DURATECH INDUSTRIES	**Quality Manual**	**Approval and Revision Page**
Document: QA1000	Revision Date: 08/15/2022	**Section1**

This manual applies to:

DuraTech Industries, Inc.
3216 Commerce Street
La Crosse, WI 54603

Revision Control Record			
Revision Date	**Requestor**	**Approver**	**Description of Change**
06/22/2017	Tim Drey	Chris Wehrle	Complete revision to align with ISO9001:2015 standard.
10/02/2017	Tim Drey	Chris Wehrle	Updated "References" in each section. 7.2 Competence: Clarified team member competence is discussed in departmental meetings and not formal reviews. Added " DuraTech strives to deliver based on customer needs and availability of materials from suppliers" to 8.4 General. 8.5 Preservation: Added key words transportation, contamination and protection.
09/28/2018	Tim Drey	Chris Wehrle	Section 4.4: Change "objects" to "objectives" 5.3: Updated roles and responsibilities diagram. 10.3: Added reference to QA4284 DuraTech Improvement Continuum
11/18/2019	Tim Drey	Chris Wehrle	Section 4.4 added manufacturing interaction map. 5.3 updated org chart titles. 8.3 added R&D/Engineering and changed to phase gate.8.5 added QA2025 to reference document list. 10.3 Removed A3 and changed to goal setting.
12/21/2020	Tim Drey	Chris Wehrle	Overview: added presentations as 5th tier of documentation. Section 4.1: Clarified SWOT with TOWS and moved to 5 year strategic plan. Section 4.4: Added metal photo and die sub to manufacturing flow. Section 5.1: Removed annual goals presentation Section 5.3: Updated org chart to reflect current positions Section 6.1: Changed Planning Team to Senior Leadership Section 6.2: Allowed flexibility of using A3 or action plan format. Section 7.2: Change HR2020 to HR2059.
06/24/2021	Tim Drey	Chris Wehrle	Added IS/IT to process interaction map. Updated org chart.
08/15/2022	Kasey Cockroft	Chris Wehrle	Fixed incorrect reference document names.

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DuraTech Industries' documented quality system has five tiers as described below.

The Quality Manual describes the corporate quality system, and states the policy, philosophy and objectives for each of the pertinent ISO 9001 requirements.

Operating procedures, on a department-level, describe what is to be done, in what order, when and by whom, to achieve specified results. Operating procedures answer the questions, "who, what, where, and when."

Work instructions describe how specific daily tasks are performed.

Records, forms and other controlled documents are the documented information which shows the results of work. They may, for example, be blank forms waiting to be used, or forms which have been filled in as a result of a work instruction.

Presentations support work instructions and are used to enhance the effectiveness of training.

The inter-relationship between the five levels of documents outlines the structure of the quality system.

Leadership reviews the quality system at least annually to show commitment of understanding the system and whether or not the resources necessary are in place to meet or exceed the requirements of all interested parties.

Reference:
QA2000 Procedure Template
QA2001 Document and Data Control
QA3000 Work Instruction Template
QA4000 Form Template
QA2005 Management Review

4.1 Context

DuraTech Industries defines the purpose and strategic direction of the organization through the Quality Management System. Key inputs are derived from the leadership S.W.O.T.(TOWS) analysis, market trends, process analysis, customer feedback, and ability to meet annual organizational goals. Through this process, DuraTech is able to identify external and internal issues and address these risks as it related to the 5 year strategic plan.

Reference:
MT4028 Strategic Business Plan
QA4279 Process Turtle Diagram
S.W.O.T. Analysis

4.2 Interested Parties

DuraTech Industries recognizes interested parties as all stakeholders involved within the Quality Management System. This group includes suppliers, team members, ownership, and customers. It is DuraTech's obligation to understand the requirements of each unique party. Requirements are monitored and reviewed during Management Review. The QMS defines requirements of each group in the following documents:

Reference:
CS2003 Order Review Process
QA2005 Management Review
SA2056 Sales Procedure
MT4028 Strategic Business Plan
Employee Handbook
Supplier Quality Manual
Customer Quality Manuals
Product Development Phase Gate and Design Considerations

4.3 Scope

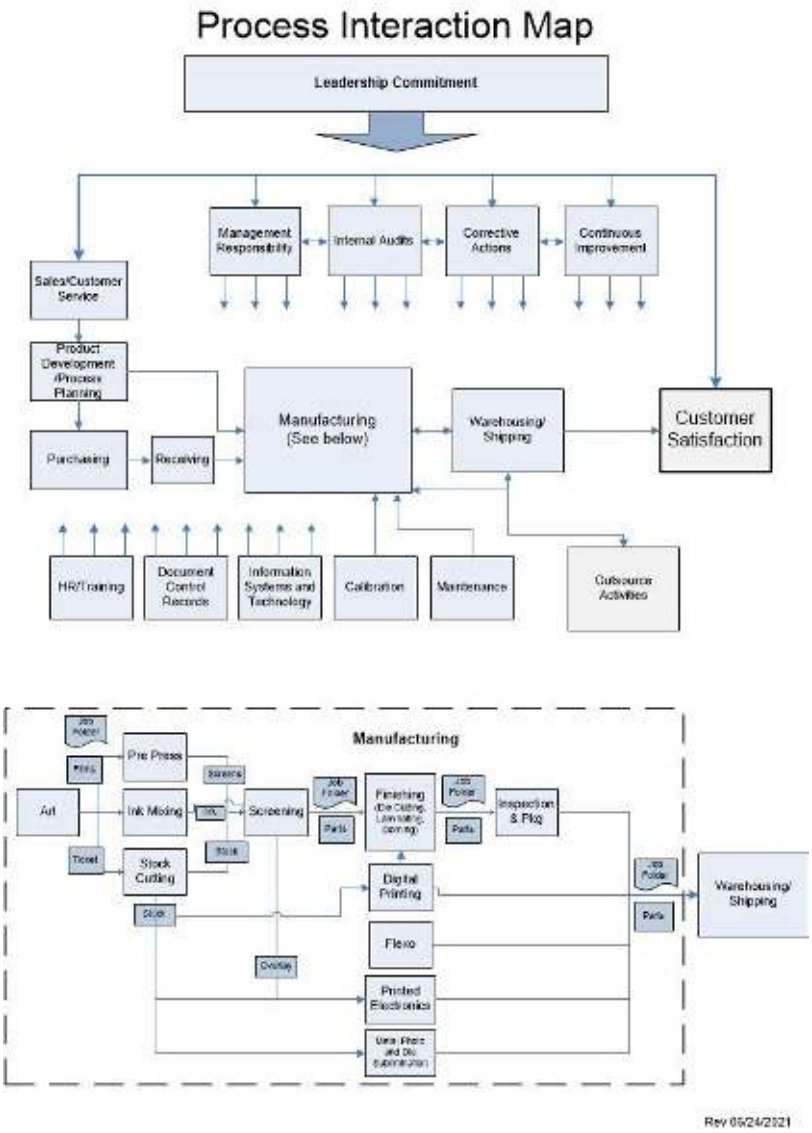
DuraTech has established and maintains a documented quality system to ensure that products and services meet the expectations of our interested parties. As per section 4.1 and 4.2 this is defined through strategic direction as determined through the expectations of said parties in the manufacture of high technology, durable, close tolerance multi-color overlays, dials, nameplates, appliques and other related products for automotive, appliance, electronics, printed electronics, medical and OEM applications

All requirements of ISO9001:2015 are applicable to the scope of DuraTech's QMS. This Quality Manual governs the system employed to control processes and product quality at DuraTech Industries. The system encompasses the entire manufacturing process (from supplier selection, to receiving and testing of raw materials, and through the manufacturing, testing and shipping of end products).

Reference:
QA1000 Quality Manual
MT4028 Strategic Business Plan

4.4 Quality Management System Processes

DuraTech Industries defines the QMS processes through analysis of the inputs and outputs needed to satisfy internal and external customers. This process defines company interactions to ensure alignment and identify risks or areas of improvement. Each process is reviewed for key inputs and outputs, including the measurements needed, to ensure the process is performing as intended. Key performance indicators may include daily monitoring, monthly company objectives or annual A3 corporate goal achievement. The scope and necessity is determined by process owners. The management review process audits effectiveness of the QMS and to ensure necessary resources have been allocated.



Reference:
QA4273 A3 DMAIC Problem Solving Form
QA4279 Process Turtle Diagram
MT4208 Operating Plan

5.1 Leadership and Commitment

Senior Leadership's commitment and involvement in the quality management system is visible throughout the organization. The vision, quality policy, strategic objectives and importance of meeting customer requirements are communicated in a number of ways, i.e. company-wide and departmental meetings, bulletin boards, corporate policies and new hire orientations.

Senior Leadership reviews organizational performance measurements, customer satisfaction feedback, continual improvement efforts and resource needs in scheduled management review meetings.

All leadership is accountable for developing and taking action toward corporate improvement goals. All DuraTech Team Members are asked for their involvement and suggestions toward improvements. Processes are reviewed for risk and opportunity to identify and prioritize improvements that will impact the organization. DuraTech uses the SMART format for communicating goals. Results of these goals are reviewed by Senior Leadership quarterly to ensure appropriate resources are in place and activities move the company toward achieving intended results. If results are not met, Leadership engages and directs team members in support as adjustments are made. Team meetings, one-on-one meetings and Gemba walks are forms of engagement DuraTech employs.

Customer focus is a priority of Leadership. DuraTech is committed to ensuring customers' requirements are met to enhance customer satisfaction. This includes applicable statutory and regulatory requirements. Management has accomplished this through the order review process and other value-added services offered, i.e. supplier managed inventory. DuraTech team members actively engage customers into improvement projects which help minimize risk and seize opportunities to improve all aspects of the supply chain.

Reference:
CS2003 Order Review Procedure
SL2056 Sales Procedure
QA2005 Management Review
MT4208 Operating Plan
QA4236 Quality Policy
DuraTech Vision Mission Values Statement

5.2 Policy

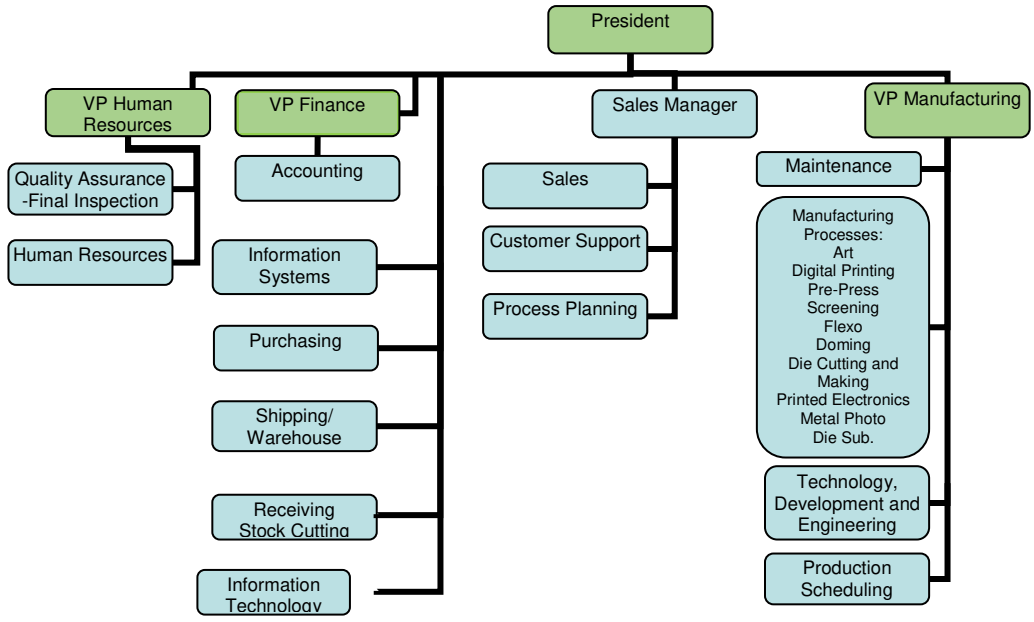
"DuraTech Industries consistently provides world-class products and legendary customer service, through continual improvement and adherence to established quality objectives, which meet or exceed customer expectations". (QA4236 Quality Policy)

DuraTech's quality policy and quality objectives are established by leadership and communicated to the organization through a variety of methods; company-wide

meetings, new team member orientation training, team meetings, electronic media, controlled documentation and bulletin boards. The mission, vision, values and policy are openly shared and communicated both internal and externally to interested parties. All team members are expected to understand and apply the policy in their work every day to support customer satisfaction.

5.3 Organizational roles, responsibilities and authorities

Leadership expects all team members to be responsible for effective communication, quality of their work and initiating corrective action for any nonconformities relating to product, process, and quality system. The responsibilities and authorities for all team members are outlined in job descriptions and procedures. Team leaders are responsible for the performance of the quality system within their areas and processes as well as communicating results. Documented procedures address problem resolution, nonconformity, planning, risk and acquisition for quality system requirements. The chart below depicts the responsibilities for each process.



Quality Assurance has established, implemented and maintains a quality system in accordance with ISO 9001 and which is customer focused. The management representative has direct responsibility to Senior Leadership for reporting on the performance of the quality system including conformity to the Standard and quality objective outputs. Leadership reviews the QMS for performance opportunities or gaps during Management Review.

Reference:
Organization Chart
Job Descriptions
QA2005 Management Review

6.1 Actions to address risks and opportunities

DuraTech Industries' Senior Leadership Team, consisting of a multi-disciplinary group of individuals, develops, reviews and maintains the planning process at DuraTech. The Senior Leadership Team reviews DuraTech's Strategic Plan and establishes the agenda for planning retreats. The Strategic plan and operating plan tie to inputs from the S.W.O.T.(TOWS) analysis and interested parties. Opportunities, weaknesses and threats identified are prioritized and integrated into the operating plan. The operating plan and objectives are reviewed at least annually in Management Review to verify the intended results are achieved. This includes maintaining or enhancing desired outcomes, preventing undesired outcomes, and showing general operational improvements.

Reference:
MT4028 Strategic Business Plan
S.W.O.T. Analysis

6.2 Quality objectives and planning

A problem solving methodology is used to approach corporate objectives and may be documented within an A3 DMAIC problem solving format or action plan. These formats promote clear communication of actions and how they have been integrated into the QMS. Measurements and controls are put in place to understand the effectiveness of actions taken. Outcomes are communicated to employees through a variety of methods that include company-wide meetings and department meetings. Process analysis tools are used to identify risks and opportunities and act as an input to the goals planning process.

Controlled copies of the strategic plan and operating plan are available electronically. Implementation of operational plans are granted the resources needed to fulfill business needs and minimize risk based on potential impact to the organization, customers or other interested parties. Operational plans and budgets include training, equipment, facilities, materials and other system requirements.

Reference:
QA4279 Process Turtle Diagram
QA4273 A3 DMAIC Problem Solving Form

6.3 Planning of changes

DuraTech Industries controls change to the QMS in many ways. All major capital expenditures are reviewed by a cross-functional team to review potential risk and gaps that may lead to unintentional consequences. Process and product changes must go through levels of authorization which depend on likelihood of risk. A risk matrix and team approach are used to ensure potential known consequences, QMS changes, resources and the proper responsibilities and authorities are considered.

Reference:
MT4194 Capital Expenditure Request
QA2055 Internal Deviation Procedure

DURATECH INDUSTRIES	**Quality Manual**	**Support**
Document:QA1000	Revision Date: 08/15/2022	**Section 7**

7.1 Resources

General

Senior Leadership plans for the equipment, people, building, financial and support resources necessary to ensure customer satisfaction. This is completed every 5 years utilizing a GAP risk analysis tool and adjusting the MT4028 Strategic Business Plan. More frequent adjustments are made as a result of Management Review action items, internal audits, and CapEx requests as needed.

People

In determining and providing the human resources needed to effectively implement the QMS, DuraTech reviews recruitment and retention measurements within management review. (QA2005 Management Review Procedure)

Infrastructure

Senior Leadership plans for equipment, building, work space and other associated support resources. Equipment preventive and predictive maintenance is performed to ensure continuing process capabilities.

Recovery plans are in place for utility interruption, labor shortage, loss of water and key equipment failure. Artwork and part information are maintained electronically. The electronic files are backed up and stored in an offsite location. Second sources for materials, human capital, equipment, transportation and technology are considerations within DuraTech's business continuity planning.

Environment

A suitable work environment is provided including cleanliness, temperature and humidity controlled areas. Aside from physical factors, DuraTech provides a work environment that ensures a positive culture to eliminate social and psychological stresses.

A health and wellness program has been established to allow employees to gain knowledge on healthy choices for community, family and personal balanced health.

A safety program has been implemented, which includes personal protective equipment, lockout/tagout, hazardous material labeling, and various other aspects of safety. The safety program is documented in more detail in CW2026 Safety Procedure.

Monitoring and Measuring

General

DuraTech has established and maintains procedures to control, calibrate, and maintain the measurement resources used to ensure conformance of specified requirements. Scheduled verification checks are established to ensure measurement and/or test equipment is capable. Records are kept and maintained for evidence of control and are made available when required by the customer. Services are monitored and measured as an outsource process and is included within the supplier quality and qualification process.

The appropriate measuring and/or test equipment is selected according to the specific requirements of each product. Inspection, measuring, and test equipment that affect product quality are calibrated and adjusted at designated intervals.

The criteria used to determine calibration methods of inspection, measuring and test equipment includes identification and details of the equipment, frequency of checks, acceptance, and action taken if results are unsatisfactory.

Measurement Traceability

Records are kept for the identification and calibration of inspection, measuring, and test equipment. Previous inspection and test results are evaluated if equipment is found to be out of calibration. Customer is notified if risk of nonconforming product is identified.

Environmental conditions are monitored to ensure they are suitable for inspection, measuring and test equipment methods.

Accuracy and fitness of measurement resources are assured through the use of proper handling, storage and training. Where possible, resources are safeguarded from adjustments.

Reference:
MT4028 Strategic Business Plan
QA2005 Management Review
QA2025 Control of Inspection Measurement and Test Equipment
Disaster Recovery Plan
CW2026Safety

Organizational Knowledge

DuraTech uses documented information to provide the knowledge necessary for the operation of processes and acceptability of product and/or services. This information is addressed in detail within section 7.5. Inputs to documented organization knowledge come from suppliers, industry experts, team members, lessons learned, trip reports and many other sources. When a gap in knowledge is determined or predicted, outside resources are used to gain the necessary information and used to update documented information. DuraTech's process analysis identifies potential knowledge/training risks and allows Team Leaders to address to the extent necessary.

Reference:
HR2020 Training
Tuition Reimbursement Policy

7.2 Competence

DuraTech has performance-based job specific instruction and a tuition reimbursement program to support employees with the appropriate outside education. Company-wide training needs are reviewed on at least an annual basis by Senior Leadership. Training needs and team member competence is discussed during departmental meetings. Team members are responsible for participation in the team member development program. Team leaders/trainers maintain records of each team members' participation in classes, training and completion of other certification requirements. Competency is determined through observation and/or testing. Internal audits measure the effectiveness of training and implementation of HR2059 Training Program Requirements.

7.3 Awareness

DuraTech provides an environment in which employees are motivated to achieve quality objectives and make continual improvements. An employee involvement program has been established by which suggestions for improvements and process optimization are submitted. These ideas include opportunities for safety improvement and more efficient workflow. Performance metrics are reviewed regularly with employees in company-wide and individual team meetings.

To ensure that all employees are aware of the relevance of their jobs and how they contribute to the achievement of the quality objectives, awareness training is conducted as part of department training programs and reviewed during performance appraisals.

7.4 Communication

Relative company management system communications and importance of meeting customer requirements are communicated in a number of ways. Formal Company-wide, Leadership and departmental meetings take place regularly. An agenda is created for each to provide structure and determine who, what, where, when and how communication will take place. Also, specific company communication is provided on bulletin boards, within corporate policies, training, presentations and new hire orientations.

7.5 Documented information

Team leaders ensure that procedures are implemented and maintained. Quality Assurance assures that the quality system reflects the current Standard.

DuraTech utilizes work instructions to detail the processes. Training is provided for the employees involved in carrying out the activities described in procedures and work instructions. Forms and records provide the documentation necessary to meet ISO 9001 requirements.

DuraTech maintains procedures and work instructions to control all documentation and data requirements needed to support our quality system. This documentation and data control policy applies to all hardcopy and electronic documentation generated and/or received (external) at DuraTech. All controlled documentation is reviewed and approved prior to issue by appropriate personnel as established in the QA2001 Document and Data Control Procedure.

A master file of current revision status of all internal documentation is maintained and readily available at the point of use. Customer information is controlled through the CS2003 Order Review Procedure.

Our controlled document distribution system ensures that all internal documents are current and available, and all obsolete and invalid documents are promptly removed. Any retained obsolete and invalid documents are clearly marked.

Any team member may initiate changes to documents. All changes to the quality manual are reviewed and approved by Senior Leadership. All changes to controlled procedures, work instructions and forms are reviewed and approved by a member of the Document Control Team or by Quality Assurance. The revision history for each document, describing the nature of the change, is shown in the document database/spreadsheet or document revision block. All team members have access to pertinent background information upon which to base their review and approval.

Procedures are established and maintained for the identification and disposition of quality records. Records, including those that may pertain to subcontracted products, are maintained to show conformance to specified requirements and to ensure the effectiveness of the quality system. All records are retained and protected for prevention of damage or loss and are kept as needed for the duration of the applicable product history and/or as designated by the customer. Records are available for customer evaluation on request.

Reference:
QA2001 Document and Data Control Procedure
CS2003 Order Review Procedure
QA2009 Process Control
HR2020 Training Procedure
MN2023 Preventive Maintenance
CW2026 Safety Procedure
IS2034 Information Systems Procedure
CW4036 Department Meeting Minutes Template

8.1 Operational planning and control

DuraTech has established and maintains an operational planning system to assure the delivery of quality products and services. The planning process is an integral part of the procedures and work instructions of our quality system. Procedures, work instructions, routings and other documented information define requirements, resources and acceptance criteria needed. Product Development and Process Planning translate customer requirements into the processes needed to meet given criteria. New products, services and processes are given special attention to identify the need for additional resources in order to achieve the required quality.

Documented information critical to understand process effectiveness and conformity is retained per QA2001 Document and Data Control Procedure.

Planned changes are controlled per the QA2055 Internal Deviation Procedure and documented within Seradex or QA4278 Internal Process Change Record as applicable.

Outsourced processes are controlled using incoming inspection and documented per QA4066 Incoming Inspection Report.

8.2 Requirements for products and services

Customer requirements and other statutory and/or regulatory requirements are reviewed by our Customer Support team prior to order acceptance to ensure accuracy and completeness of the order. Orders are officially accepted and scheduled upon confirmation with the customer.

It is the responsibility of the Customer Support Team to assure accurate information is distributed to the appropriate areas and communicated to the customer.

Products and service offerings and subsequent orders are reviewed to ensure that:

- Requirements are clearly stated, defined, and documented. This includes:
    - Customer specific requirements
    - DuraTech specific requirements
    - Statutory and regulatory requirements
    - Applicable warranty information
    - Other known/perceived requirements of end use
- Any deviations/changes from the original order are resolved prior to acceptance.
- DuraTech has, or can acquire the necessary capabilities to meet all contract requirements for offerings.

Changes to orders are documented and approved by DuraTech and the customer and communicated in a timely manner to the appropriate areas before fulfillment.

If customer requirements were not communicated by the customer, DuraTech will quote per relevant information noting any assumptions which may impact fit, form, or function.

New projects which pose high risk to the fulfillment of customer expectations, based on nature, duration and/or complexity, are managed by Product Management. Feasibility reviews are conducted and documented to ensure requirements are achieved.

Reference:
CS2003 Order Review Procedure

8.3 Design and development

Planning

Design is controlled by the customer; however, designs are validated for manufacturability during the quality planning process. Design and development of the manufacturing process to meet customer requirements is the responsibility of Project Management and Process Planning. Responsibilities and authorities are listed in job descriptions.

Project Management/R&D/Engineering develop products and process using a phase gate process. This process reviews and validates outputs with the proper team to determine if internal and external resource adjustments are needed. It also sets the levels of control needed and any resulting documented information. The Project Manager also ensures timely and accurate communication to the proper team members at each stage. This includes customers, internal teams and suppliers when applicable. Lessons learned are recorded and used for subsequent programs.

Inputs, Controls and Outputs

DuraTech Industries maintains several tools to aide in determination of design and development inputs, controls and outputs. The QA2002 Quality Planning and QA2009 Process Control procedures ensure customer expectations are met and the proper documented information is retained. Any potential foreseen risks are clearly communicated and resolved before the next stage can be started and/or the customer approves. When necessary, design reviews are conducted to better understand customer requirements and verify the process will be satisfactory. Validation activities may be conducted onsite, at 3rd party labs or by the customer. If a gate cannot be passed, the next stage will not be started unless authorized by the customer. Upon customer request, PPAP activities and validations will be conducted to satisfy monitoring requirements.

Changes

Internal process design changes are controlled by QA2055 Internal Process Deviation procedure. Customer design changes are reviewed for feasibility and applicable engineering changes and/or deviations are requested. Documented information is saved digitally within Seradex.

Reference:
QA2002 Quality Planning
QA2051 APQP
QA2055 Internal Process Deviation

8.4 Control of Externally provided process, products and services

DuraTech has established and maintains documented procedures to ensure that purchased products conform to DuraTech, governmental, safety and environmental specified requirements.

General

Per PU2022 Supplier Selection, suppliers are selected and evaluated according to their ability to meet requirements for specific DuraTech projects. This is controlled through a regularly scheduled evaluation based on quality and on-time delivery. Records of supplier evaluation and performance are maintained.

Purchase orders describe and classify the product being ordered. Specific reference is made to any other technical data necessary to process the order, such as shipping instructions, drawings, inspection or packaging requirements, and any other expected standards. Purchasing documents are reviewed and approved prior to their release. This applies to full subcontract, partial subcontract and drop shipped items that are delivered directly to the customer. DuraTech strives to deliver based on customer needs and availability of materials from supplier.

Control and Information

In addition to requirements stated within DuraTech purchase orders, a Supplier Quality Manual is distributed to communicate expectations. Self and onsite audits are conducted at suppliers to ensure the acceptability of products, services, processes, equipment, competency and release activities. Corrective Actions are issued for any non-conformity identified. Incoming inspections are conducted on all subcontract products to ensure controls have been maintained. Raw materials are inspected when high risk or past corrective actions are still within the verification process. The supplier scorecard is sent quarterly to communicate performance.

DuraTech has established and maintains procedures for inspection and verification of specified requirements for manufactured products and raw materials. The details regarding inspection and testing are covered in the work order routing sheets, inspection plan and/or documented procedures and work instructions for each inspection process.

The goal at DuraTech is to have a certified supplier base to minimize incoming inspection. Certification is based upon supplier performance.

Materials and components are verified at suppliers' premises and material certifications are provided. Targeted materials are inspected per QA2016 Incoming Receiving and Inspection Procedure.

Incoming raw materials released for urgent production prior to verification for acceptance are tagged, documented, and recorded for traceability in the event of nonconformance.

DuraTech personnel seldom verify products at the suppliers' premises. Suppliers are expected to meet DuraTech's specifications, and products may be verified at DuraTech using our Incoming Receiving and Inspection Procedure.

DuraTech's customers seldom verify products at the suppliers' premises. DuraTech offers the option for customers to arrange a visit to the supplier/subcontractors' premises. The customer verifies subcontracted products shipped directly to the customer.

Reference:
PU2012 General Purchasing
QA2016 Incoming Receiving and Inspection Procedure
PU2022 Supplier Selection
PU2041 Subcontract Receipt Procedure
QA2054 Supplier Audit Procedure
Supplier Quality Manual

8.5 Production and Service Provision

Control

Processes are controlled through the use of our quality planning system. Procedures ensure that processes directly affecting quality are controlled. The processes are planned; documented and performed by trained and competent personnel in compliance with the applicable standards/codes, procedures, work instructions, and quality/test/control plans.

Suitable equipment is planned for and provided through the use of the quality planning system. A suitable infrastructure and environment is provided including cleanliness, temperature and humidity controlled areas.

Monitoring and measuring resources ensure the control of process parameters and product characteristics at appropriate stages are handled through the use of appropriate controls such as templating, visual inspections, density charting, and product auditing. Error proofing techniques are used in place of inspection when possible.

Processes and equipment are evaluated and approved.

Workmanship standards are documented and applied, using visual samples for clear understanding of acceptable quality and product release.

Equipment preventive maintenance is performed to ensure continuing process capabilities.

Where the results of a product or process can't be validated through inspection and testing, DuraTech has special processes that are controlled through monitoring and control of process parameters to ensure that the specified requirements are met.

Carriers are chosen based on customer requirements or ability to ship acceptable product on time.

Any warranty claims or other post shipment activities are handled by Sales, Finance, Customer Support and/or Quality Assurance as required.

Identification and Traceability

Records are maintained for all processes, equipment, and personnel.

DuraTech has established and maintains procedures to identify raw materials that are received and used throughout the production process. Where required by the customer, traceability for identification of individual lots is maintained. The level of traceability is determined by customer requirements as well as DuraTech's needs. Identification records are kept at the individual job level.

Inspection and testing results are recorded and indicate product conformance or nonconformance. Inspection and testing results are maintained according to procedures to ensure product has passed the required inspection or tests before they are released. Nonconforming product may be released under authorized concession as stated in QA2011 Control of Nonconforming Product procedure.

Customer Product

DuraTech has established and maintains a material control procedure that applies to customer-supplied products, such as raw materials, components, tooling, artwork, and packaging. This procedure addresses the verification, storage and maintenance of customer-supplied product. It is expected that the customer will verify the quality of the product delivered to DuraTech.

Customer-supplied nonconforming product is identified and segregated. The disposition of nonconforming or miscounted materials is reported to the customer through our process for control of nonconforming product.

Preservation

DuraTech has established and maintains procedures for preventing damage and deterioration of raw materials and products in all phases of manufacture, storage and delivery.

Team members are provided with training in proper handling methods. Training covers safe handling methods, proper use of handling equipment, and prevention of damage to product.

Storage or stock areas are designed for prevention of damage and deterioration. Authorization methods are used for receipt and dispatch of products. Stored items are assessed periodically for suitability of use.

Packing, packaging, and marking of products are controlled throughout the production process to ensure conformance to customer requirements and prevent damage.

The methods of preservation and segregation for preventing damage and deterioration of raw materials and products are controlled through procedures and work instructions.

Final product is protected and shipped to maintain the quality of the product.

Post Delivery

DuraTech retains documentation of all statutory and regulatory documentation required at the time of manufacture. This may include statements of intended lifetime, storage conditions and potential unintended consequences. Any warranty claims are handled by Customer Support and/or Quality Assurance as required. Positive and negative feedback is solicited from customers by Marketing.

Change

Process and product changes must go through levels of authorization which are depended on likelihood of risk. A risk matrix and team approach are used to ensure potential known consequences, QMS changes, resources and the proper responsibilities and authorities are considered.

Reference:
QA2002 Quality Planning
CS2003 Order Review Procedure
QA2009 Process Control
QA2011 Control of Nonconforming Product
QA2014 Product ID and Traceability
QA2017 Customer Supplied Product
PW2018 Material Handling
MN2023 Preventive Maintenance
QA2025 Control of Inspection, Measuring and Test Equipment
QA2055 Internal Deviation Procedure
MT4194 Capital Expenditure Request

8.6 Release of Products and Services

In-process inspection and testing is detailed through the inspection plan and/or inspection procedures and work instructions.

Manufactured products are not released until inspection and/or testing is complete and all appropriate data is documented and verified at each process stage according to the work order routing sheets. All manufactured products receive in-process inspection.

Final inspection and/or testing are completed according to the inspection plan and/or procedures to verify conformance of the finished manufactured product to the specified requirements.

Inspection activities are completed according to the inspection plan prior to release of any manufactured product. Inspection and test data is made available, documented and authorized by trained personnel.

Inspection and test records are established and maintained to provide evidence of manufactured product conformance, and the acceptance or failure of inspection/tests according to defined criteria. Nonconforming products are dispositioned according to QA2011 Control of Nonconforming Product Procedure.

Reference:
QA2024 Inspection and Test Status

8.7 Control of nonconforming outputs

DuraTech has established and maintains procedures to ensure that nonconforming product is identified, documented, and segregated, where practical, to prevent

unintended use. It is reviewed and dispositioned according to QA2011 Control of Nonconforming Product procedure.

Responsibility for review and authority for the disposition of nonconforming product is defined in the procedure. Product may be reworked, accepted with or without concessions, rejected or scrapped.

Where required by contract, products that do not conform to the specified requirements are reported to the customer and dispositioned accordingly. Concessions are documented. Repaired or reworked product is reinspected according to the work order routing sheets, inspection plan or procedures.

Reference:
QA2011 Control of Nonconforming Product

9.1 Monitoring, measurement, analysis and evaluation

Measured controls needed for each type of product manufactured are identified in the inspection plan and/or control plan during the quality planning process. Statistical process measurements are carried out and verified by trained process owners.

The QA2037 Statistical Techniques procedure implements and controls the application of statistical techniques, in accordance with the work order routing sheets, control plan, inspection plan and process control requirements.

Evidence of conformity is recorded on forms included within the work order folders. This includes team member traceability and results.

Customer satisfaction is obtained through customer surveys, direct feedback and scorecards. DuraTech's NPS, performance scores and comments are reviewed during management review.

DuraTech monitors trends in operational performance, including cost of quality based on product classes, productivity, and system efficiency and effectiveness. These measures are based on corporate goals, which are compared to appropriate benchmarks. Senior Leadership reviews these operational performance measures at least annually.

DuraTech gathers customer feedback, reviews customer report cards and analyzes customer concern reports to identify trends in quality, delivery and service performance. Senior Leadership conducts long-range planning based on identified trends.

Reference:
QA2005 Management Review
QA2024 Inspection and Test Status
QA2037 Statistical Techniques
Work Order Routing

9.2 Internal audit

The quality system at DuraTech supports the activities related to internal quality audits. Procedures are in place for the planning and implementation of quality audits to ensure compliance to the quality system requirements. Audits are scheduled and pre-determined on the basis of status and importance of the process and are carried out by trained auditors independent of the direct process involved. Results of audits are recorded and communicated to the process owners and team leaders. The responsible team members implement corrective actions. All actions taken are recorded and monitored to verify their effectiveness.

Reference:
QA2019QualityAuditing

9.3 Management review

Performance measures and reviews of the quality system are the basis of continuous improvement efforts at DuraTech. Senior Leadership is responsible for reviewing the quality system annually, or as required, to ensure it is suitable and effective in satisfying the requirements of ISO9001. The management review process is described in QA2005 Quality System Management Review Procedure. Meeting minutes are retained to document results.

Reference:

QA2005 Management Review

10.1 General

DuraTech determines and selects opportunities for improvements based on many inputs. Process analysis, customer feedback, employee suggestions, SWOT analysis, corrective actions all could potentially lead to the need for improvement. Improvements address risk and/or improve performance toward the operating plan.

10.2 Nonconformity and corrective action

DuraTech has established and maintains a procedure for corrective and preventive action that focuses on eliminating causes of nonconformity. Any corrective or preventive actions of a magnitude that require a change in documented procedures are implemented and recorded through an engineering change request. The corrective and preventive action system is reviewed for effectiveness by Senior Leadership.

This procedure includes customer, supplier and internal corrective actions. The root cause of the nonconformity is identified and suitable corrective action is implemented. Corrective action follow-up ensures problems are resolved and implementation of the actions is effective.

Reference:
QA2011 Control of Nonconforming Product

10.3 Continual improvement

Preventive action is the basis of our continuous improvement effort. It is a part of the procedure for corrective action and quality planning. Information from the corrective action system and other quality records determines the scope of preventive action.

Continuous improvement is a part of DuraTech culture. Kaizen events, goal setting, rapid improvement initiative are all tools used. The Lean Team and other improvement teams review current needs, analyze data and evaluate outputs to allocate the resources necessary for improvement initiatives.

Reference:
QA2058 Continuous Improvement
QA4284 DuraTech Improvement Continuum