



QUALITY and ENVIRONMENTAL POLICY MANUAL



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MISSION STATEMENT

TriMark's mission statement is as follows:

Through innovation and relentless commitment, we safely and securely open and close the world's doors, while enriching the lives of our stakeholders.

TRIMARK'S QUALITY POLICY

TriMark's valued team strives to continually improve our processes, products, and people to meet or exceed our customer's expectations while maintaining our commitment to the environment and safety.

TRIMARK'S ENVIRONMENTAL POLICY

TriMark is a leading designer and manufacturer to the on and off-road vehicle industries. We provide latching and access solutions for the agricultural, construction, truck, recreational vehicle, power sports, and enclosure markets.

TriMark's manufacturing capabilities include zinc die casting, steel stamping, plastic injection molding. Secondary operations include machining processes ranging from simple rod bending to the use of CNC lathes and machining centers. The facility also provides both zinc and chrome plating with additional support processes such as tumbling, buffing, and assembly.

TriMark is committed to an environmental management program. This involves continuous improvement in environmental performance including the prevention of waste and pollution in support of our strategic business objectives.

TriMark's focus on *Environmental Responsibilities* to our Employees, our Community, and our Customers:

- TriMark is committed to full compliance with applicable local, state, and federal environmental regulations, as well as international laws and codes of practice.
- We will continuously work to reduce our use of energy and materials, and to decrease the amount of waste generated which includes air emissions, wastewater, and solid waste. TriMark will set annual environmental goals to monitor the effectiveness of this policy.
- TriMark is committed to the purchase, use, and disposal of products and materials in a manner that will best utilize natural resources and minimize any negative impact on the environment. Recycling receptacles are setup for the separation, collection, and recycling of corrugated cardboard and paper products.
- In addition, we will work with our suppliers and customers to encourage good environmental practices, reusing and reducing wasteful packaging materials and other products that are used in the course of TriMark's business.
- This policy will be communicated to our employees and is available to our customers and suppliers on our website.

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1.0 Scope

This Quality and **Environmental** Manual provides specifics on the policies, procedures, and processes used by TriMark Corporation to meet requirements of ISO 9001:2015, IATF 16949:2016 Automotive Quality Management System Standards, and **ISO 140001:2015 Environmental Management System**. This Quality and **Environmental** Manual demonstrates TriMark's ability to continually improve and consistently design, manufacture, and source mechanical and electronic access systems and related products for vehicular doors, windows, enclosures, and systems, to meet customer specific requirements/specifications, TriMark's specifications/requirements, and applicable regulatory/statutory requirements. TriMark's manufacturing processes include steel stamping, plastic injection molding, zinc die casting and finishing, machining, rod bending, chrome and zinc plating, and assembly. **All waste generated by these processes are recycled or disposed of according to compliance obligations in an environmentally responsible manner.** Our objective is to enhance customer satisfaction while considering internal/external issues and the impact to relevant interested parties and **the environment**. This scope covers TriMark Corporation located in New Hampton, Iowa with remote locations of the TriMark Tech Center, TriMark Service and Replacement Parts (warehouse L), and TriMark Corporation (warehouse K).

2.0 Permissible Exclusions

None

3.0 Terms/Definitions/Acronyms

The term "Supplier" and "Vendor" are synonymous and refer to the external source used to acquire purchased products, materials, and/or services by the organization.

The term "Organization" refers to TriMark Corporation internal organization.

The term "Customer" used in this manual refers to the External Customer.

The acronym QMS refers to Quality Management System

The acronym EMS refers to Environmental Management System.

The acronym APQP refers to Advanced Product Quality Planning.

The acronym PPAP refers to Production Part Approval Process.

4.0 Context of the Organization

4.1 Understanding the organization and its context

TriMark has determined external and internal issues, (both positive and negative factors), that are relevant to its purpose and strategic direction and that affect its ability to achieve the intended results of its quality and **environmental** management system. The organization monitors and reviews information about these external and internal issues. **The issues include environmental conditions being affected by or capable of affecting the organization.**

External Context:

- **Federal, State, and Local** Governmental regulations and compliance
- Political decisions impacting market segments
- Technological advancements in **processes** and product offerings
- Competitive threats
- Legal ramifications; contractual documents
- Economic concerns
- Market fluctuations and **customer requirements**
- Trade and logistics issues
- **Waste Stream Processors**
- **Local Community and Environment**

Internal Context:

- Vision, Mission, and Value system of Integrity, Respect, Accountability, Innovation, Teamwork
- Guided by written policies and procedures
- Traditional, hierarchical organizational structure with Board oversight; casual culture
- Contractual relationships with some key accounts with focus on satisfying all customers with responsive solutions to issues; serving diverse markets
- Financial liquidity
- Talent availability/competency/safety/**environmental awareness**
- Employee engagement/retention/motivation
- Future growth
- **Environmentally responsible regarding natural resources and processes (e.g. material selections, waste disposal, recycling)**

4.2 Understanding the needs and expectations of interested parties

The organization has determined:

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1. the interested parties that are relevant to the QMS and EMS and
2. the requirements of the above stated interested parties
3. which of the needs and expectations become its compliance obligations.

TriMark monitors and reviews information about these interested parties and their relevant requirements.

Interested Party	Requirements
Customers (OEMs, end users)	As identified in Supplier Requirements Manuals and associated documents
Suppliers (Materials/components/sub-assemblies; outsourced services – paint, heat treat, coatings, welding, etc.; MRO – plating chemistry, machine repair, etc.)	TriMark specifications, drawings, purchase orders, Conditions of Purchase, Supplier Requirements Manual
Employees/shareholders	Increased share value, fair wages, competitive benefit package, safe and environmentally friendly working environment
Financial/Banking/Lending Institutions/Appraisers	TriMark information/financials, covenant compliance, market information, environmental compliance
Community	Provide sustainable jobs and growth, clean environment
Insurance carriers	Low risk, low to no claims

4.3 Determining the scope of the quality and environmental management system

The organization has determined the boundaries and applicability of the QMS/EMS in establishing its scope. In doing so, TriMark considered:

- The external and internal issues
- The requirements of relevant interested parties
- The activities, products, and services of the organization
- The compliance obligations
- Its organizational units, functions, and physical boundaries
- Its authority and ability to exercise control and influence

TriMark has applied all the requirements of ISO 9001, IATF 16949, and ISO 14001 within the determined scope of its quality management system/environmental management system and is documented within this manual which is available and maintained. The scope states the types of products and services and all activities covered and there are no requirements that are not applicable.

4.3.1 Determining the scope of the quality and environmental management systems QMS/EMS – supplemental

Supporting functions, on-site or remote, are included in the scope of the QMS/EMS.

- TriMark Tech Center
- TriMark Service and Replacement Parts warehouse L
- TriMark Corporation warehouse K

4.3.2 Customer-specific requirements

Customer-specific requirements are evaluated and included in the scope of the organization's quality management system.

4.4 Quality and environmental management system and its processes

4.4.1 QMS/EMS and its processes

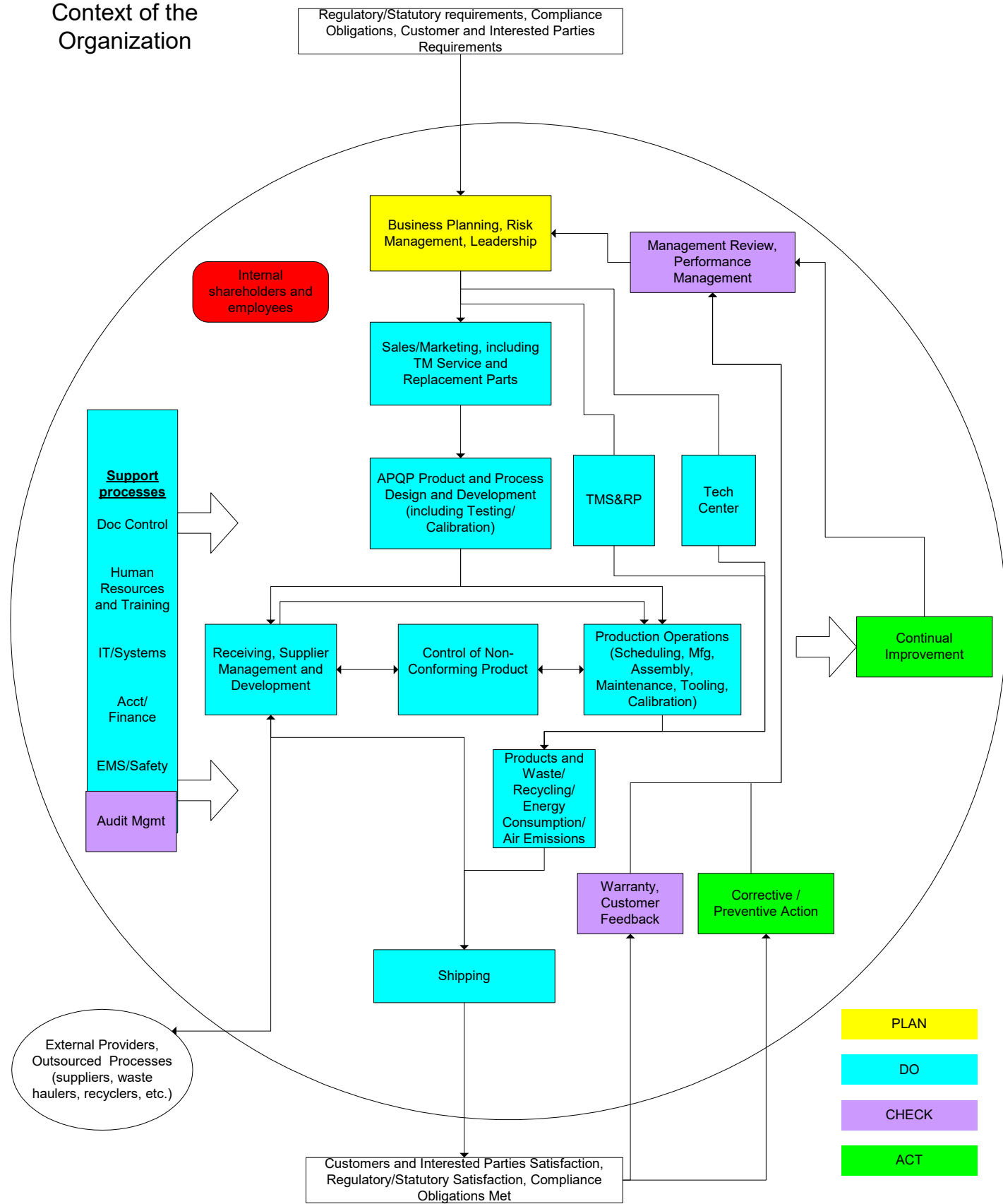
To achieve intended outcomes, including enhancing its environmental performance, the organization has established, implemented, maintains, and continually improves the QMS/EMS, including the processes needed and their interactions, in accordance with the requirements of ISO 9001, IATF 16949, and ISO 14001. TriMark has determined the processes needed for the QMS/EMS and their application throughout the organization and has:

1. determined the input requirements and outputs expected from these processes
2. determined the sequence and interaction of these processes
3. determined and applied the criteria and methods needed to ensure the effective operation and control of these processes
4. determined the resources needed for these processes and ensures their availability
5. assigned the responsibilities and authorities for these processes
6. addressed the risks and opportunities
7. evaluated these processes and implements any changes needed to ensure that these processes achieve their intended results and
8. improves the processes and the QMS/EMS

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The following flowchart is a description of the interaction between the processes of the quality management system.

Context of the Organization



4.4.1.1 Conformance of products and processes

The organization ensures conformance of all products and processes, including service parts and those that are outsourced, to all applicable customer, statutory and regulatory requirements.

Supporting documentation: APQP, PPAP, Certifications, Pilot Runs, Validation Testing

4.4.1.2 Product safety

The Organization has a documented process for the management of product-safety related products and manufacturing processes which includes but is not limited to the following, where applicable:

- Identification of statutory and regulatory product-safety requirements
 - Statutory and regulatory requirements for each product project are identified in the APQP Web
- Customer notification of said requirements above
 - Per the Project Spec contained in the APQP Web, customers are notified of product-safety related requirements. Product warnings and labels and installation instructions post manufacturing are also provided on TriMark's website
- Special approvals for design FMEAs
 - Special approvals for DFMEAs are submitted to the Product Safety Committee per SOP-APQP-DES-102 and Management Review as applicable
- Identification of product safety-related characteristics
 - ESD-004 Control Characteristics establishes the definition of special characteristics used at TriMark. ESD-015 describes testing required of on-highway vehicles
- Identification and controls of safety related characteristics of product and at the point of manufacture
 - Safety-related characteristics at the point of manufacture are identified with symbols as called out on the engineering drawing and listed in the operator's special instructions
- Special approval of control plans and process FMEAs
 - Special approval of control plans and Process FMEAs are required per SOP-APQP-DES-102
- Reaction plans
 - Reaction plans for product-safety items are performed per SOP-APQP-DES-102
- Defined responsibilities, definition of escalation process and flow of information, including top management and customer notification
 - SOP-APQP-DES-102 describes the escalation process and defined responsibilities, including customer notification, for product-safety items
- Training identified by the organization or customer for personnel involved in product-safety related products and associated manufacturing processes
 - Training for personnel involved with product safety related products is conducted per F-APQP-DES-109, DPAR Checklist as well as new product introduction training of operators
- Changes of product or process shall be approved prior to implementation, including evaluation of potential effects on product safety from process and product change
 - The Process Change Control process, SOP-PDMG-100 and F-APQP-PRO-105, Process Change form, conducts a safety analysis for process changes
- Transfer of requirements with regard to product safety throughout the supply chain, including customer-designated sources
 - The TriMark drawing ultimately indicates to the supply chain product-safety related characteristics. This is supported by early involvement of

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suppliers in the product development projects, DVP&R collaboration and supplier PPAPs

- Product traceability by manufactured lot (at a minimum) throughout the supply chain
 - TriMark's ERP system assigns lot control and traceability for all manufactured and purchased lots. In addition, TriMark utilizes first in first out (FIFO) inventory control methods and date codes products for identification and containment purposes per ES-121
- Lessons learned for new production introduction
 - Lessons learned for new product introduction is identified in the APQP Web lessons learned database, FMEAs, Management Review, and Project Post Performance phase 5

Supporting documentation: SOP-APQP-DES-109 – Product Safety

4.4.2 Documented information on the QMS/EMS and its processes

TriMark maintains documented information to support the operation of processes and retains that documented information to instill confidence that the processes are being carried out as planned.

Supporting documentation: QMS Procedures, Work Instructions, Control Plans, 1st Piece and In-process Inspection Records, Receiving Inspection Control Plans and Records, Web Systems, Windchill

5.0 Leadership

5.1 Leadership and Commitment

5.1.1 General

Top management demonstrates leadership and commitment with respect to the QMS/EMS by:

- Taking accountability for the effectiveness of the QMS/EMS
- Ensuring that the quality and environmental policies and quality and environmental objectives are established for the QMS/EMS and are compatible with the context and strategic direction of the organization
- Ensuring the integration of the QMS/EMS requirements into the organization's business processes
- Promoting the use of the process approach and risk-based thinking
- Ensuring that the resources needed for the QMS/EMS are available
- Communicating the importance of effective quality and environmental management and of conforming to the QMS/EMS requirements
- Ensuring that the QMS/EMS achieves its intended results
- Engaging, directing, and supporting persons to contribute to the effectiveness of the QMS/EMS
- Promoting continual improvement
- Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility

Supporting documentation: SOP-MGMT-100– Management Review, Securing Quality Initiative, Corporate and Process Scorecards, Risk Assessments, Strategic Planning, Quality Manual, Procedures, Work Instructions, APQP Web, FMEAs, Employee Suggestions, Organization Charts, Job Descriptions, Internal Audits

5.1.1.1 Corporate responsibility

TriMark has defined and implemented corporate responsibility policies including an anti-bribery policy, an employee code of conduct and an ethics escalation policy ('whistle-blowing policy').

Supporting documentation: Corporate Policy 2.201

5.1.1.2 Process effectiveness and efficiency

Top management reviews the effectiveness and efficiency of the QMS to evaluate and improve the organizations QMS. The results of the process review activities are included as an input to management review.

Supporting documentation: SOP-MGMT-100 – Management Review

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5.1.1.3 Process Owners

Top management has identified process owners who are responsible for managing the organization's processes and related outputs. Process owners understand their roles and are competent to perform those roles.

Process *Sub-process	Process Owner *Sub process owner
Business Planning (Strategic Planning/Operational Planning)	Senior Vice President & CFO
APQP Product Design and Development (new products and electronics)	Vice President of Research & Development
APQP Product Design and Development (mechanical)	APQP Engineering Manager
*Testing	*Test Engineering Manager
Sales/Marketing/Warranty	Director of Global Sales & Business Development
APQP Process Design and Development (Manufacturing)	Manufacturing Manager
APQP Process Design and Development (Assembly)	Assembly Manager
*Tooling Management	*Tool Room Supervisor
Resource Management/Training	Vice President of International Operations & Resources
Quality/Control of Nonconforming Product	Quality Manager
Document Control	Vice President of Global Quality Assurance/Strategic Supplier Development
Calibration	Quality Manager
Supplier Management and Development	Supplier Relationship Manager
Manufacturing Operations	Director of Manufacturing
*Production Planning and Scheduling/Inventory Management/Shipping/Receiving	*Manufacturing Support Manager
*Manufacturing	*Manufacturing Manager
*Assembly	*Assembly Manager
*Maintenance	*Maintenance & Facilities Engineer
Corrective Action	Quality Manager
Accounts Payable/Receivable	Director of Finance & Systems
Internal and External Audit Management	Vice President of Global Quality Assurance/Strategic Supplier Development
Management Review	Senior Vice President & CFO
Automotive Service Parts Sales, Distribution, Warehousing and Shipping	TM S&RP Manager
Continual Improvement/Risk Management	All Process Owners identified
IT Systems	Director of Finance & Systems
EMS	Vice President of International Operations & Resources

5.1.2 Customer Focus

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

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

Supporting documentation: Customer's Supplier Requirements Manuals, APQP Web, Project Spec/Product Spec, FMEAs, Customer Survey Results, Customer Scorecards, Securing Quality Initiative, Risk Assessments

5.2 Quality and Environmental Policy

5.2.1 Establishing the quality and environmental policy

Top management has established, implemented, and maintains a quality policy and environmental policy that:

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- Is appropriate to the purpose and context of the organization and supports its strategic direction, including the nature, scale, and environmental impacts of its activities, products, and services
- Provides a framework for setting quality and environmental objectives
- Includes a commitment to satisfy applicable requirements
- Includes a commitment to the protection of the environment, including prevention of pollution and other specific commitment(s) relevant to the context of the organization
- Includes a commitment to fulfill its compliance obligations
- Includes a commitment to continual improvement of the QMS/EMS to enhance performance

5.2.2 Communicating the quality and environmental policy

TriMark's Quality Policy and Environmental Policy is available and maintained as documented information. The policies are communicated, understood, and applied within the organization and are available to relevant interested parties, as appropriate. The policies are posted in prominent places throughout the facility to maintain high standards within our organization and communicated with new employees upon hire. Management of the facility ensures that the quality policy and environmental policy are understood by all employees. The policies are included in new employee training and training of the QMS/EMS.

5.3 Organization roles, responsibilities, and authorities

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

- Ensuring that the QMS conforms to the requirements of ISO 9001 and IATF 16949 (this responsibility is assigned to the Vice President of Global Quality Assurance/Strategic Supplier Development)
- Ensuring that the EMS conforms to the requirements of ISO 14001 (this responsibility is assigned to the Vice President of International Operations and Resources)
- Ensuring that the processes are delivering their intended outputs (this responsibility is assigned to Process Owners identified in 5.1.1.3 via scorecard management)
- Reporting on the performance of the QMS/EMS and on opportunities for improvement in particular to top management (this responsibility is assigned to Process Owners identified in 5.1.1.3 via scorecard management)
- Ensuring the promotion of customer focus throughout the organization (this responsibility is assigned to Top Management)
- Ensuring that the integrity of the QMS is maintained when changes to the QMS are planned and implemented (Process Owners are responsible to communicate any changes to Top Management for Management Review)

Supporting documentation: Job Descriptions, Organizational Chart, Scorecard Management, Management Review, SOP-PLAN-100 – Process Owner Responsibilities

5.3.1 Organizational roles, responsibilities, and authorities – supplemental

Top Management assigns personnel with the responsibility and authority to ensure that customer requirements are met. These assignments are documented as follows:

1. selection of special characteristics – APQP Project Teams
2. setting quality objectives and related training – Top Management
3. corrective and preventive actions – Quality Manager and Corrective Action Teams
4. product design and development – APQP Project Teams
5. capacity analysis – IRT (Idea Review Team) and Director of Manufacturing
6. logistics information – Manufacturing Support Manager
7. customer scorecards – Director of Global Sales & Business Development and Vice President of Global Quality Assurance/Strategic Supplier Development
8. customer portals – Account Manager/Senior Project Managers/Program Managers

5.3.2 Responsibility and authority for product requirements and corrective actions

Top Management ensures that:

- Personnel responsible for conformity to product requirements have the authority to stop shipment and stop production to correct quality problems. – Leads and Coordinators, Product Management, Manufacturing Engineers

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- *Personnel with authority and responsibility for corrective action are promptly informed of products or processes that do not conform to requirements to ensure that nonconforming product is not shipped to the customer and that all potential nonconforming product is identified and contained. – Product Management, Vice President of Global Quality Assurance/Strategic Supplier Development, Quality Manager*
- *Production operations across all shifts are staffed with personnel in charge of, or delegated responsibility for, ensuring conformity to product requirements. – Leads, Coordinators*

6.0 Planning

6.1

Actions to address risks and opportunities

6.1.1 Through Strategic Planning and Management Review meetings, the organization considers the issues identified in 4.1, requirements referred to in 4.2, the scope of the QMS/EMS, and determines the risks and opportunities that need to be addressed to:

- Give assurance that the QMS/EMS can achieve its intended result(s)
- Enhances desirable effects
- Prevents (or reduces) undesired effects, including the potential for external environmental conditions to affect the organization
- Achieve improvement

Within the scope of the EMS, TriMark has determined potential emergency situations, including those that can have an environmental impact, and has documentation of risks and opportunities.

6.1.2 Planning actions to address risks and opportunities – QMS

Also, through Strategic Planning and Management Review meetings, TriMark plans:

- Actions to address the risks and opportunities
- How to:
 - Integrate and implement the action into the QMS
 - 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.

6.1.2.1 Risk analysis

TriMark includes lessons learned from product recalls, product audits, field returns and repairs, complaints, scrap, rework, etc. into the risk analysis performed, as well as cyber-attack threats to information technology systems. TriMark retains documented information as evidence of the results of risk analysis.

Supporting documentation: Strategic Planning Minutes, Risk Assessment Results and Actions, Management Review Meeting Minutes

6.1.2.2 Preventive action

The organization utilizes APQP, lessons learned, FMEA, PPAP, and 8D problem solving techniques to determine and implement action(s) to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are appropriate to the severity of the potential issues.

TriMark has established an 8D and APQP/FMEA process to lessen the impact of negative effects of risk including:

- *Determining potential nonconformities and their causes*
- *Evaluating the need for action to prevent occurrence of nonconformities*
- *Determining and implementing action needed*
- *Documenting information of action taken*
- *Reviewing the effectiveness of the preventive action taken*
- *Utilizing lessons learned to prevent recurrence in similar processes*

6.1.2.3 Contingency plans

TriMark has comprehensive Contingency plan that:

- *Identifies and evaluates internal and external risks to all manufacturing processes and infrastructure equipment essential to maintain production output and to ensure that customer requirements are met*

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- Defines contingency plans according to risk and impact to the customer
- Prepares contingency plans for continuity of supply in the event of any of the following, but not limited to: key equipment failures; interruption from externally provided products, processes, and services; recurring natural disasters; fire; pandemics, utility interruptions; cyber-attacks on information technology systems; labor shortages or infrastructure disruptions
- Includes, as a supplement to the contingency plans, a notification process to the customer and other interested parties for the extent and duration of any situation impacting customer operations
- Periodically tests the contingency plans for effectiveness, as appropriate
- Conducts contingency plan reviews at least annually using a multidisciplinary team, including top management, and updates as required
- Documents the contingency plans and retains documented information describing any revision(s), including the person(s) who authorized the change(s)
- Includes in contingency plans the development and implementation of appropriate employee training and awareness.

The contingency plans include provisions to validate that the manufactured product continues to meet customer specifications after the re-start of production following an emergency in which production was stopped and if the regular shutdown processes were not followed.

Supporting documentation: Contingency Plan

6.1.1 Environmental aspects – EMS

Within the defined scope of the EMS, TriMark has determined the environmental aspects of its activities, products, and services that it can control and those that it can influence, and the associated environmental impacts, while considering a life cycle perspective. When determining the environmental aspects, TriMark took into account:

- Change, including planned or new developments, and new or modified activities, products, and services
- Abnormal conditions and reasonably foreseeable emergency situations

TriMark has determined the aspects that have or could have a significant environmental impact by using established criteria. TriMark communicates its significant environmental aspects among the various levels and functions of the organization, as appropriate. TriMark maintains documented information of its:

- Environmental aspects and associated environmental impacts
- Criteria used to determine significant environmental aspects
- Significant environmental aspects

6.1.2 Compliance obligations

TriMark:

- has determined and has access to the compliance obligations related to its environmental aspects,
- has determined how these compliance obligations apply to the organization,
- and has taken these compliance obligations into account when establishing, implementing, maintaining, and continually improving its EMS.

TriMark maintains documented information of its compliance obligations.

6.1.3 Planning action

TriMark plans to take actions to address its significant environmental aspects, compliance obligations, and identified risks and opportunities. TriMark plans on how to integrate and implement the actions into its EMS processes or other business processes and evaluates the effectiveness of these actions. While planning the actions, TriMark considers its technological options and its financial, operational, and business requirements.

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6.2 Quality and Environmental objectives and planning to achieve them

6.2.1 Establishing Quality and Environmental Objectives

TriMark establishes quality and environmental objectives at relevant functions, levels, and processes needed for the QMS/EMS, taking into account the significant environmental aspects and associated compliance obligations, and considering risks and opportunities. The quality and environmental objectives are:

- Consistent with the quality policy and environmental policy
- Measurable
- Take into account applicable requirements
- Relevant to conformity of products and services and enhancement of customer satisfaction
- Monitored
- Communicated
- Updated as needed

Supporting documentation: Quality Objectives, Environmental Objectives

TriMark maintains documented information on the quality and environmental objectives within the facility and communicates the objectives, targets, and performance on Communication Boards and email communications.

6.2.2 Planning to achieve Quality and Environmental objectives

When planning how to achieve the quality and environmental objectives through Strategic Planning, Operational Planning, Management Review meetings, Risk Assessments, Scorecard Reviews, Securing Quality initiative, and APQP, TriMark determines:

- What will be done
- What resources will be required
- Who will responsible
- When it will be completed
- How the results will be evaluated

TriMark considers how actions to achieve objectives can be integrated into business processes.

6.2.2.1 Quality objectives and planning to achieve them – supplemental

Top Management ensures that quality objectives to meet customer requirements are defined, established, and maintained for relevant functions, processes, and levels throughout the organization.

Supporting documentation: Strategic/Operational Planning Minutes, Manager Meeting Minutes, Scorecards

TriMark considers interested parties and their requirements when establishing the annual quality and environmental objectives and related performance targets (internal and external).

6.3 Planning of changes

The organization carries out changes to the QMS in a planned manner via Management Review and considers:

- The purpose of the changes and their potential consequences;
- The integrity of the QMS;
- The availability of resources;
- The allocation or reallocation of responsibilities and authorities.

Supporting documentation: Business Interruption/Contingency Plan, Management Review Meeting Minutes

7.0 Support

7.1

Resources

7.1.1 General

TriMark determines and provides the resources needed for the establishment, implementation, maintenance, and continual improvement of the QMS/EMS. The organization considers the capabilities of, and constraints on, existing internal resources and what needs to be obtained from external providers.

Supporting documentation: Management Review, Strategic/Operational Planning

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7.1.2 People

The organization has determined and provides the persons necessary for the effective implementation of its QMS and for the operation and control of its processes.

Supporting documentation: Organizational Chart, Management Review, Strategic/Operational Planning

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.

Supporting documentation: Strategic/Operational Planning, Capacity Planning, Management Review

7.1.3.1 Plant, facility, and equipment planning

TriMark uses a multidisciplinary approach including risk identification and risk mitigation methods for developing and improving plant, facility, and equipment plans. In designing plant layouts, TriMark:

- *optimizes material flow, material handling, and value-added use of floor space including control of nonconforming product; and*
- *facilitates synchronous material flow, as applicable; and*
- *implements cyber protection of equipment and systems supporting manufacturing.*

Methods have been developed and implemented to evaluate manufacturing feasibility for new product or new operations. Manufacturing feasibility assessments include capacity planning. These methods are also used for evaluating proposed changes to existing operations.

TriMark maintains process effectiveness, including periodic re-evaluation relative to risk, to incorporate any changes made during process approval, control plan maintenance, and verification of job set ups. Assessments of manufacturing feasibility and evaluation of capacity planning are inputs to management reviews.

Supporting documentation: Capacity Planning, Manufacturing Feasibility, Facilities Committee, Management Review

7.1.4 Environment for the operation of processes

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

Supporting documentation: Company Policies, State and Federal Agency Regulations

7.1.4.1 Environment for the operation of processes – supplemental

TriMark maintains its premises in a state of order, cleanliness, and repair that is consistent with the product and manufacturing process needs.

Supporting documentation: 5S Philosophy, Securing Safety Initiative

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. TriMark ensures that the resources provided are suitable for the specific type of monitoring and measurement activities being undertaken and are maintained to ensure their continuing fitness for their purpose. TriMark retains appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

Supporting documentation: Calibration Program and Records, ISIR Results

7.1.5.1.1 Measurement systems analysis

Statistical studies are conducted to analyze the variation present in the results of each type of inspection, measurement, and test equipment system identified in the control plan. The analytical methods and acceptance criteria used conforms to those in reference manuals on measurement systems analysis. Records of customer acceptance of alternative methods are retained along with results from alternative measurement systems analysis.

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Supporting documentation: Measurement Systems Analysis Studies

7.1.5.2 Measurement traceability

For traceability, measuring equipment is:

- calibrated and/or verified at specified intervals or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification is retained as documented information
- identified in order to determine its status
- 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 takes appropriate action, as necessary.

Supporting documentation: Calibration Program, Gagepak

7.1.5.2.1 Calibration/verification records

TriMark has a documented process for managing calibration/verification records. Records of the calibration/verification activity for all gauges and measuring and test equipment needed to provide evidence of conformity to internal requirements, legislative and regulatory requirements and customer defined requirements are retained.

The organization ensures that calibration/verification activities and records include the following details:

- *revisions following engineering changes that impact measurement systems*
- *any out-of-specification readings as received for calibration/verification*
- *an assessment of the risk of the intended use of the product caused by the out-of-spec condition*
- *when a piece of inspection measurement and test equipment is found to be out of calibration or defective during its planned verification or calibration or during its use, documented information on the validity of previous measurement results obtained with this piece of inspection measurement and test equipment shall be retained, including the associated standard's last calibration date and the next due date on the calibration report*
- *notification to the customer if suspect product or material has been shipped*
- *statements of conformity to specification after calibration/verification*
- *verification that the software version used for product and process control is as specified*
- *records of the calibration and maintenance activities for all gauging*
- *production-related software verification used for product and process control*

Supporting documentation: SOP-CALB-101 – Calibration of TriMark Gauges, SOP-CALB-100 – Internal Quality Lab Scope, Calibration Program, Gagepak

7.1.5.3 Laboratory requirements

7.1.5.3.1 Internal laboratory

TriMark's internal lab facilities have defined scopes that include the capability to perform the required inspection, test, or calibration services. The lab scope is included in the QMS documentation. The laboratory specifies and implements requirements for:

- *adequacy of the lab technical procedures*
- *competency of the lab personnel*
- *testing of the product*
- *capability to perform these services correctly, traceable to the relevant process standard*

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- customer requirements
- review of the related records

Supporting documentation: SOP-CALB-100 – Internal Quality Lab Scope, SOP-MFG-100 – Internal Plating Lab Scope, SOP-TEST-105 – Test Engineering Facility Scope

7.1.5.3.2 External laboratory

External/commercial/independent laboratory facilities used for inspection, test, or calibration services by the organization have defined lab scopes that includes the capability to perform the required inspection, test, or calibration and either:

- *the lab is accredited to ISO/IEC 17025 or its national equivalent by an accreditation body of the ILAC MRA and includes the relevant inspection, test, or calibration service in the scope of the accreditation (certificate) the certificate of calibration or test report includes the mark of a national accreditation body; or*
- *where a non-accredited laboratory is utilized, the organization is responsible to ensure that there is evidence that the laboratory has been evaluated and meets the requirements of Section 7.1.5.3.1 of IATF 16949.*

Supporting documentation: External Lab Certs

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 is made available to the extent necessary. TriMark considers its current knowledge and determines how to acquire or access any necessary additional knowledge and required updates.

Supporting documentation: Job Descriptions, Training Records, New Employee Orientation Checklists, Succession Planning, Employee Development, Experience, Documented Processes/Work Instructions, Cross Training, Strategic/Resource Planning

7.2 Competence

TriMark determines the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the QMS/EMS *performance and its ability to fulfill its compliance obligations*. The organization ensures that these persons are competent on the basis of appropriate education, training, or experience and takes action to acquire the necessary competence and evaluate the effectiveness of the actions taken. *TriMark determines training needs associated with environmental aspects and its EMS*. TriMark retains appropriate documented information as evidence of competence.

Supporting documentation: Job Descriptions, Training Records, New Hire Checklists, SOP-HRTR-100 – Request for Training Needs, Performance Evaluations

7.2.1 Competence – supplemental

TriMark establishes and maintains a documented process(es) for identifying training needs included awareness and achieving competence of all personnel performing activities effecting conformity to product and process requirements. Personnel performing specific assigned tasks are qualified with particular attention to the satisfaction of customer requirements.

To reduce or eliminate risks to the organization, the training and awareness also includes information about prevention relevant for the organization's working environments and employees' responsibilities, such as recognizing the symptoms of pending equipment failure and/or attempted cyber-attacks.

Supporting documentation: SOP-HRTR-100 – Request for Training Needs, New Employee Training Checklists, Performance Evaluations, Securing Quality Initiative

7.2.2 Competence – on-the-job training

TriMark provides on-the-job training, including customer requirements training, for personnel in any new or modified responsibilities affecting conformity to quality requirements, internal requirements, regulatory or legislative requirements (including contract or agency personnel). The level of detail required for on-the-job training is commensurate with the level of education the personnel possesses and the complexity of the task(s) they are required to perform for their daily work. Persons whose work can affect quality are informed about the consequences of nonconformity to customer requirements.

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Supporting documentation: New Employee Training Checklists, Performance Evaluations, Progress Reports, On-boarding Observations, Securing Quality Initiative

7.2.3 Internal auditor competency

TriMark has a documented process(es) to verify that internal auditors are competent, including knowledge of TriMark requirements and customer specific requirements and maintains a list of qualified internal auditors.

QMS auditors are able to demonstrate the following competencies:

- *Understanding of the automotive process approach for auditing, including risk-based thinking*
- *Understanding of applicable customer-specific requirements*
- *Understanding of applicable ISO 9001 and IATF 16949 requirements related to the scope of the audit*
- *Understanding of applicable core tool requirements related to the scope of the audit*
- *Understanding how to plan, conduct, report, and close out audit findings*

At a minimum, manufacturing process auditors demonstrate technical understanding of the relevant manufacturing process(es) to be audited, including process risk analysis (such as PFMEA) and control plan. At a minimum, product auditors are competent in their understanding of product requirements and use of relevant measuring and test equipment to verify product conformity.

If the organization's personnel provide the training, documented information is retained to demonstrate the trainer's competency with the above requirements.

Maintenance of and improvement in internal auditor competence is demonstrated through executing a minimum number of audits per year maintaining knowledge of relevant requirements based on internal changes and external changes.

Supporting documentation: SOP-AUD-100 – Internal Quality Management Systems Audit Program, Auditor Training Records, Auditor Competency Matrix

7.2.4 Second-party auditor competency

TriMark demonstrates the competence of auditor undertaking second-party audits. Second-party auditors meet customer specific requirements for auditor qualification and demonstrate the minimum core competencies:

- *Automotive process approach to auditing, including risk-based thinking*
- *Applicable customer and organization specific requirements*
- *Applicable ISO 9001 and IATF 16949 requirements related to the scope of the audit*
- *Applicable manufacturing process(es) to be audited, including PFMEA and control plan*
- *Applicable core tool requirements related to the scope of the audit*
- *How to plan, conduct, prepare audit reports and close out audit findings*

Supporting documentation: SOP-AUD-101 – 2nd Party Audits

7.3 Awareness

TriMark ensures that persons doing work under their control are aware of the quality policy, the environmental policy, significant environmental aspects and related actual or potential environmental impacts associated with their work, relevant quality objectives, environmental objectives, their contribution to the effectiveness of the QMS/EMS, including the benefits of improved performance and the implications of not conforming with the QMS/EMS requirements, including not fulfilling the compliance obligations.

Supporting documentation: Securing Quality Initiative, Securing Quality Meetings, Securing Quality Board Reviews, Communication Boards

7.3.1 Awareness – supplemental

TriMark maintains documented information that demonstrates that all employees are aware of their impact on product quality and the importance of their activities in achieving, maintaining, and improving quality, including customer requirements and the risks involved for the customer with nonconforming product.

Supporting documentation: Securing Quality Initiative, Securing Quality Meetings, Securing Quality Board Reviews

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7.3.2 Employee motivation and empowerment

TriMark maintains documented process(es) to motivate employees to achieve quality objectives, to make continual improvements, and to create an environment that promotes innovation. The process shall include the promotion of quality and technological awareness throughout the whole organization.

Supporting documentation: SOP-CI-100 – Employee Suggestion, Profit Sharing Plan, Performance Evaluations, Securing Quality Board Reviews

7.4 Communication

TriMark establishes, implements, and maintains the processes needed for internal and external communications relevant to the QMS/EMS including:

- What will be communicated
- When to communicate
- With whom to communicate
- How to communicate
- Who communicates

When establishing its communication processes, TriMark has taken into account its compliance obligations and ensures that environmental information communicated is consistent with information generated within the EMS and is reliable. TriMark responds to relevant communications on its EMS and retains documented evidence of communications, as appropriate.

7.4.1 Internal Communication

TriMark internally communicates information relevant to the EMS among various levels and functions of the organization, including changes to the EMS, as appropriate. TriMark also ensures communication processes enable persons doing work under its control to contribute to continual improvement.

7.4.2 External communication

TriMark externally communicates information relevant to the EMS, as established by the organization's communication processes and as required by its compliance obligations.

Supporting documentation: Securing Quality Initiative, Securing Quality Meetings, Weekly Securing Quality Board Reviews by Leads/Coord, Scorecards are Posted, External Communication: Customer Newsletters, Website, Supplier Portal, Supplier Ratings

7.5 Documented information

7.5.1 General

The Organization's QMS/EMS includes:

- Documented information required by ISO 9001, IATF 16949, and ISO 14001
- Documented information determined by TriMark as necessary for the effectiveness of the QMS/EMS

7.5.1.1 Quality and Environmental management system documentation

TriMark's QMS and EMS is documented and includes this quality and environmental manual which includes:

- The scope of the QMS and EMS
- Documented processes established for the QMS and EMS
- The organization's processes and their sequence and interactions (inputs and outputs) including type and extent of control of outsourced processes
- A document indicating where within the organizations QMS the customer-specific requirements are addressed

Supporting documentation: Quality and Environmental Policy Manual, SOP-PUR-106– Outsourced Services, APQP Web, Customers Supplier Requirements Manuals

7.5.2 Creating and updating

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

Supporting documentation: Controlled Document Procedures

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7.5.3 Control of documented information

7.5.3.1 Control of documented information I

Documented information required by the QMS/EMS and by ISO 9001/IATF 16949 or ISO 14001 is controlled to ensure it is available and suitable for use, where and when it is needed, and it is adequately protected.

Supporting documentation: Controlled Document Procedures

7.5.3.2 Control of documented information II

TriMark has addressed the distribution, access, retrieval, and use of documented information as well as the storage, preservation, legibility, control of changes and retention and disposition. Documented information of external origin determined by TriMark to be necessary for the planning and operation of the QMS/EMS is identified as appropriate and is controlled. Documented information retained as evidence of conformity is protected from unintended alterations.

Supporting documentation: Controlled Document Procedures

7.5.3.2.1 Record retention

TriMark has defined, documented, and implemented a record retention policy which satisfies statutory, regulatory, organization, and customer requirements for control of records. Production part approvals, tooling records (including maintenance and ownership), product and process design records, purchase orders, contracts and amendments are retained for the length of time that the product is active for production and service requirements, plus one calendar year, unless otherwise specified by the customer or regulatory agency.

Supporting documentation: SOP-DOC-101 – Record Retention Procedure

7.5.3.2.2 Engineering specifications

TriMark has a documented process describing the review, distribution, and implementation of all customer engineering standards/specifications and related revisions based on customer schedules, as required.

TriMark retains a record of the date on which each change is implemented in production. Implementation includes updated documents.

Supporting documentation: SOP-DOC-102 – External Standards & Specifications Reviews

8.0 Operation

8.1 Operation planning and control – QMS

The organizational plans, implements, and controls the processes needed to meet the requirements for the provision of products and services and implements the actions to address risks and opportunities by:

- Determining the requirements for the products and services (Product Line Plan, Project Spec, Statement of Work, Customer Requirements)
- Establishing criteria for the processes and acceptance of products and services (Process Plan, Capacity Planning, Control Plan, Print)
- Determining the resources needed to achieve conformity to the product and service requirements (Resource Planning/Operational Planning, Feasibility Assessment)
- Implementing control of the processes in accordance with the criteria (Control Plan, Training, Work Instructions, Prints)
- Determining, maintaining, and retaining documented information to have confidence that the processes have been carried out as planned and to demonstrate the conformity of products and services to their requirements (1st pc Inspection Sheets, In-Process Inspection Records, Internal Audits)

The output of this planning is suitable for TriMark's operations. TriMark controls planned changes and reviews the consequences of unintended changes, taking action to mitigate any adverse effects. TriMark ensures that outsourced processes are controlled.

Supporting documentation: Operational Planning, APQP Phase Gateways, Control Plans, Process Change Control, Design Change Control, Change of Source Process

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8.1.1 **Operational planning and control – supplemental**

The following are included when planning for product realization:

- Customer product requirements and technical specification
- Logistics requirements
- Manufacturing feasibility
- Project planning
- Acceptance criteria

Supporting documentation: APQP Phase Gateways, Project Spec

8.1.2 **Confidentiality**

TriMark ensures the confidentiality of customer-contracted products and projects under development, including related product information.

Supporting documentation: Non-Disclosure and Confidentiality Agreements

8.1 **Operational planning and control – EMS**

TriMark establishes, implements, controls, and maintains processes needed to meet the EMS requirements and to implement actions identified during planning by establishing operating criteria for the processes and implementing control of the processes in accordance with the operating criteria. TriMark controls planned changes and reviews the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary. TriMark ensures that outsourced processes are controlled or influenced. The type and extent of control or influence to be applied to the processes is defined within the EMS. Consistent with a life cycle perspective, TriMark:

- Establishes controls, as appropriate, to ensure that its environmental requirements are addressed in the design and development process for the products or services, considering each life cycle stage;
- Determines its environmental requirements for the procurement of products and services, as appropriate;
- Communicates its relevant environmental requirement to external providers, including contractors;
- Considers the need to provide information about potential significant environmental impacts associated with the transportation or delivery, use, end-of-life treatment and final disposal of its products and services.

TriMark maintains documented information to the extent necessary to have confidence that the processes have been carried out as planned.

8.2 **Requirements for products and services – QMS**

8.2.1 **Customer communication**

Communication with customers includes:

1. Providing information relating to products and services (TM Website, Tech Pubs, Tech Days, Prints, CAD Models, Quotes, Samples, VICO Reps, Warranty Policy)
2. Handling inquiries, contracts or orders, including changes (emails, phone calls, visits, customer purchase orders, SOW, Memos of Understanding, Supply Agreements, ECNs)
3. Obtaining customer feedback relating to products and services, including customer complaints (RGAs, Customer Surveys, Tech Days, Supplier Performance Reviews, Conference Calls, Customer Scorecards)
4. Handling or controlling customer property (Tooling, Containers)
5. Establishing specific requirements for contingency actions, when relevant (case by case)

8.2.1.1 **Customer communication – supplemental**

Written or verbal communication is in the language agreed with the customer. The organization has the ability to communicate necessary information, including data in customer-specified computer language format.

Supporting documentation: Primarily Communicate in English, Translators used as needed, EDI

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

When determining requirements for products and services to be offered to customers, the organization ensures that the requirements for the products and services are defined (including any applicable statutory and regulatory requirements, applicable government, safety, and environmental regulations related to acquisition, storage, handling, recycling, elimination, or

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disposal of material and those considered necessary by the organization) and that the organization can meet the claims for the products and services it offers.

Supporting documentation: APQP Web, Project Spec, Print, Application, FMVSS 206, 302 Burn, Reach, ROHS, Conflict Minerals, Prop 65, Testing Validation

8.2.2.1 Determining the requirements for products and services – supplemental

Requirements include recycling, environmental impact, and characteristics identified as a result of the organization's knowledge of the product and manufacturing processes.

Supporting documentation: Reach, ROHS, Prop 65, Environmental Policy

8.2.3 Review of the requirements for products and services

8.2.3.1 Review

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

- Requirements specified by the customer, including requirements for delivery and post-delivery activities (APQP, SOW, MOU, Supply Agreements, Purchase Orders)
- Requirements not stated by the customer, but necessary for the specified or intended use, when known (application review)
- Requirements specified by the organization (Testing Parameters/Results, APQP, PPAP)
- Statutory and regulatory requirements applicable to the products and services (FMVSS 206, 302)
- Contract or order requirements differing from those previously expressed (Purchase Order, Quality Requirements, SQRM)

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

8.2.3.1.1 Review of the requirements for products and services – supplemental

TriMark retains documented evidence of customer-authorized waivers for the requirements stated in section 8.2.3.1 for a formal review.

Supporting documentation: Customer Concessions/Approved Deviations

8.2.3.1.2 Customer-designated special characteristics

TriMark conforms to customer requirements for designation, approval documentation, and control of special characteristics.

Supporting documentation: APQP, DFMEA, PFMEA, Control Plan, Print

8.2.3.1.3 Organization manufacturing feasibility

TriMark utilizes a multidisciplinary approach to conduct an analysis to determine if it is feasible that the organization's manufacturing processes are capable of consistently producing product that meets all of the engineering and capacity requirements specified by the customer. The organization conducts this feasibility analysis for any manufacturing or product technology new to the organization and for any changed manufacturing process or product design.

Supporting documentation: APQP, Capacity Planning

8.2.3.2 Review

TriMark retains documented information on the results of the review and any new requirements for products and services.

8.2.4 Changes to requirements for products and services

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

Supporting documentation: Amended Purchase Orders/Sales Orders, JDE Updates (pricing, dates, etc.)

8.2 Emergency preparedness and response – EMS

TriMark establishes, implements, and maintains the processes needed to prepare for and respond to potential emergency situations. TriMark:

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- prepares to respond by planning actions to prevent or mitigate adverse environmental impacts from emergency situations;
- responds to actual emergency situations;
- takes action to prevent or mitigate the consequences of emergency situations, appropriate to the magnitude of the emergency and the potential environmental impact;
- periodically tests the planned response actions, where practicable;
- periodically reviews and revises the processes and planned response actions, in particular after the occurrence of emergency situations or tests;
- provides relevant information and training related to emergency preparedness and response, as appropriate, to relevant interested parties, including persons working under its control.

TriMark maintains documented information to the extent necessary to have confidence that the processes are carried out as planned.

8.3 Design and development of products and services

8.3.1 General

TriMark establishes, implements, and maintains a design and development process that is appropriate to ensure the subsequent provision of products and services.

Supporting documentation: APQP Process with PPAP

8.3.1.1 Design and development of products and services – supplemental

The requirements of section 8.3.1 apply to product and manufacturing process design and development and focuses on error prevention rather than detection. TriMark documents the design and development process.

Supporting documentation: APQP Web with PPAP documents

8.3.2 Design and development planning

In determining the stages and controls for design and development, TriMark considers:

- The nature, duration, and complexity of the design and development activities (Idea Review Team, Customer Application, Timeline/Schedule, Project Type – Express/Modification – Extension/Application/New)
- The required process stages, including applicable design and development reviews (APQP Phases)
- The required design and development verification and validation activities (DVP&R, Testing, Pilot Runs)
- The responsibilities and authorities involved in the design and development process (Cross-Functional Team Members and their responsibilities)
- The internal and external resource needs for the design and development of products and services (Project Workload and needed resources discussions)
- The need to control interfaces between persons involved in the design and development process (Phase Owners, APQP Web)
- The need for involvement of customers and users in the design and development process (Customer Schedules, Requirements and Communications, Prototypes, Mockups, Samples, Testing Validation, Proving Grounds, etc.)
- The requirements for subsequent provision of products and services (Internal Customer Requirements, Warranty, Commercial Agreements)
- The level of control expected for the design and development process by customers and other relevant interested parties (Design Control, Process Control)
- The documented information needed to demonstrate that design and development requirements have been met (APQP Web, Phase Gateways, Project Spec, etc.)

8.3.2.1 Design and development planning – supplemental

TriMark uses a multi-disciplinary approach to ensure that design and development planning includes all affected stakeholders within the organization and as appropriate its supply chain including:

- *Project management (APQP)*
- *Product and manufacturing process design activities (DFM/DFA) including consideration of use of alternative designs and manufacturing processes*
- *Development and review of product design risk analysis (DFMEAs) including actions to reduce potential risks*

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- *Development and review of manufacturing process risk analysis (PFMEAs, Process Flow Diagrams, Control Plans, and Work Instructions)*

8.3.2.2 Product Design Skills

TriMark ensures that personnel with product design responsibility are competent to achieve design requirements and are skilled in applicable product design tools and techniques which are identified by the organization.

Supporting documentation: ProE, CAD, Windchill, Job Descriptions, Training Records, Resumes, Experience, APQP/PPAP, Performance Evaluations

8.3.2.3 Development of products with embedded software

TriMark does not internally develop embedded software. Software development used in TriMark products is outsourced through contract engineering or through electronic suppliers. TriMark validates products with embedded software via regression testing and/or physical testing before being incorporated into TriMark products.

Supporting documentation: Testing Validation

8.3.3 Design and development inputs

TriMark determines the requirements essential for the specific types of products and services to be designed and developed while considering:

- *Functional and performance requirements (Product Spec)*
- *Information derived from previous similar design and development activities (Standardization, Lessons Learned)*
- *Statutory and regulatory requirements (FMVSS 206, 302)*
- *Standards or codes of practice that the organization has committed to implement (Engineering Specs/Standards)*
- *Potential consequences of failure due to the nature of the products and services (FMEA). Inputs are adequate for design and development purposes, complete and unambiguous. Any conflicting design and development inputs are resolved. TriMark retains documented information on design and development inputs.*

Supporting documentation: APQP Web, Windchill

8.3.3.1 Product design input

The organization has identified documents and reviews product design input requirements as a result of contract review. The product design input requirements include but are not limited to:

- *Product specifications including special characteristics (SOW, Product/Project Spec)*
- *Boundary and interface requirements (Space Allowance, Application, etc.)*
- *Identification, traceability, and packaging (Date Codes, Containers)*
- *Consideration of design alternatives (Materials, Concept/Design, etc.)*
- *Assessment of risks with the input requirements and the organization's ability to mitigate/manage the risks, including from the feasibility analysis (FMEA, DVP&R)*
- *Targets for conformity to product requirements including preservation, reliability, durability, serviceability, health, safety, environmental, development timing and cost (APQP, Customer Requirements)*
- *Applicable statutory and regulatory requirements of the customer-identified country of designation, if known*
- *Embedded software requirements*

TriMark has a process to deploy information gained from previous design projects, competitive product analysis (benchmarking), supplier feedback, internal input, field data, and other relevant sources for current and future projects of a similar nature. (Product Quality History)

8.3.3.2 Manufacturing process design input

TriMark identifies, documents, and reviews manufacturing process design input requirements including but not limited to:

- *Product design output data including special characteristics (DFMEA, DVP&R)*

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- *Targets for productivity, process capability, timing, and cost (Customer Requirements, MSA)*
- *Manufacturing technology alternatives (Process Engineer Process knowledge)*
- *Customer requirements*
- *Experience from previous developments (Lessons Learned)*
- *New materials*
- *Product handling and ergonomic requirements*
- *Design for manufacturing and design for assembly*

The manufacturing process design includes the use of error-proofing methods to a degree appropriate to the magnitude of the problem(s) and commensurate with the risks encountered.

8.3.3.3 Special characteristics

TriMark uses a multi-disciplinary approach to establish, document, and implement its process(es) to identify special characteristics, including those determined by the customer and the risk analysis performed by the organization and includes the following:

- *Documentation of special characteristics in the product and/or manufacturing documents (as required), relevant risk analysis (Process FMEA), control plans, and standard work/operator instructions, special characteristics are identified with specific markings and are documented in the manufacturing documents which show the creating of, or the controls required, for these special characteristics (Fit/Form/Function, Significant, Critical Characteristics)*
- *Development of control and monitoring strategies for special characteristics of products and production processes (Control Plan)*
- *Customer-specified approvals, when required*
- *Compliance with customer-specified definitions and symbols or the organization's equivalent symbols or notations, as defined in a symbol conversion table. The symbol conversion table is submitted to the customer, if required*

8.3.4 Design and development controls

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

- The results to be achieved are defined (Project Spec/Product Spec, APQP Phase Gateways, Management KPIs)
- Reviews are conducted to evaluate the ability of the results of design and development to meet requirements (APQP Phase Gateways, Project Meeting Minutes, Drawing Reviews, DPAR, DFMEA, Testing Results)
- Verification activities are conducted to ensure that the design and development outputs meet the input requirements (DVP&R, Verification Testing, Pilot Runs)
- Validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use (Validation Testing)
- Any necessary actions are taken on problems determined during the review, or verification and validation activities (Modifications at alpha revisions, Pre-launch Control Plans)
- Documented information of these activities is retained (Test Reports, APQP Web, Meeting Minutes, etc.)

8.3.4.1 Monitoring

Measurements (such as quality risks, costs, lead times, critical paths, and other measurements) at specified stages during the design and development of products and processes are defined, analyzed, and reported with summary results as an input to management review. When required by the customer, measurements of the product and process development activity is reported to the customer at stages specified, or agreed to, by the customer.

Supporting documentation: APQP Phase Gateways, Management KPIs, Management Project Reviews

8.3.4.2 Design and development validation

Design and development validation are performed in accordance with customer requirements, including any applicable industry and governmental agency-issued

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regulatory standards. The timing of design and development validation is planned in alignment with customer-specified timing, as applicable. Where contractual agreed with the customer, this includes evaluation of the interaction of the organization's product, including embedded software, within the system of the final customer's product.

Supporting documentation: Testing Validation, DVP&R, Project Schedule

8.3.4.3 **Prototype program**

TriMark has a prototype program and control plan, when required by the customer, which whenever possible uses the same suppliers, tooling, and manufacturing processes as will be used in production. Performance-testing activities are monitored for timely completion and conformity to requirements. When services are outsourced, TriMark includes the type and extent of control in the scope of its QMS to ensure that outsourced services conform to requirements.

Supporting documentation: Pilot Builds, Pre-production Runs, Tool Tryout, Supplier Certs

8.3.4.4. **Product approval process**

The organization establishes, implements, and maintains a product and manufacturing approval process conforming to requirements defined by the customer(s). TriMark approves externally provided products and services prior to submission of the part approval to the customer. The organization obtains documented product approval prior to shipment, if required by the customer, and records of such approval are retained.

Supporting documentation: AIAG PPAP, Supplier PPAPs, Customer PPAP Submissions, PPAP Approvals in Windchill and Customer Webs

8.3.5 **Design and development outputs**

TriMark ensures that design and development outputs:

- Meet the input requirements (30 G Analysis, Verification/Validation Testing, etc.)
- Are adequate for the subsequent processes for the provision of products and services (Pilot Run, Pre-Production Request, DFMEA, Warranty)
- Include or reference monitoring and measuring requirements, as appropriate and acceptance criteria (DFMEA, Control Plan)
- Specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision (Print)

TriMark retains documented information on design and development outputs. (APQP Web, Windchill, Testing Results)

8.3.5.1 **Design and development outputs – supplemental**

Product design output is expressed in terms that can be verified and validated against product design input requirements. The product design output includes the following:

- Design risk analysis (FMEA)
- Reliability study results
- Product special characteristics
- Results of product design error-proofing, such as DFSS, DFMA
- Product definition including 3D models, technical data packages, product manufacturing information and geometric dimensioning and tolerancing (GD&T)
- 2D drawings, product manufacturing information and GD&T
- Product design review results (DPAR)
- Service diagnostic guidelines and repair and serviceability instructions
- Service part requirements
- Packaging and labeling requirements for shipping

8.3.5.2 **Manufacturing process design output**

TriMark documents the manufacturing process design output in a manner that enables verification against the manufacturing process design inputs. The organization verifies the outputs against manufacturing process design input requirements. The manufacturing process design output includes the following:

- Specifications and drawings (Prints)
- Special characteristics for product and manufacturing process (Print, PFMEA, CP)

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- Identification of process input variables that impact characteristics (Process Parameters)
- Tooling and equipment for production and control including capability studies of equipment and process(es)
- Manufacturing process flowcharts/layout, including linkage of product, process, and tooling
- Capacity analysis
- Manufacturing process FMEA (PFMEA)
- Maintenance plans and instructions
- Control plan
- Standard work and work instructions
- Process approval acceptance criteria
- Data for quality, reliability, maintainability, and measurability
- Results of error-proofing identification and verification
- Methods of rapid detection, feedback, and correction of product/manufacturing process nonconformities

8.3.6 Design and development changes

TriMark 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:

- Design and development changes
- Results of reviews
- Authorization of the changes
- Actions taken to prevent adverse impacts

Supporting documentation: ECN Process/Workflow, Drawings and Rev Block, Windchill Routings, Validation Testing/Reports, Process Changes, PPCNs

8.3.6.1 Design and development changes – supplemental

TriMark evaluates all design changes after initial product approval, including those proposed by the organization or its suppliers for potential impact on fit, form, function, performance and/or durability. These changes are validated against customer requirements and approved internally prior to production implementation. If required by the customer, TriMark obtains documented approval or a documented waiver from the customer prior to production implementation. For products with embedded software, the organization documents the revision level of software and hardware as part of the change record.

Supporting documentation: PPCN to Customers and rePPAP Submission, Process Change Records, Change of Source Records, Design Change Records/ECNs

8.4 Control of externally provided processes, products, and services

8.4.1 General

The organization ensures that externally provided processes, products, and services conform to requirements. TriMark determines the controls to be applied to externally provided processes, products, and services when:

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

Supporting documentation: Receiving Inspection Control Plans, Prints, Supplier PPAP

TriMark 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 and services in accordance with requirements. TriMark retains documented information of these activities and any necessary actions arising from the evaluations.

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Supporting documentation: Annual Supplier Review, Key Supplier Identification and Criteria, Monthly Supplier Rating Reviews, Supplier Risk Assessments, New Supplier Process

8.4.1.1 General – supplemental

The organization includes all products and services that affect customer requirements such as sub-assembly, sequencing, sorting, rework, and calibration services in the scope of their definition of externally provided products, processes, and services.

8.4.1.2 Supplier selection process

TriMark has a documented supplier selection process which includes:

- *An assessment of the selected supplier's risk to product conformity and uninterrupted supply of the organization's product to their customers*
- *Relevant quality and delivery performance*
- *An evaluation of the supplier's QMS*
- *Multidisciplinary decision making*
- *An assessment of software development capabilities, if applicable*

Supporting documentation: SOP-PUR-104 – New Supplier Process, SOP-PUR-101 – Quotation Requests, Supplier Evaluation

8.4.1.3 Customer-directed sources (“directed-by”)

When specified by the customer, the organization purchases products, materials, or services from customer-directed sources. All requirements of section 8.4 (except 8.4.1.2) are applicable to the organizations' control of customer-directed sources unless specific agreements are otherwise defined by the contract between the organization and the customer.

Supporting documentation: Customer directed sources are treated like other suppliers

8.4.2 Type and extent of control

The organization ensure 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:

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

Supporting documentation: Supplier Requirements Manual, Supplier Ratings, Supplier PPAP, Supplier Quality Requirements, Supplier Risks Assessments, Control

8.4.2.1 Type and extent of control – supplemental

TriMark has a documented process to identify outsourced processes and to select the types and extent of controls used to verify conformity of externally provided products, processes, and services to internal and external customer requirements. This process includes the criteria and actions to escalate or reduce the types and extent of controls and development activities based on supplier performance and assessment of product, material, or service risks. Where characteristics or components “pass through” TriMark's QMS without validation or controls, TriMark ensures that the appropriate controls are in place at the point of manufacture.

Supporting documentation: Subcontract Purchase Orders, Control of Outsourced Services

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8.4.2.2 Statutory and regulatory requirements

The organization documents the process to ensure that purchased products, processes, and services conform to the current applicable statutory and regulatory requirements in the country of receipt, the country of shipment, and the customer-identified country of destination, if provided. If the customer defines special controls for certain products with statutory and regulatory requirements the organization ensures they are implemented and maintained as defined, including at suppliers.

Supporting documentation: Conditions of Purchase, Purchase Order, Supplier Requirements Manual

8.4.2.3 Supplier quality management system development

TriMark requires their suppliers of automotive products and services to develop, implement, and improve a quality management system, with the ultimate objective of eligible organizations becoming certified to IATF 16949 Standard. Using a risk-based model, TriMark defines a minimum acceptable level of QMS development and a target QMS development level for each supplier. Unless otherwise authorized by the customer a QMS certified to ISO 9001 is the initial minimum acceptable level of development. Based on current performance and the potential risk to the customer, the objective is to move suppliers through the QMS development progression presented in the IATF Standard.

Supporting documentation: ISO Certified Suppliers, Supplier Development Efforts, 2nd Part Audits

8.4.2.3.1 Automotive product-related software or automotive products with embedded software

TriMark requires suppliers of automotive product-related software, or automotive products with embedded software to implement and maintain a process for software quality assurance for their products. A software development assessment methodology is utilized to assess the supplier's software development process. Using prioritization based on risk and potential impact to the customer, the organization requires the supplier to retain documented information of a software development capability self-assessment.

8.4.2.4 Supplier monitoring

TriMark has a documented process and criteria to evaluate supplier performance in order to ensure conformity of externally provided products, processes, and services to internal and external customer requirements. The following supplier performance indicators are monitored:

- Delivered product conformity to requirements
- Customer disruptions at the receiving plant, including yard holds and stop ships
- Delivery schedule performance

If provided by the customer, TriMark also includes the following, as appropriate, in their supplier performance monitoring:

- Special status customer notifications related to quality or delivery issues
- Dealer returns, warranty, field actions and recalls

Supporting documentation: Supplier Rating Reviews, Supplier Risk Assessments, Supplier Development efforts, Procurement Scorecard/Metrics

8.4.2.4.1 Second-party audits

TriMark includes a second-party audit process in the supplier management approach. Based on a risk analysis, including product safety/regulatory requirements, performance of the supplier, and QMS certification levels, the organization documents the criteria for determining the need, type, frequency, and scope of second-party audits. TriMark retains records of the second-party audit reports. If the scope of the second-party audit is to assess the supplier's QMS, then the approach is consistent with the automotive process approach.

Supporting documentation: SOP-AUD-101 – 2nd Party Audits of Suppliers

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8.4.2.5 **Supplier development**

TriMark determines the priority, type, extent, and timing of required supplier development actions for its active suppliers by reviewing:

- *Performance issues identified through supplier monitoring*
- *Second-party audit findings*
- *Third-party quality management system certification status*
- *Risk analysis*

The organization implements actions necessary to resolve open performance issues and pursue opportunities for continual improvement.

Supporting documentation: Annual Supplier Review, Supplier Rating Reviews, Supplier Development Efforts, PIPs, SCARs, Supplier Risk Assessments, Supplier QMS Status

8.4.3 **Information for external providers**

The organization ensures the adequacy of requirements prior to the communication to the external provider. TriMark communicates to external providers requirements for:

- The processes, products, and services to be provided
- The approval of products and services, methods, processes, and equipment and the release of products and services
- Competence, including any required qualification of persons
- The external providers interactions with the organization
- Control and monitoring of the external providers' performance to be applied by the organization
- Verification or validation activities that the organization, or its customer intends to perform at the external providers' premises

Supporting documentation: Prints, Purchase Orders, Product Specs, Supplier PPAP, Supplier Requirements Manual, Supplier Rating, 2nd Party Audits, Certifications, Receiving Inspection Control Plans

8.4.3.1 **Information for external providers – supplemental**

TriMark utilizes a flow-down effect to its suppliers for all applicable statutory and regulatory requirements and special product and process characteristics and requires suppliers to cascade all applicable requirements down the supply chain to the point of manufacture.

Supporting documentation: Supplier Requirements Manual, Purchase Order, Conditions of Purchase, Print, Engineering Specifications and Standards

8.5 **Production service provision**

8.5.1 **Control of production and service provision**

The organization implements production and service provision under controlled conditions which include:

- The availability of documented information that defines the characteristics of the products to be produced, the services to be provided or the activities to be performed and the results to be achieved
- The availability and use of suitable monitoring and measuring resources
- The implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptable criteria for products and services have been met
- The use of suitable infrastructure and environment for the operation of processes
- The appointment of competent person including any required qualifications
- 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 and measurement
- The implementation of actions to prevent human error
- The implementation of release, delivery, and post-delivery activities

Supporting documentation: Print, Work Instructions, Calibrated Measurement Devices, Planned Production Deviation, 1st Piece Inspection, In-Process Inspections, Final Inspections, Training Records, New Hire Checklists, Audits, Mistake Proofing, PFMEA, Packaging, and Labeling

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8.5.1.1 Control plan

TriMark develops control plans at the system, subsystem, component, and/or material level for the relevant manufacturing site and all products supplied. The organization has a control plan for pre-launch and production that shows linkage and incorporates information from the design risk analysis, process flow diagram, and manufacturing process risk analysis outputs. If required by the customer, TriMark provides measurement and conformity data collected during execution of either the pre-launch or production control plans which includes:

- Controls used for the manufacturing process control, including verification of job set-ups
- First off/last off part validation, as applicable
- Methods for monitoring of control exercised over special characteristics defined by both the customer and the organization
- The customer-required information, if any
- Specified reaction plan when nonconforming product is detected the process becomes statistically unstable or not statistically capable

TriMark reviews control plans and updates as required for the following:

- The organization determines it has shipped nonconforming product to the customer
- When any change occurs affecting product, manufacturing process, measurement, logistics, supply sources, production volume changes, or risk analysis
- After a customer complaint and implementation of the associated corrective action, when applicable
- At a set frequency based on a risk analysis

If required by the customer the organization obtains customer approval after review or revision of the control plan.

Supporting documentation: 1st Piece Inspection, In-Process Inspections, Calibration, Special Characteristics, Control Plan, Reaction Plan, Customer Communication, Change of Source, Process Change, PPCN

8.5.1.2 Standardized work – operator instructions and visual standards

TriMark ensures that standardized work documents are:

- Communicated to and understood by the employees who are responsible for performing the work
- Legible
- Presented in the language understood by the personnel responsible to follow them
- Accessible for use at the designated work areas

Standardized work documents include rules for operator safety.

Supporting documentation: Special Instructions, Work Instructions, Print, On-the-Job Training, Training Records

8.5.1.3 Verification of job set-ups

TriMark:

- verifies job set-ups when performed, such as initial run of job, material changeover, or job change that requires a new set-up
- maintains documented information for set-up personnel
- uses statistical methods of verification, where applicable
- performs first-off/last-off part validation, as applicable
- retains records of process and product approval following set-up and first-off/last-off part validations

Supporting documentation: 1st Piece Inspections, Set-up Work Instructions, Standards

8.5.1.4 Verification after shutdown

The organization defines and implements the necessary actions to ensure product compliance with requirements after a planned or unplanned production shutdown period.

Supporting documentation: Start Up Procedures

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8.5.1.5 Total productive maintenance

The organization has developed, implemented, and maintains a documented total productive maintenance system which includes:

- Identification of process equipment necessary to product conforming product at the required volume
- Availability of replacement parts for the equipment identified above
- Provision of resource for machine, equipment, and facility maintenance
- Packaging and preservation of equipment, tooling, and gauging
- Applicable customer-specific requirements
- Documented maintenance objectives and preventive maintenance compliance metrics (the performance of which is an input to mgmt.. review)
- Regular review of maintenance plan and objectives and a documented action plan to address corrective actions where objectives are not achieved
- Use of preventive maintenance methods
- Use of predictive maintenance methods, as applicable
- Periodic overhaul

Supporting documentation: Maintenance Risk Assessment, Contingency Plan, Maintenance Scorecard

8.5.1.6 Management of production tooling and manufacturing, test, inspection tooling, and equipment

The organization provides resources for tool and gauge design, fabrication, and verification activities for production and service materials. TriMark establishes and implements a system for production tooling management, whether owned by the organization or the customer including:

- Maintenance and repair facilities and personnel
- Storage and recovery
- Set-up
- Tool-change program for perishable tools
- Tool design modification documentation, including engineering change level of the product
- Tool modification and revision to documentation
- Tool identification, status, ownership, and location

TriMark verifies that customer-owned tools, manufacturing equipment and test/inspection equipment are permanently marked in a visible location so that the ownership and application of each item can be determined. TriMark has implemented a system to monitor these activities if any work is outsourced.

Supporting documentation: Tool Tryout, Tool Locations, Tooling Database, Tooling Work Instructions, Tool Tags, Tool Maintenance

8.5.1.7 Production scheduling

TriMark ensures that production is scheduled in order to meet customer orders/demands and is supported by an information system that permits access to production information at key stages of the process and is order driven.

TriMark includes relevant planning information during production scheduling such as customer orders, supplier on-time deliver performance, capacity, shared loading, lead time, inventory levels, preventive maintenance, and calibration.

Supporting documentation: JDE, Job Status, Capacity Planning

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. TriMark 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.

Supporting documentation: JDE Assigned Lot Number, Date Codes, Job Numbers, Where Used, Tub Tickets

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8.5.2.1 Identification and traceability – supplemental

The organization conducts analysis of internal, customer, and regulatory traceability requirements for all automotive products, including developing and documenting traceability plans, based on the levels of risk or failure severity for employees, customers, and consumers. These plans define appropriate traceability systems, processes, and methods by product, process, and manufacturing location that:

- Enable the organization to identify nonconforming and/or suspect product
- Enable the organization to segregate nonconforming and/or suspect product
- Ensure the ability to meet the customer and/or regulatory response time requirements
- Ensure documented information is retained in the format that enables the organization to meet the response time requirements
- Ensure serialized identification of individual products if specified by the customer or regulatory standards
- Ensure the identification and traceability requirements are extended to externally provide products with safety/regulatory characteristics.

Supporting documentation: JDE, Date Codes, Job Numbers, Where Used, Tub Tickets, Hold Codes, Containment Tickets

8.5.3 Property belonging to customers or external providers

TriMark exercises care with property belonging to customers or external providers while it is under the organization's control or being used by the organization. TriMark identifies, verifies, protects, and safeguards customer or external providers' property provided for use or incorporation into the products and services. When customer or external provider property 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.

Supporting documentation: Customer Emails

8.5.4 Preservation

TriMark preserves the outputs during production and service provision to the extent necessary to ensure conformity to requirements.

Supporting documentation: JDE, Part Identification, Packaging, Handling, Storage, Transport of Product all Adequate

8.5.4.1 Preservation – supplemental

Preservation includes identification, handling, contamination control, packaging, storage, transmission or transportation and protection and applies to materials and components from external and/or internal providers from receipt through processing, including shipment and until delivery to/acceptance by the customer.

TriMark assesses the condition of stock at appropriate planned intervals including the place/type of storage containers and the storage environment in order to detect deterioration. TriMark uses an inventory management system to optimize inventory turns over time and ensures stock rotation (FIFO). TriMark ensures obsolete product is controlled in a manner similar to that of nonconforming product. The organization complies with preservation, packaging, shipping, and labeling requirements as provided by their customers.

Supporting documentation: WI-MH-107– Check Racks for Errors in location, Packaging and Labeling Requirements

8.5.5 Post-delivery activities

TriMark meets requirements for post-delivery activities associated with the products and services while considering:

- Statutory and regulatory requirements
- Potential undesired consequences associated with its products and services
- The nature, use, and intended lifetime of its products and services
- Customer requirements
- Customer feedback

Supporting documentation: REACH, RoHS, Prop 65, Warranty Policy

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8.5.5.1 Feedback of information from service

TriMark ensures that a process for communication of information on service concerns to manufacturing, material handling, logistics, engineering, and design activities is established, implemented, and maintained.

Supporting documentation: Quality Alerts, Customer Scorecards

8.5.5.2 Service agreement with customer

When there is a service agreement with the customer, TriMark:

- Verifies that the relevant service centers comply with applicable requirements
- Verifies the effectiveness of any special purpose tools or measurement equipment
- Ensures that all service personnel are trained in applicable requirements

Supporting documentation: SOP-APQP-DES-112 – Product Retrofit, SOP-APQP-DES-110 – Product Recall Procedure

8.5.6 Control of changes

TriMark reviews and controls changes for production or service provisions to the extent necessary to ensure continuing conformity with requirements and 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.

Examples of changes requiring notification	Clarification	TriMark Interpretation	Applicable Procedure
1. Use of other construction or material than was used in the previously approved part or product	For example, other construction as documented on a deviation (permit) or included as a note on the design record and not covered by an engineering change as described in Table 3.2, #3.	Self-explanatory.	SOP-PDMG-100, Process Change Control
2. Production from new or modified tools (except perishable tools), dies, molds patterns, etc. including additional or replacement tooling	This requirement only applies to tools, which due to their unique form or function, can be expected to influence the integrity of the final product. It is not meant to describe standard tools (new or repaired), such as standard measuring devices, drivers (manual or power), etc.	Refers to hard tools that produce parts and/or assist in the assembly of the finished goods. E.g., die cast molds, plastic molds, stamping tools, assembly fixtures, etc. If there are new tools (replacements) or modifications to old tools (not including normal maintenance) the change management process will need to be implemented. Does not include perishable tools.	
3. Production following upgrade or rearrangement of existing tooling or equipment.	Upgrade means the reconstruction and/or modification of a tool or machine or to increase the capacity, performance, or change its existing function. This	A change in equipment or tooling (as defined in Sect 1) that goes above normal maintenance or repair, that is expected to impact capacity, performance, and/or	SOP-PDMG-100, Process Change Control

	is not meant to be confused with normal maintenance, repair or replacement of parts, etc., for which no change in performance is to be expected and post repair verification methods have been established. Rearrangement is defined as activity that changes the sequence of product/process flow from that documented in the process flow diagram (including the addition of a new process). Minor adjustments of production equipment may be required to meet safety requirements such as, installation of protective covers, elimination of potential ESD risks, etc.	function.	
4. Production from tooling and equipment transferred to a different plant site or from an additional plant site.	Production process tooling and/or equipment transferred between buildings or facilities at one or more sites.	If we move tooling (as defined in Sect 1), equipment, or machinery to a different building or facility. This would include TME, TMX, New Hampton transfer, S&R, outside assembly companies, etc.	SOP-PDMG-100, Process Change Control
5. Change of supplier for parts, non-equivalent materials, or services (e.g. heat-treating, plating)	The organization is responsible for approval of supplier provided material and services.	Changes in supplier for finished goods, non-equivalent material changes (ex. zinc housing to aluminum housing), and/or sub-contract suppliers.	SOP-PDMG-102, Change of Source
6. Product produced after tooling has been inactive for volume production for twelve months or more.	For product that has been produced after tooling has been inactive for twelve months or more: Notification is required when the part has had no change in active purchase order and the existing tooling has been inactive for volume production for twelve months or more. The only exception is	Any hard tool (as defined in Sect 1) that has not been run for 12 months or longer. There is a separate process for this, and the change management process does not need to be implemented.	

	when the part has low volume, e.g. service or specialty vehicles. However, a customer may specify certain PPAP requirements for service parts.		
7. Product and process changes related to components of the production product manufactured internally or manufactured by suppliers.	Any changes, including changes at the suppliers to the organization and their suppliers, that affect customer requirements, e.g., fit, form, function, performance, durability.	Changes in components or manufacturing processes of components at TriMark or purchased part suppliers that affect fit, form, function, performance, and/or durability.	SOP-PDMG-100, Process Change Control
8. Change in test/inspection method – new technique (no effect on acceptance criteria)	For change in test method, the organization should have evidence that the new method has measurement capability equivalent to the old method.	Self-explanatory.	SOP-PDMG-100, Process Change Control
Additionally, for bulk materials: 9. New source of raw material from new or existing supplier. 10. Change in product appearance attributes	These changes would normally be expected to have effect on the performance of the product.	For bulk materials that TriMark purchases, such as, plastic resin, zinc, coil steel, etc this section would apply to source changes at the original manufacturer (not distributor level changes) and/or a change in appearance attributes.	SOP-PDMG-102, Change of Source or SOP-PDMG-101, Process Change Control

8.5.6.1 Control of changes – supplemental

The organization has a documented process to control and react to changes that impact product realization. The effects of any change (caused by the organization, the customer, or supplier) are assessed. TriMark:

- *Defines verification and validation activities to ensure compliance with customer requirements*
- *Validates changes before implementation*
- *Documents the evidence of related risk analysis*
- *Retains records of verification and validation*

When required by the customer, TriMark:

- *Notifies the customer of any planned product realization changes after the most recent product approval*
- *Obtains documented approval, prior to implementation of the change*
- *Completes additional verification or identification requirements such as production trial run and new production validation*

Supporting documentation: PPCN and Re-PPAP, ECN, Change of Source, Process Change, PPD, WI-ASSY-118 Blue Sheet Deviations

8.5.6.1.1 Temporary change of process controls

TriMark identifies documents and maintains a list of the process controls including inspection, measuring, test, and error-proofing devices. The list of

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process controls includes the primary process controls and the approved back-up or alternate methods, if back-up or alternate methods exist.

The organization documents the process that manages the use of alternate control methods. The organization includes in this process, based on risk analysis, severity, and the internal approvals to be obtained prior to production implementation of the alternate control method.

Before shipping product that was inspected or tested using the alternate method, if required, the organization obtains approval from the customer(s). The organization maintains and periodically reviews a list of approved alternate process control methods that are referenced in the control plan.

Standard work instructions are available for each alternate process control method. The organization reviews the operation of alternate process controls on a daily basis, at a minimum to verify implementation of standard work with the goal to return to the standard process as defined by the control plan as soon as possible.

Restart verification is documented for a defined period based on severity and confirmation that all features of the error-proofing device or process are effectively reinstated.

TriMark implements traceability of all products produced while any alternate process control devices or processes are being used.

Supporting documentation: WI-ASSY-118 Blue Sheet Deviations, SOP-APQP-PRO-105 – Temporary Change of Process Controls

8.6 Release of products and services

TriMark implements planned arrangements, at appropriate stages, to verify that products and service requirements have been met. Releasing products and services to the customer does not proceed until planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer. TriMark retains documented information on the release of products and services including evidence of conformity with the acceptance criteria and traceability to the person(s) authorizing the release.

Supporting documentation: 1st Piece Inspections, In-Process Inspections, Pick Reports, Audits

8.6.1 Release of products and services – supplemental

TriMark ensures that the planned arrangements to verify that the product and service requirements have been met encompass the control plan and are documented as specified in the control plan. The organization ensure that the planned arrangements for initial release of products and services encompass product or service approval and ensures that product or service approval is accomplished after changes following initial release.

Supporting documentation: Control Plan, JDE Job Completions

8.6.2 Layout inspection and functional testing

A layout inspection and a functional verification to applicable customer engineering material and performance standards is performed for each product as specified in the control plans and results are available for customer review.

Supporting documentation: ISIRs

8.6.3 Appearance items

When manufacturing parts designated by the customer as 'appearance items', the organization provides:

- Appropriate resources, including lighting for evaluation*
- Masters for color, grain, gloss, metallic brilliance, texture, distinctness of image and haptic technology as appropriate*
- Maintenance and control of appearance masters and evaluation equipment*
- Verification that personnel making appearance evaluations are competent and qualified to do so*

Supporting documentation: MSAs, Visual Appearance Standards

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- 8.6.4 Verification and acceptance of conformity of externally provided products and services**
TriMark has a process to ensure the quality of externally provided processes, products, and services utilizing one or more of the following:
- *Receipt and evaluation of statistical data provided by the supplier*
 - *Receiving inspection and/or testing, such as sampling based on performance*
 - *Second party or third-party assessments or audits of supplier sites when coupled with records of acceptable delivered product conformance to requirements*
 - *Part evaluation by a designated laboratory*
 - *Another method agreed with the customer*
- Supporting documentation: SPC Data, Certs, Receiving Inspection, Supplier PPAP, Supplier Rating Reviews, 2nd Party Audits, Control Plans**
- 8.6.5 Statutory and regulatory conformity**
Prior to release of externally provided products into its production flow, the organization confirms and is able to provide evidence that externally provided processes, products, and services conform to the latest applicable statutory, regulatory, and other requirements in the countries where they are manufactured and in the customer-identified countries of destination.
- Supporting documentation: Conditions of Purchase, Supplier Requirements Manual**
- 8.6.6 Acceptance criteria**
Acceptance criteria is defined by the organization and approved by the customer where appropriate or required with an acceptance level of zero defects.
- Supporting documentation: AQL = 0**
- 8.7 Control of nonconforming outputs**
- 8.7.1 Control of NCP**
TriMark ensures that outputs that do not conform to 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. TriMark deals with nonconforming product in one of more of the following:
- *Correction*
 - *Segregation, containment, return, or suspension of provision of products/services*
 - *Informing the customer*
 - *Obtaining authorization for acceptance under concession*
- Conformity to the requirements is verified when nonconforming outputs are corrected.*
- Supporting documentation: Inventory Hold, MRB Web, Containment, Sort/Rework, Customer Communications, Approved Customer Deviation or Concession**
- 8.7.1.1 Customer authorization for concession**
TriMark obtains a customer concession or deviation permit prior to further processing whenever the product or manufacturing process is different from that which is currently approved. The organization obtains customer authorization prior to further processing for 'use as is' and repair of nonconforming product. If sub-components are reused in the manufacturing process, that sub-component reuse is clearly communicated to the customer in the concession or deviation permit.
- TriMark maintains a record of the expiration date of quantity authorized under concession and also ensures compliance with the original or superseding specifications and requirements when the authorization expires. Material shipped under concession is properly identified on each shipping container (this applies equally to purchased product). TriMark approves any requests from suppliers before submission to the customer.*
- Supporting documentation: Customer PCNs, Customer Deviations**
- 8.7.1.2 Control of nonconforming product – customer-specified process**
The organization complies with applicable customer-specified controls for nonconforming product(s).

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8.7.1.3 Control of suspect product

The organization ensures that product with unidentified or suspect status is classified and controlled as nonconforming product. The organization ensures that all appropriate manufacturing personnel receive training for containment of suspect and nonconforming product.

Supporting documentation: Training Records, Inventory Hold Process

8.7.1.4 Control of reworked product

TriMark utilizes risk analysis methodology to assess risks in the rework process prior to a decision to rework the product. If required by the customer, the organization obtains approval from the customer prior to commencing rework of the product.

The organization has a documented process for rework confirmation in accordance with the control plan or other relevant documented information to verify compliance to original specifications.

Instructions for disassembly or rework, including re-inspection and traceability requirements are accessible to and utilized by the appropriate personnel.

TriMark retains documented information on the disposition of reworked product including quantity, disposition, disposition date, and applicable traceability information.

Supporting documentation: MRB Web, Sort and Rework Job Cards

8.7.1.5 Control of repaired product

TriMark utilizes risk analysis methodology to assess risks in the repair process prior to a decision to repair the product. The organization obtains approval from the customer prior to commencing repair of the product.

The organization has a documented process for repair confirmation in accordance with the control plan or other relevant documented information.

Instructions for disassembly or repair, including re-inspection and traceability requirements are accessible to and utilized by the appropriate personnel.

TriMark obtains a documented customer authorization for concession for the product to be repaired and retains documented information on the disposition of repaired product including quantity, disposition, disposition date, and applicable traceability information.

Supporting documentation: MRB Web, Customer Approved Concession

8.7.1.6 Customer notification

The organization immediately notifies the customer(s) in the event that nonconforming product has been shipped. Initial communication is followed with detailed documentation of the event.

Supporting documentation: Customer Emails

8.7.1.7 Nonconforming product disposition

TriMark has a documented process for disposition of nonconforming product not subject to rework or repair. For product not meeting requirements, the organization verifies that the product to be scrapped is rendered unusable prior to disposal.

TriMark does not divert nonconforming product to service or other use without prior customer approval.

Supporting documentation: MRB Web, Scrap Reports, Lidded Containers for Finished Good Scrap

8.7.2 Control of NCP

The organization retains documented information that:

- Describes the nonconformity
- Describes the actions taken
- Describes any concessions obtained
- Identifies the authority deciding the action in respect of nonconformity

Supporting documentation: MRB Web, Corrective Actions, NCP Documentation

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9.0 Performance Evaluation

9.1 Monitoring, measurement, analysis, and evaluation

9.1.1 General

The organization determines:

- What needs to be monitored and measured
- The methods for monitoring and measurement, analysis, and evaluation needed to ensure valid results
- When the monitoring and measuring is performed
- When the results from monitoring and measurement is analyzed and evaluated
- The criteria against which the organization evaluates its environmental performance and appropriate indicators

The organization monitors, measures, analyses, and evaluates the performance and the effectiveness of the QMS/EMS and retains appropriate documented information as evidence of the monitoring, measurement, analysis, and evaluation records.

TriMark ensures that calibrated or verified monitoring and measurement equipment is used and maintained, as appropriate.

TriMark communicates relevant environmental performance and information both internally and externally, as identified in its communication processes and as required by its compliance obligations.

Supporting documentation: Division Scorecards, Process Scorecards, Quality Objectives, Internal Audit Program & Records

9.1.1.1 Monitoring and measurement of manufacturing processes

TriMark performs process studies on all new manufacturing (including assembly or sequencing) processes to verify process capability and to provide additional input for process control, including those for special characteristics. The organization maintains manufacturing process capability or performance results as specified by the customer's part approval process requirements. The organization verifies that the process flow diagram, PFMEA, and control plan are implemented including adherence to:

- *Measurement techniques*
- *Sampling plans*
- *Acceptance criteria*
- *Records of actual measurement values and/or test results for variable data*
- *Reaction plans and escalation process when acceptance criteria are not met*

Significant process events such as tool change or machine repair are recorded and retained as documented information.

The organization initiates a reaction plan indicated on the control plan and evaluated for impact on compliance to specifications for characteristics that are either not statistically capable or are unstable. The reaction plans include containment of product and 100% inspection as appropriate. A corrective action plan is developed and implemented indicating specific actions, timing, and assigned responsibilities to ensure that the process becomes stable and statically capable. The plans are reviewed with and approved by the customer, when required. TriMark maintains records of effective dates of process changes.

Supporting documentation: Control Plans, Capability Studies, Reaction Plans, Tooling Database, Maintenance Records, Corrective Actions

9.1.1.2 Identification of statistical tools

The organization has determined the appropriate use of statistical tools and verifies that appropriate statistical tools are included as part of the APQP process and included in the design risk analysis, process risk analysis, and the control plan.

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9.1.1.3 **Application of statistical concepts**

Statistical concepts, such as variation, control (stability), process capability and the consequences of over-adjustment are understood and used by employees involved in the collection, analysis, and management of statistical data.

9.1.2 **Customer satisfaction – QMS**

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

Supporting documentation: Customer Scorecards, Customer Surveys, RGAs, Customer Complaints

9.1.2.1 **Customer satisfaction – supplemental**

Customer satisfaction is monitored through continual evaluation of internal and external performance indicators to ensure compliance to the product and process specifications and other customer requirements. Performance indicators are based on objective evidence and include:

- *Delivered part quality performance*
- *Customer disruptions*
- *Field returns, recalls, and warranty*
- *Delivery schedule performance (including incidents of premium freight)*
- *Customer notifications related to quality or delivery issues, including special status*

The organization monitors the performance of manufacturing processes to demonstrate compliance with customer requirements for product quality and process efficiency. The monitoring includes the review of customer performance data including online customer portals and customer scorecards, where provided.

Supporting documentation: Customer Scorecards, Customer Surveys, RGAs, Customer Complaints, Securing Quality, Corporate Scorecard, Process Scorecards, Warranty Claims and Reports

9.1.2 **Evaluation of compliance – EMS**

TriMark establishes, implements, and maintains the processes needed to evaluate fulfillment of its compliance obligations. TriMark:

- **Determines the frequency that compliance will be evaluated;**
- **Evaluates compliance and takes action, if needed;**
- **Maintains knowledge and understanding of its compliance status.**

TriMark retains documented information as evidence of the compliance evaluation results.

9.1.3 **Analysis and evaluation**

The organization analyzes and evaluates appropriate data and information arising from monitoring and measurement and the results of the analysis is used to evaluate:

- Conformity of products and services
- The degree of customer satisfaction
- The performance and effectiveness of the QMS
- If planning has been implemented effectively
- The effectiveness of actions taken to address risks and opportunities
- The performance of external providers
- The need for improvements to the QMS

Supporting documentation: Customer Scorecards, Customer Surveys, RGAs, Customer Complaints, Securing Quality Initiative, Internal Audit Results, Quality Objectives, Management Review Minutes, Risk Assessments, Corrective Actions, Supplier Ratings

9.1.3.1 **Prioritization**

Trends in quality and operational performance are compared with progress toward objectives and lead to action to support prioritization of actions for improving customer satisfaction.

Supporting documentation: Quality Objectives, Management Review

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9.2 Internal audit

9.2.1 Internal audit

The organization conducts internal audits at planned intervals to provide information on whether the QMS/EMS conforms to TriMark's own requirements for its QMS/EMS and the requirements of ISO 9001, IATF 16949, and ISO 14001 and is effectively implemented and maintained.

Supporting documentation: Internal Audit Program, Schedule, Reports and Records, Auditor Competence, Nonconformance Reports

9.2.2 Internal audit

TriMark:

- Plans, establishes, implements, and maintains an audit program, including the frequency, methods, responsibilities, planning requirements, and reporting taking into consideration the importance of the processes concerned, changes affecting the organization and the results of previous audits
- Defines the audit criteria and scope for each audit
- Selects auditors and conducts audits to ensure objectivity and the impartiality of the audit process
- Ensures that the results of the audits are reported to relevant management
- Takes appropriate correction and corrective actions without undue delay
- Retains documents information as evidence of the implementation of the audit program and the audit results

Supporting documentation: Internal Audit Program, Schedule, Reports and Records, Auditor Competence, Nonconformance Reports

9.2.2.1 Internal audit program

The organization has a documented internal audit process which includes the development and implementation of an internal audit program that covers the entire QMS including QMS audits, manufacturing process audits, and product audits. The audit program is prioritized based upon risk, internal and external performance trends, and criticality of the process(es). Where the organization is responsible for software development, the organization includes software development capability assessments in their internal audit program. The frequency of audits is reviewed and, where appropriate, adjusted based on occurrence of process changes, internal and external nonconformities, and/or customer complains. The effectiveness of the audit program is reviewed as a part of management review.

Supporting documentation: SOP-MGMT-100 – Internal Audit Process

9.2.2.2 Quality management system audit

The organization audits all QMS processes over a three-year audit cycle according to an annual program, using the process approach to verify compliance with IATF 16949. Integrated with these audits, the organization samples customer specific QMS requirements for effective implementation.

The complete audit cycle remains three years in length. The QMS audit frequency for individual processes, audited within the three-year audit cycle, is based upon internal and external performance and risk. TriMark maintains justification for the assigned audit frequency of their processes. All processes are sampled throughout the three-year audit cycle and audited to all applicable requirements in the IATF 16949 standard, including ISO 9001 and ISO 14001 base requirements, and any customer-specific requirements.

Supporting documentation: SOP-MGMT-100 – Internal Audit Process

9.2.2.3 Manufacturing process audit

The organization audits all manufacturing processes over each three-year calendar period to determine their effectiveness and efficiency using customer-specific required approaches for process audits. Within each individual audit plan, each manufacturing process is audited on all shifts where it occurs, including appropriate sampling of the shift handover. The manufacturing process audit includes an audit of the effective implementation of the process risk analysis (PFMEA), control plan, and associated documents.

Supporting documentation: SOP-MGMT-100 – Internal Audit Process

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9.2.2.4 Product audit

The organization audits products using customer-specific required approaches at appropriate stages of production and delivery to verify conformity to specified requirements.

Supporting documentation: SOP-MGMT-100 – Internal Audit Process

9.3 Management review

9.3.1 General

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

Supporting documentation: SOP-MGMT-100 – Management Review

9.3.1.1 Management review – supplemental

Management review is conducted at least annually. The frequency of management review(s) is increased based on risk to compliance with customer requirements resulting from internal or external changes impacting QMS and performance-related issues.

Supporting documentation: SOP-MGMT-100 – Management Review

9.3.2 Management review inputs

Management reviews are planned and carried out taking into consideration:

- The status of actions from previous management reviews
- Changes in:
 - external and internal issues that are relevant to the QMS/EMS
 - needs and expectations of interested parties, including compliance obligations
 - its significant environmental aspects
 - risks and opportunities
- Information on the performance and effectiveness of the QMS/EMS including trends in:
 - Customer satisfaction and feedback and communication from relevant interested parties, including complaints
 - The extent to which quality and environmental objectives have been met
 - Process performance and conformity of products and services
 - Nonconformities and corrective actions
 - Monitoring and measurement results
 - Audit results
 - The performance of external providers
 - Fulfillment of compliance obligations
- The adequacy of resources
- The effectiveness of actions taken to address risks and opportunities
- Opportunities for improvement

Supporting documentation: SOP-MGMT-100 – Management Review

9.3.2.1 Management review inputs – supplemental

Input to management review includes:

- Cost of poor quality (cost of internal and external nonconformance)
- Measures of process effectiveness
- Measures of process efficiency for product realization processes, as applicable
- Product conformance
- Assessments of manufacturing feasibility made for changes to existing operations and for new facilities or new product
- Customer satisfaction
- Review of performance against maintenance objectives
- Warranty performance (where applicable)
- Review of customer scorecards (where applicable)
- Identification of potential field failures identified through risk analysis (such as DFMEA)
- Actual field failures and their impact on safety or the environment
- Summary results of measurements at specified stages during the design and development of products and processes, as applicable.

Supporting documentation: SOP-MGMT-100 – Management Review

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9.3.3 Management review outputs

The outputs of the management review include decisions and actions related to:

- Opportunities for continual improvement
- Any need for changes to the QMS/EMS
- Resource needs
- Conclusions on the continuing suitability, adequacy, and effectiveness of the EMS
- Actions, if needed, when environmental objectives have not been achieved
- Opportunities to improve integration of the EMS with other business processes, is needed
- Any implications for the strategic direction of the organization

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

Supporting documentation: Management Review Minutes

9.3.3.1 Management review outputs – supplemental

Top management documents and implements an action plan when customer performance targets are not met.

Supporting documentation: Customer Scorecard Reviews, Management Review Minutes

10.0 Improvement

10.1 General

The organization determines and selects opportunities for improvement and implements any necessary actions to achieve intended outcomes of its EMS, meet customer requirements and enhance customer satisfaction including:

- Improving products and services to meet requirements as well as to address future needs and expectations
- Correcting, preventing, or reducing undesired effects
- Improving the performance and effectiveness of the QMS

Supporting documentation: Employee Suggestions, Product Improvements, Securing Quality, Corrective Actions, Lessons Learned

10.2 Nonconformity and corrective action

10.2.1 When nonconformity occurs, including any arising from complaints, TriMark:

- Reacts to the nonconformity and takes action to control and correct it and deals with the consequences, including mitigating adverse environmental impacts
- Evaluates the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere by:
 - Reviewing and analyzing the nonconformity
 - Determining the cause(s) of the nonconformity
 - Determining if similar nonconformities exist, or could potentially occur
- Implement any action needed
- Review the effectiveness of any corrective action taken
- Update risks and opportunities determined during planning, if necessary
- Make changes to the QMS/EMS if necessary

Corrective actions shall be appropriate to the significance of the effects of the nonconformities encountered, including the environmental impacts.

Supporting documentation: MRBs, Corrective Actions

10.2.2 Documented information

The organization retains documented information as evidence of the nature of the nonconformities and any subsequent actions taken and the results of any corrective action.

Supporting documentation: MRBs, Corrective Actions, Supplier Corrective Actions

10.2.3 Problem solving

The organization has a documented process(es) for problem solving, which prevents recurrence, including:

- Defined approaches for various types and scale of problems (e.g. new product development, current manufacturing issues, field failures, audit findings)

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- Containment, interim actions, and related activities necessary for control of nonconforming outputs
- Root cause analysis, methodology used, analysis and results
- Implementation of systemic corrective actions, including consideration of the impact on similar processes and products
- Verification of the effectiveness of implemented corrective actions
- Reviewing and, where necessary, updating the appropriate documented information (e.g. PFMEA, control plan).

Where the customer has specific prescribed processes, tools, or systems for problem solving, the organization uses those processes, tools, or systems unless otherwise approved by the customer.

Supporting documentation: 8D, DMAIC, Corrective Actions, Root Cause Analysis, SOP-CI-101 – Problem Solving

10.2.4 Error-proofing

The organization has a documented process to determine the use of appropriate error-proofing methodologies. Details of the method used are documented in the process risk analysis (such as PFMEA) and test frequencies are documented in the control plan.

The process includes the testing of error-proofing devices for failure or simulated failure. Records are maintained. Challenge parts, when used, are identified, controlled, verified, and calibrated where feasible. Error-proofing device failures have a reaction plan.

Supporting documentation: WI-APQP-PRO-111 – Error Proofing

10.2.5 Warranty management systems

When the organization is required to provide warranty for their product(s) the organization implements a warranty management process. The organization includes a method for warranty part analysis in the process including no trouble found. When specified by the customer, the organization implements the required warranty management process.

Supporting documentation: RGA Process, Warranty Policy, RGA/Warranty Web

10.2.6 Customer complaints and field failure test analysis

The organization performs analysis on customer complaints and field failures, including any returned parts, and initiates problem solving and corrective action to prevent recurrence.

Where requested by the customer, this includes analysis of the interaction of embedded software of the organization's product within the system of the final customer's product.

The organization communicates the results of testing/analysis to the customer and also within the organization.

Supporting documentation: Field Incident Report (FIR), RGA/Warranty Process, Testing Results

10.3 Continual improvement

The organization continually improves the suitability, adequacy, and effectiveness of the QMS/EMS to enhance performance. TriMark considers the results of analysis and evaluations and the outputs from management review to determine if there are needs or opportunities that are to be addressed as part of continual improvement.

Supporting documentation: Management review

10.3.1 Continual improvement – supplemental

The organization has a documented process for continual improvement and includes the following in this process:

- Identification of the methodology used, objectives, measurement, effectiveness, and documented information
- A manufacturing process improvement action plan with emphasis on the reduction of process variation and waste
- Risk analysis (such as FMEA)

Continual improvement is implemented once manufacturing processes are statistically capable and stable or when product characteristics are predictable and meet customer requirements.

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Revision Record

REVISION	DATE REVISED	CHANGE DESCRIPTION
1.0	02-28-03	Implemented new policy manual to meet ISO 9001:2008 requirements.
2.0	06-13-03	Changes to organizational chart.
3.0	09-26-03	Changes to organizational chart and changes to section 7.5.4.
4.0	01-06-04	Changes to Mission statement on approval page and section 5.3 and changes to organizational chart.
5.0	04-02-04	Added Therin Rentschler and Kendra Knowlton as Black Belts to Org Chart.
6.0	09-10-04	Removed Jeff Dolezal and Ken Chesney from signature page (#4) and from org chart (page 9); made the following additional changes to the org chart: moved Ann Flatjord to Cust Serv Rep; added Steph Wiltse to Shipping/Rec Clerk; added Shailesh Joshi, Warehouse Manager to TMEu section.
7.0	1-22-05	Changed Gloria Carr's name to Justin Elliott for document control manual holder.
8.0	3-23-05	Replaced all occurrences of "Top Management" with "Senior Management of the Facility. Replaced all occurrences of "Good News" with "Multimedia and Other Forms of Communication." In the first sentence took out the word "of" and replaced it with "or." In 7.5.4 added an 's to the word organizations. Replaced all occurrences of "CPI" and replaced it with "CI." Then replaced the Org Chart rev. 20 and replaced it with the Org Chart rev. 21.
9.0	6-9-05	8.5.2 Added Supporting documentation
10.0	1-6-06	7.5.4 changed NMAR System to MRB Database. 8.2.1 changed NMARs to MRB Entries. 8.5.2 changed NMAR to MRB.
11.0	5-10-6	New QMS interaction flowchart, updates to the previous interaction flowchart. Also, updates to the org chart.
12.0	9-5-06	Sections 7.5.1 & 7.5.2 updated
13.0	9-15-06	Updated the Scope and section 6.2.2
14.0	1-2-07	Deleted Mark Bouman's name from the ownership and realigned the org chart in Mark's absence.
15.0	3-24-07	Deleted the distribution list and deleted the text referring to hard copy approvals below the electronic approvals.
16.0	10-16-07	Change to organizational chart.
17.0	11-17-08	Implementation of TS.
18.0	12-3-09	New Org chart and updated registration to ISO 9001: 2008 and also added in reference to WI 167-08 First Piece & In-Process Quality Checks
19.0	10-12-10	Implementation of the Environmental Policy. Removed the TriNews Express from section 6.2.2.4 and added customer PPM reports to section 8.2.1.
20.0	3-16-11	Updated the org chart.
21.0	4-26-12	Updated the org chart, added, changed, and deleted titles from ownership and the overall content. Changed continuously to continually in the quality policy.
22.0	1-6-14	Updated org chart on page 14, numbering fixed, title updated in section 5.5.2, removed V.P. of Manufacturing from approvals, and updated supporting documents in sections 5.6.2.1, 6.2.2.4, 7.4.1, 8.2.1.1, 8.2.2.2.
23.0	11-18-14	Updated titles, Org Chart, Supporting Documentation, and section 7.6.1.
24.0	9-16-15	Update the org. chart
25.0	10-7-16	Update the org. chart
26.0	11-2-16	Updated the Interaction Flow Chart
27.0	9-1-17	Transition to ISO 9001:2015 and IATF 16949

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28.0	9-29-17	Updates to verbiage in section 8.3.2.3
29.0	10-01-18	Updated the Interaction Flow Chart; verbiage in 5.1.1.2, 6.1.2.3, 7.1.5.3.2, 7.2.3, 8.3.3.3, 8.4.2.1, 8.4.2.3, 8.5.6.1.1
30.0 & 31.0	10-22-18	Updated the Interaction Flow Chart; updated 1.0 Scope; 4.3.1 added TriMark Tech Center and TriMark Service & Replacement Parts; 5.1.1.3 added Service and Replacement Parts
32.0	9-10-19	Removed verbiage from Environmental Policy section; added TriMark Service and Replacement Parts and TMC warehouses; added APQP web; updated process owners' chart; added process owners' verbiage in section 5.3.;
33.0	6-2-20	Incorporated EMS requirements throughout the document; updated interaction of process maps for QMS and EMS; updated Process Owner table
34.0	6-2-21	Updated reference documents to new global naming convention
35.0	6-18-21	Updated new TriMark logo
36.0	8-18-21	Updated mission statement; updated interaction of process map into one combined QMS/EMS map; updated all sections per newly issued sanctioned interpretations



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