

Quality Synthetic Rubber, Inc. _____

QUALITY SYSTEM MANUAL



QSR



ISO/TS 16949 BASED QUALITY SYSTEM MANUAL

1.0 QUALITY SYSTEM MANUAL

1.1 PURPOSE:

The purpose for this *Quality System Manual* is to establish the scope of the quality management system, to define the quality management processes and their interactions, and to reference established documented procedures that provide additional structure to the system. This manual, the defined processes and the documented procedures form the basis for an effective *Quality Management System*. The goal of this system is to enhance customer satisfaction by emphasizing continual improvement and the prevention of nonconformities.

1.2 SCOPE:

The *Quality Management System* consists of 11 *processes* with interactions that satisfy the requirements of our customers and of the TS 16949 technical specification (excluding permitted exclusions). Within the description of these 11 *processes* are referenced *procedures* that guide the *processes*. All TS 16949 required *procedures* are found within these *processes*. Other *procedures* that QSR deems necessary for the performance of the *processes* are included.

All permitted exclusions are included in section 7.3 of TS 16949.

Exclusion:

All references to "Product Design and Development" in ISO/TS 16949 Section 7.3 (mainly sections 7.3.2.1 *Product design input* and 7.3.3.1 *Product design outputs*).

Justification:

QSR is not product design responsible. Product design is controlled and approved by the customer.

1.3 DOCUMENT RESPONSIBILITY:

The Quality Systems Engineer maintains the *Quality System Manual*. The process for updating the *Quality System Manual* and methods for determining the revision history are detailed in procedure QA-05-001-P, *Control of QSR Policy Manuals*.



1.4 DISTRIBUTION:

QSR electronically accesses the *Quality System Manual*. Printed copies for Sales and Auditor distribution are marked “Uncontrolled”. The methods for control and distribution are explained in procedure QA-05-001-P, *Control of QSR Policy Manuals*.

1.5 APPROVAL:

QSR records the revision level, issue date and authorized functions in the *Quality System Manual*. The President / Ceo and Quality Manager approve policy changes to the *Quality System Manual*. The Registrar is informed in writing of significant changes to the Quality System.



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3.0 INTRODUCTION

QSR was established in 1966 on the premise that a need existed within the industrial and automotive markets for a company capable of providing custom molded Elastomeric components at a consistent and high quality level. Due to careful planning, a commitment to quality, using dedicated quality-minded employees and state-of-the-art equipment, QSR has enjoyed steady growth.

Manufacturing excellence and continual improvement is the top operating priorities at QSR. The Quality System is designed to ensure that quality is built into the product by utilizing advanced product planning, manufacturing stability and control, and statistical techniques.

QSR will maintain and continually improve the Quality System to ensure that customer satisfaction is achieved.

3.1 QUALITY POLICY:

Quality Synthetic Rubber is committed to providing “World Class” precision molded Elastomeric components.

This commitment is a company wide dedication to continuous improvement and customer satisfaction.

3.2 QUALITY OBJECTIVES:

QSR is dedicated to continual quality improvement and exceeding customer requirements. QSR achieves this commitment by tracking and improving the performance of our quality objectives:

- On Time Delivery
- Total Part Scrap
- Customer Returns
- Average Molding Dollars Per Press Hour
- Shipping Dollars Per Employee

QSR’s Goal - to be recognized by our customers as number One in the field.

*To reach that goal **WE MUST CONTINUALLY IMPROVE EVERYTHING WE DO.***

QSR’s policy is understood, implemented and maintained at all levels of the organization and is relevant to QSR’s quality objectives.



3.3 RESPONSIBILITY, AUTHORITY AND COMMUNICATION

Top management ensures that the organization defines and communicates descriptions for personnel who manage, perform and verify work affecting quality in a job description format. The interrelation of personnel affecting quality is represented on the QSR Organization Chart. Reference AD-01-005-F.

3.3.1 *Responsibility for quality*

Responsibility for Quality rests with every individual employee at Quality Synthetic Rubber. Each person is responsible for the quality of their work. Personnel with the responsibility and authority for corrective actions are promptly informed of products or processes that do not conform to requirements and have the authority to stop production to correct quality problems. All shifts are staffed with personnel responsible for quality with the responsibility of ensuring product quality.

3.3.2 *Management representative*

QSR's Top Management has assigned the authority and responsibility for ensuring that QSR's Quality System is in accordance with the **ISO/TS 16949 Technical Specification** to the Quality Systems Engineer.

The Quality Systems Engineer has the responsibility to:

- a) ensure that the documentation, implementation and maintenance of the Quality System and its processes are in accordance to **ISO/TS 16949 Technical Specification**,
- b) to report on the performance of the Quality System to QSR Top Management as a basis for improving the Quality System, and
- c) to ensure the awareness of customer requirements throughout the organization.

3.3.3 *Customer representative*

QSR's Top Management has assigned the authority and responsibility for ensuring that customer requirements are addressed to the:

- * **Quality Manager** (represents the needs of the customers during selection of special characteristics, setting quality objectives (with related training) and corrective/preventative actions)
- * **Sales/ Engineering Director** (represents the needs of the customers concerning design and development specifications)
- * **Director of Technology** (represents the needs of the customers concerning design and development of raw material specifications and testing)

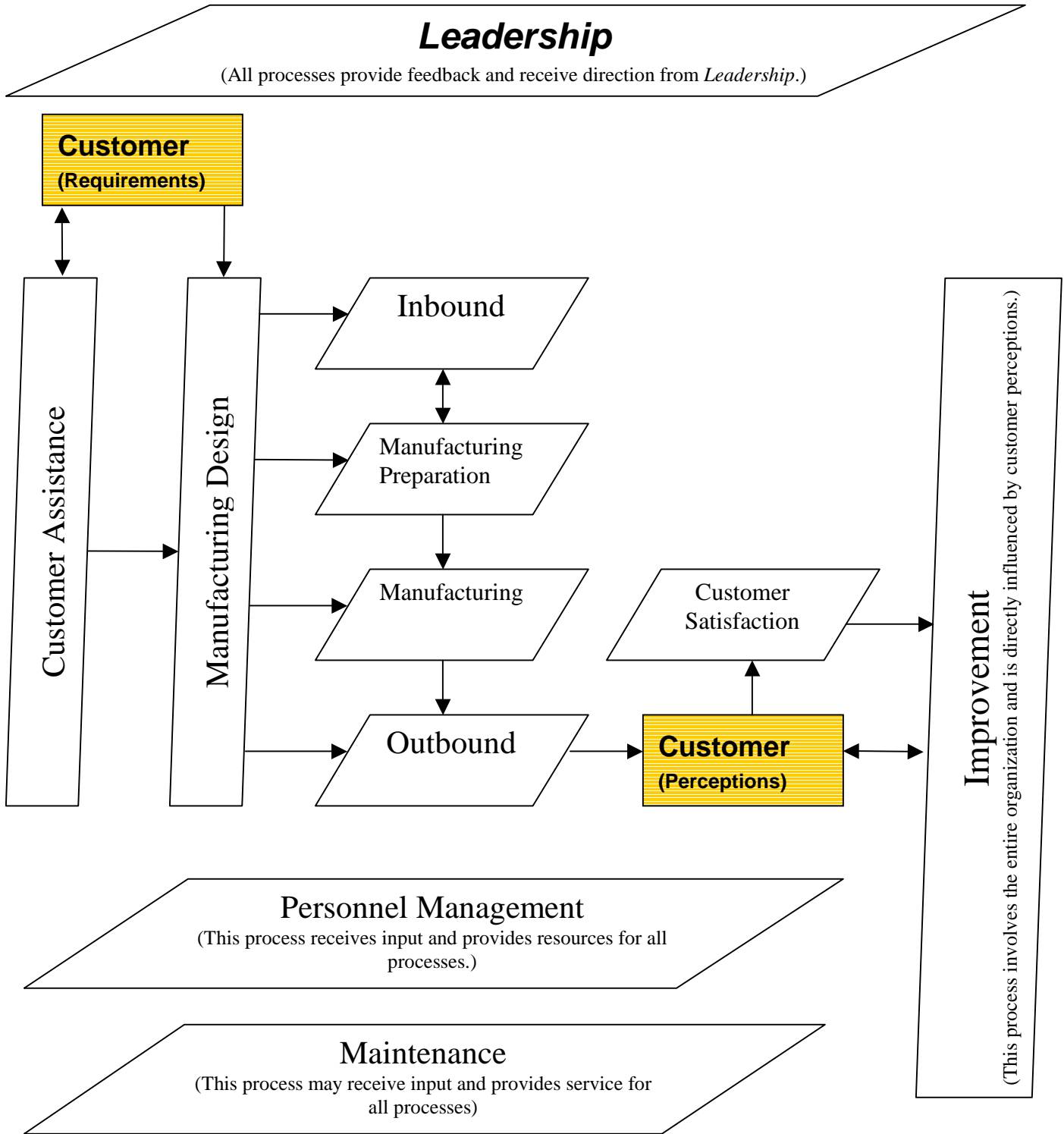
3.3.4 *Internal communication*

QSR's Top Management has ensured that the appropriate communication processes are established by authorizing the following committees:

- * **SAP Committee** (is a multi-disciplinary team with the responsibility for the quality planning process and communicating the output from this process to the appropriate job functions)
- * **Steering Committee** (has the responsibility to communicating the effectiveness of the quality management system)



3.4 HIGH-LEVEL PROCESS INTERACTIONS





3.5 PROCESS SPECIFICS

3.5.1 Leadership Process

Leadership (Q1)	
Purpose	Developing: Q. Policy, Q. Objectives Developing: Business Plan Communication of key measures Customer Focus Analyzing Data Making rational decisions Employee Recognition
Owner	President / Ceo
Required Personnel	Directors and Managers
Process Inputs	Customer Communication Management Reports
Procedures/ Methods	Management Review, AD-01-004-P Steering Committee, QA-02-004-P Business Plan, AD-01-001-P Organizational Communication Management Meetings Employee Recognition Business Trips
Equipment/Materials	Telephone Computer Network Programs
Process Outputs	Satisfied customers Business Plan Required Resources defined Improved QMS and processes
Measurement/ Assessment	Key Business Performance Indicators QMS effectiveness assessment



3.5.2 Customer Assistance Process

Customer Assistance (Q2)	
Purpose	Researching market needs and desires Locating potential customers Developing Market Strategy Selling Analyze & track customer perceptions Communicating perceptions to organization Providing customer assistance
Owner	Director of Sales
Required Personnel	President / Ceo Sales/Engineering Director Sales Reps
Process Inputs	Customer needs and desires Customer feedback
Procedures/ Methods	Customer Visits Sales Calls Feasibility Review, SA-02-001-P Inquiry Quotation, SA-03-001-P Customer Purchase Order Review, SA-03-002-P
Equipment/Materials	Telephone Computer Network Programs
Process Outputs	New customers New Orders Profitable company
Measurement/ Assessment	Sales reports Sales Rep reports Quote activity summary Feasibility Review summary



3.5.3 Manufacturing Design Process

Manufacturing Design (Q3)	
Purpose	Understand Customer Requirements Convert requirements to design inputs Design activity planning and coordinate with process leaders Develop process output to meet input Monitor design progress - Verify & Validate Communicate & control design information & documents to other processes
Owner	Sales/Engineering Director (engineering) Director of Technology (material) Quality Manager (quality)
Required Personnel	SAP committee Materials lab personnel Dimensional lab personnel Production personnel Tool Vendors
Process Inputs	Customer requirements (i.e. special characteristics) Customer drawings Customer expectations Customer production forecasts Lessons learned from prior experience Cost requirements
Procedures/ Methods	Advance Quality Planning, QA-02-001-P Simultaneous Advanced Planning, QA-02-002-P Production Part Approval Process, QA-02-003-P Prototype, EG-04-001-P Tooling Purchase Order, EG-06-001-P Prelaunch, EG-02-001-P Material Development, ML-02-001-P Customer Supplied Material, MG-07-001-P Control of Process, Inspection & Test Instructions, QA-05-007-P SAP Meetings
Equipment/Materials	Telephone Computer / Network programs Manufacturing equipment/tools Tool vendors computer programs Material & Dimensional test equipment
Process Outputs	Control plan, Router, Work instructions, Product acceptance criteria FMEA, Error-proofing, First-time quality Data for quality, reliability, maintainability & measurability Manufacturing Requirements / Material Requirements Drawings/Special characteristic requirements

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Manufacturing Design (Q3)	(continued from previous page)
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Measurement/ Assessment	<ul style="list-style-type: none"> Process Capability First-time quality PPAPs On-time Pressure Checks
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3.5.4 Inbound Process

Inbound (Q4)	
Purpose	Supplier communication Evaluate & Select Suppliers Purchasing supplies & equipment Receiving inspection Receiving product handling Optimizing Inventory
Owner	Buyer
Required Personnel	Receiving clerk Materials lab personnel Dimensional lab personnel Milling Supervisor Production Manager
Process Inputs	Drawings/Special requirements Parts Due Listing Customer specified suppliers Supplier communication Inventory Reports Regular Material Meetings
Procedures/ Methods	Purchasing Control, PR-06-001-P Vendor Control, PR-06-002-P Premium Freight, PR-06-004-P QSR Requisition, PR-06--003-P Receiving Inspection, QA-10-001-P Identification & Traceability, MG-08-001-P
Equipment/Materials	QSR Network Programs Computers/Scanners Telephone Material & Dimensional test equipment
Process Outputs	Approved Vendor List Supplier Development Good raw material Material delivery on-time Reduced Inventory Vendor Rating Analysis
Measurement/ Assessment	Supplier Evaluations Downtime due to material shortage Vendor Rating Analysis Premium Freight

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3.5.5 Manufacturing Preparation Process

Manufacturing Preparation (Q5)	
Purpose	Communication resource needs to inbound process Scheduling Work Arranging Resources Verifying raw material conformity
Owner	Director of Manufacturing Director of Technology
Required Personnel	Production Manager Raw Material personnel Material Lab personnel Dimensional Lab personnel
Process Inputs	Parts Due Listing Orders/Pull Signals Daily Production Reports Work Procedures & Instructions
Procedures/ Methods	Production Scheduling, AD-15-003-P Customer Purchase Order Review, SA-03-002-P Mold Setup, MG-09-003-P Receiving, SR-06-001-P In-Process Material, ML-10-002-P Shelf Life, ML-09-001-P
Equipment/Materials	Computers Customer Communication (EDI, Fax, Email) Network Programs Weekly Material Meetings
Process Outputs	24 hour manufacturing schedule Raw material ready for manufacturing Tooling ready for manufacturing
Measurement/ Assessment	On-time Delivery Premium Freight Customer Satisfaction Reports Rejected Material scrap dollars Benchmark of materials



3.5.6 Manufacturing Process

Manufacturing (Q6)	
Purpose	Manufacture through transformation activities Verify product conformity Providing feedback within the process Final product release
Owner	Director of Manufacturing Production Manager Quality Manager
Required Personnel	Manufacturing Supervisors Manufacturing Personnel Quality Personnel Material Lab Personnel
Process Inputs	Prepared Molds, Presses, Materials 24 Hour Manufacturing Schedule Work Procedures & Instructions Inspection Instructions
Procedures/ Methods	Identification & Traceability, MG-08-001-P Molding Process, MG-09-005-P Linecheck Inspection, QA-10-003-P Final Inspection/Material Handling, QA-10-004-P Finishing Process (Instructions in QSD) Part Audit, ML-10-003-P Statistical Process Control, QA-20-001-P
Equipment/Materials	Presses and Molds Inspection & Test equipment Computers, Scanners, Printers Network Programs Routers Finishing Equipment
Process Outputs	Good Product, Ready for Outbound process
Measurement/ Assessment	Molding/Total Scrap Failures by Classifications Customer Returns Shipping Dollars Manufacturing Dollars



3.5.7 Outbound Process

Outbound (Q7)	
Purpose	Packaging and labeling Handling of final product Scheduling transportation Storing the product (ensure preservation) Order picking Truck loading Coordinating delivery with customers
Owner	Director of Manufacturing
Required Personnel	Shipping Manager Customer Service Personnel Final Leadperson Shipping Clerks Material Handlers
Process Inputs	Parts meeting all requirements Updated Open Orders Report Order Entry Routing Instructions (Customer Specified) Purchase Order Customer Communication
Procedures/ Methods	Shipping Procedure, SR-15-001-P Control of Shipping Instructions, QA-05-009-P Final Inspection/Material Handling, QA-10-004-P
Equipment/Materials	Scales Tow Motor Computer, Scanners, Printers Network Programs Skids & Stretch wrap Labels
Process Outputs	Organized Inventory Packing List ASNs Shipping Labels Bill of Lading
Measurement/ Assessment	Customer Returns due to Shipping Issues On-time Delivery Delivery PR&Rs

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3.5.8 Customer Satisfaction Process

Customer Satisfaction (Q8)	
Purpose	Analyze & track customer perceptions Communicating perceptions to organization Providing customer assistance
Owner	Quality Manager Sales Director
Required Personnel	President / Ceo Sales/Engineering Director Quality Systems Engineer
Process Inputs	Customer feedback
Procedures/ Methods	Customer Visits / Seminars Customer Satisfaction, AD-01-002-P Nonconformance Control, QA-13-001-P Control of Nonconforming Testing, ML-13-001-P
Equipment/Materials	Telephone Computer/ Printer Network Programs
Process Outputs	Happy customers Profitable company
Measurement/ Assessment	Customer satisfaction report Customer Returns PPAP Approvals



3.5.9 Personnel Management Process

Personnel Management (Q9)	
Purpose	Determining competency needs with Leaders Recruiting appropriate personnel Assigning personnel to processes Administer programs to build competence & safety Developing policies that result in employee retention Facilitating organizational communications Mediating Conflict Ensuring legal compliance
Owner	Human Resource Manager
Required Personnel	Director of Manufacturing President / Ceo Manufacturing Supervisors
Process Inputs	Legal Requirements Manufacturing Needs
Procedures/ Methods	Organizational Communication Meetings Training System, ST-18-001-P Management Review, AD-01-004-P Internal Audit, QA-17-001-P
Equipment/Materials	Computer/Printer Network Programs Organizational Communication Postings
Process Outputs	Competent Personnel Policy Governing Personnel Programs to build competency
Measurement/ Assessment	Internal Audits Management Review Employee Turnover



3.5.10 Maintenance Process

Maintenance (Q10)	
Purpose	Determine & implement preventive maintenance Schedule work in most efficient manner possible Reacting to breakdown scenarios Performing predictive maintenance Optimizing infrastructure cost, timing, & effectiveness
Owner	Maintenance Manager (Infrastructure/Equipment) Advanced Technical Engineer (Tooling - In House) Senior Tooling Engineer (Tooling - In House & Outside Tool Repairs) Quality Manager (Calibration) MIS Manager (Network Systems)
Required Personnel	Sales/Engineering Director Maintenance Personnel Manufacturing Supervisors Tool Maintenance Personnel Quality Technician System Administrator Building Maintenance Personnel
Process Inputs	Maintenance Request/ Preventive Maintenance Schedule/ Predictive Maintenance Emergency Calls Tool Maintenance Requisitions/ Required Cleaning list Calibration Schedules System Administration Schedules
Procedures/ Methods	Preventative Maintenance, MT-09-003-P QSR Requisition, PR-06-003-P Maintenance Requisition, MT-09-007-P Maintenance Key Parts Inventory, MT-09-005-P Tool Maintenance Procedure, MG-09-002-P Calibration Control, DL-11-001-P Building Maintenance Program, MT-09-009-P Continuous Improvement Project, AD-02-001-P Computer Network Security & Maintenance, MI-05-001-P Waste Recycling, ST-09-004-P
Equipment/Materials	Machine Maintenance Tools/Equipment Mold Repair and Maintenance Equipment Measuring & Test Equipment Outside Service Suppliers Computer w/ Network programs System Administration Tools Building Maintenance Equipment

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Maintenance (Q10) (continued from previous page)	
Process Outputs	Production-ready machines Production-ready molds Production-ready Measuring & Test Equipment Reliable and User-friendly Network Systems Productive work environment
Measurement/ Assessment	Number of SPINs completed Production Downtime Due to Equipment Failures PM Activity Summary Production Downtime Due to Mold Maintenance Network Downtime Due System Failure Number of Out-of-Calibration items



3.5.11 Improvement Process

Improvement (Q11)	
Purpose	Guiding the development of procedures Managing Internal Audits Administering corrective & preventative action Report to leadership results of improvement efforts Facilitating problem-solving methods & tools Troubleshooting with customer Assisting in improving suppliers Guiding the use of statistical techniques
Owner	Quality Manager Director of Technology Maintenance Manager
Required Personnel	President / Ceo All directors and managers All personnel
Process Inputs	Management Review actions Internal Audit results Customer Input Personnel Input
Procedures/ Methods	Nonconformance Control, QA-13-001-P Corrective / Preventative Action, QA-14-001-P Technical Complaints, ML-14-001-P Internal Audit, QA-17-001-P Document control, QA-05-006-P Record Retention, QA-16-001-P Continuous Improvement Project, AD-02-001-P Statistical Process Control, QA-20-001-P Laboratory Statistical Process Control, ML-20-001-P Quality Meetings Customer Drawing Control, MG-05-002-P
Equipment/Materials	Computer w/ Network Programs Communication Meetings Customer Communication Continual Improvement Program Customer Specific Programs (Covisint)
Process Outputs	Improved Systems Improved Processes Improved Customer Satisfaction
Measurement/ Assessment	Management Review Quality Objectives Customer Complaint Status

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3.6 PROCEDURE CROSS- REFERENCE

Procedure Name	Procedure #	TS 16949 Section
Document control,	QA-05-006-P	4.2.3
Record Retention,	QA-16-001-P	4.2.4
Business Plan,	AD-01-001-P	5.4.1.1
Steering Committee,	QA-02-004-P	5.4.2
Management Review,	AD-01-004-P	5.6.1
Training System,	ST-18-001-P	6.2
Computer Network Security & Maintenance,	MI-05-001-P	6.3
Building Maintenance Program,	MT-09-009-P	6.4.2
Advance Quality Planning,	QA-02-001-P	7.1
Simultaneous Advanced Planning,	QA-02-002-P	7.1
Simultaneous Advanced Planning,	QA-02-002-P	7.2
Waste Recycling,	ST-09-004-P	7.2.1
Customer Purchase Order Review,	SA-03-002-P	7.2.2
Feasibility Review,	SA-02-001-P	7.2.2
Inquiry Quotation,	SA-03-001-P	7.2.2
Prelaunch,	EG-02-001-P	7.3
Simultaneous Advanced Planning,	QA-02-002-P	7.3
Material Development,	ML-02-001-P	7.3.1
Prototype,	EG-04-001-P	7.3.6.2
Production Part Approval Process,	QA-02-003-P	7.3.6.3
QSR Requisition,	PR-06--003-P	7.4.2
Purchasing Control,	PR-06-001-P	7.4.3
Receiving Inspection,	QA-10-001-P	7.4.3
Receiving,	SR-06-001-P	7.4.3
Tooling Purchase Order,	EG-06-001-P	7.4.3
Premium Freight,	PR-06-004-P	7.4.3.2
Vendor Control,	PR-06-002-P	7.4.3.2
Molding Process,	MG-09-005-P	7.5.1
Mold Setup,	MG-09-003-P	7.5.1.3
Maintenance Key Parts Inventory,	MT-09-005-P	7.5.1.4
Maintenance Requisition,	MT-09-007-P	7.5.1.4
Preventative Maintenance,	MT-09-003-P	7.5.1.4
Tool Maintenance Procedure,	MG-09-002-P	7.5.1.5
Production Scheduling,	AD-15-003-P	7.5.1.6
Control of Process, Inspection & Test Instructions,	QA-05-007-P	7.5.2
Linecheck Inspection,	QA-10-003-P	7.5.2
Final Inspection/Material Handling	QA-10-004-P	7.5.2
Identification & Traceability,	MG-08-001-P	7.5.3
Customer Supplied Material,	MG-07-001-P	7.5.4
Control of Shipping Instructions,	QA-05-009-P	7.5.5
Final Inspection/Material Handling	QA-10-004-P	7.5.5
Shelf Life,	ML-09-001-P	7.5.5
Shipping Procedure,	SR-15-001-P	7.5.5

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Calibration Control,	DL-11-001-P	7.6
Statistical Process Control,	QA-20-001-P	8.1
Customer Satisfaction,	AD-01-002-P	8.2.1
Internal Audit,	QA-17-001-P	8.2.2
In-Process Material,	ML-10-002-P	8.2.3
Statistical Process Control,	QA-20-001-P	8.2.3
Laboratory Statistical Process Control,	ML-20-001-P	8.2.3
Final Inspection/Material Handling	QA-10-004-P	8.2.4
Part Audit,	ML-10-003-P	8.2.4
Nonconformance Control,	QA-13-001-P	8.3
Management Review,	AD-01-004-P	8.4
Continuous Improvement Project,	AD-02-001-P	8.5.1
Corrective Action,	QA-14-001-P	8.5.2
Preventative Action,	QA-14-002-P	8.5.3
Technical Complaints,	ML-14-001-P	8.5.2