8.4.2 Type and Extent of Control

The organization ensures that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers.

The organization:

a) Ensures that externally provided processes remain within the control of its QMS,
b) Defines both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output,
c) Takes into consideration:
    1) The potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements,
    2) The effectiveness of the controls applied by the external provider,
d) Determine the verification, other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

8.4.3 Information for External Providers

The organization ensures the adequacy or requirements prior to their communication to the external provider.

The organization communicates to external providers its requirements for:

a) The processes, products and services to be provided,
b) The approval of:
    1) Products and services,
    2) Methods, processes and equipment,
    3) The release of products and services,
c) Competence, including any required qualifications of persons,
d) The external providers' interaction with the organization,
e) Control and monitoring of the external providers' performance to be applied by the organization,
f) Verification or validation activities that the organization, or its customers, intends to perform at the external providers' premises.

8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision

The organization implements production and service provisions under controlled conditions.

Controlled conditions include information that defines:

a) The availability of documented information that defines:
    1) The characteristics of the products to be produced, the services to be provided, or the activities to be performed,
    2) The results to be achieved,
b) The availability and use of suitable monitoring and measuring resources,
c) The implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control processes or outputs, and acceptance criteria for products and services, have been met,
d) The use of suitable infrastructure and environment for the operation of processes,
e) The appointment of competent persons, including any required qualifications,
f) The validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement,
g) The implementation of actions to prevent human error,
f) The implementation of release, delivery and post-delivery activities.

8.5.2 Identification and Traceability

The organization uses suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

The organization identifies the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

The organization controls the unique identification of the outputs when traceability is a requirement, and retains the documented information necessary to enable traceability.

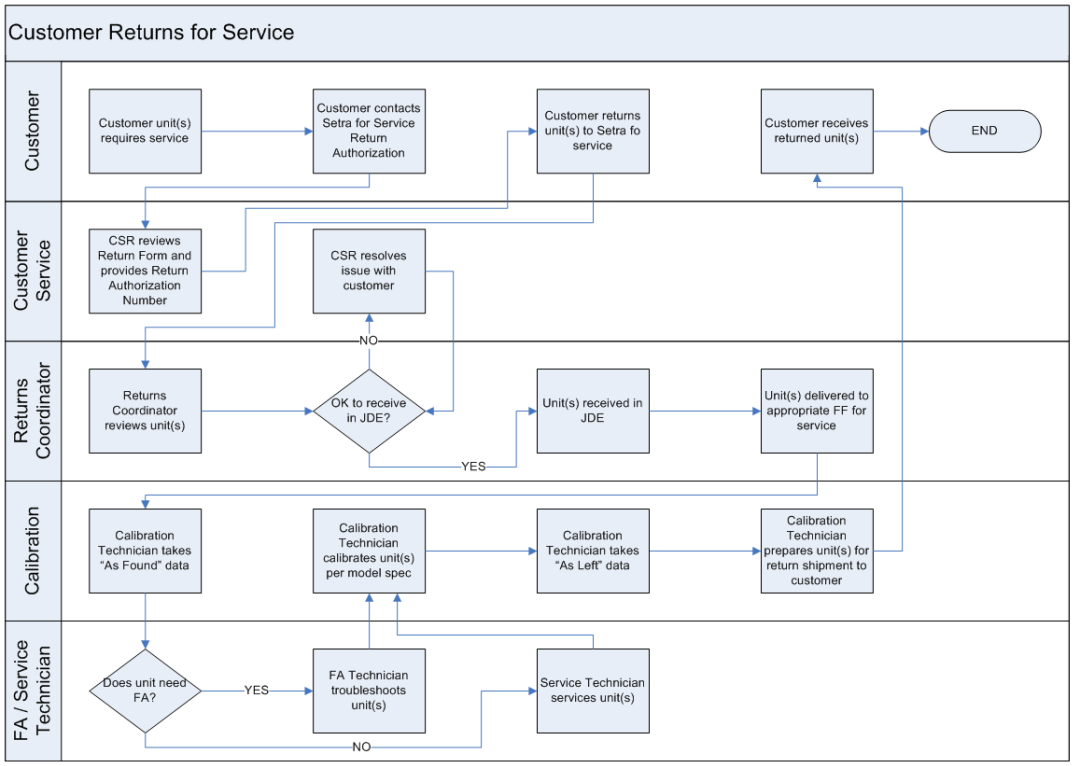
8.5.3 Property belonging to customers and external providers

The organization exercises care with property belonging to customers or external providers while it is under the organization's control or being used by the organization.

The organization identifies, verifies, protects and safeguards customers' or external providers' property provided for use or incorporation into the products and services.

When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization reports this to the customer or external provider and retains documented information on what has occurred.

Note: A customer's or external provider's property can include materials, components, tools and equipment, premises, intellectual property and personal data.



Customer Returns for Service
Figure 7

8.5.4 Preservation

The organization preserves the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

Note: Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.

8.5.5 Post-delivery activities

The organization meets requirements for post-delivery activities associated with the products and services.

In determining the extent of post-delivery activities that are required, the organization considers:

a) Statutory and regulatory requirements,
b) The potential undesired consequences associated with its products and services,
c) The nature, use and intended lifetime of its products and services,
d) Customer requirements,
e) Customer feedback.

Note: Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling and final disposal.

8.5.6 Control of changes

The organization reviews and controls changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.

The organization retains documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

8.6 Release of products and services

The organization implements planned arrangements, at appropriate stages, to verify that product and service requirements have been met.

The release of products and services to the customer does not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

The organization retains documented information on the release of products and services. The documented information includes:

a) Evidence of conformity with acceptance criteria,
b) Traceability to the person(s) authorizing the release.

8.7 Control of nonconforming outputs

The organization ensures that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

The organization takes appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This also applies to nonconforming products and services detected after delivery of products, during or after the provision of services.

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

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

Conformity to the requirements is verified when nonconforming outputs are corrected.

The organization retains documented information that:

a) Describes the nonconformity,
b) Describes the actions taken,
c) Describes any concessions obtained,
d) Identifies the authority deciding the action in respect of the nonconformity.

8.7.1 Nonconforming material process

The purpose of this section is to provide for a system and instructions, and to assign responsibilities for identification, documentation, and disposition of nonconforming product.

This procedure applies to materials, components, subassemblies, and finished products that are subjected to inspections and/or testing. This procedure directly concerns the Quality function, and is indirectly relevant to Receiving, Storage, Production, and Shipping functions.

IDENTIFICATION

Receiving inspectors and production associates are responsible for identifying nonconforming products in the course of their inspection activities. In addition, all other associates are encouraged to watch for and identify nonconforming products regardless of their other responsibilities.

Once identified, nonconforming product shall be segregated and identified as appropriate to prevent inadvertent use.

Production associates shall contact the cell lead when nonconformities are identified.

NONCONFORMITY REVIEW AND DISPOSITION

The Manufacturing Engineer shall review the nonconformity and determine disposition. Nonconforming products may be:

- Reworked/Repaired to meet original specified requirements
- Accepted “As-Is”, without customer concession if the discrepancy does not affect form, fit, function, regulatory or customer requirements

- Regraded for alternative applications, including using as is with customer acceptance if form, fit, function, regulatory or customer requirements are affected
- Scrapped

When required by contract, the client shall be contacted for concession to accept a nonconforming product or the proposed repairs that would affect the product's quality.

REINSPECTION
Repaired or reworked products shall be reinspected to verify that they comply with the same requirements as originally specified, unless a product is regraded and a new specification applies. Regraded products are clearly marked to identify their new status.

RECORDS OF NONCONFORMING PRODUCT
Cell leads are responsible for recording the nature of nonconformities in the appropriate area of the manufacturing database.

Records of actions taken, including any concessions granted, will be created and maintained by the Quality Manager.

The Receiving Inspector and Quality Engineer are responsible for recording identified nonconformities of received product into the inspection database.

PRODUCT RECALL
When shipped product has been determined to be nonconforming, the Quality Manager, or designee, shall:

a) Initiate a meeting with representation from engineering, manufacturing, marketing, materials, operations, and sales, as required, to determine:
    - The issue
    - Extent (serial number/date code range, number of customer affected, etc.)
    - Containment actions
    - Corrective actions
    - Customer notification for product return or replacement
b) Place the product on shipment hold pending implementation of containment and/or corrective actions.
c) Information, such as meeting notes, product shipment history, containment and/or corrective actions, etc. pertaining to the product recall shall be retained on the Setra's network drive (G:\groups\QC\Product RECALLS- Stop work orders folder).

9. Performance Evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

The organization determines:

a) What needs to be monitored and measured,
b) The methods for monitoring, measurement, analysis and evaluation needed to ensure valid results,
c) When the monitoring and measuring is performed,
d) When results from monitoring and measurement is analyzed and evaluated.

The organization evaluates the performance and effectiveness of the QMS.

The organization retains appropriate documented information as evidence of the results.

9.1.2 Customer satisfaction

The organization monitors customers' perceptions of the degree to which their needs and expectations have been fulfilled. The organization determines the methods for obtaining, monitoring and reviewing information.

Setra conducts a Customer Satisfaction Survey. The survey link is included in every order confirmation, customer service representative's signature line on out-going emails, and manually sent after every phone call. The survey link verbiage is as follows:

*** Please complete our short question survey so that we can better serve you, our valued customer ***
https://www.surveymonkey.com/r/Setra

Additionally, Setra's Customer Service group maintains a Daily Management Board which monitors five (5) metrics used to track Customer Satisfaction based on internal process activities. The five metrics are:

- Problem Rack: Customer Returns requiring resolution (Goal: ≤ 20 returns not resolved)
- Raw Orders: Raw Orders received but not entered by end-of-day (Goal: ≤ 5 raw orders not entered in JDE)
- Open Inquires: Customer inquiries not resolved by end-of-day (Goal: ≤ 10 inquires not resolved)
- Missed Calls: Customer calls not answered; hang-ups (Goal: 0 missed calls)
- On Holds: Orders On-Hold in JDE at end-of-day (Goal: ≤ 50 orders on hold)

Note: Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims and dealer reports.

9.1.3 Service to the Customer

Setra is willingness to cooperate with customers or their representatives in clarifying the customer's request and in monitoring Setra's performance in relation to the work performed, provided that Setra ensures confidentially to other customers.

Setra shall seek feedback, both positive and negative, from its customers. This feedback is used and analyzed to improve the management systems, calibration activities and customer service.

9.1.4 Complaints

Setra has a policy and procedure for the resolution of complaints received from customers or other parties. Records are maintained of all complaints and of the investigations and corrective actions taken by Setra.

9.1.5 Analysis and evaluation

The organization analyses and evaluates appropriate data and information arising from monitoring and measurement.

The results of analysis are used to evaluate:

a) Conformity of products and services,
b) The degree of customer satisfaction,
c) The performance and effectiveness of the QMS,
d) If planning has been implemented effectively,
e) The effectiveness of actions taken to address risks and opportunities,
f) The performance of external providers,
g) The need for improvements to the QMS.

Note: Methods to analyze data can include statistical techniques.

9.2 Internal Audit

The organization conducts internal audits at planned intervals to provide information on whether the QMS:

a) Conforms to:
   1) The organization's own requirements for the QMS,
   2) The requirements of the International Standard,
b) Is effectively implemented and maintained.

The organization:

a) Plans, establishes, implements and maintains an audit program including the frequency, methods, responsibilities, planning requirements, and reporting, which takes into consideration the

importance of the processes concerned, changes affecting the organization, and the results of previous audits,
b) Defines the audit criteria and scope for each audit,
c) Selects auditors and conducts audits to ensure objectivity and impartiality of the audit process,
d) Ensures that the results of the audits are reported to relevant management,
e) Takes appropriate correction and corrective actions without undue delay,
f) Retains documented information as evidence of the implementation of the audit program and the audit results.

Note: See ISO 19011 for guidance.

9.3 Management review

9.3.1 General

Top management reviews the organization's QMS, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization.

Setra utilizes the FBS (Fortive Business System) which is our proven system for achieving success, by driving our culture and performance, guiding what we do, measuring how well we execute and driving a continuous cycle of change and improvement. A major component of FBS is the monthly PD (Policy Deployment) meeting, where senior staff reviews CVDs (Core Value Drivers), KPIs (Key Process Indicators), and other items that pertain to Setra's QMS which would be covered in an annual QMS Management Review. As such, an annual QMS Review would be redundant, so Setra will schedule QMS updates on a biannual basis within the PD meeting agenda.

9.3.2 Management review inputs

The management review is planned and carried out taking into consideration:
a) The status of actions from previous management reviews,
b) Changes in external and internal issues that are relevant to the QMS,
c) Information on the performance and effectiveness of the QMS, including trends in:
   1) Customer satisfaction and feedback from relevant interested 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 (see 6.1),
f) Opportunities for improvement.

9.3.3 Management review outputs

The outputs of the management review include decisions and actions related to:
a) Opportunities for improvement,
b) Any need for changes to the QMS,
c) Resource needs.

The organization retains documented information as evidence of the results of management reviews.

10. Improvements

10.1 General

The organization determines and selects opportunities for improvement and implements any necessary actions to meet customer requirements and enhance customer satisfaction

These include:
a) Improving products and services to meet requirements as well as to address future needs and expectations,

b) Correcting, preventing or reducing undesired effects,
c) Improving the performance and effectiveness of the QMS.

Note: Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation and re-organization.

10.2 Nonconformity and corrective action

When a nonconformity occurs, including any arising from complaints, the organization:

a) Reacts to the nonconformity and, as applicable:
   1) Take action to control and correct it,
   2) Deal with the consequences,
b) Evaluates the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
   1) Reviewing and analyzing the nonconformity,
   2) Determining the causes of the nonconformity,
   3) Determining if similar nonconformities exist, or could potentially occur,
c) Implements any action needed,
d) Reviews the effectiveness of any corrective action taken,
e) Updates risk and opportunities determined during planning, if necessary,
f) Makes changes to the QMS, if necessary.

Corrective actions are appropriate to the effects of the nonconformities encountered.

The organization retains documented information as evidence of:

a) The nature of the nonconformities and any subsequent actions taken,
b) The results of any corrective action.

Procedures for preventive actions include the initiation of such actions and application of controls to ensure that they are effective.

10.3 Continual improvement

The organization continually improves the suitability, adequacy and effectiveness of the QMS.